Medicines & Healthcare products Regulatory Agency

MHRA Freedom of Information Act (FOIA) request Disclosure Log index

This document contains reference details for all FOIA requests which have been answered in full or in part, or for which the agency held no information.

It is a fully searchable PDF which will produce a list of all requests containing the chosen search term.

If you wish to see the original request and subsequent agency reply, please send an email headed “Disclosure Log request” to:

FOI_policy@mhra.gsi.gov.uk

As long as it is headed correctly it will not be treated as a new FOIA request. The identity of the original requester will be redacted.

MHRA FOI Disclosure List

FOI no	Subject	Date reply sent	Result of request
05/001	Scientific evaluation of 1,1,1,2-tetrafluoroethane; Ventolin Evohaler	18 January 2005	Answered - in part
05/002	Lofthouse of Fleetwood	14 January 2005	Answered - in full
05/003	Lofthouse of Fleetwood	01 February 2005	Answered - in full
05/004	Scientific evaluation of 1,1,1,2-tetrafluoroethane; Ventolin Evohaler	18 January 2005	Answered - in part
05/005	Lofthouse of Fleetwood	08 March 2005	Answered - in full
05/006	Lofthouse of Fleetwood	08 March 2005	Answered - in full
05/007	Lofthouse of Fleetwood	13 January 2005	Answered - in full
05/008	Lofthouse of Fleetwood	27 January 2005	Answered - in part
05/009	Approved justification for the combination of Hydrocortisone and Lidocaine in licensed medicines	19 January 2005	Answered - in part
05/010	Copy of CSM opinion on the application for approval of the drug Sativex	17 January 2005	Answered - in part
05/011	ROFECOXIB (SELECTIVE NSAID DRUG FOR HUMAN USE)	06 June 2005	Answered - in part
05/014	Chiron	10 May 2005	Answered - in part
05/018	Request for ADRs - STATINS and COX-2 INHIBITORS	07 February 2005	Answered - in full
05/019	ROFECOXIB Clinical trial data concerning the following two trials of rofecoxib:069, 090	06 June 2005	Answered - in part
05/020	Request for minutes of CSM meetings and other documents	03 February 2005	Answered - in part
05/021	Rosuvastatin	10 March 2005	Answered - in part
05/022	Rosuvastatin	10 March 2005	Answered - in part
05/023	Prescription and use of Seroxat	24 January 2005	Answered - in part
05/024	Request for information on Cisapride/Propulsid	13 January 2005	Answered - in part
05/026	Query regarding Diethylstilbestrol	07 February 2005	Answered - in full
05/027	SNRI drugs	03 February 2005	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/030	Request for various information in support of a complaint against an MHRA official	01 February 2005	Answered - in part
05/031	Focus Discussion Group on the Seroxat Patient Information Leaflet - request for records	09 February 2005	Answered - in full
05/033	Detailed organisational chart of the MHRA that includes reporting lines, names of job titles (heads of units, deputy heads of units) and the individuals holding the jobs	01 February 2005	Answered - in part
05/037	Information on the company Inveresk	17 January 2005	Answered - in part
05/038	Information as to the reported ocular toxicity of the heart drug Amiodarone.	10 February 2005	Answered - in part
05/039	All documentation relating to Sussex Pharmaceuticals Limited	10 February 2005	Answered - in part
05/040	Information requested on Hay Fever drugs Clarityn/Neoclarityn (Loratadine/Desloratadine)	26 January 2005	Answered - in full
05/041	All documents concerning production of Chiron's Fluvirin	10 March 2005	Answered - in part
05/044	Information on the company Inveresk	18 February 2005	Answered - in full
05/047	Annual programme for inspections of manufacturers for 2004 & 2005	11 February 2005	Answered - in full
05/048	Details of the names of the Indian Pharmaceutical Companies inspected and approved by MHRA for APIs and Formulations.	27 January 2005	Answered - in full
05/050	Lofthouse of Fleetwood	16 March 2005	Answered - in part
05/051	Audit Quality Report from the most recent inspection of PREMIER PHARMA	08 February 2005	Answered - in part
05/052	Information regarding ICT in the MHRA	21 February 2005	Answered - in full
05/053	Request for SPCs	03 February 2005	Answered - in full
05/054	Information relating Vioxx (rofecoxib) products including meeting minutes	06 June 2005	Answered - in part
05/055	Names of Indian companies given MHRA approval and list of companies where application pending /under review	02 February 2005	Answered - in full
05/056	Lofthouse of Fleetwood	18 February 2005	Answered - in part
05/057	Request for MHRA's issued advice on Risperidone and Olanzipine	27 April 2005	Answered - in full
05/059	Information concerning dealings with ITNET	21 February 2005	Answered - in full
05/061	FOIA in relation to dealing with device industry	31 January 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/062	Information about the organisation and cost of producing the CSM Expert Working Group report on the Safety of SSRI antidepressants	06 May 2005	Answered - in full
05/064	Lofthouse of Fleetwood	11 February 2005	Answered - in part
05/067	Request for EWG working papers and minutes	06 May 2005	Answered - in part
05/068	Information on lower limb paralysis caused by Myodil	23 February 2005	Answered - in full
05/069	A list of products/indications appealed to the MC from 1999 to 2004 with details of the issues reviewed, results of appeals and the resulting decision by the Licensing Authority	04 March 2005	Answered - in part
05/070	Request for list of MHRA approved, formulation manufacturing sites in India	02 February 2005	Answered - in full
05/071	Reference list of research papers considered in relation to withdrawal of Co-Proximal	14 March 2005	Answered - in full
05/073	Evans Vaccine manufacturing site / Speke, Liverpool (Chiron)	10 March 2005	Answered - in part
05/074	Supply of single dose measles and mumps vaccine	24 February 2005	Answered - in part
05/075	Medtronic needle infusion sets	02 February 2005	Answered - in full
05/076	Last two MHRA inspection reports for PCH Pharmachemie & content of any warning letters issued	07 February 2005	Answered - in full
05/079	Request for info on MHRA prosecution of Adam Knight of A&A Worldwide Trading Ltd.	04 March 2005	Answered - in part
05/080	Yellow Card data pertaining to "Yellow cards" submitted to the West Midlands CSM	07 March 2005	Answered - in full
05/083	Documents on ADRs for RU486 or Mifepristone	18 March 2005	Answered - in full
05/085	Details of any MAs containing Thrombin as an active ingredient, and copies of the SPCs	21 February 2005	Answered - in part
05/086	Request for assessment reports on Oxycontin and Palladone SR from Napp Pharmaceuticals Ltd	22 March 2005	Answered - in part
05/087	Voluntary Inspection (IMP) Report and corrective actions, relating to Excell Biotech Ltd	10 March 2005	Answered - in part
05/088	A list of any MAs for intravenous solutions or concentrates for solution containing calcium chloride	22 February 2005	Answered - in full
05/090	Human clinicall research data on Cinacalcet (Mimpara in UK)	21 February 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/092	Information in relation to parallel imports	11 March 2005	Answered - in full
05/093	Any documents relevant to special or different arrangements handling FoI requests from journalists, MPs, local or national officers of political parties. Documents relevant to any arrangements for identifying and handling FoI requests judged to be potentially sensitive or result in adverse publicity or critical comment. Documents relevant to what arrangements exist for ministers to be kept informed about or oversee the management of FOI requests.	17 February 2005	Answered - in full
05/094	Minutes of the MHRA meeting, which preceded the COX2 advice issued on 21 December	02 March 2005	Answered - in full
05/096	Background briefing to Lord Hunt on over the counter medicines	23 March 2005	Answered - in part
05/097	Copy of the risk benefit review for Co-proxamol	28 February 2005	Answered - in part
05/100	Information on Sudafed	23 March 2005	Answered - in full
05/101	Disposal of human tissue samples (Trilucent)	15 February 2005	Answered - in full
05/102	Appeal for internal review against the non-disclosure of information regarding Crestor (rosuvastatin)	07 July 2005	Answered - in part
05/103	Copies of all correspondence from the period March 1 2004 to September 1 2004, relating to the suspension of Sussex Pharmaceutical Limited's manufacturing licence.	09 March 2005	Answered - in part
05/104	Wide range of information on Vioxx, also known as rofecoxib, Celebrex, also known as celecoxib, Bextra, also known as valdecoxib, Arcoxia, also known as etoricoxib, Mobic, also known as meloxicam, and naproxen (numerous brand names). All Cox-2 inhibitors used to relieve the pain of arthritis.	19 May 2005	Answered - in part
05/106	2004 MHRA ICH GCP Inspection Report of inspection of Johnson and Johnson Pharmaceutical Research Division based in High Wycombe Buckinghamshire UK	18 March 2005	Answered - in part
05/107	Copies of the non confidential responses to ARM 24	02 March 2005	Answered - in full
05/108	Copy of inspection report Ashbourne Pharmaceuticals Ltd	14 March 2005	Answered - in full
05/109	Drug companies and research - MHRA powers and involvement	02 March 2005	Answered - in full
05/110	Request for FOI statistics	25 February 2005	Answered - in full
05/111	List of licenses held by ML Laboratories in the UK together with corresponding copies of the English approved SmPCs.	07 March 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/112	Copy of the relevant Inspectorate/DHSS files on the early development of the Orange Guide up to publication of the 1st edition, and to the 1st and 2nd impressions of the 1st Edition itself. It would also be appreciated if I could have access to the files relating to the development of the 1977 edition of the Guide.	07 March 2005	Answered - in full
05/113	MHRA structure chart	01 March 2005	Answered - in part
05/114	Details on all of laboratories audited in the UK between 2004 2005. Confirm those approved and certfied GLP approved by MHRA. Provide a list of those that failed and the reaosn why. Provide the addresses and the name of the head of the laboratories for all those assessed	16 March 2005	Answered - in part
05/116	Request for information concerning the safety of CFC Salbutamol Metered Dose Inhalers	22 March 2005	Answered - in full
05/117	SPCs for Ondansetron hydrochloride 2 mg/ml ampules registered by Pliva Pharma, PL 10622/0102 and PL 10622/0103 (date of grant 30/06/03).	08 March 2005	Answered - in full
05/118	List of addresses of manufacturers that have been GMP-approved by the MHRA in China and India	16 March 2005	Answered - in full
05/119	Recommendations for the use of HRT	30 March 2005	Answered - in part
05/120	Details of licenses issued by the MHRA for antibiotic ear preparations (either as a single ingredient or combination antibiotic/steroid) using a 2mg/ml concentration, with names of products, concentrations, indications, posology and date of approval	22 March 2005	Answered - in full
05/121	Rationale behind MHRA advice not to prescribe Rosuvastatin at higher than 20mgs	29 March 2005	Answered - in part
05/122	How many times MHRA investigated sales of prescription only available drugs being sold over the internet in the uk, how many cases led to arrest or prosecution (from 01/01/04 to 01/01/05 and 01/01/05 to 28/02/05), what prescription medicines were involved and the results of all prosecutions during this period.	30 March 2005	Answered - in full
05/123	Information on the licensing process of Sativex, with particular reference to any Government involvement in the decision and explicit reasons for it's failure to be licensed.	09 March 2005	Answered - in part
05/124	Files relating to changes of legislation considered after the Thalidomide disaster	17 March 2005	Answered - in full
05/125	Information on whether a marketing authorization license has been granted for the sodium salt of ibuprofen. If so, whether a DMF has been filed on the sodium salt of ibuprofen.	21 March 2005	Answered - in full
05/126	Information on Myodil	04 March 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/128	Details of incidents involving Roaccutain (80mg). Coroner enquiring in connection with a youth who committed suicide.	05 April 2005	Answered - in full
05/129	I would like to request access to the PV/GCP IAG minutes for those meetings that have been held until now	04 April 2005	Answered - in part
05/130	All information relating to Zoton	30 March 2005	Answered - in full
05/131	Previous minutes of the PV/GCP IAG, under the provisions of the FOI Act	06 April 2005	Answered - in part
05/132	List of companies who manufacture medical self-test kits	19 July 2005	Answered - in part
05/133	Chiron	20 April 2005	Answered - in part
05/134	Information concerning Merck, single mumps vaccine, and any rlelevany contact between MHRA and Merck	14 April 2005	Answered - in full
05/135	1994 CSM NSAID safety review	17 March 2005	Answered - in part
05/136	details of the variations submitted by Wyeth in 2004 for Ativan	03 May 2005	Answered - in part
05/137	Stats regarding ADRs	06 April 2005	Answered - in full
05/138	Drug companies and research - MHRA powers and involvement	14 March 2005	Answered - in full
05/139	Data on the different marketing authorisation procedures in United Kingdom, for years 2000, 2001, 2002, 2003, 2004.	16 March 2005	Answered - in full
05/140	What licence UKAID Ltd holds to trade and store anti retroviral drugs which apparently they buy from GSK (they particularly referred to the drug combivere). Also information concerning a court case involving antiretroviral drugs	21 March 2005	Answered - in part
05/143	Copies of internal assessment reports on Suibutex sublingual tablets.	25 May 2005	Answered - in part
05/144	Copy of the Terms of Reference for the EWG mentioned in the CSM Summary Minutes of 15th December 2004 (Pharmacovigilance, second bullet point) and CSM's decission to establish an EWG to look into cardiovascular safety of COX-2 inhibitors	22 March 2005	Answered - in full
05/145	Information regarding fault reporting by Staffordshire Ambulance Service of the Zoll M Defibrillator/Monitor. Dates and type of fault specifically.	22 March 2005	Answered - in part
05/147	Information and inspection reports and follow-ups/responses for inspections involving Evans vaccines	26 February 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/149	Report of MHRA inspection of Evans Vaccine (Chiron) in the fall of 2004. October 5, 2004 license suspension of same facility.	08 April 2005	Answered - in part
05/150	Details of the most common GMP deficiencies observed by MHRA during their inspections of drug manufacturing sites during the calander years 2003 and 2004. I am trying to secure a "Top 10" listing of GMP deficiencies industry-wide.	18 April 2005	Answered - in full
05/152	Copies of replies to public consultation on Co-proxamol	12 April 2005	Answered - in full
05/153	Request for information on Rezulin (Troglitazone)	06 March 2006	Answered - in part
05/154	MHRA manufacturing licenses - lists	26 April 2005	Answered - in full
05/155	All information held about production problems and irregularities related to the vaccine and drug production plant at Gaskill Road, Speke, Liverpool, Merseyside during the period 1995 to date	08 April 2005	Answered - in part
05/157	The date of first EU marketing authorization for sodium alendronate?	13 April 2005	Answered - in full
05/158	Case reports of efficacy failures of Advate	22 September 2005	Answered - in full
05/159	Any information concerning supply difficulties for Diamorphine Injection manufactured by Chiron	07 April 2005	Answered - in full
05/160	Data underpinning the findings of an epidemiological study commissioned by MCA (North Thames Study) regarding MMR vaccination and autism	26 April 2005	Answered - in full
05/163	MCA (MHRA) Assessment report for Atorvastatin which was approved in the UK in 1996. This would be clinical, preclinical and pharmaceutical assessment reports.	24 June 2005	Answered - in part
05/164	Information concerning the ABG1 hip prosthesis.	28 April 2005	Answered - in part
05/165	Information held by MHRA and CSM on APS/Teva's product alendronate 70mg	03 November 2005	Answered - in part
05/166	Request for emails, memos, minutes etc generated by MHRA after applicants request for information on myodil	12 May 2005	Answered - in full
05/167	Copy of the consultation for ARM 28 on Orajel Dental Gel	18 April 2005	Answered - in part
05/170	Spreadsheet of excipients used in UK licensed pharmaceutical products	10 May 2005	Answered - in full
05/175	SCOP minutes	05 May 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/176	PLUS reports in respect of Athlone's Marketing Authorisations	25 July 2005	Answered - in full
05/177	Efexor/Efexor XL (venlafaxine) request for data	27 July 2005	Answered - in full
05/178	Access to relevant documents relating to the occurrence of contaminated intravenous infusion fluids manufactured by Baxter Laboratories in or about 1972, and any other incidents associated with contaminated injections release to the UK market	09 May 2005	Answered - in full
05/179	Chiron	15 April 2005	Answered - in full
05/182	Information on legislation, regulation, enforcement and MHRA's position in relation to online pharmacies	29 April 2005	Answered - in full
05/184	Why have Daval Intenrational been stopped from making A.I.MSPRO	15 May 2005	Answered - in full
05/187	Number of Phase III clinical trials drugs from London companies, their name and their breakdown by therapeutic application, and Number of currently marketed drugs from London companies, their name and breakdown by therapeutic application	10 May 2005	Answered - in part
05/188	Sterile products/recalls and GMP compliance failures. Information on the number and type of incidents in which product defects have been reported involving failure to follow good manufacturing practices for sterile products; and the number of products that have been recalled due to lack of sterility assurance in the period since April 1972. Also how many cases have been referred to the Inspectorate Action Group relating to GMP failures in the manufacture of sterile products, with an indication of the nature of the problems and the outcome.	09 May 2005	Answered - in full
05/189	Information regarding MHRA use of IT	25 May 2005	Answered - in part
05/190	Questions regarding EWG	25 May 2005	Answered - in full
05/191	Final technical spec. for SENTINEL	25 May 2005	Answered - in full
05/192	Provide me with any advice officials received on the safety of using mercury-based products in medicines including vaccines	19 May 2005	Answered - in full
05/194	DATA ON MIRTAZAPINE	08 June 2005	Answered - in full
05/195	DATA ON FLUOXETINE	08 June 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/198	Minutes of the Committee on Safety of Medicines meeting held on Thursday 24th February 2005, subheading Legal Status A copy of the Committee's advice on the legal classification of a number of adult analgesics A copy of the committee's advice related to the supply of a treatment for cystitis A copy of the Summary of Product Characteristics. A copy of the committee's advice related to each of these bullet points.	15 June 2005	Answered - in part
05/199	MHRA manufacturing licenses - lists	10 May 2005	Answered - in full
05/200	VOLUME PROMOTION OF ANALGESIC - CONTAINING MEDICINES IN POUNDLAND STORES ("3 PACKS OF PARACETAMOL TABLETS (PACKS OF 16)")	16 May 2005	Answered - in full
05/201	Information on Seroxat and Paxil	04 July 2005	Answered - in full
05/202	Assessment report made by the UK under the Mutual Recognition Procedure through which Eisai Limited received approval for on-demand therapy of PARIET for moderate to very severe symptomatic gastro-oesophageal reflux disease (symptomatic GORD) in April 2004.	07 June 2005	Answered - in part
05/203	Audit comment and responses from MHRA audit of AstraZeneca R&D Charnwood Bakewell Road Loughborough Leics LE11 5RH Inspection dates 22 - 24 Feb 05	23 May 2005	Answered - in part
05/204	AI data available on the product Viloxazine - first registered by ICI in the early 1980s. In particular, the toxicology package first registered would be very helpful	26 July 2005	Answered - in part
05/205	Withdrawl of AimsPro	10 May 2005	Answered - in full
05/206	Comments from Co-proxamol consultation Jun -Sept 2004	10 May 2005	Answered - in full
05/207	Please provide the most recent edition of the Index of papers supplied to the EWG	12 October 2006	Answered - in full
05/208	Most recent MHRA inspection report for the GMP inspection of Biotec Distribution Wales (Authorisation number 19819, Site number 11604)	11 May 2005	Answered - in part
05/209	NEMA standards for Siemens' e.Cam dual head variable angle gamma camera. GE's variable angle mellinium and infinia dual head cameras - FWHM, FWTM, matrix size,spatial and linearity resolution.	10 May 2005	Answered - in full
05/210	Known Adverse effectsof Lipostabil	25 May 2005	Answered - in full
05/211	Information relating to the inclusion of thiomersal in DPT vaccine.	25 May 2005	Answered - in full
05/212	Information on C-FIT Hip Replacements	07 June 2005	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/213	Copy of 2004 GMP inspection report on Bracknell manufacturing site	25 May 2005	Answered - in part
05/214	All MHRA internal Guidelines and Procedures used to process Freedom of Information requests	17 May 2005	Answered - in full
05/215	Request for full details on adverse incident involving wheelchair	10 May 2005	Answered - in part
05/216	Information relating to the inclusion of thiomersal in DPT vaccine.	16 May 2005	Answered - in full
05/218	1. All reports (inspection or otherwise) on PowderJect Pharmaceuticals. 2. All reports on Evans Vaccine Ltd. 3. All reports on a plant based at Gaskill Road, Speke, Liverpool L24 9GR from when it was established until the present day (it was owned by various different companies over the years).	20 June 2005	Answered - in part
05/219	Fluticasone Nasal Spray:- information held by the MHRA in relation to the recent grant of a generic marketing authorisation in respect of Fluticasone Nasal Spray, to IVAX Pharmaceuticals Limited (IVAX).	02 November 2005	Answered - in part
05/224	Please advise which products may be manufactured at the Evans Vaccines site in Liverpool.	19 September 2005	Answered - in full
05/225	All minutes, expert and other reports that document a discussion of the potential need, or absence of need, for Asian patients warning for atorvastatin, simvastatin, pravastatin and fluvastatin, and some other info regarding statins in general.	20 June 2005	Answered - in part
05/226	Information regarding GCP compliance certificate for WELLQUEST Ltd located at WELLSPRING HOSPITAL,MUMBAI 400 013,INDIA.	20 June 2005	Answered - in full
05/227	Information on Flucanozole	20 May 2005	Answered - in full
05/230	Request for information: Co-Proxamol	07 June 2005	Answered - in full
05/232	Information on MHRAs involvement with pesticides and antiparasitic drugs	17 June 2005	Answered - in full
05/233	Copies of the responses to the : Review of the Utility of the Pain Reliever Co-proxamol (Distalgesic, Cosalgesic) and Request for Evidence on Risks and Benefits	20 June 2005	Answered - in full
05/234	MMR vaccine	16 June 2005	Answered - in full
05/236	Any information you can provide on Yellow Card reports received on the commonly distributed childhood immunisation vaccines, together with data on the number of distributed doses.	05 July 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/237	Information relating to the inclusion of thiomersal in DPT vaccine.	27 June 2005	Answered - in full
05/239	MHRA reviews on all of Dr Vijendra Singh's work on the link between MMR and autism, review on Yazbak and Goldman's study. Also, I have come across several cases of children ages 4, 5, 6 receiving the MMR for the very 1st time who have become autistic after receiving this vaccine please could you forward information to explain why this cannot be connected to the MMR.	05 July 2005	Answered - in full
05/240	A large request concerning Vioxx	07 July 2005	Answered - in part
05/241	Could you please supply a list of pharmaceutical manufacturers, UK and overseas that have had GMP inspections between 01/01/05 to 01/05/05 together with their general location (UK = county, overseas = country & region)	16 June 2005	Answered - in full
05/242	Information is sought for the following products: Xalacom Eye Drops, Solution, PL/00032/0288, Pharmacia Ltd, and Cosopt Ophthalmic Solution, PL/0025/0373, Merck Sharp and Dohme	27 October 2005	Answered - in part
05/243	Quantitative formulation of Ortho-Gynest Cream PL00242/	01 July 2005	Answered - in part
05/244	Thiomersal	30 June 2005	Answered - in full
05/245	Information on Doxazosin modified release	13 July 2005	Answered - in part
05/246	List of current members for UK GLP Monitoring Programme	22 June 2005	Answered - in full
05/247	Last week the MHRA turned down an appeal from GW Pharmaceuiticals Plc concerning the licencing of Savitex. I would like to have a copy of the Committee minutes and ask how I can obtain these.	27 July 2005	Answered - in part
05/248	License information on: PL00327/0060-Crookes/Nurofen Cold and Flu/granted 24/11/93 PL0063/0082-Reckitt B/Lemsip pharmacy power/granted 18/9/95 PL0063/0098-Reckitt B/Lemsip Flu 12 hr/granted 30/7/96 PL 0014/0600-Boots/Nirolex Cold and flu/13/1/98 PL0063/130 - Reckitt B/Lemsip cold and flu sinus 12 hr/3/6/03 PL165/152 - Whitehall/Advil Colds and Sinus/29/4/02 PL00327/87 - Crookes/Nurofen cold and Flu Hot Drink sachets/9/9/97 PL00327/96 - Crookes/Nurofen Honey & Lemon Orig Sachets/5/12/00	08 July 2005	Answered - in full
05/249	Information on the manpower structure and make-up of MHRA	28 July 2005	Answered - in full
05/251	Information on Ambisome registration	31 May 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/252	Request in respect of Sodium Valproate (re: children believed to have been injured in utero by the anticonvulsant drug sodium valproate)	27 July 2005	Answered - in full
05/254	Supporting data for Ativan licensing variation application	11 July 2005	Answered - in full
05/255	BN116: minutes and papers of the Committee on Safety of Medicines relating to Practolol	20 July 2005	Answered - in full
05/257	Information on Herceptin / Trastuzumab Information on plans to make avaiabile the drug Herceptin / Trastuzumab to women who have not not experienced metastatic breast cancer but who have tumours overexpressing the human epidermal growth factor receptor 2 (HER2)	15 July 2005	Answered - in full
05/258	Information regarding Simvastin 10mg	19 July 2005	Answered - in part
05/259	Access to yellow card data	01 July 2005	Answered - in full
05/260	I would be grateful if you could forward me all documents, data, emails, memos, letters, statistics etc in either completed form or draft form that you are in possession of regarding the drug DEPO-PROVERA ® (medroxyprogesterone acetate injectable suspension), a long-acting injectable contraceptive.	05 July 2005	Answered - in part
05/262	The underlying clinical/scientific information that led to the decision(s) on new indications for Arimidex.	12 July 2005	Answered - in full
05/263	Reasons for MHRA warnings regarding the use of Venflaxine	11 August 2005	Answered - in part
05/264	Thiomersal	01 August 2005	Answered - in full
05/265	Information regarding information submitted in support of MA for Tillomed - PL 11311/0281, plus correspondence with the MHRA relating to this application.	02 March 2006	Answered - in part
05/266	Preclinical and clinical data of Citanest 5% heavy (AstraZeneca, registered in UK form 1970 to 1978 - as far as we know)	08 August 2005	Answered - in full
05/267	Minutes of the PV/GCP IAG from March 2005 onwards, under the provision of the FOI Act	08 August 2005	Answered - in part
05/268	Defect information on the SAS One Step Pregnancy Test, on behalf of their client	20 July 2005	Answered - in full
05/269	Copy of the assessment reports for the original licensing application for Glucophage SR (Merck Pharmaceuticals), PL 11648/0054, granted on 26 Nov 2004.	04 August 2005	Answered - in full
05/270	Please can you provide me with the minutes of the CSM meeting in 1998 at which it was decided to limit OTC sales of paracetamol.	29 July 2005	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/272	Information on the illegal use of kamagra in Scotland, including any prosecutions in the uk this year	09 August 2005	Answered - in full
05/273	Information arising from recommendations in the report of the CMO: 'The withdrawal of an oral polio vaccine: Analysis of events and implications' published in June 2002.	14 October 2005	Answered - in full
05/275	Request for MHRA's issued advice on Risperidone and Olanzipine	25 August 2005	Answered - in full
05/276	How many reports there have been in the last two years of interactions between, the main atypicals (Risperidone,Clozapine,Olanzapine), SSRI's (Paroxetine,Citalopram, Fluoxetine,Venlafaxine) and illicit drugs (Heroin,Cannabis,Amphetamine etc). Also data on adverse reactions for all the above prescribed drugs in the last two years.	17 August 2005	Answered - in full
05/277	Thiomersal	01 August 2005	Answered - in full
05/278	Information on the numbers of suspected/confirmed anaphylactic/allergic reactions to the following compounds over the past five years - rocuronium, atracurium, cisatracurium, vecuronium	01 September 2005	Answered - in part
05/279	Histories of licensing of products (including changes to the SPCs following the European review) All Assessment Reports produced by the MHRA relevant to safety and Efficacy, including the original plus any subsequent updates in respect of Alvesco (ciclesonide) PL 20141/0005-6	25 November 2005	Answered - in part
05/280	Request for figures in relation to the total number of clinical trial submissions made to the MHRA per year for the last 4 years.	15 August 2005	Answered - in full
05/281	Request for a copy of all FOI requests recieved so far	02 August 2005	Answered - in full
05/284	Any information held concerning adverse effects of Armour Thyroid	28 July 2005	Answered - in full
05/285	Querying the accuracy of a Medical Device Alert on gloves	18 August 2005	Answered - in full
05/286	Information regarding herbal ingredients	03 August 2005	Answered - in full
05/287	Information on Aimspro	29 July 2005	Answered - in full
05/288	Enquiry about MHRA's Property Leases	02 August 2005	Answered - in full
05/289	Information regarding Hylamer polyethylene components sterilised by gamma-irradiation in air, especially, Hylamer Ogee Acetabular Cups	16 September 2005	Answered - in part
05/290	Generic Lamotrigine	15 August 2005	Answered - in part
05/291	Fosimax and generic	24 August 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/292	Information about MHRA's records retention policy	12 August 2005	Answered - in part
05/293	Information regarding Weelbutrin	02 August 2005	Answered - in full
05/294	Information (and anything else you may consider relevant) relating to the application for license for COSMOFER (supplied by Vitaline) and VENOFER (supplied by SynerMed)	05 August 2005	Answered - in part
05/295	Information on sheep-dip	02 August 2005	Answered - in full
05/296	Information on Aimspro	05 August 2005	Answered - in full
05/297	Information on Fluoxatine	11 August 2005	Answered - in full
05/298	Information on Aimspro	05 August 2005	Answered - in full
05/299	Information on Aimspro	05 August 2005	Answered - in full
05/300	Information relating to the inclusion of thiomersal in DPT vaccine.	05 September 2005	Answered - in full
05/302	Information on Terbinafine	25 August 2005	Answered - in full
05/303	Information regarding Aimspro	16 August 2005	Answered - in full
05/304	Information regarding herbal ingredients	25 August 2005	Answered - in full
05/306	Information on Difflam lozenges	01 September 2005	Answered - in full
05/307	Information on Terbinafine	06 September 2005	Answered - in full
05/308	Questions regarding clinical trials applications	18 August 2005	Answered - in full
05/309	CSM advice re SSRIs in children	25 October 2005	Answered - in full
05/310	Data on the product Viloxazine - first registered by ICI in the early 1980s - particularly the trial reports of the efficacy safety data from the main phase III trials (if they were done) and dosing data from Phase II	06 September 2005	Answered - in full
05/311	Copy of inspectors report for AAI Development Services, 4221 Faber Place Drive, Charleston, South Carolina 29405-8510, USA	15 November 2005	Answered - in part
05/312	Copy of inspectors report for AAI Development Services, 4221 Faber Place Drive, Charleston, South Carolina 29405-8510, USA	15 November 2005	Answered - in part
05/313	Terbinafine Impurity - copy of the evaluation report where impurity 'EE' was evaluated for potential mutagenic activity.	23 August 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/314	Terbinafine Tablets	23 August 2005	Answered - in full
05/315	Enquiry about MHRA's vehicle policies	24 August 2005	Answered - in full
05/317	Information on MMR Vaccines	09 September 2005	Answered - in full
05/318	Warfarin formulations	01 September 2005	Answered - in full
05/319	Information on MHRA's staffing policies and procedures	08 September 2005	Answered - in full
05/320	Thimerosal	05 September 2005	Answered - in part
05/321	Information relating to the inclusion of thimerosal in DPT vaccine.	05 September 2005	Answered - in full
05/322	Papers relevant to the licensing of atomoxetine (Stattera) for use in a review to be published by Drug and Therapeutics Bulletin	07 September 2005	Answered - in full
05/323	Redacted copies of the Assessors Report regarding reclassification applications for carbocisteine and/or acetycisteine	07 October 2005	Answered - in full
05/324	Information on the report presented to Sub Committee on Pharmacovigilance and CSM in the last months regarding OTC Medicines containing codeine	21 September 2005	Answered - in full
05/325	Manufacturing details for Goldshield and Norton	13 September 2005	Answered - in full
05/326	Information on Troglitazone	12 July 2006	Answered - in part
05/327	Adverse events involving Cavaterm DUB System	13 September 2005	Answered - in full
05/328	Enquiry regarding the equivalence of the new generic fentany patches available from Tillomed (Tilofyl) and the Janssen version	07 October 2005	Answered - in part
05/329	Information relating Evans Vaccines plant in Speke, Liverpool.	28 September 2005	Answered - in part
05/330	Applicant trying to establish the size of the UK Clinical Trials market for medicinal products	10 October 2005	Answered - in full
05/331	Information regarding herbal ingredients	18 October 2005	Answered - in full
05/332	Information regarding the switch from Clobazan capsules to tablets	22 September 2005	Answered - in full
05/335	What was the clinical trial that was documented in the MA for which the product Actiq (PL16260/0003-0008)approval was based. Were the patients used from hospice or were they out-patients?	04 October 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/336	Toxicity data on Adamantaneand/or Amantadine hydrochloride	13 October 2005	Answered - in part
05/337	MP's researcher requesting information on reports surrounding the usage and safety of the Guidant 'Prizm 2' (DR 1861) pacemaker.	05 October 2005	Answered - in part
05/338	MHRA audit report on BCM Limited, 1 Thane Road, Nottingham, NG2 3AA Audit dates 27 - 29 June 2005	21 October 2005	Answered - in part
05/341	MHRA correspondence relating to the B Braun Aesculap Search Total Knee Replacement	14 October 2005	Answered - in part
05/342	Questions regarding MHRA policies on medicines advertised over the internet	03 November 2005	Answered - in full
05/343	A redacted copy of the Assessors Report for ARM23	07 November 2005	Answered - in part
05/344	Information relating to an MA granted to Elan in respect of Abelcet	10 February 2006	Answered - in part
05/345	Details of the last GMP inspection by the MHRA on Boots Manufacturing, 1 Thane Road, Nottingham, NG2 3AA. In particular on the tabletting department.	21 October 2005	Answered - in part
05/346	Information from the GLP monitoring programme concerning the GLP status and type(s) of work done by Retroscreen Virology Ltd, Queen Mary's School of Medicine & Dentistry, 327 Mile End Road, London E1 4NS	17 October 2005	Answered - in full
05/347	Details of the last MHRA inspection of Dales Pharmaceuticals Limited, Snaygill Industrlial Estate, Keighley Road, Skipton, Yorkshire, BD23 2RW	19 December 2005	Answered - in part
05/348	Information, Safety Warnings and ADVERSE INCIDENT REPORTS etc associated with the "STRYKER TPS bone drill, from Stryker Orthopedics of Kalamazoo, Michigan, and information on other manufacturers of other high speed bone resecting tools if available for comparison	09 November 2005	Answered - in full
05/349	Information on the Road Knight Mini Scooter from Care-Knight in relation to an incident	10 November 2005	Answered - in part
05/350	Information on the Hepatitis B vaccine	05 December 2005	Answered - in part
05/351	Dr Ian Hudson's Declaration of Interests, and data on the EMEA's recommendation that Seroxat, should be prescribed with extra caution to those aged between 18 and 29.' It states that the drug can lead to an increased risk of "suicide-related behaviour in young adults". Please provide evidence that clearly shows Seroxat should be prescribed with caution to those aged between 18 - 29.	16 December 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/355	Information related to Guidant Corporation and the following medical device: Guidant defibrillators. All MDR's related to Guidant Corporation All MDR's related to Cardiac Pacemakers All investigation information regarding Ventak 1861 'Dear Doctor' letters submitted by Guidant Notifications by Guidant regarding all ICD's including: Ventak Prizm and Contak Renewal Any warnings, rulings or findings into any investigation into Guidant Corporation	22 November 2005	Answered - in part
05/357	Assessment repors for the following ibuprofen products approved via the mutual recognition procedure Advil 400mg film coated tablet, Advil Liqui-gel 400mg capsules, Advil liquigel 200mg capsules, DexibuprofenGebro 200mg, DexibuprofenGebro 300mg, DexibuprofenGebro 300mg	07 December 2006	Answered - in part
05/358	IT Manager's Name & email address, Director of Finance's Name & email address, name & installation date of current Financial Software, confirmation whether or not the Financial Software will be changed/upgraded within the next three year.	23 February 2006	Answered - in full
05/360	Request for copies of correspondence between MHRA and various newspapers concerning food supplements, herbal medicines, vitamins etc from May 97 to October 05	28 November 2005	Answered - in full
05/361	Request for copies of correspondence between MHRA and various drug companies concerning food supplements, herbal medicines, vitamins etc from May 97 to October 05	22 November 2005	Answered - in full
05/363	Request for copies of correspondence between MHRA and FSA concerning food supplements, herbal medicines, vitamins etc from May 97 to October 05	22 November 2005	Answered - in full
05/364	Information relating Evans Vaccines plant in Speke, Liverpool.	11 November 2005	Answered - in part
05/365	Reaction analysis print-outs: Doxazosin, Prazosin, Terazosin, Alfuzosin Reactions:1-Intra-operative floppy iris syndrome(IFIS), 2- Myosis 3- Ophthalmic reactions Product analysis print-outs: Doxazosin, Prazosin, Terazosin, Alfuzosin Anonymised single patient print-outs: Doxazosin, Prazosin, Terazosin, Alfuzosin Reaction: 1- Intra-operative floppy iris syndrome(IFIS), 2- Myosis	15 November 2005	Answered - in full
05/366	Last MHRA Inspection Report and Response for Reckitt Benckiser Healthcare (UK) Ltd, Kingston Works, Danson Lane, Hull, East Yorkshire. HU8 7DS.	10 January 2006	Answered - in part
05/367	Various GMP inspection statistics for 2004	06 December 2005	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/368	Information Required: sight of the current MHRA licensing and certification audits for Indoco Remedies Ltd.Goa & Marksans Pharma Limited, Goa	10 January 2006	Answered - in part
05/369	Request for information regarding the advertising of Efexor XL (venlafaxine)	09 December 2005	Answered - in full
05/370	Information on co-proxamol - has threatened legal action to get MHRA to lift its suspension. Also a list of all MHRA FOI queries received so far	25 November 2005	Answered - in part
05/371	GMP certificate for Ben Venue Laboratories, Bedford, Ohio, USA inspected by MHRA in December 2003.	15 November 2005	Answered - in full
05/372	All information, documents, communications etc held regarding imported blood, plasma and blood/plasma products from 1980 onwards.	25 January 2006	Answered - in part
05/373	Further information on the Road Knight Mini Scooter from Care-Knight in relation to an incident	16 December 2005	Answered - in part
05/374	I request document(s) and/or listing(s) containing the following information be provided to me: Adverse Events and Severe Adverse Events reported for Antihemophilic Factor (Recombinant) Drug: Kogenate, Antihemophilic Factor (Recombinant) Drug: Refacto AF, Antihemophilic Factor, (Recombinant) Drug: Refacto, and Antihemophilic Factor (Recombinant) Drug: Kogenate FS	20 December 2005	Answered - in full
05/376	Establishment Inspection Report for: Brecon Pharmaceuticals, Wales	19 December 2005	Answered - in part
05/381	A complete copy of MA approval audit report on Wockhardt Limited, 87/A Silver Industrial Estate, Bhimpore, Nani Daman, 396 210	30 January 2006	Answered - in part
05/382	A list of all answered or part-answered FOI queries with subjects	06 December 2005	Answered - in full
05/383	Information on SSRIs	29 September 2006	Answered - in full
05/384	I would be grateful if you would be able to provide me with copies of all Freedom of Information requests made to the Medicines and Healthcare Products Regulatory Agency from January 1 2005 until May 1 2005.	06 December 2005	Answered - in full
05/386	Request by company for information relating to MHRA investigation of them	15 December 2005	Answered - in full
05/387	Re: various vaccines 1) ingredients and quantities present 2) ages for which the vaccines were suitable for use, recommended dosage per adminstration, recommended number of adminstrations 3) date of grant and of cancellation of a Medicines Act or equivalent licence 4) number of doses that were supplied during the periods that the licences were in effect	05 January 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
05/388	Information on Nasofan nasal spray	03 January 2006	Answered - in full
05/389	Information relating to Smith & Nephew knee joint replacements	13 January 2006	Answered - in part
05/390	Most recent MHRA or other EU Medicines Inspectorate GMP Inspection report on: Unither Pharma,ZI longpre-10, rue Andre Durouchez, 850052, Amiens, Cedex 2, France Holopack Verpackungstechnik GmbH,Werk 2, Banhofstrasse, 73453, Abtsgmund-Untergroningen, Germany Unither Pharma, 50211, Coutances, France Ivax, Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook, Runcorn, WA7 3FA	16 December 2005	Answered - in full
05/391	All PSURs for Fosamax 5, 10 and 70 mg. If not available, a Product Analysis Print covering the period since the product was first launched in UK.	09 January 2006	Answered - in full
05/393	Minutes of the meetings held in February 1999 and March 2001 on the use of Pentosan Polysulphate for treatment of CJD.	17 January 2006	Answered - in full
05/394	Query related to flu vaccine and live/dead eggs	16 December 2005	Answered - in part
05/395	Records related to the research of Proteomic Profiling for Influenza, as sponsored by the National Institute of Allergy and Infectious Diseases (see also NCT00133588 at clinicaltrials.gov)	16 January 2006	Answered - in full
05/396	Records related to the development of the Influenza A/H5N1 Vaccine by Sanofi-Pasteur:	16 January 2006	Answered - in full
05/397	Information with regard to the licencing of the drug Vioxx	17 January 2006	Answered - in full
05/398	1. Identify the statute(s) and regulations which obligate the pharmaceutical industry to report suspected serious adverse drug reactions to the MHRA, and which include a definition of "serious" adverse drug reactions; and 2. a Drug Analysis Print for paroxetine which lists all of the adverse drug reactions which have been reported to the MHRA (and the former MCA) by all sources (including those reported by the marketing application holder) up to 1 May 2001.	30 December 2005	Answered - in full
05/400	Query regarding MHRA use of temporary and casual staff	13 January 2006	Answered - in full
05/401	Asking for the identity of the person/s who asked for information about them under FOI (05/376)	21 December 2005	Answered - in part

FOI no	Subject	Date reply sent	Result of request
05/402	Information on co-proxamol - has threatened legal action to get MHRA to lift its suspension. Also a list of all MHRA FOI queries received so far	10 January 2006	Answered - in full
05/404	Information in relation to the drug Risedronate (Actonel)	26 January 2006	Answered - in part
05/406	Information on adverse incidents concerning Endoscope (2005/001/028/061/008)	04 January 2006	Answered - in full
06/001	I would like to request access to the last 3 PhV Inspection Reports issued by the MHRA	27 January 2006	Answered - in full
06/003	Please would you make available all documents relating to the issue of infant vaccine mercury, and concern over its safety, prior to it becoming a public controversy in the US in 1999.	08 February 2006	Answered - in full
06/004	Information regarding reported side effects of Hep B Vaccine	13 February 2006	Answered - in part
06/005	Query regarding MHRA decision to withdraw co-proxamol	12 January 2006	Answered - in part
06/006	Failure of JRI Furlong femoral stem	03 February 2006	Answered - in part
06/007	FOI REQUEST: PAROXETINE, PLACEBO AND SUICIDE	10 February 2006	Answered - in full
06/008	Informarion on Chiron inspection in Liverpool in 2004	13 February 2006	Answered - in part
06/009	Establishment Inspection Report of:DHP Ltd, Elvicta Business Park, Crickhowell, Powys, NP8 1DF, UK	27 January 2006	Answered - in part
06/010	Methylphenidate enquiry	19 January 2006	Answered - in part
06/011	Information regarding suicides and SSRIs	23 February 2006	Answered - in full
06/013	Date of submission to the MHRA of the Marketing Applications for astemizole (PL 00242/0086 HISMANAL TABLETS 10MG) and terfenadine (PL 00027/0026 TEFADINE TABLETS 60MG)	20 January 2006	Answered - in full
06/014	Information regarding GMP deficiencies found during inspections carried out by the MHRA in 2005 of UK and overseas manufacturers of medicines marketed in the UK	16 February 2006	Answered - in full
06/016	Information re guidelines on safety aspects of the practice of polypharmacy - particularly within the area of psychiatric drugs	07 February 2006	Answered - in full
06/017	Query regarding inspections	21 February 2006	Answered - in full
06/019	Query regarding Acyclovir by Ranbaxy	03 March 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/020	A list of approved Human Drug Manufacturing sites by MHRA in India	03 March 2006	Answered - in full
06/021	MCA's scientific assessment of post-marketing cerivastatin-associated ADR reports submitted by Bayer to the MCA. The MCA assessment that I am requesting was subsequently sent to all EC regulatory authorities on 8 June 2001and Bayer's 15th June 2001 expert report on cerivastatin which was sent to, or received by, the MCA on 18th June 2001	07 August 2006	Answered - in full
06/022	A link to all GLP laboratories in Great Britain	10 February 2006	Answered - in part
06/024	A copy of the most recent (2004) Pharmasol Andover, UK MHRA inspection report as part of our risk assessment for continued use of this company	14 March 2006	Answered - in part
06/025	Thiomersal	09 February 2006	Answered - in part
06/026	Any or all information, which can be available under FOI, which supported the legal classification switch from POM to P category for Simvastatin 10mg Tablets	07 March 2006	Answered - in part
06/028	A list of the organisations that give funds and grants to the MHRA	15 February 2006	Answered - in full
06/030	Information on the interests of MHRA and Committee members	02 March 2006	Answered - in part
06/032	Information on MHRA reviews of Pemoline, Droperidol and Fenfluramine	04 May 2006	Answered - in full
06/033	Copies of the reports of the last two MHRA Medicines Inspectorate audits of Wockhardt UK Ltds Wrexham site (ML/4543/01) on 30th - 31st March 2004 and 9th-11th February 2005	03 March 2006	Answered - in part
06/036	Is Future Health Tecnnologies Ltd in Nottingham certified to store stem cells originating from cot blood, if so for how long? What is the result of the non-renewal of the licence in relation to the stem cells already deposited? What legislation regulates stem cell storage?	20 February 2006	Answered - in full
06/037	Re: Audir of Strides Arcolab Ltd - India - This company was audited by MHRA inspector on 09/01/2006. We would like to know the complete audit report as Strides Arcolab Ltd is approved manufacturer in few of our PLs both antibiotic & non-antibiotic.	24 May 2006	Answered - in part
06/038	Seroxat/Placebo suicides	07 April 2006	Answered - in part
06/040	Information regarding counterfeit drugs in the Uk and across the developed world	21 March 2006	Answered - in full
06/041	A copy of each spontaneous reaction report associated with paroxetine between 01/07/1963 to 01/05/2001 in respect of each reported reaction in various categorys	21 March 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/044	All documentation relating to the classification of red clover as a medicinal herb including scientific evidence and any expert reports considered by the MHRA.	14 March 2006	Answered - in full
06/046	Details of the bioequivalence study for itraconazole (manufactured by Sandoz) in comparison to the Sporonox (Jassen Cilag) brand	03 March 2006	Answered - in full
06/047	Inspection reports relating to the Protein Fractionation Centre, Ellens Glen Road, Edinburgh (Site number 1642) during 2005 and 2006.	31 March 2006	Answered - in part
06/049	Information regarding MHRA's risk managament procedures/strategy	14 March 2006	Answered - in full
06/050	Request for Yellow Card data	04 April 2006	Answered - in full
06/052	Information about sites outside the UK that have been inspected in connection with a Product Licence and approved by the MHRA or other European regulatory authority, in particular sites in India.	03 March 2006	Answered - in full
06/053	Seroxat/Placebo suicides	31 March 2006	Answered - in part
06/055	A list of manufacturing sites in India that are registered by the MHRA	07 March 2006	Answered - in full
06/056	The Preliminary Assessment Report of 9 December 2005 entitled: STRATTERA (atomoxetine) - Risk Benefit Assessment.	05 May 2006	Answered - in full
06/057	Drug Analysis Print for paroxetine which lists all of the adverse drug reactions which have been reported to the MHRA (and the former MCA) by all sources (including those reported by the marketing application holder) up to 1 March 2001.	05 April 2006	Answered - in full
06/058	Under the Freedom of information act I would like to know when thimerosal was banned from children's vaccines and why it was banned.	03 April 2006	Answered - in full
06/060	Information relating to the status of MHRA’s property arrangements	06 April 2006	Answered - in full
06/061	Information regarding any generic applications submitted by companies for products containing Macrogol 3350 and electrolytes or macrogol 3350 only	09 March 2006	Answered - in full
06/062	Report of Medispray audit - Goa October 2005	08 March 2006	Answered - in part
06/063	The clinical overview for the original licensing application for Alvesco (ciclesonide) PL 20141/0005-6	31 July 2006	Answered - in part
06/064	Inspection reports and responses for Bio-Vault, 24 Brest Road, Derriford, Plymouth, and Future Health Technologies, Nottingham.	21 March 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/065	The list of vaccines companies which have GLP facilities in UK (Glaxo, UCB...), with their GLP compliance status (areas of expertise)	07 April 2006	Answered - in part
06/066	The full list of responses to Simvastatin Consultation and who they came from	14 March 2006	Answered - in full
06/067	The last 3 Pharmacovigilance Inspection Reports issued by the MHRA	07 April 2006	Answered - in part
06/070	3 latest MHRA Pharmacovigilance inspection reports	07 April 2006	Answered - in part
06/071	TGN1412	11 April 2006	Answered - in part
06/072	TGN1412	11 April 2006	Answered - in part
06/073	TGN1412	12 April 2006	Answered - in part
06/074	TGN1412	12 April 2006	Answered - in part
06/075	Inspection/approval information concerning "Amlovasc" (amlodipine maleate) 5mg tablets	29 March 2006	Answered - in full
06/076	A copy of the information supplied to FOI request 06/001 of 03 March 2006 which requested Pharmacovigilance inspection reports	07 April 2006	Answered - in part
06/078	TGN1412	12 April 2006	Answered - in part
06/079	October 2004 MHRA inspection report (or latest) and the company response to any findings cited in the report for Cardinal Health	27 April 2006	Answered - in part
06/080	TGN1412	12 April 2006	Answered - in part
06/081	Request for minutes of CSM meetings and other documents	19 April 2006	Answered - in part
06/082	TGN1412	12 April 2006	Answered - in part
06/083	List of plants inspected by MHRA in India	18 April 2006	Answered - in full
06/084	1. A copy of the Clinical Expert Report/ Clinical Overview 2. A copy of the correspondence between the applicant and the MHRA or Medicines Advisory Bodies 3. A copy of any papers submitted to the Medicines Advisory Bodies A copy of any advice given by the Medicines Advisory Bodies A copy of the reasons for any advice given by the Medicines Advisory Bodies, in relation to the application made for PL 19534/0005 Fortamet XL 500mg Prolonged Release Tablets - PL holder Andrx EU Ltd, and the authorisation granted	18 May 2006	Answered - in part
06/085	TGN1412	12 April 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/086	TGN1412	12 April 2006	Answered - in part
06/087	Details of adverse drug reactions over the last 10 years for the individual glyceryl trinitrate products Nitrolingual, Nitrolingual Pumpspray, Glytrin, Coro-Nitro, Nitromin, and any other GTN pump or spray products registered	03 April 2006	Answered - in full
06/088	A copy of the latest (January 2006) MHRA inspectors report on the Protein Fractionation Centre in Edinburgh, and a copy of the report on the previous inspection in 2004, and the interim inspection in April 2005	27 April 2006	Answered - in part
06/089	Information on the re-classification from POM to P legal status of Nizatadine capsules: CSM minutes, Medicines Commission minutes, details of public consultation (both public consultation document issued by MHRA (ARM or equivalent) plus replies received.	26 April 2006	Answered - in part
06/090	A list of the overseas facilities that the MHRA has inspected for GMP in the last 3 years	07 April 2006	Answered - in full
06/093	What proportion of drug/reaction combinations in the Yellow Card database have 5 or fewer reports?	07 April 2006	Answered - in full
06/094	A copy of the Report following the Last MHRA inspection for a company called Biovault Ltd in Plymouth.	27 April 2006	Answered - in part
06/095	A copy of the attachments provided in response to the following enquiry under the FoI: 03 Mar 2006 | Major GMP deficiencies found during GMP inspections 2005	06 April 2006	Answered - in full
06/096	A copy of a disclosure you highlighted on your website related to Glucophage SR- Ref 05/378	03 May 2006	Answered - in full
06/099	Details of all adverse reactions in phase 1 drug trials in the past five years	08 May 2006	Answered - in part
06/100	Querying the licenses were cancelled for various vaccine PLs	12 April 2006	Answered - in full
06/101	Ibuprofen in early years childcare settings	19 April 2006	Answered - in full
06/102	Seeking confirmation (from MHRA) that MHRA is publishing false information regarding suicides and SSRIs	18 May 2006	Answered - in full
06/103	Names of European GMP approved manufacturing sites in India	04 May 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/104	MHRA clinical assessment report for the following generic fentanyl patch products: TILOFYL TRANSDERMAL PATCHES 25MCG/HR TILOFYL TRANSDERMAL PATCHES 50MCG/HR TILOFYL TRANSDERMAL PATCHES 75MCG/HR TILOFYL TRANSDERMAL PATCHES 100MCG/HR MA Holder: TILLOMED LABORATORIES LIMITED PL number: 11311/0311-314	06 June 2006	Answered - in part
06/105	Committee on safety of medicines (1972) Carcinogenicity tests of oral contraceptives. London, Her Majesty's Stationery Office	04 May 2006	Answered - in full
06/106	A copy of the Licensing Assessment Report in relation to the company named Allergan re: the use of Botox in the UK (which ruled that where used for cosmetic use in the UK it must be marketed under the name of Vistabel)	08 May 2006	Answered - in full
06/107	Company expert reports/CTD overall summary relating to safety and efficacy Assessment reports produced by MHRA related to safety and efficacy Legal basis for granting the marketing authorisation for PL 12063/0038 held by Wrafton Laboratories, Braunton EX33 2DL.	03 May 2006	Answered - in part
06/108	Any information or reports that you have on the closure in January 2006 of the Protein Fractionation Centre, Edinburgh	27 April 2006	Answered - in part
06/109	Information on dexamethasone - Minims eyedrops	26 April 2006	Answered - in full
06/111	How much funding has the MHRA received during 05/06 from drug companies to assist with the evaluation and implementation of new medicines (for example to assist with the development of capacity/impact models), and does the fee levied to pharmaceutical companies cover the evaluation and implementation of new medicines (for example to assist with the development of capacity/impact models)?	19 May 2006	Answered - in full
06/112	MHRA Regulatory Fees	08 May 2006	Answered - in full
06/113	A list of all overseas (third country) manufacturing sites inspected for GMP compliance by the MHRA in the past three years	10 May 2006	Answered - in full
06/114	Any information kept with regards to Blackburn Distributions	17 May 2006	Answered - in full
06/115	Continued hiding of data/Sheffield Risedronate by MHRA	03 May 2006	Answered - in full
06/116	A listing of all MHRA GMP, GLP and GCP inspections that have been conducted between January 1, 2006 and April 1, 2006, and various information regarding them.	10 May 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/117	Request for information on the frequencies as per MedDRA frequency convention for the adverse events listed in the innovator's SmPC from Sanofi-Aventis.	19 May 2006	Answered - in full
06/120	All details held on Cell Nature Remedies - product range No More! Warts, No More! Tinea, No More! Scars, No More! Herpes, No More! Acne. Case number and contents of report made by MHRA to Ebay.co.uk regarding sale of these products.	03 May 2006	Answered - in full
06/121	All information regarding HB-VAX 11 in the UK	23 May 2006	Answered - in full
06/122	A copy of the first Product Licence for the vaccine Pluserix manufactured by GSK and any subsequent amendments and copy of the first Product licence granted for Immravax manufactured by Merieux.	23 May 2006	Answered - in full
06/123	Licence particulars, specific schedules and provisions in respect of manufacturing authorisation MA 1811 held in the name of Bard Pharmaceuticals Ltd, Milton Road, Cambridge.	19 May 2006	Answered - in full
06/124	Last MHRA Inspection Report and Response for Reckitt Benckiser Healthcare (UK) Ltd, Kingston Works, Danson Lane, Hull, East Yorks, HU8 7DS	26 May 2006	Answered - in part
06/126	Consultation Proposal MLX249, 6 November 1998, relating to the Medicines for Human Use (Marketing Etc) Amendment Regulations 2000 and the changes to the Proposal which, according to the information available at http://www.mhra.gov.uk/, were announced by the Government at the MHRA Open Day on 16 July 1999.	03 May 2006	Answered - in full
06/128	Whether MHRA was ever in receipt of product licence applications for Bromfenac, Alosetron, Rapacuronium bromide	24 May 2006	Answered - in full
06/129	Information in relation to recent licensing applications for generic alendronate	26 September 2006	Answered - in part
06/130	Request for data about Strattera's deleterious effect on sexual maturation	28 April 2006	Answered - in full
06/132	Data on UK prosecutions for unlicensed medicine sales in the last three years - how many convictions for unlicensed medicine sales in that period, the highest and the average financial penalty imposed on conviction, and if any sentences of imprisonment were imposed, what those sentences were.	28 April 2006	Answered - in full
06/133	Copies of any and all 'Dear Doctor' letters sent by the MHRA relating to various drug products	25 May 2006	Answered - in full
06/134	Abbott Clearstar Pump and Giving Set	04 May 2006	Answered - in part
06/135	MHRA IT expenditure and resources	02 May 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/136	St Jude Medical Silzone coated heart valves and annuloplasty rings	26 May 2006	Answered - in part
06/140	Information on the drug 'atomoxetine'	20 June 2006	Answered - in part
06/141	Questions about patient Yellow Cards	15 May 2006	Answered - in full
06/143	Clinical and Non-Clinical Expert Report, Safety and Efficacy Summaries and Assessment reports for the original MAA and any subsequent major variations related to the target population, posology or safety for Asmanex Twisthaler (PL00201/0254-5)	31 May 2006	Answered - in part
06/144	A copy of the latest MHRA MA(IMP) inspection report for Bioreliance, Todd Campus, West of Scotland Science Park, Glasgow G20 0XA	23 June 2006	Answered - in part
06/145	A copy of the latest MA(IMP) inspection report for Cobra Biomanufacturing, Stephenson Building, The Science Park, Keele, Staffordshire ST5 5SP- the inspection was conducted in July 2005.	31 May 2006	Answered - in part
06/148	Any information held on contact etc between MHRA and the Expert group on vitamins and minerals	14 June 2006	Answered - in part
06/149	Seroxat/Placebo suicides	09 June 2006	Answered - in full
06/150	Various information related to blood policy and products	21 July 2006	Answered - in part
06/152	Details regarding MHRA staff expenses.	30 January 2007	Answered - in full
06/155	GMP inspection report for Cardinal Health Buenos Aires	05 June 2006	Answered - in part
06/157	A copy of MLX 247, including any responses to the consultation	14 June 2006	Answered - in part
06/158	MHRA rport concerning the possible interaction between the influenza vaccine and Warfarin therapy	26 May 2006	Answered - in full
06/159	Information on incidents relating to infusion devices	13 June 2006	Answered - in full
06/160	Clinical Data relevant to Perindopril 2mg and 4mg Tablets (PL 25847/0003-4 MA Holder KRKA POLSKA SP. Z.O.O.)	09 June 2006	Answered - in part
06/162	Top 10 ADR reports for the last 3 or 6 months for both HCP and patients as well as the numbers of patient reports	23 May 2006	Answered - in full
06/163	Patient Yellow Cards	02 June 2006	Answered - in full
06/164	Request for inspection report on Zhejiang Cheng Yi Pharmaceuticals 23-23/11/2005	06 June 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/166	Information regarding MHRA's information and communication strategies	14 June 2006	Answered - in part
06/169	Information on Diflucan One (fluconazole) PL 15533/0099 (NOTE: The correct PL number is PL 15513/0099)	16 June 2006	Answered - in full
06/170	MHRA Inspection Report of 19-21 January 2005 on Cipla Limited @ Kurkumbh	06 July 2006	Answered - in part
06/171	The Pharmaceutical Journal Vol 276. 20 May 2006 "GMP and GDP:a review of regulatory inspection findings ....." Please provide the information referred to on page 596 related to the five notices of intention to suspend an authorisation and the five letters of censure issued to QPs or RPs. I would like to know the reasons for the notices or letters. Please provide information of any further action taken with respect to the QPs or RPs.	31 May 2006	Answered - in full
06/172	The 2005 MHRA report on OTC codeine/ dihydrocodeine containing analgesics	06 June 2006	Answered - in part
06/173	Information relating to the withdrawal of ReNu MoistureLoc, the contact lens solution manufactured by Bausch & Lomb	23 June 2006	Answered - in part
06/174	Information concerning Vioxx (rofecoxib)	29 June 2006	Answered - in part
06/175	Asking whether a number of drug products were approved via the mutual recognition or decentralised procedures and, if so, which country acted as the reference member state for each	12 June 2006	Answered - in full
06/177	List of MHRA approved facilities in INDIA	12 June 2006	Answered - in full
06/181	Seroxat/Placebo suicides	09 June 2006	Answered - in part
06/184	Letter dated 15 May 2006 from MHRA GCP Inspectorate to the UK Minister of State for Delivery & Quality responding to questions posed by the Minister regarding a potential contravention of clinical trial legislation	08 June 2006	Answered - in part
06/185	Questions relating to an MHRA GCP inspector	20 June 2006	Answered - in full
06/186	Can the MHRA confirm whether they have referred the matter of the withholding of Paroxetine clinical trial data by GSK relating to the antidepressant Seroxat to the police for investigation	27 June 2006	Answered - in full
06/187	Information on the "Glucophage" brand of metformin 500mg & 850mg tablets	03 July 2006	Answered - in part
06/188	Questions relating to the perceived legal remit and procedures of the MHRA	29 June 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/190	information on slimming products containing Konjac Root (Glucomannan)	16 June 2006	Answered - in full
06/191	Seroxat and accusing MHRA of corruption	04 July 2006	Answered - in full
06/193	The following re: MHRA 1. the Management org chart 2. a list of LifeSciences companies that the MHRA help to guide? 3. Main drivers of the organisation 4. key business drivers and initiatives 5. How important is Regulatory Compliance to members of MHRA 21 CXFR Part 11 6. Does the MHRA provide generic training to members on basic regulatory issues? 7. How close are CRO's to the MHRA- Covance, Quintiles, etc.	08 June 2006	Answered - in full
06/195	Request for information about the recommendation of Prozac to children	05 July 2006	Answered - in full
06/197	Please could I have the references of the studies used to inform the CSM review of the use risperidone and olanzapine in older people with dementia issued on 9th March 2004.	16 June 2006	Answered - in full
06/198	Whether the UK acted as the RMS for a variety of drug products:	10 July 2006	Answered - in full
06/199	Information relating to Oxycontin	09 August 2006	Answered - in part
06/203	Copies of all correspondence concerning who made the original complaint to Swissmedic and subsequently MHRA regarding the regulatory status of Curasept solutions	07 July 2006	Answered - in part
06/204	Fluconazole and Diflucane	25 July 2006	Answered - in part
06/205	Request for an urgent safety review of Strattera	04 July 2006	Answered - in full
06/206	Papers mentioned in the Summary minutes of the biologicals and vaccines expert advisory group held on Monday 10 April 2006	29 June 2006	Answered - in part
06/207	Arms 31 - outcome document	18 July 2006	Answered - in full
06/208	Names of all courier / freight / Logistics providers who have been approved by MHRA	28 June 2006	Answered - in full
06/209	Request for copies of answers to previous FOI requests	26 June 2006	Answered - in part
06/211	Details of the most recent inspection by the MHRA for Pharmaserve Limited	30 August 2006	Answered - in part
06/213	Copies of the latest version of the CSM and SCOP NSAID safety reviews	03 August 2006	Answered - in part
06/214	Questions regarding MHRA investigation and enforcement procedures	05 July 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/215	A copy of the inspection report issued by the MHRA for the inspection carried out at Cardinal Health on January 25, 2006	13 July 2006	Answered - in part
06/216	A copy of the inspection report issued by the MHRA for the inspection carried out at Teva OSD, Jerusalem, Israel on February 5, 2006	14 July 2006	Answered - in part
06/218	A list of all the organisations and companies audited by MHRA in the last year going back to june 2005, and if the results of the audits are in the public domain	21 July 2006	Answered - in full
06/219	Information on Acyclovir creams, Zovirax(R) and the Pliva generic product (5%w/w acyclovir)	24 July 2006	Answered - in full
06/223	The MHRA audit report for Orchid Chemicals and Pharmaceuticals visit to the Alathur facilities in India for the manufacture of Cefuroxime Sodium	21 July 2006	Answered - in part
06/224	A list of overseas sites inspected for GMP by the MHRA	21 July 2006	Answered - in full
06/225	Request for the identity of the person/s reporting a suspected breach of regualtions	06 July 2006	Answered - in part
06/226	Information regarding sumatriptan	14 July 2006	Answered - in full
06/227	Requesting the identity of an informant	07 July 2006	Answered - in part
06/230	Questions regarding Paroxetine and suicides	04 August 2006	Answered - in full
06/231	Copies of reports from inspections that were carried out at the Protein Fractionation Centre in Edinburgh	01 August 2006	Answered - in part
06/232	I would like to know if the MHRA is currently conducting an inspection at Synergie Consultancy ltd to assess the level of compliance to GCPs	31 July 2006	Answered - in full
06/233	MHRA's March 2006 inspection report for; Marksans Pharma Limited Plot no L-82 & L-83 Verna Industrial Estate Verna Goa, India	11 July 2006	Answered - in full
06/234	Information on Becolex - PL 06607/0017 (50mcg), PL 06607/0018 (100mcg), PL 06607/0019 (200mcg), PL 06607/0020 (250mcg) - Marketing Authorisation Holder (MAH): Chiesi Farmaceutici SpA	08 August 2006	Answered - in part
06/235	Troglitazone	25 July 2006	Answered - in full
06/236	MHRA FOIA internal review procedures	04 September 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/238	A list of pharma and biotech companies that the MHRA have conducted GCP inspections at over the past 9 months	20 July 2006	Answered - in full
06/239	Information regarding Phase 1 clinical trials	08 August 2006	Answered - in full
06/240	Information regarding clinical trials - including the VICTOR trial	26 July 2006	Answered - in full
06/241	Evidence data of Paracetamol	01 August 2006	Answered - in full
06/243	Did MHRA provide advice on a medicine containing Glatiramer	09 August 2006	Answered - in full
06/244	A listing of all GMP inspections carried out by the MHRA between March 31, 2006 and July 1, 2006.	03 April 2007	Answered - in full
06/246	The last 5 MHRA pharmacovigilance reports	24 July 2006	Answered - in part
06/247	Questions regarding MHRA board member's non-appearance at a HOC Health Committee	27 October 2006	Answered - in full
06/248	Information on all the cord blood banks in the UK that are accredited by MHRA	25 July 2006	Answered - in full
06/250	Information regarding X-Ray machines	04 August 2006	Answered - in full
06/251	Request for copies of SOPs etc, used in inspections, and whether named inspector was trained in their use	31 July 2006	Answered - in full
06/252	Request for information about the recommendation of Prozac to children	04 August 2006	Answered - in full
06/253	Information on Qingdao Huashan Biochemical Company	04 August 2006	Answered - in full
06/254	Retin-A and associated products	30 August 2006	Answered - in full
06/255	Information on status of company called Cells4life	23 August 2006	Answered - in part
06/256	Costs of licenses for various products	30 January 2007	Answered - in full
06/257	Audit report (28th March 2006) of BioReliance ,Todd Campus, West of Scotland Science Park, Glasgow, G20 0XA	26 July 2006	Answered - in part
06/258	MHRA Inspection Report on Johnson Matthey Macfarlan Smith	17 August 2006	Answered - in part
06/259	Information regarding Strattera	27 July 2006	Answered - in part
06/260	Latest Good Laboratory Practice inspection of BioReliance - Invitrogen Biosciences, Todd Campus, West of Scotland Science Park, Glasgow, G20 0AX	21 August 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/261	Latest MHRA inspectors report on Biovault, Plymouth	01 August 2006	Answered - in part
06/262	Information from SCOP Meetings on Olanzapine/Zyprexa	06 September 2006	Answered - in part
06/263	Data from MHRA drug analysis prints	31 July 2006	Answered - in full
06/265	Bioequivalence results and methods of analysis for Apotex Europe Perindopril tablets	15 September 2006	Answered - in full
06/266	MHRA reports relating to Black Cohosh and hepatotoxicity	10 August 2006	Answered - in full
06/267	TGN1412	18 August 2006	Answered - in part
06/268	Information on MMR vaccines	04 September 2006	Answered - in part
06/269	Information on the vaccine Pluserix	11 August 2006	Answered - in full
06/271	Information in relation to the parallel import authorisation PL No 19488/0520 for Cardicor	26 August 2006	Answered - in full
06/272	I would like to request access to the last 3 PhV Inspection Reports issued by the MHRA and the PV/GCP IAG minutes for the last 3 meetings	12 September 2006	Answered - in part
06/273	Copies of CSM minutes from the Sub Committee on Safety, Efficacy and Adverse Reactions (SEAR) from 1982 to 1989 and a copy of The CSM Annual Report 1984/1985.	24 November 2006	Answered - in full
06/275	Information regarding Mucodyne Capsules and Mucodyne Syrup	18 September 2006	Answered - in full
06/276	Information regarding Melatonin	06 September 2006	Answered - in full
06/277	How many companies have the MHRA approval in China	03 April 2007	Answered - in full
06/282	List of all disclosures and documents made by MHRA to FOI requests	01 September 2006	Answered - in full
06/283	GMP inspection reports for Avecia, Billingham (UK)manufacturing site.	04 April 2007	Answered - in part
06/285	List of manufacturing sites in India, that have been inspected by the MHRA and have been considered suitable for the manufacture of products to be marketed in the UK	03 April 2007	Answered - in part
06/286	Audit reports for pharmacovigilance inspections carried out 2006, and whether there have been any prosecutions or legal actions taken against any named Qualified Person for Pharmacoviglance with details.	06 June 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/288	A listing of all MHRA inspections (including GMP, GLP and GCP) conducted at the following facilities since April 2004: -WL 20170 and WL 3070 -8824 Ipsen Biopharm Limited, Wrexham Industrial Estate Ash Road Wreham LL13 9UF -11290 Ipsen Limited, Bath Road, Slough, Berkshire, SL1 3XE -1720 Ipsen Biopharm Limited, Wrexham, Clwyd, LL13 9UF -MS 20170 / 7870 Health Protection Agency, Porton Down, Salisbury, Wiltshire, SP4 0JG Also copies of the latest inspectors reports on these facilities, and copies of reports from previous inspections conducted since 2004	18 October 2007	Answered - in part
06/289	The name of the Midlands PCT accused of, and the name of the pharmaceutical company complaining about, alleged payments of cash to persuade GPs to prescribe a certain drug.	19 September 2006	Answered - in full
06/290	Names of the members of the SDS Commissioning Group	18 August 2006	Answered - in full
06/292	Information regarding Bezalip	14 November 2006	Answered - in part
06/293	Copies of various MHRA inspection/audit reports	12 April 2007	Answered - in part
06/296	Replies to consultation MLX 312	25 September 2006	Answered - in part
06/297	Metsol 500mg/5ml Oral Solution	11 December 2006	Answered - in part
06/298	FOI statistics	08 September 2006	Answered - in full
06/299	Information on status of company called Smartcells	02 April 2007	Answered - in part
06/300	Request for consultaion replies for MLX 287	16 October 2006	Answered - in full
06/301	Information relating to potentially contaminated body parts that were allegedly stolen in the US and which may have been implanted into British patients. Biomedical Tissue Services	19 September 2006	Answered - in full
06/302	Information on MHRA audits for GMP and Pharmacovigilance in 2005 and 2006 concerninga company called Potters	19 February 2007	Answered - in part
06/303	Personal questions relating to MHRA inspector	22 September 2006	Answered - in part
06/304	Information regarding the location of hospitals using products originating from potentially contaminated sources	28 September 2006	Answered - in full
06/306	Questions relating to MHRA terminology	05 October 2006	Answered - in full
06/308	A copy of a site inspection report at site No. 1803 on 15th November 2004 (Bodycote Materials Testing Limited)	09 October 2006	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/309	Immunisation - general information	16 October 2006	Answered - in full
06/310	Copies of the responses to MLX 312	22 September 2006	Answered - in part
06/312	Information regarding Vinblastine Sulphate 1mg/ml injection - Mayne Pharma PLC, and Velbe injection 10mg/vial Genus Pharmaceuticals Limited	21 September 2006	Answered - in full
06/313	Copy of the evidence supplied by MHRA to HoL sub-comm on stemm cell research in 2001	06 June 2007	Answered - in full
06/314	Copy of the data used to support the approval of Levonelle	16 October 2006	Answered - in part
06/315	Information relating to Sodium Fusidate, Fusidic Acid andlor FUCIDIN	20 October 2006	Answered - in part
06/316	Details of investigations on companys known as "China European ltd" and "Everwell Ltd"	18 October 2006	Answered - in part
06/317	Biovaults August inspection report	16 October 2006	Answered - in part
06/318	A list of all MHRA inspections conducted at: WL 20170 and WL 3070 8824 Ipsen Biopharm Limited, Wrexham Industrial Estate Ash Road Wreham LL13 9UF 11290 Ipsen Limited, Bath Road, Slough, Berkshire, SL1 3XE 1720 Ipsen Biopharm Limited, Wrexham, Clwyd, LL13 9UF MS 20170 / 7870 Health Protection Agency, Porton Down, Salisbury, Wiltshire, SP4 0JG since April 2004	17 October 2007	Answered - in part
06/319	A copy of the Johnson & Johnson Pharmacovigilance Inspection Report. Preferably in an electronic form. Can I also have the most recent Pharmacovigilance report which is avaiable from the inspectors.	13 March 2007	Answered - in part
06/320	Information regarding pimozide and paroxatine	28 October 2006	Answered - in full
06/321	Information on MHRA communications strategy, and reports commissioned regarding the Agency's standing/public perception	06 November 2006	Answered - in full
06/322	Data presented when drug Topiramate was licensed for treatment of chronic migraine in July 2005. Was evidence of weight loss side effect presented and what studies into drug's use fo chronic migraine was considered.	23 October 2006	Answered - in full
06/323	Information regarding correspondence from the Royal Family	30 November 2006	Answered - in part
06/324	Please tel me [a] on what date (at which meeting) members of the CSM Expert Working Group on SSRIs were supplied with copies of summaries of individual case reports of the three placebo suicides reported in paroxetine trials, and [b] to which of the "assessment reports" MHRA refers were these case summaries attached	16 October 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/326	I am interested to know how much individual tablets of Lamictal may vary between batches	04 December 2006	Answered - in part
06/328	A listing of all companies for which a GMP/GCP/GLP inspection was carried out by the MHRA between March 31, 2006 and July 1, 2006, with full details	22 March 2007	Answered - in part
06/330	Details of the cases of warfarin/glucosamine interaction which were reported in the May 2006 Pharmacovigilance series.	20 October 2006	Answered - in full
06/332	Information on the registration of a product composed of: delta-9-tetrahydrocannabinol 27mg/ml and cannabidiol 25mg/ml - whether an application for an MA been submitted and when approval is expected or the status of the application.	09 November 2006	Answered - in part
06/333	Does the MHRA FOI internal review SOP apply to the NHS or MHRA only	10 October 2006	Answered - in full
06/334	GMP audit reports for Lonza, Slough, UK, facility, conducted in June 2006 and July 2006	17 October 2006	Answered - in part
06/335	Names of all contract research organisations (CRO) which are working in the UK and whose activities are regulated by MHRA	16 October 2006	Answered - in full
06/339	Correspondence dealing with companies commitment to discontinue selling Curasept	08 November 2006	Answered - in full
06/341	Information regarding new actives substances, including l Product Licences annotated as containing 'new actives' , and how many of the total NASs approved each year were new chemical entities, new biological entities and new biotechnology products. How many of the total number of new active substances approved were approved via the Mutual Recognition Procedure or via the Centralised Procedure.	06 November 2006	Answered - in full
06/342	Details of the most recent MHRA GMP inspection of: Universal Products (Lytham) Manufacturing Ltd.	19 February 2007	Answered - in full
06/343	1) a breakdown of the number of applications for MHRA trading licences in the last five years, by six monthly periods and the type of licence successfully applied for. 2) a breakdown of the number of rejected applications for MHRA trading licences in the last five years, by six monthly periods and the type of licence applied for.	03 November 2006	Answered - in full
06/344	The legal basis under which various MA were granted	08 November 2006	Answered - in full
06/345	Information regarding MHRA's information and communication strategies	14 March 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/346	A listing of all MHRA GMP, GLP and GCP inspections that have been conducted between April 1, 2006 and October 1, 2006. If possible please include the following information relative to each inspection: name of the company inspected, location of the inspection (city, state/region, country, etc).	22 March 2007	Answered - in full
06/347	The MAs for the products Epogam and Efamast were withdrawn on 7 October 2002 in the UK on the basis of unproven therapeutic efficacy. I would like to examine the evidence and expert advice on which those decisions were made	24 November 2006	Answered - in part
06/348	Information concerning Hypromellose eye drops	03 January 2007	Answered - in full
06/349	Information on the Advisory Board on the Registration of Homeopathic Products (ABRHP)	23 October 2006	Answered - in full
06/350	Seroxat placebo suicides	20 November 2006	Answered - in part
06/351	Whether phenylpropanolamine underwent any kind of review by either the Committee on the Review of Medicines or by the Committee on Safety of Medicines. If so provide a copy or copies of any such review(s).	21 November 2006	Answered - in full
06/352	Information on a phase 3 drug trial of aripiprazole	14 December 2006	Answered - in part
06/354	Most recent GMP inspection reports for Fisher Clinical Services	27 February 2007	Answered - in part
06/355	A complete copy of the MA approval audit report on the Strides Arcolab Beta Lactam and KRS Gardens sites in Bangalore	15 February 2007	Answered - in part
06/356	A copy of the MHRA routine GCP inspection report for the assessment conducted at Medeval Limted on June 27-29, 2006 (this inspection included review of one of our clinical studies)	09 November 2006	Answered - in part
06/357	CCM information (especially quantitative composition of glucophage SR, clinical summary, pharmacokinetic data) on Glucophage SR	12 December 2006	Answered - in part
06/358	All MHRA inspection reports and responses for the Welsh Blood Service, Ely Valley Road, Talbot Green, Pontyclun	13 December 2006	Answered - in part
06/361	All documents relating to MHRA evaluations of the safety of nurse and pharmacist prescribing, and all documents relating to how the evaluation is to conducted. Also all documents on the results or reports of any evaluations into the safety of nurse and pharmacist prescribing.	01 December 2006	Answered - in full
06/362	Seroxat placebo suicides	01 December 2006	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/363	TGN1412	08 November 2006	Answered - in part
06/364	Information relating to Tyrozets	27 November 2006	Answered - in part
06/365	Under the Freedom of Information please can you provide me with a complete template of the MHRA's Pharmacovigilance Inspector's report?	10 November 2006	Answered - in full
06/366	Copies of pharmacovigilance inspection reports of US based pharmaceutical companies from 2005 to the most current date.	01 February 2007	Answered - in part
06/367	Information concerning MHRA enforcement activities	07 December 2006	Answered - in full
06/369	Request for lists of publications	27 November 2006	Answered - in full
06/371	Request for copy of a GMP certificate issued after inspection	28 March 2007	Answered - in part
06/372	I request the PV Inspection reports Astellas, Altana and Kyowa Hakko to ensure auditing standards meet the expectations of the MHRA inspectors regarding PV auditing.	13 March 2007	Answered - in part
06/373	Assessment Report in respect of the registration of Atrogel Arnica Gel, registered under the Traditional Herbal Medicines Registration scheme	15 December 2006	Answered - in part
06/374	MHRA advise that "products containing up to or less than 0.005% of naphazoline are generally not regarded to fall within the above definition [of a medicinal product]. Please can you provide the assessment/information on which that opinion is based	01 December 2006	Answered - in part
06/375	A copy of the MLX 247 consultation and the responses.	20 November 2006	Answered - in part
06/376	Legal basis of Product Licence authorisation for: PL 13249/0031 Imodium instants and for PL 13249/0034 Imodium Instant Melts	05 December 2006	Answered - in full
06/377	A copy of the response to the ARM33, public consultation paper, along with the annexes	07 December 2006	Answered - in part
06/378	The formulation details of the following product granted by MHRA on the 12/9/2006: PL 15842/0039 held by Taro Pharmaceuticals (UK)Ltd - Etopan XL 600mg tablets	23 November 2006	Answered - in part
06/379	A copy of the latest MHRA inspection report for the following company Generics (UK) Limited based at Potters Bar	19 February 2007	Answered - in part
06/381	'Top-ten' devices that are most likely to be involved in an adverse incident	14 December 2006	Answered - in full
06/382	Andrx Pharmaceuticals MHRA inspection from 2-5 October 2006	19 February 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
06/383	Information regarding Nicotine Replacement Products	22 December 2006	Answered - in full
06/384	Questions arising from Prof. Sir Alasdair Breckenridge's submitted oral evidence taken before the Health Commitee	19 December 2006	Answered - in full
06/385	Paracetamol legislation	22 November 2006	Answered - in part
06/386	Information regarding Equasym XL	05 January 2007	Answered - in part
06/387	Inspection report for Cardinal Health performed April 24-26-2006	07 December 2006	Answered - in part
06/389	MHRA FOI fees	28 November 2006	Answered - in full
06/390	Information regarding proposed new set of regulations which would allow the use of homoeopathic "provings"	21 December 2006	Answered - in full
06/393	Information on the Vioxx investigation	22 December 2006	Answered - in full
06/394	A list of all products for which the MHRA have granted permission to import a product (EU and non-EU)under "Specials" (unlicensed medicinal products)	12 January 2007	Answered - in full
06/395	Information about coproxamol	22 December 2006	Answered - in full
06/398	A list of either accredited CROs or list of CROs inspected from your authority, for which GCP and/or GLP incompliance has been identified, and from which you don't accept a bioequivalence trial	19 December 2006	Answered - in full
06/399	A copy of the MHRA Inspection Report for Intas Ltd. Ahmedabad, India	12 February 2007	Answered - in part
06/400	Details of the legal basis for the following applications: Boots Congestion Relief Capsules PL 00014/0593 and Non-Drowsy Sudafed Congestion Relief Capsules PL 15513/0125	05 December 2006	Answered - in full
06/401	Information on the number of clinical trial applications which have been made in the UK per year for the last 5 years	05 January 2007	Answered - in full
06/402	Questions regarding MHRA board member	06 December 2006	Answered - in full
06/404	A copy of the CSM paper about the change in legal classification of fluconazole 150mg in July 2005.	03 January 2007	Answered - in part
06/405	Further information on MAs for the products Epogam and Efamast	09 January 2007	Answered - in full
06/407	A list of UK MA Holders who have undergone a Pharmacovigilance Inspection	20 September 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
06/408	Foreign CA asking for opinion on release of MHRA originated material	04 January 2007	Answered - in part
06/409	A copy of the inspection report of the Cardinal Health facility on April 3 - 6, 2006	22 December 2006	Answered - in part
06/415	Any information regarding the effect in CARDIOTOCOGRAHY of the phenomenon "doubling" of the fetal heart rate or other similar false readings of the fetal or maternal pulse whilst using a hand held Huntleigh doppler sonicaid or similar hand-held device	09 January 2007	Answered - in full
06/416	A copy of the most recent inspection reports for HPA (formerly CAMR) at Porton Down	07 September 2007	Answered - in part
06/417	How many clinical trials are performed in the UK on a yearly basis, and if possible split by phase	10 January 2007	Answered - in full
06/419	Outcome of investigation prompted by Doctor's allegations	20 December 2006	Answered - in full
06/420	Information on MHRA's HR structure	20 December 2006	Answered - in full
06/421	Information regarding any controlled trials on effectiveness of garlic in the prevention and treatment of the common cold	15 January 2007	Answered - in full
06/422	The reasons why MHRA has decided to refuse the proposed label for Caduet	12 July 2007	Answered - in part
06/424	Request for various MHRA monthly statistics	12 February 2007	Answered - in full
06/425	Information regarding Medtronic Talent Device	16 January 2007	Answered - in part
06/426	A copy of the most recent Pharmacovigilance Inspection Report for Novartis Pharmaceuticals	15 January 2007	Answered - in part
06/427	Request for MHRA FOI SOP	21 December 2006	Answered - in full
06/428	The total number of clinical trial which have taken place in each year by phase between 2000 and 2006	10 January 2007	Answered - in full
06/429	A listing of all inspections (GMP, GLP, GCP) conducted by the MHRA during 2006. Specific information requested would be the name of the facility inspected, the date range of the inspection, location of the facility, name of inspector(s), and the number and type of observations or deficiencies cited.	19 January 2007	Answered - in full
06/430	A list of all facilites inspected for GCP compliance since 2004 and details of all findings from these inspections	16 January 2007	Answered - in part
06/431	GMP inspection reports	01 June 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/001	Information on the total number of yellow card reports from general practitioners, hospital doctors, hospital pharmacists, community pharmacists, hospital nurses, community nurses and patients for the individual months in 2006	30 January 2007	Answered - in full
07/002	MHRA investigation into GSK and Seroxat	31 January 2007	Answered - in part
07/004	The public assessment report pertaining to the reclassification of Zocor (Simvastatin) 10 mg to OTC status in the UK	23 January 2007	Answered - in part
07/005	A June 2005 MHRA inspector's report	27 March 2007	Answered - in part
07/006	Full information on clinical trials for the new pneumococcal disease immunisation program undertaken by the DoH	12 January 2007	Answered - in full
07/007	Copies of the last inspection report and any confirmation of accreditation given to: 1. BioVault Ltd - based in Plymouth 2. Smart Cells International Ltd - based in London	01 February 2007	Answered - in part
07/012	COPY OF MOST RECENT GMP INSPECTION REPORT FOR: EVOTEC FORMULATIONS	09 March 2007	Answered - in part
07/013	Various information relating to licensing, clinical trials etc.	22 January 2007	Answered - in full
07/015	A copy (electronic or paper) of the last MHRA GMP Inspection report of: Ben Venue Laboratories Inc	19 February 2007	Answered - in part
07/017	Copy of letter sent to MHRA by an American Doctor re anti-depressants	06 February 2007	Answered - in part
07/019	A list of reclassified medicines	06 February 2007	Answered - in full
07/022	Use of Zolpidem	05 March 2007	Answered - in full
07/023	Query regarding MHRA records keeping and JVCI minutes	09 February 2007	Answered - in part
07/027	Audit report for Intas Pharmaceuticals Limited, Ahmedabad, India, start date 09.10.06, case ref. Insp GMP 17543/9621-0007	12 February 2007	Answered - in part
07/030	Details of the summary basis of approval for Non-Drowsy Sudafed Dual Relief Max - PL 15513/0126	15 February 2007	Answered - in full
07/032	Details on the level of counterfeit pharmaceutical medicinal products finding their way into the supply chain via authorised wholesalers in the UK	20 February 2007	Answered - in full
07/033	MHRA assessment of new drug application for oral contraceptive Yasmin	26 February 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/034	Information on the investigations into seroxat	26 February 2007	Answered - in full
07/035	MHRA assessment reports for Lipobay (cerivastatin)	25 April 2007	Answered - in part
07/036	Any inspection report for the Wockhardt Limited pharmaceutical manufacturing facility conducted within the past 6+ years (2000 to present)	30 May 2007	Answered - in part
07/037	Findings and issues noted during inspection of Aptuit Edinburgh Limited	27 February 2007	Answered - in part
07/039	A redacted copy of the Patient Information Leaflet User Test Report for Imigran Recovery 50mg tablets	12 February 2007	Answered - in part
07/040	Seroxat investigations	21 February 2007	Answered - in full
07/041	The public assessment report for MA PL 17926/0004 HELM PHARMACEUTICALS GMBH Co-Cyprindiol	08 March 2007	Answered - in full
07/042	Drug Analysis Print for simvastatin 10mg which lists all of the adverse drug reactions which have been reported to the MHRA by all sources (including those reported by the marketing application holder) from May 2004 to the most recently available with a breakdown of whether the event was reported by a physician, pharmacist or member of the public	26 February 2007	Answered - in full
07/043	Assessment report developed by MHRA as RMS on UK/H/0415/001. Aftasol 5% oral paste	21 December 2007	Answered - in part
07/044	ISAC minutes	12 February 2007	Answered - in part
07/046	MHRA Pharmacovigilance Inspection Reports of Japanese Companies (e.g. Takeda, Eisai, Astellas etc.) for the last 3 years	14 March 2007	Answered - in part
07/047	Inspection reports from any inspections conducted by the MHRA of the Rottendorf Pharma GmbH pharmaceutical manufacturing facility in Germany conducted from January 1, 2001 to January 31, 2007	14 February 2007	Answered - in full
07/048	Copy of MHRA's inspection of Intas Pharmaceuticals Limited	12 February 2007	Answered - in part
07/049	Copy of MHRA's inspection of Intas Pharmaceuticals Limited	15 February 2007	Answered - in part
07/050	Berlind retard batch variation	27 February 2007	Answered - in full
07/052	Information regarding Strattera	21 February 2007	Answered - in full
07/053	Information on oxiplatin	05 April 2007	Answered - in part
07/054	Information regarding Strattera	26 February 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/055	Information relating to Ortho Evra	28 February 2007	Answered - in full
07/057	Copies of the last 3 Pharmacovigilance Inspection Reports issued by the MHRA	14 March 2007	Answered - in part
07/058	Details of any licensed wholesalers or manufacturers who have notified the MHRA that they intend to import the product Toquilone Compositum (methaqualone and diphenhydramine) in the last 12 months?	26 April 2007	Answered - in full
07/059	Information about Aknemin	26 February 2007	Answered - in part
07/060	Information regarding MHRA's facilties management	07 March 2007	Answered - in full
07/061	Information regarding CANDESARTAN CILEXETIL for the Takeda Product PL No 16189/0001,2,3,4 and 7	30 April 2007	Answered - in part
07/062	A copy of the most recent inspectional report for Protherics UK Ltd Blaenwaun Ffostrasol Llandysul Ceredigion SA44 5JT	05 March 2007	Answered - in part
07/063	All data held (including age, gender and by drug) relating to the occurence of psychiatric episodes (under the MedDRA SOC "Psychiatric Disorders") in patients receiving any of the anti-TNF therapies (including etanercept, infliximab, adalimumab, anakinra, rituximab)	19 March 2007	Answered - in full
07/064	MHRA investigation into GSK and Seroxat	20 March 2007	Answered - in full
07/065	Copy of Inspection Report Following Inspection Of Edinburgh and South East Scotland Blood Transfusion Service between 18 and 20 November	22 March 2007	Answered - in part
07/066	Seroxat information	06 September 2007	Answered - in part
07/067	Board member's interests	22 March 2007	Answered - in full
07/068	Questions regarding ordering of controlled drugs from the British Pharmacopoeia	23 March 2007	Answered - in full
07/069	Information regarding Product Licence PL 0068/0165 (Airomir Inhaler)	28 March 2007	Answered - in part
07/073	Last 2 MHRA site inspection reports for Dales Pharmaceuticals, Skipton U.K. and company responses	16 April 2007	Answered - in part
07/075	MMR	07 March 2007	Answered - in full
07/076	A copy (electronic or paper) of the most recent GMP Inspection of the following company: Cardinal Health 3001 Red Lion Road Philadelphia, PA, 19114	26 March 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/077	Information on the investigations into seroxat	03 April 2007	Answered - in full
07/078	Mutual Recognition Assessment Report for apomorphine	08 May 2007	Answered - in full
07/080	Information regarding Strattera	05 April 2007	Answered - in full
07/081	MHRA Audit Report for Cardinal Health, Corby, UK	09 March 2007	Answered - in part
07/082	Esprit and Ciclosporin	22 March 2007	Answered - in part
07/084	The last three MHRA pharmacovigilance inspection reports - preferably inspection reports from a german pharmaceutical company acting globally	14 March 2007	Answered - in part
07/085	Standards etc applying to MHRA staff	27 March 2007	Answered - in full
07/089	Information regarding Lemsip Max Day & Night Cold & Flu Relief Capsules	10 April 2007	Answered - in full
07/090	Digoxin 0.125 mg -Cmax Limit-Bioequivalence study	12 April 2007	Answered - in full
07/092	A list of all MHRA Good Pharmacovigilance Practice Inspections that have been conducted to date, including those conducted in a third Country	04 April 2007	Answered - in full
07/093	Information for product PL 10590/0042, held by Galderma (UK) Limited, granted 4/19/1999	19 June 2007	Answered - in part
07/094	Information for product PL 00031/0285, for Loceryl Nail Lacquer 5% (amorolfine HCl) originally held by Roche Products Limited	19 June 2007	Answered - in part
07/095	Inspection reports for the following companies: Shasun located in Pondicherry India Clinical Trial Services located in Audobon, PA Gilead Sciences located in San Dimas, CA	17 April 2007	Answered - in part
07/096	Information provided by the company AstraZeneca to the MHRA, the CSM and NICE on the drug Nexium (Esomeprazole)	18 May 2007	Answered - in part
07/097	Number of First-Time-In-Man clinical trials performed in the UK per annum (not including drugs administered via a new route)	23 May 2007	Answered - in full
07/098	A list of manufacturing sites that have been approved by the MHRA in India for the manufacture of drugs for human consumption	26 March 2007	Answered - in full
07/099	Please forward three PILs and their User tested reports for three different products in terms of pharmaceutical form	29 March 2007	Answered - in part
07/100	Documentation on qualified nurse and pharmacist independent prescribing	27 March 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
07/101	Regulation of Benzylpiperazine	18 April 2007	Answered - in full
07/102	Inspection Report for OPD Laboratories	04 April 2007	Answered - in part
07/103	How many companies are regulated by the MHRA, and are you aware of the turnover of those companies	23 April 2007	Answered - in full
07/104	Paxil side effects	23 April 2007	Answered - in part
07/105	MHRA's response to the Report of the Select Committee, The Influence of the Pharmaceutical Industry, dated 22 March, 2005	16 April 2007	Answered - in full
07/106	Any summary documentation evidencing pre-licensure trials of Pluserix and/or Pariorix which indicate whether any trials were carried out and/or the extent of the trials and/or the outcome of the trials	26 June 2007	Answered - in full
07/109	Names of companies that have MHRA approval in China	04 April 2007	Answered - in full
07/110	Iinspection report of Angel Biotechnology's facilities	05 April 2007	Answered - in part
07/111	Information on the MMR vaccines	03 May 2007	Answered - in full
07/113	Request for letter MLX247	04 May 2007	Answered - in full
07/114	MLX 338 and MLX 336 Consultation Documents	04 May 2007	Answered - in full
07/116	GMP inspection reports pertaining to Nova Laboratories (Wigston, Leicester) and to Brecon Pharmaceuticals (Hay-on-Wye)	04 May 2007	Answered - in part
07/118	Questions relating to clinical trials	22 August 2007	Answered - in full
07/119	A list of CRO's used for BE studies conducted for medicinal products approved in the UK, particularly CRO's that have performed Bioequivalence studies for the HMG-CoA reductase inhibitors, e.g. Simvastatin	03 May 2007	Answered - in full
07/122	Information about current pre clinical and clinical trials broken down by phases, sponsors and drug/therapy type	23 May 2007	Answered - in part
07/123	Information on the interchangeability of fentanyl patches	14 May 2007	Answered - in part
07/124	Details of the legal basis of the original marketing authorisation for Actiq lozenges	08 May 2007	Answered - in full
07/125	A copy of the GMP Inspection Report for the inspection of: Almac (formerly known as Clinical Trial Services)	11 May 2007	Answered - in part
07/127	Information regarding Strattera	01 May 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
07/128	All CSM minutes of meetings for the year 1983 between the DHSS, PHLS, Committee of the Safety Of Medicines and the United Kingdon Haemophilia Centre Directors and any other interested parties that discussed imported US plasma products and the issue of AIDS - to assist the Archer Inquiry into contaminated blood	03 May 2007	Answered - in full
07/129	A copy of the material used for the training of European Pharmacovigilance Inspectors led by the MHRA in Edinburgh in March 2007, and a copy of the report for the Pharmacovigilance Inspection performed at Stiefel in February 2007.	07 June 2007	Answered - in full
07/130	Questions relating to Seroxat	22 May 2007	Answered - in full
07/131	Questions relating to Seroxat	22 May 2007	Answered - in full
07/132	Questions relating to ADR reports	04 May 2007	Answered - in full
07/133	Public Assessment Reports in relation to the drug Adartrel	27 April 2007	Answered - in full
07/135	Information regarding Strattera	23 May 2007	Answered - in full
07/137	Information on pediacel and prevenar	30 May 2007	Answered - in full
07/138	Enquiry into the background of dosage instructions of medicnes	07 June 2007	Answered - in full
07/139	Query regarding randomised controlled trial of alternative treatments to inhibit VEGF in age-related choroidal neovascularisation (IVAN Study)	01 June 2007	Answered - in part
07/141	MHRA investigation into GSK and Seroxat	11 July 2007	Answered - in full
07/145	MHRA inspection reports for various manufacturing and packing sites	11 May 2007	Answered - in part
07/146	All correspondence/documentation between MHRA (formerly MCA), Committee on Human Medicines (formerly CSM) and Denfleet Pharmaceuticals Ltd concerning Merional	31 May 2007	Answered - in part
07/148	MHRA IS/IT Strategy	25 May 2007	Answered - in full
07/149	Historical statistics on the number of clinical trials that take place in the UK and Europe (if possible)	10 August 2007	Answered - in full
07/150	Transcript of the Safety of Medicines Advisory meeting June 15, 2005 Multiple Sclerosis	19 February 2008	Answered - in part
07/151	Most recent GMP Inspection report (August 2005?) for Qualiti Burnely Limited (QBL)	23 May 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/152	Records of communications between MHRA and Pfizer Inc. regarding new emerging safety concerns related to the use of Zyvox in specific patient populations	29 June 2007	011. Disclosed followin
07/153	Information regarding Desmopressin	20 June 2007	Answered - in part
07/154	Information on Neurontin	04 June 2007	Answered - in full
07/158	Request for reports of pharmacovigilance inspections	21 June 2007	Answered - in part
07/159	Information regarding inspections carried out on the blood bank service at Caithness General Hospital, Wick, Scotland.	14 June 2007	Answered - in part
07/160	Statistics relating to accidents involving patient hoists	20 June 2007	Answered - in full
07/162	Latest GLP inspection report for Microptic Cytogenetic Services, Swansea	04 June 2007	Answered - in part
07/164	MHRA's members and committee members Declaration of Interests	29 August 2007	Answered - in full
07/165	Copies of the GLP Statements of Compliance	06 June 2007	Answered - in full
07/166	The number of notifications for named patient prescriptions in the UK for 2002 2203 2004 2005 and also 2006	07 June 2007	Answered - in full
07/168	Cost of legal services during the most recently available financial year, split between in house and external advisers and, if external advisers are used, a copy of your framework agreement or invitation to tender	26 June 2007	Answered - in full
07/169	TGN1412	14 June 2007	Answered - in full
07/170	Listing of critical deficiencies issued by MHRA from January 1, 2001 inspections forward. Specifically, those critical deficiencies identified as a result of pharmacovigilance-related issues/inspections. Details needed would be the date of the inspection, site inspected, observation/deficiency title, and text of the critical deficiency.	07 June 2007	Answered - in part
07/171	Copy of the attached documents connected to the FoI request 06/374 relating to why concentrations of nephazoline less than 0.005% are not considered to be medicinal products	19 June 2007	Answered - in part
07/172	Data on the number of deaths associated with the drug Epilim	29 June 2007	Answered - in full
07/175	All data held (including age, gender and by drug) relating to the occurence of lupus/systemic lupus erythematosus episodes in patients receiving any of the anti-TNF therapies (including etanercept, infliximab, adalimumab, anakinra, rituximab)	20 June 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
07/176	Information related to tissue from possibly contaminated sources	28 June 2007	Answered - in full
07/177	How many employees are currently employed in your licensing division	19 June 2007	Answered - in full
07/179	Data for the past 10 years: How many clinical trials were done in Scotland, London, the UK per year? How much money was spent conducting clinical trials each year? Detailed data broken down by phase level and therapeutic group. Profiles of pharmaceutical companies or non-profit agencies that conducted such studies	14 August 2007	Answered - in full
07/180	Was a GCP/PV inspection conducted for the MAH Sato Limited and, if so, a copy of the inspection report.	12 June 2007	Answered - in full
07/181	Sulpiride	26 June 2007	Answered - in full
07/182	Information regarding the submission or application documents and approval documents for Nicorette Gums and any other medicated gums containing nicotine or nicotine resinate	06 November 2007	Answered - in part
07/183	Legal dispute involving Bracco UK Ltd (Bracco) leaflet entitled "Unchallenged Renal Tolerability"	06 July 2007	Answered - in part
07/184	Information regarding marketing authorisations of generics	26 June 2007	Answered - in full
07/186	Information about Reminyl (Galantamine hydorbromide)	14 August 2007	Answered - in part
07/187	Information for the Archer Public Inquiry into contaminated blood supplies	10 July 2007	Answered - in part
07/188	A copy of the audit report for Almac (Craigavon)	10 July 2007	Answered - in part
07/189	A copy of the audit report for Patheon (Swindon)	11 July 2007	Answered - in part
07/190	The last inspection reports for M&A Pharmachem Ltd & Zeta Laboratories Ltd	06 July 2007	Answered - in part
07/191	How many Yellow Card or other adverse reaction reports have been made citing multiple sclerosis as a suspected adverse event of the administration of a vaccine	20 June 2007	Answered - in full
07/192	MMR	13 July 2007	Answered - in full
07/193	A copy of the last MHRA inspection of J M Loveridge plc	11 July 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/194	Details of overseas sites inspected for GMP compliance for 2005/2006 and any more current information on those sites. Also any data on the impact of the clinical trials directive on companies that manufacture gmp imps for clinical trials	13 July 2007	Answered - in full
07/195	Copies of the two most recent Periodic Safety Update Reports (PSURs) for Avastin (bevacizumab), and copies of the two relevant assessment reports, one for each PSUR	19 July 2007	Answered - in part
07/196	Information regarding Strattera	20 July 2007	Answered - in full
07/197	Copies of the following guidances: MAL 32, MAL 30, MAL 4	17 July 2007	Answered - in full
07/198	Information regarding varaitions in GSK's NiQuitin marketing authorisations	24 July 2007	Answered - in part
07/199	Various questions regarding licenses and appliactions for devices and medicines	03 July 2007	Answered - in full
07/200	Acting on behalf on a client who was injured as a result of using a defective Wheelchair	13 July 2007	Answered - in part
07/201	Information on the MHRA licences granted for Phenytoin capsules	25 July 2007	Answered - in part
07/202	A copy of the MHRA inspection report for Aesica Pharmaceuticals based in Cramlington, UK performed over the period 31st October - 2nd November 2005	24 July 2007	Answered - in part
07/205	Information regarding clinical trials	15 August 2007	Answered - in full
07/206	Request for MHRA FOI SOP	25 July 2007	Answered - in full
07/208	Information regarding policy and practice taken by the MHRA over Statins	01 August 2007	Answered - in full
07/210	the most recent laboratory inspection reports for Bodycote Laboratories and Broughton Laboratories	02 August 2007	Answered - in part
07/211	GMP Inspection report of Astron Research	03 August 2007	Answered - in part
07/212	All data elating to the occurence or exaccerbation of interstitial lung disease in patients receiving biologic therapy for rheumatic diseases - including the anti-TNF therapies (including etanercept, infliximab, adalimumab), anakinra and rituximab.	25 July 2007	Answered - in full
07/213	A list of all products for which the MHRA have granted permission to import a product (EU and non-EU) under “Specials” (unlicensed medicinal products)	01 August 2007	Answered - in full
07/215	Legal basis information required on Omacor capsules from Solvay Healthcare Limited	01 August 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
07/216	MHRA's most recent audit report of Nova	26 July 2007	Answered - in part
07/217	A list of all overseas sites inspected by the MHRA in the last 3 years	01 August 2007	Answered - in full
07/219	Information regarding Belford Hospital inspection reports	27 July 2007	Answered - in full
07/220	MHRA IT strategy and expenditure	25 July 2007	Answered - in part
07/221	Public Assessment Reports on any preparations containing meloxicam	27 July 2007	Answered - in full
07/222	The latest MHRA MIA(IMP) GMP inspection report for Nova Laboratories Ltd., Leicester	15 August 2007	Answered - in part
07/223	The latest MHRA MIA(IMP) GMP inspection report for Cobra Biomanufacturing plc in Keele	28 August 2007	Answered - in part
07/224	Any information on the outomce of pregnancy in partners of rheumatoid arthritis patients receiving anti-TNF therapy	21 August 2007	Answered - in part
07/225	Copies of recent MHRA inspections of Progenix Research at Rosyth and the VLA at Weighbridge	31 July 2007	Answered - in part
07/226	The GMP approval of Cardinal Health - latest inspection report for the production part	23 August 2007	Answered - in part
07/227	GMP / GLP inspection reports for International Laboratory Services (ILS), SafePharm, Reading Scinetific Services Ltd (RSSL)	16 August 2007	Answered - in part
07/229	Copy of MHRA's inspection of Alembic Limited, Panelav, Alembic Road, Vadodara 390 003, India	16 August 2007	Answered - in part
07/230	Information relating to Evra	27 September 2007	Answered - in part
07/231	A copy (electronic or paper) of the last MHRA GMP Inspection report of: IncAptuit Limited, Scotland	28 August 2007	Answered - in part
07/232	A list of all PLPIs which are currently held where the source stock for these licenses originates from the Rep of Ireland	07 August 2007	Answered - in full
07/234	UKPARS for 2mg and 4mg nicotine lozenges	31 August 2007	Answered - in full
07/237	Details of all overseas sites inspected by the MHRA for finished product manufacture and separately for API production	21 August 2007	Answered - in full
07/239	Any information on whether any products containing urapadil hydrochloride (as active ingredient) have been the subject of marketing authorisation applications in the UK	16 August 2007	Answered - in part
07/240	Information for product PL 00101/0566 held by Galderma (UK) Limited, granted 30 November 1999	25 September 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/241	Information regarding HRT E2 implants by MFG	06 September 2007	Answered - in full
07/242	All pharmacovigilance inspection reports about Pfizer or Pfizer Consumer Health	04 September 2007	Answered - in part
07/243	Consultation on 'pharmaceutical' substances used in medical devices	11 September 2007	Answered - in part
07/244	Information regarding recently approved variation to the Durogesic D-Trans SPC	11 September 2007	Answered - in part
07/246	Questions relating to Yellow Card scheme	30 August 2007	Answered - in full
07/247	Information in relation to the pharmaceutical and medical devices industries, namely regulatory breaches, product recalls, clinical trial incidents and lawsuits brought in UK jurisdiction arising out of pharmaceutical products/medicines	13 September 2007	Answered - in part
07/249	Transcriptions of any CSM meetings relating to quinolones, in particular levofloxacin and their effects on tendons	26 November 2007	Answered - in part
07/250	GCP SOP	28 August 2007	Answered - in full
07/252	Most recent MHRA inspection reports for: Almac Pharma Services Ltd, Fisher Clinical Services Ltd, and Cardinal Health	11 September 2007	Answered - in part
07/254	Summary basis of approval of Riamet (Artemether and Lumefantrine-Novartis)	25 September 2007	Answered - in part
07/255	The last 5 MHRA Pharmacovigilance Inspection Reports	21 September 2007	Answered - in part
07/257	Evidence base / justification for change from BAN to rINN	11 September 2007	Answered - in full
07/258	Have any PV inspections been performed by the MHRA following a request by the EMEA? if so, were they performed jointly with other European inspectorates	18 September 2007	Answered - in full
07/260	MHRA investigation into GSK and Seroxat	28 September 2007	Answered - in full
07/261	EPAR for aliskiren (Rasilez)	13 September 2007	Answered - in full
07/262	Repost re: possibility of back conversion of the inactive metabolites of perindopril and perindoprilat during LC-MS-MS analysis of biological samples	28 September 2007	Answered - in part
07/263	A listing of all MHRA GMP, GLP and GCP inspections that have been conducted overseas between 1 January 2003 and 29 August 2007	24 September 2007	Answered - in part
07/265	Information on co-proxomal	06 September 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/266	A copy of the full inspection report that was carried out by MHRA in Cali on 22nd to 24th November 2004 (Your Ref IN/20177/002 - PRODUCT LICENCE NOs: PL20177/0002 & 0004 & 0006).	10 September 2007	Answered - in part
07/268	Clinical Trial statistics for Pharmaceiticals and Medical Devices	18 September 2007	Answered - in full
07/270	Information for a coroner's inquiry	21 September 2007	Answered - in full
07/271	MHRA's use of videoconferencing	18 September 2007	Answered - in full
07/272	Copies of MHRA (Inspector(ate) reports on the Protein Fractionation Centre (PFC) Edinburgh for the year(s) 2006, 2007	05 October 2007	Answered - in part
07/274	A copy of PRECLINICAL (especially toxicology but also pharmacology and pharmacokinetics) and CLINICAL data associated with the product licence application for viloxazine and (if available) the agency's preclinical and clinical ASSESSMENT REPORTS	04 October 2007	Answered - in part
07/275	Audit report, on Pfizer manufacturing plant in Kalamazoo, Michigan, USA on September 12-16, 2005.	20 September 2007	Answered - in part
07/277	3 recent MHRA PhV Inspection Reports - including some Major Findings- and PhV/GCP IAG minutes for the last 3 meetings.	29 October 2007	Answered - in part
07/278	Copies of the audit reports for Renata (Bangladesh) a GMP site of manufacture for prednisolone tablets, and the Indian factory of Mcleod as a GMP manufacturer	10 October 2007	Answered - in part
07/279	A list of overseas sites inspected for GMP by the MHRA in the last 3 years	10 October 2007	Answered - in full
07/280	Copy of MHRA's inspection of Alembic Limited, Panelav, Alembic Road, Vadodara 390 003, India	12 October 2007	Answered - in part
07/281	Public assessment report (PAR) for VERSATIS° (lidocaine).	16 November 2007	Answered - in full
07/282	Various and extensive information regarding Lexapro/Escitalopram	15 November 2007	Answered - in part
07/283	Any documents related to the basis for approval of Tegretol Retard Tablets 200mg and 400mg - authorised to Novartis Pharmaceuticals UK Ltd in 1997.	02 January 2008	Answered - in part
07/285	Information on Mezolar Matrix Transdermal Patch	16 October 2007	Answered - in part
07/286	Pharmacokinetic and Dissolution data on Minocin MR and ACNAMINO MR 100 mg capsules of Minocycline HCL (Dexcel Pharma)	29 November 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/287	The public assessment report pertaining to DCP UK/H/0886/001/DC	19 October 2007	Answered - in full
07/289	Information relating to Propulsid/Cisapride	29 November 2007	Answered - in part
07/292	Questions relating to Eli Lilly; Janssen Pharmaceutica; and Astra Zeneca	26 October 2007	Answered - in full
07/293	Questions relating to Bristol-Myers Squibb	09 October 2007	Answered - in full
07/294	Query relating to the tests for HIV/AIDS	10 October 2007	Answered - in full
07/295	Glucomed Art 29(4) - Request for access to documents from the public	11 October 2007	Answered - in full
07/297	Public assessment report (PAR) for Rectogesic° (nitrate de glycéryle).	23 April 2008	Answered - in full
07/300	Information on the MMR vaccines	07 November 2007	Answered - in part
07/301	Statistics on drug mortality rates	05 November 2007	Answered - in full
07/303	Details of any departmental consideration of proposals to ban the sale of over-the-counter cough and cold medicines for young children at any time since 1997	20 November 2007	Answered - in part
07/305	A detailed listing of all inspections conducted in China from Dec 31, 2004 to Present	02 November 2007	Answered - in full
07/306	Information on the MMR vaccines	13 November 2007	Answered - in full
07/307	Copies of the inspection documentation (inspection report, response, certification) related to the most recent GMP inspection by the MHRA of the BeamOne facility in San Diego, California, U.S.A.	12 November 2007	Answered - in part
07/309	Information about dealings between MHRA and public affairs firms in the last five years	06 December 2007	Answered - in part
07/310	Information regarding the licenses:Thiamine Hydrochloride 50mg Tablets, PL 17507/0056; Thiamine Hydrochloride 100mg Tablets, PL 17507/0057, approved March 2007.	28 November 2007	Answered - in full
07/312	Copy of the Assessment Report relating to the article on page 4 of Drug Safety Update Volume 1 Issue 1 August 2007 about IFIS as a possible class effect of all alpha blockers	21 November 2007	Answered - in full
07/313	Request for PAR for Irinotecan 20Mg/Ml Concentrate for solution for infusion, UK/H/1013/001/DC	26 November 2007	Answered - in full
07/317	The last three MHRA pharmacovigilance inspection reports - preferably from german pharmaceutical companies acting globally	23 November 2007	Answered - in part
07/318	Information on proposed discontinuation of co-proxamol	21 November 2007	Answered - in full

FOI no	Subject	Date reply sent	Result of request
07/319	Request for registers of interests and gifts	30 November 2007	Answered - in full
07/320	Board Minutes of the MHRA for the last three Board Meetings, dates for the next 3 Board Meetings, list of all subsidiary Committees to the Board of the MHRA, and list of all advisory Committees to the MHRA.	04 December 2007	Answered - in part
07/321	GMP audit report for Strides Arcolab in Bangalore	30 November 2007	Answered - in part
07/322	A copy of the MHRA inspection report of Isotron	27 November 2007	Answered - in part
07/323	Information regarding Strattera	29 November 2007	Answered - in full
07/324	Information on Pharmacovigilance Inspection Metrics	15 November 2007	Answered - in part
07/326	Information regarding tenders	04 December 2007	007. Not held
07/330	Audit reports on the following API manufacturers: McFarlane Smith – Scotland, Glenmark – Ankleshwar India, Orchid - Aurangabad India	03 December 2007	Answered - in part
07/331	Queries regarding Hepatitis B vaccine and associated research into link with auto-immune damage	10 December 2007	Answered - in part
07/333	Drug alerts for GMP failures	20 November 2007	Answered - in part
07/334	Details of MHRA Inspectors	04 December 2007	Answered - in part
07/335	Details of MHRA Inspectors	04 December 2007	Answered - in part
07/337	Most recent audit report possible for the penicillin block at Strides Arcolab in Bangalore	30 November 2007	Answered - in part
07/339	Information on the MMR vaccines	21 November 2007	Answered - in full
07/342	Information relating to the granting of a 'specials' license to the Breakspear Hospital in Hertfordshire to produce antigen vaccines	27 November 2007	Answered - in full
07/344	Information regarding procedures involving variations	20 December 2007	Answered - in full
07/347	Information on proposed discontinuation of co-proxamol - copies of 145 letters and emails to MHRA about withdrawal of co-proxamol	21 November 2007	Answered - in part
07/349	Request for information on GPRD partnership with manufacturer	29 November 2007	Answered - in part
07/352	Information on any reports of Birth Defects - limb abnormalities while patient (pregnant mother) being prescribed Cymbalta	07 December 2007	Answered - in part

FOI no	Subject	Date reply sent	Result of request
07/353	Request for MHRA comment regarding pharmacokinetic data on "Episenta"	06 December 2007	Answered - in full
07/354	The result of the investigation of MHRA to see if Merck Sharp & Dohme breached medical legislation in the case of VIOXX	04 January 2008	Answered - in full
07/355	Information regarding Strattera	03 January 2008	Answered - in full
07/356	A list of all past and settled court cases against or instigated by the MHRA over the past seven years (2001; 2002; 2003; 2004; 2005; 2006; 2007)	04 January 2008	Answered - in full
07/359	Information regarding Vioxx investigations by MHRA	07 January 2008	Answered - in full
07/360	MHRA assessment report for Combigan (brimonidine tartrate/timolol maleate)	18 January 2008	Answered - in part
07/361	Information on the sources of Active Ingredients (API's) used in medicines licensed by the health ministry	20 December 2007	Answered - in part
07/363	Copy of the regulatory safety data submitted to MHRA by the manufacturer(s) of the cervical cancer vaccine envisaged for launch in the UK	02 January 2008	Answered - in full
07/364	Any data on Avandia (rosiglitazone)	18 February 2008	Answered - in part
07/370	The date when the MHRA was approached by Daval Intrenational Limited for the approval to conduct a trial for their product AIMSPRO	22 April 2008	Answered - in full
07/371	Any referenced submissions from a Dr David Shaffer of Columbia University, New York, USA sent to the Committe on the Safety of Medicines on or shortly after 24th November 2003	17 December 2007	Answered - in part
07/372	The last five cGMP inspection reports of any of the Pharmaceutical Manufacturing company operating from India	15 January 2008	Answered - in part
07/373	Which DMF's have been assessed and approved by MHRA for Hydrocortisone	23 January 2008	Answered - in full
07/374	Which DMF's have been assessed and approved by MHRA for Isonzid	02 May 2008	Answered - in part
07/376	A list of all companies who have undergone a Pharmacovigilance inspection during 2007	08 January 2008	Answered - in full
07/377	MHRA's use of Information technology	08 January 2008	Answered - in part
07/378	Marketing Authorisation query regarding the generic Temozolomide	09 January 2008	Answered - in full
07/379	Quinolones drops for Topical use in the Ears	07 January 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/001	Have there been any complaints regarding any eye drops in particular Opterx, or against the manufacturers	22 January 2008	Answered - in full
08/002	Stem Cells storage by Smart Cells International	09 January 2008	Answered - in full
08/003	Information on the MMR vaccines	15 January 2008	Answered - in full
08/004	Query regarding the effects of Champix with alcohol	04 February 2008	Answered - in full
08/005	Asking if MHRA has been defendant in litigation at any time	31 January 2008	Answered - in full
08/006	Hospitality/expenses details for MHRA CEO and Chairman	15 February 2008	Answered - in part
08/007	Information relating to Propulsid/Cisapride	12 February 2008	Answered - in part
08/008	Reasons for this revokation MA for Metatrace FDG Solution for injection 3000 MBq per mldocumented report justifying this revokation.	30 April 2008	Answered - in full
08/010	Inspection reports for GMP Compliance in 2006 regarding - Sterigenics Inc (Gurnee, IL, United States)	21 January 2008	Answered - in part
08/011	Information regarding Strattera	12 February 2008	Answered - in part
08/013	Copies of the safety review data for (1) Aprotinin and (2) Statins resented to the Pharmacovigilance Expert Advisory Group on the 7th November 2007.	25 January 2008	Answered - in part
08/014	Withdrawal of co-proxomal	13 February 2008	Answered - in part
08/015	Historical data on GMP inspection findings - specifically an annual breakdown of the % of non compliance findings (major/minor/critical) that were due to a facilities QMS / SOP's	04 February 2008	Answered - in full
08/016	The last 3 PhV Inspection Reports issued by the MHRA, as well as the PV IAG minutes for the last 3 meetings.	22 January 2008	Answered - in part
08/017	MHRA correspondence regarding co-proomal	13 February 2008	Answered - in part
08/018	An inspection report for Andrx Pharmaceuticals from 2-5 October 2006	18 January 2008	Answered - in part
08/019	GMP inspection reports pertaining to Penn Pharmaceutical Services (Gwent, Wales)	22 January 2008	Answered - in part
08/020	The following documents from the publication of Inspection Reports for manufacturers: - Guidance to manufacturers re:inspections - Annual programme for inspections for 2007 and 2008 - Number and reasons for inspections extra to programme (anonymised)	30 January 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/022	A copy of a letter that was issued by the European Commission and in possession of the MHRA. This letter deals with the product Escitalopram	10 March 2008	Answered - in full
08/023	Request for copy of last information audit	18 February 2008	Answered - in full
08/024	Requests for multiple answers to previous FOI requests	28 January 2008	Answered - in part
08/025	Seroxat - corrrespondence between GSK and MHRA	09 April 2008	Answered - in part
08/027	Information regarding HIB vaccine	12 February 2008	Answered - in full
08/028	The last 3 GMP inspection reports that can be released	13 February 2008	Answered - in part
08/029	Information regarding escitalopram	27 February 2008	Answered - in part
08/030	The number of notifications for named patient prescriptions in the UK for 2002 till now	25 January 2008	Answered - in full
08/031	Copies of MHRA carrespondence relating to withdrawal of co-proxomal	13 February 2008	Answered - in part
08/032	GMP audit reports	13 February 2008	Answered - in part
08/033	The full report on the inspection of Caithness Laboratory Blood Bank carried out on 4th October 2006	13 February 2008	Answered - in part
08/034	Estates and Facilities Management	29 January 2008	Answered - in full
08/037	Phase 1 first-in-man trials and the number of them to which MHRA's precautionary approach was applied in finalisation of study design	02 May 2008	Answered - in full
08/038	Query regarding any instances of inappropriate or incorrect transfer of legacy data from one MAH to another, following a change in the MAH for the product	13 February 2008	Answered - in full
08/039	Information regarding cases of Nephrogenic Systemic Fibrosis (NSF) associated with gadolinium-containing contrast agents	02 April 2008	Answered - in part
08/040	Information concerning MHRA inspections of the Blood Bank at Clinical Laboratory, Caithness General Hospital, Blood Bank, Belford Hospital, Fort William, Raigmore Hospital, Inverness, and the "grade" or job title of person in NHS Highland to which any reports were sent.	13 February 2008	Answered - in part
08/042	Biographies for I & S inspectors	14 February 2008	Answered - in full
08/043	Any report on MRHA by the Office of Surveillance Commissioners	06 May 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/044	Request for information on -and access to- the GPRD	14 February 2008	Answered - in full
08/046	Recent MHRA inspections reports for following organisations 1) Glenmark, India 2) Cadila, India 3) Arbindoo, India 4) Any other Indian company 5)UK Generic solid dosage manufacturing	03 March 2008	Answered - in part
08/047	A list of all unlicensed medicines for which import notifications have been received by the MHRA in the last 12 months, with the number of import notifications received in respect of each unlicensed medicine in this list	13 February 2008	Answered - in full
08/048	Request regarding co-proxomal	04 March 2008	Answered - in full
08/049	MHRA Inspection report - Flamingo Pharmaceuticals, Taloja, India	15 February 2008	Answered - in part
08/050	Any MHRA inspections that have taken place at the Blood Products Laboratory, Elstree over the last twelve months	14 February 2008	Answered - in part
08/051	Any recent marketing authorisation applications recently filed at the MHRA containing the active substance valproate semisodium (also known as divalproex sodium)	05 March 2008	Answered - in full
08/053	Information on applications for Mas citing German reference products	27 April 2008	Answered - in part
08/055	Information for product PL 00015/0206 held by Boehringer Ingelheim Limited, MA granted 3 February 1997	22 May 2008	Answered - in part
08/057	A copy of the two inspections prior to Sept 2007 of the Blood Products Laboratory, Elstree over the last twelve months	01 March 2008	Answered - in part
08/059	A copy of MHRAs urgent safety restriction SOP	05 March 2008	Answered - in full
08/060	Requests relating to fatal ADRs	17 March 2008	Answered - in full
08/061	Please provide all MHRA inspection reports and responses for the Welsh Blood Service, Ely Valley Road, Talbot Green, Pontyclun, from 1st November 2006	12 March 2008	Answered - in part
08/063	Hyoscine efficacy	07 March 2008	Answered - in full
08/064	Questions relating to MHRA risk/benefit analysis methodology and definition of drug "benefit"	18 March 2008	Answered - in full
08/065	Yellow card data related to Pavivac mumps virus	14 March 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/068	Copy of the last MHRA audit report for the Ranbaxy site in India at Paonta Sahib, District Sirour Himachal Pradesh 173 025 India	25 March 2008	Answered - in part
08/070	Details of the regulatory approval accorded to Biocontrol Ltd, and the health and safety data provided by Biocontrol to satisfy MHRA requirements for regulatory approval in respect of a clinical trial of Pseudomonas bacteriophages as a therapeutic agent against chronic ear infections in humans	02 May 2008	Answered - in part
08/071	Responses to ARM8	25 March 2008	Answered - in full
08/073	Information on the amount of idebenone coming into the UK under "specials" provision	03 March 2008	Answered - in part
08/074	Last audit report for the Welsh Blood Service	12 March 2008	Answered - in part
08/075	The two most recent reports for inspections conducted at GSK's Harlow IMP "manufacturing" facility	28 March 2008	Answered - in part
08/077	List of all marketing Authorisation holders of products containing propofol as an active ingredient. Any details regarding GMP status, manufacturing license approval etc for an API manufacturer called QiLu Pharmaceutical Corp. Ltd. in China and a copy of their respective GMP certificate or audit summary	21 March 2008	Answered - in part
08/078	Information regarding Tyvera 50mg Tablets and Tyvera 100mg Tablets	09 April 2008	Answered - in full
08/079	Questions relating to communications between MHRA and Pfizer Inc.	28 March 2008	Answered - in full
08/080	Information relating to Propulsid/Cisapride	03 April 2008	Answered - in part
08/081	Query regarding investigation of GSK	06 March 2008	Answered - in full
08/082	research into history of Pharmacovigilance, and lessons from drug withdrawals	19 March 2008	Answered - in full
08/084	questions regarding SSRI antidepressant medication	08 April 2008	Answered - in full
08/085	Enquiry about the registration of the fixed combination product Combigan in the UK	01 April 2008	Answered - in full
08/086	Inspection reports for the 3M Loughborough site	25 March 2008	Answered - in part
08/087	A list of the overseas sites that you have visited, audited and / or inspected	03 April 2008	Answered - in full
08/088	MMR	28 April 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/090	A Summary of the results of assays of samples you have seized of the following "indian generics" Kamagra (Sildenafil) Tadora (Tadalafil)	03 April 2008	Answered - in full
08/091	Request regarding Seroxat	20 May 2008	Answered - in full
08/092	Query regarding Professor Sir Alasdair Breckenridge	10 April 2008	Answered - in full
08/093	A copy of the summary report (letter detailing inspection observations) of the latest inspection of the Blaenwaun facility of Protherics @ Blaenwaun, Llandysul, Ceredigio	03 April 2008	Answered - in part
08/094	GMP inspection report forCP PHARMACEUTICALS LIMITED, ASH ROAD, WREXHAM INDUSTRIAL ESTATE, WREXHAM, CLWYD, UNITED KINGDOM, LL13 9UF	04 April 2008	Answered - in part
08/096	Request for unredacted minutes from various MHRA Committee meetings regarding rofecoxib (Vioxx) and cox-2 inhibitors	23 April 2008	Answered - in full
08/097	Requests for evidence of claims given in adverting of skincare products	07 April 2008	Answered - in part
08/098	There have been nine known reported cases where fake drugs have reached pharmacy and patient levels. Approx how many patients administered these fake drugs?	14 April 2008	Answered - in full
08/099	MHRA correspondence regarding co-proxomal	06 May 2008	Answered - in full
08/102	Any reports submitted and/or any violations documented concerning Products manufactured and/or sold under the following company names: Caesarea Medical Electronics; and/or CME, and/or McKinley Medical.	15 April 2008	Answered - in part
08/103	Request for List of MHRA inspected sites in India	25 March 2008	Answered - in part
08/104	MRHA qualifications for the post of Good Clinical Practice Expert Inspector	17 April 2008	Answered - in full
08/105	Record of any incidents caused by different colour codes for blood specimen containers	04 April 2008	Answered - in full
08/106	Information regarding adverse reactions reported due to breast implant surgery	03 April 2008	Answered - in full
08/107	A list of overseas sites inspected for GMP by the MHRA in the last 3 years	15 April 2008	Answered - in full
08/108	Query relating to adverse reactions to herbal medicines	17 April 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/109	Copies of MHRA inspection reports for the GMP inspection of the Fisher Clinical Services facility located at 7554 Schantz Road, Allentown, PA 18106-9032, America. The inspection occurred July 10 - 11, 2007.	09 April 2008	Answered - in part
08/111	Query regarding approve of variation application updating prostate cancer indication for Prostap SR 3.75 mg and Prostap 3 Leuprorelin Acetate Depot Injection 11.25 mg	22 April 2008	Answered - in part
08/114	A register (if one exists) of either foreign API or formulation facilities that the MHRA has audited for GMP compliance	24 April 2008	Answered - in full
08/115	Questions relating to generic version of Gaviscon	21 April 2008	Answered - in full
08/116	Questions relating to communications between MHRA and Pfizer Inc.	29 April 2008	Answered - in part
08/117	Query from participant regarding Sativex clinical trial	04 April 2008	Answered - in full
08/119	Copies of the inspection reports from two inspections at Brecon Pharmaceuticals Limited	21 April 2008	Answered - in part
08/121	Information regarding clofazimine (brand name: Lamprene)	22 April 2008	Answered - in full
08/122	Request for information on -and access to- the Adverse Reactions Database	02 May 2008	Answered - in full
08/123	Recent MHRA GMP Inspection report and a copy of the post inspection letter for Shire Pharmaceuticals Plc, Alliance Pharma Plc., Genericks (UK) Ltd. And Recipharm UK	27 April 2008	Answered - in part
08/124	Request from adverse incident reporter for correspondence between MHRA and a mobiliy device manufacturer	18 April 2008	Answered - in full
08/125	A list of companies who had Pharmacovigilance inspections during 2007 where more than two critical deficiencies were recorded OR a copy of inspection reports for PV Inspections during 2007 and 2008 where more than 2 critical deficiencies were recorded	23 April 2008	Answered - in full
08/126	Request for Seroxat correspondence between MHRA and GSK	24 April 2008	Answered - in full
08/127	Copies of responses to Public Consultation MLX 345	02 May 2008	Answered - in full
08/128	1. Number of trials approved by the MHRA in 2005, 2006 and 2007, and 2. Number of paediatric trials approved by the MHRA in 2205, 2006 and 2007.	06 May 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/129	Company nonclinical and clinical expert reports for safety and efficacy 2. Assessment reports produced by MHRA relating to nonclinical and clinical safety and efficacy in relation to TOBI 300 mg/5 mL Nebuliser Solution	06 May 2008	Answered - in part
08/131	Usage levels and adverse reactions reports concerning RU486	30 April 2008	Answered - in full
08/133	Matters relating to GSK investigation	06 May 2008	Answered - in full
08/134	Information regarding adverse incident involving hip prosthesis	23 April 2008	Answered - in full
08/135	All trials data and evaluations of Gardasil including its authorisation process	13 May 2008	Answered - in full
08/136	1. Legal basis of the application, 2. Whether the applications were supported by new clinical studies, a bibliographic approach or a combination of the two, 3. Whether the application relied on any data pertaining to the MA approvals of Cellcept and Myfortic 180mg & 360mg film-coated gastro-resistant tablets	13 May 2008	Answered - in full
08/137	Information regarding ongoing clinical trials of risperidone where the participants have any form of learning disability with or without challenging behaviour	15 May 2008	Answered - in full
08/138	Request from applicant for copies of correspondence between MHRA and manufacturers in respect of a deceased relative	02 May 2008	Answered - in full
08/139	GMP Certificate or Site Approval Letter for Sterigenics Inc (Gurnee, IL, United States)	28 April 2008	Answered - in part
08/140	Query asking for any information concerning adverse incident reports for ICD leads	09 May 2008	Answered - in full
08/141	A list of the GCP inspections conducted in non-EU countried from 2004 to current date	02 May 2008	Answered - in full
08/142	Request for information on MHRA prosecutions of pharmaceutical companies	13 May 2008	Answered - in full
08/144	The last MHRA inspection report and responses for Fisher Clinical Services Ltd, Langhurstwood Road, Horsham, West Sussex, RH12 4QD	30 May 2008	Answered - in part
08/145	Request for latest audit report of Vifor Pharma Potters Ltd	30 May 2008	Answered - in part
08/146	Information regarding the withdrawal of Vioxx	01 May 2008	Answered - in full
08/147	Request for any reply to March 08 letter from MHRA's CEO to GlaxoSmithkline	01 May 2008	Answered - in full
08/148	Information regarding the early psychiatric side-effects associated with corticosteroids	22 May 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/149	Inspection report for Nova Laboratories, Wigston, Leicester	07 May 2008	Answered - in part
08/150	The Inspection Report from the GMP Inspection at St. George´s Hospital, Tooting (Date 06/02/2007)	30 May 2008	Answered - in part
08/151	How many EU cases of counterfeit medicines or medical devices were reported to the MHRA or the Defective Medicines Report Centre in 2007	05 June 2008	Answered - in full
08/152	Matters relating to counterfeit drugs	14 May 2008	Answered - in full
08/155	A list of companies inspected for PV in 2008 to date, and the inspection reports from the following companies inspected in 2007:- Actavis and Rosemont Pharmaceuticals	30 May 2008	Answered - in part
08/156	Confirm that MHRA have tested samples of the "Indian Generic" versions of Sildenafil and Tadalafil for both the presence and amount of active ingredient therein and supply details of any test results that do not comply with the label for active ingredient and amount	05 June 2008	Answered - in full
08/158	LOCKETS - Request for file information and Notification of authorised personnel	05 June 2008	Answered - in full
08/159	Clinical Trial Data regarding the Soy Oil filled Trilucent Breast Implants, especially the rabbit tests.	22 May 2008	Answered - in part
08/160	Copies of the last MHRA GMP inspection reports for North Bristol NHS Trust (Pharmacy Departments, Southmead & Frenchay Hospital, Bristol, BS10 5NB) & content of any warning letters issued	04 June 2008	Answered - in part
08/161	Copies of MHRA Clinical Assessment Reports relating to the MRP for Strattera (atomoxetine/Eli Lilly) at the conclusion of the National licence stage (May 2004), at Day 90, 27 Oct 2004. Additionally, a copy of the updated Clinical AR from the second round of MRP (concluding early 2006)	18 June 2008	Answered - in part
08/162	All details of the decision making process involved in the withdrawal of Co-proxamol	01 July 2008	Answered - in part
08/163	Request in regards to MHRA's Infomation Communcation Technology (ICT)	09 June 2008	Answered - in full
08/165	Party Pills containing BZP	11 June 2008	Answered - in full
08/166	PV inspection performed at Akos Ltd	04 June 2008	Answered - in part
08/167	A copy of the last MHRA GMP Inspection report of: Intercell Biomedical Ltd.	04 June 2008	Answered - in part
08/169	Information requested on rectal Diazepam	10 June 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/171	The three most recent pharmacovigilance inspection reports relating to European pharmaceutical companies acting across and outside of EU	18 June 2008	Answered - in part
08/172	Information regarding the withdrawal of co-proxamol	09 June 2008	Answered - in part
08/173	Information regarding the withdrawal of Bextra (valdecoxib),l	22 May 2008	Answered - in full
08/174	Usage levels and adverse reactions reports concerning RU486	10 June 2008	Answered - in full
08/175	To know if any actions have been taken against Osmetech plc, Gordon J. Hall, James N. White, David A. Sandilands	11 June 2008	Answered - in full
08/178	Summary basis of approval or PAR (as available) for Day Nurse Capsules & Day Nurse, particulary any information regarding the clinical programme which supported the combination product	04 June 2008	Answered - in full
08/180	Copies of the VMD (MHRA) pharmacovigilance inspection of the Norbrook Laboratories facility located in Northern Ireland in 2007 (October)	17 October 2008	Answered - in part
08/183	Copy of the report of the Pharmacovigilance inspection of the UK affiliate of the company Lundbeck GmbH	12 June 2008	Answered - in part
08/184	A copy of the Public Assessment Report for UK/H/951/01-4, PL 18909/0187-190 Topiramate Tablets	29 May 2008	Answered - in full
08/186	A copy of the last MHRA GMP Inspection report of MedImmune UK Ltd	25 June 2008	Answered - in part
08/187	A list of all drugs licensed between 1998 and 2008 and information on drugs where licensing has been withdrawn and the reasons behind the withdrawal between 1998 and 2008.	16 June 2008	Answered - in part
08/188	Availability of Ventolin in the UK	27 June 2008	Answered - in full
08/189	Assessment report regarding Laxido	13 June 2008	Answered - in full
08/190	The most recent full audit reports for Keats Healthcare and A.D. Allen Pharma Ltd	12 June 2008	Answered - in full
08/191	Data relating to 1. the number of open trials, by phase which are open at the current time in the UK, and 2. the above for trials abroad, registered with the MHRA	23 June 2008	Answered - in full
08/192	Information relating to a company named Square Pharma Ltd	19 June 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/193	A copy of the GLP inspection report that was performed on 11th July and 16th August 2007 on Clinical Trials Laboratory Services (CTLS), a laboratory with address: Unit 3, Acorn Centre, 30-40 Gorst Rd, London, NW10 6LE	12 June 2008	Answered - in part
08/194	A copy of the most recent GMP inspection and findings for : Intercell Biomedical Ltd Site ID 22643	12 June 2008	Answered - in part
08/195	Questions relating to various issues concerning linezolid	25 June 2008	Answered - in full
08/196	Query regarding MHRA's dealings with drug users pressure groups	17 June 2008	Answered - in full
08/197	Query regarding omeprazole	06 June 2008	Answered - in full
08/199	Copies of the reports for the last 5 completed GMP inspections conducted at pharmaceutical manufacturers by a named	18 December 2009	Answered - in part
08/200	Questions relating to Myfortic 180mg & 360mg film-coated gastro-resistant tablets	18 June 2008	Answered - in full
08/203	Query regarding authorisation of a medicinal product in Greece with the active substance Progesterone, in the pharmaceutical form of a vaginal pessary using Cyclogest as a reference product	02 July 2008	Answered - in full
08/204	Information relating to Propulsid/Cisapride	11 July 2008	Answered - in part
08/209	Drug Analysis Printouts and Reaction Analysis Printouts for levofloxacin	24 July 2008	Answered - in part
08/211	Information regarding Procedures UK/H/1057-1058/01/DC concerning applications made under the Decentralised Procedure in the UK.	21 July 2008	Answered - in full
08/213	Inspection report for the MHRA audits of Tepnel Research Products and Services, performed on 7.11.07, and J C Analytical performed on 18.12.06	27 June 2008	Answered - in part
08/215	Public Assessment Reports for Asacol mr 400mg tablets, Mesren mr 400mg tablets and Ipocol 400mg Tablets	30 June 2008	Answered - in part
08/216	Query regarding MHRA's dealings with drug users pressure groups	17 June 2008	Answered - in full
08/217	The most recent inspection letter outlining any company deficiencies for Novartis Vaccines and Diagnostics Ltd	23 June 2008	Answered - in part
08/218	Public Assessment Reports for Marketing Authorisation Licences for Single Dose Oral Solution Sachets	30 June 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/219	Contact email addresses for each of the medicines advisory bodies, commissions or committees that are subject to the FOI Act by virtue of their listing in Schedule 1, Part 6	01 July 2008	Answered - in full
08/222	Metrics for GMP inspections of holders of manufacturing authorisations for medicinal products	04 August 2008	Answered - in part
08/224	Adverse incidents and Yellow Card scheme in relation to herbal medicine	18 July 2008	Answered - in full
08/225	Questions regarding advice given to MHRA by a member of the Patient Information Expert Advisory Group	14 July 2008	Answered - in full
08/227	Last GMP Inspection report for Thompson & Capper (MIA 1359) Hardwick Road Astmoor Runcorn Cheshire WA7 1PH	30 June 2008	Answered - in part
08/228	The total value of expense claims made by each board member and each employee of director level and above	24 July 2008	Answered - in full
08/229	The full job title (including department) of every employee earning a total salary of £100,000 or more, and the actual total salary they receive	18 July 2008	Answered - in full
08/231	The latest MHRA GMP inspection report for Aptuit (formerly Evotec), Todd Campus, West of Scotland Science Park, Glasgow	22 July 2008	Answered - in part
08/233	Information on clinical trial number CTMK02	24 July 2008	Answered - in part
08/236	Questions regarding MHRA estates policies and strategies	03 July 2008	Answered - in full
08/237	Pharmacokinetics, bioequivalence and dissolution data on Minocin MR Capsules Acnamino MR Capsules Sebomin MR Capsules	16 July 2008	Answered - in part
08/238	Correspondence related to co-proxomal withdrawl	25 July 2008	Answered - in part
08/239	Details on MHRA investigations of trade mark infringements	24 July 2008	Answered - in part
08/240	A copy of the last MHRA Inspection report for Qualiti (Burnley) Ltd	28 July 2008	Answered - in part
08/241	Request for information on Vioxx/rofecoxib	17 September 2008	Answered - in part
08/242	MHRA correspondence regarding co-proxomal	25 July 2008	Answered - in part
08/243	MHRA correspondence regarding co-proxomal	25 July 2008	Answered - in part
08/245	MHRA correspondence regarding seroxat	30 July 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/246	Registration of manufacturing site of Istin UK	17 July 2008	Answered - in full
08/247	A copy of the last MHRA Inspection report for William Ransom	01 August 2008	Answered - in part
08/251	License confirmation for Integrated Pharmaceutical Services (IPS) Limited Company registration No. 3989404	14 July 2008	Answered - in part
08/252	Copies of MHRA correspondence relating to withdrawal of co-proxomal	25 July 2008	Answered - in part
08/253	Copies of MHRA correspondence relating to withdrawal of co-proxomal	25 July 2008	Answered - in part
08/254	Questions relating to various issues concerning linezolid	05 August 2008	Answered - in part
08/256	Information MHRA holds which records how a decision was reached to withdraw Propulsid (cisapride), along with Drug analysis prints for each year co-proxamol was on the UK market	15 July 2008	Answered - in part
08/257	GMP Inspection report for Nova Laboratories, Wigston, Leicester	06 August 2008	Answered - in part
08/258	Information regarding LEVOCETIRIZINE 5mg TABLETS	05 August 2008	Answered - in part
08/259	Copies of MHRA Board minutes	05 August 2008	Answered - in part
08/261	Request concerning co-proxomal correspondence received by MHRA	25 July 2008	Answered - in part
08/263	Zirconia Ceramic Femoral Head manufactured by Zimmer Ltd license and recall August 2001	04 August 2008	Answered - in full
08/264	Various information regarding medicinal product Revocon 25mg Tablets	13 August 2008	Answered - in part
08/265	Questions regarding the registrations of companies producing Custom Made Devices with generic code K1 - Dental Appliances/Prostheses	15 August 2008	Answered - in part
08/267	Copy of the inspection report of the audit conducted from 25th - 28th Feb 08 at the premises of Bioreliance Glasgow covered by manufacturing authorisation number MIA(IMP) 22774 which supports the certificate MIA(IMP) 22774 Insp IMP 22774/4473-0011	22 August 2008	Answered - in part
08/268	Names and addresses of all MHRA approved manufacturing sites in India and China	04 August 2008	Answered - in full
08/270	Information regarding Strattera	19 August 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/271	I would greatly appreciate learning the specific efficacy and safety criteria used to approve antidepressant medications. If these have changed since the introduction of SSRIs, I would like to know what the past criteria were, what changes were made, and when these changes were made.	06 August 2008	Answered - in full
08/272	Based on clinical trial data there is any difference in terms of the side effects "weight gain, increased appetite" (incidence, severity, time course) when comparing mirtazapine orally disintegrating tablets (Remeron SolTab) to the conventional mirtazapine tablet formulation	04 August 2008	Answered - in full
08/273	Roaccutane (Isotretinoin) - pharmacovigilance data in respect of psychiatric reactions	10 November 2008	Answered - in part
08/274	Copies of last two GMP inspection reports for Quay Pharmaceuticals Ltd Bassendale Road Apex Court Wirral	28 August 2008	Answered - in part
08/275	A list of Indian drug manufacturing sites inspected by the MHRA	15 August 2008	Answered - in full
08/276	Inspection report for API producer Zhejiang Hisun Pharma Co Ltd., 46 Waisha Road, Jiaojiang District, Tiazhou City, Zhejiang Province, 318000, P.R. China	06 August 2008	Answered - in full
08/277	Copies of the three most recent pharmacovigilance inspection reports of Quintiles (any location)	29 August 2008	Answered - in part
08/278	Is there a document listing U.S. companies that have applied for or received MHRA approval for selling pharmaceuticals into the U.K or are otherwise subject to MHRA GMP criteria	04 August 2008	Answered - in full
08/279	Request for details of any MHRA investigation resulting from allegation made by requesters ex-employer	29 August 2008	Answered - in part
08/281	How many cases on a year by year basis has the he MHRA Enforcement Team investigated and how many prosecutions have been made regarding internet advertising and supply of medicines	01 September 2008	Answered - in full
08/282	Query regarding Marketing Authorisations for Citalopram and Escitalopram	08 September 2008	Answered - in part
08/283	Documentation submitted before licences were granted for various generics	19 August 2008	Answered - in part
08/284	Please confirm the legal basis for the MAA leading to approval of Dovobet(r) 50 microgram/g + 0.5 mg/g ointment - also confirm whether (and if possible provide a summary of) any new non clinical studies used to support the MAA	14 August 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/285	I request animal testing results and published or unpublished animal data regarding the following five drugs: Vioxx, Celebrex, Bextra, Arcoxia, Prexige.	05 November 2008	Answered - in part
08/287	I am trying to locate a document : CSM Expert Working Group on the Safety of SSRIs: Risk Benefit Evaluation of Paroxetine	12 September 2008	Answered - in full
08/288	I would like to request some details on the level of counterfeit pharmaceutical products that enter the supply chain via authorised wholesalers in the UK	03 September 2008	Answered - in full
08/289	Good Pharmacovigilance Practice (GPvP) and assessment (inspection) reports regarding compliance with UK and EU legislation relating to the monitoring of the safety of medicines given to patients in general with regard to companies (additionally or mainly) focussed on manufacturing phytopharmaceuticals or herbal products or vaccination products	04 September 2008	Answered - in part
08/291	Requesting information regarding the identities and nature of any complaints received about the company by MHRA	05 September 2008	Answered - in part
08/292	Information on paediatric reports to the MHRA in 2007	09 September 2008	Answered - in full
08/294	The full assessment report for the medicinal product Nicam gel (nicotinamide 4%)	11 September 2008	Answered - in part
08/295	Request for details of all companies that run clinical trials involving human subjects	08 September 2008	Answered - in part
08/296	Information regarding bioequivalence data for fosimax compared with the alendronic acid (currently being used by the NHS)	03 September 2008	Answered - in full
08/297	Information on the authorisation system of generic medicine for new products - 'essentially similar'- for introduction to the UK market	18 September 2008	Answered - in full
08/298	Various questions regarding prescribing of antidepressants in the UK, warnings regarding SSRi's, warnings about Zyprexa, education GPs received re SSRIs and identifying depression and/or withdrawal, statistics regarding mental illness, and adverse reaction reporting for SSRIs	12 September 2008	Answered - in full
08/299	Questions relating to various issues concerning linezolid	12 September 2008	Answered - in part
08/300	Requesting further details on FOI requests 08/219 & 08/236	02 September 2008	Answered - in part
08/301	Requesting further details on MHRA co-proxomal correspondence	02 September 2008	Answered - in part
08/302	UKPAR for MA 25081/0001 Alateris 625mg tablets	03 September 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/303	Query regarding the flouridation of water and whether it is considered to be "mass medication"	28 August 2008	Answered - in full
08/304	Control assay data for allopurinol 100mg Tablets (Teva UK)	03 September 2008	Answered - in full
08/305	Please provide details (preferably a redacted assessment report) detailing the scope of the clinical and non clinical studies performed in order to support the MAA for Tramacet	16 September 2008	Answered - in part
08/308	A list of members of the IRPB for the year 2008 and a listing of the interests	29 August 2008	Answered - in full
08/310	How many NON-COMMERCIAL/ACADEMIC IMP trials have been authorised by the MHRA between 2005-2008?	08 September 2008	Answered - in full
08/311	Copy of inspection report for Sanofi-Synthelabo Ltd., Edgefield Avenue, Fawdon, Newcastle Upon Tyne, Tyne and Wear, NE3 3TT, United Kingdom	24 September 2008	Answered - in part
08/312	A certified copy of MHRA's minutes of the meeting with Seroxat Users Support Group	24 September 2008	Answered - in full
08/314	Questions regarding counterfeit medicines	10 September 2008	Answered - in full
08/316	Vioxx questions	25 September 2008	Answered - in full
08/317	All the information (including dossiers, papers, reports, evidence and assessments) submitted by AstraZeneca UK Limited or any of its affiliates to the MHRA in connection with the MHRA's review of the market authorisations of LHRH analogues	02 October 2008	Answered - in part
08/319	All information you hold with regards to SSRI anti-depressants, especially citalopram and escitalopram with regards to withdrawal effects, irritability, aggression, hostility, violence, akathisia, agitation, and all forms of other abnormal behaviour.	03 December 2008	Answered - in part
08/320	Details of inspections carried out over the last three years at: Catalent Pharma Solutions Sedge Close, Headway, Great Oakley Corby, Northamptonshire NN18 8HS, England	02 October 2008	Answered - in part
08/321	Questions regarding MHRA procedures involving drug reclassification	10 September 2008	Answered - in full
08/323	How much income does MHRA receive from fines, if any, resulting from successful prosecutions	18 September 2008	Answered - in full
08/324	A copy of the GMP inspection on the inspection of Afton Scientific Corp. 2030 Avon Ct., Charlottesville, VA 22902 USA	15 December 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/325	Asking if MHRA has had an application to import and distribute a product called Tunguska Blast	24 September 2008	Answered - in part
08/327	MHRA inspection report from the inspection carried out at Phillips Plastics Corporation facility located at the Origen Center, 428 Technology Drive East, Menomonie, Wisconsin 54751 U.S.A.	17 October 2008	Answered - in part
08/328	Iinformation available on the clinical assessment/approval of the product Mesren MR 400mg tablets - specifically information that would have been contained with the Clinical Overview/Expert Review documents	08 October 2008	Answered - in part
08/329	Information regarding the VentolinTM EvohalerTM	01 October 2008	Answered - in part
08/330	Questions relating to various issues concerning linezolid	10 December 2008	Answered - in part
08/331	Questions relating to generic version of Gaviscon	06 October 2008	Answered - in part
08/332	GlaxoSmithKline's HPV Vaccine, Cervarix and the MHRA's stance on it	08 October 2008	Answered - in full
08/333	Request relating to NEORAL 10 mg Soft Gelatin Capsules	26 September 2008	Answered - in part
08/334	Last 3 GMP Audit assesment reports on Penn Pharmaceutical Services Ltd and ALMAC GROUP LTD	17 October 2008	Answered - in part
08/337	Information MHRA holds which records how a decision was reached to withdraw Secholex (polidexide) and Eraldin (practolol), along with Drug analysis prints for each year Secholex (polidexide) was on the UK market	09 October 2008	Answered - in full
08/338	All publicly available information on Lifeforce Immune System Bank plc, especially with regard to their licence as a Blood Establishment - specifically, the scope of their licence and whether it includes a 'specials' for manufacturing.	17 December 2008	Answered - in part
08/339	Marketing Authorisation information regarding Actiq compressed lozenges with integral oromucosal applicator	29 October 2008	Answered - in part
08/341	The last GMP inspection report and responses for Nova Laboratories Limited Martin House Gloucester cresent Wigston Leicester LE18 4YL	23 October 2008	Answered - in part
08/342	Request for organisational details for Marketing, HR and Comms within MHRA	30 September 2008	Answered - in part

FOI no	Subject	Date reply sent	Result of request
08/344	The MHRA inspection reports for The Laboratory, Belford Hospital Blood Bank from 2007 onwards, and for The Laboratory, Caithness General Hospital Blood Bank from 2006 onwards	24 October 2008	Answered - in part
08/348	A copy of the last MHRA GMP Inspection report of Almac 4204 Technology Drive Durham, NC 27704 USA	28 October 2008	Answered - in part
08/349	Copy of a report by the CRM on the safety-benefit of hyoscine butylbromide	07 October 2008	Answered - in part
08/350	A copy of the Reasoned Opinion of the European Commission to the UK delivered 6 February 2008 to do with the sale and marketing of "borderline medicinal products", a copy of UK's response to the Commission's Reasoned Opinion by letter dated 28 May 1998, and UK government letter dated 6 August 1998	20 October 2008	Answered - in part
08/351	A list of product licence which has been cancelled in the last three months by the Companies and also the name of the companies concerned	28 October 2008	Answered - in full
08/352	Original Assessment Report from the first authorisation, and assessment reports for any major variations/changes to the product Caverject Dual Chamber 10 or 20 micrograms - particularly introduction of the dual chamber device	16 October 2008	Answered - in part
08/353	Requesting the outcome of a complaint to comlpiance regarding products put on market that are not sterile for urine sample collection	10 March 2009	Answered - in part
08/354	A copy of the most recent Office of Surveillance Commissioners inspection report	27 October 2008	Answered - in part
08/355	Request for GMP report on Bilcare Global Clinical Supplies (Europe) Ltd of Waller House, Elvicta Business Park, Crickhowell, Powys, NP8 1DF	04 November 2008	Answered - in part
08/356	A copy of the Risk Management Plan, which would have been submitted by the marketing authorisation holder as part of the Type II variation to amend the formulation of the product TAZOCIN	29 October 2008	Answered - in part
08/359	Information regarding Vioxx investigations by MHRA	03 November 2008	Answered - in full
08/360	In the financial year ending 5 April 2008 did MHRA make any advance payments for the following financial year? If so, provide the breakdown	06 November 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/361	Detail of the preclinical and clinical studies used in the registration of various forms of the following products; Canesten, Clotrimazole, Dermovate, Elocon, Betnovate, Eumovate, Emla, Diprosalic, Bactroban, Trimovate, Daktacort, Timodine	13 November 2008	Answered - in part
08/362	Last MHRA inspection reports for Almac Clinical Services, and Fisher Clinical Services UK Limited	12 November 2008	Answered - in part
08/363	Information regarding clinical trials for tomoxetine	03 November 2008	Answered - in full
08/365	A copy of the “Medical Assessment” leading to the approval of fluoxetine for the treatment of depression. Preferaly the entire assessment report, but if that is too large, please send the sections summarizing efficacy data and placebo controlled studies	27 November 2008	Answered - in part
08/366	Concerns regarding the quality and reliability of supplied fluid infusion sets	04 November 2008	Answered - in part
08/368	Request for Yellow Card data on Infliximab, Efalizumab, Methotrexate, Cyclosporin, Acitretin and Eternacept	06 November 2008	Answered - in part
08/370	A copy of the Good Pharmacovigilance Practice inspection report on Novartis in the UK	24 October 2008	Answered - in part
08/371	Complete summary basis of approval for Lercanidipine Hydrochloride Tablets 10mg and 20 mg. with specific information related to pharmacokinetics of Lercanidipine hydrochloride	27 January 2009	Answered - in part
08/372	All data and assessment reports available for nicorandil (Ikorel)	06 February 2009	Answered - in part
08/374	Copy of assessment report for MR number: UK/H/0241/0001/ - RMS Country: United Kingdom - Date of day 90: 7/07/1998 - MA Held by: Janssen-Cilag Ltd PO Box 79 Saunderton, High Wycombe Bucks. HP14 4HJ	15 January 2009	Answered - in part
08/375	Copies of all letters / notes / memos etc. sent to and from the MHRA by/to medical professionals regarding all known withdrawal effects, side effects, and dangers (including homicidal related events) of escitalopram and citalopram	06 November 2008	Answered - in full
08/376	A listing of Product Licences (with company name) that have been suspended due to non-compliance with Title V of Council Directive 2001/83/EC (as amended), Article 59(3), patient readability testing of patient information leaflets	19 November 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/377	A copy of the Public Assessment Reports generated on completion of the assessment of 'NiQuitin CQ' 7, 14 & 21mg patches. MR number: UK/H/0287/001/ / Date of Day 90: 1999-05-04 MR number: UK/H/0287/002/ / Date of Day 90: 1999-05-04 MR number: UK/H/0287/003/ / Date of Day 90: 1999-05-04 The UK was the RMS for all three applications.	07 November 2008	Answered - in full
08/378	Is Cipla Kurkumbh India certified by you, and until when	10 November 2008	Answered - in full
08/381	A copy of the MHRA inspection report from the most recent inspection of the Catalent facility located at the following address: Frankland Road, Blagrove, Swindon, Wiltshire, SN5 8RU, UK	13 November 2008	Answered - in part
08/385	The number of licenses which have not been the subject of a user test application	04 December 2008	Answered - in full
08/386	Registration dates of UK Medicines	28 November 2008	Answered - in part
08/387	A list of MHRA inspected facilities in India and China for the last 3 years, including the categories under which the sites were inspected eg. tablets, capsules, beta-lactam etc	05 December 2008	Answered - in part
08/388	Copy of the data set used for producing the report by the SSRI Working Group (citalopram and escitalopram)	03 December 2008	Answered - in part
08/390	Questions relating to various issues concerning linezolid	12 January 2009	Answered - in part
08/391	Request for information regarding GCP inspections and NHS Trusts	17 November 2008	Answered - in part
08/393	Stability data on adrenaline 1 in 1000 in a plastic syringe, and any data on the stability/shelf-life of Herceptin when reconstituted and diluted in an IV bag ready for administration.	18 November 2008	Answered - in part
08/394	Request for information on a bowel cleansing product called CitraFleet	08 December 2008	Answered - in part
08/395	Request for information regarding Sub Committee on Pharmacovigilance (SCOP) and the Committee on Safety of Medicines (CSM) assessements of the number of reports of abuse of OTC codeine and dihydrocodeine containing medicines	25 November 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/397	1. What date did the Covance Clinical Research Unit (Hyde Street, Leeds) last undergo a GCP inspection 2. Have they applied for a Phase I accreditation? 3. A copy of their last GC_inspection report and/or inspection certificate.	17 November 2008	Answered - in part
08/398	Metformin Oral Solution	22 December 2008	Answered - in part
08/403	How many Phase II/III clinical trials with new medicines are approved each year by the MHRA, what proportion are sponsored by the pharmaceutical and biotechnology industries, what is the estimated annual value of clinical/medical R&D spend, and what proportion of this comes from the pharma/biotech industries?	16 December 2008	Answered - in part
08/404	General information on escitalopram, and details of any studies that have looked at comparisons between escitalopram and citalopram	27 November 2008	Answered - in full
08/405	Disulfuram (Antabuse) information such as MAA documents and assessment reports	13 December 2008	Answered - in part
08/408	Periodic Safety Update Report (PSURs) for Ledermycin® (demeclocycline) Florinef® (fludrocortisone) Propylthiouracil Ismelin® (Guanethidine) Ethyol® (amifostine)	17 December 2008	Answered - in part
08/410	information required: i am interested to know about the allergic risks and the function of the following ingredients as a lubricant both on the surface of the skin and internally rectally. PROPYLENE GLYCOL HYDROXYETHYL CELLULOSE CHLORHEXIDINE DIGLUCONATE	12 December 2008	Answered - in part
08/411	Dow Corning Silastic breast implants	08 December 2008	Answered - in part
08/412	Clinical data presented to support the indication for Zimovane (zopiclone) PL: 000 12/0259 (6/5/1993).	11 December 2008	Answered - in part
08/413	Organisation chart for MHRA divisions	15 December 2008	Answered - in full
08/415	MHRA report carried out in the Ulster Hospital Blood Bank (Upper Newtownards Road Belfast BT16 1RH) which was undertaken in March 2008	29 December 2008	Answered - in part
08/418	An updated list of overseas sites that MHRA have inspected. MHRA have produced a list - "Pending overseas sites 20/07/2006" I would request an updated version as there have been a number of additions to this list within the last two years. GMP sites, in particular the following countries China India Bangladesh	18 December 2008	Answered - in full

FOI no	Subject	Date reply sent	Result of request
08/421	Inspection report for the following company: Thompson and Capper Astmoor Industrial Estate Runcorn Cheshire WA7 1PH	27 November 2009	Answered - in part
08/422	Information MHRA holds which records how a decision was reached to withdraw: Benoxaprofen (Brand name: Opren) Indoprofen (Brand name: Flosint) Clomacran (Brand name: Devryl) along with Drug analysis prints for each year they were on the UK market	16 December 2008	Answered - in part
08/424	Details of MHRA Inspectors	18 December 2008	Answered - in full
08/425	A list of Chinese and Indian sites inspected by MHRA for GMP done in last three years.	09 December 2008	Answered - in full
08/427	A list of all currently audited Indian manufacturing facilities and what types/classes of products they are 'approved' to manufacture	18 December 2008	Answered - in part
08/430	Stability of lantus insulin at Room Temperature	16 January 2009	Answered - in full
08/431	Addresses of blood storage facilities in the UK	16 January 2009	Answered - in full
08/433	Information regarding Salbutamol Inhaler (IVAX)	15 January 2009	Answered - in part
08/434	Minutes of the Paediatric Medicines EAG meeting held on 09/10/2008 refer under "Variations" to advice on "medicine used for the treatment of constipation"	15 January 2009	Answered - in part
08/439	Information on deaths related to mifepristone (Mifegyne™) induced abortion	16 January 2009	Answered - in full
08/440	Request for information regarding ongoing Devices investigation	10 March 2009	Answered - in part
09/004	Copies of documents considered by EAGs or advisory Commission/Committee meetings relating to sodium cromoglicate	30 January 2009	Answered - in part
09/006	WasCipla Ltd., D-7 & D-22, MIDC, Kurkumbh 413802 District Pune (Maharashtra), India, inspected for APIs, namely trimetazidine dihydrochloride. If so what was the inspection outcome and when was it performed?	09 February 2009	Answered - in full
09/007	Assessment report of the P to GSL reclassification of Sodium Cromoglicate 2% w/v Eye Drops	30 January 2009	Answered - in part
09/009	Public Assessment Reports for Mesalazine EC Nordic 250, and Mesalazine EC Nordic 500	15 January 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/011	A copy of FOI disclosure 08/332 regarding GlaxoSmithKline's HPV Vaccine, Cervarix and the MHRA's stance on it - 08 October 2008, Answered - in full	16 February 2009	Answered - in part
09/012	MHRA Inspection staff expenditure/costs	03 February 2009	Answered - in full
09/014	GMP Inspection report for Brecon Pharmaceuticals, Hay-on-Wye	09 February 2009	Answered - in part
09/016	Sample Assessment Report where providing clinical/pharmacodynamic studies has been an issue for the applicant	29 January 2009	Answered - in full
09/017	Request for information regarding ongoing Devices investigation	10 March 2009	Answered - in part
09/018	A copy of the MHRA GMP inspection report the Acculogix facility located in Bristol, Pennsylvania (USA)	10 February 2009	Answered - in part
09/020	Any information on bioequivalence between generic salbutamol MDI and Ventolin MDI	26 January 2009	Answered - in part
09/021	Details of the approved MA's from Jan 2001 to till date	10 February 2009	Answered - in full
09/022	Request for names of committees considering adverse reactions in vaccines, and minutes	13 February 2009	Answered - in full
09/023	Information on the MMR vaccines	10 February 2009	Answered - in full
09/025	All information held with regards to paroxetine (Seroxat) and congenital birth defects, intra-uterine death, abortion, spontaneous abortion and elective termination, including yellow card reports and all other material on file	23 February 2009	Answered - in part
09/026	MHRA organisational information	19 February 2009	Answered - in full
09/027	When did Scotia Pharmaceuticals GMP status lapse?	10 February 2009	Answered - in full
09/028	Assessment report for NuvaRing	03 February 2009	Answered - in part
09/031	Drug Analysis Print and a breakdown of fatal outcomes reported as being due to Paroxetine (also under trade name Seroxat) reported to the MHRA by all sources for each calendar year from 2005 to 2008 inclusive - if it is possible also show who made the report eg physician, pharmacist or member of the public	30 April 2009	Answered - in full
09/032	Information on ADRs and on Paroxetine (also under trade name Seroxat)	23 February 2009	Answered - in full
09/033	List of all MHRA regulated Pharmaceuticals, Biotech, CROs and SMOs in the UK	07 April 2009	Answered - in full
09/034	Inspection report for Zeta Analytical Ltd, Unit 3 Colonial Way Watford, 27.11.08	24 February 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/035	Reports of cancers with COCs/PcCs/HRT/fertility drugs	24 February 2009	Answered - in full
09/036	Copies of any specific advice concerning the pool hoist at Stoke Mandeville Stadium	25 February 2009	Answered - in full
09/037	Details relating to Pindolol - The expert reports (overviews) - The assessment reports	24 February 2009	Answered - in part
09/038	1) list of medical devices´ field safety corrective actions of last 5 years (companies, products concerned, problem occured), and whether FSNs where issued 2) any statistical evaluations of the above.	11 February 2009	Answered - in part
09/039	Information regarding mifepristone	27 February 2009	Answered - in full
09/040	Question regarding the use of refined peanut oil as an ingredient in vaccinations	13 February 2009	Answered - in full
09/041	Copy of the latest MHRA Inspection Report for "Zhejiang Hisun Pharma Co. Ltd., 46 Waisha Road, Jiaojiang District, Tiazhou City, Zhejiang Province, 318000, PR China" and any associated documents	27 February 2009	Answered - in part
09/042	Details of all regulatory applications for approval made by DEXO BIOPHARM LIMITED including date of application, product name/description and current status	23 February 2009	Answered - in part
09/044	A list of all UK based companies/organisations that underwent an MHRA GMP inspection last year,and a list of all UK based companies/organisations that are currently being investigated by the MHRA GMP Inspection Action Group	10 February 2009	Answered - in full
09/045	The agency clinical summary and the company clinical summary that was part of the original Topamax and Betaloc submission and approval	02 March 2009	Answered - in part
09/047	Information on the MMR vaccines	11 March 2009	Answered - in full
09/048	I am looking for the documents regarding the marketing approval of Varicella vaccines (Varivax and Varilrix)	03 April 2009	Answered - in full
09/050	A list of all gifts, hospitality or donations supplied to your organisation by Scientology organisations, over the past 5 years	11 March 2009	Answered - in full
09/051	Paper presented to the Pharmacovigilance expert advisory group meeting of 14/01/09 concerning information on trends for the prescribing of pain-relieving drugs between 2003 and 2008, in relation to the withdrawal of co-proxamol between 2005 and 2007	10 March 2009	Answered - in part
09/052	Information regarding infant mortality in connection with measles single vaccine	03 April 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/054	Details of any applications submitted by the current licence holder to change the formulation or manufacturing process of Procarbazine 50 mg Capsules, in particular copies of the expert reports submitted with the applications and the assessment reports generated	25 February 2009	Answered - in part
09/055	A list of Product Licences which have lapsed or been terminated from 1 Oct 2008 till 31 January 2009 due to Sunset clause	30 March 2009	Answered - in full
09/056	A list of all Manufacturing sites outside the EU and currently approved by MHRA	23 February 2009	Answered - in full
09/057	Two studies submitted to MHRA by Aventis Pharmaceutical in 2002 - European epidemiological studies on the drug levofloxacin, a type of fluroquinolone, marketed under the name Tavanic, and in the US as Levaquin	12 March 2009	Answered - in part
09/060	How many prosecutions have MHRA instigated against clinical investigators under section 29 of the medicines for human use regulations 2004 for failing to comply with the protocol How many prosecutions have MHRA instigated against clinical investigators under section 16 of the medicines for human use (amendment) regulations 2006 for committing a serious breach? How many cases have been reported to MHRA under S27 of the medicines for human use (clinical trials) regulations 2004 of clinical trial sponsors prematurely terminating trials at sites pursuant to S16 of the medicines for human use (clinical trials) amendment regulations 2006, i.e. resulting from a serious breach?	18 March 2009	Answered - in full
09/061	The latest MHRA GMP audit reports for the following companies: Dales Pharmaceuticals Penn Pharmaceuticals Encap Drug Delivery Almac	20 March 2009	Answered - in part
09/064	A list of institutes in the UK who carry out clinical trials and are required to follow GCP regulations	18 December 2009	Answered - in part
09/065	Information on Galenica's Ferinject / Injectafer	12 March 2009	Answered - in full
09/067	A list of all prescription medicines that have currently been licenced for use in the UK	17 March 2009	Answered - in full
09/068	Information regarding Orlistat (Xenical)	23 March 2009	Answered - in part
09/069	A copy of the Periodic Safety Update Report data for Aerodiol (MAH = Servier)	25 March 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/073	Most recent GMP Inspection Reports for the following companies: Aptuit (Riccarton, Bathgate and Deeside sites) Catalent Westhoughton, Bolton Almac Pharma Services Craigavon Bilcare Clinical Services (site formerly DHP Ltd)	27 March 2009	Answered - in part
09/074	How many prosecutions (including impending) have there been to date by the MHRA in respect of BZP	24 March 2009	Answered - in part
09/075	Contact details for various MHRA Divisions/staff	24 March 2009	Answered - in full
09/076	Adverse incidents involving breast implants	19 March 2009	Answered - in part
09/078	Information on MHRA's travel & expense policy	06 March 2009	Answered - in full
09/079	Variation data on COPAXONE° (glatiramer)	04 June 2009	Answered - in part
09/080	Information regarding MHRA expenditure on consultancies	07 April 2009	Answered - in full
09/082	Latest Inspection reports for Keats Healthcare Ltd, Pitcairn House, Crown Square, First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW	03 April 2009	Answered - in part
09/083	Complaint regarding Fenistil Cold Sore Cream	30 June 2009	Answered - in part
09/084	GMP status of Hyaluron (USA)	10 March 2009	Answered - in full
09/086	Query regarding MHRA Antidepressant suicide warning (on or about Aug 2000)	09 April 2009	Answered - in part
09/087	Public Assessment Report Pentasa 1g suppositories PL 03194/0045 (active: mesalazine), and any information on the legal basis of the application, i.e. which article was used to grant the authorisation	20 April 2009	Answered - in part
09/088	Any information held on adverse effects caused by the following orthopaedic plates: 1. Synthes DCP 4.5 board 12 hole 1.99 plate SST product code 226.12 or any orthopaedic plate produced by Synthes; and 2. Orthosolutions 6-screw plate or any orthopaedic plate produced by Orthosolutions.	09 April 2009	Answered - in full
09/089	A list of manufacturing sites in India which have been inspected by MHRA and approved for medicines destined for the UK market	20 March 2009	Answered - in part
09/090	MHRA Audit Report for Taiwan Regulatory Authority on the Lyophilisates facility	16 April 2009	Answered - in part
09/091	Updated list of MHRA Approved / Certified Pharmaceutical Manufacturing plants in india	09 April 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/092	Questions to do with pharmacovigilance and the MHRA	15 April 2009	Answered - in full
09/095	The agency clinical summary and the company clinical summary that was part of the Topamax license extension to include the clinical indication 'Prophylaxis of migraine headache'	16 April 2009	Answered - in part
09/096	A Copy of MHRA's inspection of Recipharm Ltd (formerly Ashton Pharmaceuticals), at their manufacturing site at Ashton-under-Lyne, Vale of Bardsley, Lancashire, OL7 9RR, United Kingdom	20 April 2009	Answered - in part
09/097	Copy of the GMP/GDP inspection reports for inspections performed between 2005 and 2009 at BIO PRODUCTS LABORATORY, and AMBER PARK 1 & 2	20 April 2009	Answered - in part
09/098	In December 2004, the Paediatric Working Group of the Committee on the Safety of Medicines recommended a paediatric update to the Cozarr tablet licences PL 00025/0336, 0324 and 0416. They requested the company to update sections 4.2 and 5.1 of the SPC. Could you please confirm that these variations were submitted and if they have been approved,	27 March 2009	Answered - in full
09/099	MHRA information on Chinese API sites	27 November 2009	Answered - in part
09/100	MHRA Certificates of GMP compliance issued to Indian Pharma Companies during last two years	20 April 2009	Answered - in full
09/101	Availability and prescribing of Co-proxamol	30 March 2009	Answered - in full
09/104	Query regarding any MHRA contact with the charity named Common Purpose	15 April 2009	Answered - in full
09/105	The latest MHRA GMP inspection reports for R5 Pharmaceuticals Ltd., and SCM Pharma	03 June 2009	Answered - in part
09/106	The latest inspection report for Catalent	06 April 2009	Answered - in part
09/107	A copy of the Clinical Expert Report/Clinical Overview, and any correspondence between the applicant and the MHRA or Medicines Advisory Bodies including assessment reports, requests for supplementary information (questions) from the agency and responses submitted by the applicant in respect of Glucophage SR 500mg Sustained-Release Tablets	27 May 2009	Answered - in part
09/108	Questions regarding SSRIs and ADRs	27 May 2009	Answered - in part
09/109	A list of MHRA approved facilities in CHINA	06 April 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/110	Information MHRA holds which records how a decision was reached to withdraw: Zomax (zomepirac) Osmosin (indomethacin-modified release) Zelmid (zimeldine) along with Drug analysis prints for each year they were on the UK market	06 April 2009	Answered - in part
09/112	Medicines Inspection reports and subsequent correspondence for the following two companies manufacturing APIs: Hanmi Fine Chemicals, Kyonggi-Do, Korea 1st - 5th December 2008 PT Sinkona, Subang 4128, Indonesia 4th - 5th August 2008	01 June 2009	Answered - in part
09/114	Queries regarding Seroxat, and meetings with MHRA etc	07 May 2009	Answered - in full
09/115	Nicorandil - request for information mentioned originally in documents pertaining to FOI 08/372	27 May 2009	Answered - in part
09/116	Copies of all Dear Doctor letters sent in 1995, 1996 and 1997	24 April 2009	Answered - in full
09/117	MHRA's handling of a British TV advert regarding 40over40.com	28 April 2009	Answered - in part
09/118	Request for 3 previous FOI disclosures	08 May 2009	Answered - in part
09/120	We have reviewed an MHRA report of unlicensed import requests that have been approved (01 Jan 2007-31 Dec 2007). According to this 110 requests were made for Procarbazine. We would like to know the countries of origin of the products and the MA holders in those countries of origin.	15 June 2009	Answered - in part
09/121	A copy of the MHRA inspection report issued for the inspection of the Catalent Pharma Solutions facility in Corby, United Kingdom - April - May 2008?	11 May 2009	Answered - in part
09/122	A copy of the MHRA inspection report issued for the inspection of the Sun Pharmaceutical Industries facility in Gujarat, India - late 2008 or early 2009?	17 November 2009	Answered - in part
09/123	Redacted copies of the audit reports, associated IAG follow ups and responses if available for the inspections carried out at Aptuit Incorporated in Kansas City, Missouri on 12-16th May 2008 and in December 2007	22 June 2009	Answered - in part
09/124	Complete names and addresses list of all MHRA Authorised Blood Establishments.	01 June 2009	Answered - in full
09/125	Queries regarding Dorothy Black report 1984 (drugging girls / Kendall House care home) & medical precedent to suggest that such powerful drugs could cause genetic abnormalities	30 April 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/127	Information regarding MHRA addressing SSRI/SRNI issues around suicidal ideation	30 April 2009	Answered - in part
09/128	The last GMP inspection report and responses for Phillips Plastics Corporation Origen Center 428 Technology Drive East Menomonie WI 54751 United States	11 May 2009	Answered - in part
09/129	A list of names and addresses of pharmaceutical manufacturers' which have been GMP approved in India	18 May 2009	Answered - in full
09/130	Query regarding any MHRA contact with the charity named Common Purpose	15 April 2009	Answered - in full
09/131	Steroid Treatment Cards Guidelines - Prednisolone Tablets	30 April 2009	Answered - in full
09/132	Questions regarding the GMP status of Cadila Pharmaceuticals Ltd, 1389 Trasad Road, Dholka, Ahmedabad - 387810, Gujarat, India	18 May 2009	Answered - in full
09/134	A copy of the inspection report issued to the Norbrook Laboratories facility located in Newry, United Kingdom. The inspection took place in October 2008	24 June 2009	Answered - in part
09/135	Information about any costs incurred by MHRA relating to translation services	21 May 2009	Answered - in part
09/136	A copy of the Periodic Safety Update Report data for Aerodiol (MAH = Servier)	28 April 2009	Answered - in part
09/137	Most recent GMP Inspection Reports for the following companies: Brecon Pharmaceuticals, Wye Valley Business Park, HR3 5PG	23 April 2009	Answered - in part
09/139	How many reports associated with anti-depressants received from consultant physciatrists in Gloucesterhire	19 May 2009	Answered - in full
09/140	Supply the First Approved dates for the following drugs Fluvoxamine Maleate Mirtazapine Nefazodone Hydrochloride Paroxetine Hydrochloride Sertraline Hydrochloride Tryptophan Tryptophan L-tryptophan	01 May 2009	Answered - in part
09/141	Last MHRA GMP inspection reports for Cobra Biomanufacturing Plc BioReliance Ltd	09 September 2009	Answered - in part
09/142	A list of generic lamotrigine with their bioequivalence %	27 May 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/143	Query regarding MHRA correspondence in respect of Jbol/Whiz products	28 May 2009	Answered - in full
09/144	Details of any submitted, pending or granted MA applications for products containing the INN enoxaparin	18 May 2009	Answered - in part
09/145	Which UK product licences have been cancelled under the Sunset Clause, and Which UK product licences are likely to cancelled under the Sunset Clause?	18 May 2009	Answered - in part
09/146	Request for data supporting approval of Levonelle	21 May 2009	Answered - in full
09/147	Co-proxomal	29 May 2009	Answered - in part
09/148	Audit results on PharSafer Ltd	29 May 2009	Answered - in full
09/149	Details of MHRA register of licensed (human & veterinary) wholesale dealer sites	11 May 2009	Answered - in part
09/152	Details of MHRA's annual inspection programme for 2009	01 June 2009	Answered - in full
09/153	Details of cases of Ovarian Hyperstimulation Syndrome as a result of preparation for fertility treatment by stimulating hormones reported to MHRA during each of the last 3 years	03 June 2009	Answered - in full
09/154	A list of MHRA audited sites in India and China, and a list of pending audits for the forthcoming year	01 June 2009	Answered - in full
09/155	MHRA/VMD GMP inspection reports for January to March 2009	02 June 2009	Answered - in part
09/160	Co-proxomal	05 June 2009	Answered - in part
09/161	Any PV and GMP inspection results for Potters by the MHRA which are less than 5 years old	12 June 2009	Answered - in part
09/163	Correspondence between the Inspector of Microbiology and MHRA since 2004 regarding IVD, Class I and urine collecting devices	09 June 2009	Answered - in part
09/164	Information regarding Combigan 2 mg/ml + 5 mg/ml Eye Drops, Solution	29 June 2009	Answered - in part
09/165	All documents (e.g., reports, correspondence, notes) concerning the Kansas City, Missouri facility of Aptuit, Inc	22 June 2009	Answered - in part
09/166	Last MHRA inspection report for the Pharmaceutical Manufacturing Unit for Torbay Hospital	09 June 2009	Answered - in part
09/167	The most recent pharmacovigilance and GCP inspections reports for Merck Sharp and Dohme	11 June 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/168	Information in relation to the applications for marketing authorisations Tavanic 250mg tablets, Tavanic 500mg tablets and Tavanic iv 500 granted to Hoechst Marion Roussel Limited on 6 June 1997	02 June 2009	Answered - in full
09/171	The number of fatalities attributed to the use of drugs listed as Hypnotics and Anxiolytics, Drugs used in Psychoses & Related Disorders, Antidepressant Drugs, CNS stimulants and drugs used for ADHD	08 June 2009	Answered - in full
09/172	Request for reply to 09/051	22 May 2009	Answered - in full
09/173	Request for reply to 09/075	22 May 2009	Answered - in full
09/175	Overall Clinical Overview for: Seretide Evohaler 25/50 PL10949/0337 Seretide Evohaler 25/125 PL10949/0338 Seretide Evohaler 25/250 PL 10949/0339	04 June 2009	Answered - in part
09/176	Information on medical device alerts, hazard notices etc, to aid dissertation into risk management of software faults	02 June 2009	Answered - in full
09/178	Question relating to Tobramycin (Bramitob®)	16 June 2009	Answered - in part
09/180	Minutes of the reported meeting between Director of Communications Simon Gregor and member of the public at 11am on Friday 15th 2009.	12 June 2009	Answered - in full
09/182	Miacalcic and prostate cancer	17 June 2009	Answered - in part
09/185	Clinical data from the reference marketing authorisation for Benylin Childrens Tickly Cough Syrup	12 June 2009	Answered - in part
09/187	Questions regarding the use of Lignocaine 5% & Phenylephrine 0.5% topical solution (Aurum Pharmaceuticals) in trial of opthalmic surgery procedure of LACRIMAL DUCT DILITATION in children	22 June 2009	Answered - in part
09/189	Final inspection report (public GMP, GCP and GLP) for CIPLA Ltd. Verna Industrial Estate, VERNA, GOA, INDIA for unit of production Hard gelatin Capsules anti-cancer (cytotoxic)	11 June 2009	Answered - in part
09/190	Questions regarding adverse reactions to drugs both fatal and non-fatal (2008 figures) following an article in the Mail newspaper,	23 June 2009	Answered - in full
09/191	Devices compliance unit SOP	17 June 2009	Answered - in part
09/192	A list of bioequivalence centers (CRO) inspected by MHRA in India, and the procedure to get inspected and approved by MHRA to conduct bioequivalence studies	17 June 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/194	Query regarding expenses etc in relation to: 1. Advisory Board on Registration of Homeopathic Medicines 2. Independent Review Panel for Borderline Products 3. Herbal Medicines Advisory Committee 4. MHRA 5. Independent Review Panel for Advertising of Medicines 6. CHM 7. British Pharmacopoeia Commission	10 July 2009	Answered - in full
09/195	Details of the protocol and the results of the study referred to in MHRA's UK PAR for Imigran Recovery	16 June 2009	Answered - in part
09/196	Query regarding Device compliance procedure in relation to dates required for compliance etc	24 June 2009	Answered - in full
09/197	Co-proxomal	08 June 2009	Answered - in part
09/198	Co-proxomal	11 June 2009	Answered - in part
09/201	A list of successfully inspected CROs	23 September 2009	Answered - in full
09/202	The full responses to document MLX299	23 June 2009	Answered - in full
09/203	State how many staff members in your organisation are currently paid more than £100,000 per annum, listing the position of each such staff member	17 June 2009	Answered - in full
09/204	Copies of the most recent GMP inspection reports: 1. Alkem Laboratories Ltd, Dabhel, DAMAN, India 2. IPCA Laboratories Ltd, Ratlam, MADHYA PRADESH, India 3. AMI Life Sciences Ltd, Baroda, GUJARAT, India	24 June 2009	Answered - in part
09/206	A current list of all authorized blood establishments and hospital blood banks	09 June 2009	Answered - in full
09/209	All correspondence between MHRA and ebay UK, and all related subsidiary companies and organisations which determined ebay UK to make the decision to prohibit the sale of electronic cigarettes, including component parts for sale from ebay UK	08 June 2009	Answered - in part
09/210	I would like to ask for which products or at least for which manufacturing site / manufacturing lines the MHRA has inspected and accepted Eskayef Pharmaceuticals in Bangladesh.	02 July 2009	Answered - in full
09/212	Various PSUR reports for Seroquel & Seroquel XR	06 July 2009	Answered - in full
09/214	A list of overseas sites inspected for GMP by the MHRA in the last 3 years	16 June 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/215	Co-proxomal	13 July 2009	Answered - in part
09/216	Co-proxomal	13 July 2009	Answered - in full
09/217	GMP Inspection Report for Medifill UK Limited, and also a copy of the Inspection Report for Thorpe Laboratories	18 June 2009	Answered - in part
09/218	Information on the manufacturing and packaging sites for AstraZeneca UK Limited 's product, Nexium tablets	13 July 2009	Answered - in part
09/219	Drug approval date & DAPs enquiry Citalopram Duloxetine Fluoxetine Paroxetine	13 July 2009	Answered - in full
09/221	The MHRA clinical assessment and the company clinical summary and overview (or equivalent) that was part of the Xalatan 0.005%w/v eye drop solution MAA	23 July 2009	Answered - in part
09/229	Information on on Nu-Seals 75 , PL 16853/0062: was this grant of license based on Bio-equivalent study or bibliographic reference only? If bio-equivalent study, what study was it (fasting/ fed etc.)	18 August 2009	Answered - in full
09/231	All correspondence between the MHRA and the BNF by way of electronic emails and/or via the postal service	20 July 2009	Answered - in part
09/234	MHRA correspondence regarding co-proxomal	13 July 2009	Answered - in part
09/235	Most recent MHRA GMP Inpsection Reports for Pharmaserve Ltd., Boots Manufacturing, Analytical Services, 1 Thane Road, Beeston, Nottingham., and Hamol Ltd., Factory 1, Nottingham.	24 July 2009	Answered - in part
09/237	Query regarding adverse reactions in relation to Cervarix (the HPV vaccination / cervical cancer vaccine)	23 July 2009	Answered - in full
09/238	Copy of full assessment report for MR number: UK/H/0544/001/ - Concerta XL 18mg prolonged release tablets	27 July 2009	Answered - in part
09/242	Request for presentations referred to in the minutes of the MHRA's pharmacovigilance and expert advisory group's meeting on 15 April 2009 "how regulatory action for particular medicines had impacted on the health of the general population; the safety of tranexamic acid (a treatment to prevent bleeding, such as in menorrhagia—abnormally heavy menstrual periods); and a study looking at how safely an asthma medicine containing budesonide and formoterol is being used by patients.	28 July 2009	Answered - in part
09/243	GMP Inspection report for Penn Pharmaceutical Services, Gwent, Wales	01 December 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/245	Request for annexes to minutes of CSM SCOP meeting 98/2nd	13 July 2009	Answered - in part
09/246	Information regarding Hydroxocobalamin	24 July 2009	Answered - in part
09/247	Company name(es), business address(es) and adress(es) of the manufacturing site(es) of the contract manufacturer(s) of the products that are the subject of various Class2 drug Alerts	05 August 2009	Answered - in full
09/248	Micro-Vention USA- Hydrocoils	28 July 2009	Answered - in part
09/251	A copy of the site inspection report corresponding to Certificate no UK GMP 31450Insp GMP 31450/360311-0001, carried out at IND-SWIFT LIMITED	09 September 2009	Answered - in part
09/252	MHRA inspection report for Aptuit (address: 10245 Hickman Mills Drive, Kansas City, MO 64137, USA)	07 July 2009	Answered - in part
09/253	List of contents of internal MHRA file	15 July 2009	Answered - in full
09/256	GMP audit report and/or a GLP audit of Dales Pharmaceuticals	19 November 2009	Answered - in part
09/257	Clinical trials - N-Acetylcysteine & Trichotillomania	04 August 2009	Answered - in full
09/258	UKPAR for Salbutamol pressurised inhalation, suspension 100 mcg/dose	13 July 2009	Answered - in part
09/259	Request for inspection report on Smuthri Organics Ltd, India	30 June 2009	Answered - in part
09/260	Query regarding EMEA approval of Clopidogrel	06 August 2009	Answered - in full
09/261	Information MHRA holds which records how a decision was reached to withdraw: Feprazone Alphaxalone Fenclofenac along with Drug analysis prints for each year they were on the UK market	20 July 2009	Answered - in part
09/262	Various adverse incident stats from 1st April 2008-31st March 2009 from within NHS City & Hackney	10 August 2009	Answered - in full
09/263	All Periodic Safety Update Reports (PSURs) received in the last three years for products containing the active substance "midazolam hydrochloride" plus copies of any subsequent correspondence/ assessment reports related to them	22 September 2009	Answered - in part
09/264	Seroxat liquid - PIL	10 August 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/265	Assessment report for Tavanic Tablets - UK/H/0203/001	31 July 2008	Answered - in part
09/266	Copy of letter to the MCA Dated 2 November 2000 concerning fluoridation	22 July 2009	Answered - in part
09/268	A list of manufacturing sites inspected by MHRA in China	04 August 2009	Answered - in full
09/269	MHRA inspection report and related correspondence for: SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST PHARMACEUTICAL MANUFACTURING UNIT, KEMMINGS CLOSE, PAIGNTON, DEVON, UNITED KINGDOM, TQ4 7TW	13 August 2009	Answered - in part
09/270	Cumulative medical device recall data between 2000-2008 related to Point of Care (POC) devices used in the NHS to measure cardiac biomarkers during the diagnosis of suspected acute myocardial infarction	30 July 2009	Answered - in part
09/271	The last 3 MHRA inspection reports for Bio Products Laboratory (BPL)	14 August 2009	Answered - in part
09/273	List of approved MHRA facilities in India	20 July 2009	Answered - in full
09/276	Clinical trial approvals	17 August 2009	Answered - in full
09/277	Details of MIA and WDL inspections carried out by a named MHRA inspector	06 August 2009	Answered - in full
09/278	MHRA Inspection Report from Aptuit, Todd Campus, West Of Scotland Science Park, Acre Rd, Glasgow, Lanarkshire G20 0XA performed in May/ June 2009	17 August 2009	Answered - in part
09/279	MHRA inspection Aptuit facilities @ Todd Campus, West of Scotland Science Park, Acre Road, Glasgow, Scotland in June 2009	17 August 2009	Answered - in part
09/281	MHRA/CHM clinical assessment report and all pooled data, used in the evaluation of corticosteroids and their potential risk of early psychiatric side effects, which formed the basis for the information provided in the Drug Safety Update Sept 2007; Volume 1, Issue 2, pages 9-10	29 July 2009	Answered - in part
09/283	CHM advice on psychatric warnings for corticosteroid products	29 July 2009	Answered - in part
09/285	I would like to know the numbers of hip resurfacings and metal on metal hip replacements revised each year for which data are available. I would also like to know the manufacturers of the implants revised if possible	13 August 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/286	Financial details regarding: 1. In Vitro Diagnostic Advisory Committee 2. Independent Review Group on silicone gel breast implants 3. Independent Review Panel for Advertising 4. Independent Review Panel for Classification of Borderline Products 5. Independent Scientific Advisory Committee for MHRA Database Research 6.Microbiology Advisory Committee.	17 August 2009	Answered - in full
09/287	Overseas plants inspected in the last three years	06 August 2009	Answered - in part
09/288	The Assessment Report Codipar Caplets produced by Goldshield Pharmaceuticals Ltd, including information of the legal basis of the application and any details of the level of clinical information inluded in the submission	14 August 2009	Answered - in part
09/289	Informatiion relating to TOBI 300 mg/5 mL Nebuliser Solution	16 September 2009	Answered - in part
09/290	Could you confirm if Church & Dwight, USA are registered as a manufacturer of the active ingredient Sodium Bicarbonate and, if so, could you confirm the type of product for which they are registered, i.e. IV solution, PD solution, oral product etc	20 August 2009	Answered - in part
09/291	Questions regarding MHRA's ICT policies and spending	13 November 2009	Answered - in part
09/293	Questions regarding GLP and GMP inspections	09 September 2009	Answered - in part
09/294	MR Assessment Report ,and any available RMS/CMS correspondence, for Glaxo Wellcome's Nimbex Solution for Injection medical product	24 August 2009	Answered - in part
09/295	The latest GMP Inspection report for J MLoveridge	19 August 2009	Answered - in part
09/296	Various PSUR reports for: PSUR Ritalin 2007-08 PSUR Seroquel 2007-08 PSUR Tryptisol 2007-08 PSUR Seroxat 2008 PSUR Prozac 2007-08	26 August 2009	Answered - in part
09/298	Reason for withdrawal of Viloxazine	01 September 2009	Answered - in full
09/300	Information regarding bioequivalence studied performed and submitted on Lipitor or other atorvastatin containing medicines. The information should include studies design and results.	13 August 2009	Answered - in part
09/301	A copy of the inspection report which was issued prior to their Manufacturing Licence for Catalent UK Swindon Encaps Ltd	20 August 2009	Answered - in part
09/302	Details of all of the organisations audited by MHRA (including follow ups) in the last three years, with industry type and outcomes	21 August 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/303	Information regarding bioequivalence studied performed and submitted on Actonel or other Risedronate containing medicines. The information should include studies design and results.	27 August 2009	Answered - in part
09/306	Fetal Anti Convulsant (FAC) Litigation	07 September 2009	Answered - in full
09/307	When was the Northwick Park Institute for Medical Research last inspected by the GLP monitoring authority and a copy of the inspection report	09 September 2009	Answered - in part
09/308	Drug licencse fees	17 August 2009	Answered - in full
09/309	Healy - SSRI Withdrawal Protocol	21 August 2009	Answered - in part
09/310	Figures for Adverse Events reported re Vascular Closure Devices, Catheters, Guidewires and Angiography Accessories	07 September 2009	Answered - in part
09/311	Has the UK had any ADR reports for Ferinject or Injectafer or for the particular drug substance 'Ferric carboxymaltose`	21 August 2009	Answered - in full
09/313	A listing of all GMP inspections carried from January 1, 2008 through July 1, 2009, including inspections of both Animal Health and Human Health facilities, with the dates of the inspection, name and address of the facility inspection and number and type of deficiencies cited (critical, major, minor/other).	08 September 2009	Answered - in part
09/314	Information held in support of the MHRA's objection to granting a Marketing Authorisation relating to the single component Leningrad Zagreb strain of mumps vaccine.	15 September 2009	Answered - in part
09/317	Ministerial correspondence with MHRA	16 September 2009	Answered - in part
09/318	The last 5 PV inspection reports of any company	18 December 2009	Answered - in part
09/320	Details of clinical trials submitted to support the product licence submission for Immucyst	04 September 2009	Answered - in part
09/321	Adverse effects of chemotherapy drug Taxotere	11 September 2009	Answered - in full
09/322	Minsterial correspondence with MHRA	16 September 2009	Answered - in part
09/323	Co-proxomal and FOI requests in general	02 September 2009	Answered - in part
09/324	FOI 06/384 and Chairman's representations to the Health select committee in 2005	18 September 2009	Answered - in full
09/325	Asking if MHRA has had information requests for the "ResQ Club"	16 September 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/326	Applicants expert reports or overviews and summaries on quality, nonclinical and clinical data, plus MHRA assessment reports on quality, nonclinical and clinical data for Atrogel Arnica Gel (THR 13668/ 0009, Traditional Herbal Registration Holder Bioforce UK LImited)	17 September 2009	Answered - in part
09/327	Which companies manufacture generic levothyroxine for the UK market, and what range of bioequivalences did they each provide for their licensing submission	21 September 2009	Answered - in part
09/328	MHRA Press Officers and salaries	08 September 2009	Answered - in part
09/329	Various minutes from the Biologicals sub-committee between 1990 and 1996	21 September 2009	Answered - in part
09/331	Query regarding MHRA use of FOIA Section 14 - vexatiousness	17 September 2009	Answered - in full
09/332	Any information held on adverse effects caused by the Zimmer Durom Cup Prosthetic Hip	21 September 2009	Answered - in part
09/333	Certification of SQUARE Pharma, Bangladesh	10 September 2009	Answered - in part
09/334	Who is responsible for the pharmacovigilance system for the Marketing Authorisation of Trientine dihydrochloride capsules 300mg	23 September 2009	Answered - in full
09/338	Information for the period 2005 – to date of adverse incidents in hospitals, care homes and domestic premises involving hoisting and transfer equipment	21 September 2009	Answered - in full
09/340	Report of alleged faulty bedclamp design, and request for MHRA staff qualifications	23 September 2009	Answered - in full
09/342	Costs and resources of the MHRA website	30 September 2009	Answered - in full
09/343	Financial and salary information regarding MHRA	04 September 2009	Answered - in part
09/345	A report from MHRA's information systems to assist in signal detection using disproportionality	21 September 2009	Answered - in full
09/346	Request for information on simvastin	22 October 2009	Answered - in part
09/347	GMP Approved Facility list	22 September 2009	Answered - in full
09/348	A copy of all information held about myself and/or C&W Aesthetics Ltd by the MHRA	02 October 2009	Answered - in part
09/349	A copy of the inspection report from the most recent (2009) MHRA pharmacovigilance inspection of the King Pharmaceuticals facility	08 October 2009	Answered - in part
09/350	UK Universities and involvement with clinical trials	28 September 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/351	Various PSUR reports for: Ritalin Tryptisol Seroxat Prozac	22 October 2009	Answered - in part
09/354	Homeopathic products A list of products: - registered under the national rules scheme. - a list of products registered under the simplified scheme -a list of any homeopathic products for which Par is available (I have arnicare arnica 30c pillules) Also the number of current applications under the national and simplifies schemes	24 September 2009	Answered - in full
09/357	Which Committee decides whether or not the medicine Sativex will be approved by the MHRA, what is the schedule of forthcoming meetings of the Committee, and at which committee meeting a decision whether or not to approve Sativex is most likely to be made	24 September 2009	Answered - in full
09/358	MERCK MMR PRODUCT	24 September 2009	Answered - in part
09/360	Phase I units in the UK	24 September 2009	Answered - in full
09/362	Adverse effects of chemotherapy drug Taxotere	12 October 2009	Answered - in full
09/363	How many DMFs have been approved for the active drug susbstance Nitrofurantoin, and the name of the manufacturers	05 October 2009	Answered - in part
09/364	A list of companies inspected in the last the 3 months for PV inspections	23 September 2009	Answered - in full
09/365	MHRA PV inspection reports from the past 12 months	19 October 2009	Answered - in full
09/366	Any information available that can be provided similar to that in the EPAR for Relenza i.e the toxicology and clinical package of data used to obtain the initial MA	13 October 2009	Answered - in part
09/368	Inspection reports for Medifill UK Ltd 59 Third ave Deeside Flintshire	22 September 2009	Answered - in part
09/369	Medicines Inspection reports and subsequent correspondence for the following company manufacturing sterile products: Strides Arcolab Ltd, Bangalore, India	20 October 2009	Answered - in part
09/371	Copies of the inspection reports and GMP certification documents issued as a result of the MHRA inspection at the Bio-Reliance facility in Glasgow, UK on June 2009, July 2008 and February 2008	09 November 2009	Answered - in part
09/373	Inspection reports for Medifill UK Ltd from January 2009 and July 2009 and a copy of the last inspection report (2009) for Pharmapak Uk Ltd	19 December 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/376	Information on ADRs relating to breast implants and breast enlargement surgery	22 October 2009	Answered - in part
09/378	Copies of the inspection report and GMP certification issued as a result of the February 2009 MHRA inspection of the Catalent Pharma Solutions (new name of Cardinal Health) facility located in Humacao, Puerto Rico (P.O. Box 889)	11 November 2009	Answered - in part
09/379	MHRA/European guidance on medical and IVD devices	22 October 2009	Answered - in full
09/380	Copies of the MHRA inspection report and any GMP certification issued as a result of the MHRA inspection at the Sun Pharmaceuticals (formerly MJPL or SPIL) facility in India	27 October 2009	Answered - in part
09/383	All documentation of the advice given by the MHRA to Minister O'Brien	27 October 2009	Answered - in part
09/384	Information regarding staff uptake of private medicial care	22 October 2009	Answered - in full
09/387	List of MHRA staff by seniority and job title	20 October 2009	Answered - in full
09/388	A copy of the variation assessment report for Seroquel XL's recent approval, extending the use to patients with bipolar disorder experiencing major depressive episodes	29 October 2009	Answered - in part
09/389	Copies of the MHRA inspection report and the certification issued as a result of the inspection at the Provimi facility in August 2008	30 October 2009	Answered - in part
09/391	Questions in regard to IVD's	27 October 2009	Answered - in full
09/392	Public Assessment Report for Visclair Tablets 100mg	15 October 2009	Answered - in part
09/393	The ciclosporin blood-concentration data and human bioequivalence studies that supported certain marketing authorisations	02 November 2009	Answered - in full
09/394	A copy of the inspection report and any kind of GMP certification issued as a result of the MHRA inspection at the Micron Technologies facility located in Exton, Pennsylvania (USA	19 November 2009	Answered - in part
09/395	A copy of the inspection report and any kind of GMP certification issued as a result of the MHRA inspection at the Mustafa Nevzat Pharmaceuticals facility in Yenibosna-Istanbul, Turkey. The inspection occurred in May 2008	03 November 2009	Answered - in part
09/396	A copy of the inspection report and any GMP certification documentation issued as a result of the MHRA inspection of the Hisun facility located in Zhejiang Province in the Peoples Republic of China.	03 November 2009	Answered - in part
09/397	Query regarding marketing authorisations and fraud	02 November 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/398	All MHRA GMP/GLP/GCP inspection reports for the company Cadila or Zydus Cadila based in India perfromed in the last 10 years	16 November 2009	Answered - in part
09/401	A copy of the Johnson & Johnson Pharmacovigilance Inspection Report and the most recent Pharmacovigilance reports which are avaiable	10 November 2009	Answered - in part
09/404	How many adverse reactions have been reported to MHRA relating to Cervarix, the vaccination against HPV since it was approved for use, and how many of these reports were classed as "serious" by the reporter.	02 November 2009	Answered - in full
09/406	Query regarding I export certificates, and parallel import licenses	30 October 2009	Answered - in full
09/407	Problems with urostomy medical device	09 October 2009	Answered - in part
09/408	Current GMP certificate for IDIS Limited, Idis House, Churchfield Road, Weybridge, Surrey, KT 13 8BD	12 November 2009	Answered - in part
09/409	Adverse drug reactions - suicide and suicidal ideation	29 October 2009	Answered - in full
09/410	Conduct, validity and regulation of clinical trials	07 November 2009	Answered - in full
09/411	Various questions relating to numbers and sponsors of clinical trials	09 November 2009	Answered - in full
09/412	Patient and Public Engagement Strategy	19 October 2009	Answered - in full
09/413	Request for contact details within MHRA	30 October 2009	Answered - in part
09/414	A list of companies to be inspected in the coming 6 months for PV inspections	09 November 2009	Answered - in part
09/415	A copy of the report arising from the 2009 MHRA GMP inspection of Qualiti (Burnley) Limited.	09 November 2009	Answered - in part
09/416	A copy of the GMP Inspection Report arising from the 21 Nov 2007 inspection of William Ransom & Son plc, Witham, Essex along with correspondence between MHRA and the manufacturing site which concluded that a voluntary recall of the products containing purified water from this facility was not required.	09 December 2009	Answered - in part
09/417	Organisation chart for MHRA communications division	16 October 2009	Answered - in part
09/418	GMP Inspection Report of June 2009 inspection of M.J. Biopharm Pvt Ltd of MIDC Industrial Area, Tajola, District Raigad, 410 208, Navi Mumbai, India	11 November 2009	Answered - in part
09/420	Patient and Public Engagement Strategy	05 November 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/421	Query regarding MHRA correspondence	12 November 2009	Answered - in full
09/423	Licensing of generic ciclosporins	23 November 2009	Answered - in full
09/424	Pharmacovigilance Inspection reports for: Chemidex (2007) Auden McKenzie (2009) Dr Reddy's (2009)	09 November 2009	Answered - in part
09/425	A list of all current registered pharmacy wholesalers (pharmacists or pharmacies which hold a wholesalers dealers license) since 1995	13 November 2009	Answered - in full
09/426	A list of Generics Manufacturing Companies in India which are approved by MHRA to supply their Generic Products in UK for Sale in UK	11 November 2009	Answered - in part
09/429	A copy of the Public Assesment Report for Nicorette Combi PL 15513/0356	16 November 2009	Answered - in full
09/430	Copy of MHRA inspection report for the inspection report for 30 June 2009 at Melbourn Scientific Ltd. Saxon Way Melbourn Herts. SG8 6DN	09 November 2009	Answered - in part
09/431	Updated list of MHRA approved sites in India and China	09 November 2009	Answered - in part
09/434	Information regarding Chloraprep	30 November 2009	Answered - in part
09/436	Questions regarding chemotherapy treatment FMD	23 November 2009	Answered - in full
09/437	PARs or MHRA assessments reports of UK medicines for the treatment of alcohol dependance, specifically of the following compounds: 1. naltrexone (Nalorex /Opizone) 2. disulfiram (Antabuse) 3. acamprosate (Campral)	02 December 2009	Answered - in part
09/438	Details of drug dissolution of Prograf caps and detailed Pharmaco-kinetic profile in human volunteers	04 December 2009	Answered - in part
09/439	1. MHRA PAR for Provigil (PL 16260/0001, PL 16260/0002) with nonclinical and clinical information and Risk Management Plan 2. MHRA PAR for Modafinil "Teva" (MRP generic application UK/H/0834/001) with nonclinical and clinical information and Risk Management Plan	07 December 2009	Answered - in part
09/441	The ciclosporin blood-concentration data and human bioequivalence studies that supported certain marketing authorisations	04 February 2010	Answered - in part
09/442	Blood bank licencing information	16 November 2009	Answered - in full
09/443	Adverse incident reports relating to vaginal speculums (particularly plastic speculums as opposed to metal ones)	10 November 2009	Answered - in full

FOI no	Subject	Date reply sent	Result of request
09/445	MHRA approved plants in India	13 November 2009	Answered - in part
09/447	Request for Yellow Card data on Infliximab, Efalizumab, Methotrexate, Cyclosporin, Acitretin and Eternacept	17 December 2009	Answered - in full
09/448	Copies of the reports from 2009 arising from the MHRA Inspections of Penn Pharmaceutical Services based at Units 23 to 24 Tafarnaubach Industrial estate, Tredegar, Wales NP22 3AA.	01 December 2009	Answered - in part
09/451	List of companies due to be inspected in the next 3-6 months accross GXP	25 November 2009	Answered - in full
09/452	OTC Cough and Cold Medicines licensed for use in children - request for letter to MAHs	23 November 2009	Answered - in full
09/453	Information on the inspection of Aptuit (Glasgow) Ltd. on 3 June 2009	25 November 2009	Answered - in part
09/454	For the Committee on the Safety of Devices: the total number of people employed nationwide and the annual budget allocation (or 2008 figure) received from the sponsoring Government department.	23 November 2009	Answered - in full
09/455	Query with regards triamazon	04 December 2009	Answered - in full
09/456	Various PSUR reports for Seroxat	10 December 2009	Answered - in part
09/457	A copy of the last inspection report for Catalent Pharma Solutions, Frankland Road, Blagrove, Swindon, Wiltshire SN5 8RU, UK.	08 December 2009	Answered - in part
09/458	A copy of the latest MHRA MA(IMP) inspection report for Bioreliance, Todd Campus, West of Scotland Science Park, Glasgow G20 0XA	25 November 2009	Answered - in part
09/459	Information regarding Isotretinoin and Minocycline	18 December 2009	Answered - in part
09/460	the public assessment report pertaining to the reclassification of Zocor (Simvastatin) 10 mg to OTC status in the UK, including: 1. CSM Statin Workshop 25 September 2003 Abridged application for a change in legal classification of Zocor Heart 10 mg tablets 2. Further information relating to Enclosure 1, September 2003 3. CSM Paper 30 October 2003 Application for a change in legal classification from POM to P of Zocor Heart 10 mg tablets 4. CSM Final advice Application for a change in legal classification from POM to P of Zocor Heart 10 mg tablets 5. CSM Paper March 2004 Responses to consultation ARM	26 November 2009	Answered - in part
09/461	A list of facilities inspected and approved by MHRA in last 3 years in India and markets other than EU	09 December 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/469	Antipsychotic adverse drug reactions	10 December 2009	Answered - in full
09/470	The most recent GMP inspection reports and responses for the Shire Pharmaceuticals facility at Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP	01 December 2009	Answered - in part
09/471	Most recent GMP Inspection reports on the following companies: Aptuit Bathgate EH48 2EH Almac Portadown Craigavon Bilcare Global Clinical Services Brecon Pharmaceuticals Wye Valley HR3 5PG	30 November 2009	Answered - in part
09/472	Most recent GMP Inspection reports on: Catalent - Corby Northants NN18 8HS	03 December 2009	Answered - in part
09/473	Change in side effects listed on statins label	11 June 2010	Answered - in full
09/474	PAR for Isovorin for Colorectal Indication	22 December 2009	Answered - in full
09/475	All results of studies into potential and observed side effects in humans of "Swine Flu" vaccines whatever their source	14 December 2009	Answered - in full
09/476	A list of sites where the term "botox" has been removed and a separate list of sites that are in the process of complying	10 December 2009	Answered - in part
09/477	A copy of the inspection report for the MHRA GMP inspection performed this year at Reckitt Benckiser, Beeston, Nottingham	04 December 2009	Answered - in part
09/479	Details of all meetings (including dates, agendas and minutes) and correspondence (including letters, emails, notes of telephone conversations and memos) between the MHRA and Weber Shandwick and or named staff member since January 2008	23 December 2009	Answered - in full
09/480	Latest audit report for Amlodipine 5mg and 10 mg tablet manufacturer Jubilant Organosys Limited, Village Sikandarpur Bhainswal, Roorkee Dehradun Highway, Bhagwanpur, Roorkee, Distt.- Haridwar, Uttaranchal – 247661, India	09 December 2009	Answered - in part
09/481	Inspection report for Pharmapac (Uk) Ltd in 2009	19 December 2009	Answered - in part
09/482	GMP Inspection Reports issued in the last five years for Chequer Foods Limited (MA 24940)	18 December 2009	Answered - in part
09/483	MHRA Christmas expenses and procurement provenance	31 December 2009	Answered - in full
09/484	A copy of the Public Consultation Document MLX215 relating to the Prescription to Over the Counter Status of Fluconazole and copies of the resultant advice from the CSM	14 December 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/485	MEETING OF COMMISSION ON 15 OCT 2009 during which mumps vaccine (L-Zagreb) was discussed	14 December 2009	Answered - in full
09/486	The most recent GMP inspection reports and responses for Vindon Scientific Limited at its facilities in Kiln Green, Diggle, Oldham, Lancashire, OL3 5JY and in John Boyd Dunlop Drive, Kingsway Business Park, Rochdale, OL16 4NG?	15 December 2009	Answered - in part
09/487	Which pharmaceutical companies, biotech companies and Contract Research Organisations (CROs) are scheduled to have a Pharmacovigilance Inspection during 2010 (approx. which month) and details indicating if these are follow-up , for cause or routine inspections	18 December 2009	Answered - in full
09/488	Query regarding MHRA policy on unreasonable complainers	06 January 2010	Answered - in full
09/492	Copies of the Standard Operating Procedures that the MHRA use in the process of assessing an application for a Clinical Trial Authorisation. Also how amendments to the Clinical Trial Authorisation might be assessed	06 January 2010	Answered - in full
09/494	GMP inspection reports for: Aptuit - Bathgate, Scotland Site and Glasgow, Scotland site (Todd Campus, West of Scotland Science Park, Acre Road - Glasgow, Scotland) Aptuit Kansas City. Missouri, USA 10245 Hickman Mills Drive, from 2006 on, with associated follow up and responses if available. DSM Pharmaceuticals, Greenville, North Carolina, USA	18 December 2009	Answered - in part
09/495	MHRA GMP /GCP inspections for Fisher Clinical Services, for the facilities located in: - Horsham, United Kingdom - Mount Prospect, Illinois, United States	21 December 2009	Answered - in part
09/496	Inspection report for: Aseptic Manufacturer inspected: Hyaluron Contract Manufacturing Address: 99 S. Bedford Street, Burlington, MA 01803, USA	22 December 2009	Answered - in part
09/498	Query regarding the registration certificate for ProAct Medical Ltd (based in Corby NN18 9AS)	04 May 2010	Answered - in full
09/499	Information regarding Retinoic Acid	16 December 2009	Answered - in part
09/500	Information MHRA holds which records how a decision was reached to withdraw: Suprol along with Drug analysis prints for each year they were on the UK market	22 December 2009	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/501	Clinical Trials Statistics	23 December 2009	Answered - in full
09/502	Data on the number of yellow cards received for SSRIs where there are alcohol interactions	18 January 2010	Answered - in full
09/504	GLP accredidation status for Severn Trent laboratories Runcorn (aka STL Runcorn)	23 December 2009	Answered - in full
09/506	A list of companies due to undergo Good Manufacturing Practice, Good Distribution Practice, Good Clinical Practice and Good Pharmacovigilance Practice in 2010 (or for the period for which a schedule has been confirmed)	06 January 2010	Answered - in full
09/507	The number of 'suspected unexpected serious adverse reactions' which were 'fatal or life-threatening' reported under the Medicines for Human Use (Clinical Trials) Regulations 2004 in the following years: 2005, 2006, 2007, 2008, 2009. The number of 'suspected unexpected serious adverse reactions' which were 'not fatal or life-threatening' reported under the Medicines for Human Use (Clinical Trials) Regulations 2004 in the following years: 2005, 2006, 2007, 2008, 2009.	14 January 2010	Answered - in full
09/509	To identify any criminal prosecutions that have been instituted under Regulation 21 of the Medicines (Advertising) Regulations 1994 as amended (SI 1994/1932). The prosecution may have been brought under Regulation 23 of the these Regulations but the underlying contravention will have been Regulation 21 which makes it an offence to indice any doctor/other medical professional etc. to prescribe any medicines	22 December 2009	Answered - in full
09/510	GMP Inspection Report of Kopran Ltd, Village Savroli (Khopoli) site. Inspection performed in October 2008	07 January 2010	Answered - in part
09/511	Questions regarding MHRA's staffing levels and composition	20 January 2010	Answered - in full
09/512	Question re. marketing authorisation of eformoterol	19 January 2010	Answered - in full
09/513	Details of all UK Market authorisations for the following molecules; please provide data in relation to: acarbose acramposate adrenal cortex alverine balsalazide capsaicin ciprofibrate dilsufiram erythromycin/zinc inositol nicotinate misoprostol mucopolysaccharide mucopolysaccharide/salicylic acid nimodipine ramipril/amlodipine combination sodium docusate	19 January 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
09/514	Suspected Adverse Reaction to Pandemrix generated from Northern Ireland.	20 January 2010	Answered - in full
09/516	A list of all overseas manufacturing sites inspected for GMP compliance (for the finished formulation sites) by the MHRA in the past two years	05 January 2010	Answered - in part
10/001	Rifinah relabelling issues	26 January 2010	Answered - in part
10/002	A copy of the 2009 GMP inspection report for Boots Manufacturing Nottingham NG90 2PR	19 January 2010	Answered - in part
10/005	DB Care - Herbal Products company allegedly trading illegally	04 February 2010	Answered - in part
10/006	A list of all overseas manufacturing sites inspected for GMP compliance (for the finished formulation sites) by the MHRA for 2006/7	07 January 2010	Answered - in full
10/007	Information for the period to date of adverse incidents in hospitals, care homes and domestic premises involving hoisting and transfer equipment	15 January 2010	Answered - in full
10/008	Chloramphenicol over the counter eye drops	03 February 2010	Answered - in part
10/009	1. List of inspections of manufacturers and suppliers of generic drugs in the UK. 2. List of inspections of the premises of overseas suppliers of generic drugs. Time span early 2008 to end 2009	08 January 2010	Answered - in full
10/011	How does the MHRA deal with cases of alleged scientific deception, with examples and stats	05 February 2010	Answered - in part
10/012	Has Apligraf (Organogenesis Inc) has been approved for use in the UK, either for clinical trials or commercial use	08 February 2010	Answered - in full
10/013	What is the duration of the contracts which the MHRA holds with external lab service provider and what is the value of those contracts.	14 January 2010	Answered - in part
10/015	The legal basis classifications for which the following Marketing Authorization Applications were made: Sudafed Decongestant Nasal Spray PL 15513/0074 (McNeil Products Ltd). Vicks Sinex Micromist PL 00129/0133 (Procter & Gamble). Vicks Sinex Decongestant Nasal Spray PL 0129/5011R (Procter & Gamble). Galpharm Nasal Decongestant Spray PL 16028/0049 (Galpharm Ltd). Boots Nasal Spray PL 00014/0292 (Boots Company PLC).	05 February 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/018	Has the UK had any ADR reports for Ferinject or Injectafer or for the particular drug substance 'Ferric carboxymaltose`	09 February 2010	Answered - in full
10/019	Current status of the PL for Adcortyl in Orabase. Is the lisense expired. All material associated with this lisense such as proof of efficacy and saftey.	04 February 2010	Answered - in part
10/021	Any MHRA GMP/GDP Inspection Reports issued since 01 May 2004 for Quintiles Limited, Guy's Drug Research Unit (GDRU), 6 Newcomen Street, London SE1 1YR. MIA(IMP) 4141 / SIte ID: 7237	21 January 2010	Answered - in part
10/022	Any GMP Inspection Reports issued for: RICHMOND PHARMACOLOGY LIMITED ST GEORGE'S HOSPITAL MEDICAL SCHOOL, CRANMER TERRACE, TOOTING, LONDON, UNITED KINGDOM, SW17 0RE	26 January 2010	Answered - in part
10/023	Any GMP Inspection Reports issued by MHRA since 01 May 2004 for: COVANCE CLINICAL RESEARCH UNIT LIMITED, SPRINGFIELD HOUSE, HYDE STREET, LEEDS, WEST YORKSHIRE, UNITED KINGDOM, LS2 9LH Licence Holder MIA(IMP) 13101 SITE ID : 21095	22 January 2010	Answered - in part
10/024	the latest inspection report for the following company: Pharmarama Unit 7 Capital Business Park, Manor Way, Borehamwood, Hertfordshire, WD6 1GW, United Kingdom The inspection took place on the 11th August 2009 and was a GMP inspection	21 January 2010	Answered - in part
10/025	Lease start date, lease expiry date, lease break date if applicable, area occupied under the lease (in either square metres or square feet), and the number of employees for Market Towers	19 January 2010	Answered - in full
10/026	Any GMP Inspection Reports issued since 01 May 2004 for the following site: AUXILIUM UK LIMITED ORCHARD LEA, WINKFIELD ROAD, WINDSOR, BERKSHIRE, UNITED KINGDOM, SL4 4RU Licence Holder MIA(IMP) 18829 SITE ID : 11378	21 January 2010	Answered - in part
10/028	A list of overseas pharmaceutical sites that has been inspected by MHRA during the last three years	22 January 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/029	Information underpinning the MHRA's opinions/views on the risks/benefit for healthy subjects of statin treatment in terms of CVD AND separetely in terms of ALL mortality/causes	22 January 2010	Answered - in full
10/030	Further questions relating to MHRA answer to request for data on the number of yellow cards received for SSRIs where there are alcohol interactions (09/502)	18 February 2010	Answered - in full
10/031	Request for list of MHRA inspected sites in India	26 January 2010	Answered - in full
10/032	Information regarding hair loss product (Nourkrin)	09 February 2010	Answered - in full
10/033	A list of MHRA inspected manufacturing sites abroad to date, and a list of wholesalers registered with MHRA	26 January 2010	Answered - in full
10/034	Correspondence between MHRA and Alan Milburn/various named companies	01 March 2010	Answered - in part
10/035	Correspondence between MHRA and Patricia Hewitt/various named companies	01 March 2010	Answered - in part
10/036	Correspondence between MHRA and Melanie Johnson	25 January 2010	Answered - in part
10/037	A copy of the Expert Report submitted in support of the clinical assessment for Bupivacaine Hydrochloride 1mg/ml and Fentanyl 2mcg/ml solution for injection or Infusion (PL 12064 0062)	21 April 2010	Answered - in part
10/038	Various information in respect of Zocor Heart 10mg Tablets	26 January 2010	Answered - in part
10/039	Inspection report for medifill uk ltd of 59 third avenue deeside industrial park	28 January 2010	Answered - in part
10/040	Information underpinning the MHRA's opinions/views on the risks/benefit for healthy subjects of statin treatment in terms of CVD AND separetely in terms of ALL mortality/causes	22 February 2010	Answered - in part
10/041	A copy of the original UKPAR for amisulpride	19 February 2010	Answered - in part
10/043	Inspection reports issued by the MHRA as a result of inspections carried out at the Covance Laboratories facility in Harrogate, United Kingdom. Also copies of GMP certificates if issued as a result of those inspections	03 February 2010	Answered - in part
10/044	A copy of the 2009 GMP inspection report for Isotron Plc Moray Road Elgin Industrial Estate Swindon SN2 8XS	29 January 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/045	A copy of the Assessment Report of Atacand (MRP No. UK/H/0197) and/or Blopress (MRP No. UK/H/0198)	23 February 2010	Answered - in part
10/046	Information on MHRA operational matters	01 February 2010	Answered - in part
10/047	An MAA Assessment Report for PL 21799/0017	23 February 2010	Answered - in part
10/048	The number of reports received indicating Tetraspan as the cause of an anaphylatic reaction in patients, and the evidence which led to the following comment in the SmPC: 'To ensure correct blood typing, a blood sample should be taken before administration of Tetraspan 6%'	16 February 2010	Answered - in part
10/049	List of MHRA approved facilities in INDIA	09 February 2010	Answered - in part
10/050	Adverse effects of chemotherapy drug Taxotere	25 February 2010	Answered - in full
10/051	The name/address of the pharmacetical organisations who have had PV or GCP inspection in last 6 months, specifying when each organisation was inspected, type of inspection i.e. PV or GCP, major or ciritical findings and in what area these findings were associated	12 February 2010	Answered - in part
10/052	MHRA GCP Inspectors SOP on the evaluation of risk from organisations completing the compliance report to establish risk factors in GCP Inspections	03 February 2010	Answered - in full
10/053	Has an application has ever been received to add an indication for stroke to an oral immediate release dipyridamole formulation	04 February 2010	Answered - in part
10/055	Information relating to the production and marketing authorisation for Boots branded Silicea 30C	01 March 2010	Answered - in part
10/056	GMP inspection report for: Moredun Scientific Pentlands Science Park Bush Loan Penicuik Edinburgh Scotland EH26 0PZ	05 February 2010	Answered - in part
10/058	Please provide a list of UK companies due to be inspected in GCP, GCP, GPvP, GLP and GDP in the next 6 months	19 February 2010	Answered - in full
10/059	List of Clinical Research Organisations (CRO's) regulated in the UK	01 March 2010	Answered - in part
10/060	Which pharmaceutical companies are scheduled to have a Pharmacovigilance Inspection by the MHRA during 2010	19 February 2010	Answered - in full
10/061	Information and documents relating to Nicorette Inhalator	02 March 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/062	Questions regarding MHRA guidance and possible dental manufacturer fraud	28 February 2010	Answered - in part
10/064	Parallel import of "Specials" (Unlicensed medicinal products)	15 February 2010	Answered - in full
10/065	MHRA and prompt payment of supplier's invoices	05 March 2010	Answered - in part
10/066	Waiting time to drive after taking Entonox	18 February 2010	Answered - in full
10/067	Information on product licences granted by the MHRA and also a set of minutes of the Committee of Safety of Medicines (Biologicals sub-committee) regarding Hepatitis C/HIV acquired infection from NHS treatment in Scotland with blood and blood products	08 March 2010	Answered - in part
10/068	A copy of the Public Consultation Document MLX215 relating to the Prescription to Over the Counter Status of Fluconazole and copies of the resultant advice from the CSM	15 February 2010	Answered - in full
10/069	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/070	Details of the BNF, and MIMS publications between 1988 and 1992 where the Pluserix vaccine by GSK is listed alongside the inverted black triangle logo indicating a new product on the market	25 February 2010	Answered - in full
10/071	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/072	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/074	Safer alternatives to Atorvastatin	18 February 2010	Answered - in full
10/075	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/076	Questions regarding Primodos/Norethisterone	25 February 2010	Answered - in full
10/077	A copy of the audit report and certificated of GMP compliance related to the MHRA inspection of DPT laboratories in San Antonio, Texas, USA on 28 and 29 September 2009	05 March 2010	Answered - in part
10/078	Request for the original raw data and supporting documentation for PL 20117/0036-41	13 May 2010	Answered - in part
10/079	A copy of the most recently completed MHRA GDP inspection report for Movianto UK Limited, Unit 3, The Merlin Centre, Lancaster Road, High Wycombe, HP12 3QP Licence Holder WL 14172 / Site ID 5677	01 March 2010	Answered - in part
10/080	A copy of the MHRA SOP on calculating the PV risk scores for sponsors completing the Compliance Report for Pharmacovigilance?	19 February 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/081	Request for the original raw data and supporting documentation for PL 20117/0036-41	12 March 2010	Answered - in part
10/082	A copy of a redacted GMP audit report for the following site: Site: Aptuit (Glasgow), MIA(IMP)# 19124 Date: 03-05 June 2009	15 February 2010	Answered - in part
10/083	What is the rationale for the ‘ 0.15% potassium chloride ’ and ‘acute diarrhoea’ restrictions in SI 1998/2170	26 February 2010	Answered - in part
10/085	Potency specification of a finished product in respect of one of the components of a combined paediatric vaccine	15 March 2010	Answered - in full
10/086	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/088	Information MHRA holds which records how a decision was reached to withdraw: Pexid and Merital along with Drug analysis prints for each year they were on the UK market	24 February 2010	Answered - in part
10/089	Copy of MHRA letter to BSi, dated 14 November 2007, concerning complaint regarding BSi competence	22 February 2010	Answered - in part
10/090	Details of MHRA Inspectors	19 March 2010	Answered - in part
10/091	Information about any sites in India in particular that have been audited and found to comply with MHRA/European GMP requirements	24 February 2010	Answered - in part
10/092	Details of MHRA Inspectors	19 March 2010	Answered - in part
10/094	A copy of the most recently completed MHRA GMP Inspection report for DSM, Dalry.	03 March 2010	Answered - in part
10/095	A copy of the recent MHRA inspection report for Lonza Biologics, plc in Slough UK	18 March 2010	Answered - in part
10/096	MLX 364 - public consultation - ban on electronic cigarettes	23 February 2010	Answered - in part
10/098	Public Assessment Reports for a number of lipid lowering products	23 March 2010	Answered - in full
10/101	Manufacturing sites approved for finished product manufacturing in India and China	23 March 2010	Answered - in full
10/103	Tacrolimus blood-concentration data, identified by subject number and treatment name, and a full description of the human bioequivalence studies used by the MHRA to grant marketing authorisation marketing authorisations	19 May 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/104	A copy of an MHRA Inspection report of an API site in India: Matrix Laboratories Limitied, Sinnar, India	18 March 2010	Answered - in part
10/105	UKPAR for Nicorette Inhalator	24 March 2010	Answered - in part
10/108	Enquiry regarding "Pivotal Asia Efficacy Study" (ELT209)	19 March 2010	Answered - in full
10/109	The most recent MHRA inspection reports for: Recipharm Limited – Vale of Bardsley, Ashton Under Lyme, Lancashire, UK, OL7 9RR – MIA 32446 Pharmaserve Limited – Clifton Technology Park, Wynne Avenue, Swinton, Manchester, UK, M27 8FF – MIA 10110	18 March 2010	Answered - in part
10/110	A copy of a GMP Inspection report performed at Pharma Mondial in 2009	19 March 2010	Answered - in part
10/111	A listing of unlicensed melatonin products approved for import giving various details for each approval	08 March 2010	Answered - in part
10/112	Details of Manufacturing and Marketing License holders of Nicotine Polacrilex in Europe	23 March 2010	Answered - in part
10/113	Copies of pharmacovigilance inspection reports for Takeda and Johnson & Johnson for the last 3 years	03 March 2010	Answered - in part
10/115	MLX 364 - public consultation - ban on electronic cigarettes	25 February 2010	Answered - in full
10/116	Using Norethisterone during pregnancy	08 March 2010	Answered - in full
10/117	Info on complications on the use of new silk stents used to treat cerebral aneurisms	26 March 2010	Answered - in full
10/118	The MHRA assessment reports for Naprotec and Arthrotec	29 March 2010	Answered - in part
10/119	Salary and bonuses information on MHRA employees earning £100k+	29 March 2010	Answered - in part
10/120	copies of the Inspection reports for: Zeroderma IXL Pharma Co-Pharma (last 3 reports) Goldshield Claris Neolabs Also, the last 5 Inspection reports where there were critical findings made (and are still not subject to any Regulatory activity precluding them being sent).	31 March 2010	Answered - in part
10/121	MLX 364 - public consultation - ban on electronic cigarettes	31 March 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/122	Information and documents relating to Nicorette Inhalator	30 March 2010	Answered - in full
10/123	Information regarding a drug called Strontolac, with the active ingredient Strontium Lactate	10 March 2010	Answered - in full
10/124	A list of all prospective and current Marketing Authorisation holders (MAH) inspected by the MHRA since 01 January 2007	22 March 2010	Answered - in part
10/125	MLX 364 - public consultation - ban on electronic cigarettes	01 April 2010	Answered - in full
10/126	Safety advice relating to Dopamine Agonist medication	29 March 2010	Answered - in full
10/127	The number of complaints received about Clearblue Easy pregnancy tests (and other blue dye pregnancy tests) produsing false positive results, the content of these complaints, and any action taken by the company to correct	23 March 2010	Answered - in full
10/128	Recommendations to ministers following Public consultation (MLX 362): Sale, supply and administration of medicines by dental hygienists and dental therapistsunder a Patient Group Direction	29 March 2010	Answered - in full
10/130	Adverse effects of chemotherapy drug Taxotere	31 March 2010	Answered - in full
10/131	A copy of the original appendices mentioned in UKPAR for amisulpride	07 April 2010	Answered - in part
10/132	All UK (National) or EU (MRP/DCP) assessment reports including public assessment reports where the MHRA has been involved, had input or issued such documentation in relation to nicotine products, tobacco products, nicotine containing products (NCP) and nicotine replacement therapies (NRT)	07 April 2010	Answered - in part
10/133	All information in relation to nicotine products, tobacco products, nicotine containing products (NCP) and nicotine replacement therapies (NRT) considered by the Expert Working Group and/or CHM since 2005 to date	07 April 2010	Answered - in part
10/134	All minutes, agendas, proposals, concept/draft documents, problem statements, concerns, representations for, representations against, source documentation preceeding and/or triggering the current MHRA consultation MLX 364 "the regulation of nicotine containing products (NCP)"	07 April 2010	Answered - in part
10/136	Statistics on rupturing breast implants	15 March 2010	Answered - in part
10/137	PEAG Review of Post SSRI Sexual Dysfunction	12 April 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/139	Results of all analytical testing/analytical surveillance undertaken by the MHRA or analytical data provided to the MHRA by other laboratories/intsitutes e.g. OMCL, EDQM, Department of Health and trading standards since 2007 in relation to nicotine medicinal products, tobacco and nicotine containing products which include electronic nicotine delivery systems	01 April 2010	Answered - in full
10/140	Confirm that Sauflon Pharmaceuticals do not currently hold a Manufacturing Site (Human) License. Provide the date that the manufacturing license was terminated. Provide details regarding the reason for termination.	15 March 2010	Answered - in full
10/141	How is MHRA specifically involved with monitoring and regulating the use of off-label medications in the UK How MHRA acts when made aware (through the processes described in question 1) of incidents where the prescription of off-label medications may be a danger to patients How many times the MHRA has had to act in the ways described in question 2 over the past 10 years, stating: the names of the drugs/devices in question How the MHRA has dealt with the incidents	12 April 2010	Answered - in full
10/142	MHRA's Assessment Report for Zyvox (INN: linezolid) and any MHRA assessment reports for different pharmaceutical forms or strengths of that drug. In particular, please can you provide me with any information on the alleviation of signs and symptoms of bacterial infection 48 to 72 hours after taking Zyvox	13 April 2010	Answered - in part
10/143	Information relation to clinical trial approvals in the UK for each of the last ten years up to and including 2009	15 April 2010	Answered - in full
10/144	A copy of the original UKPAR for famotidine	14 April 2010	Answered - in part
10/145	A copy of the original UKPAR for Ibuprofen	27 April 2010	Answered - in part
10/146	The most recent MHRA GMP Inspection Report for Thornton & Ross, Linthwaite Laboratories, Linthwaite, Huddersfield, HD7 5QH	23 March 2010	Answered - in part
10/148	A list of Indian companies who have been inspected by Medicines and Healthcare products Regulatory Agency for Good Manufacturing Practice (GMP) compliance	18 March 2010	Answered - in part
10/151	Clarification of the patient population used in a bioequivalence study used to support the marketing authorisation of Hydroxyurea/Hydrocarbamide and confirmation that this study was conducted in healthy volunteers	30 March 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/154	Information held by MHRA on the properties of PCV-1 virus and its potential effects on man, on the contamination of Rotarix Vaccine with PCV-1? When did it first learn of this issue?	21 April 2010	Answered - in full
10/155	Conduct, validity and regulation of clinical trials	16 April 2010	Answered - in full
10/156	A list of manufacturing sites in India that are registered by the MHRA	28 March 2010	Answered - in part
10/157	A list of overseas sites approved for GMP by the MHRA	09 April 2010	Answered - in part
10/158	MLX 364 - public consultation - ban on electronic cigarettes	21 April 2010	Answered - in full
10/160	Have MHRA Audited (in the areas of GMP and PV) of the following company; SSL international.	09 April 2010	Answered - in part
10/163	The last five cGMP inspection reports for Manufacturere of Finished Medicinal Product	09 April 2010	Answered - in part
10/164	Has the MHRA prosecuted (successfuly or otherwise) a Sponsor company following persistent non-compliance to GCP? If so, how many prosecutions have there been and what was the nature of the non-compliance?	27 April 2010	Answered - in full
10/165	Various recent GDP/GMP inspection reports: Unidrug Distribution Group Limited (UDG) Amber Park 1,2 and 3 Berristow Lane South Normanton Alfreton Derbyshire DE55 2FH DHL Supply Chain (McGregor Cory Limited) Cherwell 1 & 2 Middleton Close Banbury Oxfordshire OX16 4RS POLAR SPEED DISTRIBUTION LIMITED UNIT 8, CHARTMOOR ROAD, LEIGHTON BUZZARD, BEDFORDSHIRE, UNITED KINGDOM, LU7 4WG	15 April 2010	Answered - in part
10/166	Information regarding Clenbuterol, a beta 2 agonist	16 April 2010	Answered - in full
10/168	MHRA mileage re-imbursement figures	18 June 2010	Answered - in full
10/169	Effect of posture devices on non-powered wheelchairs	28 April 2010	Answered - in part
10/170	Information on dates product licences granted by the MHRA for various blood products, and a copy of the MCA annual report for 1983/84	28 April 2010	Answered - in part
10/171	Branding Guidelines for MHRA	19 April 2010	Answered - in full
10/174	Figures and explanations regarding adverse drug reactions and terms used	04 May 2010	Answered - in full
10/175	A copy of a GMP Inspection report performed at Ind Swift in India from 09/08/2007	01 April 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/177	Various information regarding In Vitro Diagnostic Medical Devices (IVDs) e.g. registrations, incident etc	07 May 2010	Answered - in part
10/178	A list or organisation names, addresses and dates who have have had: 1. PV inspection completed in last 6 months 2. PV inspections planned in the next 6 months 3. GCP inspection completed in last 6 months 4. GCP inspections planned in next 6 months	16 April 2010	Answered - in full
10/179	Information regarding: 1. NAROPIN INJECTION (ROPIVACAINE HCl INJECTION) 2. RISPERDAL CONSTA INJECTION (RISPERIDONE INJECTION)	07 April 2010	Answered - in full
10/180	Detailed information relating to hip-resurfacing procedures, with the number of cases carried out, the number or percentage of failures, and the advice issued to health professionals and patients, as to benefits or otherwise	30 April 2010	Answered - in part
10/181	Abridged assessment reports for mesren, pentasa and ipocol	05 May 2010	Answered - in part
10/182	A list of registered GMP pharmaceutical production facilities in the UK, with details of the address, company using the facility and first year of registration	06 May 2010	Answered - in part
10/183	Latest GMP Inspection report for: Pharmaserve Limited, Clifton Technology Park, Swinton, Manchester, M27 8FF, UK.ML/10110	09 April 2010	Answered - in part
10/184	GMP inspection reports for at least five manufacturers of finished medicinal products for humans located in India and inspected recently	16 April 2010	Answered - in part
10/185	Information regarding Labcor bio-prosthetic aortic heart valves	28 April 2010	Answered - in part
10/186	Fentanyl	29 April 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/187	Public assesment report of Abridged application (Generic) for: Beclazone 250mcg,500mcg (Beclomethazone Dipropionate) Norton Healthcare - RMS - UK Clickhaler Beclomeatas - Inhalation powder 100.0UG/AC, 250.0UG/AC - Innovata Biomed - RMS - UK Asmasal Clickhaler - Inhalation powder - Salbutamol sulphate - 95 mcg - Medeva - RMS - UK Clickhaler Salbutamol - Innovata - Inhalation powder - Salbutamol sulphate - 95 mg - RMS - UK Salamol Easi Breathe I - Salbutamol sulphate - Norton Healthcare - RMS - UK Ventolin Easi-Breath I - Glaxo Wellcome - 100mcg - Salbutamol - RMS - UK	06 May 2010	Answered - in part
10/188	Query on Wholesale Dealer's Licence - Colorama Pharmaceuticals / Manufacturer's Licence - Thame Laboratories	07 May 2010	Answered - in full
10/190	Additional information related to the Assessment Report on Solian already provided. The following CLINICAL appendix pages/tables, referred to in the text of the assessment report, are required: - Dossier Part IV-A2, Appendix 1, pages 31-36 (PHARMACOKINETICS). - Dossier Part IV-B, Appendix 3, pages 48-59 (CLINICAL SAFETY). - Dossier Part IV-A2, Appendix 4, pages 61-88 (PHARMACOKINETICS).	13 May 2010	Answered - in part
10/195	Questions regarding MHRA guidance and possible dental manufacturer fraud	22 May 2010	Answered - in part
10/199	A copy of the latest Pharmacovigilance inspection report for FDC India and FDC International Limited	07 May 2010	Answered - in part
10/200	The list of oral dosage form manufacturing facilities inspected and approved in India by MHRA	14 May 2010	Answered - in part
10/201	Assessment Report of both the national and the MR procedure for Zyvox	29 June 2010	Answered - in part
10/204	A list of all GMP compliance certificate issued to companies in the far east that manufacture in particular tiger balm or similar products or are capable of manufacturing similar products, including manufacturer details and location or region they reside in	20 May 2010	Answered - in part
10/206	Inspection reports for the following Companies: Claris Pharma – 2009/10 Auden MacKenzie – 2009 EUSA Pharma - 2010	07 May 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/207	Copies of the most recent GMP/GLP inspection reports and responses for the Exova facility at 17 Doman Road, Camberley, Surrey, DU15 3DF	20 May 2010	Answered - in part
10/209	Report of the last GPvP MHRA inspection performed for various companies.	24 May 2010	Answered - in part
10/210	Results of testing on silicone gel found in pip implants	29 April 2010	Answered - in full
10/211	Any publicly available information of reports of adverse events relating to the xanthine medicines (Phyllocontin Continuos®, Phyllocontin Forte®, Nuelin SA®, Nuelin SA-250®, Slo-Phyllin® and Uniphyllin Continuos®) when supplied by pharmacists as “P” medicines without a prescription from a medical doctor	19 May 2010	Answered - in full
10/212	PAR for Atenolol 50mg/100mg	16 May 2010	Answered - in part
10/213	Updated list of all the MHRA accredited Pharma Companies in India as well as in China	07 May 2010	Answered - in part
10/214	A list of all unlicensed medicines for which import notifications have been received by the MHRA in the last 12 months	14 May 2010	Answered - in full
10/215	Information regarding correspondence between the Highgrove group and MHRA	25 June 2010	Answered - in part
10/216	Information on Adverse Incidents involving Sprint Fidelis 6949 leads	26 May 2010	Answered - in part
10/217	Lithium Bioavailability values	07 May 2010	Answered - in full
10/218	Preclinical Expert Report Request for Polysorbate 80 for Injection	06 May 2010	Answered - in full
10/219	How many MHRA staff who are, or were at the time staff, given formal warnings in each year since 2001, and how many were given final written warnings in each year since 2001	04 June 2010	Answered - in full
10/220	Assessment report for Amias (candesartan)	01 June 2010	Answered - in part
10/221	Information about sites outside the UK inspected in connection with a Product Licence and approved by the MHRA or other European regulatory authority, in particular sites in India and China. Also, information about any sites in these two countries in particular that have been audited and found to comply with MHRA / European GMP requirements?	28 May 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/222	The licence date for Monoclate-P (Armour). The dates when any of the following ceased to be licensed:- The relevant Factor VIII products (and manufacturer) were: Replenate (BPL) Monoclate (Armour) Monoclate-P (Armour) Alpha-8 or Alphanate (Alpha) HemofilM (Hyland/Baxter) KoateHP (Cutter/Miles/Bayer) OctaVI or Octanate (Octapharma) The relevant Factor IX products (and manufacturer) were: Replenine(BPL) Mononine(Armour AlphanineSD (Alpha) Octanine(Octapharma) A copy of the annual report for the The Medicines Commission (or its predecessor or successor body) for the year 1983/84 or for 1983 if these reports were issued for calendar rather than financial years (as it appears to have been in 1977).	25 May 2010	Answered - in full
10/223	The data package that was submitted to support the approval of Lenoxe (Xenon) by Air Liquide	27 May 2010	Answered - in part
10/224	A list of companies that were inspected in China, factories that were given a GMP satisfaction report	07 May 2010	Answered - in part
10/225	A copy of the last audit carried out by the MHRA of AsparPharmaceuticals Ltd, 29-30 Capitol Way, Colindale, London. NW9 0EQ	14 May 2010	Answered - in part
10/226	An up to date report of Phototoxicity/Photoallergic yellow card returns over the last decade prior to a British Photodermatology Group sponsored workshop on this subject	28 May 2010	Answered - in full
10/227	To check if BOC gases UK is registered with MHRA and if there has been any adverse incidents / warning letters / recalls issued to BOC gases	28 May 2010	Answered - in full
10/228	Inspection performed by MHRA on 08-12 February 2010 on the following company: Aseptic Manufacturer inspected: Hyaluron Contract Manufacturing Address: 99 South Bedford Street, Burlington, MA 01803, USA	24 May 2010	Answered - in part
10/229	All updates and information on pips implants	17 May 2010	Answered - in part
10/231	The last three MHRA inspection reports from Boots Manufacturing D10 and Specials	25 May 2010	Answered - in part
10/232	A summary of the bioequivelance data and the number of subjects used in the bioequivelence study conducted for Dipyridamole oral suspension	09 June 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/233	A list of MHRA approved India manufacturers for Primary Packaging	28 May 2010	Answered - in part
10/234	Information on the MRI-compatible pacemaker produced by Medtronic "EnRhythm MRI SureScan"	14 June 2010	Answered - in part
10/235	Information on the MRI-compatible pacemaker produced by Medtronic "EnRhythm MRI SureScan"	14 June 2010	Answered - in part
10/236	CHM/CSM reports, responses and assessment reports for reclassification applications on various Calpol products	08 July 2010	Answered - in part
10/237	Copies of the most recently issued GMP Inspection reports for: Aptuit (Deeside) Limited and Aptuit (Edinburgh) Limited	28 May 2010	Answered - in part
10/239	Inspection reports from the last GMP MHRA inspection performed for the following companies, specifically for the activities covering “Batch Certification Only” 3M HEALTH CARE LIMITED HOSPIRA UK LIMITED NOVARTIS PHARMACEUTICALS UK LIMITED ROCHE PRODUCTS LIMITED GLENMARK GENERICS (EUROPE) LIMITED T J SMITH & NEPHEW LIMITED WINTHROP PHARMACEUTICALS UK LIMITED PIRAMAL HEALTHCARE UK LIMITED CATALENT UK PACKAGING LIMITED AMDIPHARM PLC BIOTEC SERVICES INTERNATIONAL LIMITED BRISTOL LABORATORIES LIMITED CHIESI LIMITED DR REDDY'S LABORATORIES (UK) LIMITED FRESENIUS KABI ONCOLOGY PLC GALPHARM INTERNATIONAL LIMITED JENSON PHARMACEUTICAL SERVICES LIMITED NEOLAB LIMITED QP-SERVICES UK LIMITED SANDOZ LIMITED	15 June 2010	Answered - in part
10/240	The last inspection report for the pharmaceutical company Archimedes Pharma UK Limited, 250 South Oak Way, Green Park, Reading, Berkshire, RG2 6UG, United Kingdom	03 June 2010	Answered - in part
10/241	Request for public assessment reports Public assessment reports for the following products: Colosol powder (PL 08637/0004) Endofalk powder Movicol (PL 00322/0070)	11 June 2010	Answered - in part
10/242	PARs for Abelcet and AmBisome	21 June 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/243	GMP Inspection Report for Medifill UK Limited, and also a copy of the Inspection Report for Thorpe Laboratories	03 June 2010	Answered - in part
10/246	Any regulatory inspection documents (inspection reports, regualtory actions) regarding: Dr. Reddy's Laboratories (UK) Limited 258 Bath Road, Slough, Berkshire, SL1 4DX	15 June 2010	Answered - in part
10/247	Details of the formal approval process which was in place when the MMR vaccine was approved	15 June 2010	Answered - in full
10/248	Reports relating to the facilities run by Quest Healthcare at Unit 5, Mount Street Business Park, Mount Street, Nechells, Birmingham, B7 5QU. Specifically, inspection reports relating to Good Manufacturing Practice and any associated action plans.	07 June 2010	Answered - in part
10/249	MLX 364 - public consultation - ban on electronic cigarettes	28 June 2010	Answered - in full
10/250	MHRA GMP Inspectors report of Ecolab Ltd., Lotherton Way, Garforth. September 2009	07 June 2010	Answered - in part
10/251	Names of Companies that manufacture and supply the drug Thalidomide	29 June 2010	Answered - in part
10/252	Information regarding Pergolide, a dopamine-agonist medication for treatment of Parkinson's Disease	10 June 2010	Answered - in part
10/253	Lyclear Dermal Cream - information specifically pertaining to efficacy	24 June 2010	Answered - in full
10/254	A copy of the last GMP audit of Shasun Chemicals and Drugs Ltd Shasun Road Periakapet Pondicharry - 605 014 India	07 June 2010	Answered - in part
10/255	Query regarding the licensing of Monoclate(dry heated) and MonoclateP (pasteurised)	01 July 2010	Answered - in full
10/257	Encapsulation stability data on amlodipine and perindopril (arginine)	16 June 2010	Answered - in part
10/259	PIP breast implants	16 June 2010	Answered - in full
10/260	Inspection report for: Sharon Bio-Medicine Ltd C-312, BSEL Tech Park, Sector 30(A), Vashi, Navi Mumbai- 400703	25 June 2010	Answered - in part
10/261	Claris Lifesciences - which products manufactured by this company are supplied to the UK market	29 June 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/262	List of products for which the MHRA have granted permission to import a product under specials licence.	02 July 2010	Answered - in full
10/263	Details of all instances in the last 2 years where the MHRA has approved the import of any products containing lenalidomide (including, without limitation, the branded unlicensed product LENALID, manufactured by Natco Pharma Limited) following notification by an importer pursuant to paragraph 7 of Schedule 2 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789)	15 June 2010	Answered - in full
10/265	Any data relating to the effect that any HPV vaccine (primarily Gardasil and Cervarix) may appear to have had on verrucas (Verruca plantaris) or other warts (Verruca vulgaris)	02 July 2010	Answered - in full
10/267	CIPLA Unit V Audit report	16 June 2010	Answered - in part
10/268	MHRA yellow card data on patients with wet or neovascular age-related macular degeneration (nAMD)	28 June 2010	Answered - in full
10/269	A copy of the Public Assessment Report for the reclassification of Sumatriptan following ARM 32 in October 2005, plus a copy of the Risk Management Plan assopiated with the reclassification or confirm there was no requirement for a RMP at the time of the classification	21 June 2010	Answered - in part
10/270	A list of all those Trusts / hospitals in the UK that are licensed to conduct clinical trials	17 June 2010	Answered - in full
10/274	A copy of the declared interests of the members of the Committee On The Safety Of Medicines between January 1990 and December 1991	06 July 2010	Answered - in full
10/275	The number, and level (using the cabinet office defined 0-5 scale) of events [personal data breaches] that have been reported to the Information Commissioner by the MHRA since 1st April 09	28 June 2010	Answered - in full
10/276	PARs for: Mezavant XL 1200mg Tablets PL 08081/0040 Salofalk 1.2g Granules PL 08637/0016	14 July 2010	Answered - in part
10/277	A copy of the LHRH analogues review	10 December 2010	Answered - in part
10/278	Questions regarding the Alfacalcidol aqueous drop product	12 July 2010	Answered - in full
10/284	A list of all unlicensed medicines for which import notifications have been received by the MHRA in the last 12 months, and specify the number of import notifications received in respect of each unlicensed medicine in this list	29 June 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/285	All inspections, inspection reports, correspondence and other documents relating to Community Blood Services, Paramus, New Jersey, USA	05 July 2010	Answered - in part
10/286	Details of any meetings held between the british pharmacopoeia and reckitt benckiser between 2002 and 2006 concerning plans to issue a monograph for the manufacture of an alginate compound	25 June 2010	Answered - in full
10/287	Querying what information MHRA holds on the company Pure U	30 June 2010	Answered - in part
10/288	Various information regarding counterfeit medicines, facts, figures etc	23 June 2010	Answered - in full
10/289	Query regarding Zanza Laboratories Ltd	01 July 2010	Answered - in full
10/290	A copy of each of the last 2 inspection reports for Custom Pharmaceuticals, Hove, Sussex	08 July 2010	Answered - in part
10/291	Information regarding adverse incidents concerning Cloverleaf PIP Implants	30 June 2010	Answered - in part
10/292	A list of overseas sites inspected for GMP by the MHRA	29 June 2010	Answered - in full
10/293	For years 2004, 2005, 2006, 2007, 2008 and 2009, please the supply the number of requests for authorisation from the MHRA of a Clinical Trial on Medicinal Product for Human Use from non commercial and commercial sponsors.	15 July 2010	Answered - in full
10/294	MRHA's inspection intentions regarding Claris Lifesciences	13 July 2010	Answered - in full
10/295	Information on the HPV Vaccine	15 July 2010	Answered - in full
10/296	A list of clinical trials in mental health submitted to the MHRA for approval since April 2008, with details of the study title, and the date of submission	28 July 2010	Answered - in part
10/297	Latest list of plants in India which are MHRA certified	13 July 2010	Answered - in part
10/298	The latest MHRA inspection report on: WuXi Apptec Inc. 1265 Kennenstone Circle Marietta, GA 30066 USA	14 July 2010	Answered - in part
10/299	Which formulations have relied on cross-referencing to Gestone	31 August 2010	Answered - in part
10/300	Most recent MHRA GMP inspection report for: Jubilant Organosys Sikandarpur Bhainswal Bhagwanpur, Roorkee-247661 Distt. Haridwar, Uttarakhand, India	14 July 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/301	MHRA GMP inspection report for the following manufacturer, leading to a class 2 recall (29th June 2009): MJBiopharm Pvt Ltd L-7, MIDC, Taloja Dist. Raigad Taloja,Maharashtra,INDIA 410208	22 July 2010	Answered - in part
10/303	Copy of last GMP inspection report by MHRA for Macfarlan Smith Ltd, Wheatfield Rd, Edinburgh, EH11 2QA, UK. Company no 1108	22 July 2010	Answered - in part
10/304	Inspection report on M & A Pharmachem Ltd	04 August 2010	Answered - in part
10/305	Information regarding ·Dosage Form ·Routes of Administration ·Strengths For nicotine products	20 July 2010	Answered - in full
10/306	Copy of PAR that was the basis for the approval by the MHRA of the product Lodotra 1, 2 and 5 mg modified-release tablets	28 July 2010	Answered - in part
10/307	Names of companies whose plants were inspected by MHRA in India during the period January 2009 to date	16 July 2010	Answered - in full
10/309	Clarification of information that has been published on a Public Assessment Report (PAR) for the product Clobazam Tablets 10mg	23 July 2010	Answered - in full
10/310	Further details of any meetings held between the british pharmacopoeia and reckitt benckiser between 2002 and 2006 concerning plans to issue a monograph for the manufacture of an alginate compound following MHRA reply to FOI 10/286	20 July 2010	Answered - in part
10/311	GMP Audit reports that cover the following sites: 1. McGregor Cory (DHL) Cherwell 1 & 2, Middleton Close, Banbury, Oxon OX14 4RS 2. Aptuit (Edinburgh) Ltd Inchwood, Bathgate EH48 2EH 3. Catalent Packaging Ltd Lancaster Way, Westhoughton, Bolton BL5 3XX	30 July 2010	Answered - in part
10/314	Request for access to clinical evidence/information regarding Bocouture - a botulinum toxin product (BOTOX)	12 August 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/315	A redacted copy of the MHRA GMP Inspection Report issued for the following site since implementation of the Clinical Trials Directive in May 2004: CATALENT UK PACKAGING LIMITED LANCASTER WAY, WINGATES INDUSTRIAL ESTATE, WESTHOUGHTON, BOLTON, LANCASHIRE, UNITED KINGDOM, BL5 3XX SITE ID: 31218 LICENCE HOLDER MIA(IMP) 1380	30 July 2010	Answered - in part
10/316	Post SSRI Sexual Dysfunction	25 August 2010	Answered - in full
10/317	Three recent GMP inspection reports of any sterile product's manufacturer in India	13 August 2010	Answered - in part
10/318	Excretion rates for anti-androgens and progestagens	12 August 2010	Answered - in part
10/319	How many GMP facilities are in the UK, how many additional facilities are working towards GMP compliance, and details of who they are and/or a breakdown of the applications in use?	13 August 2010	Answered - in full
10/321	Request for information regarding named MHRA staff	13 August 2010	Answered - in part
10/322	Statistics and other information relating to asthma treating drugs	11 August 2010	Answered - in full
10/323	MHRA approved sites in India from 2000	29 July 2010	Answered - in full
10/324	For years 2004, 2005, 2006, 2007, 2008 and 2009, various information regarding notifications of End of Clinical Trials from non commercial and commercial sponsors.	17 August 2010	Answered - in full
10/325	Details of pharmacovigilance inspection in 2009 of Goldshield Group plc	13 August 2010	Answered - in part
10/326	Copy of inspection report from GMP inspection performed on 14 May 2008 at Afton Scientific Corporation 2030 Avon Court Charlottesville 22902 United States	30 July 2010	Answered - in part
10/328	Information regarding MHRA inspection of Takeda UK in 2009	30 July 2010	Answered - in part
10/330	A list of all eye drops licensed and/or approved for supply in the unite kingdom, a list of the excipients used in those products including quanititative information on the range of concentrations/quantities used, and advise how many of these products meet the PH Eur 'A' preservative efficacy requirements and which do not meet the 'A' criteria but do meet or exceed the 'B' criteria.	30 July 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/331	Review of Data pertaining to Perfalgan (IV Paracetamol) - safety of intravenous paracetamol	23 August 2010	Answered - in part
10/333	Information regarding the justification for Echinaforce to be registered as traditional herbal medicianl product in the UK	28 July 2010	Answered - in part
10/334	A list of all companies/organisation in the UK that are currently members of the GCP compliance program. Also a list of all companies/organisation in the UK that are currently members of the GMP compliance program, and for each list the org/company name, address, and date of last inspection.	23 August 2010	Answered - in full
10/335	Information regarding Submissions Centre Co-ordinator vacancy interviews within MHRA	29 July 2010	Answered - in part
10/336	MHRA inspection report issued as a result of the Agency's inspection of the Catalent facility located at Sedge Close, Headway, Great Oakley, Northamptonshire Corby, United Kingdom,	30 July 2010	Answered - in part
10/339	Details of the membership of the CHM/CSM independent group which considered and advised MHRA on Rosiglitazone in 2007 -	01 September 2010	Answered - in part
10/340	The details of each member of the steering committee for the current review of unlicensed medicines	02 September 2010	Answered - in full
10/342	The latest inspection report for: Covance Clinical Research Unit Ltd Springfield House Hyde Street, Leeds LS2 9LH, United Kingdom	13 August 2010	Answered - in part
10/344	The legal basis of the applications for the following products: PL 15142/0034 Aller-Eze Nasal Spray PL 15142/0035 Azelastine Eye Drops 0.05% w/v PL 15142/0036 Optilast Eye Drops 0.05% w/v PL 15142/0037 Rhinolast Nasal Spray 0.1% w/v	31 August 2010	Answered - in full
10/345	Copies of the most recent joint GMP/GLP inspection reports and responses for the Exova facility at 17 Doman Road, Camberley, Surrey, GU15 3DF Also any further communication between Exova and the MHRA regarding the inspection - performed during Feb/Mar 2010.	07 September 2010	Answered - in part
10/346	A current list of all pharmaceutical manufacturing sites that have been inspected by the MHRA specifically in INDIA and BANGLADESH	13 August 2010	Answered - in full
10/347	The last inspection report for Thornton & Ross	27 August 2010	Answered - in part
10/348	A listing of site inspections preformed by the MHRA over specific time periods	13 August 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/349	How many prosecutions have been heard in court and have been successful during the past 5 years for infringements of the MDD that have resulted in a) a custodial sentence b) a fine of greater than £50k Technical infringements of the technical files/validation only	31 August 2010	Answered - in full
10/350	Documents relating to clinical safety data - sections 7 (efficacy) and 8 (safety) of the PAR mentions publications and literature reviews- for picosulfate (CitraFleet°)	16 September 2010	Answered - in full
10/351	Wholesale dealers license inspection reports for the following company site: AAH Pharmceuticals Ltd	27 August 2010	Answered - in part
10/358	Public Assessment Report for Zocor Heart Pro	20 September 2010	Answered - in part
10/359	A list of contact manufacturing organisations based in the UK and the rest of the world that the MHRA have inspected and approved	27 August 2010	Answered - in part
10/360	Release of previously redacted material in connection with TGN1412 clinical trial at Northwick Park	11 October 2010	Answered - in part
10/361	Medicines act expemtions - podiatrists and optometrists - annomaly	15 September 2010	Answered - in part
10/363	The two latest MHRA GMP Inspections for Custom Pharamceuticals @: Custom Healthcare Group Ltd, Conway Street, Hove, East Sussex, BN3 3LW, UK Custom Pharmaceuticals, Unit 2 Fairway Trading Estate, Moulsecoombe, Brighton, East Sussex, BN2 4QL	17 September 2010	Answered - in part
10/364	Nicobrevin Stop Smoking Support Course	22 September 2010	Answered - in part
10/365	Are MHRA aware of any adverse health issues regarding the circulation booster supplied by High Tec Health Ltd.	26 August 2010	Answered - in part
10/366	Galenica's Ferinject/Injectafer	22 September 2010	Answered - in full
10/367	For years 2004, 2005, 2006, 2007, 2008 and 2009, various information regarding applications for authorisation from the MHRA of a Clinical Trial on Medicinal Product for Human Use from non commercial sponsors	28 September 2010	Answered - in full
10/368	1. A list of companies who have had a MHRA PV Inspection over the last 6 months. 2. A list of companies who are due to have an MHRA PV Inspection in the next 6 months.	23 September 2010	Answered - in full
10/369	A redacted copy of the most recent GDP inspection report for Cradlecrest Ltd, 2 Peterwood Way, Croydon, Surrey CR0 4UQ	23 September 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/370	The CSM/ Assessment correspondence concerning the following reclassification applications: 1. Zirtek Tablets (Cetirizine Dihydrochloride 10mg) 2. Galpharm Hayfever and Allergy Relief (Cetirizine hydrochloride 10mg) 3. Sea-Legs (Meclozine hydochloride 12.5mg)	10 December 2010	Answered - in part
10/372	Questions regarding MHRA's participation and expenditure in resepct of political party conferences	13 September 2010	Answered - in full
10/375	The latest list of UKMHRA approved plants inspected by MHRA	24 September 2010	Answered - in part
10/378	A copy of the GMP inspection report for: Jiangsu High Hope Int. Group Wuxi Company Limited 7F Customs Building Xishan Jiansu CHINA	24 September 2010	Answered - in full
10/379	The last Glenmark Pharmaceuticals Inspection report, and the last 10 Inspections with critical findings	08 October 2010	Answered - in part
10/380	The last GMP Inspection report of Nova Laboratories, Leicester, UK, LE18 4YL in support of their MA(IMP) specials license	17 September 2010	Answered - in part
10/381	Post SSRI Sexual Dysfunction - various categories of information required	06 October 2010	Answered - in full
10/382	All documents/information relating to the "accelerated application status" in respect of the licensing of the Pluserix vaccine (manufactured by GSK) 1986-1988	24 September 2010	Answered - in full
10/383	The public assessment reports for the following marketing authorisations: PL 05221/0001 PL 08972/0032 PL 00039/0542 PL 00039/0561 Pl 00289/0388 interested particularly in the legal basis for grant	06 October 2010	Answered - in full
10/384	Register of accredited decontamination providers	07 October 2010	Answered - in full
10/385	A copy of any GMP inspection report for: Lonza Guangzhou Limited 39 Jinhui Road Haizhu District 510 288 Guangzhou China	24 September 2010	Answered - in part
10/386	UKPAR for Nicorette Nasal Spray	08 October 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/387	MHRA GMP inspection reports of the following companies: 1. Gedeon Richter Budapest Hungary 2. Douglas Pharmaceuticals Auckland New Zealand	24 September 2010	Answered - in part
10/389	Minutes from the meetings of the CSM Sub Committee on the Safety Efficacy and Adverse Reactions (SEAR) between 1/9/90 and 31/12/90 (MMR related query)	30 December 2010	Answered - in part
10/390	Minutes from the Meeting on the 4th September 1992 by SEARS (Sub Committee CSM ..Safety Efficacy and Adverse Reactions) and ARGOS (Adverse Reactions Group of SEARS) (MMR related query)	13 December 2010	Answered - in part
10/391	Details of Yellow Card or safety reports of reactions in patients, including subgroups having sentinel lymph node biopsy in surgery for breast cancer if this is known, injected with Patent V dye (also known as Patent Blue, Patent Blue dye, Patent Blue V, Patent Blue V dye, Patent Violet, Patent Violet dye, Patent Blue Violet, Patent Blue Violet dye) in the financial year 2005/2006 and in the financial year 2009/2010	12 October 2010	Answered - in full
10/392	The latest GMP / GDP inspection report for ITH Pharma at the following site address; Unit 4, Premier Park Rd, London, NW10 7NZ	08 October 2010	Answered - in part
10/393	Breast implants and adverse reaction statistics	27 September 2010	Answered - in full
10/394	The incidence of Drug-Drug interactions, Drug-Non-drug interactions, and Drug-Disease interactions that occur for HMG-CoA reductase inhibitors	13 October 2010	Answered - in full
10/395	Any information on medical mattresses legislation	07 October 2010	Answered - in full
10/396	Reports of adverse reactions to childhood vaccines	18 October 2010	Answered - in full
10/397	All documents relating to the interaction between Galantamine and benzodiazepines, including the documentation submitted for the Galantamine / Reminyl/ Reminyl XL product licence	12 October 2010	Answered - in full
10/399	Statistics on major events and number of deaths linked with medical nicotine products in the UK since 2004	18 October 2010	Answered - in full
10/400	Adverse reactions to vaccines in North Tyneside area	20 October 2010	Answered - in part
10/401	Assessment Report for Navelbine Capsule	20 October 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/402	Current Schedule of Contracts	22 November 2010	Answered - in part
10/404	ASPPs specifically for Imigran Recovery from 2006-present. This specifically is the OTC version of sumatriptan 50mg tablets. Also include ASPPs for the other OTC Sumatriptan products, Migraleve Ultra, Galpharm Migraine Relief.	19 October 2010	Answered - in full
10/405	The Regulatory status of the following laboratory: Select Pharma Labs Sciantec Analyical Ltd Stockbridge Technology Centre Cawood, North Yorkshire Y08 3SD United Kingdom	19 October 2010	Answered - in part
10/406	All pharmacovigilance system inspection reports produced since 2006 for the following companies: Johnson & Johnson;Pfizer; Roche; GSK; Sanofi-Aventis; AstraZeneca; Abbott Laboratories; Merck and Co; Bayer Healthcare; Eli Lilly; Bristol Myers Squibb; Schering Plough and information on any critical findings	26 October 2010	Answered - in part
10/408	Details of any adverse events reported or product recalls ordered in relation to blood products in 1994	23 March 2011	Answered - in full
10/409	Inspection/audit report for the product Arsuamoon manufactured in China by, Guilin Pharmaceutical Co. Ltd No. 17 Shanghai Road, Guilin,Gaungxi,China 541002	28 October 2010	Answered - in full
10/410	Assessment reports on which the original licenses were granted to Janssen for risperidone in 1993, and to Eli Lilly for the licensing of olanzapine in 1996	14 October 2010	Answered - in part
10/411	Documents on the reclassification of tamsulosin to OTC	26 October 2010	Answered - in part
10/412	The latest inspection report for: Covance Clinical Research Unit Ltd Springfield House Hyde Street, Leeds LS2 9LH, United Kingdom	29 October 2010	Answered - in part
10/413	Information regarding Methylphenidate	26 October 2010	Answered - in full
10/414	for the past 3 financial years - 1) The income generated from the registration fees of homeopathic products 2) The cost to the MHRA of regulating homeopathic remedies in the UK on an ongoing basis (eg staff costs, GMP inspection of homeopathic manufacturers costs, etc) 3) Costs associated with one-off activities related to the regulation of homeopathic remedies such as public consultations	05 November 2010	Answered - in full
10/415	Various questions regarding staffing, finance, Ministerial submissions since May 2010	25 October 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/416	For years 2004, 2005, 2006, 2007, 2008 and 2009, various information regarding applications for authorisation from the MHRA of a Clinical Trial on Medicinal Product for Human Use from commercial and non-commercial sponsors where the IMP is an Advanced Therapy IMP (ATIMP)	30 March 2011	Answered - in full
10/417	All MHRA GMP Inspection Reports for the following site since implementation of Directive 2001/20/EC on 01 May 2004: TD PACKAGING LIMITED GROUNDWELL INDUSTRIAL ESTATE, UNIT 6, STEPHENSON ROAD, SWINDON, WILTSHIRE, UNITED KINGDOM, SN25 5AX SITE ID : 92016 MIA(IMP) 2635	02 November 2010	Answered - in part
10/418	Assessment Report for Ambisome	05 November 2010	Answered - in part
10/419	Strattera 5, 10, 18, 25, 40 and 60mg Capsules (UK/H/0686/001-6/E01)-first use MRP	05 November 2010	Answered - in full
10/420	Information regarding the compassionate use of methacholine chloride in the UK over the last 10 years	22 October 2010	Answered - in full
10/421	Side effects for Scottish girls vaccinated with Cervarix	08 November 2010	Answered - in full
10/423	Licensing information on various OTC painkillers	28 October 2010	Answered - in part
10/424	How many adverse reactions there has been in the UK after having the HPV vaccine Gardasil	29 October 2010	Answered - in full
10/425	Query regarding ARGOS and SEAR minutes	26 November 2010	Answered - in full
10/426	ADVERTISEMENT OF "BOTOX" - www.dentalcare62.com	18 October 2010	Answered - in part
10/427	Safety advice relating to Dopamine Agonist medication	10 November 2010	Answered - in part
10/428	Actavis' application to include Alopecia as an adverse effect in their Patient Information Leaflet for Citalopram	01 November 2010	Answered - in full
10/429	Query regarding Glucosamine and it's classification	09 November 2010	Answered - in part
10/431	A list of all overseas manufacturers who are inspected and approved by the MHRA	29 October 2010	Answered - in part
10/432	Details relating to : Drug Alert - 18 August 2009 MDR 84-07/09 Karib Kemi Pharm Ltd	05 November 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/433	Information regarding a Traditional Herbal Registration Certificate for the traditional herbal medicines Sinueeze Coated Tablets (THR 32294/001) and Sinuherb Coated Tablets (THR 32294/002)	05 November 2010	Answered - in part
10/435	Public Assessment Report (or a document to that effect) for Persantin 25/100mg Tablets	10 November 2010	Answered - in part
10/436	To be in compliance with updated requirement for GMP documentation in Turkey we request the following: 1. Inspection report, summary report, factual report etc. provided to the applicant from the last inspection 2. Corrective and preventive steps, if any, taken at the manufacturing site after the last inspection.	02 November 2010	Answered - in part
10/438	The public assessment reports for the following marketing authorisations: PL 00201/0173 CLARITYN SYRUP 1MG/ML SCHERING-PLOUGH LIMITED PL 00201/0175 CLARITYN TABLETS 10MG SCHERING-PLOUGH LIMITED PL 00201/0209 Clarityn Rapide Allergy Tablets SCHERING-PLOUGH LIMITED Should this information not be available, then the legal basis for grant and date granted. If any of these licences were issued as the result of a change of ownership application, provide the aforementioned information for the root licence.	09 November 2010	Answered - in full
10/440	Appendices to assessment reports on which the original licenses were granted to Janssen for risperidone in 1993, and to Eli Lilly for the licensing of olanzapine in 1996	05 November 2010	Answered - in part
10/441	A list of Pharmacy production sites that over the past 18mths have been failing inspection or who have been reported and must improve their facilities to comply to MHRA licencing	05 November 2010	Answered - in part
10/442	Copies of the 2009 and 2010 MHRA audit reports for the site/company below: Site details are: Pharmaserve (North West) Ltd, 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU	02 November 2010	Answered - in part
10/444	What kinds of information do MHRA hold on adjuvants	25 October 2010	Answered - in full
10/445	Asking for details of various prosecution cases	03 November 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/448	The clinical expert report of the MRP dossier and the RMS final assessment report of the MRP application for SOLARAZE 3% gel	15 November 2010	Answered - in part
10/449	Any pharmacovigilance inspection reports published from January 2006 to present day on the following companies: Novartis Pfizer Astellas Ipsen Sanofi GlaxoSmithKline	23 November 2010	Answered - in part
10/451	Questions regarding MHRA's ICT	02 November 2010	Answered - in full
10/452	The total number of serious adverse reactions recorded by the agency to childhood vaccines in the past 10 years, by region	03 December 2010	Answered - in full
10/453	A list of sites from India having accredation from MHRA	26 November 2010	Answered - in part
10/454	Details of all UK Market authorisations for various molecules	16 November 2010	Answered - in full
10/455	Please can you provide me with the results of the post-licensing study that was requested by the CHM and was a condition of the MHRA's approval of the reclassification on sumatriptan 50mg (Imigran Recovery). The study methodology and the number of subjects included in the study are also requested. Finally what, if any, actions were taken on the basis of the findings of this study	26 November 2010	Answered - in part
10/456	Bio-equivalency information on Aspirin Enteric Coated Tablets 75mg and Pravagettes Tablets ACETYLSALICYLIC ACID 81 MG	02 December 2010	Answered - in full
10/457	Iformation on adverse events regarding the use of Lariam/Mefloquine	29 November 2010	Answered - in full
10/458	ASPPs specifically for Imigran Recovery from 2006-present. This specifically is the OTC version of sumatriptan 50mg tablets. Also include ASPPs for the other OTC Sumatriptan products, Migraleve Ultra, Galpharm Migraine Relief.	30 November 2010	Answered - in part
10/459	The latest GMP Inspection Report for: a) Guy's and St Thomas' NHS Foundation Trust's Pharmacy Manufacturing Unit b)Calderdale and Huddersfield Pharmacy Manufacturing Unit	29 November 2010	Answered - in part
10/460	Please provide the MA number date of grant and legal basis for grant, for the Marketing Authorisation which PL 00201/0175 referred to, along with the MA number, date of grant and legal basis for grant for the first loratadine 10mg tablet Marketing Authorisation issued in the UK	03 December 2010	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/462	How many Staff are directly employed by or on behalf of the MHRA? (Head Count, not WTE's)	08 December 2010	Answered - in full
10/464	Yellow card data for Devon and Derriford Hospital	02 December 2010	Answered - in full
10/466	The final MHRA assessment report for the original Abelcet (Amphotericin B Lipid Complex)	29 November 2010	Answered - in part
10/467	documentary reports to elaborate fully on the rejection of a proposal for reclassification from P (pharmacy) to GSL (general sales licence) of benzocaine 3% in throat sprays, throat pastilles, throat lozenges and throat tablets	07 December 2010	Answered - in part
10/468	Trade of fake Viagra - information requested for research project	25 November 2010	Answered - in full
10/470	Information from adverse incident investigations into Medtronic Xtrail and Medtronic Synergy	29 November 2010	Answered - in part
10/471	Questions regarding staff travel and associated expenses	18 April 2011	Answered - in part
10/472	Combination therapy - zinc oxide tablets	07 December 2010	Answered - in part
10/473	Information regarding hypnotic sedative Halcion	24 November 2010	Answered - in part
10/474	Information in relation to the SystmOne GP software which reports yellow card (ADR) into the MHRA	07 December 2010	Answered - in full
10/475	A list of Manufacturing sites in India inspected and approved by the UK MHRA	26 November 2010	Answered - in part
10/476	Any incidents involving an MRI Scanner (1.5T HD 8 Channel High Res Brain Array for the GE HDx MR System)	07 December 2010	Answered - in full
10/478	Environmental Risk Assessment for ceftazidime pentahydrate	15 December 2010	Answered - in full
10/480	A copy of the latest MHRA inspection report for Food and Drug Analytical Services Ltd, Biocity, Pennyfoot Street, Nottingham NG1 1GF	20 December 2010	Answered - in part
10/481	A copy of the latest MHRA inspection report for NTMRL Collindale. National Blood Service, Colindale Avenue, London NW9 5BG	21 December 2010	Answered - in part
10/482	Information on Benzodiazepines	17 December 2010	Answered - in full
10/484	Inspection reports: CP Pharmaceuticals, Wrexham	16 December 2010	Answered - in part
10/485	Approved manufacturers in India who have been inspected in last 24 months	23 December 2010	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/486	Approval information for Levact (Bendamustine)	03 December 2010	Answered - in full
10/487	Information on Alginate suspensions	22 December 2010	Answered - in part
10/489	Information regarding Sitaglyptin	30 November 2010	Answered - in full
10/490	Finasteride side effects	30 November 2010	Answered - in full
10/491	MMR	22 December 2010	Answered - in full
10/492	Information regarding MHRA's use of IT	10 December 2010	Answered - in full
10/493	Public Assessment Report for Dexsol 2mg/5ml Oral Solution	30 December 2010	Answered - in part
10/495	1.Copies of the clinical assessment Acortyl In Orabase Dental paste (PL00034/0321) 2.The common technical document used to license the above product (PL00034/0321) 3.The MA license application form for Adcortyl In Orabase (PL00034/0321)	16 December 2010	Answered - in part
10/497	Sites inspected by MHRA in INDIA	23 December 2010	Answered - in part
10/499	A list of all companies holding marketing authorisations in the UK, applied for via an abridged application (i.e. for generic medicines) or a hybrid application, using either the national procedure or the decentralised procedure with the UK as the RMS. The list should include name of the company, indications whether the company`s marketing authorisation(s) pertain to prescription only (POM), pharmacy (P), or general sales list (GSL) products, or a combination of these.	24 December 2010	Answered - in full
10/500	An assessment report (or equivalent generated at that time) for PL 11002/0001 granted 21/11/2002 to Trenka Chem-Pharm Fambrik GmbH	26 January 2011	Answered - in part
10/501	An assessment report related to the Copaxone SmPC update dated February 2009	07 January 2011	Answered - in part
10/503	Records relating to the approval by the MHRA of the PREDICTIVE trial for insulin detemir (Levemir) manufactured by Novo Nordisk	09 December 2010	Answered - in part
10/506	A copy of each available GMP/GDP Inspection report for: Macfarlan Smith Limited Wheatfield Road Edinburgh EH11 2QA Scotland, UK	05 January 2011	Answered - in full
10/507	MHRA inspected pharmaceutical manufacturer in India	23 December 2010	Answered - in part
10/508	Information on Benzodiazepines - evidence of pre-clinical testing	04 January 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
10/509	Voluntary redundancies in MHRA	24 December 2010	Answered - in full
10/510	A copy of the report and the company response letter arising from the MHRA audit of the CIPLA Verna Plant in Goa in 6 to 10 July 2009	07 January 2011	Answered - in part
10/512	Various questions regarding Ministerial submissions in respect of the Public Bodies and Comprehensive Spending reviews	13 January 2011	Answered - in full
10/514	Updated list of overseas GMP inspected and approved sites	17 January 2011	Answered - in part
10/516	The Public assessment Report for Cositam XL 400 microgram prolonged-release tablets, and the legal basis on which the MA was granted	17 January 2011	Answered - in part
10/517	Questions regarding MHRA staff numbers based in Blackpool	17 December 2010	Answered - in part
10/519	The Public Assessment Report for Adoport 0.5mg, 1mg & 5mg. The MAH is Sandoz, Bordan, Hants	12 January 2011	Answered - in part
10/520	A questionnaire to collect information on pharmaceutical sales over the internet with special emphasis on drug regulations	10 January 2011	Answered - in part
10/521	Request for information on specific MHRA inspectors	17 January 2011	Answered - in part
10/522	Query regarding classification issues involving borderline and IVD devices	19 January 2011	Answered - in full
10/523	Monthly performance on vetting of advertising	05 January 2011	Answered - in part
10/524	Query regarding 2 drugs on the "New drugs under intensive surveillance" list: Repevax Infanrix-IPV	20 January 2011	Answered - in full
10/525	Questions regarding GPRD finances and operations	21 January 2011	Answered - in part
10/526	Assessment report for the Priorix (MMR Vaccine)	24 January 2011	Answered - in full
10/527	Query regarding FOI requests received by the MRA	20 January 2011	Answered - in full
10/529	Submissions made to the MHRA as part of the consultation Review of medicines legislation: Informal consultation on the provisions for patient group directions (PGDs) and other matters, and the MHRA's response to the consultation	28 January 2011	Answered - in full
10/531	Safety Policy Enforcement/testing responsibilites	19 January 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
10/532	The total number of MHRA employees at the end of financial year 2009-10 The total spent on MHRA employees during financial year 2009-10	14 January 2011	Answered - in full
10/533	Concomitant use of quetiapine and methadone	01 February 2011	Answered - in part
11/001	MHRA staff financial links to pharmaceutical companies	02 February 2011	Answered - in full
11/002	HPV vaccines and adverse reactions	24 January 2011	Answered - in full
11/003	MHRA approved sites in India from 01/01/2010 to 31/12/2010	17 January 2011	Answered - in part
11/004	Lorazepam questions	13 January 2011	Answered - in part
11/005	Documents held by or on behalf of the MHRA in relation to the grant of a marketing authorisation in respect of Omega-3-Acid Ethyl Esters 90 (Zodin), to Pronova Biocare AS (granted on 12/12/2005)	27 January 2011	Answered - in part
11/006	Query regarding device registration details	03 February 2011	Answered - in full
11/008	All pharmacovigilance system inspection reports produced since 2006 for the following companies: Johnson & Johnson;Pfizer; Roche; GSK; Sanofi-Aventis; AstraZeneca; Abbott Laboratories; Merck and Co; Bayer Healthcare; Novartis; Bristol Myers Squibb; Schering Plough and information on any critical findings	28 January 2011	Answered - in part
11/009	Copies of MHRA GMP/GDP inspection reports issued since 2005 for: THORPE LABORATORIES LIMITED GOLF ROAD INDUSTRIAL ESTATE, MABLETHORPE, LINCOLNSHIRE, UNITED KINGDOM, LN12 1NB	31 January 2011	Answered - in part
11/010	A copy of the report arising from the MHRA inspection of the following standalone GMP QC laboratory site on 27 November 2008: Zeta Analytical Ltd. Unit 3 Colonial Way Watford Herts WD24 4YR Scope of work: Chemical/Physical	31 January 2011	Answered - in part
11/011	Information required regarding Statins, specifically Simvastatin & Lipitor	03 February 2011	Answered - in part
11/012	1) A copy of the current list of board members' interests 2) Details of gifts, hospitality, travel, entertainment or other benefits provided to Board members, directors and staff by entities other than the MHRA itself, over the past three years.	07 February 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/014	List of approved sites by MHRA in India	26 January 2011	Answered - in part
11/015	A list showing the names of all companies classified as 'contract research organisations', which are subject to MHRA inspections (ie- GCP/GLP), and are based in: 1. USA 2. India	08 February 2011	Answered - in full
11/016	Annual Reports for the Committee on Safety of Medicines are published by DHSS each year. I am seeking these reports for the years 1979 to 1985 inclusive	14 January 2011	Answered - in full
11/017	Copy of GMP certificate for Microlabs - situated in Bonnasandra, Bangalore	31 January 2011	Answered - in part
11/018	Supply of drugs to be used in executions	27 January 2011	Answered - in part
11/019	Homeopathic industry advertising issues	07 February 2011	Answered - in full
11/020	The assessment report for the medicine listed below as well as any additional information on the publications/information supporting its use in the pediatric poppulation: 16853/0057 28/09/2001 ALLIANCE PHARMACEUTICALS LIMITED Distamine 125mg tablets D-PENICILLAMINE BASE 125 MG O PL 16853/0058 28/09/2001 ALLIANCE PHARMACEUTICALS LIMITED Distamine 250mg tablets D-PENICILLAMINE BASE 250 M	09 February 2011	Answered - in part
11/022	GMP Inspection reports for Aptuit (Edinburgh) Ltd, Inchwood Bathgate West Lothian Scotland EH48 2EH Almac, Clinical Services, 20 Seagoe Industrial Estate, Criagavon, Northern Ireland BT 63 5PW. Catalent Pharma Solutions Sedge Close, Headway, Great Oakley Corby Northamptonshire England NN18 8HS	10 February 2011	Answered - in part
11/023	A list of all GCP accredited labs	28 January 2011	Answered - in full
11/024	Adverse sexual effects associated with SSRIs	10 February 2011	Answered - in full
11/025	List of plants inspected by MHRA in Mexico	28 January 2011	Answered - in full
11/026	Implantable cardioverter defibrillator (ICD) failure rates	10 February 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/028	A copy of the Pharmacovigilance inspection report for Newport Pharmaceuticals Ltd, Ireland which I believe was conducted in November 2010	15 February 2011	Answered - in part
11/030	Queries regarding MHRA Devices Compliance Unit	28 January 2011	Answered - in full
11/031	HPV vaccines and adverse reactions	18 February 2011	Answered - in full
11/034	Medical Enquiry Regarding All Drugs With Animal Components and Their Alternatives	23 February 2011	Answered - in full
11/035	Information Relating to Chronic Obstructive Pulmonary Disease (COPD) - information relating to clinical studies performed for the indication of COPD.	18 February 2011	Answered - in part
11/036	Obtaining of medicines using online pharmacy sites, specifically without a prescription	28 January 2011	Answered - in full
11/037	Implantable cardioverter defibrillator (ICD) failure rates - healthcare providers	18 February 2011	Answered - in full
11/039	Request to see if certain companies recieved warning letters following inspections	28 March 2011	Answered - in full
11/040	Questions regarding Pluserix and/or Immravax MMR vaccine	23 February 2011	Answered - in part
11/042	How many die each year from drug effects, drug interactions etc.	22 February 2011	Answered - in full
11/043	The MR Assessment Report, and any available RMS/CMS correspondence, for Schering-Plough's Asmanex Twisthaler medicinal product	10 February 2011	Answered - in part
11/044	All preclinical data on aceclofenac - Toxicity (acute, subacute), mutagenicity, teratogenicity studies	22 February 2011	Answered - in part
11/046	Questions regarding medical products containing propyl paraben	24 February 2011	Answered - in part
11/047	The UK PARs for: PL 16431/0128 PL 21538/0015	14 February 2011	Answered - in part
11/048	The most recent MHRA Inspection report for the following site: Pharmasol Limited North Way Walworth Industrial Estate Andover Hampshire SP10 5AZ	16 February 2011	Answered - in part
11/049	A copy of MHRA Audit of Aptuit site in Bathgate performed in August 2009	11 February 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/050	Information (type PAR) on 1. the review and approval of Nubain Injection 10mg/ml, 1ml and 2ml ampoules (PL 11184/0108) granted on 28/02/2002 to BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED and subsequent withdrawal from the market in October 2005. 2. information on other approved medicinal products containing nalbuphine hydrochloride	25 February 2011	Answered - in part
11/051	Any claims of unlawful activity, citations or license revocations for BR Pharma or Pharmarama	24 February 2011	Answered - in full
11/053	Clinical Assessment Report for Eucarbon Tablets (PL 11002/0001)	28 February 2011	Answered - in full
11/054	Chlorhexidine based mouthwash products	16 February 2011	Answered - in full
11/055	Has a license application been filed by Bristol Myer Squibb and Astra Zeneca for Kombiglyze XR (Saxagliptin and MetformHCl extended release) in UK/europe - it received FDA approval in the US in November 2010	07 February 2011	Answered - in part
11/059	Information regarding a costs application made by the MHRA in the high court matter	04 March 2011	Answered - in full
11/060	Periodic Safety Update Reports filed by Link Pharmaceuticals Ltd. and Archimedes Pharma UK Ltd. from January 2005 until the present date for the drug thiopental	16 March 2011	Answered - in part
11/061	A list of manufacturing sites in India that are registered by the MHRA	10 February 2011	Answered - in part
11/062	Historical Lorazepam documentation request	02 March 2011	Answered - in part
11/063	Amoxicillin capsules BP 500mg - MDR 19-10/10	28 February 2011	Answered - in part
11/065	A list of the GMP approved manufacturers that have any of the following QC Laboratories listed on their licenses. : Astron Research - 62872/89567 FDAS - 62716/89536 Herd Mundy Richardson Ltd. - 14083/4655 Keane Analytical Ltd - 22578/30444 Minerva Scientific Ltd. - 19575/12378 Zeta Analytical Ltd. - 62515/89520	28 February 2011	Answered - in part
11/066	Assessment report for the original approval of Glaxo Smith Klines vaccine called Varilrix	07 March 2011	Answered - in part
11/069	Which companies currently have MRHA approval for the manufacture of probiotic for clinical trials	18 February 2011	Answered - in full
11/070	All information that MHRA holds in relation to the pharmaceutical company Dream Pharma	09 March 2011	Answered - in part
11/071	PAR for Ibusol	02 March 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/072	A copy of Module 2.5 Clinical Overview for Foster/ Fostair (pressurised inhalation solution containing beclometasone dipropionate (BDP) 100 micrograms and formoterol fumarate (FF) 6 micrograms per metered dose) that supported the MRP procedure DE/H/0873/001/MR	01 April 2011	Answered - in part
11/075	Questions regarding buttock implants and adverse incidents	28 February 2011	Answered - in full
11/076	The last 2 Pharmacovigilance Inspection reports for the Actavis Group	10 March 2011	Answered - in part
11/080	Assessment Report of both the nationals and the MR procedures for ARCOXIA® film-coated tablets	10 March 2011	Answered - in part
11/081	Documents relating to Alginate Raft forming Oral Suspensions and Compound Alginate Antacid Oral Suspensions	16 March 2011	Answered - in part
11/082	A redacted version of the report of the inspection of DSM (Lonza Guangzhou Ltd) based in China	10 March 2011	Answered - in part
11/084	Documents relating to the publication of generic names for alginate raft forming preparations	16 March 2011	Answered - in part
11/085	A copy of the inpspection reports for the following sites over the last 26 month period. PETNET SOLUTIONS LIMITED SITE ID : 261281 SITE ID : 311833 IBA Molecular UK Limited SITE ID : 342930 SITE ID : 407006	23 March 2011	Answered - in part
11/086	MHRA's Conflicts of Interest Standard Operating Procedure	10 October 2011	Answered - in full
11/089	PIP silicone gel breast implants recall	23 March 2011	Answered - in full
11/090	A copy of the clinical justification as reference in Section III.3.1, Clinical Pharmacology with regards to the Public Assessment Report of Imodium Plus Caplets	13 April 2011	Answered - in part
11/092	Documents relating to the granting of BP monographs for generic medicines	17 March 2011	Answered - in part
11/093	Please confirm that the Cannabis based medicine Sativex (AKA re-branded tincture) is being considered for licensing in the treatment of cancer pain, and that Sativex contains all the same cannabinoids as cannabis and as such would have to be listed in the schedules according to its botanical name ie, 'Cannabis', also confirm that the active ingredients in Sativex (cannabis) must be listed in accordance with the proven harm rule that applies to the licensing of all other drugs of medical efficacy	25 March 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/094	Copies of the calcium/vitamin d supplements papers referenced within the minutes of the latest published CHM minutes (Thu 13 Jan 2011) follow up to FOI 11/077	08 March 2011	Answered - in part
11/095	Any information held on Dream Pharma	29 March 2011	Answered - in part
11/096	Requesting to have any information removed from GPRD records	04 March 2011	Answered - in full
11/100	Information and documentation letters etc, regarding the antibiotic known as Cipro / Ciprofloxacin / Ciproxcin between January 1st 2001 and the present day	28 March 2011	Answered - in part
11/103	Documentation held by MHRA, relating to meetings of the MHRA Expert Advisory Group looking at soft tissue reactions associated with metal-on-metal hip replacements, held in the last five years. Information about declarations of conflict of interest declared by advisory group members at these meetings – records of the declarations and the action taken on these declarations.	17 June 2011	Answered - in full
11/105	Various questions regarding MHRA's payments processes	09 March 2011	Answered - in full
11/106	Documentation held by MHRA relating to committee meetings of the MHRA safety of devices committee held in the last five years, also information about declarations of conflict of interest declared by committee members at these meetings – records of the declarations and the action taken on these declarations.	07 March 2011	Answered - in full
11/107	Public Assessment Report for Synercid (dalfopristin/Quinupristin)	29 March 2011	Answered - in part
11/108	Historical Lorazepam documentation request	21 March 2011	Answered - in part
11/109	1) How many contract research organisations (CROs) are currently regulated by the MHRA? 2) How much total revenue did these organisations accrue in a recent year? (2009? 2008?)	25 March 2011	Answered - in full
11/110	All correspondence between the MHRA and pharmaceutical companies relating to 3,4 DAP. This should include memos, letters and advisory statements as well as less formal communication.	01 April 2011	Answered - in part
11/111	Various documents in relation to Naxogin	01 April 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/112	Details of the total number of individuals registering adverse or unusual reactions after taking Cipro / Ciprofloxacin / Ciproxcin or other fluoroquinolones including Levaquin or Avelox, that form part of the wider fluoroquinolone class of antibiotics, between January 1st 2000 and the present day. Also, copies of any correspondence - including emails,letters, minutes of meetings, memos or any other documents - held by MHRA and including internal documents and correspondence between MHRA and third parties relating to health impacts / safety of Cipro / Ciprofloxacin / Ciproxcin and other fluoroquinolone antibiotics, including Levaquin or Avelox, from January 1st 2000 and the present day.	04 April 2011	Answered - in part
11/113	Details of any prosecutions against Responsible Persons that the MHRA have initiated in the last 5 years	29 March 2011	Answered - in full
11/114	Documentation held by the MHRA relating to adverse incident reports involving the Depuy Corail/Pinnacle hip system over the past 5 years. To include detail of the nature of the incidents reported, as well as the numbers of incidents reported, and also to include all correspondence between the MHRA and the manufacturer relating to problems with the Corail/Pinnacle hip system.	09 March 2011	Answered - in part
11/115	The last inspection report for IDIS pharma	01 April 2011	Answered - in part
11/118	Documents relating to Bonjela Once and other mouth ulcer treatments	07 April 2011	Answered - in part
11/119	The latest Company Inspection reports for: Claris Life Sciences Goldshield Three Rivers EUSA Pharma Auden Mackenzie Chemidex http://documents:7779/webtop/drl/objectId/0b0003e98443efcd	07 April 2011	Answered - in part
11/121	Why was Navoban (active ingredient tropisetron) intended for use for post-operative nausea and vomiting removed from the UK market	17 March 2011	Answered - in full
11/122	All documents filed by Iroko Cardio as part of a variation submission to obtain approval of a new dosing regimen for Aggrastat® (tirofiban hydrochloride) (High Dose Bolus (HDB) 25mcg/kg over 3 minutes followed by an infusion of 0.15mcg/kg/min) in PCI	11 April 2011	Answered - in part
11/123	UK Public Assessment Report (or equivalent) and Summary of Product Characteristics (or equivalent) for Colgate Chlorohex 1200	08 June 2011	Answered - in part
11/124	Information in relation to capital expenditure transaction code 600060569 (ANALYTIK LTD)	29 March 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/125	Does the Medical Health Regulatory Agency (MHRA) class thermal breast imaging as a Grade 1 screening procedure?	07 April 2011	Answered - in full
11/126	ENQUIRY RELATING TO EPHEDRINE SOLUTION FOR INJECTION	17 March 2011	Answered - in full
11/128	The assessment report and the date of approval for the addition of the "Nurofen for Children Orange Baby" to the following licence: Nurofen for Children Orange Nurofen for Children Orange Baby Nurofen for Children 3 months to 9 years Orange Please also provide the assessment report and date of approval of the addition of the"Nurofen for Children Strawberry Baby" to the following licence: Nurofen for Children Strawberry Baby Nurofen for Children 3 months to 9 years Strawberry	17 March 2011	Answered - in full
11/129	How many times has MHRA used its statutory powers to: a)withdraw a product from the market b)prosecute a medical device company Documentation held by MHRA relating to this - the products and companies involved, along with reasons given for the use of the statutory powers	13 April 2011	Answered - in part
11/130	Documentation held by the Medicines and Healthcare Products Regulatory agency (MHRA) relating certificates of conformity of medical devices, which have been: a)withdrawn by a notifying body b)suspended by a notifying body in the last five years. Please provide the details of devices and the reasons given for withdrawal/suspension	11 April 2011	Answered - in part
11/131	The total number of yellow card submissions for the last two years broken down by year and month	12 April 2011	Answered - in full
11/133	Information regarding costs involved in ongoing investigation	08 April 2011	Answered - in full
11/134	MHRA GMP inspection and certificates BioReliance Glasgow BioReliance Ltd. Todd Campus West of Scotland Science Park Glasgow G20 0XA Scotland	14 April 2011	Answered - in part
11/139	Information regarding MHRA's use of IT	24 March 2011	Answered - in full
11/140	Re: Corsodyl 0.2% Mouthwash Provide the assessor's report(s) on the variation concerning the re-formulation of this product which removed ethanol (96%) as an excipient	05 April 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/141	Most recent establishment inspection(MHRA) report of Strides Lab., Bangalore, India and most recent establishment inspection (MHRA) report of GSK, UK	14 April 2011	Answered - in part
11/142	MHRA Inspection Report issued (and any other available documentation) as a result of a GLP inspection at Charles River Laboratories in Tranent, Edinburg, UK in April 2010	14 April 2011	Answered - in part
11/143	Listing of GMP Inspections conducted by the MHRA/EMA in 2010	01 April 2011	Answered - in part
11/144	Listing of GLP Inspections conducted by the MHRA/EMA in 2010	01 April 2011	Answered - in part
11/145	Listing of GCP/vGCP Inspections conducted by the MHRA/EMA in 2010	01 April 2011	Answered - in part
11/146	Query regarding the manufacture of Generic Medications	15 April 2011	Answered - in part
11/147	Traditional Herbal Medicinal Products Directive	28 March 2011	Answered - in full
11/148	Yellow Cards and Warning regarding unlicensed herbal medicines on sale over the internet	18 April 2011	Answered - in full
11/150	All reports for GMP inspections carried out i n the last 5 years for Torbay Pharmaceutical Manufacturing Unit Long Road Paignton Devon TQ4 7TW	15 April 2011	Answered - in part
11/151	First submission date of Coversyl Arginine in the UK, a copy of the Public Assessment Report, a copy of the Mutual Recognition Assessment report, and date of first submission in the Reference Member State (France)	19 April 2011	Answered - in part
11/152	Questions regarding marketing authorisations in the context of environmental pollution	21 April 2011	Answered - in part
11/153	Queries regarding the salaries and terms of office of MHRA's CE and Chairman	21 April 2011	Answered - in part
11/154	Documents relating to PL 18909/0191-4 Arrow Generics Limited, cabergoline	21 April 2011	Answered - in part
11/156	Request for information re fluconazole	01 April 2011	Answered - in part
11/158	Between 21 March 2010 and 21 March 2011: 1.How many people were reported to the MHRA for not offering the statement of manufacture to the patient? 2.How many of these cases came from the GDC? 3.How many prosecutions are pending and how many convictions have there been?	20 April 2011	Answered - in part
11/159	The Cymbalta NDA, including but not limited to all correspondence between the MHRA and Eli Lilly concerning Cymbalta which refer to withdrawal, discontinuation, dependence or addiction	19 April 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/160	FOI and the Heads of Medicines Agency and EMA recommendations on transparency	04 May 2011	Answered - in full
11/161	Information for the period 01/01/2010 – 31/12/2010 of adverse incidents in hospitals, care homes and domestic premises involving hoisting and transfer equipment	11 April 2011	Answered - in full
11/165	Current list of the companies that have UK MHRA approved pharma plants in India	01 April 2011	Answered - in part
11/166	A copy of the last MHRA GMP Inspection report for MSD Biologics (UK) Limited, Belasis Avenue, Billingham, Cleveland, TS23 1YN. Formally known as Avecia	15 April 2011	Answered - in part
11/167	Query regarding the manufacture of Generic Medications	15 April 2011	Answered - in part
11/168	Data for research purposes - Temozolomide GENQ-00074588	11 April 2011	Answered - in full
11/169	THe MHRA was the reference member state for a MR procesure for Nasonex in November 2004, wherein the already approved product was granted and additional indication for the treatment of nasal polyps. Is it possible to obtain the Assessment Report for this procedure	21 April 2011	Answered - in part
11/170	Acceptable levels of Chromium and Cobalt in the human body	27 April 2011	Answered - in full
11/171	A list of showing all the unlicensed medicines for which the MHRA has received requests for import permissions over the last 6 months. Please indicate requests which have been approved and which have been refused. Where requests have been refused please indicate the reason given	27 April 2011	Answered - in part
11/172	Inspection report for Ind Swift, Village Jawaharpur, Punjab, India, ref. certificate no. UK GMP 31450. Date of inspection 15/12/2010	27 April 2011	Answered - in part
11/173	A list of all Homepathic products that you have approved under the "National Rules Scheme	03 May 2011	Answered - in full
11/174	2011 Pharmacovigilance Inspection report for the inspection conducted on Astra Zeneca	06 May 2011	Answered - in part
11/175	Incidents involving the Physio-Med Professional 300 Couch	27 April 2011	Answered - in part
11/176	MHRA's postal and mailing requirements	29 September 2011	Answered - in full
11/178	Research that informed banning of aspirin use in children in the UK	17 May 2011	Answered - in part
11/179	Waxsol Ear Drops: Was the Pharmacy status change in November 2001 instigated by the MAH or by the MHRA/EMEA and the reasons for the change as it is unusual to move from 'GSL' to 'P'	04 May 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/182	A copy of any available MHRA GMP Inspection report(s) relating to: Onyx Scientific Units 97/98 Silverbriar Sunderland Enterprise Park East Sunderland SR5 2TQ (MHRA GMP Manufacturer Authorisation No. UK API 21862 GMP 21540/21862-0002)	06 May 2011	Answered - in part
11/185	The failure rate of the contraceptive pill Microgynon 30, which is available on the NHS. How many unwanted pregnancies have been recorded in the UK in the past five years while the women in question were taking this oral contraceptive, broken down year by year. Also whether the suspected reasons for these failures are recorded, and if so, what are the most common reasons for the contraceptive's failures?	18 May 2011	Answered - in full
11/186	Assessment reports for the following PL 27827/0025 Flotros 20mg FC tablet PL 25843/0002 Regurin 20mg tablets PL25843/0003 Regurin XL 60mg	19 May 2011	Answered - in part
11/187	A request under FoI legislation for the "paperwork for this transaction" which was "seized by enforcement for investigation." (page 1/amo/22/3/06) - see FOI 11/070	17 May 2011	Answered - in part
11/188	FOI 10/420 - follow-up request re Methacholine Chloride Imports	11 May 2011	Answered - in full
11/189	Last MHRA inspection report of Kopran Pharmaceuticals, Village Savroli(Khopoli) Taluka Khalapur Dist Raigad Maharashtra 410202 India	19 May 2011	Answered - in part
11/190	How many medical device companies are operating in the UK	09 May 2011	Answered - in full
11/191	Copies of the inspections undertaken in China since 2004	23 May 2011	Answered - in part
11/192	Inspection Reports of Almac at the Seagoe Industrial Area Northern Ireland	11 May 2011	Answered - in part
11/193	Queries regarding the salaries and terms of office of MHRA's CE and Chairman	27 May 2011	Answered - in full
11/194	Figures for reported complications from defibrillators, specifically electrical shocks (to staff/bystanders) and fires due to defibrillators	15 June 2011	Answered - in full
11/195	Questions regarding adverse drug reactions during 2010	26 May 2011	Answered - in full
11/199	Pharma companies compliance with PIL requirements	24 May 2011	Answered - in full
11/200	A copy of the responses made to ARM 55	31 May 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/203	MHRA GMP inspection report for SCM Pharmaceuticals in the UK. I have a not that there was an inspection by MHRA in March 2009	25 May 2011	Answered - in part
11/204	Assessment reports for variations to the product Zoladex implants marketed by Astra Zeneca (PLs 17901/0064 and 0065) relating to the changes to the indications in section 4.1 of the SPC and to changes in the pharmacodynamic properties in section 5.1 of the SPC	01 June 2011	Answered - in part
11/205	Clinical study reports and protocols for placebo-controlled trials of fluoxetine	25 May 2011	Answered - in part
11/206	The latest inspection report information relating to: Aptuit, Unit 107, Tenth Avenue Deeside Industrial Park Deeside, CH5 2UA	26 May 2011	Answered - in part
11/207	Adverse sexual effects associated with SSRIs	08 June 2011	Answered - in full
11/209	A list of all pharmaceutical agents for which there has been at least one Adverse Drug Reaction report of allergic alveolitis (alternative names: hypersensitivity pneumonitis, pneumonitis, alveolitis) and as a separate list all agents reported to have casued lung fibrosis/ pulmonary fibrosis - including the corresponding number of such ADR reports for each agent	21 June 2011	Answered - in full
11/210	To date in 2011 how many counterfeit medical devices have been found to have reached the NHS supply chain? For each of these items please state what the item was and where (which hospital) it was found in.	13 June 2011	Answered - in part
11/211	The latest stats of adverse events following vaccination in Northern Ireland	14 June 2011	Answered - in full
11/212	Details on various categories of Agency spending for last 3 years	23 June 2011	Answered - in full
11/217	Information relating to breast implants: Poly Implant Prothèse	29 June 2011	Answered - in part
11/218	Data for research purpose- Temozolomide GENQ-00074588 (see also FOI 11/618)	20 June 2011	Answered - in full
11/219	Assessment Report or UK PAR for Docusol	24 June 2011	Answered - in part
11/220	ICT Structure, contact details for Director of Finance and the Commerical Director	17 June 2011	Answered - in full
11/222	Adverse event reporting data relating to the Ethicon ENDOPATH ETS-FLEX endoscopic articulating linear cutter (vascular/thin) – 35mm	04 July 2011	Answered - in part
11/224	Access to any reproductive toxicology studies on minoxidil.	29 June 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/225	Reasons for withdrawl of Nicobrevin from the UK market	17 June 2011	Answered - in full
11/227	Information confirming the saftey and effectiveness of using lidocaine both topically (in the form of EMLA) and via injection.	04 July 2011	Answered - in full
11/228	information regarding the clinical and nonclinical data of the innovator product in ranitidine (Zantac)..to compare the data of Zantac and want to prepare ranitidine mucal tablets as a hybrid product from that Zantac tablets	04 July 2011	Answered - in part
11/229	Questions regarding marketing authorisations in the context of environmental pollution	05 July 2011	Answered - in part
11/231	Various questions regarding Government Procurement Cards	07 July 2011	Answered - in full
11/232	Contamination of pharmaceuticals with di-isodecyl phthalate and other phthalates in licensed products	08 July 2011	Answered - in full
11/235	PAR for Dipyridamole 50mg/5ml Oral Suspension (RosemontPharmaceuticals Ltd)	23 June 2011	Answered - in full
11/236	All correspondance regarding homeopathy between the MHRA and the following skeptics is requested from January 2010 to the present date.	18 July 2011	Answered - in part
11/237	Administrative Complaint about the MHRA	06 July 2011	Answered - in part
11/239	Suspected Adverse Reaction Reports Re: FOI 11/040	25 July 2011	Answered - in full
11/243	A list of all the accredited clinical laboratories in UK including the Laboratory Manager name, phone number and what tests they claim to be accredited to run.	05 July 2011	Answered - in part
11/244	MHRA assessment report for the product Arthrotec modified release tablets	15 July 2011	Answered - in part
11/246	Report for the most recent MHRA GMP audit of Licence Holder MIA(IMP) 16901 QUOTIENT CLINICAL LIMITED	18 July 2011	Answered - in part
11/247	Adverse Incident involving an Incontinence Sling, MHRA ref: 2011/003/010/401/001	21 July 2011	Answered - in part
11/248	List of attendees at a meeting held on13thy May at BPR plus Agenda and minutes	26 July 2011	Answered - in part
11/249	How many clinical studies conducted by Indian CTOs were assessed by the MHRA over the last few years	05 July 2011	Answered - in full
11/250	Update relating to ongoing problems and discussions on polypropylene synthetic mesh in the medical devices TVT, TVTO and TOT which is classed as an adverse incident	21 July 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/251	List of MHRA approved facilities in INDIA	18 July 2011	Answered - in part
11/252	European Public Assessment Report - UK/H/0361/001on TOBI 300 mg/5ml Nebuliser solution	27 July 2011	Answered - in full
11/253	A list of all warning letters issued to drug manufacturing sites inspected by the MHRA both within and outside the UK in the past 5 years	20 July 2011	Answered - in full
11/254	Public assessment Report for PL 00289/1142 Flectone XL prolonged-release tablets 400 microgram	19 July 2011	Answered - in full
11/255	PAR request for Promixin 1 million international units (IU) powder for nebuliser solution	01 August 2011	Answered - in full
11/256	Request to see original complaint regarding information on the website the La Belle Forme clinic and alleged misuse of the word "Botox"	29 July 2011	Answered - in part
11/258	Acopy of the complete Submission form and a copy of the CE Mark Approval of MHRA Ref: CA 010377 Device: 02 Vaginal Trainers	02 August 2011	Answered - in full
11/259	Inspection reports for Intrapharm and Meadow Laboratories	22 July 2011	Answered - in part
11/261	MHRA GMP inpsection reports and resposnes made by the companies for three companies in the last 2 years Hospira Aspetic Services Healthcare at Home B Braun Medical Ltd	27 July 2011	Answered - in part
11/263	Details of contracts regarding MHRA's use of telephony	03 August 2011	Answered - in full
11/264	Contamination of pharmaceuticals with di-isodecyl phthalate and other phthalates in licensed products	05 August 2011	Answered - in part
11/265	Information regarding clinical trials at hospitals which are members of an Academic Health Sciences Centre	08 August 2011	Answered - in full
11/267	Public Assessment Report(s) - PL 00057/0985, PL 00057/0976, PL 00057/0980, PL 00057/0981, PL 00057/0982, PL 00057/0977, PL 00057/0979 (Treatment of venous thromboembolism (VTE) presenting clinically as deep vein thrombosis (DVT), pulmonary embolism (PE) or both	10 August 2011	Answered - in part
11/269	Information on convictions for selling illegal hair creams	20 July 2011	Answered - in full
11/273	Request for the last available PV Inspection report for Pierre Fabre Médicament.	04 August 2011	Answered - in part
11/274	Inspection reports for Aptuit in Kansas City, Missouri, USA for the December 2006 and May 2007 inspections	20 July 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/275	Information regarding the recall of Isotretinoin 20mg capsules	26 October 2011	Answered - in part
11/276	Adverse effects caused by Enalapril (Aug 1991)	03 August 2011	Answered - in full
11/277	PSURs for the ingredients in combination Ibuprofen plus Pseudoephedrine and for Zolmitriptan 2,5mg ODT (Orodispersible Tablets).	26 September 2011	Answered - in part
11/278	A List of MHRA approved facilities in INDIA	18 July 2011	Answered - in part
11/279	PAR for Epirubicin made by Ebewe PL 14510/0022	19 July 2011	Answered - in full
11/280	Inspection report for the Blood Bank Kings Park Hospital Stirling 6/1/11 (link to FOI 11/137)	12 August 2011	Answered - in part
11/282	PSURs relevant to the UK for the period 1992-96 for Prozac. Specifically, how many i) suicides or ii) suicide attempts or iii) 'serious' adverse events were reported in response to the patient reducing or withdrawing from Prozac (fluoxetine). This should include any of these adverse events being experienced up to 4 weeks post last dose	16 August 2011	Answered - in part
11/283	Information on the advertising complaint and investigation published 19/07/2011 by MHRA concerning the complaint "Corsodyl brochure produced by GSK- October 2010"	16 August 2011	Answered - in part
11/284	Reaction to SSRI's in relation to sexual dysfunction on cases reported to MHRA	16 August 2011	Answered - in full
11/288	Information regarding inspection and enforcement in respect of Chinese made drugs	12 August 2011	Answered - in part
11/289	Information regarding the MHRA estate holdings	31 August 2011	Answered - in full
11/291	PV inspection reports for: Intrapharm Laboratories Limited Meadow Laboratory Limited	05 August 2011	Answered - in part
11/292	Information on preservatives in eye drops about which MHRA has pronounced a concern	10 August 2011	Answered - in full
11/296	Information regarding the administration of the Pandemrix vaccine e.g. adverse effects	22 August 2011	Answered - in full
11/299	The amount of funding and staff time given to trade unions including money paid to all trade unions	31 August 2011	Answered - in full
11/300	Citalopram and carcinogenesis preclinical trial data	05 September 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/301	INSPECTION OUTCOMES including any GMP, GCP or pharmacovigilence violations for biotech, generics, pharmaceutical companies, CRO companies whose clinical investigation (human drug development) sites have been inspected in the last 12 months, ncluding names of inspectors, location details, dates and reason for inspection	23 August 2011	Answered - in part
11/302	Copies of the last MHRAGMP/GDP inspection reports on the following companies (LICENSE NUMBERS INCLUDED) DURBIN 4321 DISSPEC 32712 UL MEDICINES 25634 MASTERS 17220 ALAN PHARMACEUTICALS 4637 CRAIG AND HAYWARD 17832 QUANTUM SPECIALS 21923 LEXON 15184 NUPHARM LABORATORIES 20670 THE SPECIALS LABORATORY 17661 ORBIS CONSUMER PRODUCTS 17862 IPS/VERTICAL PHARMA 32879 BCM SPECIALS 34777 ROSEMONT 427 SPECIAL PRODUCTS 16786 PHARMARAMA 19054 NOVA LABORATORIES TEMAG 35315	25 August 2011	Answered - in part
11/303	Information on this years inspection of Rutland Biodynamics MIA 28255	17 August 2011	Answered - in part
11/304	Continuous monitoring of standards and products supplied by companies offering cut price medicines to patients through the NHS	02 September 2011	Answered - in part
11/305	Any information provided to MHRA by AstraZeneca concerning the effect of Seroquel on the QT interval - Study 0093, Study 013, Study 015 and Pfizer study 054.	06 September 2011	Answered - in part
11/307	A copy of the new analysis of the three randomised control trials as mentioned in the case of Risperidone. Licence of Risperidone in people with Dementia	07 October 2011	Answered - in part
11/310	Requesting information regarding the approval of Epogam for the treatment of eczema. 1. Safety 2. Toxicology 3. Clinical Trials	08 September 2011	Answered - in part
11/311	Comparison between fluoride in water and health salts in relation to being labelled medicinal products	05 September 2011	Answered - in full
11/313	Suspension of Notified Body for (Institute for Healthcare Quality Improvement and Hospital Engineering)	31 August 2011	Answered - in full
11/314	Temozolomide GENQ-00074588 request for data	09 September 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/316	Citalopram and carcinogenesis preclinical datas reviewed by MCA in 1989. Have MHRA done another study on this medicine, if so a copy of the results	05 September 2011	Answered - in part
11/317	A list of all MHRA transactions with the organisation Solace.	18 August 2011	Answered - in full
11/318	Copies of the original review documents (Chemistry, preclinial and clinical information) for Navoban (tropisetron) indicated for treatment of chemotherapy induced post-operative nausea and vomiting.	14 September 2011	Answered - in part
11/320	WERE ANY VACCINES USED IN THE UK EITHER NOW OR IN THE PAST CONTAIN MDCK CELLS OR THE MF59 ADJUVANT?	22 August 2011	Answered - in full
11/321	The last 10 Companies that received critical findings and the last Inspection for Claris Pharma and IS Pharma.	16 September 2011	Answered - in part
11/323	An anonymised summary of the adverse incident reports received relating to suburethral slings. The number of incidents reported and the type of incidents.	20 September 2011	Answered - in full
11/324	What are the outcomes of the public consultations? ARM 71 RADIAN B IBUPROFEN 5% W/W GEL 100G - REQUEST TO RECLASSIFY A PRODUCT FROM P TO GSL ARM 65 ALGOPAIN-EZE 140 MG MEDICATED PLASTER - REQUEST TO RECLASSIFY A PRODUCT FROM POM Ibuleve Speed Relief Max Strength Gel 10% W/W, Voltarol Pain-Eze Emugel and Voltarol Emugel P	28 November 2011	Answered - in part
11/326	Hip replacement problems with metal on metal implants	29 September 2011	Answered - in part
11/327	Details requested of any adverse incidents reported relating to broken P2 pump clips or faulty PS power supplies relating to Braun Infusomat space or perfusor space infusion devices.	26 September 2011	Answered - in part
11/329	Information on the total number of yellow card reports from market authorisation holders, general practitioners, hospital doctors, hospital pharmacists, community pharmacists, nurses and patients for the individual years between 2001 and 2010.	26 September 2011	Answered - in full
11/330	Inspection Reports (Years, 2003-2010) for DePuy International ,Limited	06 September 2011	Answered - in part
11/331	Adverse incidents and investigations related to heart lung machines during the last 5 years	26 September 2011	Answered - in part
11/332	Category 1b data for metronidazole for two routes of administration: Oral and Intravaginal	27 September 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/333	Assessment Report (or equivalent) for Pro-Plus, a product containing the active ingredient caffeine	22 September 2011	Answered - in part
11/334	Assessment report for the MAA of Benadryl Skin Allergy Relief Cream Benadryl Allergy Skin Cream PL 15513/0078 McNeil Products Limited or if not available the clinical expert report of the MAA	29 September 2011	Answered - in part
11/335	Questions regarding the demographics of employees at the MHRA Centre for Assistive Technology site at 241 Bristol Avenue, Bispham, Blackpool	03 October 2011	Answered - in full
11/336	Breakdown and details of adverse incident reports and near misses in relation to Magnetic Resonance Imaging within the UK over the last 10 years.	09 September 2011	Answered - in full
11/337	MHRA Audit C09068 - Richmond Pharmacology	29 September 2011	Answered - in part
11/338	The number of patients who reported adverse sexual effects caused by SSRIs to the MHRA prior to June 2006 whose contact information has been retained by the MHRA.	30 July 2011	Answered - in full
11/339	Artificially Fluoridated Water Satifies Definition of Medicine	26 September 2011	Answered - in full
11/340	Latest GMP inspection report for Pharmaserve Limited Clifton Technology Park Wynee Avenue Swinton Manchester M27 8FF	16 September 2011	Answered - in part
11/341	Various information regarding Proscar and Procepia	02 July 2012	Answered - in part
11/342	How many ADRs have been reported, and what action is being implemented in relation to CrescentPharma Metronidazole 400mg.	05 October 2011	Answered - in full
11/343	MHRA GMP inspection report for Catalent Pharma Solutions - Zydis in Swindon, Wiltshire, UK. An inspection occurred in April 2009	13 September 2011	Answered - in part
11/344	Request for MHRA's FOI statistics	12 September 2011	Answered - in full
11/345	Questions relating to Tamiflu and adverse reactions	12 October 2011	Answered - in full
11/346	Generic names of Sandoz	24 October 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/347	Any MHRA inspection report and findings for DHL Supply Chain Cherwell 1 Middleton Close Banbury Oxon UK during the years 2009 thru 2011	29 September 2011	Answered - in part
11/348	GDP inspection reports for Alliance Healthcare licence holder WL 538 SITE IDs : 16319, 16313, 884309, 16307, 16306, 16311, 16308, 16326	03 October 2011	Answered - in part
11/349	Information on the company operating as Pergamon Ltd	13 October 2011	Answered - in part
11/350	Request for Inspection reports for Genopharm and Alkopharma	05 October 2011	Answered - in full
11/351	GMP reports on latest list of plants inspected by MHRA in India	21 September 2011	Answered - in full
11/352	MHRA inspection report relating to Milan Laboratories Private Ltd	26 September 2011	Answered - in part
11/353	Risk assessments and policy documents relating to ministers advice	17 October 2011	Answered - in full
11/356	Details of the number of “undesirable effects” reported during the nationwide HPV vaccination programme .	17 October 2011	Answered - in full
11/357	MHRA report on GMP inspection of Catalent Pharma Solutions - Zydis in Swindon, Wiltshire, UK.	30 September 2011	Answered - in part
11/358	Request for the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery and a complete breakdown of the side effects	20 October 2011	Answered - in full
11/359	All MHRA inspections for Calea UK Ltd MS 18542 for the period 2005 up to and including the end of September 2011	14 October 2011	Answered - in part
11/361	MHRA GMP inspection report for Catalent Corby resulting from May 4-7, 2010 inspection	12 October 2011	Answered - in part
11/362	Does the MHRA holds records of risk assessments of medical devices. If so please provide 2 or 3 examples of such documents.	30 September 2011	Answered - in part
11/363	Questions relating to the equivalence (or otherwise) of generic products, and their site of manufacture.	03 October 2011	Answered - in full
11/364	Details of staff employed at Bispham Wheeled Mobility Centre	24 June 2013	Answered - in full
11/365	Details of information required the most recent MHRA GDP inspection reports for AAH sites	12 October 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/366	The assessment report on digifab	26 October 2011	Answered - in full
11/367	Request for all information relating to MMR vaccines	22 December 2011	Answered - in part
11/368	Research into CRC energy efficiency scheme and its potential longer-term effect on users of data centres.	29 March 2012	Answered - in full
11/370	The Clinical Assessment Report (or equivalent) in respect of the scientific evidence concerning the approved indication for relief of the symptoms of Irritable Bowel Syndrome	01 November 2011	Answered - in part
11/372	Request regarding generic drug substances. List attached to request	25 October 2011	Answered - in part
11/373	Details of the Rubicon inspection with any compliance or non-compliance statements generated.	14 October 2011	Answered - in part
11/374	Request for public documents/information – including public assessment reports; marketing authorization applications; quality/safety/efficacy documentation; inspection reports – for three product licenses:	25 October 2011	Answered - in part
11/375	How many clinical trials have been a - suspended b - terminated by the MHRA in the past five years?	03 November 2011	Answered - in full
11/376	1. Names of biotech, generics, pharmaceutical companies, CRO companies whose clinical investigation (human drug development) sites have been inspected in the period 01 August 2011 to 10 October 2011 2. Names of biotech, generics, pharmaceutical companies, CROs, CMOs whose manufacturing facilities and or headquarters have had GMP, GCP or pharmacovigilence inspections in the period 01 August 2011 to 10 October 2011 3. Location details and dates of the above sites and reason for inspection 4. Names of inspectors who visited these sites 5. INSPECTION OUTCOMES including any GMP, GCP or pharmacovigilence violations noted, any "warning" letters and reinspections that were issued as a result, involving the following companies: Novartis, Astrazeneca, Bayer, Roche, GlaxoSmithKline, Merck & Co, Bristol-Myers Squibb and Pfizer (in the period 01 August 2011 to 10	26 October 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/377	• Assessment reports produced by the MHRA – safety, quality and efficacy; • Papers submitted to Medicines Advisory Bodies; • Reasons for decisions taken by Medicines Advisory Bodies; and • Any general, non-specific information encompassing non-clinical and clinical development of the medicinal product(s); in relation to any Marketing Authorisation Applications submitted to the MHRA for fixed-dose combinations of amlodipine and atorvastatin.	20 October 2011	Answered - in full
11/379	Copies of any assessment by MHRA on relevant differences between escitalopram and citalopram	11 November 2011	Answered - in part
11/380	All copies of correspondence between MHRA and the people listed below, since April 2011, to the present time. Simon Singh David Colquhoun Peter Blanchard Alan Henness AP Gaylard Maria Maclachan	21 November 2011	Answered - in part
11/382	The last MHRA inspection report of our third party Pharmacovigilance service provider- PharSafer® Associates Ltd 29 Frederick Sanger Road, Guildford, Surrey. GU2 7YD.	10 November 2011	Answered - in part
11/383	We request the last MHRA inspection report for our third party medical information service provider- Professional Information Limited Olliver, Richmond, DL10 5HX, UK	10 November 2011	Answered - in part
11/384	Why have British health authorities have granted market approval for a Chloramphenicol-drug despite the known risk of aplastic anemia, which had led to the market withdrawal of this drug in many European countries.	12 October 2011	Answered - in full
11/385	The clinical pharmacology section of the Public Assessment Report for Cabergoline tablets (PL 18909/0191-4) refers on page 54 to two comparative bioequivalence studies. In relation to such studies, please provide: i) a copy of the application for clinical trials authorisation; ii) confirmation of the date on which clinical trials authorisation was granted; and iii) a copy of the full report provided to the MHRA of the Phase I trials in question.	12 December 2011	Answered - in part
11/386	Please provide a copy of the GMP Inspection report(s) from the 2011 inspection of Hospira Healthcare Pvt Ltd, Irungattukottai, Chennai, India. I understand that the inspection took place in April 2011. I would also appreciate a copy of any response that was submitted from the site if it is available.	27 October 2011	Answered - in part
11/387	Request for all copies of Atomoxetine hydrochloride (Strattera) used in the treatment of ADHD	14 November 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/388	How many Marketing Authorisations(MA) MHRA have issued each year? How many of them have been withdrawn due to manufacturing and quality issues each year? The names of companies who have had their MA's withdrawn due to manufacturing/quality issues	26 October 2011	Answered - in full
11/390	Request for information relating to the clinical overview (clinical expert report) package for the product Flixotide Evohaler	07 December 2011	Answered - in part
11/391	Copies of the inspection reports on Penn and Pharmarama	28 October 2011	Answered - in part
11/392	Information on the number of Incident reports you have received for Blood Glucose testing meters and their outcomes	27 October 2011	Answered - in full
11/393	Request a list of products that may have been granted as specials licenses over the last couple of years	14 November 2011	Answered - in full
11/394	Request for information on any unpublished clinical trials where participants with a schizophrenia-spectrum disorder diagnosis (or early psychosis) have been randomised under blind conditions to receive either quetiapine IR or placebo	19 December 2011	Answered - in part
11/395	The document required by MHRA from vaccine manufacturers regarding safety criteria and risk assessment before being government endorsed as a safety product	18 November 2011	Answered - in full
11/396	I would like to re-apply for a request for information for the latest GMP Inspection Report for Guy's and St Thomas NHS Foundation Trust Pharmacy Manufacturing Unit.	28 October 2011	Answered - in part
11/398	Relating to Tamiflu and adverse drug reactions/investigations	22 November 2011	Answered - in full
11/399	Various questions on The Directive on Traditional Herbal Medicinal Products (Directive 2004/24/EC)	22 November 2011	Answered - in part
11/400	Marketing authorisations submitted to the MHRA for fixed-dose combinations of amlodipine and atorvastatin. Assessment reports & Papers submitted to Medicines Advisory Bodies	08 November 2011	Answered - in full
11/402	Names of biotech, generics, pharmaceutical companies, CRO companies whose: clinical investigation sites have been inspected. manufacturing facilities and or headquarters have had GMP, GCP or pharmacovigilence inspections. INSPECTION OUTCOMES	16 November 2011	Answered - in part
11/404	Please could you provide each app that has been placed on the MHRA register as a medical device:	21 November 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/405	Request for information relating to trials	28 November 2011	Answered - in full
11/407	Has the MHRA received information relating to dental devices/implants and alloys	01 December 2011	Answered - in full
11/408	Clinical Assessment report for Galpharm Dual Action Diarrhoea Relief	24 November 2011	Answered - in part
11/409	PIL leaflets omissions	10 November 2011	Answered - in full
11/415	Request for inspection reports of all manufacturing facilities of GlaxoSmithKline since 2005	30 November 2011	Answered - in part
11/416	MAs and Manufacturers details for various Agents	29 November 2011	Answered - in part
11/417	Information relating to fitness equipment and classes in the MHRA	16 November 2011	Answered - in full
11/418	Information relating to clopidogrel and metabolism	05 December 2011	Answered - in part
11/419	Request for information concerning the dangers of using quetiapine with opioids;	30 November 2011	Answered - in part
11/420	All adverse event reports of patients taking voriconazole that developed squamous cell carcinoma;	15 November 2011	Answered - in full
11/421	PL 14207/0019 - Cardiolite Kit for the preparation of Technetium Tc 99m Sestamibi - Clinical expert report on DuP 843-044, DuP843-045 clinical trial	24 November 2011	Answered - in full
11/422	A copy of audit report and correspondences for Unique Pharmaceutical	14 November 2011	Answered - in part
11/423	MHRA GMP Inspection report for Aptuit (Glasgow) Limited Block K, Todd Campus, West of scotland Science Park, Acre Road, Glasgow, G20 OXA, United Kingdom	14 November 2011	Answered - in part
11/424	Citalopram and QT prolongation figures requested	07 December 2011	Answered - in full
11/425	PAR request for Nuromol 200mg/500mg tablets	24 November 2011	Answered - in full
11/426	There is a clear public interest public safety is potentially being compromised as a result of a failure of the Medicines and Healthcare products Regulatory Agency (MHRA) to enforce a Directive on Traditional Herbal Medicinal Products, which came into effect in May 2011	05 December 2011	Answered - in part
11/427	Request for EUSA Pharma PV inspection report where PharSafer (PV service provider) are listed as the responsible person	10 November 2011	Answered - in part
11/428	Request for assement reports of the medicinal product Cerazette (desogestrel 0,075 mg).	06 December 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
11/429	Clinical Trial data on TGN 1412 run by Paraxel at Northwick park	09 December 2011	Answered - in full
11/430	Request the clinical assessment for Mirena IUD (levenogestrel)	09 December 2011	Answered - in part
11/431	Request for a detailed explanation on why Fluoride in water is not a medicine	14 November 2010	Answered - in full
11/432	Questions regarding the importation of counterfeit drugs - Operation Singapore	14 December 2011	Answered - in full
11/433	Query relating to counterfeit drugs being seized in a recent operation with the UK Border Agency and Scotland Yard, culminating in 13000 websites closing down	15 December 2011	Answered - in full
11/434	MHRA clinical assessment reports for various transdermal FENTANYL patches;	08 December 2011	Answered - in part
11/435	The most recent copy of the MHRA audit report for Huntingdon Life Science,Suffolk, UK.	24 November 2011	Answered - in part
11/438	The Assessment Report (or equivalent) concerning the clinical data on safety and efficacy of AAA Mouth and Throat Spray (containing the active ingredient benzocaine)	12 December 2011	Answered - in part
11/439	Adverse reaction statistics relating to champix	19 December 2011	Answered - in full
11/440	Adverse reaction statistics relating to all medicines	19 December 2011	Answered - in full
11/443	Adverse reactions top ten drugs and top ten drugs that have caused fatalities between 1/1/2000 and 20/11/2011.	19 December 2011	Answered - in full
11/444	Public Assessment reports requested for: PL 17507/0148 PL 17507/0149	01 February 2012	Answered - in part
11/445	past and present positions of MHRA on the status of mephedrone (4-methylmethcathinone) as a medicinal product	19 December 2011	Answered - in full
11/447	Request for the most recent inspection report for Lonza Biologics, plc	09 December 2011	Answered - in part
11/448	Establish which companies hold current import licences for any of Ferring products.	07 December 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/449	My questions relate to Tamiflu and are as follows: * Please can you supply me with appropriately redacted copies of all letters and emails concerning Tamiflu that the MHRA has received through 2010 and 2011. * Has the MHRA ever made any complaints to Roche relating to the use, effective administration, quality, performance, safety and durability of the product? If so, please detail complaints and replies. * Please detail all data and information made known to the MHRA obtained by Roche whether in clinical trials or otherwise or any other matters relating to the safety and/or efficacy of the product including the balance of risk and benefits of using the product. * Has the MHRA been informed by Roche of any actual or suspected adverse reaction to the product not described in the summary of product characteristics? If so, please detail such."	21 December 2011	Answered - in part
11/451	Request for PAR details on Corocard ASA 5/75 mg Capsules and Corocard ASA 10/75 mg Capsules	30 November 2011	Answered - in full
11/453	Request for the latest inspection reports of certain manufacturing facilities	09 December 2011	Answered - in part
11/454	MA on Spiriva HandiHaler documents requested.	22 December 2011	Answered - in part
11/455	Request for a copy of inspection report for Alkem Laboratories, Dr. Reddy's Laboratories	05 December 2011	Answered - in part
11/456	The number of seizures of fake/ counterfeit medicines for the months from January 2005 to (and including) October 2011 The number of seizures of fake/ counterfeit medical devices for the months from January 2005 to (and including) October 2011	29 December 2011	Answered - in part
11/457	How many people have to report a vaccine before MHRA recognise it has a safety issue	16 December 2011	Answered - in full
11/458	PAR for breast indication in the investigation of patients with suspected breast cancer when the results of mammography are unsatisfactory or equivocal	22 December 2011	Answered - in part
11/459	request for access to the PV Inspection Report of the MAH "B. Braun Melsungen AG"	01 December 2011	Answered - in part
11/461	Request for a report of the funds received by the MHRA by Herbal companies granted the THR or whose licensing of herbal products is being reviewed.	19 December 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/462	Request for minutes of various meetings relating to the Traditional Herbal Medicinal Products Directive (Directive 2004/24/EC)	20 December 2011	Answered - in part
11/463	Information on the scientific evaluation performed by the MHRA during the marketing authorisation applications of Ventolin Evohaler (CFC free)and Airomir Inhaler (CFC free)	03 January 2012	Answered - in part
11/464	Information on Glivec (imatinib) in relation to changes in authorisations	16 December 2011	Answered - in part
11/466	Inspection report on MUNRO WHOLESALE MEDICAL SUPPLIES LIMITED/STRATHCLYDE PHARMACEUTICALS) LIMITED	09 December 2011	Answered - in part
11/468	All information relating to Tribulus terrestris as a medicine	03 January 2012	Answered - in full
11/469	PAR on Zoladex3.6mg and 10.8mg	03 January 2012	Answered - in part
11/471	Inspection report for MIA 14 THE BOOTS COMPANY PLC	09 December 2011	Answered - in part
11/473	Explanation of assessment process and communication with Ethicon	06 January 2012	Answered - in part
11/474	I am requesting to be informed of the number of reports received by the MHRA of adverse sexual effects caused by SSRIs.	09 January 2012	Answered - in full
11/475	Information on SSRIs.	15 December 2011	Answered - in full
11/476	SODIUM FLUORIDE information required on matters which were considered by the Commission on Levels and availability	15 December 2011	Answered - in full
11/479	The name of the company that received the "formal caution" in October 2011 and to be advised of the five complaints (companies) who have been investigated and found not to be in breach	10 January 2012	Answered - in part
11/481	Request for Inspection report for AMRI	05 January 2012	Answered - in part
11/482	Query of export of medicines in short supply	10 January 2012	Answered - in part
11/483	Request for a copy of any GMP Inspection Report(s) issued for Auxilium UK Limited in 2010-2011	16 December 2011	Answered - in full
11/484	Request for information of possible link between HPV vaccine and CFS	11 January 2012	Answered - in full
11/486	MA Assessment report requested	17 January 2012	Answered - in part
11/488	Information on Manufacturers in China	16 December 2011	Answered - in full

FOI no	Subject	Date reply sent	Result of request
11/490	Request for Pharmacovigilance reports with critical findings.	12 January 2012	Answered - in part
11/491	PAR for ropinirole extended release tablets	22 December 2011	Answered - in part
11/492	Request for Import notifiations for unlicensed product Rimso 50	22 December 2011	Answered - in part
11/494	Request for a Periodic Safety Update Report (PSUR) for VIAGRA ®	11 January 2012	Answered - in part
11/495	Request for various information on Clozapine for project	21 February 2012	Answered - in part
11/497	Request for GMP Inspection Report of MACFARLAN SMITH LIMITED	22 December 2011	Answered - in part
11/498	The CHM, CPS and Haematology Expert Advisory Groups comments in September 2011 in respect of Iron Sucrose 20mg/ml Solution UK/H/3488/01/DC	19 January 2012	Answered - in part
12/002	Various questions about Clozapine with a pre-existing Sinus Tachycardia and Right Atrial Enlargement as found on ECG.	27 January 2012	Answered - in full
12/003	PIP breast implants	12 March 2012	Answered - in part
12/005	Clozapine in respect of "reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders"	30 January 2012	Answered - in full
12/006	Licensing of GSK's Avandia / Rosiglitazone by the EMA and MHRA	31 December 2011	Answered - in full
12/007	Request for number and details of Clinical Phase II trials and the value of each for 2011	02 February 2012	Answered - in part
12/008	A copy of the latest GMP Inspection Report for the GSK site at Worthing, West Sussex, UK	13 January 2012	Answered - in part
12/009	Details (Both actual figures and estimates) for the last 5 years of: The quantity of unregulated sildenafil purchased by UK consumers. The quality of the unregulated product and how it compares to the licensed product both quantitatively and qualitatively in terms of active ingredients, excipients, impurities etc. Are there any emerging trends IE an increase/ decrease in quality? Details of suspected Adverse Drug Reactions (including deaths) related to the use of unregulated sildenafil and any assessments undertaken of whether this may relate directly to the quality of the unlicensed product. Details of the supply chain from manufacturer to consumer eg internet sales etc.	31 January 2012	Answered - in full
12/016	Adverse reports from Roche in relation to Tamiflu	03 April 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/017	Any details of UK trials using 3mg immediate release melatonin - either tablet or capsule	10 February 2012	Answered - in full
12/018	Various questions regarding Neurolite	16 January 2012	Answered - in part
12/019	Periodic Safety Update Report - Dibenyline Capsules 10mg	03 February 2012	Answered - in part
12/020	The last/latest MHRAGMP inspection report on-- Macleods Pharmaceuticals Ltd, Village Theda, P.O Lodhi Majra, Tehsil Nalagarh, District Solan, Himachal Pradesh, 174 101, INDIA.	17 January 2012	Answered - in part
12/021	Copies of the most recent MHRA GDP/GMP inspection reports for the following companies, and copies of their responses:- UL Medicines license number 31610 Masters Pharmaceuticals license 8394 Safedale 4370 Manichem 31260 J N K company 6775 Craig and Hayward license number 17832 John Bell and Croyden 13315 Clinigen 31644	26 January 2012	Answered - in part
12/023	Supply of Trifloroperazine 1mg tablets, progress of application to the MHRA by Goldshield.	03 February 2012	Answered - in full
12/024	Various questions about Clozapine and Amisulpride.	15 February 2012	Answered - in full
12/025	The two latest MHRA GMP inspection reports + responses for Quay Pharmaceuticals Ltd (Quay Pharma)	26 January 2012	Answered - in part
12/027	Minutes of the CHM meeting regarding Iron Sucrose	10 February 2012	Answered - in part
12/028	Generic versions of 'Propecia'	19 January 2012	Answered - in part
12/030	Disclosure of the MHRA pre-clinical and clinical assessment reports for DigiFab® 40 mg/vial digoxin immune Fab, powder for solution for infusion (PL 21744/0001), that are releasable, not containing commercially confidential information.	03 February 2012	Answered - in full
12/031	Members of expert working group, meeting minutes to date and other details regarding the review of the use of N-Acetylcysteine for treatment of paracetamol overdose	30 October 2012	Answered - in part
12/032	Assessment report for Solian 50 and Solian 200 (PL 15819/0001 and PL 15819/0002)	05 March 2012	Answered - in part
12/033	Fludara IV and Fludara PO - original and extension of indication assessment reports.	17 February 2012	Answered - in part
12/035	PSURs / safety relevant data for Paracetamol.	02 April 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/036	All the notifications received by the MHRA under SI2005/2789 in the period 01 jan 2011 to March 2011?	24 January 2012	Answered - in full
12/037	Various details relating to the safety trials of the HPV vaccine, Cervarix.	27 February 2012	Answered - in full
12/039	Recent inspectional information MHRA may hold on various Indian and Chinese sites	31 January 2012	Answered - in part
12/040	An explanation as to the requirement for 5 inspectors and when in the last 10 years has this been occasioned on a routine inspection.	21 February 2012	Answered - in part
12/041	A breakdown of the Board's hardware maintenance and costs: A list of the models of the physical servers, storage devices, tape libraries, network switches and routers under support contracts; as well as the cost and duration of said contracts, with start and end dates and service level associated with the equipment. Also the names of the suppliers of aforementioned support services? The name of the person/s in your organisation responsible for the maintenance support contracts.	27 January 2012	Answered - in full
12/042	Information on inspections and investigations into Ranbaxy.	22 February 2012	Answered - in full
12/043	Location of sites for pivotal clinical trials. Rofecoxib Rosiglitazone Drospirenone	22 February 2012	Answered - in part
12/044	Differences in generic brands and name brand of Effexor.	02 February 2012	Answered - in full
12/045	Investigations, product recalls, removal of ingredients/claims and legal/informal actions regarding food supplements.	27 February 2012	Answered - in part
12/046	Risk assessments of sling, crossbar and gantry hoist	10 November 2011	Answered - in full
12/047	Number of patients who reported adverse sexual effects caused by SSRIs	28 February 2012	Answered - in full
12/049	Lists of Phase 1 Accredited Units published on the MHRA website between April 2009 and November 2011.	01 February 2012	Answered - in full
12/050	List of all unlicensed medicines for which import notifications have been received by the MHRA in 2008, 2009, 2010, 2011, with the number of import notifications received in respect of each unlicensed medicine in this list together with the Non-Proprietary Product Name and Proprietary Name(s) for each product	01 February 2012	Answered - in full
12/051	Copy of the last MHRA inspection report for Movianto	28 January 2011	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/055	Cerazette 75 mg tablet - any reports/data that would help to determine whether the sponsor was required to conduct a bone-mineral density study or anything to do with either bone-mineral density or metabolism as this is a progestin-only pill	01 March 2012	Answered - in part
12/057	Request for all documents/emails meeting reports , minutes and official communications on PIP implants timescale to Jan 01 2010 - June 30 2010?	02 March 2012	Answered - in part
12/058	Any information on Data and information relating to the composition of the filler used in PIP implants and any information resulting from testing of this filler. Who makes the filler, it's name/brand name, along with it's composition	06 March 2012	Answered - in part
12/060	Names of biotech, generics, pharmaceutical companies, CRO companies, CMOs who have had various inspections in July to December 2011, including locations and names of inspectors.	05 March 2012	Answered - in part
12/061	Correspondence relating to Bedrocan and/or its prescription or availability in the uk held by the MRHA. Any documents issued as guidance or any correspondence between the PCT's and the MHRA regarding the limitation or inability to prescribe non-uk licensed European drugs in particular any that relate to cannabinoid medications.	02 March 2012	Answered - in part
12/063	Various questions relating to Sativex and Bedrocan.	02 March 2012	Answered - in part
12/066	(SmPCs) for various ROBINUL expired MA's.	20 February 2012	Answered - in part
12/067	Intended indication for certain Glycopyrrolate imports, their expected treatment duration in these indications and their preparation strengths?	17 February 2012	Answered - in part
12/068	Various questions on powers of entry 2008 – 2011, including: how many times such powers were used in the past three years, the legislation they were requested under, the criminal offence or allegation being investigated and the outcome of their use, if any.	01 March 2012	Answered - in part
12/070	Most up-to-date list of "MHRA APPROVED MANUFACTURING PLANTS (SITES) BASED IN INDIA" for manufacturing of Generic drugs,	14 February 2012	Answered - in full
12/071	How many MHRA audits have been conducted on Aptuit Drug Manufacturing Services sites in past 5 years in EU, USA and Rest of the World? Any audit reports available? Any critical issues?	13 March 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/072	How many MHRA audits have been conducted on Pharmaceutics International Inc (Pii) Drug Manufacturing Services sites in past 5 years in EU, USA and Rest of the World? Any audit reports available? Any critical issues?	21 February 2012	Answered - in full
12/075	Information relating to the HPV vaccines, Cervarix and Gardasil. Policy and methodology on investigating adverse drug reaction reports highlighted by the yellow card scheme in relation to the HPV vaccines.	12 March 2012	Answered - in full
12/076	Information about the 2 fatal reports in the reports of side effects by Gardasil.	01 March 2012	Answered - in full
12/078	Details of your current contracts for the provision of temporary or agency staff.	15 April 2012	Answered - in part
12/079	Which 'Controlled Drug' is Sativex?	15 March 2012	Answered - in full
12/083	All complaints to the MHRA between 2000 and 2012 and how they were dealt with.	20 March 2012	Answered - in part
12/086	Copy of the inspection report of the audit conducted from 28th June – 2nd July 2010 at the premises of Bioreliance Glasgow	22 February 2012	Answered - in part
12/089	List of pediatric paxil/seroxat clinical trials that caused glaxosmithkline to report adverse reactions or safety concerns to the MHRA in periodic safety update reports between april 2004 and September 2002.	20 March 2012	Answered - in part
12/090	PSURs / safety relevant data for Cimicifuga racemosa.	21 March 2012	Answered - in part
12/091	Latest inspection / audit reports for the following pharmaceutical (import / export) wholesale companies; - SPL (2004) Limited (licence holder WL 33273) - Ecosse Pharmaceuticals Limited (licence holder WL 19065)	06 March 2012	Answered - in part
12/092	Documents concerning application to MCA by Penn Pharmaceuticals (and possibly others) to allow wider distribution of their drug Paradote. Specifically, copies/transcripts of a hearing on or about June 22, 1996 concerning this matter as well as any related comments or submissions by the sponsor and other interested parties.	20 March 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/093	Detailed cases of dosing errors related to the solution Retrovir° from the UK national pharmacovigilance and/or medication errors database; the latest PSUR related to Retrovir° oral Solution. A paediatric investigation plan is it being developed on zidovudine, indicating the development of distinct forms, concentrations, packaging adapted to different paediatric populations?	20 March 2012	Answered - in part
12/094	Whether various companies and individuals have ever been investigated by the UK government/MHRA (specifically in relation to counterfeit drugs)?	20 March 2012	Answered - in full
12/095	List of Contract Research Organisations currently subject to MHRA licensing	28 February 2012	Answered - in full
12/096	Obtaining leaflets in alternative formats	27 February 2012	Answered - in part
12/097	Questions about the marketing authorization for Cardiolite	23 March 2012	Answered - in full
12/098	Various questions on benzylpenicillin (penicillin G) potassium, benzylpenicillin sodium and Crystapen injection and their MA's.	12 March 2012	Answered - in part
12/099	Number of ' Possible systemic adverse reactions' filed by GP's for the years 2007,8,9,10,11 and 2012 in relation to the PIP implant.	03 July 2012	Answered - in full
12/100	Latest list of plants inspected by MHRA in India.	27 February 2012	Answered - in full
12/102	Various questions about British Pharmacopoeia (license, costs, format, compilation etc..).	14 March 2012	Answered - in part
12/103	Information on the legal basis of approval, year of approval, and assessment information as provided in the Preclinical and clinical expert reports for Venofer and any other information relevant to it's use.	26 March 2012	Answered - in part
12/104	Information on the legal basis of approval, year of approval, and assessment information as provided in the Preclinical and clinical expert reports for Fersaday and Fersamal and any other information relevant to it's use.	28 February 2012	Answered - in full
12/105	Details of concerns linking benzodiazepines and z drugs to an increased risk of death referred to by the MHRA in the article (Guardian - Dr D F Kripke) including any related documents, minutes of meetings/discussions mentioning these dangers.	27 March 2012	Answered - in part
12/106	Details of the complainant to MHRA (of complaint received about advertising of "Botox")	05 March 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/108	Dates on which follow up requests were made in relation to the 32 ADR reports of SSRI induced sexual dysfunction which were received prior to the change to the ADR database in 2006 that were followed up after the change to the database. Also the number of these follow up requests that were made prior to Freedom of Information Act request 11/284 received on 19/07/2011 regarding the follow up of ADR reports.	28 March 2012	Answered - in full
12/110	Information on whether any criminal charges were filed against any employees of Aptuit working at the Riccarton facility.	13 March 2012	Answered - in full
12/112	Validity conformation of GMP certificate № UK GMP 35012 Insp GMP 35012/860416-0002 issued on name UNIQUE PHARMACEUTICAL LABORATORIES, India, Daman, postcode 396210	05 March 2012	Answered - in full
12/113	Last inspection report of Professional Information Limited	14 March 2012	Answered - in part
12/114	Summary for the period 1st January 2009 to 31st December 2011 covering urine collection bags (bed bags and patient leg bags).	26 March 2012	Answered - in full
12/115	Information on the legal basis of approval, year of approval, and assessment information as provided in the Preclinical and clinical expert reports for Fersaday and Fersamal	26 March 2012	Answered - in part
12/119	MHRA inspection dates for UK registered sites for both GCP and GMP Registered Facilities for 2012.	02 April 2012	Answered - in full
12/120	Licensing information on beclomet(h)asone inhaler drugs and beclometasone-formoterol inhaler drugs, in particular the evdince supporting its licensing, and the details of those trials.	29 March 2012	Answered - in full
12/121	MHRA's Mobile Phone and PBX/VOIP maintenance contracts	04 April 2012	Answered - in full
12/122	Eli Lilly Medication Olanzapine / Zyprexa Whether MHRA is fully aware that Olanzapine / Zyprexa causes severe health risks. Whether the MHRA is aware of Olanzapine / Zyprexa Legal class Action in the USA and that this has been successful. Why Olanzapine / Zyprexa is still being prescribed in The UK despite open knowledge that it causes severe health risks. whether the MHRA has knowledge of the VIva Zyprexa and Zyprexa Limitless marketing campaigns.	11 April 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/123	Copies of any adverse event reports received by the MHRA for the following products: Lemsip Cold & Flu Breathe Easy (PL 00063/0041) Lemsip Max All in One Breathe Easy (PL 00063/0538) Beechams Flu Plus Hot Lemon (PL 0079/0323) Beechams Flu-Plus Hot Berry Fruits (PL 00079/0336)	09 March 2012	Answered - in full
12/125	Copies of all q&a style documents that the MHRA press office has used in the past 12 months regarding the PIP implant story and a copy of the MHRA press office's current crisis management strategy, and copies of the current Q&A's that it refers to in its dealings with the media.	17 April 2012	Answered - in part
12/127	2010 GMP inspection report and company repsonses for Rusan Pharma Ltd Plot no. 59 to 65, sector II Kandla special economic zone, Gandhidham, Kutch- 370230 Gujarat. India	23 March 2012	Answered - in part
12/129	All available Pharmacovigilance Inspection reports released by the MHRA in the last 2 years	23 March 2012	Answered - in part
12/130	Why is Woodwards Gripe Water being investigated	23 March 2012	Answered - in full
12/131	All the information you have about the privacy design for the Clinical Practice Research Datalink (CPRD)	18 April 2012	Answered - in part
12/132	Assessment Report(s) associated with the increase in GSL pack size 20 to 40 tablets, subject of ARM 26, concerning Dulcolax.	17 April 2012	Answered - in part
12/133	Correspondence between MHRA and Amgen between 1 January 2006 and 31 December 2008 that addresses the safety and efficacy of biosimilar medicinal products.	23 May 2012	Answered - in part
12/134	Information on DSM Pharmaceutical Products Inc. (part of Royal DSM-NV) Relating to the manufacture of both drug product and drug substance. 1. How many MHRA audits have been conducted on their sites in past 5 years in EU, USA and Rest of the World? 2. Any audit reports available? 3. Any critical issues?	26 March 2012	Answered - in full
12/139	Up to date numbers of supplies on a monthly break down (or similar) requested as Notifications under S11999/4 or SI 2005/2789 for the import of unlicensed methacholine products	27 March 2012	Answered - in full
12/141	Information regarding MHRA staff salaries, benefits and bonuses	30 April 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/142	Summary of the Vasoconstriction study for the following Clobetasone Licences: Eumovate Cream – Glaxo Wellcome UK Limited – PL 10949/0035 Eumovate ointment – Glaxo Wellcome UK Limited – PL 10949/0037	20 April 2012	Answered - in part
12/143	Information about MHRA's use of the Regulation of Investigatory Powers Act 2000 (RIPA) and the Regulation of Investigatory Powers Act 2000 Scotland (RIPSA)	24 April 2012	Answered - in full
12/146	Request for information on Adverse Reactions and outcomes	25 April 2012	Answered - in full
12/147	Toxicology information relating to the composition of the filler used in PIP implants and any information resulting from testing of this filler	25 April 2012	Answered - in part
12/148	The information held by the MHRA notified bodies and confidentiality regulations	26 April 2012	Answered - in part
12/149	The total number of PV and GCP inspections performed by the MHRA in the last two years, detailing which country they were performed in	23 April 2012	Answered - in full
12/152	Paradote Tablets (PL 04351/001	30 April 2012	Answered - in part
12/154	The figure of any and all children that have died whilst on BNF category 4.4 CNS stimulants and drugs used for ADHD	01 May 2012	Answered - in full
12/155	A summary of the efficacy and safety data supporting the MAAs for Amibsome and Abelcet, which are liposomal formulations of amphotericin B	27 April 2012	Answered - in part
12/156	Please provide the tentative dates and company names of MHRA's planned Pharmacovigilance related inspections for 2012	23 April 2012	Answered - in full
12/158	Summary of the efficacy and safety data submitted to support the MA Application for Amphocil (amphotericin B), MAH: Beacon Pharmaceuticals Ltd	31 May 2012	Answered - in part
12/160	Public Assessment Reports (or equivalent) for products which received a marketing authorisation prior to 2005.	04 May 2012	Answered - in part
12/161	List (dates and name of inspected parties) of all MHRA GCP inspections conducted and planned in 2012.	04 April 2012	Answered - in part
12/163	Whether a UK marketing authorisation has ever been sought for the product FOCALIN XR (Dexmethyphenidate)	01 May 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/164	Total number of ADRs received in 2011 and how many drugs were involved, how many of those ADRs contained a fatal outcome, which ten drugs (ie the ten highest) had the highest fatal outcome reports and how many of each;	04 May 2012	Answered - in full
12/167	Questions about exports, logistics for moving to "England" for distribution and what controls are in place for "dangeorus copy drugs" produced by "54 allegedly unregulated Chinese drug factories".	08 May 2012	Answered - in part
12/168	RMP and date of authorisation for generics on the market with the 500mg strength product (of Zithromax Capsules, licensed to Pfizer Limited)	26 April 2012	Answered - in full
12/170	Listing of all GMP inspections conducted by MHRA in 2011	12 April 2012	Answered - in full
12/172	MHRA GMP inspection reports for Emcure Pharmaceuticals in Pune, India.	03 May 2012	Answered - in part
12/174	The 2010 and any more recent GMP inspection reports for IPCA Laboratories Limited in Silvassa, India	23 April 2012	Answered - in part
12/175	Various questions on the number of Subject Access Requests and the agency's performance in answering them over the last 3 financial years.	01 May 2012	Answered - in full
12/176	Case notes / ADR report made for the enquirer (while he was a patient).	09 May 2012	Answered - in full
12/180	GMP Inspection Reports issues for the following API manufacturing site: SAFC PHARMA THE OLD BRICKYARD NEW ROAD GILLINGHAM DORSET SP8 4XT UNITED KINGDOM From the GMP Certificate posted on the company website it appears that an inspection was performed by Malcolm Olver on 28/09/2009.	09 May 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/184	ADRs for the following BNF categories. 1) Re: BNF Category 4.1. Total Number of ADRs reported on Drugs used for Hypnotic and Anxiolytics for the past 10 years. Include in this report a breakdown of numbers of where the ADRs originated from, i.e. number from pharmaceutical companies, number from healthcare professionals and number from patients, etc.. 2) Re: BNF Categeory 4.2. Total Number of ADRs reported on Drugs used in Psychoses related disorders.for the past 10 years. Include in this report a breakdown of numbers of where the ADRs originated from, i.e. number from from pharmaceutical companies, number from healthcare professionals and number from patients, etc. 3) Re: BNF Category 4.3. Total number of ADRs reported on Antidepressant drugs. Include in this report a breakdown of numbers of where the ADRs originated from, i.e. number from from pharmaceutical companies, number from healthcare professionals and number from patients, etc. 4) Re: BNF Category 4.4. Total number of ADRs reported on CNS stimulants and drugs used for ADHD. Include in this report a breakdown of numbers of where the ADRs originated from, i.e. number from from pharmaceutical companies, number from healthcare professionals and number from patients, etc.	21 May 2012	Answered - in full
12/186	Copies of the following in relation to the above product: •Papers submitted to Medicines Advisory Bodies •Reasons for decisions taken by Medicines Advisory Bodies •Company expert reports/Common Technical Document relating to overall summary- safety, quality and efficacy: specifically the clinical overview (or clinical expert report) for the Marketing Authorisation granted on 15th September 2010 by the MHRA for the product Nuromol 200mg/500mg tablets; UK MA number: PL 00063/0579	18 May 2012	Answered - in part
12/187	Copies of the following in relation to the above products: •Papers submitted to Medicines Advisory Bodies •Reasons for decisions taken by Medicines Advisory Bodies •Company expert reports/Common Technical Document relating to overall summary- safety, quality and efficacy: specifically the clinical overview (or clinical expert report) for the Marketing Authorisation granted on 22 June 2011 by the MHRA for the products Perindopril /Amlodipine 4mg/5mg, 4 mg/10 mg, 8 mg/5mg and 8 mg/10 mg tablets; UK MA number: PL 01656/0114-7 & 0133-40	15 June 2012	Answered - in part
12/191	Copy of letters between Novartis and MHRA regarding Methylphenidate	30 May 2012	Answered - in part
12/192	Reason for inspection performed at Richmond Pharmacology Ltd in August 2010.	30 April 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/193	Multiple questions regarding the contact between senior MHRA staff and Ministers/stakeholders over THM Directive implementation and guidance note 8.	28 May 2012	Answered - in part
12/195	Complaints received from clinical trial sponsors about Richmond Pharmacology Ltd. and the identities of the Production manager, QA manager and QP on their MIA IMP license.	03 May 2012	Answered - in part
12/196	Copy of CSM guidance and recommendations distributed to GP's in England on 9 March 2004 concerning Olanzapine and Risperidone.	04 May 2012	Answered - in full
12/199	Did any trust make a return relating to BSQR that stated:- 1. That they had no non-compliances (ie they were fully compliant). 2. That they had critical or serious non compliances. 3. Where trusts reported as at 1. or 2. - what action did MHRA take on these reports.	04 May 2012	Answered - in full
12/200	Blood Compliance Reports	31 May 2012	Answered - in full
12/201	Information regarding the granting of a marketing authorisation in respect of co-codamol	20 June 2012	Answered - in part
12/202	Traditional Herbal Medicinal Products - what plans does the Medicines and Healthcare products Regulatory Agency (MHRA) have to launch a formal consultation on MHRA Guidance Note 8 'A guide to what is a medicinal product'	07 June 2012	Answered - in full
12/203	How many applications were approved for importation of unlicensed medicines under SI 2005/2789. Please detail, by product (Brand and generic named) and ALSO by manufacturer of product how many applications were approved for import for the last 12 months.	11 May 2012	Answered - in part
12/204	Details of prosecutions brought by MHRA	06 June 2012	Answered - in full
12/205	Various questions relating to MHRA's IT strategy, procurement, staffing etc	11 June 2012	Answered - in part
12/206	Letters/e-mails sent from the manufacturer of Concerta, Janssen-Cilag, to MHRA as part of the application process for Concerta to adults.	12 June 2012	Answered - in part
12/207	Various questions about cannabinoid levels and substances in Sativex.	28 May 2012	Answered - in part
12/208	Copy of the last MHRA inspection report of Oman Pharmaceuticals.	18 May 2012	Answered - in part
12/210	Warfarin public assessment report stabilty data.	20 June 2012	Answered - in part
12/211	Information on the clinical evaluation of Panadol Night (PL 00071/0423), including the clinical aspects and summaries of the clinical studies conducted	12 June 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/213	Copy of the Clinical Expert Report or a summary of the clinical data supporting the MA Application for Transtec transdermal patches	14 June 2012	Answered - in part
12/215	Number of adverse drug reactions reported on herbal medicines/remedies, homeopathic medicines/remedies, phytomedicines, ayurvedic medicines etc. And adverse drug reactions to any of the areas of complementary medicine.	27 June 2012	Answered - in full
12/218	The last 3 pharmacovigilance inspection reports for GNE/Roche	24 May 2012	Answered - in part
12/220	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs, broken down into various categories	19 June 2012	Answered - in full
12/221	A copy of the MHRA inspection report of Melbourn Scientific Limited , 3 - 4 May 2011	30 May 2012	Answered - in part
12/223	Names of biotech, generics, pharmaceutical companies, CRO companies whose clinical investigation (human drug development) sites have been inspected in the period 01 January 2012 to 30 April 2012 2. Names of biotech, generics, pharmaceutical companies, CROs, CMOs whose manufacturing facilities and or headquarters have had GMP, GCP or pharmacovigilence inspections in the period 01 January 2012 to 30 April 2012 3. Location details and dates of the above sites and reason for inspection 4. Names of inspectors who visited these sites 5. INSPECTION OUTCOMES including any GMP, GCP or pharmacovigilence violations noted, major or critical findings that were issued as a result, any "warning" letters that were issued as a result, any reinspections that were issued as a result.	20 June 2012	Answered - in part
12/224	The last pharmacovigilance inspection reports for the following companies: Gilead, Amgen, Johnson and Johnson	15 June 2012	Answered - in part
12/225	Various questions on the approval process, post marketing surveillance results and other assessment reports/scientific papers on Zoloft (sertraline), a selective serotonin reuptake inhibitor (SSRI) developed, manufactured, and distributed by Pfizer.	04 July 2012	Answered - in part
12/226	Covance Laboratories of Harrogate report into constituent parts of PIP Breast Implants	11 June 2012	Answered - in part
12/227	Information regarding the status of the trials in Nottingham University relating to the use of helminths in autoimmune diseases? More specifically - is there a possibility that helminths may be granted a pharmaceutical license to allow them to be used/prescribed within an NHS setting, in particular for Crohn's disease?	13 June 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/228	What type of information does the MHRA hold regarding ongoing or past approvals under the CE mark process for medical devices under EU regulations?	20 June 2012	Answered - in part
12/231	Inspection report (copy) for the site issued by MHRA for Milan Laboratories	14 June 2012	Answered - in part
12/232	Information regarding List of MHRA approved facilities in Turkey	14 June 2012	Answered - in full
12/233	All data relating to and results of the commissioned toxicity testing, genotoxicity and chemical toxicity on PIP implants. Names and credentials of "relevant experts" with whom data from the above referenced tests was shared for opinion.	16 July 2012	Answered - in part
12/234	The exact list of chemicals found in PIP breast implants, and the concentrations they were found in The amount of implants tested A brief assessment of the particular methods used to extract these chemicals	16 October 2012	Answered - in part
12/236	Environmental Risk Assessment (ERA) of a combination therapy containing ceftazidime	03 July 2012	Answered - in full
12/238	MHRA reportedly wrote to a number of detox manufacturers asking them to withdraw medical claims. State for each case the details of what law was being broken and why, as specifically communicated to the manufacturers in the MHRA request to ask them to stop.	03 July 2012	Answered - in part
12/240	Formulation and approval of Chloramphenicol 1.0% w/w Eye Ointment (PL17918/0004)	02 July 2012	Answered - in part
12/243	PV Inspection reports sent with FOI 07/084	06 July 2012	Answered - in part
12/245	Correspondence between the MHRA and Ainsworths regarding the regulation of unlicensed homeopathic medicines, since January 2011. Correspondence between the MHRA and Helios Homoeopathy regarding the regulation of unlicensed homeopathic medicines, since January 2011.	23 July 2012	Answered - in part
12/246	The MHRA GMP Inspection Report (between the years 2009 and 2012) of Almac Clinical Services 4204 Technology Drive Durham, NC 27704 USA	06 July 2012	Answered - in part
12/248	Various questions about impurities, contaminants, degredation products in Sativex and whether Sativex falls into a class B drug.	26 July 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/249	Copies of all documents submitted (to date) to Professor Sir Bruce Keogh's expert advisory group relating to analytical work carried out by LGC on PIP breast implants and medical grade breast implants, all reports/findings/documents produced by or related to the independent toxicology and chemical expert group led by Professor Ian Kimber submitted (to date) to Professor Sir Bruce Keogh's expert advisory group, copies of all test results relating to FTIR (Fourier Transform Infrared Spectroscopy), GC-MS (Gas Chromatography Mass Spectrometry) and ICP-MS (Inductively Coupled Plasma Mass Spectrometry) tests on both PIP implants and medical grade breast implants. Disclose whether LGC will be able to or has supplied information on the concentrations of siloxanes in the batches of PIP and medical grade silicone that they have analysed.	30 July 2012	Answered - in part
12/250	Various questions on the drug Primodos, including copies of minutes of meeting which requester, Minister and MHRA & DH officials were present at in December 2010.	02 July 2012	Answered - in full
12/251	Outcomes for the last 3 MHRA inspections reports for each of the territorial health boards in NHS Scotland.	26 July 2012	Answered - in part
12/252	The name of each individual ingredient (substances) in the make up of; and the quantity of each individual ingredient for Betahistine Hydrochloride and Betahistine Di-Hydrochloride.	03 July 2012	Answered - in part
12/255	What the 68 chemicals/chemical compounds are in PIP breast implants.	31 July 2012	Answered - in part
12/256	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/257	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/258	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/259	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/260	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/261	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/262	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/263	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/264	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/265	The PIL or the SmPC of Utrogestan 200mg capsules (PL16468/0007), and whether a formulation change is currently under review by the MHRA?	12 July 2012	Answered - in part
12/266	Various questions about the contact centre / IVR system.	13 July 2012	Answered - in full
12/268	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	13 August 2012	Answered - in part
12/269	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	13 August 2012	Answered - in part
12/270	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/271	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/272	Copies of the most recent Risk Based GMP Inspection reports of: Almac Clinical Trial Supplies Catalent Bathgate Catalent Deeside Bilcare GCS	20 July 2012	Answered - in part
12/273	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/274	All toxicology tests on PIP implantsand the findings regarding the chemicals found in PIP implants	31 July 2012	Answered - in part
12/275	Questions regarding licensing problems relating to Reckitt Benckiser - particularly products containing Tolnaftate	30 July 2012	Answered - in full
12/276	Please provide a copy of each of the last two GMP audit reports for Custom Pharmaceuticals at the following addresses: Conway Street, Hove, East Sussex, BN3 3LW Unit 2 Fairway Trading Estate, Moulsecoombe, Brighton, East Sussex, BN2 4QL	31 July 2012	Answered - in part
12/277	A list of UK Blood Establishments	03 August 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/278	Copy of a report referred to in an article published by the Daily Star on 28 May 2012, regarding PIP implants.	31 July 2012	Answered - in part
12/279	The Risk Management Plan for Symbicort Turbohaler (PL 17901/0092)	08 August 2012	Answered - in part
12/280	How many healthy volunteer phase 1 studies involving a monoclonal antibody have been conducted in the UK since 1980 ?	30 July 2012	Answered - in full
12/282	NPSA Alerts of all types issued via CAS (Patient Safety Alerts, Safer Practice Notices or Rapid Response Reports). MHRA alerts do not need to be included.	16 July 2012	Answered - in full
12/284	Country of Manufacture Disclosure on Medicines	19 July 2012	Answered - in part
12/290	Information request for the amount of funding and staff time given to trade unions	13 August 2012	Answered - in full
12/291	Availability of Asmasal inhalers for asthma	16 August 2012	Answered - in full
12/292	MHRA proposals regarding UK Life Sciences and early access	23 July 2012	Answered - in full
12/293	The MHRA inspection reports for laboratory, blood bank, caithness general hospital , wick and also the inspection reports for the laboratory blood bank, belford hospital, fort william, any submitted serious adverse reaction & events from both blood banks, and the blood compliance reports.	03 August 2012	Answered - in part
12/294	All audits which have been carried out since 01/01/2012- company name, date audited and outcome. All audits which are scheduled during 2012, company names and dates due.	09 August 2012	Answered - in part
12/296	Galenica's Ferinject/Injectafer	13 August 2012	Answered - in full
12/299	Public Assessment Reports for the original approvals and all subsequent new indication approvals for Genotropin and Neupogen.	24 August 2012	Answered - in full
12/300	Minutes of all meetings of the Advisory Board on the Registration of Homeopathic Products held since 13 December 2011.	30 July 2012	Answered - in part
12/302	Date that the product licence for Robinul (glycopyrrolate) Tablets 1 mg was withdrawn? Can you provide the reason for withdrawal? Available information for the 'specials' or 'unlicensed' use of glycopyyrolate in UK for last 10 years i.e. volumes of usage, strength and type of dosage form, indication for use, age of patients etc	24 August 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/303	The total number of mobile devices currently utilised and the type of device (eg, Mobile/Smartphone/Tablet) The contract expiry date of these products. The annual expenditure.	08 November 2012	Answered - in full
12/304	Specific details of incidents involving reusable devices used for gynaecological and fertility procedures between January 1992 and July 2012. Including, 1.Type of medical device, including batch number 2.Nature of incident 3.Date of incident 4.Outcome for the patient	01 March 2013	Answered - in part
12/305	Questions regarding the shortage of Lanvis (drug for crohns disease).	02 August 2012	Answered - in full
12/306	Further details on meetings for the ABRHP.	01 August 2012	Answered - in full
12/307	Breaches and losses of the DPA by MHRA in table format	06 August 2012	Answered - in full
12/308	The number and a breakdown of counterfeit medical devices, from the calender year 2008 - 2012. The number and a breakdown of counterfeit electronic chips inside medical devices, from the calender year 2008- 2012.	13 August 2012	Answered - in part
12/309	Various questions about defective prosthetic devices, specifically the Pinnacle Ultamet cup on a Corail, Corail AMT or SROM cementless stem.	20 September 2012	Answered - in full
12/311	Levothyroxine 100mcg. the identity of all Marketing Authorisation Holders and manufacturers to date	07 September 2012	Answered - in part
12/312	Copy of the Assessment Report for the latest GMP Inspection of Marksans Pharma, Goa, India	23 August 2012	Answered - in part
12/313	Full details of all registered or authorised kits of homeopathic products. Please also supply a list of all homeopathic products registered or authorised since list of Homeopathic registrations was generated.	04 September 2012	Answered - in part
12/314	Various questions regarding the MA for Medabon issued to Sun pharmaceuticals.	04 September 2012	Answered - in part
12/315	Copy of the pharmacovigilance inspection report for GlaxoSmithKline Consumer Healthcare from the inspection conducted in 2012. Copy of the response that GlaxoSmithKline Consumer Healthcare provided to the MHRA for the inspection conducted in 2012.	30 August 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/318	Current MHRA staff, chairpersons and committee members declarations of interests between February 2010 to date - PIP related	12 October 2012	Answered - in full
12/319	Copy of all inspection reports carried out by the MHRA of Nelsons' premises. Also whether Nelsons had notified you of any of these issues and, if so, when?	06 September 2012	Answered - in part
12/321	Copies of all literature prepared by the Clinical Practice Research Datalink (CPRD) intended for patients whose data may be sent to CPRD. All literature prepared by CPRD for distribution to Data Suppliers regarding the confidentiality of any information supplied to CPRD. If CPRD has prepared any posters or leaflets intended to be posted in GP waiting rooms or distributed by Data Suppliers to patients	10 September 2012	Answered - in full
12/322	All reports in full compiled by the MHRA over the last 12 months into the Blood Transfusion Service at Mid Staffordshire NHS Foundation Trust	05 September 2012	Answered - in part
12/323	All reports in the last five years of inspections, investigations and action taken against vendors / manufacturers of Homeopathic products.	10 September 2012	Answered - in part
12/324	Copy of the MHRA inspection report for the following site: AMSAL CHEM PVT LTD A 401/402/403 GIDC INDUSTRIAL AREA, DISTRICT BHARUCH, ANKLESHWAR, GUJARAT, 393 002, INDIA	24 August 2012	Answered - in part
12/325	Pharmacovigilance inspection reports from 01Jan 2012 to date	07 September 2012	Answered - in part
12/330	Copies of Expert reports and assessment reports for Prograf (tacrolimus) submitted in 1992/3: Expert report on the Pharmaceutical documentation, Expert Report on the Pharmaco-Toxicological Documentation, Expert Report on the clinical Documentation. MHRA assessment reports relating to the submission	18 September 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/332	Copies of the minutes of any meetings of The British Pharmacopoeia Commission (BPC) and the Expert Advisory Groups (EAGs), Panels of Experts and Working Parties where 18 Formulated Products have been discussed and any reports, papers or internal correspondence relating to this matter. Copy of the current (2012) British Pharmacopoeia monograph for Levothyroxine Tablets. Copies of documentation with details of the revised dissolution test for Levothyroxine Tablets and the reasons why the current monograph should be revised. Documentary evidence of checks that have been made to ensure that suppliers have met the current published standards throughout the shelf life of Levothyroxine formulated products Copies of the full specification for impurities that are acceptable for Levothyroxine formulated products Complete list of all the different products that constitute 'Levothyroxine formulated products' Copy of the revised draft monograph for Levothyroxine Tablets.	21 September 2012	Answered - in part
12/334	1. Names of biotech, generics, pharmaceutical companies, CRO companies whose clinical investigation (human drug development) sites have been inspected in the period 01 January 2012 to 31 July 2012 2. Names of biotech, generics, pharmaceutical companies, CROs, CMOs whose manufacturing facilities and or headquarters have had GMP, GCP or pharmacovigilence inspections in the period 01 January 2012 to 31 July 2012 3. Location details and dates of the above sites and reason for inspection 4. Names of inspectors who visited these sites 5. INSPECTION OUTCOMES including any GMP, GCP or pharmacovigilence violations noted, major or critical findings that were issued as a result, any "warning" letters that were issued as a result, any reinspections that were issued as a result.	19 September 2012	Answered - in part
12/336	Various questions about Levothyroxine 100mcg Tablets.	21 September 2012	Answered - in part
12/341	Correspondence and other information about Copaxone (PL10921/0023). See PDF	25 September 2012	Answered - in part
12/344	For each quarter from the beginning of 2002 to the present day, the number of adverse event reports from any source during that quarter for: epotin alfa (Rinn), each epoetin alfa product, filgastim (Rinn) and each filgastim product.	18 September 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/345	Clinical Practice Research Datalink (CPRD) 1. who will be able to access the data? 2. what precautions have be taken to prevent data inference? 3. the audit procedures	28 September 2012	Answered - in full
12/346	Additional inspection or investigation reports of Richards Pharma	17 September 2012	Answered - in part
12/348	Questions on Clarke and Boericke homeopathic provings.	02 October 2012	Answered - in part
12/350	A list of the names of kits MHRA have agreed to and the name of the manufacturer concerned, also confirm whether MHRA allow both registered and authorised homeopathic products in the same kit, and whether MHRA agree with the manufacturer the products that are sold as the kit or whether the manufacturer can change the contents as he sees fit?	02 October 2012	Answered - in full
12/351	Risk Management Plans for (Methylphenidate) Concerta XL and (Celecoxib) Celebrex.	10 October 2012	Answered - in part
12/352	Information on the use of echinacea products by children under 12 years old.	17 September 2012	Answered - in full
12/354	Various questions on e-cigarettes.	27 September 2012	Answered - in full
12/355	A copy of the last MHRA inspection report of Glochem Industries Unit III, Green Industrial Park, SEZ, Jadcherla.	26 September 2012	Answered - in part
12/356	Current and past use of Thiomersal (Ethylmercury) in medicines in the UK	08 October 2012	Answered - in part
12/357	Registration details with MHRA of poly implants protheses. CE marks and other quality certification on poly implants protheses. The date in which the first conformation of substandard materials were used in poly implants protheses. Registration details with MHRA of Harley Medical Centre Ltd 11 Queens Anne road London.	27 September 2012	Answered - in part
12/358	A copy of the GMP Inspection Report of the following site on 02/11/2009: Dr Reddy's Laboratories Limited Chemical Technical Operations Unit-1 Plot Nos 137, 138, 145 and 146, Sri Venkateswara Co-operative Industrial Estate Bollaram Jinnaram Medak District Andhra Pradesh 502 325 India	27 September 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/360	For the 2011 calendar year state the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery. For the 2011 calendar year's Adverse Reactions to breast implants used in breast enlargement surgery a complete breakdown of the side effects that the reporter has claimed.	03 October 2012	Answered - in full
12/362	Why were loxapine oral formulations withdrawn from the UK market.	10 October 2012	Answered - in full
12/363	Repeat of FOI ref 11/302 with the latest updated information for each licence holder and last inspection report and also a copy of their response to each deficiency found Also provide the inspection report for Pillbox chemists 37251that caused the licence to be suspended.	09 October 2012	Answered - in part
12/365	Is there is any evidence of the efficacy of buttercup syrrup?	10 October 2012	Answered - in full
12/367	Recent drug safety update regarding maximum dose Simvastatinwith Amlodipine and Diltiazem. Would it be possible to sent a copy of the clinical trial data from which this recommendation comes from?	15 October 2012	Answered - in full
12/368	How many cases (preferably in the last 12 months) you have dealt with regarding the illegal prescribing, sale and supply of a POM i.e. botox. Also confirm whether any of these cases have related to a patient requesting botox by name from the prescriber who has then prescribed as per the patient requests? Have these figures increased in comparison to the previous 12 months and what action was taken against the prescriber in said cases?	12 October 2012	Answered - in full
12/374	A copy of 'MAL36 Guidelines on the performance of pre-marketing animal reproduction studies 1974 (as amended)'.	24 September 2012	Answered - in full
12/375	MHRA GMP inspections of the following company: Hanmi Fine Chemical Co., Ltd., South Korea - any GMP certificates/Inspection reports that have been issued.	17 October 2012	Answered - in part
12/376	Copy of the October(?) 2010 audit carried out by the MHRA Inspectorate at the D10 facility near Nottingham of Boots Contract Manufacturing.	18 October 2012	Answered - in part
12/377	if you are aware of unpublished trials from pharmaceutical companies (of Atomoxetine for Attention Deficit Hyperactivity Disorder).	27 September 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/378	Copies of all internal correspondence and communications relating to the drug Clozapine from June 19 to July 16, 2012. Copies of all external correspondence and communications relating to the drug Clozapine from June 19 to July 16, 2012.	19 October 2012	Answered - in part
12/380	The last 2 Bioforce Inspection reports	22 October 2012	Answered - in part
12/382	The last MHRA GMP inspection report for the GSK Harlow facility for IMP.	22 October 2012	Answered - in part
12/383	Enquiry on multiple vaccines	18 October 2012	Answered - in part
12/384	All information and copies of any documents in which such information is enshrined relating to the MHRA's referral of calcitonin-containing medicinal products to the CHMP under Article 31 of Directive 2001/83, as amended, (EMEA/H/A-1291).	25 October 2012	Answered - in part
12/385	The number of inport notifications the MHRA has received since January 2012 for the unlicensed monovalent mumps vaccine Medi mumps.	03 October 2012	Answered - in full
12/387	The latest GMP Inspection Report concerning the manufacturing facility of Custom Helthcare Group Conway Street, Hove, East Sussex, BN3 3LW, UK	19 October 2012	Answered - in part
12/389	Diclofenic - questions related to response curve, toxicity curve and other questions.	26 October 2012	Answered - in part
12/390	List of overseas sites inspected for GMP by the MHRA in the last 3 years.	19 October 2012	Answered - in full
12/391	information on adverse side effects reports on GnrH medication (Triptorelin, Leuprorelin, Goselerin, Buserelin) reported to the MHFR. There has been a study performed by the marketing holder of Leurrorelin in the UK GPRD to which I also would like to have access to. The study is mentioned in the PhVWP December 2011	01 November 2012	Answered - in full
12/393	The latest MHRA inspection report for JM Loveridge	30 October 2012	Answered - in part
12/394	The last pharmacovigilance inspection reports for the following companies: Aspen, Chiesi and Merck	31 October 2012	Answered - in part
12/395	any documentation that contains the calculation of the BA (basic pay award 07/08 and 08/09).	26 October 2012	Answered - in full
12/396	a copy of the current risk management plan for capecitabine (Xeloda).	06 November 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/398	Adverse incident data for urine meters (urine measuring devices used in critical care). Please could you provide a summary for the period 1st January 2009 to 30th September 2012 concerning urine meters. I am requesting this information under the Freedom of Information Act 2000.	22 October 2012	Answered - in full
12/399	I am interested in adverse incident data for needle-free sample-ports/connectors (specifically those that utilise a split septum type design). Please could you provide a summary for the period 1st January 2009 to 30th September 2012 concerning needle-free sample ports/connectors. I am requesting this information under the Freedom of Information Act 2000.	22 October 2012	Answered - in full
12/400	In the last 3 years how many fines or prosecutions have resulted from the inappropriate use of dental alloys in dental devices? (further supplementary questions - see request section).	19 October 2012	Answered - in full
12/401	A copy of the redacted inspection report from the inspection of Mediva Pharma limited for a wholesalers licence. WL number 40848, site number 5512788, licence granted 29/05/12	05 November 2012	Answered - in part
12/402	Various questions about SSRI's	09 November 2012	Answered - in part
12/403	Request for SOP M109 (on-site inspection conduct)	17 October 2012	Answered - in full
12/404	Is any product licensed for use as a human medicine which contains Lissamine Green and the licensed indications for use of the product(s) concerned. Are any current clinical studies (for pharmaceuticals or medical devices) being undertaken in the United Kingdom involving the use of Lissamine Green.	02 November 2012	Answered - in full
12/406	Copies of the reports resulting from the last two MHRA Inspectorates audits of Boots Contract Manufacturing site D10 in Beeston/Nottingham.	12 November 2012	Answered - in part
12/407	Copies of the original review documents (Chemistry, preclinial and clinical information) for Navoban (tropisetron) indicated for treatment of chemotherapy induced post-operative nausea and vomiting.	12 November 2012	Answered - in part
12/408	What is the process for approving a batch of medication for release to market.	12 November 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/409	Confirmation that the following four companies in India had UK-MCA GMP compliance / site-clearance Certifications of their plants for the manufacture of tablets and capsules (for the years 2000/2001 and earlier), and copies of the GMP Compliance certificates if available. The Indian companies are: 1. Cipla Ltd. 2. Intas Pharmaceuticals Ltd. 3. Unichem Laboratories Ltd. 4. Ipca Laboratories Ltd.	02 November 2012	Answered - in part
12/410	A copy of the last inspection report for Medco Health solutions SITE ID : 5096983 Also provide a copy of the full inspection report, deficiencies and company response to them	22 October 2012	Answered - in part
12/413	Names of all organisations Audited by MHRA since 2007 till date for GPvP compliance or Pharmacovigilance Inspections.	13 November 2012	Answered - in full
12/414	Breakdown of suspected adverse reactions (ADRs) compiled by you in the 2011 calendar year in relation to vaccines, by individual vaccine type.	15 November 2012	Answered - in full
12/416	Various questions on Metatone and Minadex "tonics".	14 November 2012	Answered - in part
12/417	Request for CSV exports of: 1. MHRA – Clinical Investigations 2. MHRA – Compliance Database 3. MHRA – Adverse incident tracking system.	07 February 2013	Answered - in part
12/419	A copy of the clinical efficacy study for Infacol which was included in the registration dossier and considered by the Committee on Safety of Medicines, if possible copies of both Infacol clinical data and the CSM deliberations	08 November 2012	Answered - in part
12/420	Which motor manufacturers, motor dealers or leasing companies do you have contracts with for the supply of passenger motor vehicles and light commercial vehicles? What is the number (and where possible to provide), make and model of vehicles supplied under each contract?	23 October 2012	Answered - in full
12/421	2 Queries regarding Epanutin being transferred from Pfizer to Flynn Pharma Ltd.	07 November 2012	Answered - in full
12/422	Dr.Reddy's Atorvastatin tablets 80mg	15 November 2012	Answered - in full
12/423	Blood sampling/cross matching in Belfast NHS	15 November 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/424	The last two GMP inspection reports relating to: 1. BIO-HEALTH LIMITED, Licence Holder MIA 15817, SITE ID : 7147 STIRLING HOUSE, CULPEPER CLOSE, MEDWAY CITY ESTATE, ROCHESTER, KENT, UNITED KINGDOM, ME2 4HU 2. HERBS IN A BOTTLE LIMITED, Licence Holder MIA 37212, SITE ID : 115169 MEADOW PARK INDUSTRIAL ESTATE, BOURNE ROAD, ESSENDINE, LINCOLNSHIRE, UNITED KINGDOM, PE9 4LT	19 November 2012	Answered - in part
12/426	Details of warnings and sanctions taken against drug companys 2009-2012	21 November 2012	Answered - in full
12/427	Request for infomation on the safety of use of REPEVAX in pregnancy	05 November 2012	Answered - in full
12/428	Details of certain MA's held by Arrow and Alpharma, in connection with legal action	23 November 2012	Answered - in part
12/429	Request for various papers, reports etc for Panselect Protium 20 mg Protium 40 mg	20 December 2012	Answered - in part
12/431	Copy of the request and response for FOI request number 11/115 please be provided?	13 November 2012	Answered - in full
12/433	Copies of the most recent MHRA inspection reports for Hetero Drugs Ltd Unit III Jeedimetla Hyderabad India Dr Reddys Laboratories, Unit FT02 Bachupally Hyderabad India	27 November 2012	Answered - in part
12/434	Freedom of Information request for commissioning an external organisation (for instance, a private investigator) to undertake surveillance	29 November 2012	Answered - in full
12/435	Questions relating to the marketing/prescribing of plain 75mg aspirin tablet made by and licensed to Norbrook Laboratories Ltd of Newry, Northern Ireland	26 November 2012	Answered - in full
12/436	Inspection report on Marksans Pharma Limited, Plot No. L-82, Verna Industrial Estate, Verna, Goa, IN-403 772, India. Inspection date 17.01.2012. Ref 19826/39398-0002.	13 November 2012	Answered - in part
12/437	All adverse side effect reports by individual case / report since approval of GnrH medication (Triptorelin, Leuprorelin, Goselerin, Buserelin). Also details on the length of the side effects, and a redacted version of the study of the marketing authorisation holder of leuprorelin.	28 November 2012	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/438	Various questions about the HPV vaccine.	09 November 2012	Answered - in part
12/439	Follow up details request re Hyoscine Hydrobromide (ADR 21815952)	19 November 2012	Answered - in part
12/440	Various questions about inspections of biotech, generics, pharmaceutical companies, CRO companies in the period 1 January to 30 September 2012.	10 December 2012	Answered - in part
12/441	Total number of deaths caused by prolonged use of methylphenidate(Ritalin), per year, since 2005. Total number of children under 18 years diagnosed with ADHD, per year, since 2005	30 November 2012	Answered - in full
12/442	Questions about the source of a generic brand of Tambocor (flecainide).	13 November 2012	Answered - in part
12/443	Various information on the UK Clinical Trials procedures and data.	16 November 2012	Answered - in full
12/444	A copy of a new Wholesale Dealers License application that was made by a company called Rokshaw Ltd.	20 November 2012	Answered - in part
12/445	Access to MA Dossiers - Sandoz B.V. and Momaja S.R.O.	13 November 2012	Answered - in part
12/447	A copy of all available information regarding Simavastatin and Amlodipine in connection with a health alert	05 December 2012	Answered - in full
12/448	Various questions relating to Risperdal Consta 12.5mg	28 November 2012	Answered - in full
12/449	Information relating to various hip replacements/resurfacing systems: 1) When it was first introduced into the UK/Europe 2) If and when a first warning was issued 3) Details of subsequent warnings 4) If and when it was recalled	29 November 2012	Answered - in full
12/450	Various questions about ADRs for: alendronate sodium trihydrate, rimonabant, omeprazole and flutamide.	04 December 2012	Answered - in full
12/456	MHRA inspection report re: Shandong Xinhua Pharmaceutical Co Ltd - Plant 206, 14 Dongyi Road, Zhangdian District, Zibo, Shandong, RC-255005, China. Inspection date 20.05.11. Ref. GMP 13607.	05 December 2012	Answered - in part
12/457	Various questions relating to the status and licensing position of Levonelle 1500 Levonelle 2 Levonorgestrel 1.5mg Levonelle 1500 reference products	10 December 2012	Answered - in part

FOI no	Subject	Date reply sent	Result of request
12/458	All information relating to the investigation into the safety of Teva and Numark 100 microgram levothyroxine and the suspension of the manufacture and distribution of these tablets in May 2012.	10 December 2012	Answered - in part
12/459	A copy of the current risk management plan for dalteparin (Fragmin).	14 December 2012	Answered - in part
12/464	Pre-clinical toxicity data on approved antimalarial medicines	14 December 2012	Answered - in part
12/465	The number of contracted staff at MHRA who receive private health care benefits as part of their employment contract. The amount of money spent on this benefit broken down annually over the last five years A full list of the different employment benefits offered to staff	11 December 2012	Answered - in full
12/466	The number of industry sponsored cardiology clinical trials approved in 2010 in the UK.	10 December 2012	Answered - in full
12/467	A copy of the UK Public Assessment Report for Lemsip Max Cold and Flu Capsules granted in 1998. If such a report is not available, details of the legal basis of the marketing authorisation application (with reference to the relevant article of directive 65/65/EEC as amended). Also confirm if this product can be considered a 'reference medicinal product' under the requirements of article 10.1 of Directive 2001/83/EEC.	14 December 2012	Answered - in part
12/468	Cases brought under the clinical trial directive for non compliance with GCP by investigators as one issue, and for fraud as another, in relation to clinical trials by investigators, being specific regarding actual charges. (follow up from 12/430)	17 December 2012	Answered - in full
12/469	All adverse drug reaction reports you have on Strattera specifically where that adverse reaction has been related to suicidal behaviours or thoughts? ii) Specifically any adverse drug event reports in connection with the case of a patient who took his life in September 2011 while on medication for ADHD?	21 December 2012	Answered - in full
12/471	Various questions relating to Gardasil and vigilance of that drug	03 January 2013	Answered - in full
12/472	A copy of the previously disclosed document, 'Request for Inspection reports for Genopharm and Alkopharma', FOI no 11/350, 05 October 2011. Please could you also send me all information available surrounding the licencing and authorisation of 'Primius Lab Limited', 6th floor, 77 Gracechurch Street, London EC3V 0AS, in February 2012.	02 January 2013	Answered - in part
12/473	Various questions relating to Gardasil and vigilance of that drug	03 January 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/474	Data on yellow cards or other sources of possible alcohol or substance adverse events which were suspected or associated with SSRI.	14 December 2012	Answered - in full
12/475	How many naltrexone implants, or naltrexone injections (depots) of any make or brand, or strength, were imported under any MHRA license, from 2007-2012.	19 December 2012	Answered - in part
12/477	A copy of the most recent inspection report for: Rusan Pharma, Plot 59 to 65, Sector II Kandla Special Economic Zone, Kutch, Gandhidham, Gujarat, 370230, India	07 January 2013	Answered - in part
12/479	A copy of the last MHRA inspection report for the following site: Mawdsleys Clinical Services MIA 741 Unit 22, Quest Park, Wheatley hall Road, Doncaster DN2 4LT, UK Site no. 1686685	04 January 2013	Answered - in part
12/480	Amiodarone Hydrochloride - Multiple questions.	04 January 2013	Answered - in full
12/481	Audit Report for Catalent	31 January 2013	Answered - in part
12/482	The original UK Public Assessment Report and product documentation (SPC and PIL) for the product Pepti-Calm 525.6mg/30ml Oral Suspension.	09 January 2013	Answered - in part
12/485	Seroquel (quetiapine) AstraZeneca (various questions)	10 January 2013	Answered - in part
12/487	Various questions about what MHRA has done to combat sales of unlicensed glucosamine (as food supplements making alleged medicinal claims etc..)	10 January 2013	Answered - in part
12/488	Has any case has been brought in the courts for criminal fraud or any cases under the medicines act and clinical trials legislation.	14 December 2012	Answered - in full
12/489	Public AR for Lanreotide UK/H/0723/001 – 003 Ipstyl 60 mg, 90mg, 120mg solution for injection.	10 January 2013	Answered - in part
12/490	Various questions about IT outsourcing.	11 January 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
12/494	(a) A list of the ADR's/conditions which were made known to the MHRA during the 4 years but which were not recognised side effects or acknowledged by the manufacturer in their data in respect of Cervarix. (b) The number of ADR's received by the MHRA under each condition which was not recognised as a side effect of Cervarix (c) The condition, not recognised as a side effect of Cervarix, most reported as an ADR to the MHRA. (d) What investigations the MHRA undertook re ADR's brought to their attention in respect of Cervarix, which were not recognised side effects. (e) In the 4 years of usage, were any of the ADR's not viewed/acknowledged as side effects of Cervarix but which were brought to the attention of the MHRA, subsequently included as a recognised ADR for Cervarix?	16 January 2013	Answered - in full
12/495	Information on vigilance reports submitted by similar IVD companies (ie manufacturers incident report forms).	16 January 2013	Answered - in full
12/497	List of deficiencies found in audits of cases brought in the courts for criminal fraud or any cases under the medicines act and clinical trials legislation	15 January 2013	Answered - in full
12/498	Details of developments associated with an action point on addiction to medicines arising from a meeting iwith DH in September 2011 - including details of inclusions in the product information for benzodiazepines and z drugs	08 January 2013	Answered - in full
12/499	Information for PL 00063/0118 Senokot Max (various).	22 January 2013	Answered - in part
12/501	Which CE marked T and B lymphomas kits for IVD use are already registered and available in your country	25 January 2013	Answered - in part
12/502	A copy of the risk management plan for Seroquel XL 150mg	23 January 2013	Answered - in part
12/503	A copy of all Pharmacoviiglance inspection reports and responses from Jan 1, 2006 onwards for: Apotex Actavis Watson Pharmaceuticals Amgen Glenmark Pharmacetuicals Ranbaxy Astra Zeneca	24 January 2013	Answered - in part
12/505	A copy of the current risk management plan for drospirenone & ethinylestradiol (Yasmin).	31 January 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/001	A copy of any available GMP Inspection Reports for the following site: Licence Holder MIA 35095 AUDEN MCKENZIE (PHARMA DIVISION) LIMITED MCKENZIE HOUSE, BURY STREET, RUISLIP, UNITED KINGDOM, HA4 7TL	29 January 2013	Answered - in part
13/002	Various questions about the relationship between the UK and US regulators and imports/exports, of medicinal products and medical devices, legal or otherwise, between the two countries.	29 January 2013	Answered - in part
13/003	Request for access to Yellow Card data (category Ib) - Atropine	29 January 2013	Answered - in full
13/004	Various PIP questions (test results and incident reports).	01 February 2013	Answered - in full
13/005	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs. (categories also listed).	01 February 2013	Answered - in full
13/006	Clinical Trials transfer patents Subutex - Suboxone.	07 March 2013	Answered - in part
13/007	Inspection Report on Broughton Laboratories Ltd,	25 January 2013	Answered - in part
13/009	Has MHRA received notification from the manufacturer/supplier in the UK, Sandoz Ltd(?), of the medicine Carbo-Dome Cream given such a notification (to withdraw from the market).	28 January 2013	Answered - in full
13/012	A breakdown of all the alleged side effects associated with those drugs as reported to you under the yellow card scheme.	07 February 2013	Answered - in full
13/013	Top 20 applications made to the MHRA to allow the distribution of parallel imports in the UK	21 January 2013	Answered - in full
13/015	Periodic Safety Update Reports (PSUR´s) for the medicinal product Copaxone	12 February 2013	Answered - in part
13/016	Confirmation of the initial submission dates of certain national Marketing Authorisations Applications granted to Arrow Generics Limited.	21 January 2013	Answered - in full
13/018	Medicines for the public containing genetically modified material	07 February 2013	Answered - in part
13/019	A list of all Medical Device organisations that have had audits in 2011 and 2012 A list of Medical Device organisations that are due to go through an Audit in 2013 All the events the MHRA attended in 2011 and 2012	30 January 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/021	Last five Pharmacovigilance Inspection reports that have been made available under the FOI scheme.	04 February 2013	Answered - in part
13/023	Any cases (particularly criminal prosecutions) referring to the Medical Devices Regulations 2002 and particularly “off label use”.	17 January 2013	Answered - in part
13/025	A copy of the most recent Periodic Safety Update Report and the most recent Risk Management Plan for Copaxone (glatiramer acetate).	13 February 2013	Answered - in part
13/027	A copy of the Seroquel (Quetiapine) MAH Astra Zeneca Risk Management Plan.	24 January 2013	Answered - in part
13/029	The non-confidential answers received following the MHRA's public Consultation on advanced therapy medicinal products	08 February 2013	Answered - in part
13/030	Various questions on Adverse Drug Reactions (“ADRs”)	14 February 2013	Answered - in part
13/031	A copy of the most recent GMP MHRA inspection report for the following laboratory; Food & Drug Analytical Services Ltd	11 February 2013	Answered - in part
13/032	A list of manufacturing sites inspected in India over the last 5 years.	04 February 2013	Answered - in full
13/033	How many adverse reactions to vaccines among children were recorded in 2012? How much money has been paid out by the Vaccine Damage Payment Unit?	19 February 2013	Answered - in part
13/034	Various questions about prosecutions brought, assets recovered and new legislation.	28 January 2013	Answered - in full
13/039	A summary for the period 1st January 2009 to 31st December 2012 concerning foley catheters	08 March 2013	Answered - in full
13/040	A summary for the period 1st January 2009 to 31st December 2012 concerning anti-microbial urological catheters	08 March 2013	Answered - in full
13/043	Inspection report for MIA 39307 Syri Limited, Unit 4 Bradfield Road, Ruislip, HA4 0NU	18 February 2013	Answered - in part
13/044	Various questions related to Actavis.	21 February 2013	Answered - in full
13/045	Evidence to support the use of Strepsils to treat sore throat? Benefit to be expected from the use of Stepsils in place of a boiled sweet?	21 February 2013	Answered - in full
13/048	A copy of the PAR for Seretide Evohaler UK/H/0392/001-003 (PL 10949/0037-9).	20 March 2013	Answered - in part
13/049	The UKPAR for OxyNorm Injection (oxycodone HCl), 10mg/mL, licence number PL 16950/0128.	21 February 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/052	Inspection findings on GMP standards of the Newcastle Biomedicine Cellular Therapies Facility.	25 February 2013	Answered - in part
13/054	Please disclose information regarding the steps taken when the MHRA were notified by the FDA (or others) in or around March and April 2012 that counterfeit Altuzan had been discovered in the US which had been sourced through the UK market.	05 March 2013	Answered - in full
13/055	Public assessment report on the below molecules. Molecule - Diltiazem Prolonged release capsules Brand Name- ADIZEM XL Marketing authorisation holder- Napp Pharmaceuticals Strengths- 120, 180, 200, 240, 300 mg	04 March 2013	Answered - in part
13/056	A copy of the assessment report (or equivalent) in regard to the grant of PL 0129/0115 (Vicks Ultra Chloraseptic Throat spray)	07 March 2013	Answered - in part
13/058	Most recent MHRA GMP Inspection Reports on: 1. Licence Holder MIA 4394 D D D LIMITED / FLEET LABORATORIES LIMITED SITE ID : 3787 94 RICKMANSWORTH ROAD, WATFORD, HERTFORDSHIRE, UNITED KINGDOM, WD18 7JJ 2. Licence Holder MIA 19951 PHARMASOL LIMITED SITE ID : 12849 NORTH WAY, WALWORTH INDUSTRIAL ESTATE, ANDOVER, HAMPSHIRE, UNITED KINGDOM, SP10 5AZ	06 March 2013	Answered - in part
13/059	How many applications were processed to import the product called propantheline 15mg tablets as an exempt medicine while the UK shortage was occuring.	15 February 2013	Answered - in full
13/060	Why has distribution of Syndol been put on hold by the manufacturer?	11 March 2013	Answered - in full
13/061	Various questions relating to: Migraleve and Migraleve Pink	13 March 2013	Answered - in part
13/062	Mobile Phones and Telephone Maintenance in MHRA	14 February 2013	Answered - in full
13/064	GMP inspection report for manufacturing sites with noted start or planned start date of inspection: Patheon - Swindon United Kingdom20-Feb-12 Micron Technologies (Malvern)28-Mar-11 Brecon Pharmaceuticals (Hereford)16-Apr-12 Lonza (Winnersh, UK)28-Mar-11 Lonza (Slough, UK)05-Sep-11 Patheon - Swindon United Kingdom23-Jul-12 DHL Supply Chain - Banbury - UK18-Jul-12 Fisher Clinical Services (Horsham UK)31-Jul-12 Alkermes (Ohio)25-Jun-12 Patheon - Cincinnati, Ohio13-Aug-12 Mustafa Nevzat Yenibosna12-Nov-12 Patheon - Cincinnati, Ohio03-Dec-12	12 March 2013	Answered - in part
13/067	List of sites inspected by MHRA in India	19 February 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/073	Copies of correspondence concerning Tobramycin Teva.	28 March 2013	Answered - in part
13/074	Has Softgel Health care private had a recent visit from MHRA	08 March 2013	Answered - in full
13/075	EIPICO Inspection report.	21 February 2013	Answered - in part
13/076	Request for MA Dossiers for Omega 3-acid-ethyl esters 1000mg soft capsules.	13 March 2013	Answered - in part
13/077	The latest GMP inspection report for Recipharm Ltd Vale of Bardsley Ashton under Lyne Lancashire OL7 9RR	20 March 2013	Answered - in part
13/078	A copy of report regarding device malfunctions of Avonex prefilled pens (Biogen product).	07 May 2013	Answered - in full
13/079	The pharmacovigilance inspection reports from January 2009 to present day for Astellas Pharmaceutical Company.	20 March 2013	Answered - in part
13/082	Copies of application form containing administrative data submitted by Chesi Limited for Bramitob Nebuliser Solution.	28 March 2013	Answered - in part
13/083	Various questions about Richards Pharma.	19 March 2013	Answered - in full
13/084	The latest GMP audit report for Exova (UK) Ltd,	22 March 2013	Answered - in part
13/086	Various questions regarding aluminium entering the bloodstream from vaccines.	22 March 2013	Answered - in full
13/087	Safety advice relating to Dopamine Agonist medication (Cabergoline) - follow up to 10/427.	19 March 2013	Answered - in part
13/092	The latest GMP inspection report for Dales Pharmaceuticals Ltd (part of the Dechra Pharmaceuticals Manufacturing group), Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, England, BD23 2RW	02 April 2013	Answered - in part
13/093	Various questions relating to Duration of Effectiveness of Childhood Vaccines.	31 March 2013	Answered - in full
13/094	A list of overseas sites (in India) inspected for GMP by the MHRA in the last several years.	20 March 2013	Answered - in full
13/095	Drug Analysis Print - Sodium Chloride	22 March 2013	Answered - in part
13/096	Evidence for the clinical efficacy (of strepsils) in these conditions - i.e. symptomatic relieve of mouth and throat infections	28 March 2013	007. Not held
13/097	Information on the 100 most recent MHRA FOI requests	05 March 2013	Answered - in full
13/098	Breakdown of the hardware maintenance and costs of MHRA IT infrastructure	03 June 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/099	Questions related to Actavis (in follow up to 13/044).	04 April 2013	Answered - in part
13/101	How many applications were approved for importation of unlicensed medicines under SI 2005/2789. Please detail, by product (Brand and generic named) and ALSO by manufacturer of product how many applications were approved for import for the last 12 months.	20 March 2013	Answered - in full
13/102	Request to make European review of reboxetine (Edronax®), or the Pfizer meta-analysis and its update, publicly available	08 April 2013	Answered - in part
13/103	Composition of Working Group considering issues relating to safety of insulin for type 2 diabetes	03 May 2013	Answered - in full
13/106	Questions regarding MHRA IT infrastructure	14 May 2013	Answered - in full
13/107	Request further to 13/064 regarding GMP inspection reports for various manufacturing sites with noted start or planned start date of inspection:	10 April 2013	Answered - in part
13/109	Details of the actions taken to prevent further deaths from the same cause, following the Coroners' Rule 43 recommendation -to consider a review of the use of tables with wheels in order to prevent them being used as walking aids- made in May 2012 which is shown below. Details of outcomes achieved as a result of the actions taken to prevent further deaths from the same cause.	27 March 2013	Answered - in part
13/110	Details of the actions taken to prevent further deaths from the same cause, following the Coroners' Rule 43 recommendation -to consider closing down websites that purport to supply controlled drugs without a prescription- made in May 2012 which is shown below. Details of outcomes achieved as a result of the actions taken to prevent further deaths from the same cause.	27 March 2013	Answered - in full
13/112	An explanation as to why z drugs have not been addressed in the recently launched learning module on benzodiazepines?	21 March 2013	Answered - in part
13/114	Whether Adenosyl cobalamin (a form of vitamin B12) has MHRA approval for use in clinical trials.	10 April 2013	Answered - in full
13/116	A full public AR for Magnevist® and which procedure was this, with what RMS and which CMS?	03 April 2013	Answered - in full
13/117	The 5 most recent Pharmacovigilance Inspection reports available. I am most interested in inspections performed after July 2012 to review how MHRA inspectors are taking into account the new EU Pharmacovigilance requirements.	15 April 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/118	AR for Gadopentetate dimeglumine 469mg/ml solution for injection	21 March 2013	Answered - in part
13/121	Various questions about inspections of biotech, generics, pharmaceutical companies, CRO companies in the period 1 November 2012 to 01 March 2013.	10 April 2013	Answered - in part
13/122	The amount of times personal medical information relating to mental health has been made available or shared through the Clinical Practice Research Datalink between the period of August, 1st 2012 and March 1st, 2013 - in which the information itself was not fully anonymised and informed consent was not secured.	22 April 2013	Answered - in full
13/124	On how many occasions has personal medical information, which contains patient-identifiable data, been shared with third-parties through the CRPD since the 1st of September 2012 and the 1st of February, 2013.	22 April 2013	Answered - in full
13/125	PSUR related to Ritalin°; ● Concerta ● Equasym ● Medikine	25 April 2013	Answered - in part
13/127	The last two GMP and GCP inspection reports for the Belfast Health and Social Care Trust. If available please provide the latest inspection findings of the radiopharmacy and cyclotron units from March 2013.	23 April 2013	Answered - in part
13/128	Information on the number of generic product manufacturers, world-wide (including those in UK) who do, or could potentially, supply medicinal products to the UK market? How many different products do they (or could they.potentially) supply?	25 April 2013	Answered - in part
13/129	Further questions about Richards Pharma.	23 April 2013	Answered - in full
13/130	How many enforcements there have been, since 30 April 2011, against herbal medicinal products, specifically on the grounds that they are being illegally sold without licences?	12 April 2013	Answered - in full
13/132	Copies of the last 3 Pharmacovigilance Reports issued by the MHRA before 15 March 2013	15 April 2013	Answered - in part
13/136	Fixed Telephony and Internet Services	11 April 2013	Answered - in part
13/138	CERVARIX VACCINATION - all information relating to correspondents ADR Yellow Card report.	01 May 2013	Answered - in part
13/139	Unregistered device manufacturers (various questions, 7 in total).	12 April 2013	Answered - in part
13/140	The last 10 Inspection reports that have had critical findings.	01 May 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/141	Smith & Nephew replacement hips. (Questions about documentation, test results, copy of licence and conditions, copy of med device alert and other articles.	03 May 2013	Answered - in part
13/142	Questions about UK decision to place black box warnings on certain SSRI anti-depressants and when it was acknowledged that these medications caused people to be suicidal.	01 May 2013	Answered - in full
13/146	The last PSUR related to mannitol-ARIDOL° diagnostic tool ?	07 May 2013	Answered - in part
13/147	All documents and submissions (e.g., letters, written arguments) held by the Independent Borderline Review Panel (Panel) for cases that resulted in a finding by the Panel that the product concerned was not a medicine. Specifically those involving milk thistle.	30 April 2013	Answered - in part
13/148	What is the "EU Testing laboratory" and other questions, reagarding Bristol Laboratories	09 May 2013	Answered - in part
13/150	Yellow Card Reports submitted with CFS (Chronic Fatigue Syndrome) or ME (Myalgic Encephalomyelitis) or CFS/ME as an adverse reaction.	10 May 2013	Answered - in full
13/151	Enquiries about vaccination adverse events	10 May 2013	Answered - in full
13/152	The latest GMP inspection report issued by the MHRA for the following manufacturer: Nestor UK Ltd	14 May 2013	Answered - in part
13/153	The total number of adverse drug reactions (ADRs) reported through the Yellow Card scheme in the 2012 calendar year	14 May 2013	Answered - in full
13/156	Are any 1,000IU vitamin D3 products licensed in the UK	29 April 2013	Answered - in full
13/158	Under what classification were (multiple list of) MAs approved according to the EU directive and whether any of them were approved based on the provision of a BE study and if so which ones.	17 May 2013	Answered - in part
13/160	A listing of all unlicensed medicines import notifications that have been received by the MHRA in the last 12 months. Identifying by product the individual number of import notifications that have been received.	25 April 2013	Answered - in full
13/162	Various questions on Suspected unexpected serious adverse reactions (SUSARs).	14 May 2013	Answered - in full
13/166	Copy of 5th March 2012 Letter to Department of Health entitled "Re: Allergies in children and vaccinations" Copy of correspondence and/or other documents recording the request to which the letter is a reply.	21 May 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/167	1. What action did the MHRA take with the 400 or so manufacturers suspected by the DLA of not being registered? 2. Are these names available to the MHRA now? 3. If not what happened to the names?	10 May 2013	Answered - in part
13/168	Questions regarding PIP testicle implants, and Rofil M-implants breast implants	10 May 2013	Answered - in part
13/170	Information on the licensing strategy of GSK product PL 12063/0118	25 April 2013	Answered - in full
13/171	MHRA inspection report (or latest) and the company response to any findings cited in the report for the following companies: 1. The manufacturer: SQUARE PHARMACEUTICALS LTD Site address: DHAKA UNIT, KALIAKOIR, GAZIPUR, 1750, BANGLADESH 2. The manufacturer: INCEPTA PHARMACEUTICALS LIMITED - ZIRABO PLANT Site address: DEWAN IDRIS ROAD, BARA RANGAMALA, ZIRABO, SAVAR, DHAKA, BANGLADESH	21 May 2013	Answered - in part
13/172	Copy of the Assessment report for Decapeptyl 11.25mg authorising the indication for use in the treatment of central precocious puberty in children.	21 May 2013	Answered - in part
13/177	Request for MHRA to make available the original Wakefield article on MMR on the internet	07 May 2013	Answered - in full
13/179	1. All inspections which have been carried out since 01/09/2012- company name, date audited and outcome, please include GMP and GCP 2. All inspections which are scheduled during 2013, company names and dates due please include GMP and GCP	10 June 2013	Answered - in part
13/180	Detailed pre-clinical safety data on Diclofenac sodium injection by Novartis, earlier Ciba geigy	24 May 2013	Answered - in part
13/182	Requesting the identity of the reporter of a site advertising Botox treatment	14 May 2013	Answered - in full
13/183	The list of the PV and GCP inspections conducted/planned by the MHRA for 2013.	20 May 2013	Answered - in full
13/184	GMP report on inspection of Melbourn Scientific Nov 2012	23 May 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/185	The number of individuals MHRA has taken action against in the UK for selling and/or distributing illegal skin lightening creams which contains steroids and are therefore classed as a medicinal product for the years 2000, 2009, 2010, 2011 and 2012. The number of individuals MHRA has taken action against in London for selling and/or distributing illegal skin lightening creams which contains steroids and are therefore classed as a medicinal product for the years 2000, 2009, 2010, 2011 and 2012.	23 May 2013	Answered - in full
13/186	All the drugs and vaccines for which the licence was withdrawn, suspended or changed significantly due to safety concerns or a revised risk/benefit analysis.	31 May 2013	Answered - in part
13/187	GMP inspection report on Milan Laboratories Private Limited, Mumbai, India. Inspection start date 22.10.12, case ref. Insp GMP 33423/498770-0006.	23 May 2013	Answered - in part
13/188	Various questions about the MMR vaccine and side effects.	05 June 2013	Answered - in full
13/193	Implanon MHRA report.	16 September 2013	Answered - in full
13/195	Copies of correspondence between MHRA, London Borough of Bromley, and any of the listed manufacturers over use of patient sling	03 June 2013	Answered - in full
13/200	Various questions about Avastin Batch 003837.	10 June 2013	Answered - in part
13/201	The Corrective Action Preventive Action Plan of this inspection together with the inspection result, as STADA has products concerned at the site mentioned (Zhejiang Hisun Pharmaceutical, East Campus, Tiazhou City in China).	12 June 2013	Answered - in part
13/202	A copy of the application for phenytoin PLPI 39352/0067 02/08/2012 KOSEI PHARMA UK LIMITED EPANUTIN 100 MG HARD CAPSULES	12 June 2013	Answered - in part
13/204	1. All inspections which have been carried out since 01/09/2012- company name, date audited and outcome 2. All inspections which are scheduled during 2013, company names and dates	30 May 2013	Answered - in full
13/205	Most recent inspection reports for: Healthcare at Home, BUPA Home Healthcare, Alcura UK Ltd.	13 June 2013	Answered - in part
13/206	Any reports MHRA has done on Actos or pioglitazone that involved adverse effects or events.	10 June 2013	Answered - in part
13/208	What investigations are planned into potential wrong-doing in connection with Ranbaxy's MAs in the UK?	13 June 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/209	The total number of companies/organisations that have applied for import approvals for over the following periods? 2010 2011 2012	20 May 2013	Answered - in full
13/211	Information of the drug penthixol	17 June 2013	Answered - in part
13/213	What specific actions have MHRA taken to monitor the quality of Ranbaxy products sold in the UK	13 June 2013	Answered - in full
13/215	Query received on the prescribing of sodium valproate (Epilim) for the treatment of epilepsy	21 June 2013	Answered - in part
13/219	Advice from the Committee on Safety of Medicines Meeting held on 11 December 2002 on issues relating to dioxins in cod liver oil and other fish oils	24 June 2013	Answered - in full
13/221	In 2011 it appears there was a spike in the number of suspected ADR reports with a fatal outcome (1,863 in 2011 compared to 1,433 in 2010 and 1,555 in 2012). Could you let me have any research or statistical analysis of the figures that you hold that was carried out to explain this/or that was carried out for another purpose buts sheds some light on why this spike occurred?	24 June 2013	Answered - in full
13/222	The number of people (of all ranks) that are currently available to carry-out GMP inspections of manufacturers of medicinal products: a. In UK? b. Overseas? c cpmbined?	13 June 2013	Answered - in full
13/223	Toxicological information on terbutaline sulfate, currently marketed in the UK as Bricanyl®.	21 June 2013	Answered - in part
13/224	The 3 most recent Pharmacovigilance Inspection reports available.	07 June 2013	Answered - in part
13/225	2012 MHRA inspection report (or latest) and the company response to any findings cited in the report for the following companies: 1. The manufacturer: LUPIN LIMITED Site address: 15B, PHASE 1A VERNA INDUSTRIAL AREA, VERNA, SALCETTE, IND-403722, India 2. The Manufacturer: LUPIN LIMITED Site address : 198-202 NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, DISTRICT RAISEN, IN 462 046, India	19 June 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/226	Feb 2013 MHRA inspection report (or latest) and the company response to any findings cited in the report for the following companies: 1. The manufacturer: INTAS PHARMACEUTICALS LIMITED Site address : PLOT NUMBERS 457 AND 458, SARKHEJ- BAVLA HIGHWAY, MATODA, SANAND, AHMEDABAD, IN-382210, India 2. The manufacturer: GLENMARK GENERICS LIMITED Site address : PLOT 2, PHASE II, PHARMA ZONE SEZ, PITHAMPUR, DHAR DISTRICT, IN-454 774, India	19 June 2013	Answered - in part
13/227	2012 MHRA inspection report (or latest) and the company response to any findings cited in the report for the following companies: 1. The manufacturer: DR REDDY'S LABORATORIES LIMITED FTO - UNIT 3 Site address: SURVEY NO. 41, BACHUPALLY VILLAGE, QUTUBALLAR MANDAL, IN-500 090, India	05 June 2013	Answered - in part
13/230	1. The Medicines and Healthcare products Regulatory Agency's policy on the use by your staff of airmiles obtained from travel undertaken as part of fulfilling their functions for their private purposes. 2. What safeguards are in place to ensure adherence by staff to your policy, and how the safeguards are enforced. 3. If staff are found not to adhere to your policy, how you would manage this.	24 June 2013	Answered - in full
13/231	Details of the MHRA process for addressing new evidence, who is involved and what procedures are in place to update guidance to professionals and patients and when the Medical Devices Alert and/or the Health Crisis Management budgets and systems will be deployed.	01 July 2013	Answered - in full
13/233	Copies of all documentation relevant to the processing of the application by the MHRA Copies of all correspondance received by, or dispatched from, the MHRA with regard to the application (Kenalog IA/IM Injection 40 mg/ml Adcortyl Injection 10 mg/ml)	28 June 2013	Answered - in part
13/234	All information (except for any personal information) included on all 'YellowCard' adverse drug reaction reports submitted to MHRA where the suspected drug was Misoprostol and where prescribed for induction of labour For each report I would like to know the name of the relevant hospital or institution that submitted it.	28 June 2013	Answered - in part
13/237	Information on the incidence and outcome of pregnancies for women taking Lyrica (Pregabalin)	28 June 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/238	The latest Periodic Safety Update Report(s) for: Lemsip Max All Night Cold & Flu Tablets and/or Lemsip Max All Night Flu Relief Tablets and/or Nurofen Day & Night Cold & Flu 200mg/5mg Tablets	28 June 2013	Answered - in part
13/240	How many drugs or appliances which were allowed onto the UK market for 2011-2012 were subsequently withdrawn from the market due to adverse drug reactions or serious complications or diseases as a result of taking drugs or using appliances which did not outweigh the benefits of taking the drug or using the appliance? How many drugs/appliances were developed in 2011-2012? How many drugs and appliances which passed pre-clinical (animal trials) subsequently failed to reach phase 3 clinical trials for 2011-2012?	04 July 2013	Answered - in part
13/242	A list of medical conditions made known to the MCA(CHM) by doctors when submitting applications for import of unlicensed single vaccines supporting their argument that these conditions make the administration of the MMR vaccine unsuitable. A list of medical conditions recognised by the MCA/CHM from those submitted by GP's seeking import of single vaccines making the administration of MMR unsuitble, which result in them granting permission for the import of a single vaccine for an individual.	18 June 2013	Answered - in full
13/244	The most recent inspection reports for the following organisations: Amgen Chiesi Valeant Pierre Fabre	08 July 2013	Answered - in part
13/246	- The number of clinical trials registered or carried out in the UK (preferably with a principal investigator based in the UK) per year, since the beginning of 2008 - The proportion of these clinical trials investigating the following: medicinal products; psychological interventions; service evaluations; other The numbers of these trials that were observational, and the number that were investigational - Numbers of the above trials in each phase of research (feasibility/pilot; phase 1; phase 2	08 July 2013	Answered - in part
13/247	A copy of the risk management plan for paricalcitol (Zemplar)	09 July 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/249	Copies of all correspondence between the MHRA and "ASH" (Action on Smoking and Health) relating to the subject of e-cigarettes for the period 1 January 2013 to 13 June 2013. "Correspondence" should include (but not limited to) any and all emails, letters, notes from meetings and telephone calls as available. 2. Please supply any reports/briefing notes or advice that has been provided to the MHRA by ASH (Action on Smoking and Health) on the topic of e-cigarettes.	09 July 2013	Answered - in part
13/250	A copy of the report for the inspection dated 15/12/2010 of the following site: IND-SWIFT LIMITED OFF NH-21 VILLAGE JAWAHARPUR TEHSIL DERA BASSI DISTRICT SAS NAGAR (MOHALI) PUNJAB PIN-140507 INDIA	20 June 2013	Answered - in part
13/256	You propose regulating electronic cigarettes. Please tell me how much you have spent to-date on this:- Including: meetings time, working parties, writing reports and press releases, purchasing products and the consultation you have undertaken. Also please advise me as to how and why the whole process began, whose idea was it, who raised concerns and what were those concerns.	09 July 2013	Answered - in part
13/261	The name and email address (as known on the 14th June 2013) of: The name of all Directorates as they currently stand The name and emial address of all HR and Recruitment staff as they currently stand Any Assistants / Deputies / Associates of Operations	12 July 2013	Answered - in part
13/262	All correspondence between the MHRA and the following organisations with regards to NCPs for the period January 1 2013 to June 14: - British American Tobacco (including any affiliate and/or company working on its behalf) - Imperial Tobacco (including any affiliate and any affiliate and/or company working on its behalf) - Japan Tobacco International (including any affiliate and/or company working on its behalf) - Forest - Tobacco Manufacturers' Association - Ecita	11 July 2013	Answered - in part
13/263	Minutes of the Working Group of the CHM on Nicotine Containing Products. Please disclose all minutes taken of meetings conducted since the MHRA launched a consultation on NCPs in 2010, in addition to those minutes currently on the website.	28 June 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/264	Contact with MHRA team covering alteplase (for acute ischaemic stroke)	08 July 2013	Answered - in full
13/265	Various questions about funding the MHRA has received for each of the 3 past financial years	21 August 2013	Answered - in part
13/266	A list of all homeopathic medicines registered under the Homeopathic Registration Scheme, the dates on which registration was granted and dates of the last renewal of registration. Please also confirm whether or not authorisations under the National Rules scheme require renewal after a period of time, and, if so, please say what that period is and please supply the same information for all those products.	12 July 2013	Answered - in full
13/267	Public Assessment Reports - Zoladex (Goserelin Acetate)	08 July 2013	Answered - in part
13/270	Confirm the legal category for which the application was made (MAH: Mercury Pharmaceuticals Ltd) i.e. was this a full application (including clinical trials)?	09 July 2013	Answered - in part
13/273	Copies of or a summary of the responses made by stakeholders to the above public consultation (MLX 263 EMERGENCY CONTRACEPTION: LEVONORGESTREL 0.75mg PROPOSED AMENDMENT TO THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) ORDER 1997) in May 2000 under the freedom of information act.	11 July 2013	Answered - in part
13/275	How many of the studies used to support this proposal (regulation of NCPs) were funded by companies involved in the manufacture or distribution of tobacco products? Two samples of electronic liquid were supplied by ECITA. The released paper states that the results of analysis on these samples was redacted at the request of ECITA. Who at ECITA requested this redaction and on what grounds?	15 July 2013	Answered - in part
13/276	Are any homeopathic products currently licensed by MHRA as suitable for medicinal use? If so, how many of these products are licensed? What was the evidence of efficacy that allowed these products to be granted a medical license?	15 July 2013	Answered - in full
13/277	The SGS Vitrology MHRA inspection reports (including the internal spreadsheet used for the risk assessment and background information for the GLP inspection report detailed as (Insp GLP 33228/464870-0005) and the additional summary report and risk assessment for the GMP inspection detailed as (Insp GMP/IMP 33228/46470-0006)	16 July 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/279	Details of all GMP inspections carried out at Astrazeneca's Macclesfield manufacturing facility to date, including details of all the deficiencies (Critical, Major, or Other) observed at the facility. - Astrazeneca's response to each GMP inspection (above)	11 July 2013	Answered - in part
13/280	A complete list of all marketing authorisation holders in the UK including (where possible) contact details.	16 July 2013	Answered - in part
13/281	Information in respect of the licensing agreements which were granted to OPAL.	16 July 2013	Answered - in full
13/283	Any information you hold about products under the Forever Living brand e.g. whether their products are licensed at all, if they're allowed to be sold with claims that imply effectiveness in treating a condition etc.	18 July 2013	Answered - in full
13/286	Homeopathic Registrations	15 July 2013	Answered - in full
13/288	Query relating to PIP implants - document CON143660 PDF refers	02 August 2013	Answered - in full
13/294	Various questions on the sale of homeopathic unlicensed medicines	16 July 2013	Answered - in full
13/295	Any information in the public domain for the POM to P switch of Triamcinolone acetonide (nonpressurised nasal spray) in 2000.	23 July 2013	Answered - in part
13/296	The companies and the provisional dates or estimated dates of each MHRA PV inspection (not GCP or GMP).	10 July 2013	Answered - in full
13/300	Further Questions related to Actavis (in follow up to 13/044 and 13/099).	11 July 2013	Answered - in part
13/301	The total number of complaints, whether upheld or not received by the MHRA that relate to the attached list of blood glucose meters and strips that you have received in each of the last 5 years	01 August 2013	Answered - in part
13/303	Various questions about inspections of biotech, generics, pharmaceutical companies and CRO companies.	25 July 2013	Answered - in part
13/304	Are there any products produced by the company Biotonic which are registered, licenced and allowed to be sold with health claims?	29 July 2013	Answered - in full
13/309	1. Since the yellow card scheme was first set up, how many reports of adverse drug reactions have you received and what is the average amount for each year 2. Adverse drug reaction figures for NI and other countries in the UK for the past 5 years 3. The top 10 adverse drug reactions reported from NI and the other UK countries for the past 5 years	23 July 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/311	Minutes of all meetings that discuss the safety and efficacy of incretin mimetic drugs Emails about safety concerns between the market application holders of incretin drugs and the MHRA Emails between the MHRA and the members of the CSM about the safety of incretin mimetic drugs	10 September 2013	Answered - in part
13/314	Further questions on PIPs and the Keogh MHRA review and testing ("How many implants were tested? Did these include implants that had been removed from women? Did these tests include the fluid found around ruptured implants on affected women?", also substantiate what the evidence is for the recent NHS claim that: 'Initially reports also linked the implants to a rare form of cancer known as ALCL. This cancer link has been now been firmly discounted by medical experts here and in Europe.')	25 July 2013	Answered - in full
13/316	Accutane: Monitoring issues (mental health)	02 August 2013	Answered - in full
13/317	Information on Sargramostim.	05 August 2013	Answered - in full
13/318	Copies of the last 2 Good Distribution Practice Inspection Reports (redacted as necessary)for the following Wholesale Dealer's: Wigmore Medical Ltd (WL 8698) Holburn Pharmacy Ltd (WL 40135) FAB Medic Limited (WL 35910) Pharma Cure Health Care Limited (WL 34535) Borehamwood Supplies Ltd (WL 31900) Life Pharmaceuticals Limited (WL 32124) Theiam Limited (WL 40127)	30 July 2013	Answered - in part
13/322	A copy of the inspection report of MHRA audit of Reliance Life sciences In Thane India June 2012.	18 July 2013	Answered - in part
13/323	Summary of the bioequivalence study report used to support the application for Prochlorperazine 3mg Tablets (PL 21880/0126).	16 July 2013	Answered - in full
13/324	Names of all contract research organisations (CRO) which are working in the UK and whose activities are regulated by MHRA.	16 July 2013	Answered - in full
13/325	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs. (categories also listed).	07 August 2013	Answered - in full
13/326	Copies of the last 3 GDP inspection reports for Wigmore Medical Ltd Licence Holder WL 8698 SITE ID : 93796 23 WIGMORE STREET, LONDON, UNITED KINGDOM, W1U 1PL	01 August 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/327	The legal basis (type of application) for the following licenses. Also, the Public assessment reports for these licenses: 1. PL 17905/0065 - Boots Pharmacy Tension Headache Tablets (also called Paracetamol, Codeine, Caffeine & Doxylamine Compound Tablets) 2. PL 04416/0363 Propain Plus Tablets	06 August 2013	Answered - in full
13/329	Copies of Modules 2.4 & 2.5 of the marketing authorization dossier for Sudafed 0.1% Nasal Spray	06 August 2013	Answered - in part
13/330	PIP implants and breast feeding	02 August 2013	Answered - in full
13/331	In relation to product licences PL 21806/0038 and PL 21806/0039, issued on 08/04/2013 in the name of ACINO AG (IVACONICA (rivastigmine) transdermal patch 4.6 MG/24 H and 9.5 MG/24 H, respectively), please provide copies of the following parts of the MA dossier (using EU CTD references): - Section 1.8.2 Risk-management System - Section 3.2.P Drug product - Section 5.3.1 Reports of Biopharmaceutic Studies	25 July 2013	Answered - in part
13/334	What progress has been made towards MHRA's Review of Medicines Act 1968: Informal consultation on issues relating to the product licences of right (PLR) regime and homeopathy	05 August 2013	Answered - in full
13/335	LAST 10 INSPECTIONS WITH CRITICAL FINDINGS	06 August 2013	Answered - in part
13/337	The number of packs of Ergotamine Tartrate which have been granted import approvals over the past 12 months. Broken down according to the form/strength	19 July 2013	Answered - in full
13/338	(1) How many herbal products has the Borderline Section assessed in order to determine their medicinal status in the last 12 months? (2) Of the herbal products assessed in (1), how many have received a final determination and how many are pending? (3) How many products containing the herb Milk Thistle were assessed during the last 12 months? (4) Of these products in (3), how many received a final determination and how many are pending? (5) Of the Milk Thistle products that did NOT receive a final determination in (3), what was the highest amount of Milk Thistle in the products? (6) Are any Milk Thistle containing herbal products currently under assessment for medicinal status by the Borderline Section?	13 August 2013	Answered - in full
13/341	Electronic cigarettes	13 August 2013	Answered - in part
13/343	Inspection reports for 2012-2013 for Idis limited and/or any other available information	13 August 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/344	Electronic cigarettes	09 August 2013	Answered - in full
13/345	What action has been taken against named websites apparently in breach of advertising regulations	12 August 2013	Answered - in part
13/347	Various questions regarding devices compliance action	15 August 2013	Answered - in part
13/348	Contact with MHRA team covering alteplase (for acute ischaemic stroke)	31 July 2013	Answered - in part
13/350	Copy of European review of scientific evidence" for a positive efficacy conclusion for Reboxetine	20 August 2013	Answered - in part
13/351	Questions regarding Agency use of air miles and prevention of abuse by staff	20 August 2013	Answered - in full
13/352	The brands of the following vaccines: A20CA277A (haemophilus B) A20LA277A (DTp) NF47110 (MMR)	29 July 2013	Answered - in part
13/358	Information about the total amount of money paid to trade unions by MHRA, the amount of staff time spent on trade union duties and/or activities and the payment of subscriptions	23 August 2013	Answered - in full
13/362	Copy of any audit report for Mallinckrodt Chemicals in Raleigh Durham North Carolina USA. In particular for the API facility for Paracetamol	22 August 2013	Answered - in part
13/364	MHRA provisional determinations by the Borderline Review Panel	29 August 2013	Answered - in full
13/369	A copy of the MHRA inspection report for the continuance of Manufacturer's Authorisation MIA 35682 for Fairview Health Limited, Harrow, HA1 2SP, carried out on 04.05.2012.	22 August 2013	Answered - in part
13/370	SCOPE: Protocol Review - Provings of homeopathic medicines - MHRA-2013-05-Homeopathic-provings	02 September 2013	Answered - in full
13/371	A list of all unlicensed medicines for which import notifications have been received by the MHRA in 2012, and the number of import notifications received in respect of each unlicensed medicine in this list.	12 August 2013	Answered - in full
13/372	A copy of the PAR for the Diclofenac Plaster that was authorised as a hybrid application, as presumably therapeutic equivalence was needed compared to a reference product? Are there also PARs available for Ibuprofen Gel formulations authorised as hybrid applications compared to a reference a product?	14 August 2013	Answered - in part
13/375	(Re alteplase for acute ischaemic stroke) - The papers discussing the extended therapeutic window.	03 September 2013	Answered - in full

FOI no	Subject	Date reply sent	Result of request
13/378	Numbers/statistics of Manufacturer's and wholesale dealer's licences issued in the past 5 years.	19 August 2013	Answered - in full
13/379	How many chlorhexidine related sensitivity, allergic or anaphylactic reactions have been reported to MHRA to date?	12 September 2013	Answered - in full
13/380	Any data that reports information on herbal products (THR and unlicensed) that have been reported via the yellow card scheme since the introduction of THR regulations and information on plant species reported via the yellow card scheme.	09 September 2013	Answered - in full
13/382	The establishment inspection report of Reliance Life Sciences Pvt Ltd, which was conducted in year 2012.	13 September 2013	Answered - in part
13/385	Inspection report on Cipla Limited (Unit II), Plot No L-139, S-103 & M-62, Verna Industrial Estate, Verna, IN-403 722, india, dated 2012-10-08. GMP 14694/1071884-003 refers.	13 September 2013	Answered - in part
13/386	Inspection report for Indoco Remedies Limited, L-14, Verna Industrial Area, Verna IN-403 722, India. Inspection date 2011-11-30. GMP 19756/12594-0005 refers.	13 September 2013	Answered - in part
13/388	Most recent inspection report for Cipla Ltd (Unit 1), Plot No L/139-146, Verna Industrial Area, Verna, IN-403722, India. GMP 14694/12331 refers. If this site is no longer inspected, please provide reason.	13 September 2013	Answered - in part
13/389	Copy of the RMS Day 210 Final Assessment Report - copy of the clinical overview - copy of literature references For Ibuprofen and Phenylephrine hydrochloride 200mg/5mg film-coated tablets	04 September 2013	Answered - in part
13/390	Various questions on use of on line procurement companies.	27 August 2013	Answered - in full
13/391	A copy of the last GDP/GMP inspection report for: BR Lewis license number WL 8929 Amimed Direct WL 17168	13 September 2013	Answered - in part
13/393	UK product licenses for sleeping pills	13 September 2013	Answered - in full
13/394	The 3 most recent Pharmacovigilance Inspection reports.	12 September 2013	Answered - in part
13/395	Why the UKPAR published by the MHRA in 2011 for Fultium-D3 has retrospectively had information on a study removed from the public domain?	17 September 2013	Answered - in full
13/396	A copy of the reports provided in FOI 13/140 The latest 3 inspection reports of inspections performed to non-commercial organisations (eg. Cancer research UK)	13 September 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/397	ADRs to HPV vaccines (various questions), inlcuding about POTS (postural orthostatic tachycardia syndrome) and autonomic dysfunction.	18 September 2013	Answered - in full
13/398	Copies of the correspondence between ASH UK and MHRA, as referenced in The Times, August 20th, this year.	20 September 2013	Answered - in part
13/400	Yellow card reporting query	12 September 2013	Answered - in full
13/401	The last two most recent GMP inspections of the Radiopharmacy in the Belfast Health and Social Care Trust, the last two most recent GMP inspections of the Cyclotron Facility in the Belfast Health and Social Care Trust, a copy of any minutes from the Inspection Action Group regarding this facility.	23 September 2013	Answered - in part
13/403	A copy of 150 pages of emails -previously released under the FOIA- between ASH's chief executive, and the MHRA official who led the review of electronic cigarettes, in the six months leading up to the announcement in June 2013.	20 September 2013	Answered - in part
13/404	Information on the MHRA's consultation on nicotine containing products.	20 September 2013	Answered - in part
13/405	Batch Code Release Certificates for HPV Vaccines	09 September 2013	Answered - in full
13/407	A copy of the Board paper of December 2011 covering the current and future strategy for the British Pharmacopoeia. Its reference was COM11(37)	25 September 2013	Answered - in part
13/408	A copy of the MHRA inspection report for the continuance of Manufacturer's Authorisation MIA 35682 for Fairview Health Limited, Harrow, HA1 2SP, carried out on 04.05.2012.	23 September 2013	Answered - in part
13/410	In October 1994, Beechams All-in-One oral solution (active ingredients: paracetamol, phenylephrine hydrochloride and guaifenesin) was authorised in the UK (PL 00079/0320). We understand that the excipients for this product currently include sorbitol. Please kindly confirm whether this product (whether under the PL 00079/0320 or as a separate PL) has ever been authorised without the addition of sorbitol.	04 September 2013	Answered - in full
13/411	Questions regarding Myodil	07 November 2013	Answered - in part
13/412	A copy of the Public Assessment Report for the following licenses: 1) Hidrasec 100 mg hard capsules PL 39418/0003 2) Hidrasec Children 30 mg granules for oral suspension PL 39418/0002 3) Hidrasec Infant 10 mg granules for oral suspension PL 39418/0001	04 September 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/413	A copy of the public assessment report for PL 04416/0406 granted on 18 February 2005 to Sandoz Limited	24 September 2013	Answered - in part
13/414	Information request which relates to the MHRA's Wi-Fi contract(s).	12 September 2013	Answered - in full
13/416	Last MHRA Inspection report for Pharmaserve Clifton Business Park Wynne Avenue Swinton Manchester M27 8FF	30 September 2013	Answered - in part
13/418	Questions about MHRA's Telephone System Maintenance	22 October 2013	Answered - in full
13/419	Gamma linoleic acid containing products	01 October 2013	Answered - in full
13/420	Was the protocol N° BA0858081/Project N°BA0858081-01 one (Study performed on april 2008)? (Bioequivalence study submitted for marketing authorization of the product losartan potassium 50 mg)	13 September 2013	Answered - in full
13/423	Assessment report for the variation to amend the summary of product characteristics for Decapeptyl SR11.25mg.	08 October 2013	Answered - in part
13/424	Any and all documents in your possession concerning Lustral and birth defects and/or Lustral and pregnancy in any way.	10 October 2013	Answered - in part
13/425	Various questions on solid doses of Vitamin D3 (ergocalciferol).	09 October 2013	Answered - in part
13/427	A summary of completion by reporter, I.e. % of reports from pharmacists that were complete etc (Yellow card).	01 October 2013	Answered - in full
13/428	ISE 13-1364 - Escitalopram 5, 10, 15 and 20mg film-coated tablets (Teva UK Limited) (PL 00289/1724-1727)(follow up to previous request)	20 September 2013	Answered - in full
13/429	A breakdown of the number of all the alleged side effects associated with Yasmin contraceptive pills as reported to you under the yellow card scheme.	08 October 2013	Answered - in full
13/430	For the 2012 calendar year could you please state the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery. For the 2012 calendar year's Adverse Reactions to breast implants used in breast enlargement surgery please could you give me a complete breakdown of the side effects that the reporter has claimed.	11 October 2013	Answered - in full
13/431	Information on current and historic Medical Device Alerts for various devices.	07 October 2013	Answered - in full
13/432	Server (Hardware and Software) and Storage (SAN) contracts	09 October 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/433	LAN/WLAN Contracts	09 October 2013	Answered - in part
13/435	All correspondence with the Advertising Standards Authority on e-cigarettes since February 2010.	15 October 2013	Answered - in part
13/437	Assessment reports for Decapeptyl 3mg (1 monthly) and 11.25mg (3 monthly) preperations.	15 October 2013	Answered - in part
13/438	MHRA GMP report resulting from inspection on 19/07/2012 for Synergy Health Sterilisation UK Limited; Moray Road; Elgin Industrial Estate; Swindon; Wiltshire; SN2 8Xs; UK	10 October 2013	Answered - in part
13/439	How many of the subcutaneous tissue related reactions referred to in the 2012 review of hpv relate specifically to alopecia? Why has Japan banned gardasil?Why are alopecia and not having periods seen as a side effects when you put 'Gardasil side effects' in a search engine.	16 October 2013	Answered - in full
13/440	Fleet Management- Contract Information	01 October 2013	Answered - in full
13/443	The associated ADR data for 2013 as referred to in the report summary (FOI 13.380), and the breakdown of the data by substance or plant species, whether THR, other licensed or non-licensed and by reporter type (data per year)	05 March 2014	Answered - in full
13/444	Various questions on Lyrica TM, Pfizer.	21 October 2013	Answered - in full
13/445	Risk Management Plan for Spiriva Respimat 2.5 mg solution for inhalation (NL/H/0718/001/DC).	17 October 2013	Answered - in part
13/446	Whether the Borderline Independent Review Panel has overturned any provisional determinations made by the MHRA that a product was medicinal that was subsequently referred to the Panel during the last 12 months. Details of the product(s) concerned and the reasons behind the determination.	21 October 2013	Answered - in full
13/447	Copies of the assessment reports for clinical data and per-clinical data, for: - Beechams All-in-One oral solution - Beechams All-in-One oral tablets.	23 October 2013	Answered - in part
13/448	UK clinical trial authorisation assessment performance: Phase I Metrics	22 October 2013	Answered - in full
13/451	If the MHRA carried out tests on the chemical compostion of the PIP shells and whether they found DEHP. If the MHRA actually carried out its own tests on the industrial grade silicon used in the PIP implants and how and where these tests were carried out and if they found DEHP. If not, what tests are you using as a basis for your report on PIP.	16 October 2013	Answered - in part
13/452	Report from inspection (Of Tillomed Laboratories).	18 October 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/455	Yellow card data for: 1) all cardiac-related adverse events in which azithromycin is the primary suspect 2) all adverse events in which ezetimibe or any drug in which ezetimibe is an ingredient is the primary suspect 3) all deaths in which gabapentin is the primary suspect. Also, all completed suicides and attempted suicides in which gabapentin is the primary suspect.	28 October 2013	Answered - in full
13/458	Various questions about inspections of biotech, generics, pharmaceutical companies and CRO companies.	25 October 2013	Answered - in part
13/459	NJR report to the MHRA concerning the Pinnacle Ultamet Audit	24 October 2013	Answered - in part
13/460	The total cost the MHRA has spent on introducing Lean Six Sigma into the Information Processing Unit? The number of staff in each pay category and their salary range, within the information processing unit on 1st September 2012 and 1st September 2013.	22 October 2013	Answered - in full
13/463	Chifeng Pharmaceutical EDQM inspection (MHRA inspection report).	09 October 2013	Answered - in part
13/467	The most recent completed inspection reports for: Hammersmith Medicines Research Ltd, DHL (McGregor Cory Ltd) & Mc Gregor Cory Ltd.	24 October 2013	Answered - in part
13/470	Emails between MHRA and ICO, and MHRA and Pfizer regarding FOI request 08/330 regarding Linezolid	05 November 2013	Answered - in part
13/471	A copy of the last GMP/GDP Inspection reports for Mitovie Pharma and Temag please	05 November 2013	Answered - in part
13/474	Copy of the most recent AR for the GMP Inspection of Pharmasol, Andover. A copy of the AR for the most recent GMP Inspection of Bafna Pharmaceutical, Grantlyon Village, Chennai, India.	24 October 2013	Answered - in part
13/475	The two most recent MHRA inspection reports for Seven Seas Limited & Brunel Healthcare Manufacturing Limited	05 November 2013	Answered - in part
13/476	Correspondence from February 2010 to October 11 2013 between the MHRA and British American Tobacco on nicotine containing products.	08 November 2013	Answered - in part
13/478	Correspondence to and from MHRA's Group Manager Therapeutic review, in the last year, related to patients' long-term use of and addiction to prescribed benzodiazepines, z drugs and SSRIs.	11 November 2013	Answered - in part
13/479	"Sexual effects" caused by SSRI's.	08 November 2013	Answered - in full
13/482	Assessment report in relation to PL 00101/0511, 0512 and 0513 (Sandostatin LAR).	11 November 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/483	Last 3-5 full PV system inspection reports	13 November 2013	Answered - in part
13/488	Are any board members still working for any Pharmeceutical companies either as paid consultants or salaried staff	06 November 2013	Answered - in full
13/490	Any PSUR - Study Purpose	24 October 2013	Answered - in part
13/491	A redacted copy of the most recent GMP/GDP Inspection Report for ACCORD HEALTHCARE LIMITED.	14 November 2013	Answered - in part
13/492	All events related to the tuberculosis drug bedaquiline (also known as Sirturo or TMC207), including details of type of adverse event, date, location of subject etc.	21 November 2013	Answered - in part
13/493	A copy of the most recent MHRA GMDP Inspection Report for: Licence Holder MIA(IMP) 15140 HAMMERSMITH MEDICINES RESEARCH LIMITED CUMBERLAND AVENUE, LONDON, UNITED KINGDOM, NW10 7EW.	15 November 2013	Answered - in part
13/494	Various questions about clinical trials.	21 November 2013	Answered - in full
13/495	Further questions relating to PIPs	21 November 2013	Answered - in full
13/498	Information for HPV Vaccines	21 November 2013	Answered - in full
13/501	A redacted copy of the most recent MHRA GMP/GDP Inspection Report for: SHIRE PHARMACEUTICALS LIMITED	19 November 2013	Answered - in part
13/502	How many witnessed audits the MHRA conducted on third party repair services in the UK in the last 5 years.	28 November 2013	Answered - in full
13/503	Various questions about disposal of old IT material.	21 November 2013	Answered - in full
13/505	Dates and outcomes of inspections for the past 12 months.	27 November 2013	Answered - in part
13/506	All MHRA inspection reports for the period 2010-2013 (inclusive) for the Blood Transfusion Laboratory in Southport & Ormskirk Hospital NHS Trust.	28 November 2013	Answered - in part
13/507	Yellow card data request.	26 November 2013	Answered - in full
13/508	All findings (Anonymised) from the last 10 reported pharmacovigilance inspections of MAHs, carried out by MHRA.	27 November 2013	Answered - in part
13/509	Copies of the Minutes of the Meetings in October and December 1988 from the ARGOS committee. (Adverse reaction group of SEARS).	29 November 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/511	Breakdown of suspected adverse reactions (ADRs) compiled by MHRA in the 2012 calendar year in relation to vaccines, where the report was of a fatal ADR please state the vaccine type and what type of person was responsible for filing the report.	29 November 2013	Answered - in full
13/512	Latest figures etc related to citalopram and birth defects.	13 November 2013	Answered - in full
13/514	Last 10 Companies receiving critical findings in Pharmacovigilance inspections.	27 November 2013	Answered - in part
13/518	Address of Counterfeit Avastin Distributor Escaped Capture Now Living In Safety In Canada.	05 December 2013	Answered - in full
13/519	Other groups such as advisory boards or NIBSC or CPRD members (still paid by pharmaceutical industry).	06 December 2013	Answered - in full
13/520	"True date of declarations" from Wockhardt.	04 December 2013	Answered - in full
13/521	Information on the One Year Extension of Marketing Protection	03 December 2013	Answered - in part
13/525	A list of all Jbol's and or REDACTED FOI's and DPA to the MHRA with their reference nos and if they were appealed.	03 December 2013	Answered - in full
13/528	Various details of each party/organisation that the MHRA has contacted in its research and discussions (regarding First tier Tribunal ref no Re: EA/2011/0199).	06 December 2013	Answered - in part
13/529	MHRA correspondence dated 10 June 2008, 25 November 2008 and reply 5 December 2008 re: 08/330 referenced in FOI 13/470	05 December 2013	Answered - in part
13/531	Copy of the latest inspection report for Eaststone Limited.	05 December 2013	Answered - in part
13/532	Whether Minocycline IV has ever been registered in the UK and if so, what was the approved SmPC and why was the product withdrawn.	04 December 2013	Answered - in part
13/535	Last PSURs of Zolpidem and Zopiclone.	10 December 2013	Answered - in part
13/537	Withdrawal of Recipharm's 100mcg and 50mcg Levothyroxine Sodium tablets.	10 December 2013	Answered - in full
13/538	SPC's for: Zopiclone (Zimovane), Zolpidem Tartrate (Stilnoct), Lormetazepam, Flurazepam Monohydrochloride (Dalmane), Loprazolam, Nitrazepam (Mogadon), Temazepam, Diazepam (tablets, marketed by Actavis UK), Lorazepam (marketed by Genus Pharmaceuticals), Circadin	06 December 2013	Answered - in full
13/541	Copy of the last 2 GMP Inspection Reports for Accord Healthcare Ltd Harrow and Haverhill sites	10 December 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/542	More questions relating to transfer of PLRs for Homeopathics.	06 December 2013	Answered - in full
13/543	Importation of unlicenced medicines	02 December 2013	Answered - in full
13/544	Most recent GMP Inspection Report of Nestor (UK) Ltd.	09 December 2013	Answered - in part
13/547	All adverse reactions reported concerning herbal and any CAMs product over the last 5 years.	17 December 2013	Answered - in part
13/551	Further questions about PIP breast implants.	17 December 2013	Answered - in full
13/552	Disclosure of all flexible/part time working requests including all request that have been approved and please also confirm the sex of each employee and whether or not he/she has a disability.	06 December 2013	Answered - in part
13/553	How much money the MHRA paid the York Health Economics Consortium for the York Report.	17 December 2013	Answered - in full
13/554	Adverse incident data for wound care products including wound dressings, gels, ointments, rinses etc.	17 December 2013	Answered - in full
13/555	Drug analysis prints for oral phenylephrine (single active constituent) oral pseudoephedrine (single active constituent) oral paracetamol (single active constituent) oral acetylsalicylic acid (single active constituent)	23 December 2013	Answered - in full
13/556	Information on Flu Vaccines	13 December 2013	Answered - in part
13/558	E-cigs and Stakeholders	23 December 2013	Answered - in part
13/559	MHRA Policy and practice (regarding First tier Tribunal ref no Re: EA/2011/0199).	24 December 2013	Answered - in part
13/560	MHRA GMP inspection report for Aesica Pharmaceuticals.	09 December 2013	Answered - in part
13/561	A copy of the current RMP for Zyvox.	27 January 2014	Answered - in part
13/562	A breakdown of all the alleged side effects associated with the drugs as reported to you under the yellow card scheme (for isotretinoin).	10 January 2014	Answered - in full
13/563	GMP report for the inspection conducted at Hisun Pharmaceutical Company, Ltd. - Zhejiang	05 December 2013	Answered - in part
13/564	Periodic Safety Update Report and Risk Management Plan for Copaxone.	27 January 2014	Answered - in part
13/565	Formulation switching of antiepileptic drugs - various questions including about consultation.	24 December 2013	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/567	All committee meeting correspondence (various different groups), regarding the use of ACTC's MA-09 RPE cells to treat Stargardt's disease)	18 February 2014	Answered - in part
13/568	The recent or last three inspection observations made by named inspectors in India for any pharma company.	17 December 2013	Answered - in part
13/569	The last GDP inspection for Lornamead UK Ltd.	10 December 2013	Answered - in part
13/570	If the MHRA receive payments by pharmaceutical companies to pass their drugs and devices with a CE label for sale/USE in the UK.	15 January 2014	Answered - in part
13/572	Various questions regarding Yellow card data.	02 January 2014	Answered - in part
13/574	GMP Inspection reports for Pharamserve Northwest.	20 December 2013	Answered - in part
13/577	Marketing authorisation applications and post marketing safety and efficacy studies (Phase IV) for Arcoxia® (etoricoxib)	06 January 2014	Answered - in part
13/578	A copy of the last MHRA GMP Inspection report conducted at Afton Scientific Corporation	20 December 2013	Answered - in part
13/579	Priorix (MMR Vacc),Prevenar and Menitorix	24 December 2013	Answered - in part
13/580	MHRA PV inspections in the last 2 years.	07 January 2014	Answered - in part
13/581	Licenses for rational PHYTOS in the UK.	16 December 2013	Answered - in part
13/583	All the articile 266 letters sent to the MHRA	24 December 2013	Answered - in part
13/584	Various questions about pregnancy test kits.	03 January 2014	Answered - in part
13/585	Copies of the recent inspection reports for Wockhardt (the UK (Wrexham) and all the Indian Manufacturing Sites)	03 January 2014	Answered - in part
13/586	All brands for human use been discontinued in England… Details of Export / Import ban, Not suitable for human use, Brand rename (used as alternate name) etc	07 January 2014	Answered - in part
13/587	A copy of the Environmental Risk Assessment (ERA) submitted in procedure No: UK/H/0676/002/DC (Duac Once Daily Gel).	08 January 2014	Answered - in part
13/588	The assessment report for Deep Relief (PL 00189/0027)	08 January 2014	Answered - in full
13/591	Original documents from MA Application by Roche for zalcitabine (Hivid).	10 January 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
13/594	Various questions about the Herbal Medicines Advisory Committee.	16 December 2013	Answered - in part
13/595	Request for redacted post inspection letters	20 December 2013	Answered - in part
13/598	Symbicort Turbohaler Inhalarion powder Risk Management Plan	10 January 2014	Answered - in part
13/599	Various questions about the agency IT network infrastructure.	13 January 2014	Answered - in part
13/600	Pre- and post-marketing reports from prescribers, patients, and/or any healthcare professional. For the drug pregabalin.	14 January 2014	Answered - in full
13/601	A copy of the minutes for each Pharmacovigilance Consultative Committee meeting since the committee was established in November 2004.	14 January 2014	Answered - in part
13/603	Roles and responsibilities in relation to data protection controller(DPC).	13 December 2013	Answered - in part
13/604	Last GMP inspection report AND company responses to letters for Waymade Plc.	10 January 2014	Answered - in part
13/606	Available information/detail specific to molgrastim/molgramostim.	10 January 2014	Answered - in part
13/607	Available information/detail specific to sargramostim.	13 January 2014	Answered - in part
13/608	Reports of Cancelled First In-Human Clinical Trials due to Unexpected Adverse Effects	02 January 2014	Answered - in full
13/611	Information about ADJUSTAMATIC Adjustable bed with the massage therapy.	19 December 2013	Answered - in part
13/612	Copies of the five most recent GPvP inspection reports which have reported findings relating to risk management plans.	14 January 2014	Answered - in part
13/619	MHRA review on antiepileptic drugs.	10 January 2014	Answered - in part
13/620	All correspondence with the following from June 2013 to date on the TPD: 1. E-cigarette Consumer Association 2. Electronic Cigarette Industry Trade Association 3. British American Tobacco 4. Imperial Tobacco	21 January 2014	Answered - in part
13/621	• details of all members of MHRA staff who have a work from home agreement in place and the details of these agreements. • details of request which have been refused and the grounds for refusal • details of all appeals with grounds for appeals and details of the outcomes of these.	08 January 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/002	A breakdown of all the alleged side effects reported to you under the yellow card scheme between 1.7.12 and 30.6.13 (for Co-Cyprindiol).	30 January 2014	Answered - in full
14/003	Who the top three pharmaceutical industries who funded the MHRA were in the years of 2004, 2005, 2006, 2007, 2008 and 2009.	31 January 2014	Answered - in full
14/005	The number of ADR reports /yellow card reports received in respect of the Pluserix MMR vaccine which included the term "deafness".	31 January 2014	Answered - in full
14/007	Licensing dates, SPC and PIL of a medicine called Lutigest 100mg vaginal tablets.	10 January 2014	Answered - in part
14/008	Copy of the III.3. Clinical Aspects Pharmacokinetics and a copy of Clinical Expert Report (for Memantine Hydrochloride ABDI film coated tablets)	04 February 2014	Answered - in part
14/014	Name of allergy drug or drugs used for Deaths from allergy drug for asthmatics introduced from approximately 1978 to 1982.The drug was withdrawn or had it's licence revoked due to recurring deaths.	10 February 2014	Answered - in part
14/015	How many Yellow Cards have been received for the Gardasil HPV Vaccination since it was introduced in England and how many reports have been categorised as 'serious'	06 February 2014	Answered - in full
14/019	Various questions about Chloromycetin	11 February 2014	Answered - in part
14/020	The evidence the MHRA has to support its statement that "A local specialist will be able to advise on authoritative guidelines for benzodiazepine withdrawal "	23 January 2014	Answered - in full
14/022	Whether this Guidance (re the requirements of the EC medical Devices Directives for clinical investigations) or similar guidance was available from the MHRA in published form in 2007?	12 February 2014	Answered - in full
14/023	The latest audit reports for Martindale Pharma, Romford.	29 January 2014	Answered - in part
14/025	Latest audit reports for Martindale Pharma, Brentwood.	29 January 2014	Answered - in part
14/026	Latest audit reports for Wockhardt, Runcorn site.	29 January 2014	Answered - in part
14/029	Information of the process of subsequent manufacturers of the tapes both a) being able to have a summary application and b) not being withdrawn post the original product being taken off the market for "safety" reasons.	31 January 2014	Answered - in full
14/030	Various information on Adverse Incidents relating to Medical Devices.	12 February 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/032	Copies of the Interception of Communications Commissioner's inspection reports for 2011 and 2012	03 March 2014	Answered - in part
14/033	Module 2.5 of Catacrom 2% w/v eye drops, solution	13 March 2014	Answered - in part
14/034	Copy of the most recent MHRA inspection report for Wickham Laboratories Limited	18 February 2014	Answered - in part
14/036	PSUR for Thymoglobulin.	11 March 2014	Answered - in part
14/038	A list of all the companies who have had a PVG inspection since 2012 and found to have major/critical findings.	13 February 2014	Answered - in full
14/039	Request for the last 12 calendar months showing notification approval for unlicensed medicine importation and the manufacturer name and country of origin as per the application form.	03 February 2014	Answered - in part
14/042	Names of various companies and CT investigators that have been inspected and the inspection outcomes.	18 February 2014	Answered - in part
14/043	1. How many hoist deaths have occurred each year in the past ten years 2. the causes of these hoist deaths	12 February 2014	Answered - in full
14/047	Copies of all correspondence relating to: - why 1 report per 1000 doses administered was not considered unexpected (this is 300 reports per 100,000 recipients.	04 March 2014	Answered - in full
14/048	Copies of these 2 studies (CFS/HPV vaccination) and your recent correspondence which identified that these studies exist.	10 March 2014	Answered - in full
14/049	Information regarding all reclassification applications for the active substance Naproxen	25 February 2014	Answered - in part
14/050	The minutes/records of the March 2012 (CHM) meeting and, -A copy of the documents sent out by MHRA in the consultation and a list of the consultees (trade associations and industry)	26 February 2014	Answered - in part
14/051	Further questions regarding work from home agreements.	14 February 2014	Answered - in part
14/052	What companies have GMP and GCP scheduled audiits for the MHRA over the inext 6 months? What companies have been audited to GCP and GMP standards by the MHRA in the last 6 months?	18 February 2014	Answered - in part
14/053	The release of the clinical overview for: SPASMONAL Forte 120 mg, Hard capsules (PL15142/0241)	04 March 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/057	Various questions about inspections of Ranbaxy Indian manufacturing plants.	03 March 2014	Answered - in part
14/059	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs.	10 March 2014	Answered - in full
14/065	Agendas, papers and minutes of the formal IVD External Stakeholder Meetings held over the time period specified.	17 February 2014	Answered - in full
14/066	The originator RMP, or alternatively a list of identified risks (FOR PARACETAMOL).	13 March 2014	Answered - in part
14/067	Emails between MHRA,/MHRA representative and ICO re: FS50--237119 appeal to in late 2013 early 2014.	08 April 2014	Answered - in full
14/068	A copy of the latest GMP audit report for Macfarlan Smith Ltd., 10 Wheatfield Road, Edinburgh, EH11 2QA	04 March 2014	Answered - in part
14/071	Various questions relating to a file to the FTT.	10 March 2014	Answered - in part
14/073	Various details about british Pharmacopoea	17 March 2014	Answered - in part
14/075	Latest MHRA GMP Inspection Reports for MACLEODS PHARMACEUTICALS LIMITED (2 sites).	17 March 2014	Answered - in part
14/076	Latest MHRA GMP Inspection Report for PECKFORTON PHARMACEUTICALS LIMITED.	04 March 2014	Answered - in part
14/077	3 recent Pharmacovigilance Inspection reports, for inspections performes after 01-Jun-2013.	19 March 2014	Answered - in part
14/078	Copy of the generic risk management plan, including the proposed educational materials, for bosentan authorised to Mylan (PL 04569/1397-1398).	20 March 2014	Answered - in part
14/079	The MHRA GMDP Inspection Reports issued within the last 3 years for HONEYWOOD LIMITED	17 March 2014	Answered - in part
14/080	The most recent GDP report for Mawdsley Brooks & Company Limited	20 March 2014	Answered - in part
14/081	Information on the marketing and scientific advice regarding copaxone	08 April 2014	Answered - in part
14/085	Any MHRA Inspection Reports of Moorfields Eye Hospital/Institute of Ophthalmology in the last 10 years	25 March 2014	Answered - in part
14/086	Queries relating to drug manufacturing at Indian Pharmaceutical company, Ranbaxy	24 March 2014	Answered - in full
14/089	The MHRA GMP inspection of Waymade PLC which was conducted on 01.02.2012	26 March 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/090	GMP Inspection report for Dr Reddys laboratories in India.	27 March 2014	Answered - in part
14/093	Various questions on PIP implants, including the registry and Adverse events.	01 April 2014	Answered - in part
14/094	GMP audit report for Lifeplan Products Limited.	31 March 2014	Answered - in part
14/095	Contract information relating to insurance services which include1.Motor, 2.Property, 3.Accident and Liability	31 March 2014	Answered - in part
14/096	Distribution of laptops to staff	17 March 2014	Answered - in full
14/097	Copies of the last two GDP inspection reports forMedipharma Ltd	31 March 2014	Answered - in part
14/099	A copy of the clinical overview of all studies conducted for the original licensing application for Glucophage SR (Merck Pharmaceuticals), PL 11648/0054, granted on 26 Nov 2004.	04 April 2014	Answered - in part
14/100	Data about NHS use of biocides as sealer's when mercury amalgam was used in 1996	07 April 2014	Answered - in part
14/102	GMP Inspection Report for SHASUN PHARMACEUTICALS LIMITED.	04 April 2014	Answered - in part
14/110	Names of various companies and CT investigators that have been inspected and the inspection outcomes up to 28 Feb 2014	08 April 2014	Answered - in part
14/114	Has kings College Hospital (or any other hospital / institution) registered medical devices for use in the ears, with the code/ product number KT00059 and KT00310.	11 April 2014	Answered - in part
14/115	Various questions about the MHRA Report Levothyroxine Tablet Products 'A Review of Clinical + Quality Considerations - 07 Jan 2013	11 April 2014	Answered - in full
14/117	Various questions on Marketing Authorisation applications for fulvestrant.	27 March 2014	Answered - in part
14/118	Details, under the Ib category, for Yellow card submissions for herbal medicines only.	04 April 2014	Answered - in full
14/119	List of drugs/medicines currently prescribed where all the "application files and data" from the original licensing decision have been destroyed and details of the original trials that led to fluoxetine's original approval.	16 April 2014	Answered - in full
14/120	Various questions relating to MHRA expenditure on court case involving the requester.	15 April 2014	Answered - in part
14/122	A copy of the MHRA report for the inspections carried out at MIA 14814 OPD Laboratories Ltd.	14 April 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/123	Various questions regarding an investigation and court case from 2010 which involved the requester.	16 April 2014	Answered - in part
14/124	Inspection report and GMP Compliance certificate for the last GMP inspection performed by the MHRA of Eden Biodesign Ltd.	14 April 2014	Answered - in part
14/126	Various questions regarding alleged complaint made regarding the subjects product on 16 January 2009.	15 April 2014	Answered - in part
14/127	Various questions on MHRA policy of accountability and transparency.	15 April 2014	Answered - in part
14/128	A list of all the exceptions in part 9 (of court judgement).	16 April 2014	Answered - in full
14/129	UK educational material for Renvela	23 April 2014	Answered - in full
14/131	The last GMP audit report for LACSA (PTY) L TO	17 April 2014	Answered - in part
14/133	The number of cases in the UK of Crohn's Disease that have been reported as a side effect after patients of any age were prescribed the antibiotic Oxytetracycline for the treatment of any condition since 1984.	22 April 2014	Answered - in part
14/134	Various questions on Nicorette Inhalator - PL 15513/0358	08 April 2014	Answered - in part
14/139	The total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2013 calendar year.	30 April 2014	Answered - in full
14/140	A list of Banned/Failed Metal and Ceramic hip repalcenments and when these items were suspended/banned.	30 April 2014	Answered - in full
14/143	The MA dossier for LEUCOMAX, including reports of the clinical studies, nonclinical studies and module two summaries.	30 April 2014	Answered - in part
14/144	Is Risperdal Consta 12.5mg (PL 00242/0627) is on the UK Market?	03 April 2014	Answered - in part
14/145	A copy of the MHRA GMP Inspection Report arising from the 2011 inspection of the following standalone laboratory: MCS Laboratories Ltd.	28 April 2014	Answered - in part
14/147	Meeting notes from the Clinical Trials and Biologicals & Vaccine Expert Advisory Group held on January 13, 2014 and also February and March 10, 2014.	08 April 2014	Answered - in part
14/149	GPvP report for AstraZeneca that includes a review of TCS	28 April 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/150	Regarding the numbers of CTA applications received annually (or quarterly if possible) by MHRA since the introduction of statutory instrument 2004 No. 1031.	17 April 2014	Answered - in full
14/151	Communications between the MHRA and Pfizer, Inc. regarding the MHRA's Advertising Complaint: Zyvox (linezolid) - Advert in British Medical Journal (BMJ) 17 November 2006	07 May 2014	Answered - in part
14/152	Various questions about e-cigarettes.	08 May 2014	Answered - in part
14/153	Why an MDA alert was sent out regarding Sigmoidoscope and anoscope systems and accessories	30 April 2014	Answered - in full
14/161	Please could you provide me a redacted copy of the last MHRA inspection of: Idis Idis House Churchfield Road Weybridge KT13 8DB United Kingdom	08 May 2014	Answered - in part
14/162	Yellow Card reporting in respect of Cervarix, Chronic Fatigue Syndrome and fatigue syndromes	16 May 2014	Answered - in part
14/167	Educational material for the healthcare professionals FAQ Brochure (Q&A format) to include: Educational material (information brochure) for the patients and their caregivers for Abilify	19 May 2014	Answered - in full
14/172	Request for information of internal audits and auditing committee	15 May 2014	Answered - in part
14/174	A list of the date of each report to the Yellow Card Scheme of psychiatric disorders associated with the drugs Desogestrel and Norethisterone since the records began.	29 May 2014	Answered - in full
14/175	A list of the dates of each report to the Yellow Card Scheme of psychiatric disorders associated with the drugs Etynodiol Diacetate and Levonorgestrel.	29 May 2014	Answered - in full
14/176	Questions on the Declaration of Interests of Professor Kimber and the CSD.	21 May 2014	Answered - in part
14/177	Latest GMP audit reports for Torbay Pharmacy Manufacturing Unit.	20 May 2014	Answered - in part
14/178	Up-to-date data on ADRs reported through the Yellow Card system on the HPV vaccines (by vaccine brand) and also with the 3-in-1 teenage booster Td/IPV.	28 May 2014	Answered - in part
14/179	Investigations ongoing in to the side effects of RoAccutane	30 May 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/181	What is the bioequivalence specification for hydrocortisone 10mg tablets. Do MHRA have an assurance from Amdipharm that the pregelatinised starch employed in the manufacture of these tablets will be free of trace gluten impurities?	22 May 2014	Answered - in full
14/183	Findings and/or reports of any MHRA inspections of the Horsham, UK facilities of Fisher Clinical Services.	21 May 2014	Answered - in part
14/187	A list of Device alerts on recalled prosthetics, types of pacemakers – defibrillators – hip, knee and shoulder prosthetic parts.	22 May 2014	Answered - in full
14/192	All the registered Manufacturer's "Specials" Licence holders, that are valid for importing unlicenced medicinal products from outside the EEA.	28 May 2014	Answered - in full
14/194	Latest audit reports for Moorfields Pharmaceuticals.	21 May 2014	Answered - in part
14/197	All declarations of interest made by Professor David Nutt from 2000 to 2014	22 May 2014	Answered - in full
14/198	Various questions on Marketing Authorisation applications for fulvestrant.	12 May 2014	Answered - in full
14/200	Results for MHRA GMP, GCP & PV inspections in UK based pharmaceutical organisations and dates of planned new ones.	29 May 2014	Answered - in part
14/202	PL29498/0003 Quinoderm Lotio-Gel 5% I require a copy of the current approved information held by the MHRA regarding: 1. API manufacturers 2. Finished Product Manufacturers 3. QC Sites 4. Sites of Batch Release 5. Any other sites named on the licenses (e.g. storage) 6. Finished Product Specification 7. List of variations	02 June 2014	Answered - in part
14/204	How many ovarian cysts and enlarged spleens have been reported through the Yellow Card scheme after HPV Vaccines.	10 June 2014	Answered - in full
14/205	Various questions about Colecalciferol containing products.	04 June 2014	Answered - in part
14/206	The total alcl cases reported for all breast implants and other questions about implants.	06 June 2014	Answered - in full
14/208	Inspection report for the last GMP inspection performed by the MHRA of BioReliance Site (Stirling) Ltd.	11 June 2014	Answered - in part
14/209	Periodic safety update reports (PSURs) for Venofer, Ferinject and Cosmofer	19 June 2014	Answered - in part
14/211	Last Pharmacovigilance inspection report of Omega Pharma	17 June 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/212	Inpection report relating to Teva Eastbourne MIA 289, inspection date 2012-09-11.	19 June 2014	Answered - in part
14/213	The most recent pharmacovigilance inspection reports for Amgen, Johnson and Johnson and Meda (covering consumer and prescription products if applicable)	20 June 2014	Answered - in part
14/215	A complete list of all ingredients in all recommended vaccinations for children under 5 years old, plus questions on vaccine damage payments.	23 June 2014	Answered - in part
14/216	Evidence for the claims that PIP silicone gel breast implants would not pose any significant risk and that there is no evidence of harm to breast feeding infants and that siloxanes have been found in breast milk samples.	26 June 2014	Answered - in part
14/218	The assessment reports of 2 procedures on Myoview.	23 June 2014	Answered - in part
14/219	Have certain types of electronic cigarettes products applied for licenses.	11 June 2014	Answered - in part
14/220	Certain 1b level data from GP practices contained in yellow card reports.	16 June 2014	Answered - in full
14/221	A total breakdown of the following: • Total number of third party mobile applications purchased/implemented by your organisation broken down over the last three years – please include the name of the application and detail on the cost and if possible the estimated number of users.	30 June 2014	Answered - in full
14/223	Copy of the current approved information held by the MHRA regarding various manufacturers, sites and other details for PL29498/0003 Quinoderm Lotio-Gel 5%.	15 July 2014	Answered - in part
14/224	Names of BIOTECH, GENERICS, PHARMACEUTICAL COMPANIES, CROs whose clinical investigation (human drug development) sites have been inspected in the period 01 March 2014 to 31 May 2014, including names of investigators and outcomes.	30 June 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/225	It has come to our attention that Sandostatin LAR powder and solvent for suspension for injection was registered in theh UK. In keeping with the Freedom of Information Act, we would like to request any public assessment reports which may exist on the registration of this product or any subsequent variation or in-line extension documentation in your possession. Of particular interest, the original formulation of Sandostatin LAR was developed in the 10, 20 and 30 mg strength and is provided with a 2.5 mL bottle of solvent and a 19 gauge needle. A subsequent version appeared in certain markets in the 10, 20 and 30 mg strength and is provided with a 2.0 mL bottle solvent, which now contained poloxamer 188, and a 20 gauge needle. Is it at all possible to disclose if Novartis submitted a variation for this product to your agency? Could any of the type of data presented by Novartis to demonstrate similar safety and efficacy (equivalence) of these two different formulations be disclosed?	25 June 2014	Answered - in part
14/226	Any information held about a clinical trial called HEAT-PPCI (UKCRN ID 12503).	11 June 2014	Answered - in part
14/228	The most recent GMP inspection for Qualasept Ltd.	26 June 2014	Answered - in part
14/230	The inspection report for Cadila Pharmaceuticals Limited	09 June 2014	Answered - in part
14/231	The GMP / GDP inspection report for ITH Pharma's premises in NW London in 2010.	13 June 2014	Answered - in part
14/232	Various information on the Herbal Medicine Regulatory Working Group.	30 June 2014	Answered - in full
14/233	A copy of the latest version of the PSURs for 'Aricept' and 'Combivent Respimat'.	27 June 2014	Answered - in part
14/235	A copy of any report, finding or determination by the MHRA after its investigation into the data integrity issues at Aptuit's Riccarton Facility.	03 July 2014	Answered - in part
14/236	The number of incidents of social media misuse within MHRA over the last five years 2009-2014.	27 June 2014	Answered - in full
14/238	Statistics on variations.	30 June 2014	Answered - in full
14/239	A copy of the Pilot Study that led to the scrapping of the UK Breast Implant Registry.	24 July 2014	Answered - in full
14/240	PARs and other information for Naropin injection and Risperdal Consta.	12 June 2014	Answered - in part
14/245	Whether certain companies were the only named importers that were included under Quadrant Pharmaceuticals Limited PLPI 20774/0935:	24 June 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/246	Question about when the MHRA discharged its responsibility for continued monitoring of adverse incidents for PIP silicone implants.	24 June 2014	Answered - in full
14/247	Details of organisational structure for ICT Department and top 20 suppliers of ICT services.	09 July 2014	Answered - in part
14/248	Yellow Card data clotrimazole, fluconazole and miconazole.	03 July 2014	Answered - in full
14/249	Information, namely for the particular expert evidence used in support for marketing authorization of drug Bedranol SR.	09 July 2014	Answered - in part
14/250	The last 2 Pharmacovigilance Inspection reports for FLYNN PHARMA.	08 July 2014	Answered - in part
14/251	The number of secondments between the MHRA and Johnson & Johnson; Ethicon; American Medical Systems and BARD.	19 June 2014	Answered - in full
14/253	Whether any current board members of the Medicines and Healthcare products Regulatory Agency have any associations in Johnson & Johnson; Ethicon; BARD; American Medical Systems.	23 June 2014	Answered - in full
14/254	The number and value of any payments, fees, dividends, payments in kind, expenses, gifts or hospitality made to employees, consultants and board members of the MHRA from Johnson & Johnson; BARD; Ethicon and American Medical System since 2000	23 June 2014	Answered - in part
14/259	Details of the number of individual tests carried out on Transvaginal Mesh Implant devices in each of the last ten years.	11 July 2014	Answered - in full
14/261	Copies of inspection reports for last 3 years for Calea UK Limited.	04 July 2014	Answered - in part
14/262	The most recent inspection report for Quantum Pharmaceuticals Ltd.	19 June 2014	Answered - in part
14/263	The most recent inspection report for Portsmouth Hospitals NHS Trust.	04 July 2014	Answered - in part
14/264	Copy of the latest approved PSUR for Fosamax 70mg tablets (PL 00025/0399).	17 July 2014	Answered - in part
14/265	Various questions relating to MAA's for the active substance dimethyl fumarate.	25 June 2014	Answered - in part
14/266	Details of any pending, declined, approved and withdrawn marketing authorisation application decisions for various products including: Diltiazem hydrochloride, Glycopyrronium Bromide, Levomepromazine, Magnesium Glycerophosphate, Melatonin, Midazolam and Omeprazole.	09 July 2014	Answered - in part
14/267	The list of all products for which the MHRA have granted permission to import a product.	04 July 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/269	Copies of the assessment/other reports for clinical data, for VENTIDE.	25 July 2014	Answered - in part
14/272	The number of applications made for licences for NCP products for electronic cigarettes and various correspondence concerning them.	25 June 2014	Answered - in part
14/273	All correspondence and communications relating to Primodos from January 1, 2014, to today's date.	16 July 2014	Answered - in part
14/274	A list of the 2014 planned and conducted MHRA inspections.	04 July 2014	Answered - in full
14/278	Information on Rectogesic 4 mg/g Rectal Ointment.	21 July 2014	Answered - in part
14/279	The public assessment report for Somatuline® Autogel® 60/90/120 mg, solution.	25 June 2014	Answered - in part
14/282	Drug reactions which have resulted in hospital admissions due to GI bleeds/haematemesis/malaena	16 July 2014	Answered - in full
14/284	Efficacy data that would have to be submitted in order for Baxter Plasmalyte to be licensed.	01 August 2014	Answered - in part
14/285	A list of all companies that have been subject to a MHRA pharmacovigilance inspection in the last 2 years.	23 July 2014	Answered - in part
14/288	Inspection observations related to QRM, quality defects reported to MHRA and recalls reported to MHRA, all for 2006 through 2013,	22 July 2014	Answered - in part
14/289	Data on the submission of Yellow Cards/reporting of adverse reactions to the HPV vaccination	21 July 2014	Answered - in part
14/291	A copy of the MHRA GMP Inspection Report arising from the July 2013 inspection of LGC Health Sciences.	18 July 2014	Answered - in part
14/293	GMP Inspection report of Quest Healthcare.	16 July 2014	Answered - in part
14/295	Further information on the Herbal Medicine Regulatory Working Group.	31 July 2014	Answered - in part
14/298	External/3rd Party Hosting (software).	06 August 2014	Answered - in part
14/299	MMR Vaccine AS1426P (information on batch testing)	22 July 2014	Answered - in full
14/302	Any GMP Inspectorate reports on the Clinical Pathology service at Dorset County Hospital from 2009.	16 July 2014	Answered - in full
14/303	Various Adverse Reaction safety data informaiton concerning Seroxat.	01 August 2014	Answered - in full
14/304	Reported Adverse Reactions to HPV Vaccine	04 August 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/305	A full copy of the report which was submitted on behalf of STD Pharmaceutical Products Ltd.	17 July 2014	Answered - in full
14/306	Results from MHRA inspections between 1st March 2014- present for GMP, GCP, GDP, Validation, PV and scheduiled ones for 2014-15.	31 July 2014	Answered - in part
14/308	Copy of the scientific information and assessment report on the currently discontinued aclarubicin containing product ACLACIN FREEZE-DRIED POWDER.	07 August 2014	Answered - in part
14/311	A list of each and every FOI request received and the time in days taken to respond to each.	07 August 2014	Answered - in full
14/312	Copy of 5 March 2012 request addressed to the Department of Health and/or the JCVI headed Re: Allergies in children and vaccinations and copies of the information sources.	25 July 2014	Answered - in full
14/314	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs.	11 August 2014	Answered - in full
14/315	The last 8 inspection reports issued by (a named) MHRA inspector.	08 August 2014	Answered - in part
14/317	A copy of the data that was presented for licensing of movicol paediatric plain for both use in under 5's and over 5's for faecal disimpactation.	12 August 2014	Answered - in part
14/318	Request for previous answers to other various FOI requests regarding MHRA inspections.	12 August 2014	Answered - in part
14/319	ADR information for Razoxane.	13 August 2014	Answered - in full
14/322	Copies of the last two MHRA Good Pharmacovigilance Practice Inspection reports for GlaxoSmithKline	04 August 2014	Answered - in part
14/324	Inspection report relating to MIA 14704 Surepharm Services Ltd, Bretby, Burton upon Trent, DE15 0YZ. Inspection date 2012-08-28.	31 July 2014	Answered - in part
14/325	If MHRA or EMEA inspected this Romanian pharmaceutical company, the GMP inspection report for it. Company name: (Europharm SA-GlaxoSmithKline). 2 Panselelor street Brasov 500419 , Romania	28 July 2014	Answered - in full
14/326	Various EU regulatory information on figitumumab.	21 August 2014	Answered - in full
14/327	A copy of clinical overviews for the following product Permethrin 5% w/w Cream , PL 04416/0456 under the Freedom of Information Act	18 August 2014	Answered - in part
14/328	Stem cells technique	19 August 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/329	Questions regarding the Breast register UKBIR (1) what happened to the records when the register was closed, (2) the policy for the retention of the collected data and (3) the schedule for disposal.	11 August 2014	Answered - in full
14/330	Etonox use and B12 deficiency	18 August 2014	Answered - in part
14/331	How many cases of M.E/CFS have been reported following vaccinations, how many relate to flu vaccinations. A full total or figures that date from 2007-to date.	15 August 2014	Answered - in full
14/333	Information, by study or review, regarding SSRi adverse reactions of aggression including harmful behavior to others (including injury).	18 August 2014	Answered - in part
14/334	Additional February 2012 Inspection report of Quest Healthcare.	08 August 2014	Answered - in part
14/335	How many days the Chairman worked in the last financial year?	14 August 2014	Answered - in full
14/337	Information/data on the number/types of Complaints that have been received on different Insulin Pen Needle brands in the last 5 years.	22 August 2014	Answered - in part
14/338	Redacted copies of any MHRA GMDP Inspection reports issued for Auxilium (UK) Limited since 2011.	21 August 2014	Answered - in part
14/339	For the period 2005 to today, a list of medicines and devices [eg hip/knee implants] whose manufacture was stopped or banned in the UK and in the EU.	12 August 2014	Answered - in part
14/340	All information that the agency hold in relation to the prescription of Nitrofurantoin.	29 August 2014	Answered - in part
14/341	Number of adverse drug reactions reported in each of the past ten years in relation to the lariam/mefloquine reported by the pharmaceutical industry, the public and other sources.	29 August 2014	Answered - in part
14/350	Full details that you can legally supply of complaints made against your organisation in the last calendar year.	21 August 2014	Answered - in part
14/352	Various questions about fulvestrant.	12 August 2014	Answered - in part
14/353	Various information on patient and public involvement programmes.	10 September 2014	Answered - in full
14/355	Details of the number of adverse incident reports the MHRA has received for contact lens related infections over the past few years.	12 August 2014	Answered - in full
14/356	The last 8 Inspection reports issued by a named MHRA inspector	12 August 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/357	A copy of an MHRA audit inspection of Lacsa (Pty) Ltd situated at 72 Ballantrae, Merebank, Durban-4052 South Africa, Kwazulu Natal. Lacsa (Pty) Limited is an Active Pharmaceuticla Ingredient (API) company which manufacturs Lactulose bulk. This site has been audited by MHRA in 2008 and 2010.	20 August 2014	Answered - in part
14/358	Henoch Schonlein Purpura - Links to MMR vaccinations and/ or other causes	09 September 2014	Answered - in full
14/359	Questions about clinical studies for Nurofen Migraine Pain tablets containing 342mg ibuprofen lysine.	27 September 2014	Answered - in part
14/360	How many, if any, “complex” parallel import licence applications were approved in each of the following years: 2011, 2012 and 2013.	08 September 2014	Answered - in full
14/361	Files relating to kidney injury suffered by patient.	02 September 2014	Answered - in part
14/362	Copy of a previous FOI response.	08 September 2014	Answered - in full
14/363	Various questions on Video Conferencing.	01 September 2014	Answered - in full
14/365	Results from MHRA inspections between 1st August 2014- present for: GMP, GDP and PV.	02 September 2014	Answered - in full
14/366	The number of employees who received remuneration of more than £100,000 in 2013-14.	17 September 2014	Answered - in part
14/367	The full anonymised case report forms/CIOMS listings as relevant, or if literature based the relevant citations for Razoxane.	16 September 2014	Answered - in part
14/371	Names of all Contract Research Organisations (CRO) which are working in the UK and whose activities are regulated by MHRA.	05 September 2014	Answered - in part
14/372	Copies of the two most recent inspection report, responses and all associated communications for the licences held by MOORFIELDS EYE HOSPITAL NHS FOUNDATION TRUST.	11 September 2014	Answered - in part
14/374	Hospital names, procedures, devices type, nature of incident and manufacturer concerned with the injuries and deaths involving medical devices between 2011 and 2013.	11 September 2014	Answered - in part
14/376	The total number of contracts put out for tender by your organisation during January 1, 2010 - December 31, 2010 and January 1, 2013 - December 31, 2013.	18 September 2014	Answered - in part
14/377	A breakdown of data into those < 18 yrs and those over 18 yrs of age for a period of (the last) ten years for Methylphenidate.	10 September 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/378	For the 2013 calendar year the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery and a breakdown of the side effects claimed.	24 September 2014	Answered - in full
14/381	Risk Management Plans for SEROQUEL	16 September 2014	Answered - in part
14/384	Software contracts.	15 September 2014	Answered - in part
14/385	Copies of the GMP Inspection reports for Lonza Biologics September and December 2013	01 October 2014	Answered - in part
14/386	Names and addresses of Pharma companies, and CROs inspected for GCP compliance, between 1st October 2011 and 30 September 2012	29 September 2014	Answered - in full
14/387	Latest copy of GMP inspection report for MCS Laboratories Ltd.	29 September 2014	Answered - in part
14/388	Various questions about simvastatin.	19 September 2014	Answered - in full
14/391	Inspection reports and Licences held by Medpharm	30 September 2014	Answered - in part
14/394	Information regarding the following PARS: e.g. Submission dates Clock stops Date Consensus achieved Dossier Validation time period, for: Pantoprazole 40mg Gemcitabine 200mg powder Rabeprazole sodium Ratiopharm	25 September 2014	Answered - in full
14/395	Information on the product Hydrex 0.5% Pink which is a licenced medicinal product indicated for the pre-operative skin disinfection prior to minor surgical procedures.	09 October 2014	Answered - in full
14/398	Information regarding the following PARS: Dorzolamide / Timolol 20mg/ml + 5mg/ml Ratiopharm Mycophenolate	25 September 2014	Answered - in full
14/399	Various communications between MHRA and Ethicon On 26th January 2012.	07 October 2014	Answered - in part
14/403	Copies of presentations made in Device meeting held on 19th July 2012.	06 October 2014	Answered - in part
14/407	The number of Local Anaesthetic systemic toxicity events that have occurred using Las reported to the yellow card system.	08 October 2014	Answered - in part
14/409	Any documentation/correspondence held by MHRA relating to the possibility of kidney damage caused by the long term use of antibiotics.	16 October 2014	Answered - in part
14/410	Pharmacovigilance inspection reports from the last quarter.	15 October 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/411	Numerous and various questions about pay, allowances, benefits and qualifications of agency full time equivalent employees.	14 October 2014	Answered - in part
14/412	The most recent GMP inspection report for Calea UK Limited.	29 September 2014	Answered - in part
14/414	A copy of FOI request 10/223 from 27 May 2010.	26 September 2014	Answered - in part
14/415	Whether any export licenses have been issued to export Utrogestan (Progesterone) 100mg Capsules – 30 Pack from the UK.	01 October 2014	Answered - in full
14/417	A copy of the MHRA Inspection Report for Quality Control North West.	10 October 2014	Answered - in part
14/420	Can you confirm if the MHRA carried out tests on the chemical compostion of PIP shells and whether they found DEHP?	22 October 2014	Answered - in full
14/421	Which current uk vaccines are under the 'black triangle' label at the moment and why, and the numbers of 'yellow card' reports and reported side-effects for vaccines, particularly nasal flu vaccine	22 October 2014	Answered - in full
14/422	Various questions about Traction and Pin adverse incidents and reports	01 October 2014	Answered - in part
14/425	1. Is PIM designation hard to earn, or mostly a formality once an application is deemed complete? 2. Approximately how many companies have expressed interest in participating in EAMS?	08 October 2014	Answered - in full
14/426	Request for previously provided information, and query about patient ID numbers	27 October 2014	Answered - in full
14/428	The most recent GMP inspection report for B BRAUN MEDICAL LIMITED	24 October 2014	Answered - in part
14/431	Does the MHRA receive payments from medical device companies or the notified bodies and if so how much. If a medical device is suspended can the pharmaceutical companies claim compensation from the MHRA for loss of orders and revenue.	29 October 2014	Answered - in full
14/432	Various questions about Traction and Pin adverse incidents and reports		Answered - in part
14/438	UK contract GMP QC testing laboratory inspection reoprts for 4 individual QC labs	29 October 2014	Answered - in part
14/441	All discussions with the GMC and Cabinet Office about "Good practice in prescribing and managing medicines and devices" (GMC document) and off-label/unlicensed prescribing of bevacizumab for wet AMD.	03 November 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/444	Copies of the last two MHRA GMP Inspection Reports for Butterworth Laboratories Ltd and ILS Ltd.	03 November 2014	Answered - in part
14/445	Various questions on sponsor organisations.	04 November 2014	Answered - in full
14/447	GDP report from the most recent MHRA inspection of Campdale Pharmaceuticals Ltd.	27 October 2014	Answered - in part
14/448	Pages of various reports and communications from/between Pfizer and the MHRA from 2006/2007 including material from previous FOI requests.	07 November 2014	Answered - in part
14/449	Various questions on TVT.	12 December 2014	Answered - in part
14/451	Various questions about authorisations granted to Arrow.	20 November 2014	Answered - in full
14/452	Various questions about a marketing authorisation application for buprenorphine transdermal patches - including if one has actually been submitted.	13 October 2014	Answered - in part
14/453	Documents regarding the safety and efficacy of terlipressin from circa 1983.	04 November 2014	Answered - in part
14/456	Question about a previous FOI request.	07 November 2014	Answered - in full
14/459	Questions about a report on the Os Calcis Pin and Traction.	10 November 2014	Answered - in full
14/461	Request for RMP for Invita & Fultium.	10 November 2014	Answered - in part
14/463	Various questions about the Early Access to Medicines Scheme (EAMS).	21 October 2014	Answered - in full
14/466	Follow up to previous questions on Hydrex 0.5% Pink, concerning content of carmoisine.	21 October 2014	Answered - in part
14/467	Correspondence regarding the use of Avastin being unlicensed as opposed to off-label.	13 November 2014	Answered - in part
14/468	Copy of inspection reports for Micron Technologies, facilities at Dartford UK and Malvern, Pennsylvania US.	07 November 2014	Answered - in part
14/469	Various questions about inspections of Biotech, generic, pharmaceutical companies, CRO's and clinical trial investigators who have been subject of inspections since May 2014 and the inspection outcomes.	10 November 2014	Answered - in part
14/470	Copy of review of a previous FOI request 08/330.	14 November 2014	Answered - in full
14/472	Details of which three drugs have been responsible for the most spontaneous suspected ADR in each of the past five years and the number of reports received for each in each year.	14 November 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/473	The last 10 PV and 10 GCP Inspection reports.	17 November 2014	Answered - in part
14/476	Asking about benzalkonium chloride eye drops and if there have been any problems with with Bausch & Lomb products - proxymetacaine hydrochloride and flourescein sodium	14 November 2014	Answered - in part
14/477	Information on adverse reactions to depakene for epilepsy.	14 November 2014	Answered - in full
14/478	RMP for the reference product ARCOXIA® and its related safety concerns.	18 November 2014	Answered - in part
14/479	Various questions about staff absence, disabilities and work adjustments.	21 November 2014	Answered - in part
14/480	Blood glucose testing strips options available in the local health economy	17 November 2014	Answered - in part
14/481	Five most recently available GPvP inspection reports where critical findings have been reported	18 November 2014	Answered - in part
14/489	Copy of the MHRA Statutory Pharmacovigilance Inspection GPvP 11515/122759-0001 conducted March April 2008.	24 November 2014	Answered - in part
14/490	MHRA GMDP Inspection Report arising from the 2013 inspection of Quality Control North West.	07 November 2014	Answered - in part
14/491	Questions about a report on the Os Calcis Pin and Traction (follow up to request 14/432).	11 November 2014	Answered - in part
14/493	All new documents of Hormone Pregnancy tests and also the drug Primodos that Minister is instructing his department to release (MHRA).	27 November 2014	Answered - in part
14/495	Various questions on suspected adverse reactions to Ciprofloxacin, Levaquin and Avelox.	27 November 2014	Answered - in full
14/496	Yellow Card data about Levonorgestrel.	27 November 2014	Answered - in full
14/497	Results from MHRA inspections between 1st September 2014- present for UK GMP, GDP and PV.	26 November 2014	Answered - in part
14/498	A breakdown of suspected adverse reactions compiled by you in the 2013 calendar year in relation to vaccines.	28 November 2014	Answered - in full
14/499	Email addresses used by an MHRA staff member to communicate with the public.	27 November 2014	Answered - in full
14/501	Request for GVP inspections for Pfizer, GSK and Afgen for 2013 and 2014	25 November 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/504	All the clincal information that's ever been studied on the effects or Roaccutane (Isotretinoin) or any Vitamin A related drug on bones and growing bones. Also to know the results from the review into the effects of Roaccutane on depression		Answered - in full
14/505	List of Parallel import companies in the UK companies that have been approved an MIA license in 2014 (that haven't previously had one).	02 December 2014	Answered - in full
14/506	MRP procedure for Cabergoline with the UK as RMS, Arrow Generics Ltd Reasons for the length of time between closure of the MRP in August 2007, and the UK grant of MA in March 2008 and provide any correspondence beween MHRA and Arrow relating to the grant of this MA during the period August 2007 to March 2008 (inclusive).	25 November 2014	Answered - in part
14/508	Request for a transcript of a case on advertising of medicines	02 December 2014	Answered - in part
14/509	Adverse incident reports for wound dressing, gels ointments rinses etc between November 2013 and October 2014	01 December 2014	Answered - in full
14/510	Whether the MHRA report on "benefits of use outweigh risks" for TVT mesh had input in any form, from mesh manufacturers, surgeons or any other outside organisation, their names and whether MHRA received any financial support from mesh manufacturers or outside organisations for the funding of this report	01 December 2014	Answered - in full
14/511	Details of staff who work on FoI appeals and requests,and reviews to see if such staff have a conflict of interest	16 January 2015	Answered - in part
14/513	Follow up request regarding adverse drug reaction reports for vaccines.	08 December 2014	Answered - in part
14/515	Information concerning the long term suspected adverse reactions to the HPV vaccination.	19 December 2014	Answered - in full
14/516	Remuneration and time commitment of non-executive boards.	01 December 2014	Answered - in full
14/518	The number of adverse incidents reported to the MHRA involving the use of Metal On Metal Mix-match and/or Off-label implants during the last 10 years.	10 December 2014	Answered - in full
14/519	The number of adverse incidents reported to the MHRA in respect of denture pastes and/or denture adhesives during the last 5 and 10 years.	28 November 2014	Answered - in full
14/521	Copy of previous FOI request 13/579.	10 December 2014	Answered - in part
14/524	All MHRA GMDP Inspection Reports issued in the last five years for TILLOMED LABORATORIES LIMITED	15 December 2014	Answered - in part

FOI no	Subject	Date reply sent	Result of request
14/527	Blank spaces on the the MHRA report to Dame Sally Davies to be filled in.	10 December 2014	Answered - in part
14/528	PAR (Public Assessment report) for various PHARMASCOPE medicines.	27 November 2014	Answered - in full
14/531	A copy of the procedure regarding a drug company using drugs that are unlicensed.	28 November 2014	Answered - in full
14/533	Inspection report GPvP 11515/122759-003 Date 05/12/2011	02 December 2014	Answered - in part
14/535	The list of the 2014 and 2015 (conducted and planned) GCP MHRA inspections.	15 December 2014	Answered - in full
14/541	Incidences of symptoms/possible side effects with simivastatin.	23 December 2014	Answered - in full
14/544	The number of (BIA-ALCL breast implant) cases/fatalities reported to the MHRA to date and if the DoH is planning to amend its advice to UK women and recommending PIP removal.	19 December 2014	Answered - in full
14/545	information on the MHRA's equivalent German organization and has any action been taken on the synthetic mesh implant medical devices problem.	19 December 2014	Answered - in part
14/546	Most recent pharmacovigilance inspection report of Novartis Consumer Healthcare.	30 December 2014	Answered - in part
14/547	Most recent pharmacovigilance inspection report of Novartis Vaccines.	30 December 2014	Answered - in part
14/548	Questions about Porcine Thyroid Extract.	31 December 2014	Answered - in full
14/549	Which year the MHRA introduced on line reporting system for patients, clinicians etc to report their adverse incidents for medical devices and how patients reported their adverse incidents to the MHRA before it went on line.	06 January 2015	Answered - in full
14/551	Details of any granted marketing authorisations in force in the United Kingdom relating to generic medicinal products containing aripiprazole.	23 December 2014	Answered - in full
14/553	How many suspected adverse drug reactions caused by Lariam (Mefloquine) have been reported to the MHRA in each year between 1999 and 2014.	16 December 2014	Answered - in full
14/555	ADRs for HPV	12 January 2015	Answered - in full
14/556	2 recent Pharmacovigilance Inspection reports, for inspections performed after 01-Jan-2014.	30 December 2014	Answered - in part
14/557	Has the MHRA or the MHPHR issued a safety alert or guidance on the stoppage of an orthopaedic medical device made by the manufacturer Zimmer.	29 December 2014	Answered - in full

FOI no	Subject	Date reply sent	Result of request
14/560	The last completed GMP and GDP MHRA Audit Report for Healthcare at Home Ltd and Polar speed Distribution Ltd.	07 January 2015	Answered - in part
14/561	Number of fatal adverse reactions over the past five years.	13 January 2015	Answered - in full
14/562	A copy of a document, sent to SGS.	09 January 2015	Answered - in part
14/564	SSRIs and sexual dysfunction	08 January 2015	Answered - in full
14/565	The number of reports received by the MHRA of adverse sexual effects caused by SSRIs.	14 January 2015	Answered - in part
14/568	Update on adverse incident reports involving brachytherapy devices for the remainder of 2014.	22 December 2014	Answered - in part
14/569	Various questions about Riboflavin eye drops.	06 January 2015	Answered - in part
14/570	The structure for MHRA Finance, HR, IT, Procurement, Payroll (including names and direct lines where possible).	09 January 2015	Answered - in part
14/572	The data except ADR caused by Ovran or Eugynon without the emergency contraceptives.	23 December 2014	Answered - in part
14/573	The value and instances of bonuses paid to members of HR for the financial year 2012/2013 as well as year to date 2013/2014.	12 January 2015	Answered - in full
14/577	Desogestrel 75mcg reclassification from POM to P	30 December 2014	Answered - in part
14/578	The total number of reported cases of BIA-ALCL in women with fraudulent PIP breast implants.	24 December 2014	Answered - in full
14/579	The findings following agency audits of Specials Manufacturing organisations.	21 January 2015	Answered - in part
14/580	The number of inspections carried since the updated 2013 GDP guidance and what deficiencies were found.	23 January 2015	Answered - in full
14/581	Information on licenses and correspondence, between the MHRA and various companies, on parallel trade.	08 January 2015	Answered - in part
14/583	Information about individual pharmacies or pharmacists in England, Northern Ireland, Scotland and Wales who have engaged in undesirable practices.	21 January 2015	Answered - in part
14/585	The originator RMP for Atomoxetine	07 January 2015	Answered - in full
14/586	Adverse reports -concerning an orthopaedic medical device made by the manufacturer Zimmer- from speciied sites	14 January 2015	Answered - in part

FOI no	Subject	Date reply sent	Result of request
15/001	Latest GMP inspection for Fisher Clinical Services.	23 January 2015	Answered - in part
15/004	Any breast localization adverse event.	02 February 2015	Answered - in part
15/005	A list of the drugs which by frequency were reported to have had the most side effects reported last year?	03 February 2015	Answered - in full
15/008	Information regarding the sale of aniracetam in the UK online or otherwise.	12 January 2015	Answered - in full
15/009	Minutes of meetings, emails, briefings with Novartis about referring Avastin for wet AMD to NICE for assessment.	16 February 2015	Answered - in part
15/011	A breakdown of all the alleged side effects for Co-Cyprindiol reported under the yellow card scheme between 1.7.13 and 30.6.14.	27 January 2015	Answered - in full
15/012	Details and copies of risk minimisation measures for Rivastigmine 13.3 mg/ 24 hour transdermal patch.	06 February 2015	Answered - in part
15/013	Information about members of the Association of Pharmaceutical Specials Manufacturers (APSM) who have engaged in undesirable practices.	28 January 2015	Answered - in part
15/015	Most recent (2014) MHRA Inspection Report for Fisher Clinical Services.	26 January 2015	Answered - in part
15/017	All information regarding the change of Efudix, Fluoricil 5%.	21 January 2015	Answered - in part
15/018	The full clinical trial submitted in the application and MHRA's assessment of them for Theraflu.	04 February 2015	Answered - in part
15/019	Pharmacovigilance inspection reports from the last 2 years.	29 January 2015	Answered - in part
15/022	Assessment report for risperidone.	10 February 2015	Answered - in full
15/023	A list of all of the products for which the MHRA granted permission to import as an unlicensed medicinal product in the year 2009.	29 January 2015	Answered - in full
15/025	What advice was given by the Committee on Safety of Medicines to prescribers concerning the teratogenic effects of Valproate in pregnancy in 1974?	24 February 2015	Answered - in full
15/026	Correspondence between the MHRA and Sanofi in the past two years, including with regards to 'current problems 9 January 1983 entitled: Sodium Valproate and congenital abnormalities'.	12 February 2015	Answered - in part
15/027	Information on the Anti-psychotic drug Pimozide.	12 February 2015	Answered - in part

FOI no	Subject	Date reply sent	Result of request
15/029	All MHRA Pharmacovigilance Inspection Reports on Kyowa Hakko Kirin Co.	17 February 2015	Answered - in part
15/030	The inspection reports for all MHRA pharmacovigilance inspections undertaken between July 2014 and December 2014.	12 February 2015	Answered - in part
15/031	Product Analysis Prints and Drug Analysis Prints for various products.	18 February 2015	Answered - in full
15/032	A copy of the licensing of Primodos before 1970 and after.	19 February 2015	Answered - in part
15/033	Further information regarding the change of Efudix, Fluoricil 5%, regarding what lead to the revision of inforation for the product.	19 February 2015	Answered - in full
15/037	A breakdown of all the alleged side effects associated with Ropinirole.	19 February 2015	Answered - in full
15/038	A copy of the FOI number 13/168.	06 March 2015	Answered - in part
15/043	Further information on the frequency of side effects and three main dugs for causing them of: Flatulence, Decreased appetite, Sexual Desire disorders, pathological gambling, compulsive shopping, Transvestism and yawning.	24 February 2015	Answered - in full
15/046	Under-reporting Medical Device complications.	12 March 2015	Answered - in part
15/048	How many products have been authorised under a marketing authorisation, over the past three years.	23 February 2015	Answered - in part
15/049	Question regarding electronic cigarettes as licensed NCPs for smoking cessation.	25 February 2015	Answered - in part
15/050	Question about Pen Needle Adverse incidents.	24 February 2015	Answered - in part
15/051	Various questions on adverse reactions relating to the drug Ciprofloxacin.	27 February 2015	Answered - in full
15/052	Further questions on symptoms and deaths relating to the drug Ciprofloxacin.	27 February 2015	Answered - in full
15/054	The amount of people that have contacted the MHRA regarding adverse affects to fluroquinolones over the last ten years.	26 February 2015	Answered - in full
15/055	Pharmacovigilance data for over-the-counter Fluconazole 150mg capsules	27 February 2015	Answered - in part
15/058	Request for information on ICT provision - including training- in MHRA	04 March 2015	Answered - in full
15/059	Is it possible to receive the mock-ups for DHCP and Physician's Guide and associated tools.	10 February 2015	Answered - in full

FOI no	Subject	Date reply sent	Result of request
15/060	Request relating to a diagnosis of "Delusional parasitosis", and the duration of the drug pimozide prescribed for this condition	12 February 2015	Answered - in full
15/061	Inspection reports for Actavis, Warner Chilcott, Forest Laboritories	02 March 2015	Answered - in part
15/062	Contract information with regards to the organisation's telephone system maintenance contract (VOIP or PBX, other) for hardware and Software maintenance and support	06 March 2015	Answered - in part
15/065	MHRA INSPECTION REPORT OF R&D Leeds Teaching Hospitals NHS TRUST dating back from the last 5 years.	05 March 2015	Answered - in part
15/066	ICT contract(s) for Server Hardware Maintenance, Server Virtualisation License and Maintenance and Storage Area Network Maintenance/Support which may include:	09 March 2015	Answered - in part
15/068	Risk Management Plan for valsartan.	26 February 2015	Answered - in part
15/069	List of any notifications to the MHRA for the importation into the UK of cholic acid.	02 March 2015	Answered - in part
15/072	Whether there have been any updates to educational material for aripiprazole (Abilify).	04 March 2015	Answered - in part
15/073	Innovator's summary of the RMP, atomoxetine.	25 February 2015	Answered - in part
15/074	The last pharmacovigilance inspection reports of the MHRA concerning the company AstraZeneca in the UK.	05 March 2015	Answered - in part
15/078	The start and end dates of certain X-Ray frameworks/contracts.	20 February 2015	Answered - in full
15/079	Request for summary of RMP - Kivexa	16 March 2015	Answered - in part
15/080	Various questions about glatiramer acetate.	16 March 2015	Answered - in part
15/081	Yellow Card reports in connection with the contraceptive Cerazette since it was first marketed.	11 March 2015	Answered - in full
15/082	Various questions about ICT contracts.	16 March 2015	Answered - in part
15/084	Information on clinical trial authorisations by month	17 March 2015	Answered - in full
15/087	A copy of the 2014 report to the JCVI of adverse reactions to vaccines reported by Yellow Card.	19 March 2015	Answered - in full
15/090	Informaiton on Lines, Minutes, Broadband and WAN	09 March 2015	Answered - in part
15/091	Notes from oral presentation by MHRA staff member on HPV Vaccine Safety.	23 March 2015	Answered - in full

FOI no	Subject	Date reply sent	Result of request
15/092	ICT information	23 March 2015	Answered - in part
15/093	Information on investigations following AE report for a medical device	03 March 2015	Answered - in part
15/094	Inspection reports or inspection data showing the findings (Critical and Major) related to the last 3 PV Inspections for 3 pharma companies.	24 March 2015	Answered - in part
15/096	A breakdown of all the alleged side effects associated with isotretinoin, reported under the yellow card scheme, for the period 1.7.13 to 30.6.14.	25 March 2015	Answered - in full
15/100	RMP for Seretide Evohaler.	26 March 2015	Answered - in part
15/102	Legal advice services for MHRA.	31 March 2015	Answered - in full
15/105	MHRA Inspection Reports from GMP inspections performed at the former AstraZeneca R&D site at Charnwood, Bakewell Road, Loughborough	31 March 2015	Answered - in part
15/106	Reports of incidents with either femoral or acetabular brushes.	05 March 2015	Answered - in full
15/107	How many patients who have taken part in voluntary drugs trials in the United Kingdom have developed/been diagnosed with health issues?	18 March 2015	Answered - in full
15/113	Summary of the RMP for the reference medicinal product (for Linezolid).	17 March 2015	Answered - in part
15/114	A copy of the GDP Inspection report on Alcura UK Limited.		Answered - in part
15/124	Number of cases of POTS/autonomic dysfunction reported each year for HPV from 2009 to 2014 and any other vaccination from 2000 to 2014.	07 April 2015	Answered - in full
15/129	Public reports of any inspection visits by the MHRA to a company.	08 April 2015	Answered - in part
15/144	A copy of the report about the production facilities of Imunno biotech in Cambridgeshire.	31 March 2015	Answered - in part