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

This document contains reference details for all A 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:

_policy@mhra.gsi.gov.uk

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

Updated: 06 September 2018

FOI no	Subject	Date reply sent	Result of request
18/151	Information about Gardasil	30/04/2018	Disclosed in full
18/153	Copy of some elements of the Common Technical Document (CTD) for the following products: Mylan Sirdupla pMDI, UK/H/5607/001-002/DC Flutiform pMDI, UK/H/2872/001-003/DC.	30/04/2018	Disclosed in part
18/154	HPV vaccine - side effects and putting onto the market	25/04/2018	Disclosed in full
18/155	Courier service procurement information on CHM	09/04/2018	Disclosed in full
18/157	Courier service procurement information on MHRA	09/04/2018	Disclosed in full
18/159	Problems with Myodil manufactured by Glaxo	30/04/2018	Not held
18/160	Gastrografin adverse effects	30/04/2018	Disclosed in full
18/161	A list of all requests to the MHRA on the subject of a) benzodiazepines b) z drugs and c) antidepressants in the last three years 2. Copies of all the suggested replies and background information drafted by the MHRA for Parliamentary Questions on a) benzodiazepines b) z drugs and c) antidepressants in the last three years	02/05/2018	Disclosed in part
18/162	Clinical Overview (Module 2.5) of the initial registration dossier, the related responses to MHRA questions (if applicable) as well as the MHRA Assessment report	30/04/2018	Disclosed in part
18/163	Number of “standard” and "complex" parallel import licence applications were approved in each of the following years: 2014, 2015, 2016, 2017 and 2018 (to end of March)?	23/04/2018	Disclosed in full
18/164	Amount of colleagues at the Agency who have secured more than £10,000 of funding for Learning & Development per year, for the past 5 years?	10/04/2018	Disclosed in full
18/165	Efficacy of SSRIs for Treatment of Mild and Moderate Depression	30/04/2018	Disclosed in full
18/169	Licensing status for shingrix vaccine	30/04/2018	Disclosed in full
18/170	RMP Nefopam HCL 30mg	02/05/2018	Disclosed in part
18/171	RMP Metformin Tablets	26/04/2018	Disclosed in part
18/173	Chiral drugs list and safety and efficacy of the drugs	08/05/2018	Disclosed in part
18/176	What is the Department of Health and NICE or MHRA’s, official Rules and Legislation or Guidance, plus Safe Guards over prescribing and issuing Prescription Medication to Vulnerable Patients?	11/05/2018	Disclosed in part
18/181	When did MHRA / UK approve the use of Trans-Vaginal-Tape (TVT) Mesh?	08/05/2018	Disclosed in full
18/182	Micro suction	10/05/2018	Not held
18/185	Risk Management Plan (RMP) for PL 17901/0106 - Betaloc I.V. Injection	19/04/2018	Not held
18/186	The number of adverse reactions to the PRP product	15/05/2018	Not held
18/187	Licensing info for Diphtheria/acell/pertussis/haem influ b & polio line plus pneumococcal.	14/05/2018	Disclosed in full
18/188	2017 MHRA published for brachytherapy devices	11/05/2018	Disclosed in full
18/191	Adverse reports associated with laparoscopic Adjustable Gastric bands	15/05/2018	Disclosed in full
18/192	Data from 2015 to present period that related to patients (i) within the UK, and (ii) segmented in accordance to the 44 Sustainable and Transformation Partnerships (STPs)* across the UK	15/05/2018	Disclosed in full

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18/196	Inspection reports for MIA(IMP) # 44168 (Cellular Therapeutics Ltd, Manchester) MIA(IMP) #14523 (Rayne Cell therapy Suite)	22/05/2018	Disclosed in part
18/197	Did MHRA Benefit from The Ban On Co-proxamol?	31/05/2018	Disclosed in full
18/199	RMP for Nicovations Limited E-Voke 10mg electronic inhaler – PL 42601/0003	14/05/2018	Disclosed in part
18/202	Risk management plan (RMP) for Kytril 1mg film-coated tablets under the Freedom of Information Act?	26/04/2018	Not held
18/203	Information about information reports made regarding ADR reactions after MMR vaccine in under 7's.	24/05/2018	Disclosed in full
18/206	Request information on adverse sexual effects caused by antidepressants	24/05/2018	Disclosed in full
18/209	Please could you tell me the total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2017 calendar year? In relation to the figures for 2017 could you also provide (i) the number of UK suspected ADR reports received with a fatal outcome, (ii) number of ADR reports received which resulted in prolonged hospitalisation and (iii) the number of reports received which resulted in prolonged hospitalisation AND had a fatal outcome?	25/05/2018	Disclosed in full
18/210	Inspection Reports for MS 14620, MS 11387 and MS 44301	25/05/2018	Disclosed in part
18/211	HPV vaccine tests against Placebo	25/05/2018	Not held
18/212	Information about importation of a product.	24/05/2018	Disclosed in part
18/214	We would request if you can please let us know the volume of imported medicines in last 1 years. May I please request for you to share information regarding the importation of Probenecid 500mg Tablets	24/05/2018	Disclosed in full
18/215	Generic licences granted or ongoing applications for Lithium Carbonate prolonged release 200&400mg tablet (PL 04425/0322) (Innovator Sanofi Priadel) in the UK	08/05/2018	Disclosed in part
18/216	I would like to obtain a copy of the last MHRA inspection for license holder #41630. I would also like to see a copy of the full GDP report, a copy of the company responses to any findings as well please.	25/05/2018	Disclosed in part
18/217	A request for information under the provisions of the Freedom of Information Act 2000 as amended in relation to UK marketing authority for Moxifloxacin PL 25298/0087 Please supply all applications to vary the original licence with supporting documentation. Please supply all documentation in support of the original application for a marketing authority	22/05/2018	Disclosed in part
18/218	request for full version (body + all annexes) of Pfizer's RMP for Viagra Connect® (OTC)	02/05/2018	Disclosed in part
18/219	Request for RMP of Nicorette Quickmist 1mg/spray Mouthspray	25/05/2018	Disclosed in full
18/220	I would like a print out/line listing of individual Adverse Drug Reaction cases/reports submitted with regards to HPV vaccines (Gardasil, Cervarix and unknown)	18/05/2018	Disclosed in full
18/224	the last three Pharmacovigilance Inspection Reports performed by the MHRA for Marketing Authorisation Holders with no Centrally Authorised Products - i.e. National only including MRP & DCP.	04/06/2018	Disclosed in part
18/225	Efficacy of SSRIs for Treatment of Mild and Moderate Depression	04/06/2018	Disclosed in part

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18/227	Request documentation and data held by you concerning the suspension of the Bayer Plc Essure sterilisation device in the UK. This is to include any reports; field safety notices.	14/05/2018	Disclosed in part
18/228	Request for Interim report of the committee on safety of medicines' expert working group on selective serotonin reuptake inhibitors, 2003 and Committee on Safety of Medicines. Selective serotonin reuptake inhibitors (SSRIs): overview of regulatory status and CSM advice relating to major depressive disorder (MDD) in children and adolescents including a summary of available safety and efficacy data	22/05/2018	Disclosed in part
18/229	NOVARTIS_SANDOSTATIN Powder and solvent for suspension for injection_PL00101/0511-0513_PAR REQUEST/QUESTION	11/05/2018	Not held
18/230	Information on all discussions pertaining to the competent authority discussions on classification of probiotics as a medicine as opposed to a medical device that the MHRA hold	17/05/2018	Disclosed in part
18/233	Request to share information regarding the withdrawal of Fungizone (Amphotericin B) Oral suspension from BMS.	15/05/2018	Disclosed in full
18/234	Request number of adverse advents reported to you from the hpv injections. Also a copy of the latest symptoms list/ numbers that has been reported to you.	06/06/2018	Disclosed in full
18/235	Request a table for all Yellow Card reports (one line for each Yellow Card) with the following information for cards submitted by MALES between 1st January 2008 and 30th April 2018. drug ingredient (for Gardasil, please indicate whether Gardasil or Gardasil 9). Age group, reaction and reaction outcome.	22/05/2018	Disclosed in full
18/236	Please supply all documentation in support of the original application for UK marketing authorisation of Ciprofloxacin (PL 32019/0023-26).	22/05/2018	Disclosed in part
18/237	CHMP for the Menigetec vaccine as well as the documents which are used to get marketing authorization in Europe?	25/05/2018	Disclosed in part
18/238	Questions on polypropelene mesh, aka vaginal mesh, aka hernia mesh.	07/06/2018	Disclosed in part
18/239	Up-to-date data on injuries/deaths for the use of bed rails over the last 2-3 years.	11/06/2018	Disclosed in full
18/242	Request for copy of the Risk Management Plan for Epilium 400mg Powder according to the () Act.	11/05/2018	Not held
18/243	Request copy of the Risk Management Plan for Anatera 100mg/ml Solution for Injection according to the () Act.	11/05/2018	Not held
18/244	Request copy of a Memorandum of Understanding between the MHRA and the Guernsey Health and Social Services Department. I believe it was signed prior to 2009 but have not been able to establish an exact date, or any further details. I have checked both the MHRA and Guernsey HSSD websites without success. Please would you confirm if the MoU is publicly available and, if so, send me a copy?	06/05/2018	Disclosed in full
18/245	MHRA inspection report from Feb 2016, in order to provide a copy of the report to the Ukrainian authorities	11/06/2018	Disclosed in full

FOI no	*Subject*	*Date reply sent*	*Result of request*
18/246	Risk management plans (RMP) for following listed drug product. 1) Half Securon SR (Verapamil 120mg SR Tablets), PL46302/0025; Mylan Products Limited. 2) Securon SR, PL46302/0027, Mylan Products Limited. 3) Vertab SR 240mg tablets, PL14017/0024; Dexcel Pharma Limited and 4) Verapamil Tablets BP 120 mg; PL0142/0283; Accord UK Ltd	14/05/2018	Not held
18/247	UK/H/6547/001/MR and UK/H/5129/001/E/01 - Example of innovator targeted Metformin questionnaire and updated RMP following Article 31	21/05/2018	Disclosed in part
18/248	We as a Trust are eager to initiate faecal transplantation for the treatment of some cases of C.difficile and understand that you as an organisation are looking into the process around this. Please can you give some indication as to when this treatment is likely to become available.	11/05/2018	Not held
18/249	Inspection report from the GVP inspection carried out by the MHRA in 2015 on East Midland Pharma.	07/06/2018	Disclosed in part
18/250	Request for the most recent 300 EMA inspection post inspection letters for GMP/GDP inspections	12/06/2018	Disclosed in part
18/251	I wish to request information relating to the organisation's energy management system.	01/06/2018	Disclosed in part
18/256	Please could you supply a copy of the MHRA GDP Inspection report arising from the 02 Feb 2018 inspection of the wholesale distributor UNIVERSAL MARINE MEDICAL LIMITED	13/06/2018	Disclosed in part
18/257	I am writing on freedom of information basis to request a copy of information leaflet supplied with the home Doppler sold to pregnant women for personal use at home	17/05/2018	Not held
18/258	Request ALL the safety studies that have been carried out on vaccines that are given at the same time as each other ie the study where the combined polio and the meningitis vaccines happen at the same time which you state is safe to do so?! Could you please provide those studies. Not the manufacturer's details on their own product????	18/05/2018	Disclosed in full
18/259	Request for the Pharmacovigilance inspections between 1st Jan 2002 – 31st Dec 2003 please	14/06/2018	Disclosed in part
18/260	Request access to details that have been kept from us. In particular the measures taken by CE regulators in response to concerns raised by MHRA in 2007 and details of all non-conformities identified in PIP during the various audits including the recertification auit in Septemer 2007 with details of any recommended actions or measures.	12/06/2018	Not held
18/261	How do I find out who the notified bodies are for surgical mesh manufacturers? What market surveillance have you carried out for surgical mesh Implants in the last ten years? With surgical Mesh (under the New EU directive) going to a class lll device what additional information have the device manufacturers had to provide? Are the audits if notified bodies publicly available? Can medical devices be approved on the basis of 'equivalence'? The complication percentages you provide for surgical mesh doesn't include the percentage for dyspareunia complications, why is that?	07/06/2018	Disclosed in full
18/262	Reqest all of the inspection reports for CD MEDICAL based in Bolton Lancashire. The inspection reports should be for GMP; GDP and pharmacovigilance please.	18/06/2018	Not held
18/264	Clarify whether the hydroxyethyl-starches (HES) have now been completely withdrawn and the product license suspended in the UK and EU	06/06/2018	Disclosed in full

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18/265	Documentation relating to marketing authorisations of two particular drugs, one being nicotinamide tablets and the other carbogen gas (2% carbon dioxide, 98% oxygen	06/06/2018	
18/266	Licence information for levonorgestrel 1500 mg	06/06/2018	Disclosed in full
18/267	PAR • Voltarol® Suppositories 12.5mg, 25mg, 50mg and 100mg • Econac 100 mg suppositories	05/06/2018	Disclosed in full
18/268	Copies of the last 3 MHRA / VMD GDMP Inspection reports and deficiencies for Dechra Pharmaceuticals / Veterinary products manufacturing site in Skipton, UK.	19/06/2018	Not held
18/269	CBD licensing information	18/06/2018	Not held
18/271	The relevant studies in non-clinical and clinical trials relating to the most recently approved Pregabalin-class medicine. If this remains too broad, please only include clinical studies. Please can you also let me know how many (just a figure will suffice) of this class of medicine has been approved for use since 1 Jan 2016.	05/06/2018	Disclosed in part
18/274	HERNIA mesh fitted during Laparoscopic Ventral Mesh Rectopexy.2015	12/06/2018	Disclosed in part
18/275	Information about gardasil	11/06/2018	Disclosed in full
18/276	I am looking for any information you can give me on the suspension of production imposed on Bristol laboratories. Can you please tell me if there has been any progress made in resolving the issues found by inspectors or is the current situation expected to continue for the foreseeable future	20/06/2018	Disclosed in full
18/277	have is if there have been an increase in yellow card incidents recording adverse events with Denosumab in regards to vertebral fractures and if so what information you could share in regards to the numbers of incidents and the detail?	19/06/2018	Disclosed in full
18/278	Request for a copy of a letter sent by an inspector of the then Medicines Control Agency to the Blood Products Laboratory in approximately January 1991. The Medicines Control Agency reference number on this letter is MF 93/6614/1.	22/06/2018	Not held
18/281	Request reports concerning the device NeuRx/4 diaphragm pacing system (Synapse Biomedical) used for patients with respiratory muscle weakness due to Amyotrophic lateral sclerosis in the UK?	20/06/2018	Disclosed in part
18/282	Request UKPAR of Indometacin Suppositories BP 100mg of Accord-UK Ltd & Indocid Suppositories 100 mg.	15/06/2018	Not held
18/283	I am asking for the safety studies which have been carried out when two drugs are mixed together at the same time and shows the effects and adverse reactions not if the antibodies for that vaccine shows up in the bloodstream	15/06/2018	Disclosed in full
18/284	Questions about whehter Morningside and Teva submitted all necessary clinical trial data as well as completing all MHRA regulatory paperwork.	06/06/2018	Disclosed in full
18/285	I would like to find out what is a status of Sci-B-Vac vaccination for Hep B that is offered to patients in the UK (travel and occupational health clinics).	13/06/2018	Disclosed in full
18/286	CJD and vCJD	18/06/2018	Disclosed in full
18/287	Vaccines with untested products	26/06/2018	Not held
18/288	Is medical cannabis approved in UK ? If yes, when was the legislation approved? · Can you give me a brief history of medicinal cannabis in UK?	15/06/2018	Disclosed in part

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18/289	I would be grateful if you could let me know when ERENUMAB will be licensed for use in the UK	05/06/2018	Disclosed in part
18/290	Question regarding PARs/user-tests	25/06/2018	Disclosed in full
18/291	Omeprazole Actavis 20mg gastro-resistant hard capsules N28 Reg. No. PL 00142/0517 / PIP: 1098904	07/06/2018	Not held
18/292	Request risk Management Plan submitted by Indivior UK limited for Subutex 2mg and 8mg sublingual tablets (PL 36699/0002 and PL 36699/0003)	04/06/2018	Not held
18/293	Public assessment report, including the clinical, non-clinical & quality assessment, for the marketing authorisation assessment for Pulmozyme (dornase alfa). The information is requested electronically or in paper.	07/06/2018	Not held
18/295	Information about adverse reactions to vaccines, fatalities and herbal products	29/06/2018	Disclosed in full
18/296	Request adverse reactions to vaccines and homeopathic products recorded under the Yellow Card Scheme from January 2000 to December 2017.	29/06/2018	Disclosed in full
18/297	Risk management plan for Amantadine Hydrochloride 100mg capsules Lime Pharma product.	14/06/2018	Disclosed in part
18/300	Specific case reports on methylprednisolone	13/06/2018	Disclosed in full
18/301	Information relating to any reported adverse effects and/or complications associated with the surgical procedure known as sacrohysteropexy	25/06/2018	Not held
18/302	I would like to request information on which clinical trials on safety and efficacy was alimemazine (trimeprazine) given UK license for the indication of urticaria by MHRA or its predecessors.	04/07/2018	Disclosed in part
18/304	GPV inspection reports whereby findings were made in regard to digital/ social media from 2012 to present.	05/07/2018	Disclosed in part
18/305	I am writing to request a breakdown of the top 10 centres each year reporting mesh removals for vaginal surgery for prolapse and incontinence. Please could I request this information for the years 2014, 2015, 2016 and 2017	29/06/2018	Not held
18/306	Details related to the first MHRA approval of a medicine containing the following active ingredients Paracetamol, Caffeine and Phenylephrine Hydrochloride. For this combination, Reckitt Benckiser would like to know the date of MHRA approval, the marketing authorisation holder and PL number.	26/06/2018	Disclosed in full
18/307	Information about counterfeit abortion pills seized in England.	03/07/2018	Disclosed in part
18/308	A copy of the latest inspection report for East Midland Pharma	04/07/2018	Disclosed in part
18/309	Information concerning the types of accounting software and applications that may be in use by your organisation.	05/07/2018	Disclosed in full
18/310	Hospira UK Limited, a Pfizer company requests documentation for the product Neupogen which was approved via DCP for which the UK acts as the Reference Member State (procedure number is UK/H/0019/01-09/DC). We request an electronic copy of the most recent Risk Management Plan (RMP) for this procedure	11/06/2018	Disclosed in part
18/311	1. How many employees or full time equivalents at the MHRA are employed in Greater London? 2. How many employees or full time equivalents are employed in the South East and East of England regions? 3. How many employees or full time equivalents are employed in regions outside London, the South East and East of England regions, and where are these employees located?	29/06/2018	Disclosed in full

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18/312	Information about adverse reaction reports received in relation to (a) Olanzapine (b) Risperidone.	15/06/2018	Other
18/313	I understand that the MHRA have concluded that there is not enough evidence to withdraw mesh from clinical usage (specifically mesh used for SUI and POP) Please could you provide me with the evidence you have used to come to this conclusion	04/07/2018	Disclosed in full
18/314	Timescales for formulating J. Collis Browne's Mixture	13/06/2018	Not held
18/315	Files containing keyword:"Factor VIII"	09/06/2018	Disclosed in full
18/316	Inspection report for Licence Holder MS 17249 HARROGATE AND DISTRICT NHS FOUNDATION TRUST	09/07/2018	Disclosed in part
18/317	Public Assessment Report for Fluorescein Sodium 100mg/ml Solution for Injection	15/06/2018	Disclosed in full
18/318	I would like to request a copy of the Risk Management Plan for Amantadine Hydrochloride 100mg Capsules (PL 20620/0085)	15/06/2018	Disclosed in part
18/319	Request PL 00025/0633 variation and scientific rationale submitted by MA Holder	03/07/2018	Disclosed in part
18/320	Risk management for Magnesium Sulfate 20% (PL 39280/0007)	26/06/2018	Disclosed in part
18/321	Information regarding PL 00289-1870 – with UK H/5648/001/DC.	11/07/2018	Disclosed in part
18/322	Request a list of active substances which are currently under any form of EAMS assessment.	27/06/2018	
18/324	Further questions on the Ban On Co-proxamol?	06/07/2018	Disclosed in full
18/325	Request the MHRA to share UKPAR of the product - Hydroxocobalamin 1mg in 1ml, solution for injection (PL 20075/0691); MAH - Accord Healthcare Limited	15/06/2018	Not held
18/326	Mobile phone contracts	05/07/2018	Disclosed in full
18/327	Request public assessment report of DC-procedure UK/H/6468/01-03/DC Levothyroxin oral solution.	03/07/2018	
18/329	Could I please have the last 2 inspection reports for Torrent Pharmaceuticals please?	18/07/2018	Disclosed in part
18/330	Oral Hearing into Adveres effects of Fluoroquinolone antibacterials	12/07/2018	Disclosed in part
18/331	Why UK Liothyronine tablets are 20 mcg compared to European liothyronine which is in tablets of 25mcg? Are the words 'repackage' and 'manufacture' - interchangeable with respect to liothyronine tablets? In other words, are the UK's 20 mcg liothyronine tablets imported from abroad and repackaged here in the UK? Is actual manufacturing of liothyronine 20 mcg tablets taking place within the UK boundaries? Has any UK liothyronine manufacturing facility been visited by MHRA?	10/07/2018	Disclosed in full
18/333	Licence literature available on Vaginal mesh and Other Products	16/07/2018	Disclosed in part
18/334	Further question on Energy Management - please share the meter points separately for HH and NHH.	11/07/2018	Disclosed in full
18/335	Request PAR for the procedure UK/H/0611/001 for metronidazole 7,5 mg/g ended in February 2004.	25/06/2018	Not held
18/336	Request PAR for Loratadine 10mg Film-coated Tablets (UK/H/0508/001/MR; PL 04569/0478)	25/06/2018	Not held
18/337	Request information relating to the review and approval of the Syancthen Depot product	09/07/2018	Not held

FOI no	*Subject*	*Date reply sent*	*Result of request*
18/338	Teronac (mazindol), Novartis - does MHRA still hold the MAA, MA/PL document and internal assessment documents?	05/07/2018	Disclosed in full
18/340	Request information on ADR(s) to pregabalin (Alzain, Axalid, Lecaent, Lyrica, Rewisca.	05/07/2018	Disclosed in part
18/341	Clinical Study Reports of Pitavastatin and Pravastatin from primary prevention of cardiovascular accidents	20/07/2018	Disclosed in part
18/342	Data analysis and extraction request on Yellow Card reporting on musculoskeletal diseases and biologics	20/07/2018	Disclosed in full
18/343	Can you forward me the decision making process to remove GCMAF from selective consideration of cancer treatments, Plus how they supported their findings evidence wise and what was the evidence based on? This should also include the people involved and their position within the organisation	11/07/2018	Disclosed in full
18/344	Pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from Jan 1st 2012 – 31st March 2012.	20/07/2018	Disclosed in part
18/345	All documents that led to the policy on in house manufacture that NHS trust laboratories are not placing on the market and the regulations do not apply. I am especially interested in documents that identify the organisations and departments that originated the policy and any documents that identify lobbying calling for the policy to be developed that were successful	12/07/2018	Not held
18/346	Information regarding the post authorisation safety survey mentioned in the Public Assessment Report of Viagra connect PL 00165/0392.	24/07/2018	Disclosed in part
18/347	HPRA - Freedom of Information request (18/05/001)_MHRA	29/06/2018	Disclosed in part