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

This document contains reference details for all 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 request. The identity of the original requester will be redacted.

No	Subject	Date reply sent	Result of request
19/162	Inspection report from the MHRA visit to Poole Hospital's Pathology dept. on 27/03/19	02/04/2019	Disclosed in part
19/164	Please could you make available all MHRA Inspection reports for GxP (incorporating GMP, GDP, GCP and GVP) inspections performed by the MHRA inspection group at all global Bristol-Myers Squibb premises from Jan 2009 to Mar 2019.	03/05/2019	Disclosed in part
19/165	Public assessment reports for PL 20072/0239 and 20072/0240-Carbimazole 5mg and 20mg tablets	15/05/2019	Disclosed in full
19/166	Falsified medicines in the UK	03/05/2019	Disclosed in full
19/167	I would like to request all the studies that were presented to the EWG in the original study which was carried out by the EWG on Primodos	07/05/2019	Disclosed in full
19/168	Inspection reports for several sites	07/05/2019	Disclosed in part
19/169	Inspection reports for several sites	07/05/2019	Disclosed in part
19/170	In accordance with the FIO Act, I would like to request a copy of the report and data, together with the associated expert opinion, of the comparative in-vitro data that was submitted and used to substantiate the claim of therapeutic equivalence with the reference products.	02/05/2019	Disclosed in full
19/171	Please provide the 20 most recent pharmacovigilance inspection reports for all companies, for inspections conducted prior to 31 Dec 2018	08/05/2019	Disclosed in part
19/172	request on statistics for MESH implants	07/05/2019	Disclosed in full
19/173	Steps Taken For Assessment	17/04/2019	Disclosed in full
19/177	could you please tell me about your tests and findings on RIGVIR and what your recommendations	08/05/2019	Not held
19/178	young people and antidepressant withdrawal	13/05/2019	Disclosed in full
19/180	URGENT RECALL OF MONARC SUBFACIAL HAMMOCK 15 OCTOBER 2015	02/05/2019	Disclosed in full
19/182	I need a copy of MIA-17857 version-03&04 (manufacturing and importing authorisation) for Pantheon UK Limited, Kingfisher drive, Swindon, SN35BZ.	15/05/2019	Disclosed in part
19/184	Periodic Safety Update Reports from 1980 to 2019 for the drug Valproate, Valpromide, Sodium Valproate and Epilim	07/05/2019	Disclosed in full
19/185	Request from whatdotheyknow.com for the most up to date list of opioid medicines licensed for prescription in England	14/05/2019	Disclosed in full
19/186	Medicines and Healthcare Products Regulatory Agency - Spending over £25,000	17/04/2019	Disclosed in part
19/188	Acopy of the non clinical and clinical overview for PL 41344/0053 COLONIS PHARMA Melatonin tablets 3 mg	26/04/2019	Disclosed in part
19/189	•Clinical overview submitted to support the licence approval of Halls Dry Cough Lozenges (PL 00094/0248)	10/05/2019	Disclosed in part
19/191	Statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years	17/05/2019	Disclosed in full
19/192	Request total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2018 calendar year? In relation to the figures for 2018 could you also provide (i) the number of UK suspected ADR reports received with a fatal outcome, (ii) number of ADR reports received which	10/05/2019	Disclosed in full

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	resulted in prolonged hospitalisation and (iii) the number of reports received which resulted in prolonged hospitalisation AND had a fatal outcome? In relation to the fatal outcomes could you please provide a table showing the ten drugs that were most frequently recorded as having caused such a reaction along with the number of times each one was recorded as having a fatal outcome.		
19/193	Request - All the Ferinject (ferric carboxymaltose) Risk Management Plans since registration in 2007.	17/05/2019	Disclosed in part
19/195	Information regarding Izinova (sodium sulfate anhydrous, magnesium sulfate heptahydrate, potassium sulfate)	17/05/2019	Disclosed in full
19/197	The MHRA has stated that the first report of enduring sexual dysfunction caused by antidepressants came from 1987 (18/206). Can you tell me which drug this was? I appreciate that it could be linked to a drug not then on the market and was only reported some years later but with an occurrence date of 1987.	23/05/2019	Not held
19/199	pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from 1st January 2014 –30th June 2014.	24/05/2019	Disclosed in part
19/200	According to MRI database procedure UK/H/6497/001/DC was closed on 8th May 2018 but so far there is no Public Assessment Report available. With regard to the Freedom of Information Act, may we kindly ask you to provide us with the relevant Public Assessment Report?	23/05/2019	Not held
19/201	How do I access the data for 2017 and 2018 for MMR vaccine?	23/05/2019	
19/202	Request PARs for 1) Maxitram SR caps PL 08829/0163 2) Tramquel SR caps PL 04569/1774 3) Zamadol SR caps PL 46302/0150	02/05/2019	Not held
19/203	IT Solutions and contracts	15/05/2019	Disclosed in full
19/205	Register of Licensed Manufacturing Sites 2019	24/05/2019	Disclosed in full
19/206	I am looking for all reported vaccine injuries regarding all the vaccines that are part of the current schedule	24/05/2019	
19/208	MHRA Opioid Expert Working Group, the list of names in the MHRA opioid expert working group,the minutes from the first meeting on 12 Feb 2019 and,the upcoming dates of future meetings for the group	30/05/2019	Disclosed in part
19/209	please provide a copy of your most recent annual report for the JCVI (VACCINE-ASSOCIATED SUSPECTED ADVERSE REACTIONS REPORTED VIA THE YELLOW CARD SCHEME)	08/05/2019	Disclosed in full
19/210	Levothyroxine	30/05/2019	Disclosed in full
19/211	Could you please provide the report/review mentioned above including: 1) sales data on OTC codeine-containing products and dihydrocodeine medicines at 6 and 12 months after the amendment, 2) ADR reports at 6 and 12 months after the amendment and, 3) the conclusions made as to the effectiveness of the Drug Safety Update.	30/05/2019	Disclosed in part
19/212	I would like to submit an request for the Pharmacovigilance inspection report of Tesaro, Inc. conducted by MHRA in December 2018	22/05/2019	Disclosed in part

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19/213	How much has your department spent on preparing for Brexit between 2017 and 2018. How much has your department spent on preparing for Brexit between April 2018 and April 2019.	04/06/2019	Disclosed in full
19/214	Bonuses paid to staff for brexit	05/06/2019	Disclosed in full
19/215	MHRA GMP Inspection Deficiency Data Trend for 2018	30/05/2019	Disclosed in full
19/216	All toxins (botox, muscle relaxants, other aesthetic injectables) currently undergoing the validation process	16/05/2019	Disclosed in part
19/217	Further information regarding fast tracked companies	04/06/2019	Disclosed in full
19/219	I would like to request a copy, in any format available, of the MHRA GMP inspection report resulting from the 09-13 MARCH 2015 inspection at the following drug manufacturing site: Patheon UK Limited	04/06/2019	Disclosed in full
19/220	Details of GPVP inspection findings relating to Collection and collation of adverse drug reactions, literature searching	10/06/2019	Disclosed in full
19/224	Clinical study report	20/05/2019	Disclosed in part
19/225	Adverse Incident Report	29/05/2019	Disclosed in part
19/226	Assessment Report for XIFAXANTA 200 mg film-coated tablets	16/05/2019	Disclosed in part
19/227	I'm looking a FDF named if they have done BE or clinical trial for this product. And if there are any other companies who has done the same in UK market.	17/05/2019	Not held
19/228	How many patients died as a result of general anaesthesia in England and Wales in 2018, 2017, 2016 and 2015. How many patients died as a result of being given a general anaesthetic for the purpose of carrying out a diagnostic scan/test (MRI, CT etc) in 2018, 2017, 2016 and 2015. How many patients died as a result of being given a general anaesthetic for the purpose of carrying out an MRI scan in 2018, 2017, 2016 and 2015.	17/05/2019	Not held
19/229	With regards to the below authorised Beclometasone Dipropionate containing products by Cipla (EU) Ltd. (Procedure No. UK/H/6541/001-002/DC): Kelhale 50 micrograms per actuation pressurised inhalation solution (PL 36390/0229). Kelhale 100 micrograms per actuation pressurised inhalation solution (PL 36390/0230). I note from the Public Assessment Report that reference is made to in-vitro data for both the 50 and 100 mcg formulations and in-vivo PK studies performed with the 100mcg formulation. I request copies of the associated reports and data, together with the associated expert opinion, for these in-vitro and in-vivo studies that were submitted and used to substantiate the claim of therapeutic equivalence with the reference products.	12/07/2019	Disclosed in part
19/230	GMP Inspections List	04/06/2019	Disclosed in full
19/231	Sight Loss after Flu Vaccination.	06/06/2019	Disclosed in full
19/233	How many extra staff have been employed by the MHRA to work primarily or specifically on Brexit preparations or policy? How many staff have been seconded or transferred from other government departments or agencies to the MHRA to work on Brexit? How many staff have been seconded or transferred out	17/05/2019	Disclosed in full

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	of the MHRA into other departments or agencies to work on Brexit? How many of the staff currently within the MHRA and working on Brexit are working primarily or specifically on preparations for a 'no deal' Brexit?		
19/234	Enquiry about the licencing of Thiosix	20/05/2019	Disclosed in part
19/235	As a request are you able to give me the data on the incidence of adverse reactions to the prolonged use of betnesol drops in the paediatric population for ENT problems.	18/06/2019	Disclosed in full
19/236	Please can you send me all MHRA GVP inspection reports for Janssen over the last 5 year period (i.e. between Apr-2014 and Apr-2019)?	17/06/2019	Disclosed in part
19/237	if I just asked for this table to be updated with the latest figures plus Yellow Fever? This was published in the Independent in May 2015. I think MHRA update it annually - can you confirm this? How many deaths were due to vaccines in the last 10 years? Can you tell me how many requests you receive for this information on average per annum?	18/06/2019	Disclosed in full
19/240	Samantha Atkinson business expenses July - September 2018. Details of document required: Title: Samantha Atkinson business expenses July - September 2018. Original format: pdf - Please tell us: 1. What makes this format unsuitable for you? 2. What format you would prefer? Probably using my data!	11/06/2019	Disclosed in full
19/241	We would like to receive the GPvP Inspection report of Aegerion pharmaceuticals, conducted in December 2018	17/06/2019	Disclosed in part
19/242	Please may we request a copy of the follow up questionnaires for off-label use, overdose, drug interactions with P-glycoprotein and CYP3A4 inhibitors and use in pregnancy and lactation for Colchicine Tablets which form part of Annex 4 of the Risk Management Plan for the following licences. PL 42765-0002, PL 36282-0015 & PL 20117-0262. Please may we also request copies of the RMPs	18/06/2019	Disclosed in part
19/243	I am wanting sight of data covering all childhood scheduled vaccine adverse effect/side effect for years 2013 - 2018 I would like to understand: - total number of yellow card referral/reports - broken down into individual figures per childhood vaccines - associated reported side effect/reaction - age of child Is it possible to also request the same data for specific referrals made by my medical practice?	21/06/2019	Disclosed in full
19/244	Information on the international travel (business, not personal) undertaken by Jonathan Mogford, director of the policy in the last 5 years including: 1. Where he went 2. Whether this was EU exit related 3. The cost of that travel, including class and star ratings of hotels 4. Justification for the travel and the cost to the tax payer. 5. The method of payment. 6. Whether he obtained any personal benefits from this for example air miles and hotel loyalty points.	21/06/2019	Disclosed in full
19/245	Marketing authorizations PL 04425/0281 and PL 04425/0631 were issued for Phenergan (Promethazine Hydrocloride). The relevant SPCs and leaflets mention "Treatment of insomnia in adults" in the list of therapeutic indications. Under the	26/06/2019	Disclosed in part

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	Freedom of Information Act, I would like to request copies of the relevant Application for Marketing Authorization, as well as any documents you may hold pertaining specifically to the efficacy of promethazine for the treatment of insomnia.		
19/246	Further to the request from Dec 2018. Following your advise I would like to reapply for any further MHRA inspection reports for 2018 that had not been closed at the time. (Previous 18/665 All MHRA pharmacovigilance inspection reports for the last 12 month period from any company. This can be restricted to those with major and/or critical findings).	25/06/2019	Disclosed in part
19/247	Under the rules please can you tell me 1) Did ethics approval at each hospital know about this trial.2) Were women warned of mesh risks. 3) What were these operations coded as in NHS data. 4) Did the hospital Medical Directors know about this trial. https://clinicaltrials.gov/ct2/show/NCT02407145#studydesign 5) Are any hospitals listed in this trial who didn't end up taking part?	12/06/2019	Not held
19/249	Can you please provide me with electronic copies of all the information relating to the MHRA's guidance/advice/instruction given to stakeholders throughout the UK medicines supply chain regarding the Falsified Medicines Directive (FMD) since 1st January 2019, relating to all possible Brexit scenarios including but not limited to the possible need for compliance with the FMD after a 'deal' Brexit and through any transition period, and what to do if there is a 'no deal' Brexit. Also, what plans does the MHRA's have for introducing our own UK system if the UK is not able to continue to implement the European FMD after a 'deal' or 'no deal' Brexit?	25/06/2019	Disclosed in part
19/250	Under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please.	01/07/2019	Disclosed in full
19/251	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please.	01/07/2019	Disclosed in full
19/252	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please.	01/07/2019	Disclosed in full
19/253	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please	01/07/2019	Disclosed in full
19/254	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please	01/07/2019	Disclosed in full
19/255	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are	01/07/2019	Disclosed in full

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	suspected to have died following routine NHS vaccines over the past 5 years please		
19/256	As per my rights under the Freedom of Information Act (2000) I hereby request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 5 years please	01/07/2019	Disclosed in full
19/257	RISK MANAGEMENT PLAN - topiramate	18/06/2019	Not held
19/258	The number of dental device manufacturers referred by the GDC to the MHRA in the last year to check if they are registered with the MHRA	10/06/2019	Not held
19/261	A panel of independent experts, set up by the Medicines and Healthcare Products Regulatory Agency, looked at evidence between birth defects and hormone pregnancy tests in 2017/2018. 1)How much did the Independent expert working group review cost in total?" 2)What is the break down of those costs?	04/07/2019	Disclosed in full
19/262	Request for Imuran RMP	07/06/2019	Not held
19/263	Could you please send me a detailed list / data base of INDIAN PHARMACEUTICAL MANUFACTURING COMPANIES that have MHRA registered medicines in the UK. 1. The names of these companies with full address details. 2. The names and complete details of each of the medicines manufactured by each of the above Indian Pharmaceutical Manufacturing Companies with their respective MHRA licence numbers. 3. Dates of issuance of the MHRA licences and Expiry dates	10/06/2019	Disclosed in part
19/264	Total number of ADRS, Serious reports for 2015, 2016, 2017 & 2018	05/07/2019	Disclosed in full
19/266	Please provide me with an aggregate of all reports made by health care professionals AND patients directly to the Yellow Card system relating to adverse events/illnesses involving breast implants since January 2014, or the earliest date where reports regarding breast implants are kept on the Yellow Card system. • Breakdown of reports into region/hospital? • Details of what the event/illness involved? I.E. BIA-ALCL, or autoimmune syndrome induced by adjuvants (ASIA syndrome)? • Age of patient? • Outcome of report – surgical or otherwise?	05/07/2019	Disclosed in full
19/269	I am just wondering what is the story about arbaclofen, bumetanide, and balovaptan and autism and will they ever be approved via large scale double blind research trials that are taking place in UK, if you don't mind me asking?	17/06/2019	Disclosed in full
19/270	For each of the different types of cyber security services can you please provide me with: Who is the existing supplier for this contract? What does the organisation annual spend for each of contract? What is the description of the services provided for each contract? Please do not just state firewall. Primary Brand (ONLY APPLIES TO CONTRACT 1&2). What is the expiry date of each contract? What is the start date of each contract? What is the contract duration of contract? The responsible contract officer for each of the contracts above?	05/07/2019	Disclosed in full

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	Full name, job title, contact number and direct email address. Number of Licenses (ONLY APPLIES TO CONTRACT 3).		
19/271	Request information about hepatitis B vaccines and the more severe side effects reported. More specificity i would like to know severe reactions reported in uk, and how many reported have neurological side effects of possible.	09/07/2019	Disclosed in full
19/273	Under the Freedom of Information Act, would you be able to share with me the Risk Management Plan submitted by Pfizer Limited UK for Lustral 50mg and 100mg Tablets (PL 00057/0308 and PL 00057/0309)?	14/06/2019	Disclosed in full
19/274	Please provide electronic documents of all conducted and completed GMP inspections by MHRA in 2013. Please include all international, including overseas companies.	08/07/2019	Disclosed in full
19/275	I am hoping to locate the most recent output from the CPRD monitoring study of valproate in girls and women in the UK. The output I have located (Jan 2010 – June 2018, attached here) mentions a six monthly update that will be made available on the MHRA website.	25/06/2019	Disclosed in full
19/276	RMP for Sertraline 50mg Film-coated Tablets, Sertraline 100mg Film-coated Tablets (PL 34424/0034-0035)	18/06/2019	Disclosed in part
19/277	Request ADR Roaccutane - breakdown of all the alleged Isotretinoin / Roaccutane side effects reported to you under the yellow card scheme over the last 10 years, with reporter type. Total number of UK suspected adverse drug reactions following sotretinoin / Roaccutane prescription from 1983 (or the most recent date from which you have records). Total number of UK reports of psychiatric disorders following Isotretinoin / Roaccutane prescription from 1983 (or the most recent date from which you have records). Total number of UK reports of suspected suicide following Isotretinoin / Roaccutane prescription from 1983 (or the most recent date from which you have records).	15/07/2019	Disclosed in full
19/279	Could you please provide the most recent submitted risk management plans (RMP) for AMIODARONE TABLETS (100 mg and 200 mg).	18/06/2019	Not held
19/280	Statements issued to Channel 4's Dispatches programme	10/07/2019	Disclosed in part
19/281	Alerts and warning concerning Teva Levothryrine	09/07/2019	Disclosed in part
19/282	Request for AZAFALK RMP	02/07/2019	Disclosed in part
19/283	Request the currently approved RMP is version 1.0 topiramate	19/06/2019	Disclosed in part
19/284	Request a copy of the clinical overview used in support of the National Approval of PL 20416/0653 Doxepin 50mg Capsules.	16/07/2019	Disclosed in part
19/285	Can you please forward the mats inspection report for BCB International.	09/07/2019	Disclosed in part
19/286	Request information electronically 1) Since the introduction of the vaccines to the public, how many people have died, suffered permanent deafness or blindness, encephalitis or serious complications as a result of the Measles or MMR	17/07/2019	Disclosed in full

No	Subject	Date reply sent	Result of request
	vaccine? 2) Since the introduction of the vaccines to the public, how many people have died, suffered permanent deafness or blindness, encephalitis or serious complications within a month of receiving the Measles or MMR vaccine? 3) Details and results of the clinical trials carried out prior to the introduction of the Measles vaccine? 4) Details and results of the clinical trials carried out prior to the introduction of the Measles vaccine? 5) Details and results of what ongoing monitoring and tracking of the MMR vaccine (and Measles-only vaccine, if available) is taking place? 6) How often is the recommended UK vaccination schedule reviewed?		
19/287	MHRA website it shows manufacturer as Waverly however it is being imported from reliance India? Kindly clarify the status of the Capecitabine Tab 500mg in reply email that MHRA has approved reliance life science India as manufacturer of this drug for UK?	12/07/2019	Disclosed in part
19/288	Capecitabine Waverley 500mg is manufactured by Reliance Life Sciences , India , kindly confirm.	12/07/2019	Disclosed in part
19/289	Please disclose the number of 'abortion pills' (mifepristone and misoprostol) seized between in 2018 which were intended to be delivered to addresses in the UK.	15/07/2019	Disclosed in full
19/290	Request number of sets of abortion pills addressed to addresses in England and Wales seized by drug enforcement officers between January 2018 - January 2019. Please supply me with this information electronically to email address above or in paper form.	15/07/2019	Disclosed in full
19/291	Please provide a copy of the RMP for PL 20416/0653 Doxepin 50mg Capsules	12/07/2019	Disclosed in part
19/292	Under the Freedom of Information Act, would you please be able to share with me the Risk Management Plan of PENDRAMINE®?	25/06/2019	Not held
19/293	Can the following pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from July 1st 2014 – 31st December 2014	18/07/2019	Disclosed in part
19/294	CHM decision on Glycopyrronium	17/07/2019	Disclosed in part
19/295	I am specifically interested in the report for Pharmapac UK (UK) Ltd (MIA 15632), Inspection number 31154-0027 conducted on 17th July 2017.	22/07/2019	Disclosed in part
19/297	PAR for PL 14434/0042 LABORATOIRE AGUETTANT Metaraminol injection 0.5 mg/ml MA granted 21/06/2019	01/07/2019	Disclosed in part