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.

Updated: 5 July 2019

no	Subject	Date reply sent	Result of request
FOI 18/544	Public Assessment Report - Prednisolone 5mg Suppositories PL 36301/0055	05/10/2018	Disclosed in full
FOI 18/541	I am interested in gaining access to reports I wrote and presented to the EAGs on drug safety and cardiovascular health on adherence to statin medication sometime in 2009-2011, while I was working for the pharmacoepidemiology unit at MHRA	16/10/2018	Disclosed in part
FOI 18/540	Counterfeit medicines	24/10/2018	Disclosed in full
FOI 18/539	Please advise how MHRA monitors all suspected ADR s on drugs and vaccines, and how MHRA addresses any safety concerns? what number of reports constitutes a safety concern? if a death of a healthy child is reported after being given a drug or vaccine, how is the death investigated to find out if any causal relation to drug or vaccine taken? How many deaths must be reported before it is a 'safety concern'? Why are adverse reports to vaccines not published on your website like other drug adverse event reports?	30/10/2018	Disclosed in full
FOI 18/542	I would like to request details on all complaints/issues raised about the breast implants made by "poly implant prosthesis" between the dates 2000 & 2008	29/10/2018	Disclosed in part
FOI 18/543	For the 2017 calendar year could you please state the number of Adverse Reactions reported relating to breast implants used in breast enlargement surgery	29/10/2018	Disclosed in full
FOI 18/593	online medicine sellers registry	02/11/2018	Disclosed in full
FOI 18/547	I would like all recent research (links to full peer reviewed research) and current clinical trial information that the government hold on vaginal mesh and vascular devices	16/10/2018	Disclosed in part
FOI 18/546	requesting for the data that shows that breaking tablets is not acceptable to administer lower doses of liothyronine and publicly accessible data as in "e.g. in a freely accessible online journal"	01/11/2018	Disclosed in full
FOI 18/550	I am interested in the transparency of scientific information used by government departments. The audit project conducted by ISAC has been identified as a case of interest since its 2014 annual report indicated an intention to publish the findings of the project. However, the minutes from January 2017 indicated that ISAC then decided not to make the findings public but only to present them to the CPRD user group. In order to further understand this decision, I am requesting the following information. (1) The paper which was considered by ISAC in January 2017 when reaching this decision. (2) All materials (e.g. paper, slides) used in the presentation made to the CPRD user group.	16/10/2018	Not held
FOI 18/552	I am requesting a copy of the pre-clinical study report L-791,456: Five-Week Oral Toxicokinetic Study in Mice	22/10/2018	Not held

no	*Subject*	*Date reply sent*	*Result of request*
FOI 18/553	I am requesting a copy of the pre-clinical study report L-791456: Single-Dose Oral Toxicokinetic Study in Female Mice	22/10/2018	Not held
FOI 18/554	I am requesting a copy of the pre-clinical study report L-791456: Single-Dose Oral Toxicokinetic Study in Mice	22/10/2018	Not held
FOI 18/551	I am requesting a copy of the pre-clinical study report L-791,456: Fourteen-Week Oral Range-Finding Study in Mice	25/10/2018	Not held
FOI 18/549	I would like to know why the MHRA rejected the original application and whether there is any difference between the Xonvea formulation and the original. Did the company provide more evidence that managed to persuade the MHRA to approve the application second time round?	05/11/2018	Disclosed in full
FOI 18/558	One last thing I wondered whether you hold records for was the deaths caused by meningitis over the last 10 years? Do you have a breakdown which shows what strain of bacteria caused each meningitis death? For example deaths by meningitis b over the last 10 years?	19/10/2018	Not held
FOI 18/559	We understand that the company Sandoz Limited ("Sandoz") obtained on 6th September 2018 marketing authorisation in the UK for "Lenalidomide Sandoz" 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg Hard Capsules (PL 04416/1523-9). Could we please request the UK specific documentation relating to the RMP, such as the educational materials and communications to healthcare professionals, patient information, and prescription authorisation form. Of course, we accept that commercially confidential information and personal data within this document may be redacted	19/10/2018	Not held
FOI 18/590	Funding and Fees from Pfizer	05/11/2018	Disclosed in full
FOI 18/560	FOI Request for Carbimazole and Nitrofurantoin RMP / safety concerns	12/11/2018	Disclosed in part
FOI 18/563	FOI for warnings issued for Graseby products. Can we narrow it down to Graseby syringe drivers or Patient Control Analgesia (PCA) machine?	12/11/2018	Disclosed in full
FOI 18/562	ADRS for over 65s vaccinations	14/11/2018	Disclosed in full
FOI 18/565	Can I receive any pharmacovigilance inspection reports for the time period of October 1st 2012 – 31st December 2012 where there were major or critical findings please	15/11/2018	Disclosed in part
FOI 18/570	Please can you provide me with an update as to when I can receive these reports to FOI 18/481	15/11/2018	Disclosed in part

no	Subject	Date reply sent	Result of request
FOI 18/568	Request for disclosure of data relating to probation of last 5 years	12/11/2018	Disclosed in full
FOI 18/569	How many flu vaccine related deaths have been reported to MHRA since the school flu vaccinations programme was started? How many HPV vaccine related deaths have been reported to MHRA since the school HPV vaccinations programme was started?	13/11/2018	Disclosed in part
FOI 18/587	Can the following pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from January 1st 2013 – 30th April 2013.	16/11/2018	Disclosed in part
FOI 18/572	The GPhC has asked us to investigate a concern it has received regarding the dispensing of Cipramil	16/11/2018	Disclosed in full
FOI 18/574	An inventory list of files you hold which contain any of the following keywords in the title where the content of those files is likely to cover periods between 1972 - 1975: " Factor VIII"	19/11/2018	Not held
FOI 18/575	Have you received any notice or instruction not to destroy documentation or files which may be relevant to the Infected Blood Inquiry from any source? Please supply copies of all Factor VIII Product License Applications received in 1973,1974,1975 & 1976. Please supply copies of all Factor VIII Product License Applications received in 1984 & 1985.	19/11/2018	Disclosed in part
FOI 18/571	Could you provide me details of all cases in the last 5 years (since January 2013) where an Epipen has been cited in a death or serious illness, eg, paralysis. Please provide dates, the reason why the Epipen was used and the outcome. Please call me for any clarification	16/11/2018	Disclosed in part
FOI 18/576	Would it be possible to split the ADR data of 2016 before and after September? For my project I'm interested in the reports before and after a specific article was published in September 2016, so this would be very helpful as it cannot be provided by month. I would also like to request the total number of UK spontaneous ADR reports you have received for the High Level Group Term depressed mood disorders and disturbances for each hormonal contraceptive between 2013 and 2018 by month, without the additional 1B data.	20/11/2018	Disclosed in part
FOI 18/580	Please supply PAR for UK/H/6018/001 CARBOCISTEINE UNITHER PHARMACEUTICALS 750 mg/10 ml, ADULTS WITHOUT SUGAR, oral solution in sachet 31.05.2013	05/11/2018	Disclosed in full
FOI 18/573	Please could you provide all such subsequent quarterly reports from the last that has been published via your website. If these are not available, please could you provide the data for the last 12 months for import notices i.e number of notifications and if possible the volume of the following products	12/11/2018	Disclosed in full
FOI 18/577	We would like to request the information of the application data and the review contents of the authority for the first authorization such as public assessment report for the product below. What we request to you is some detail information, not just a summary.	22/11/2018	Disclosed in part
FOI 18/598	Primacor safety concerns	22/11/2018	Disclosed in full
FOI 18/578	Please supply copies of the MHRA GDP Inspection Reports arising from inspection of the following sites, ROOM 114 & 115, FARNBOROUGH AIRPORT, FARNBOROUGH, GU14 6XA 1ST FLOOR, MEADOW GATE, FARNBOROUGH AIRPORT, FARNBOROUGH, GU14 6XA	16/11/2018	Disclosed in part

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FOI 18/584	Clinical study reports, Robinul Tablets (GLYCOPYRRONIUM BROMIDE)	21/11/2018	Disclosed in full
FOI 18/583	Please can you help me clarify the qualifications of a nutritionist, Dr XXX. He claims he was a senior scientific adviser to the Committee on the Safety of Medicines 'in the 1970s'. Is this true?	12/11/2018	Not held
FOI 18/581	number of suspected reactions to the HPV vaccination reported to the MHRA since 1 January 2008	16/11/2018	Disclosed in full
FOI 18/582	Statistics of people suffering adverse from Rigevidon	22/11/2018	Disclosed in full
FOI 18/599	can you please re-assure that you are looking to licence cheaper generic buprenorphine from other manufacturers, eg in India?	27/11/2018	Disclosed in full
FOI 18/585	reports following taking SSRIs	23/11/2018	Disclosed in full
FOI 18/589	excipient details for specific products	23/11/2018	Disclosed in full
FOI 18/591	PAR for PL 00063/0733	07/11/2018	Not held
FOI 18/595	Can you clarify & send me the documents showing the tests against placebo as those tests have obviously been done to be able to give a license for HPV vaccine	23/11/2018	Disclosed in full
FOI 18/592	Pay rates and settlements for staff	29/11/2018	Disclosed in full
FOI 18/594	Could I please request t RMP for PL 00289/2182-2188	05/11/2018	Not held
FOI 18/596	could you please issue me with the latest number of adverse advents reported to you from the hpv injections. Also I would like a copy of the latest symptoms list/ numbers that has been reported to you	29/11/2018	Disclosed in full
FOI 18/597	I would like to clarify that I am only interested in SCS salaries. Please exclude non-SCS information. Further request to FOI 18/557	03/12/2018	Disclosed in full
FOI 18/604	Adverse event data glycopyrronium tablets	03/12/2018	Disclosed in full
FOI 18/601	Request of information CCTV Maintenance	03/12/2018	Disclosed in full
FOI 18/600	Numbers of Agency Lawyers 3 Sep 2018 and Cost of agency legal workers 2016/2017	05/12/2018	Disclosed in full
FOI 18/579	Who was the MAH until 1987 for Do-Do ChestEze product	19/11/2018	Disclosed in full
FOI 18/602	We request a copy of the most recent Risk Management Plan (RMP) for this procedure which is version 4.0 dated 04 August 2017 for Neupogen	26/11/2018	Disclosed in part
FOI 18/621	Pending information for Rhopressa and Vyzulta	27/11/2018	Disclosed in part
FOI 18/605	In each of the last five years, how many counterfeit or non-compliant dental devices have been seized by the MHRA	10/12/2018	Disclosed in part
FOI 18/606	provide copies of all internal documents held by MHRA about this recall, including the number of packs that were returned and the number that were not returned, provide details of any adverse incidents including adverse reactions/liver disorders/cancers linked to these St John's Wort tablets	11/12/2018	Disclosed in part
FOI 18/567	Request access to Clinical overview submitted to support the licence approval of Nurofen Lemon Meltlets (PL 00063/0382). Clinical overview submitted to support the licence approval of Nurofen chewable capsules (PL 00063/0727, UK/H/5966/001/DC). Clinical data presented to support the licensed indications for Nurofen for Children/ Nurofen for Children Orange 3 months to 12 years (PL 00063/0665)	12/12/2018	Disclosed in full
FOI 18/610	please provide us with the Public Assessment Report for any of the below licences of Baclofen 10mg Tablets. PL 00289/0243 TEVA UK Baclofen Tablets 10mg. PL 28444/0030 ACTIVASE PHARMA BACLOFEN TABLETS 10MG. PL 04569/0158 GENERICS UK	22/11/2018	Disclosed in full

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	BACLOFEN TABLETS BP 10MG and PL 13606/0066 CO-PHARMA BACLOFEN TABLETS BP 10MG		
FOI 18/609	Please can you send a copy of the inspection report for GMP/IMP 47794/28762-0019	13/12/2018	Disclosed in part
FOI 18/619	Request for the "overview of the aims and objectives of audits of ISAC-related activities" and the "summary of the outcomes of the discussions of the subcommittee" which are alluded to section 9.1 of the July 2016 minutes.	20/11/2018	Disclosed in full
FOI 18/618	Please supply copies of all Factor VIII Product License Applications received in 1975 & 1976	13/12/2018	Not held
FOI 18/614	Please supply copies of all GMP & GDP inspection reports issued in the last 5 years for Alloga UK Limited (formerly known as UDG)	14/12/2018	Disclosed in part
FOI 18/615	a list of the current GMP Contract Testing Labs	14/12/2018	Disclosed in full
FOI 18/616	Please could I request a breakdown of MHRA staff numbers (separated for each division eg policy, licencing, vigilance and risk management of medicine etc.) separated by number of permanent contracts and fixed term contracts (separated by the length of contract) as well as the grade of staff member	14/12/2018	Disclosed in full
FOI 18/620	please could you provide the data for the last 12 months for import notices i.e number of notifications and if possible the volume of the following products; Diazoxide Oral Suspension Chlorthiazide Oral Suspension Benzathine Benzylpenicillin Injections Albendazole 400mg Tablets Progesterone injections Povidone-iodine 5% ophthalmic solutions	20/11/2018	Disclosed in full
FOI 18/622	Pending information for Lanreotide acetate 60mg, 90mg, 120mg injection	23/11/2018	Disclosed in part
FOI 18/634	Has the MHRA discussed VSL3 with any authority this year including the ACBS ? 3. Is there any issue the MHRA have seen related to patient safety or efficacy ? 6. Could you please supply me with copies of minutes of meetings which the MHRA participated in which resulted in the change of status for reimbursement of this product on the NHS	21/12/2018	Disclosed in full
FOI 18/627	Could we please request the UK specific documentation relating to the RMP to PL 04416/1523-9	27/11/2018	Not held
FOI 18/630	Online medicines seller registry - Who is on the registry?	14/12/2018	Disclosed in full
FOI 18/671	Critical major Inspection findings	21/12/2018	Disclosed in full
FOI 18/626	My request assumed that these were provided in the form of one or more documents and it is these that I am requesting. If they were not provided to ISAC in document form (but verbally say) please could you confirm that. If there were relevant documents provided to ISAC in July 2016 please could you either provide them to me or explain your reason(s) for not doing so	27/11/2018	Disclosed in part
FOI 18/632	I'd like to request information on how many morcellator related injuries and complications have been ever reported to MHRA or Patient Safety NHS? How many have been reported by Gynaecologists? How many leiomyosarcoma, sarcoma or occult cancer that have been inadvertently morcellated have been reported? How many involved power morcellation as opposed to morcellation with a knife/scalpel? The NICE Guidelines on Hysterscopic Morcellation state that the procedure has the potential for serious complications and that complications should be monitored and audited and patients informed of the risks? Who is responsible for ensuring that there is a central database of complications and who regulates and monitors this?	18/12/2018	Disclosed in full
FOI 18/640	HPV vaccine tested against placebo	21/12/2018	Disclosed in full
FOI 18/631	We would like to request the information of the application data and the review contents of the authority for the first authorization such as public assessment report. What we request to you is some detail	24/12/2018	Disclosed in part

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	information, not just a summary. Requested Product : Deep Relief (PL 00189/0020)		
FOI 18/628	PAR, Clinical Overview, The clinical studies performed in relation to the product for PL 00094/0036, PL 00094/0038 and PL 00094/0253	13/12/2018	Disclosed in part
FOI 18/629	Please could you provide the data for the last 12 months for import notices i.e the number of notifications and if possible the volume of the following products Diazoxide Oral Suspension (Proglycem), Chlorthiazide Oral Suspension, Benzathine Benzylpenicillin Injections, Albendazole 400mg Tablets, Progesterone injections, Povidone-iodine solutions and Metolazone Tablets	08/01/2019	Disclosed in full
FOI 18/635	GcMAF - Youtube video - 1) the lead person/s responsible for issuing the propaganda (bias, misinformation, disinformation) & (2) all the persons involved in drawing up the propaganda.	06/12/2018	Disclosed in full
FOI 18/633	data on specific medDRA terms that we've received ADR reports	31/12/2018	Disclosed in full
FOI 18/650	Silimed breast implants - biocompatibility tests	31/12/2018	Not held
FOI 18/652	We would like to request PAR for Eskazole Tablets 400 mg PL 00002/0202 (MA holder: SMITHKLINE & FRENCH)	14/12/2018	Not held
FOI 18/637	provide me with a spreadsheet of anonymised reported adverse events of surgical mesh	14/12/2018	Disclosed in full
FOI 18/642	Has the MHRA received any notifications regarding an adverse drug reaction or general concerns, either direct to the MHRA or via The Yellow Card Scheme, in the last three years about Gadolinium-containing contrast agents (GdCAs)? Please list by year, the drug product and give specific detail on the concern/drug reaction	31/12/2018	Disclosed in full
FOI 18/638	FOI on adverse incidents from breast implants	03/01/2019	Disclosed in full
FOI 18/639	Falsified medicines	03/01/2019	Disclosed in part
FOI 18/641	please can you send me all GMP inspection reports for the Cell and Gene Therapy Catapult (MIA 48152 and MIA(IMP) 48152).	03/01/2019	Disclosed in part
FOI 18/644	Inspection History for the last three years for List of the Clinical Investigator sites, List of the Bionalytical laboratories and reference safety laboratories, List of the Pharmaceutical manufacturing units and List of the Contract Research Organizations	20/12/2018	Disclosed in part
FOI 18/653	Use of acrylic cement	04/01/2019	Disclosed in full
FOI 18/675	Please supply me with documented evidence that the cases and testimonials of the patients that he helped were all based on fraud and were not true. Also, please supply me with documented evidence that GCMAF supplied b harmed and lead to his patients' deaths	02/01/2019	Disclosed in full
FOI 18/647	FOI request for RMP for Aripiprazole	04/01/2019	Disclosed in part
FOI 18/648	MHRA regulation of medical products containing Ephedrine	08/01/2019	Disclosed in full
FOI 18/651	We are particularly interested to receive the GPvP inspection reports, including agreed CAPAs of:European based MAHs, operating globally, those MAH of innovative and established products, Is MAH of a Biological product, Is outsourcing PV tasks to vendors.	28/12/2018	Disclosed in full
FOI 18/654	RMP for PL 16363/0402 - Milpharm Limited – Fluoxetine capsules 60mg, PL 20117/0152 Morningside Healthcare Limited - Fluoxetine capsules 10mg, PL43461/0053 Flamingo Pharma(UK) Limited - Fluoxetine capsules 20mg and PL44041/0016 Noumed Life Sciences Limited - Fluoxetine capsules 20mg	09/01/2019	Disclosed in part
FOI 18/663	Request to provide Risks of Lanreotide	09/01/2019	Disclosed in part
FOI 18/655	1 - Can you kindly provide the number of rejected application for Glycoperronium tablets (all strengths) by the MHRA from 1st January 2014 to 10th December 2018. 2- Can you kindly disclose any internal review undertaken regarding Glycoperronium tablets	10/01/2019	Disclosed in part

no	*Subject*	*Date reply sent*	*Result of request*
FOI 18/659	RMP for Paroxetine	10/01/2019	Disclosed in part
FOI 18/656	Please could you provide me with a breakdown of suspected adverse reactions (ADRs) compiled by you in (a) the 2016 and (b) the 2017 calendar year in relation to vaccines? 2. For all reactions where the report was of a fatal ADR please state the vaccine type and what type of person was responsible for filing the report to you?	11/01/2019	Disclosed in full
FOI 18/660	RMP for Nitrofurantoin	13/12/2018	Not held
FOI 18/661	REVOKED LICENCES	14/01/2019	Disclosed in part
FOI 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	15/01/2019	Disclosed in part
FOI 18/611	Any information relating to the number of potentially contaminated Varlsatan that has been prescribed to UK patients since the change in the manufacturing process in 2012;.For the same period, please provide a list of all medicines prescribed in the UK that contain ingredients manufactured by Zhejiang Huahai and information relating to the numbers prescribed and Please provide any communication with health ministers or their office relating to this recall	16/01/2019	Disclosed in part
FOI 18/669	A list for the year of 2017 and the year of 2018 on the PV Inspections that occurred during those years. If you could provide a listing with the name of the company/facility it would be greatly appreciated.	14/01/2019	Disclosed in full
FOI 18/667	Adverse Drug Reaction to the MMR Immravax	17/01/2019	Disclosed in full
FOI 18/668	illegal custom-made dental devices	17/01/2019	Disclosed in full
FOI 18/678	The Licensing date for the cell grown quadrivalent vaccine (QIVc)	03/01/2019	Disclosed in full
FOI 18/672	a list of all marketing authorisations which are still active which have a sunset exemption, the date of the previous exemption requests and the reason for the previous exemptions.	07/01/2019	Disclosed in full
FOI 18/676	We would like to request the submitted Risk Management Plans for all approved rosuvastatin tablet products	17/01/2019	Disclosed in part
FOI 18/673	RMP for product Neupogen	21/01/2019	Disclosed in part