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: 6 December 2018

no	Subject	Date reply sent	Result of request
18/361	Request information regarding the DEAC. Please provide me with all documents possessed or produced by the committee in relation to the following areas. Neural stimulation (also known as neurostimulation). Spinal cord stimulation, Deep brain stimulation or other forms of electrical brain stimulation and Brain-computer interfaces.	10/07/2018	Not held
18/352	Documentation submitted to the MHRA from Babylon to seek approval for Class 1 device registration.	12/07/2018	Not held
18/353	Disclosure of notes and records pertaining to a vaccination administered to clients for JMP Solicitors	01/08/2018	Disclosed in part
18/356	Can the following pharmacovigilance inspection reports be provided for all companies that had major or critical findings please from April 1st 2012 – 3oth June	01/08/2018	Disclosed in part
18/355	All the reports made to the Yellow Card system relating to medical devices since January 2015, or the earliest date where reports of devices are kept on the Yellow Card system, as per the variables in the attached spreadsheet.	02/08/2018	Disclosed in full
18/357	Please provide me with an aggregate of all the reports made by health care professionals to the Yellow Card system relating to adverse events involving medical devices since January 2015, or the earliest date where reports of devices are kept on the Yellow Card system, as per the following: Device type (Artificial Limb, Wheeled mobility Device, Artificial Limb, Breast Implant, Cochlear Implant, General Device, IVD, Orthotics Implant, Pacemaker, Wheeled mobility Device). Age group (in five-year bands if possible). Gender (male/female).	02/08/2018	Disclosed in full
18/358	How many letters to coroners has the MHRA provided relating medical devices or implants between 2007 and 2018? Please provide a year-by-year break down of how many letters each year, up until the most recent year for which figures are available. Please provide all letters relating to medical implants or devices that the MHRA has provided to coroners since 2007. We acknowledge that specific device names may need to be redacted. How many warnings about medical devices or implants has the MHRA issued since 2007? Please provide year by year breakdown of figures, up until the most recent year for which figures are available. Please provide a list of the year and device type of any medical implants or devices that the MHRA has issued warnings about since 2007, in response to coroners' reports. Please provide a list of the year and device type of any medical implants or devices that the MHRA has ordered to be withdrawn from the market since 2007. Please provide a list of the year and device type of any medical implants or devices that the MHRA has ordered to be withdrawn from the market since 2007, in response to coroners' reports.	02/08/2018	Disclosed in part
18/359	Provide a spreadsheet showing the breakdown of all communications spend incurred by MHRA with regard to each of: HPV Vaccine, Valproate and Vaginal Mesh. I request this spend is provided per medical product by year between 2006 and July 2018 and broken down to show the actual spend per cost code (name and number).	30/07/2018	Disclosed in full
18/360	What action has or will the MHRA take in light of the fact that there exists now a distinct possible link between aluminium, from sources such as vaccine adjuvants, travelling across the blood-brain barrier and potentially having a role in autism?	01/08/2018	Disclosed in full
18/363	The number and value of counterfeit and non-compliant dental devices and equipment seized by the MHRA since 2012, broken down by year. I would like the above information to be provided to me in an electronic format as a spreadsheet.		Disclosed in part
18/364	Information from the last 24 months involving illegal activity in the area of custom-made dental Devices, to include the number of cases and the nature of the illegal activity. Whether they involved illegal imports. What kind of devices were involved. Any other information that would help to give a complete picture of illegal activity in this area.	01/08/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/365	Can you please indicate for me how much your organisation spent on public engagement activities for each of the last two financial years.	02/08/2018	Disclosed in full
18/393	Info about requests made by the ICIJ.	01/08/2018	Disclosed in full
18/382	Correspondence from the MHRA to the National Drugs Advisory Board (NDAB), Irish Medicine Board (IMB) also from the Drugs Division in the Department of Health (DoH) in Ireland from 1972, 1973, 1975 and thereafter up until 1995 regarding the drug Sodium Valproate (Epilim) Act.	08/08/2018	Disclosed in part
18/392	I am writing to request information relating to the number of recorded reports of Henoch Schonlein Purpura (HSP) following vaccination, and specifically the Meningitis ACWY Vaccine	08/08/2018	Disclosed in full
18/367	Can you please advise of all past, present, and planned clinical trials involving cannabidiol (CBD)?	08/08/2018	Disclosed in part
18/375	Can the following pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from July 1st 2012 – 3oth September 2012.	09/08/2018	Disclosed in part
18/374	How many Dental Laboratories you currently have registered?	26/07/2018	Disclosed in part
18/376	Please can you supply details of all yellow cards raised by Sandyford Surgery,1119 Argyle Street, Glasgow from 2007 to 2018?	30/07/2018	Disclosed in part
18/368	The full copies (including any annexes) of the clinical and non-clinical data presented to you with regard to the safety and effectiveness of Pregabalin PL 44041/0065-72, as requested.	02/08/2018	Disclosed in part
18/370	Please could you send me the following information for the period 1st April 2018 to 30th June 2018, for all Yellow Cards submitted to report serious SAEs for HPV vaccination in the format: Product (for Gardasil please specify if Gardasil or Gardasil 9). Male/Female patient, Age group, Reported reaction (s) and Outcome(s). Please could you send a table for the period 1st January 2008 to 30th June 2018 for all Yellow Cards submitted for any vaccination detailing numbers of reports for the following, with each different vaccination having a separate row - all with outcome of unresolved or unknown: Postural Orthostatic Tachycardia Syndrome / autonomic nervous system imbalance, Complex Regional Pain Syndrome, ME/CFS / chronic fatigue syndrome, Narcolepsy, Migraine and any menstrual disorder. Number of Yellow Cards submitted for HPV vaccination. Number of Yellow Cards for HPV vaccination that have at least one outcome of unresolved or unknown.	09/08/2018	Disclosed in full
18/371	Please supply a copy of the MHRA GDP Inspection Report arising from the inspection of INDIVIOR EU LIMITED, 215 BATH ROAD, SLOUGH, SL1 4AA, United Kingdom - UK WDA(H) 42362. EudraGMDP indicates the last inspection was conducted on 2015-03-12. (GDP Certificate No: UK WDA(H) 42362 Insp GDP 42362/11565298-0003).	13/08/2018	Disclosed in part
18/377	We would like to request additional information relating to the Cyclizine Lactate 50 mg/ml Injection - Phoenix Labs - PL 35104/0021 pharmaceutical product which was recently granted a Marketing Authorisation (MA) by the MHRA on 14th June 2018.	25/07/2018	Disclosed in part
18/373	Please confirm the numbers of reports received of Breast Implant Cancer, BIA-ALCL. All Other Malignancies, including breast cancer and MGUS in UK women with breast implants.	09/08/2018	Disclosed in full
18/378	Under the Freedom of Information Act, would you be able to share with me the Risk Management Plan submitted by Pfizer Ltd UK for Neurontin 300mg Capsules (PL 00057/0536)?	18/07/2018	Not held
18/379	A list of MHRA registered internet sites. I have accessed the online register, but it totals 76 pages and a total of 759 registrants, as you appreciate the act of retrieving this information would be extremely time consuming	03/08/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/385	How many repurposed drugs have the Medicines and Healthcare products Regulatory Agency assessed for the treatment of brain tumours? Of the repurposed drugs assessed for brain tumours, what has been the outcome of each assessment?	01/08/2018	Disclosed in part
18/391	A list of the manufacturers for each individual vaccine that is on the infant immunisation schedule for the U.K at present. Or alternatively if you could send the insert for each of the vaccines?	13/08/2018	Disclosed in part
18/383	Request full RMP for one of the products already registered on UK market: Gabapentin Accord 300 mg hard capsules (PL 20075/0453)?	31/07/2018	Disclosed in part
18/384	During the last 5 years or less if data isn't available: How many reports have you received in relation to (a) Olanzapine (b) Risperidone? What was the lowest dosage notified in each case for an adverse reaction? How many reports of adverse reactions for each of these were for (a) men (b) women? What was the average age of patients who had an adverse reaction to (a) Olanzapine? (b) Risperidone? What were the adverse reactions reported for (a) Olazapine? And (b) Risperidone? What is the process following a yellow card report being submitted? Has any action or recommendations been made following reports of (a) Olanzapine or (b)Risperidone?	17/08/2018	Disclosed in full
18/386	Request number of packs and doses of each of the following 2 products that have been authorised for import into the UK on an unlicensed basis under the MHRA's regulated process of notification of intent to import unlicensed medicines. The products: AQUASOL-A, (MAH Hospira Inc now Pfizer Inc), VITAMIN-A NEPALM, (Nepalm France). Please provide data over the time period of 2008-2018 (10 years).	20/07/2018	Disclosed in part
18/387	Can you please detail how much total revenue (including fees, funding or any other monies received) you received from Pfizer in the last 5 financial years? Please break this down into financial years.	26/07/2018	Disclosed in part
18/388	Please supply details of all cases of uveitis, iritis, eye inflammation and macular oedema reported following vaccination.	15/08/2018	Disclosed in full
18/389	Documentation relating to 'Factor VIII' where the content of that documentation is likely to cover period 1987 – 1992.	10/08/2018	Disclosed in full
18/394	Request for Clinical Study Reports of Pitavastatin (18/341)	17/08/2018	Disclosed in part
18/398	Please can you provide a copy of the evidence re HPV Vaccine (including reports, meeting minutes and scientific research) considered by the CHM to enable the following statement by Professor Kent Woods, Chief executive in the MHRA Drug Safety Update of 2009 "These have alleged that the vaccine has been responsible for a wide range of conditions such as paralysis, encephalitis, epilepsy and chronic-fatigue conditions. As agreed by the CHM, the evidence does not indicate that the vaccine has caused these conditions and the associations are merely coincidental. "	14/08/2018	Disclosed in part
18/403	Can you let me know when Medical Cannabis will be now be widely available throughout NHS GPs?	09/08/2018	Not held
18/395	Please can you state the total number of 'Yellow Card' reports received by the MHRA in relation to side-effects of a medicine, vaccine, herbal or homeopathic remedy in 2017.	15/08/2018	Disclosed in full
18/407	Public Assessment Reports and Art work for several products	16/08/2018	Disclosed in full
18/400	Please can you confirm the internal or external methods for healthcare professionals to report adverse events or adverse reaction to medication in England. Please can you supply the number of these type of reports each year for each individual route - For Southern Health NHS Foundation Trust for the last 6 years. All the other Mental Health Trusts in England for the last 6 years	28/08/2017	Disclosed in full
18/401	Request for the category 1b data that you describe on page 2 of your letter. If your database is able to stratify for healthcare professionals and patients that would also be helpful, but we accept if that is not possible. We request data with respect to the following specific drugs: Adalimumab; Certolizumab; Etanercept; Golimumab; and Infliximab.	28/08/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/402	All software/apps that MHRA have certified as medical devices and also those for which an application for CE marking is in progress. I would like to know the name of the software/app/device, the publisher/manufacturer (with contact details/web address if possible), the intended function and the application and approval dates if approved. If any additional information is available e.g. trial/testing data, technical information is shareable, that would be appreciated too.	31/07/2018	Disclosed in full
18/404	Pharmacovigilance inspection reports for the following companies: AbbVie Ltd. Amgen Janssen Eisai Ltd Eli Lilly Gilead Sciences International Limited Hikma Pharmaceuticals Sanofi Aventis Pharma Takeda Novartis Astra Zeneca	23/08/2018	Disclosed in part
18/405	UK PAR for Lipiodol Ultra Fluid, 480 mg Iodine/mL, solution for injection	08/08/2018	Not held
18/408	Information about your Agency's ICT expenditure	24/08/2018	Disclosed in part
18/410	Would like to view the public assessment report for E-cigarette/e-liquid eg E-Voke and Voke as approved by the UKMHRA	09/08/2018	Disclosed in full
18/411	Would like to view the public assessment report for product Tekcis, radionuclide generator as approved by the UKMHRA	09/08/2018	Not held
18/414	Access to the editions of MAIL (Medicines Act Information Letter) published by the MCA in the 1990s. In particular, I am interested in copies of MAIL published between 1992 and 1998 inclusive. I've got electronic copies from MAIL 117 (Jan/Feb 2000) onwards but nothing before that	22/08/2018	Disclosed in full
18/413	RMP for 1) Alimemazine tablets 10mg- PL 12762/0534- MERCURY PHARMACEUTICALS and 2) Syri Alimemazine Tartrate Syrup 7.5mg/5ml- PL 39307/0085 -SYRI LIMITED	16/08/2018	Disclosed in part
18/415	Medicine pharmacokinetic data	30/08/2018	Disclosed in part
18/427	Teronac (mazindol) PL00101/0079R: request for variation assessment report of variation	09/08/2018	Disclosed in full
18/417	Pharmacovigilance Inspection Reports prepared by the MHRA following an inspection of any Pharmacosmos group entity as a UK marketing authorization holder (MAH).	28/08/2018	Disclosed in part
18/418	Inspection reports for Protherics UK Limited, MedImmune UK Limited, Recipharm, Aesica Formulation and Development and BTG / Protherics site at unit 6 regent drive	31/08/2018	Disclosed in part
18/419	The information that I require pertains to some information related to the IT department of Medicines and Healthcare Products Regulatory Agency	22/08/2018	Disclosed in full
18/420	As part of my research project I wanted to have a look at the number of yellow cards completed with the ADR recorded as a 'fall', and what the medicines related to that was. I wanted to have a look at the data for the different Health Boards in Wales and to see if there had been any differences within the last 5 years.	04/09/2018	Disclosed in full
18/421	Following a previous request- your reference MHRA reference 17/338, under the Freedom of Information Act I would like to know how many notices or alerts does the MHRA issue per year; broken down by: ·Class 1 Medical Devices · Class 2 Medical Devices· Class 3 Medical Devices	23/08/2018	Disclosed in full
18/422	Would you please confirm whether Indivior has submitted licence applications for Sublocade or RBP-6000 for use in the UK and if these licences have been granted and when?	15/08/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/423	in preparation for the CHM meeting on 15th/16th October 2015, were the members of the CHM provided with a copy of this paper: HPV vaccine – Gastrointestinal motility disorders, Signal April 2015 p.20-25, Uppsala monitoring Centre, WHO collaborating Centre for international drug monitoring.	04/09/2018	Disclosed in full
18/426	We would like to request the Clinical and Non-clinical Reviews for PL 20117/0094-0095, under the Act	23/08/2018	Disclosed in part
18/428	Individual patient data listings for the following clinical study reports: (protocol B1Y-MC-X065, protocol B1Y-MC-HCJE, protocol B1Y-MC-HCJE (Relapse), protocol B1Y-MC-HCJW and protocol B1Y-MC-HCIU)	04/09/2018	Not held
18/434	A list of any licensing changes since 2013 that would limit the supply of any povidone iodine based product through pharmacy or general sales list or online within the UK. Reference to any material that MHRA is aware of that might explain the change in the market supply of iodine based antiseptic to the retail market (i.e through pharmacies or general sales list) – for example regulatory, clinical or government recommendations, safety, research, patent/IP related, market research, commerciality etc.	03/09/2018	Disclosed in full
18/429	All clinical studies and data presented to you with regard to the safety and effectiveness of Lyrica capsules, which were first authorised by Pfizer UK on 6 July 2004. This should include full reports (including all results from all studies) on the safety and effectiveness of the drug prior to its authorisation	10/08/2018	Disclosed in part
18/431	We request disclosure of all relevant documentation from you. MHRA 2014/003/005/401/010 NIAIC ST12012	03/09/2018	Disclosed in part
18/432	I will like to please request if it is possible for me to obtain records/ report for TGN1412 (Tegenero) preclinical study	15/08/2018	Disclosed in full
18/433	I would like to request the last 3 sequential GMP and GDP inspection reports for the above license holders (IDIS & Clinigen) WDA 8733 and 31644	04/09/2018	Disclosed in part
18/446	We are preparing a RMP for Methylphenidate and our medicinal reference product is Concerta. After checking the CMDH website, we have seen that this drug has an education material. Unfortunately, as a generic company, we don't have access to this material and I would like to kindly ask you for your support to include it in our RMP	05/09/2018	Disclosed in part
18/436	Have any applications been submitted to the Agency in the last six months for medicinal products containing dimethyl fumarate as the active substance, either as the sole active substance of a medicinal product or in combination with monoethyl fumarate? If yes, have any of these applications been validated, invalidated or rejected by the Agency or are these applications still pending.	07/09/2018	Disclosed in part
18/437	Can you please provide the most recent submitted risk management plans (RMP) for following listed drug product: PL 20075/0458 ACCORD HEALTHCARE Spironolactone tablets 100 mg ACCORD HEALTHCARE LIMITED. Also, if there are any other Spironolactone that has been authorised and have RMP available with MHRA, can we request a copy of that as well please.	23/08/2018	Disclosed in part
18/438	I would like to make a freedom of information request for the clinical and non clinical overview submitted with the application PL 16853/0117- Vitamin E Suspension 100mg/ml	04/09/2018	Disclosed in part

no	Subject	Date reply sent	Result of request
18/439	Was the MHRA informed of the various directives-cum-memoranda issued by the FDA in response to concerns about the safety of fluoroquinolone antibiotics; specifically about Cipro/Ciprofloxacin? Specifically, the ones issued in: July 2008; August 2013; May 2016 and July 2016? Which of these aforementioned FDA directives were received by the MHRA and at what dates and times? Who received the information/warnings and what did the warnings consist of? Did the MHRA receive notification about the FDA warnings directly from the FDA or from intermediary agencies like the EMA? If so, which agency communicated such information and at what points did these occur?	10/09/2018	Disclosed in full
18/442	Can you inform me of the size of the Prozac Gold File, and give me a precise breakdown of its contents, by year and subject, up to the end of 1996? I am interested in whether the file has information about reported adverse events associated with Prozac. I do not necessarily need the entire file.	15/08/2018	Disclosed in part
18/443	I would like to request information on how many reports of adverse reactions you have had regarding the HPV vaccinations. Both Cervarix and Gardasil.	10/09/2018	Disclosed in full
18/444	Thank you for the information you provided, however would it be possible to have the list with associated registered postcodes of the premises.	04/09/2018	Disclosed in full
18/445	The Public Assessment Report (PAR) in respect of Cyclizine lactate 50 mg / ml Injection, PL 35104 / 0021, Phoenix Labs, on page 5, fifth paragraph states “The application was presented to the Commission on Human Medicines (CHM) on 17.03.2017. Further data were subsequently submitted by the applicant. The application was considered to have satisfied the necessary requirements and therefore could be approved.” A request is made under Freedom of Information for the following. The referral letter / list of questions to the Applicant from the CHM. The applicant response to the CHM referral letter / list of questions. The CHM assessment of the applicant response to the CHM referral letter / list of questions.	10/10/2018	Disclosed in part
18/454	Information about staff pay and emoluments	20/08/2018	Disclosed in full
18/455	Have you received any reports through the Yellow Card system or from the manufacturer relating to vaginal pessaries	23/08/2018	Disclosed in part
18/447	You previously mentioned that 70 marketing authorisations have been granted for products containing the active pregabalin since January 2016. Are you able to confirm whether (and if not how many were / were not) all these applications for approval were submitted to you as abridged national applications, claiming to be generic versions of Lyrica capsules, which were first authorised by Pfizer on 6 July 2004?	11/09/2018	Disclosed in full
18/448	I refer to the information supplied by yourselves in respect of 18/295: The total number of adverse vaccine reactions - 57394 - recorded under the Yellow Card Scheme from January 2000 to December 2017 and the number of fatalities – 373. Under the Freedom of Information Act, will you please let me have within the prescribed period of twenty working days: A detailed breakdown of these figures, showing the total number of adverse reactions by individual vaccine, by manufacturer. A detailed breakdown of these figures, showing the total number of fatalities by individual vaccine, by manufacturer.	05/09/2018	Not held
18/450	Please tell me how many reports of safety concerns have been made to you through your Yellow Card Scheme regarding e-cigarettes since May 2016. Please provide me with details about the nature of the complaints, and also the month and year in which they were received.	13/09/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/451	I would be grateful if my request could be reconsidered for only the following information only: The number of 'Yellow Card' reports received by the MHRA related to contact lenses between 1st January 2013 and 1st January 2018. The number of 'Yellow Card' reports received by the MHRA related to intraocular lenses between 1st January 2013 and 1st January 2018. A breakdown of the number of requests per year and if they were from healthcare professionals or the public would be helpful but not absolutely necessary if that would mean Section 12 applies.	23/08/2018	Disclosed in full
18/456	Non clinical and clinical data for Glycopyrronium Bromide 1mg/2mg Tablets, and have learned that the Glycopyrronium Bromide 1mg/2mg Tablets [PL 30684/0125-0126]	30/08/2018	Disclosed in part
18/458	Co-proxamol supply	04/09/2018	Disclosed in part
18/459	Bioequivalence study details that supported Warfarin 1mg, 3mg, 5mg, PL 20416/0168-0170 MA application	30/08/2018	Not held
18/461	Yellow Card' reports received by the MHRA between 1st January 2013 and 1st January 2018 related to the following glaucoma drainage valves and stents including iStent, Ahmed valve, Molteno, Baerveldt, EX-PRESS, Hydrus, CyPass.	30/08/2018	Disclosed in part
18/462	Yellow Card' reports received by the MHRA between 1st January 2013 and 1st January 2018 related to the following keratoprostesis including Boston, osteo-Odonto-Keratoprosthesis, AlphaCor and KeraKlear.	30/08/2018	Disclosed in part
18/463	Yellow Card' reports received by the MHRA between 1st January 2013 and 1st January 2018 related to the following artificial pupils, orbital implants and orbital prostheses.	29/08/2018	Disclosed in full
18/464	Clinical and Non-clinical reviews for Sialanar 320 micrograms /ml oral solution EU/1/16/1135/001.	22/08/2018	Disclosed in part
18/465	Summary of Yellow card reports on Ophthalmic devices- Intraocular lenses, glaucoma valves/ istents etc? eg: how many reports did MHRA have ? Reasons for reports will be helpful too. (We do not need detailed information)- Information similar to iDAP(interactive drug analysis profiles) will be sufficient.	31/08/2018	Disclosed in full
18/467	Prostap/ Lupron - clinical trials and ADR info	18/09/2018	
18/468	Could we have the product artwork and PAR for Dexamethasone 0.5mg tablets manufacturer Ennogen?	23/08/2018	Disclosed in full
18/469	A list of all adverse reactions reported as a result of the infranix hexa vaccine which is routinely given to babies of 4, 8 and 16 weeks old. I look forward to hearing from you.	19/09/2018	Disclosed in full
18/471	Information on cochlear implant device	12/09/2018	Not held
18/480	Request for any prescriber information (PI) materials that the Agency can supply for any colecoxib or diclofenac Mas	20/09/2018	Disclosed in full
18/472	Provide a list of all Scottish adverse incidents involving the use of mesh for hernia repairs in the last 3 years. It would be helpful if you could send me a list of what you've got for the last 3 years, including member of the public reports	29/08/2018	Disclosed in full
18/475	Humira/Adalimumab information	12/09/2018	Disclosed in full
18/476	List of active API	11/09/2018	Not held
18/491	Licensing info and RMP for Glycopyrronium Bromide 1mg/5ml Oral Solution PL 41344/0010	21/09/2018	Disclosed in part
18/479	Can you provide me with any risk assessments which cover the transportation of medicines, specifically in relation to temperature control. How many confirmed cases of falsified medicines entering the legal supply chain have been reported to the agency in the last ten years? How many cases of adverse reactions to ambient medicines have been identified in the last 2 years as being due to those medicines being stored outwith the required ambient temperature conditions? By ambient I mean non-fridge products.	24/09/2018	Disclosed in part
18/482	Request a list of pharmaceutical drugs that have a hybrid licence.	10/09/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/483	Are there was any differences in whether the method of administration for (a) Olazapine and (b) Risperidone was (a) oral tablets or (b) injection had any impact on the side effects which would complete the puzzle?	24/09/2018	Disclosed in full
18/485	PL 00289/2182-2188 In terms of the national specific documents, I would like to request these, such as the educational materials and communications to healthcare professionals, patient information, and prescription authorisation form.	10/09/2018	Not held
18/486	Request yellow card reports for all vaccines on the uk schedule, up to date please, including the LAIV Fluenz vaccine.	25/09/2018	Disclosed in full
18/489	Drug incidents involvling anticoagulants and antiplatelets	25/09/2018	Disclosed in full
18/494	We would be much obliged if you could share us the PAR or MHRA assessments reports of medicine for the treatment of alcohol dependence, Disulfiram (Antabuse).	25/09/2018	Disclosed in part
18/492	Request public assessment report UK/H/6369/001 sucrofer 20 mg iron/ml solution for injection	25/09/2018	Disclosed in full
18/493	Please can you forward to me the names and homeopathic potencies of the 7 products included in 18/296. ie Adverse drug reactions to homeopathic products under yellow card scheme for June 2000-December 2017.	11/09/2018	Disclosed in part
18/495	We learned that the Glycopyrronium Bromide 1mg/5mL Oral Solution [PL 41344/0010] was granted under Article 10a (WEU), therefore we would like to request the Clinical and Non-clinical Reviews for PL 41344/0010, under the Act	02/10/2018	Disclosed in part
18/496	Under Freedom of Information, please provide a copy of the report mentioned in point 3. of your reply - the complete paper provided to the CHM on the HPV vaccination at their meeting of 15th/16th October 2015, including any appendices and list of references.	11/09/2018	Disclosed in part
18/504	In regards to larc is the product under review at the moment in the UK,is or has the product been trialled, or in the trial period now. Would this be a product also advertised as in the office - something that takes very little time.would this be a product also advertised as in the office - something that takes very little time.	27/09/2018	Disclosed in part
18/498	Request to determine the level and incidence of yellow card and adverse reporting received by the MHRA on anticoagulation therapy across Scotland.	04/10/2018	Disclosed in full
18/503	Please may I request information under the A on Factor VIII batch NY 807 manufactured by the Protein Fractionation Centre in Edinburgh. This batch is sometimes referred to as just “807”, but I believe it should have the two-letter prefix. The batch was in use from early 1984 until about December 1984	27/09/2018	Not held
18/500	Request a copy, in any format available, of the most recent MHRA GMP inspection report for the following drug manufacturing site: Patheon UK Limited, Patheon Building Kingfisher Drive, Swindon, SN3 5BZ	05/10/2018	Disclosed in part
18/515	Sentinel Project & Policy Request	19/09/2018	Disclosed in part
18/501	PV inspection reports	09/10/2018	Disclosed in part
18/502	I would like to see a copy of the latest report of the MHRA for Joint Committee on Vaccination and Immunisation: VACCINE-ASSOCIATED SUSPECTED ADVERSE REACTIONS REPORTED VIA THE YELLOW CARD SCHEME: Adverse reactions to Vaccines under the Freedom of Information Act. Could you send me a copy?	13/09/2018	Disclosed in full
18/507	Request information for Flamingo Pharma under Act. PSUR for Glycopyrronium Bromide, ADR data for Glycopyrronium, Public assessment report for Doxepin 25 mg and 50 mg Capsules and Cloral Betaine 707mg Tablets.	09/10/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/511	Does the MHRA have any impact assessment of Falsified Medicines Directive requirements? This will place huge pressure on goods in departments in all wholesalers, who will now have to break down every outer box and scan every individual pack UI received from a supplier who is not from one of the exempt groups. Does the MHRA expect there to be delays and problems with medicine supply based on this requirement? Is the MHRA considering permitting wholesalers to % sample "higher risk" products for verification rather than mandating the verification of 100% of unique identifiers? Does the MHRA have a risk assessment which addresses the verification of UIs by wholesalers? Does the MHRA consider there to be a reduction in patient safety risk by the verification of 100% of "higher risk" UIs by wholesalers, given that all UI's will ultimately be verified prior to dispensing to patients?	09/10/2018	Disclosed in full
18/529	I am trying to access the public assessment report for the initial approval of Xalatan Eye Drops (PL 00057/1057; Pfizer Limited)	01/10/2018	Disclosed in full
18/509	Request HPV for all other vaccinations (please list numbers for each vaccination) from 2006 to 31st August 2018: Postural Orthostatic Tachycardia Syndrome, Autonomic nervous system imbalance/dysautonomia, Complex Regional Pain Syndrome, Gastrointestinal disorder, Chronic Fatigue Syndrome, Post Viral Fatigue Syndrome, Narcolepsy, Autoimmune Thyroiditis/Hashimoto's Thyroiditis, Any other thyroid conditions, Guillain Barre Syndrome, Small fibre/Peripheral neuropathy, Migraine. A table for YC reports classified as serious with the following information for cards submitted between 1st April 2018 and 31st August 2018: drug ingredient (for Gardasil, please indicate whether Gardasil or Gardasil 9), age group, male or female, reaction, reaction outcome.	10/10/2018	Disclosed in full
18/522	Recurrent UTIs are a serious issue which are devastating for those affected (including myself) and they contribute to antibiotic resistance. Could I speak to someone who may be able to say more about whether the vaccine is due to be licensed for use in the NHS anytime soon	08/10/2018	Disclosed in full
18/510	Reporting of adverse events or adverse reaction to medication by Mental HealthTrusts in the UK. Provide information from the CCG 's as requested.	11/10/2018	Disclosed in full
18/518	Medical device certificate. How, in your view, disclosure would be harmful to the public interest; How disclosure of the records would be harmful to your interests – please note that you are required to provide evidence to support this, it is not sufficient to propose that there may be an adverse effect to your interest, it has to be something concrete that can be clearly seen as a possible event; Any evidence or other supporting arguments in support of your views.	27/09/2018	Disclosed in full
18/512	Request a copy of the Pulmicort Respules (budesonide) nebuliser suspension Risk Management Plan (RMP), licence number PL 17901/0161. Please could you confirm if you are able to provide this?	17/09/2018	Not held
18/513	How many cases of transfusions have been reported in the last year or so where the wrong group of plasma has been given?	20/09/2018	Disclosed in full
18/517	Can you provide me with a list of all the branded generic medicines currently. Can you provide me with a list of all the biologics. Can you provide me with a list of all medicines that use a device	01/10/2018	Disclosed in part
18/519	Group-and Screen data in England	08/10/2018	Disclosed in part
18/520	I've asked for bioequivalence details assuming that Warfarin 1mg, 3mg, 5mg, PL 20416/0168-0170 MA is a generic product. Could you kindly confirm the legal basis of this product?	08/10/2018	Disclosed in full

no	Subject	Date reply sent	Result of request
18/525	We would like to know what date the following applications were made by the respective companies, when the assessment started and who they were assessed by at MHRA. PLPI 15184/1771 22/08/2018 LEXON (UK) LIMITED BRALTUS 10 MICROGRAM PER DELIVERED DOSE INHALATION POWDER, HARD CAPSULE TIOTROPIUM BROMIDE. PLPI 20492/0602 16/08/2018 CD PHARMA LIMITED BRALTUS 10 MICROGRAM PER DELIVERED DOSE INHALATION POWDER, HARD CAPSUL. PLPI 15184/1812 09/08/2018 LEXON (UK) LIMITED BRALTUS 10 MICROGRAM PER DELIVERED DOSE INHALATION POWDER, HARD CAPSULE TIOTROPIUM	25/09/2018	Disclosed in part
18/545	Reports from 2012 to the present day of adverse events relating to nicotine. This may be in the form of patches ,sprays, gums, e-cigs or indeed any other avenue . Please tabulate into a useable format	11/10/2018	Disclosed in full
18/514	Please could you let me have (under legislation) data on yellow card reporting for the flu nasal spray for the past 2 years. Also I've seen figures to show that it's 26% effective for 2-17 year olds please could you break this down further for example 2-7, 8-11.	15/10/2018	Disclosed in full
18/516	Request for Prochlorperazine Maleate RMP & Bisacodyl Safety Concerns/RMP	15/10/2018	Disclosed in part
18/521	Data analysis and extraction request on Yellow Card reporting on musculoskeletal diseases and biologics	17/10/2018	Disclosed in full
18/523	I was just looking for data for the vaccines in the current UK childhood schedule so the vaccines and brand names are below. Looking for reports/data of adverse reactions and deaths per year in the UK by each vaccine	15/10/2018	Disclosed in full
18/526	Requests concerns the documentation for the product Neupogen which was approved via DCP for which UK acts as Reference Member State and for which the procedure number is UK/H/0019/01-09/DC. The Risk Management Plan of Neupogen refers to a 20 year follow up report from the SCNIR registry that will be available in 2016. The following information is requested under the Act: The 20-year-follow-up report from the SCNIR registry that was required by 2016. The authority assessment report on the 20-year-follow-up report from the SCNIR registry and the actions taken on the basis of the findings in this registry.	16/10/2018	Disclosed in part
18/536	Letter regarding BGMA scheme for generics	01/10/2018	Disclosed in part
18/527	I would like to request category Ib data on the following hormonal contraceptives between 2013 and 2017	19/10/2018	Disclosed in full
18/528	Can the Agency provide me with any risk assessments on the subject of transportation of medicines, and temperature control during transport	04/10/2018	Not held
18/530	Please can I have a list of Melatonin import notifications with non-objections to import under SI2005/2789 from Jan 2016 till date?	22/10/2018	Disclosed in full
18/531	I am specifically interested in the report for Laleham Health and Beauty Limited, or Sycamore Park, Alton, GU34 2PR (MIA 3063), conducted on 1st May 2018	23/10/2018	Disclosed in part
18/532	Please send me all SAEs in regard to products of Ranier Technology Limited (Cambridge) since 2009.	19/10/2018	Disclosed in part
18/533	All serious adverse event reports (SAEs) from that time period pertaining to the CAdisc-L	18/10/2018	Disclosed in part
18/538	Could you send me a list of drugs that have been reported to be associated with RP in the last 20 years please. The number of times the drug has been associated with RP during this time would also be helpful	23/10/2018	Disclosed in full
18/556	I am trying to find any information about the licensing of an immunotherapy drug named Pembrolizumab, specifically for the treatment of mesothelioma. I could be wrong but believe it has already passed several stages of the licence approval but is not quite there yet. I am looking to find out how this is progressing and, if the licence is granted, if it is likely to be in 6 months, a year, five years etc	15/10/2016	Disclosed in full

no	*Subject*	*Date reply sent*	*Result of request*
18/535	Clinical and Non-clinical Reviews for Glycopyrronium Bromide 1mg/2mg Tablets [PL 44710/0017-0018] &• Clinical and Non-clinical Reviews for Glycopyrronium Bromide 1mg/2mg Tablets [PL 30684/0125-0126]	15/10/2018	Disclosed in part
18/537	I have selected 13 different side effects that can be reported to you as a side effect of medication under the yellow card scheme. For each of the side effects please state how many reports you received of that side-effect across all medications/drugs in the 5 year period from the 1st January 2013 to the 31st December 2017	19/10/2018	Disclosed in full
18/561	PARs for several licences	23/10/2018	Disclosed in full