

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.

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/299	Bioequivalence study details that supported Doxepin 25mg Capsules (PL 48441/0001) and Doxepin 50mg Capsules (PL 48441/0002) marketing authorisation application. Bioequivalence study details that supported Doxepin 25mg Capsules (PL 20416/0652) and Doxepin 50mg Capsules (PL 20416/0653) marketing authorisation application	03/07/2019	Disclosed in full
19/300	Approval of Transvaginal Mesh Medical Devices	25/07/2019	Disclosed in full
19/302	The organisation's primary corporate Finance Software Solution	30/07/2019	Disclosed in full
19/303	Could you please provide, in csv/excel format ideally, anonymised raw case data for all reported adverse events (between 2008 – 2019) for the following vaccines: MMR, Hib/Men C, Pneumococcal and Men B (Bexsero)	25/07/2019	Disclosed in full
19/304	Request the clinical and non-clinical overviews for Permethrin 5% w/w Cream PL 4416/0456.	25/07/2019	Disclosed in part
19/305	A copy of the MHRA GVP inspection reports for Lloyds Pharmacy Clinical Homecare (Scimitar Park, Roydon Road, Harlow, Essex, CM19 5GU).	26/07/2019	Disclosed in full
19/306	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 from 2014 - to the publication of its final report in November 2017. I am making a freedom of information request for the following information: 1) What was the total cost spent on Barristers working on behalf of the MHRA throughout the review? 2) What was the total cost spent on Solicitors working on behalf of the MHRA throughout the review? 3) What was the total cost spent on MHRA personnel (who attended all seven meetings) throughout the review? 4) What is the breakdown of those costs?	16/07/2019	Disclosed in full
19/307	Incidents reported by Ultroid UK Ltd (ref: M-0038424)	17/07/2019	Disclosed in full
19/308	Please could you provide me with all data you have collected on NHS commissioned vascular services at Imperial Healthcare NHS Trust and Oxford University Hospitals. This includes data in adverse events, clinical audits and quality account data.	10/07/2019	Disclosed in part
19/310	Could I please request the Mmr vaccine and dtap reported adverse reactions for the last 10 years	02/08/2019	Disclosed in full
19/312	I'm writing for a freedom of information request for the side effects reported on the drug propecia /fanasteride since it was approved in 1997 . I'm after number of side effects reported and what kind of side effects they are	02/08/2019	Disclosed in full
19/313	GMP Inspections List/Log	07/08/2019	Disclosed in full

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/314	I'm requesting any papers and/or slides which were presented to ISAC at the October 2018 meeting in relation to item 7 - "ISAC Audit Closure Report".	16/07/2019	Disclosed in full
19/315	Could you please inform me of how many clinical trials were approved in the United Kingdom in each of the past 5 years? If possible, could you inform me of the total number of studies as well (including observational research)?	17/07/2019	Disclosed in full
19/316	Please can you provide the Risk Management Plan (RMP) that has been approved for doxepin capsules (25mg and 50 mg strengths) authorised to Crescent Pharma Ltd (PL 20416/0652-3)	16/07/2019	Disclosed in part
19/317	"The MHRA wants UK thyroid medicines to be manufactured to specifications that are tighter than those in other countries, including in those other European countries where Liothyronine is used." I would like to know it what specific ways that statement makes sense. Does the MHRA want these tighter specifications. Or does the MHRA currently require these higher standards? Or is there some other interpretation I should be putting on the statement?	07/08/2019	Disclosed in part
19/319	Public Assessment Reports related to historic reclassifications. reports for Zovirax Cream 5% w/w aciclovir POM to P (1993) and P to GSL (2004	02/08/2019	Disclosed in part
19/320	RISK MANAGEMENT PLAN - Temazepam	17/07/2019	Not held
19/321	Do you have Clinical Trials figures for the numbers of approved applications, or a general approval rate you could share with me?	02/08/2019	Disclosed in full
19/322	Safety assessments and clinical trials of Hepatitis B vaccine for infants	08/08/2019	Disclosed in full
19/324	RMP Request - 19/H/0026/001-003	22/07/2019	Disclosed in part
19/325	PSURs	03/09/2019	Disclosed in part
19/326	Artwork for Triamcinolone Acetonide 10mg/ml	19/07/2019	Disclosed in full
19/327	I would like to see the suspected and reported reactions for all of the childhood vaccines	15/08/2019	Disclosed in full

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19/328	Has there been any investigation into stem cell therapy regeneration for joint issues? If so, has any of this been approved by the Medicines and Healthcare products Regulatory Agency?	12/08/2019	Disclosed in full
19/330	As a freedom of information request, the name of the person and the company they work for who carried out the translation work of Schering's documents and all the German paperwork that was provided to the MHRA relating to Primodos/Duogynon for the EWG.	30/07/2019	Not held
19/331	I should be grateful if you would supply me with copies of the MHRA's policy and procedure (including timescales) for the production and publication of UK Public Assessment Reports for medicines in accordance with EC Directive 2004/27/EC.	24/07/2019	Disclosed in part
19/332	Tender regarding Waste Services for the Medicines & Healthcare Products Regulatory Agency	31/07/2019	Disclosed in full
19/334	The number of laboratory confirmed UK measles cases by year for the last 10 years split by measles vaccination status and then further by age group of the patients. I am looking to understand how many of the people who contracted measles each year for the last 10 years were vaccinated against measles and what age groups the vaccinated/unvaccinated fall into. Of the laboratory confirmed measles cases, could you tell me how many developed encephalitis and pneumonia each year for the last 10 years	26/07/2019	Not held
19/335	Please could you provide any safety studies conducted to assess the impact on infant health, particularly the kidneys, of administering multiple vaccines/injections in one visit	14/08/2019	Disclosed in part
19/336	Can you please provide me with any papers, slides or other forms of presentations which were tabled at those meetings in relation to the audit project. The minutes of the 2018 meeting suggest it was discussed under the heading "ISAC quality assurance" (Item 8) on that occasion	29/07/2019	Disclosed in part
19/338	CHM assessment of application for Cyclizine Lactate 50mg/ml Injection [PL 35104/0021]	05/08/2019	Disclosed in part
19/339	Epilim and Valpromide PSURS	22/08/2019	Not held
19/341	We would like to request the clinical, non-clinical overviews and risk management plan for Orobalin 1 mg film-coated tablets (Cyanocobalamin)	14/08/2019	Disclosed in part
19/342	ADR's in association with the MMR vaccine	27/08/2019	Disclosed in full
19/343	Please tell me the number of reports of products containing Melantonin II that the Yellow Card scheme has received in each of the calendar years 2014-2019 to date.	27/08/2019	Disclosed in full

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19/344	RMP for "Lenalidomide Sandoz" 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg Hard Capsules (PL 04416/1523-9).	31/07/2019	Not held
19/347	I would like to know the number of lost laptops, mobile phones and tablet computers (iPads etc) reported lost/missing or stolen by employees within your organisation over the last three financial years.	16/08/2019	Disclosed in full
19/348	1.The number of "prohibition notices to ban the supply of any goods which are considered unsafe or do not comply with regulations;" issued by the MHRA 2. The number of "notices to warn which requires a manufacturer to issue a warning at his own expense about any relevant goods, which are considered unsafe". 3. The number of "suspension notices to suspend the supply of any goods for up to six months, where it is suspected that a safety provision has been contravened" 4. The number of site or premises inspections the MHRA has carried out	28/08/2019	Disclosed in full
19/350	Q1. Would you kindly share with me the researchers' request submitted to you on 14 April 2010? Q2. Would you kindly share with me the MHRA reply sent on 15 April 2010 in response to the above? Q3. Would you kindly share with me the criteria or rules in effect in April 2010 on which the MHRA based its conclusion that the UCL Institute of Child Health / GIDS research trial was not, in fact, a clinical trial of a medicinal product?	09/08/2019	Disclosed in part
19/351	I would be grateful if you could send copies of the last three (3) inspection reports for 1) Calea UK / Fresenius Kabi site, Runcorn, UK 2) AstraZeneca Macclesfield Works, UK 3) Norgine, South Wales, UK 4) I would also be grateful if you could supply a list of medicines product recalls (by class), product and company name for the past 3 years.	29/08/2019	Disclosed in part
19/352	We would like to request a copy of the Public Assessment Report (UKPAR) for following product, under the A : • Melatonin 3 mg film-coated tablets, Colonis Pharma Ltd, PL 41344-0053	01/08/2019	Disclosed in full
19/354	1) What information did the Tavistock & Portman's Gender Identity Development Service provide to you in their communication of 14 April 2010 about their proposed trial using triptorelin to treat children suffering from gender dysphoria? 2) On what grounds did you assure them on 15 April 2010 that this did not constitute a clinical trial?	09/08/2019	Disclosed in part
19/355	TEVA levothyroxine query	29/08/2019	Disclosed in part
19/357	Could you please provide me with any and all correspondence between the MHRA and the following corporate entities: Pharmassist (Solutions) Limited PAS Holding Company Limited Dataplast Limited Cambrian Alliance Limited Veratis Group Limited CamRx Limited IT Pharm Limited Epos Logic Solutions Limited	29/08/2019	Disclosed in part

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19/358	MHRA and EMA correspondence on Primodos Duogynon Hormonal Pregnancy Tests	29/08/2019	Not held
19/360	Waymade / Glycopyrronium [CMCK-UK.FID14346008] to 18/655	21/08/2019	Disclosed in part
19/361	Public Assessment Report request/ Legal basis of approval (PL 01883/0343)	28/08/2019	Disclosed in full
19/362	Calea inspection 2017	28/08/2019	Disclosed in part
19/363	British Pharmacopoeia Commission Software Systems	28/08/2019	Disclosed in full
19/364	I wish to request a copy of the non-clinical overview used in support of the National Approval of PL 20416/0653 Doxepin 50mg Capsules	07/08/2019	Disclosed in part
19/365	I am currently contacting you as I would like to kindly ask whether you could urgently provide us with the main body RMP of Seroquel (quetiapine), as well as the annexes regarding Specific adverse drug reaction follow-up forms AND proposed additional risk minimisation activities(if applicable).	27/08/2019	Disclosed in part
19/367	Please could you send the first report requested, as suggested. Vaccine, Year, Age and Reaction reported Outcome	23/08/2019	Disclosed in full
19/370	Pre-clinical and clinical trials of product Amizon	12/08/2019	Not held
19/372	Info on adverse reactions to HPV vaccines.	21/08/2019	Disclosed in full
19/373	Two of the papers you provided - file names 20170117_ISAC_Audit_Redacted and Paper 5_ISAC Audit Principles - appear to date from January 2017 and July 2016 respectively. However, I was interested in information from the January 2016 and January 2018 meetings of ISAC.	09/08/2019	Disclosed in part
19/374	Catering Services, Security Services, Cleaning Services, Hard and Soft Maintenance Services, Mechanical and Electrical Services from the past two years	29/08/2019	Not held

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19/375	Information regarding reported data for amlodipine use in pregnancy and associated maternal-fetal outcomes	04/09/2019	Disclosed in full
19/376	Request details of all work carried out by McKinsey & Co. for MHRA from 1 January 2016 to 1 August 2019. Please could you include the dates the work was carried out, as well as what McKinsey & Co. was commissioned to do. Please also state how much McKinsey was paid. Could you also give details of any McKinsey & Co people who have been seconded to MHRA in this time period and the policy area they worked on.	16/08/2019	Not held
19/377	I wondered if you could tell me roughly (or precisely) how many children in the UK present to hospital for a fracture each year?	12/08/2019	Not held
19/378	GcMAF cancer cure, prevented for use by the MHRA for 24 years. Which (names and positions and company worked for) of the 30 highest paid members of MHRA staff have previously worked for a Pharmaceutical company or a cancer charity? As your organisation is there to protect the public I expect you to be able to provide the following stats What % is the cancer cure rate of Radio therapy? What % is the cancer cure rate of Chemo therapy? As Chemo and Radio therapy is highly toxic how many patients have died as a DIRECT consequence of Chemo and Radio therapy in the last 1 year and 10 years. What is the procedure for licensing Natural medicines/treatments and why is it different to synthetic/non natural medicine/treatments? How many natural treatment/medicines were licensed for use in 2018? How many synthetic/non natural treatments were licensed in 2018? There are many GcMAF peer reviewed scientific research papers published in PubMed USA by many scientists. Will you apologise for and correct your incorrect statement/lie on your page of our government's web site?	05/09/2019	Disclosed in part
19/379	Request details of the most recent GDP / GMP inspection reports on the following authorised suppliers: ANP Pharma: WDA(H) 36080, ADEC Marine: WDA(H) 43533, OCEAN SAFETY: WDA(H) 42918, BCB INTERNATIONAL : WDA(H) 13314, FAB MEDICAL: WDA(H) 33479, HEALTHCARE EUROPE (MARINE) LIMITED: WDA(H) 42114.	09/09/2019	Disclosed in part
19/380	Tavistock & Portman's Gender Identity Development Service provide to you in their communication of 14 April 2010. The email of 14 April 2010 to you from UCL included an attachment, "a copy of the study protocol". I would be most grateful if you also provide this attachment.	21/08/2019	Disclosed in full
19/382	My request is as follows: Please disclose the amount paid in compensation in the financial years 2016/17, 2017/18 and 2018/19 for personal injuries to staff; Please disclose how many individual claims this represented; Please provide a breakdown showing the nature of the claim, (e.g. broken leg after slip), how much compensation was paid in each case and the total known third party legal fees paid.	29/08/2019	Disclosed in full
19/383	Public Assessment Report including Annexes, SmPC and pre-clinical & clinical scientific review for Navoban 5mg capsules (generic name: tropisetron). Navoban (tropisetron) was approved for prevention of nausea and vomiting. It was marketed by Novartis but the tablet form was discontinued in the UK in 2004; and all forms discontinued on 31st October 2008. In addition, please can you confirm whether Navoban 5mg capsules have a current marketing authorisation in the UK.	19/08/2019	Not held
19/384	Request inspection report supplied is the most recent report for site 9957325 and also new site SITE ID : 18768596	09/09/2019	Disclosed in part

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19/386	Request Paper 4 from the October 2013 meeting of ISAC. In the published minutes of that meeting of the Committee this paper was entitled: "ISAC Audit – Comparing publications with protocols to identify deviations".	19/08/2019	Disclosed in full
19/387	Request details of the most recent GDP / GMP inspection reports on the following authorised suppliers: SITE ID : 9736176 MEDICAL SUPPORT OFFSHORE LIMITED WDA(H) 43014.	13/09/2019	Disclosed in part
19/388	There is some information missing - clinical trials and safety assessments on the long term impacts of administering Hepatitis B vaccine to infants under 16 weeks. The studies cited in the scientific discussion only looked at reactions up to a few days following vaccination. I don't believe this is adequate, especially given the extremely miniscule chance of an infant contracting Hepatitis B in the UK. Additionally, the only rationale for introducing this vaccine to the UK schedule is because the WHO suggested it? Given the extremely miniscule risk of a not-at-risk infant contracting Hepatitis B in this country, you would hope that the impact of adding more vaccines to the schedule would be considered at greater length, especially given the complete lack of understanding of the long term impacts of these vaccines on infants. Could you please comment on this? Could you also please confirm who conducted the clinical trials? The manufacturer themselves, or an independent third party?	06/09/2019	Disclosed in full
19/389	The estrogen-replacement drug Premarin, prescribed to menopausal women is made from horse urine; in fact, the drug's name is short for PREgnant MAREs' urine. About 750,000 mares are impregnated each year for the sole purpose of collecting their estrogen-rich urine. Tied in small stalls, unable to move either backwards, forwards, or sideways or lie down comfortably, they stand with sacks strapped to their groins for months on end. In order to make the urine more concentrated, their water intake is restricted, so the horses are constantly thirsty. The foals are considered "by products," and most are fattened up, slaughtered, and sold for horsemeat or turned into dog food. I would be grateful if you could tell me in the first instance if this is in fact true and if so, what are the alternatives to this drug. I am particularly interested in a drug which guards against osteoporosis.	18/09/2019	Not held
19/392	Request statistics of the number of confirmed cases of measles in the UK in the last 5 years. I would also like to know out of these cases how many were unvaccinated, how many received one dose of MMR and how many received both doses of the MMR. I would also like to know how many of these individuals died of measles in the UK in the last 5 years.	19/08/2018	Not held
19/393	Request last Pharmacovigilance Inspection reports for Shire Pharmaceutical Ltd and The Medicines Company UK Ltd.	16/09/2019	Disclosed in part
19/398	The information I request is as follows: By species: How many animals were used in the Forced Swim Test (o r'Porsolt Forced Swimming Test') by The Public Authority from January 2018 until June 2019? By drug type: Number of these licensed procedures as either primary purpose or as part of the licensed procedure heroin(morphine and derivatives), MMA/ecstasy(methylenedioxy-methamphetamine), cocaine(benzoylmethylecgonine),d-amphetamine (dextroamphetamine), amphetamine(alpha-methylphenethylamine), ketamine(ketamine hydrochloride) and or their derivatives that were carried out by The Public Authority. that the primary purpose of each study was ie depression tests. I must stress that I do not seek data which identifies those under the institution's employ and agree for such information to be redacted within reason.	29/08/2019	Not held
19/399	Request Epilim and Valpromide PSURs	20/09/2019	Disclosed in full

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19/400	Request under FOIA, a copy of the application for CTA submitted by Cell Therapy Limited for Celixir.	09/09/2019	Disclosed in part
19/401	Request information about preclinical studies and clinical trials of the antiviral efficiency of the medicinal product Amizon (Enisamium iodide), produced by JCS «Farmak» (63, Kyrlyivska Street, Kyiv, 04080 Ukraine), in your country. We also ask you to provide open information about the results of these studies and trials.	29/08/2019	Not held
19/404	Request the Public Assessment Reports (PARs) for the products Melatonin 1mg/ml oral solution.	28/08/2019	Disclosed in full
19/408	Why were we, the patients of Calea and the NHS never informed of the 2017 inspection findings and why were we never told of the possible risks to our health. Being told of these risks would have at least allowed us to choose to move to a different supplier. Why are Calea still allowed to operate despite endangering public safety and not informing us, the patients again, the findings of the MHRA? Also I would like a copy of the inspection reports carried out in 2015/2017 and 2019. Why did it take you 4 years effectively and certainly two to stop Calea using unsafe production methods?	25/09/2019	Disclosed in part
19/409	I would like you to provide the following please: A copy of the non clinical and clinical overviews / summaries / expert reports for: PL 00063/0045 (now PPL 10972/0045) - Ibuprofen 5% gel PL 10972/0082 - Fenbid Forte 10% gel, 2/0045, PL 10972/0045.	26/09/2019	Disclosed in part
19/411	Please could you send me the HPV reports for girls by year. I don't need all the details - just: 2008: xx 2009: xx from 2008 to the same endpoint as for these reports.	13/09/2019	Disclosed in full
19/412	You have always banned safe natural treatments. GcMAF is the latest. Why did you not encourage Immuno Biotech to get it into the NHS? GcMAF is a safe natural human protein and a human right. It exists in a billionth of a gram. Why are you denying the British people their human rights? On your website, you proudly state you are involved with innovation in medicines. Why did that not apply to Immuno Biotech Ltd and GcMAF? Is it true that when you raided Macro Innovations on 28th January 2015 that you had never read a GcMAF research paper? Why did you not telephone Macro Innovations and ask for an appointment first to discuss what they were doing? You employed a blood fractionation expert as part of the raid, expecting to find vats of blood. In fact, there was only one gram of vitamin D binding protein imported from FDA approved companies. Doesn't that indicate you had no idea what you were doing? Please state the total number of scientific research papers on GcMAF in peer-reviewed scientific journals. Please state the total number of scientific research papers on GcMAF on the American National Library of Medicine. Please state the total number of scientific research papers on GcMAF in Google Scholar. Was that to keep GcMAF hidden for another 25 years? Two million people have died unnecessarily from cancer because GcMAF has been concealed from them for 25 years. You are mainly responsible. It will be a two trillion pound lawsuit on behalf of the families, levied against the board and governors of the MHRA since its inception. Can they afford to pay?	20/09/2019	Disclosed in full
19/413	I would like to submit a request for the Pharmacovigilance inspection report of Aegerion Pharmaceuticals, conducted by MHRA in December 2018. Please let me know if you need additional information or have any questions.	24/09/2019	Disclosed in part

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19/414	I would like to make a request for all of the stability data, the clinical trial reports, the clinical and non clinical overviews, and risk management plan that you hold for the product Erwinase (PL 44403/0002).	30/09/2019	Not held
19/417	Metuxtan SR 500, Accord, batch PX00496 - requesting for the chronology of communication along with method (phone, email, etc)between MHRA and Accord.	20/09/2019	Disclosed in part
19/418	All correspondence (electronic or otherwise) received or sent between 1st October 2017 and 30th November 2017 by the MHRA/CHM or its staff members, relating to the drafting, redrafting and final publication of the Report of the Commission on Human Medicines' Expert Working Group on Hormone Pregnancy Tests, published 15th November 2017.	29/10/2019	Disclosed in part
19/420	Request for Public assessment report for Prostag SR	26/09/2019	Disclosed in full
19/422	PARs for Salbutamol 2.5 mg/2.5 mL Nebuliser Solution	26/09/2019	Not held
19/423	Please provide me with the following information on staff numbers• Total number of staff • Total number of SCS1 finance staff • Department structure • Total number of agency workers / contractors (please include those on fixed term contract but not internal secondment) • Frameworks used to procure interim staff in this area	30/09/2019	Disclosed in full
19/426	I am particularly interested in the contents of your file relating to all correspondence/communications sent to and received from the drug implant manufacturer and/or its representatives concerning MHRA's sentiments about transitioning from the legacy Implanon product to the modified (newly radiopaque) Nexplanon product. More to the point, what was conveyed to the manufacturer by the MHRA, and what pressures were brought to bear by the MHRA, ahead of the approval/release of the next-generation implant, Nexplanon	26/09/2019	Disclosed in part
19/427	QUESTIONS RELATING TO RECOMMENDATIONS PUBLISHED BY MHRA ON 30 AUGUST 2019	07/10/2019	Disclosed in full
19/428	Electronic cigarettes notification	18/09/2019	Not held
19/429	GMP Inspection List 2013	03/10/2019	Disclosed in full
19/430	Hospitality gifts	04/10/2019	Disclosed in part
19/431	All vaccines on the schedule	04/10/2019	Disclosed in full

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19/434	In preparation for my interview I was hoping that you would be able to furnish me with the list of Metrics measured by the MHRA in relation to clinical trials carried out in institutions such as The Christie.	12/09/2019	Disclosed in full
19/435	inspection reports be provided for all Companies that had major or critical findings please from January 1st 2015 – 30th June 2015.	07/10/2019	Disclosed in part
19/437	Request Software systems	16/09/2019	Disclosed in full
19/438	Recruitment and costs	11/10/2019	Disclosed in full
19/439	Please provide a breakdown of all suspected adverse reaction reports in relation to e-cigarettes since January 1, 2018	11/10/2019	Disclosed in full
19/440	Please can I see the data relating to the MMR vaccine. The statistics of adverse reactions after receiving this vaccine in the UK. Also if possible any safety studies involving the MMR vaccine tested against subjects who did not receive the MMR vaccine	11/10/2019	Disclosed in full
19/442	Since 2015, does the MHRA have a record of how many fake/counterfeit/illegal medical abortion pills (mifepristone and/or misoprostol) have been intercepted via checks on the postal system in England or seized as part of raise?	14/09/2019	Not held
19/445	Could we please have a copy of 'The Cardiff Study on Congenital Malformations'	02/10/2019	Not held
19/446	Please can you provide the adverse reactions to the MMRPROVAX vaccine since it was licenced for use. Please break the information down into the following categories: Type of adverse reaction in males, females by ethnicity please include the number of death	20/09/2019	Disclosed in part
19/447	I would like to please make a freedom of information request for details of these 62 adverse reaction reports, broken down similarly to medicines adverse reactions on the YellowCard iDAPs system.	11/10/2019	Disclosed in full
19/450	Could it also be confirmed to as any recalls that occurred with the relevant batch numbers, for the above medications of 1. Simvastatin 2. Atorvastatin 3. Levothyroxine 4. Clarithromycin	10/10/2019	Disclosed in full
19/451	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	21/10/2019	Disclosed in full

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19/453	Yellow card reports to date of all vaccines on current uk schedule (differentiating Live flu spray from inactivated injection)	09/10/2019	Disclosed in full
19/454	Complaints of side effects to Leuprolide Acetate Leuprolide Leuprorelin Acetate Leuprorelin Goserelin	11/10/2019	Disclosed in full
19/455	We would like to make a Freedom of Information request to receive the clinical study data for the female sub-cohort in the PK/PD study for the Epipen devices submitted as part of the Article 31 referral.	23/10/2019	Disclosed in part
19/456	Inspection report for ALS Laboratories Ltd	18/10/2019	Disclosed in part
19/458	Adverse reactions to Vaccines	15/10/2019	Disclosed in full
19/459	Access to any reports regarding vaccines and their side effects please	18/10/2019	Disclosed in full
19/460	Please could you send me all information you have on the Fluenz flu mist. Specifically I am looking for information about adverse reactions	15/10/2019	Disclosed in full
19/462	Further information regarding M-M-RII and M-M-RVAXPRO.	24/10/2019	Disclosed in full
19/464	Victoria Derbyshire Programme Report On Illegal Diazepam	28/10/2019	Disclosed in full
19/465	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 had life changing reactions following routine NHS vaccines over the past 5 years please.	04/10/2019	Disclosed in full
19/466	I would like to request statistics on the number of children who are suspected to have died following routine NHS vaccines over the past 10 years	21/10/2019	Disclosed in full
19/467	Please release the data of total reports and Adverse Reactions including totals for mild, moderate, severe and lethal, for all routine vaccinations in the last 10 years.	28/10/2019	Disclosed in full

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19/468	Solutions and contract budgets for agency	28/10/2019	Disclosed in full
19/472	PHARMARON UK LIMITED - Inspection report	29/10/2019	Disclosed in part
19/473	Could you please provide the number of adverse events reported by psychiatrists in 2018 and for every previous year since your records began	30/10/2019	Disclosed in full
19/474	Please provide the MHRA's internal review and the CHM's report on this issue	18/10/2019	Disclosed in part
19/475	Any information or documents submitted by Shenzhen OVNS Technology Co., Ltd in relation to the brand/product OVNS JC01; the product ID is listed as "02244-18-00112" and the product type is listed as "Electronic cigarette – Refillable, device only."	30/10/2019	Disclosed in part
19/476	This is a request for a copy of the Non Clinical Overview used in support of the application for PL 29831/0462 Levomepromazine Injection	15/10/2019	Disclosed in part
19/477	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	21/10/2019	Disclosed in full
19/479	I request a copy of the following information relating to: 1. Which supplier is providing IT architecture and governance services into the MHRA 2. What is the Contract Value for the supplier of IT architecture and governance services into the MHRA 3. What was the Start date for the supplier of IT architecture and governance services into the MHRA 4. What is the End date for the supplier of IT architecture and governance services into the MHRA 5. How was the IT architecture and governance services procured and by which framework 6. Who is the Service owner, within the MHRA for the supplier of IT architecture and governance services into MHRA	01/11/2019	Disclosed in full
19/480	Public Assessment Report request - PL 36065/0004	21/10/2019	Not held
19/481	Carbimazole details	04/10/2019	Disclosed in part
19/482	Please can you provide me with the Drug Analysis Print (DAP) reports of suspected adverse reactions to the current childhood vaccines listed on the routine immunisation schedule.	28/10/2019	Disclosed in full

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/484	Pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from July 1st 2015 – 31st December 2015	31/10/2019	Disclosed in part
19/486	We would like to access EPAR this recently granted AND RISK MANAGEMENT PLAN for Slenyto 1 mg prolonged-release tablets and Melatonin oral solution	15/10/2019	Not held
19/487	Under the Freedom of Information act, can you please email me all the Sodium Chloride notifications found with the term "Bacteriostatic" in the proprietary name manufactured by Hospira between 1/01/2017 until 30/09/2019.	15/10/2019	Disclosed in full
19/488	Following the response, with regards to the "14 declarations of hospitality taken as part of a conference/meeting in relation to staff attending conferences etc to speak as a representative of the MHRA", for reach please disclose: 1 the name of the conference/meeting 2 the location 3 the nature of the hospitality, ie hotels, dinner, lunch, flights etc. 4 the estimated total cost of the hospitality 5 where possible, the name of the company giving the hospitality	11/11/2019	Disclosed in full
19/489	Request copies of Yellow Card Report records for Fluenz/Fluenz Tetra nasal spray for the previous two years. Also for the quadrivalent injected flu vaccine for age 18-65 for last year.	11/11/2019	Disclosed in full
19/490	I would like to request module 3 (Quality) documents which the Agency would be able to disclose (I am aware some parts are exempt as per the previous request: 19/402) from GW pharma for Sativex PL 18024/0009	17/10/2019	Disclosed in part
19/491	2019 pay settlement	12/11/2019	Disclosed in full
19/493	ADR reporting statistics query	22/10/2019	Disclosed in full
19/494	RMP for Voriconazole	06/11/2019	Disclosed in part
19/495	I would like to obtain the details of all the advertising complaints received, and details of which individuals/organisations raised those complaints - that were directed at my employer Manual.	16/10/2019	Disclosed in part
19/496	Abridged Application approvals (Generics) no Bioequivalence study	18/10/2019	Not held
19/497	I would also like to request a copy of Calea's reply to the MHRA letter dated 22/12/17 post GMP Inspection of 11-14 /12/17.	13/11/2019	Disclosed in part

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/498	Information on clinical trials data	18/10/2019	Disclosed in full
19/499	Reports under the Yellow Card scheme relating to specific side effects	06/11/2019	Disclosed in full
19/500	It is the annual review of the post market surveillance and would like the information on a radioactive seed source used in brachytherapy	28/10/2019	Disclosed in full
19/501	Adverse Reactions reported relating to breast implants used in breast enlargement surgery	08/11/2019	Disclosed in full
19/502	Lariam side effects	12/11/2019	Disclosed in full
19/503	I am requesting to be informed of the number of reports received by the MHRA of adverse sexual effects caused by SSRIs	18/11/2019	Disclosed in full
19/504	Please provide recorded information, in relation to the case of ineffectiveness of Macleods carbimazole in 2018	04/11/2019	Disclosed in part
19/505	Intranet Queries	13/11/2019	Disclosed in full
19/506	Parallel Import Licences and country of origin	24/10/2019	Disclosed in full
19/508	Intranet queries	19/11/2019	Disclosed in full
19/510	Trans-vaginal mesh products for the treatment of pelvic organ prolapse	14/11/2019	Disclosed in part
19/513	Please may I also have information in respect of all vaccines which, since MHRA has been in place, have reached a level whereby MHRA has deemed it necessary to investigate further, or take additional action	11/11/2019	Disclosed in full

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/514	Gammabin Batches	12/11/2019	Disclosed in full
19/516	Freedom of Information request - Intranet queries	13/11/2019	Disclosed in full
19/520	Would you please be able to share the Risk Management Plan of generics with active substance "ursodeoxycholic acid" (also known as "ursodiol")?	22/11/2019	Disclosed in part
19/521	This is a request under the Freedom of Information act, for a list of all medications withdrawn in the UK by MHRA in the past 10 years	08/11/2019	Disclosed in part
19/522	RFI on HRT	22/11/2019	Disclosed in full
19/523	The clinical expert report and/or clinical overviews and summaries (module 2.5 + 2.7) -Non-clinical expert reports/non-clinical overviews and summaries (module 2.4 + 2.6) for Buttercup Syrup Bottom (THR 02855/0011)	20/11/2019	Disclosed in full
19/524	Mean and median earnings and Salary minima and maxima for each grade	26/11/2019	Disclosed in full
19/525	Ranitidine and Zantac 75mg	19/11/2019	Disclosed in full
19/526	Could you please provide the number of adverse events reported by psychologists in the mental health field from mental health medications and treatments in 2018, and for every previous year since your records began.	22/11/2019	Disclosed in full
19/527	Investigation into the safety data for propylene glycol and glycerol usage in e-Cigs	20/11/2019	Disclosed in full
19/528	Could I submit a similar request but this time requesting 'country of origin' information on 'Parallel Import Licences' from 01 January 2015 to 31 August 2019 and October 2019?	06/11/2019	Disclosed in full
19/530	Could you please provide all of the Pharmacovigilance and GCP Inspection Reports for both Actavis and Allergan from 2012 to present? If possible, could we also receive the Responses?	28/11/2019	Disclosed in part

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/531	PV inspections for 1. Tesaro 2. Biogen 3. Norgine 4. Takeda 5. Pfizer	19/11/2019	Disclosed in part
19/534	Information about all Marketing Authorisations	07/11/2019	Disclosed in part
19/535	Request 2016 stats for ADRs Levothyroxine	28/11/2019	Disclosed in full
19/536	HPV Quarterly Data Request Q3 2019	28/11/2019	Disclosed in full
19/537	I would like to make a request under the Act for a comparison in the number of adverse events by type and severity reported across the same months in 2018 and 2019 for the Trivalent Fluad Vaccine	18/11/2019	Disclosed in full
19/538	Hello I have recently learned that vaccines including the rubella part of the mmr is made using cell lines from aborted babies! Is this true for our vaccines	20/11/2019	Disclosed in full
19/539	I wondered whether you could share the basis behind the MHRA approval of surgimend. Is this information available.	19/11/2019	Not held
19/541	ICT Service Desk (or IT Service Management)	05/12/2019	Disclosed in full
19/543	MSP Enquiry - Cannabis-based Medicines/ Compassionate Use (Case Ref: LF10143)	28/11/2019	Disclosed in part
19/545	Celixir and Royal Brompton trial	06/12/2019	Disclosed in part
19/546	Risk Management Plan for Trimipramine	15/11/2019	Not held
19/551	MAA Procedure Route Confirmation - Chlorpromazine Tablets	15/11/2019	Not held

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/552	If it would be possible to aggregate in that way, it would answer my request (19/509 re HPV vaccine related deaths) 1) in age bands spanning three years, plus age unknown 2) by male, female, plus sex unknown 3) by regions, as you record them, plus region unknown	04/12/2019	Disclosed in full
19/553	Can the following pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from 1ST January 2016 – 31st May 2016	04/12/2019	Disclosed in part
19/554	information held by the Agency relating to the Association of Children Damaged by Hormone Pregnancy Tests	13/01/2019	Disclosed in part
19/555	Request number of adverse reactions to the 2018/2019 flu vaccine that were reported. Also what was the nature of the adverse reactions.	09/12/2019	Disclosed in full
19/557	Can you advise me if the MHRA has moved from an onsite Server to an cloud hosted Server? Are any systems required to be operated from an onsite Server?	10/12/2019	Disclosed in full
19/558	I would like to be provided with the raw dataset for the negative effects/adverse reactions to e-cigarettes since May 2016 to October 2019 broken down by: the manufacture/type of e-cigarette; the date; geographical location; nature of reaction. I am particularly interested in fertility/adverse sexual effects.	12/12/2019	Disclosed in full
19/560	Class I medical devices registered with MHRA/MDA between 1997 and 2002	09/12/2019	Disclosed in part
19/561	I would like to extend my request to the MHRA and ask for a summary of all the information held regarding this clinical trial	20/11/2019	Disclosed in full
19/562	Please could you provide information about the clinical or bio studies that MA holder of Gestone performed	12/12/2019	Not held
19/564	Please provide the Public Assessment Record (PAR) for PL 41344/0050 (Melatonin 1mg/ml oral solution).	05/12/2019	Disclosed in full
19/565	Please could you disclose the log for 'UKPAR for Sulfasalazine 500mg tablets' dated 01/03/2018	06/12/2019	Disclosed in full
19/568	GLP Work in China	17/12/2019	Not held

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/569	GMP reports dossier 18F036 UK	17/12/2019	Disclosed in part
19/570	New CEO correspondence CEO 18645 - levothyroxine	11/12/2019	Disclosed in part
19/571	The number of WDA (H) inspections carried out in each of the last 3 years. The number of critical, major and other findings in each of those three years. The number of inspections carried out broken down by inspector. (The inspectors can be anonymised.) The number of critical, major and other findings broken down by inspector and year. (Again anonymised is fine.)	16/12/2019	Disclosed in full
19/573	Request for Pharmacovigilance Inspection Reports from MHRA	16/12/2019	Disclosed in part
19/575	Please provide a breakdown showing the number of staff formally disciplined in 2018 and to date in 2019. In the breakdown, please provide a description of the behaviour or misconduct which resulted in the disciplinary action and the nature of the action taken.	12/10/2019	Disclosed in full
19/577	Under the freedom of information act I would like to request the following information for UK MA approved 14 June 1989/24 Jan 1995 – Aramine (metaraminol tartrate) Injection 10mg/mL (Merck Sharp Dohme), PL 00025/5020R: Clinical report & Overview Nonclinical report & Overview	12/12/2019	Not held
19/578	Please provide RMPs and Clinical Overviews for these two licences - Celton XL, 2mg prolonged release tablets (PL 00289/2203), Melatonin 3 mg f/c tablets, (PL 41344/0053)	22/01/2020	Disclosed in part
19/579	CFS and POTS reports from 2008 to present for HPV against same info for all other childhood vaccines	23/12/2019	Disclosed in full
19/580	PARSs for 1. Ethosuximide 250 mg/5 ml oral solution 2. Mefenamic Acid 500 mg Tablets 3. Ethosuximide 250 mg Soft Capsule & 4. Chlorpromazine 25mg, 50mg & 100mg Tablets	27/11/2019	Disclosed in full
19/582	Can you please tell me how many wholesale dealer licences have been suspended in the last 3 years? To be clear, I would like to know how many instances of suspension there have been. For example, if one wholesale dealer was suspended on two separate occasions, this would count for two. Of these suspension events, how many were made under Reg. 28 of the Human Medicines Regulations, and how many were made using the procedure reg. 27.	27/12/2019	Disclosed in full
19/583	Inspection reports	02/12/2019	Disclosed in part
19/584	SSRI data documentation	24/12/2019	Disclosed in full
19/585	Stage of clinical trials for Lasmiditan	04/12/2019	Disclosed in full

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/586	Please send us the minutes of all MHRA meetings at which ketamine has been discussed	27/12/2019	Disclosed in part
19/587	Communications & Telephony Request	19/12/2019	Disclosed in full
19/588	Communications & Telephony Request	19/12/2019	Disclosed in full
19/589	Use of Personal devices for work activity in BP	16/12/2019	Disclosed in full
19/590	MHRA Inspection reports for all inspections performed by the MHRA inspection group at all applicable Modepharma Ltd site (WDA(H) 40009) from Jan 1999 to Nov 2019	27/12/2019	Disclosed in part
19/591	Could you please provide the most recent submitted risk management plans (RMP) for AMIODARONE TABLETS (100 mg and 200 mg).	02/12/2019	Not held
19/592	A copy of the Risk Management Plan (section 1.8.2 of the approved dossier) of Viagra Connect 50 mg film-coated tablets (Sildenafil citrate)	05/12/2019	Disclosed in part
19/595	If you would be good enough to give me information with regards to all the negative reactions to the drug protopic that have been reported over the past 24 months.	30/12/2019	Disclosed in full
19/598	Can the following pharmacovigilance inspection reports be provided for all Companies that had major or critical findings please from June 1st 2016 – 31st October 2016.	09/01/2020	Disclosed in part
19/599	Information about enforcement work in relation to dangerous dietary supplements.	07/01/2020	Disclosed in full
19/600	Request RMP for the PL 20117/0299 - Amantadine 100mg Capsules	10/12/2019	Disclosed in part
19/603	Request a copy of the clinical expert reports and clinical safety data (adverse events) submitted for the first renewal of PL 00063/0045 (now PL 10972/0045) - Ibuprofen 5% gel. This would have been likely been submitted in the year 2000/ 2001.	19/12/2019	Not held

<i>No</i>	<i>Subject</i>	<i>Date reply sent</i>	<i>Result of request</i>
19/605	Request Information on fatal ADR MMRVAXPRO (Live MMR Vaccine) Exp: Sept 2020 Batch Number: R023751 (29th May 2019). MMRVAXPRO (Live MMR Vaccine) Exp: Sept 2020 Batch Number: R030631 (24th July 2019). ZOSTAVAX (Live Shingle Vaccine) Exp: Nov 2019 Batch Number R017557 (26th June 2019). VYPE Crisp Mint E-Cigarette	10/01/2020	Disclosed in full
19/606	How many times over the past ten years has it come to the attention of MHRA that generic medication has had an inferior quality and lesser efficacy on patients/ a patient than the brand medication. Including my communication	30/12/2019	Disclosed in full
19/608	Please could you provide me with this year's report relating to adverse reactions to vaccines, in relation to 2018?	20/01/2020	Disclosed in full
19/611	Online Investigation Software contracts	15/01/2020	Disclosed in part
19/612	Telephony and Network contracts	21/01/2020	Disclosed in part
19/613	A copy of the MHRA GMP inspection report for Selcia Limited conducted on 2017-09-28 (Inspection GMP 27830/119738-0009	20/01/2020	Disclosed in part
19/615	Yellow Card Report' related to e cigarettes and vaping	16/01/2020	Disclosed in full
19/616	Request minutes on UK company, Celixir	21/01/2020	Disclosed in part