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

This document contains reference details for all FOIA 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:

FOI_policy@mhra.gsi.gov.uk

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

Updated: 02 August 2018

| FOI no | Subject | Date reply sent | Result of request |
|--------|---|-----------------|-------------------|
| 18/001 | Information on HPV vaccination between 1st October 2017 and 31st December 2017; Drug name (please specify Gardasil or Gardasil 9) age, gender, reaction & outcome | 30/01/2018 | Disclosed in full |
| 18/002 | Copies of the Clinical and Non-Clinical Overviews for Sennosides 7.5 mg tablets PL 33831/0029 | 19/01/2018 | Disclosed in part |
| 18/003 | Azzalure and Dysport | 25/01/2018 | Disclosed in full |
| 18/004 | Applications made by overseas MF for Liothyronine Sodium 20mcg tablets | 29/01/2018 | Disclosed in part |
| 18/005 | Requesting details of the controlled distribution system(s) in place for each company marketing bosentan. | 31/01/2018 | Disclosed in part |
| 18/006 | FOI requests 'answered in part' from 2017 onwards. In particular, the sections used for refusal (as is supplied for the requests not answered). | 15/01/2018 | Disclosed in full |
| 18/007 | Full breakdown of expenditure by staff in your department on the Government Procurement Card, or any other credit card paid out public funds for a)2016/17 and b)2017/18 to date | 06/02/2018 | Disclosed in part |
| 18/008 | Ashfield Healthcare | 02/02/2018 | Disclosed in full |
| 18/009 | Request report (Petersen J., Wise, L. Prescribing trends of bisphosphonates in general practice, UK 1995-2008. Pharmacoepidemiology and Drug Safety. '19. 'S315). | 11/01/2018 | Disclosed in full |
| 18/010 | Request MHRA to share RMP summary or summary of safety concerns for Injection. | 10/01/2018 | Not held |
| 18/013 | Copies of all comparable data regarding the use of Electroconvulsive Therapy (ECT) as a treatment method in all of the NHS Mental Health trusts in England from 1948 to date. | 22/01/2018 | Not held |
| 18/014 | Confirm the serious adverse side effects (also name of vaccine) from child hood vaccines in the UK from period of 2003 to present day 2018 | 07/02/2018 | Disclosed in full |
| 18/015 | Request assessment of the dossier for Alateris 625 mg tablets, Alka-Seltzer XS, Quinine Sulfate 300 mg tablets, Gregovite Ca tablets, Forceval capsules, Synthamin 14, 8.5 Amino Acid Intravenous Infusion. | 05/02/2018 | Disclosed in part |
| 18/016 | Prozac PILs | 07/02/2018 | Disclosed in full |
| 18/018 | Unicough 14mg/ 135 mg/ 1.1 mg/ 5 ml Oral Solution variation registration date 23.04/2015 | 21/02/2018 | Disclosed in part |
| 18/020 | Request Public Assessemnt reports for Calpol | 02/02/2018 | Disclosed in full |
| 18/021 | Request about flights your organisation has paid for since 1 January 2015. | 06/02/2018 | Disclosed in part |
| 18/025 | Volume of applications you receive for new drug approvals/licences to market drugs, by origin, preferably by year, over the last 10 years. | 09/02/2018 | Disclosed in full |
| 18/027 | Pharmacovigilance inspection reports from November 2017 and December 2017. | 09/02/2018 | Disclosed in full |
| 18/028 | Request for information on PEEK implant for shoulder surgery | 15/02/2018 | Disclosed in full |
| 18/029 | Request for a breakdown of all the alleged Co-Cyprindiol side effects reported to you under the yellow card scheme between 1.7.16 and 30.6.17. | 14/02/2018 | Disclosed in full |

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|--------|---|-----------------|-------------------|
| 18/030 | Request information your organisation hold that pertains to, or implicates, any Freemason to any alleged crime. | 09/02/2018 | Not held |
| 18/031 | Request paperwork that was sent from Scherings to the Committee On Safety Of Medicines to confirm the change of use of Primodos in 1970 and why had the change been made? | 19/02/2018 | Not held |
| 18/032 | Request for Risk Management Plan submitted by Medice for <i>Amfexa 10mg and 20mg Tablets</i> (PL 11243/023-0024) | 13/02/2018 | Disclosed in part |
| 18/033 | Would you kindly confirm if you are aware of any regulatory or compliance matters Emcure have been involved in either with yourselves or any other relevant drug authoritiesn such as the FDA | 19/02/2018 | Disclosed in full |
| 18/034 | Energy Suppliers | 19/02/2018 | Disclosed in full |
| 18/036 | Social media account and expenditure | 22/02/2018 | Disclosed in full |
| 18/037 | Request the latest inspection reports for Martindale and Ethypharm. | 19/02/2018 | Disclosed in part |
| 18/039 | Did the MHRA give approval for the use of G-CSF, EPO and research grade TGF-3 beta for the intervention performed under compassionate use on the child patient, Ciaran Lynch? (Lancet 2012). | 15/02/2018 | Disclosed in full |
| 18/040 | Investigations and research program methods in progress into systemic neurological and any other damage caused by human in vivo chrome-cobalt alloy hip and other implant components. | 23/02/2018 | Not held |
| 18/042 | Update on metal on metal implant | 23/02/2018 | Disclosed in part |
| 18/043 | Request Public Assessment Report for ISOSORBIDE DINITRATE 0.1% (PL 13079/0003). | 09/02/2018 | Disclosed in full |
| 18/044 | Details on the number of adverse incident reports received after hernia mesh in both men and women from 2006 to date. | 23/02/2018 | Disclosed in full |
| 18/045 | Latest M & A Pharmachem Inspection report | 14/03/2018 | Disclosed in part |
| 18/047 | Inspection report for Manx Pharma WDA(H) 15833 | 01/03/2018 | Disclosed in part |
| 18/048 | Inspection report for Universal Marine Medical Supply WDA(H) 43439 | 01/03/2018 | Disclosed in part |
| 18/049 | Inspection report for ANP Pharma WDA(H) 36080 | 01/03/2018 | Disclosed in part |
| 18/050 | Inspection report for Hutton & Co Ship Chandlers WDA(H) 35764 | 01/03/2018 | Disclosed in part |
| 18/051 | Inspection report for Kays Medical WDA(H) 3485 | 01/03/2018 | Disclosed in part |
| 18/052 | Cradelcrest Ltd (T/A Wells Offshore) WDA(H) 8431 | 01/03/2018 | Disclosed in part |
| 18/053 | Infrmation on Ropinirole side effects | 23/02/2018 | Disclosed in full |

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| 18/054 | Risk Management plans for 1) Mucodyne 375mg capsules, Hard 2) Carbocisteine capsules 375mg 3) Carbocisteine chanelle medical capsules 375mg 4) Carbocisteine capsules 375mg | 23/02/2018 | Disclosed in part |
| 18/056 | List of all reported adverse events taking into account the longest period of time for Dysport and Azzalure | 05/03/2018 | Disclosed in full |
| 18/057 | Why are vaccine DAP's are not readily accessible alongside all the other pharmaceutical products available on line. | 19/02/2018 | Disclosed in full |
| 18/058 | Numbers of failure(s) and patient numbers affected by a failure in formalin based fixatives. | 22/02/2018 | Disclosed in full |
| 18/059 | Inspection reports for all MHRA pharmacovigilance inspections of Cipla? | 07/03/2018 | Disclosed in part |
| 18/060 | Lariam (mefloquine) Roche Drug Safety Reports for 01 Jan 1999 - 31 Dec 1999. | 06/03/2018 | Disclosed in part |
| 18/062 | Provide all copies of all drug safety updates relating to Gadolinium contract agents from period from 1 January 2012 to present | 05/03/2018 | Disclosed in full |
| 18/063 | Please provide a list for all successful requests, or those disclosed in part from September 2017 until the end of the year | 08/03/2018 | Disclosed in full |
| 18/064 | Information about medicines exported to Libya. | 20/03/2018 | Disclosed in part |
| 18/065 | Pharmacovigilance inspection reports from November 2016 and December 2016. | 08/03/2018 | Disclosed in part |
| 18/066 | Levothryroxine information | 06/03/2018 | Disclosed in part |
| 18/068 | Information about whether the Liothyronine manufacturing process, plant and update the analytical tests was modernised in accordance with new MHRA standards. | 07/03/2018 | Disclosed in part |
| 18/069 | Information about studies on histomorphological changes in ovaries, ovulation and ovulatory capacity for GARDASIL and GARDASIL 9 | 26/02/2018 | Disclosed in full |
| 18/070 | What information and processes did the MHRA use to compare and benchmark their revised manufacturing standards for Liothyronine against those of other regulators, e.g. those in Europe? | 07/03/2018 | Disclosed in part |
| 18/071 | What specific documents (or information) did the MHRA use to set their revised manufacturing standard requirements on Liothyronine? | 07/03/2018 | Disclosed in part |
| 18/073 | Public assessment reports for glycopyrronium bromide (1mg/5ml), chloral hydrate (5mg/5ml, 100mg/5ml) and levothyroxine | 21/02/2018 | Disclosed in full |
| 18/074 | Request risk management plans for Voltarol 1.16% Emulgel (MAH: GlaxoSmithKline Consumer Healthcare (UK) Trading Limited; PL 44673/0157). Ibuleve gel (MAH: Diomed Developments Limited; PL 00173/0060). Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe (MAH: Aurum Pharmaceuticals Ltd; PL 12064/0125) | 23/02/2018 | Disclosed in part |
| 18/075 | Request information on adverse events reported for implantable mesh devices between 2006-present date. Mesh for SUI, Mesh for pelvic organ prolapse, Abdominal/Hernia Mesh & Mesh for other areas. | 13/03/2018 | Disclosed in full |
| 18/077 | What applications have been made by Indivior and Braeburn to licence drugs to treat addiction | 15/02/2018 | Disclosed in part |
| 18/078 | Breakdown of expenditure by staff in your department on the Government Procurement Card or any other credit card paid out using public funds, in the financial year 2017/18 to date. | 13/03/2018 | Disclosed in part |

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| 18/079 | Request the latest annual report from the MHRA to the JCVI vaccine-associated suspected adverse reactions reported via the yellow card scheme | 21/02/2018 | Disclosed in full |
| 18/081 | Breakdown of expenses for your board members for 2017/18 and 2016/17 | 15/03/2018 | Disclosed in full |
| 18/082 | A copy of the GORMET study report, which covers safety aspects of two of metoclopramide and domperidone. | 16/02/2018 | Disclosed in full |
| 18/083 | Information about whether MHRA has a performance-based bonus scheme for its employees. | 13/03/2018 | Disclosed in full |
| 18/085 | DAIICHI SANKYO UK LTD - copies of educational material | 09/03/2018 | Not held |
| 18/086 | Copies of the following educational materials. STRATTERA Physician's Guide including additional tools. Checklist for actions to take before prescribing/dispensing or administering atomoxetine | 09/03/2018 | Disclosed in part |
| 18/087 | do MHRA have any information/knowledge/concerns past or present regarding the Boston Scientific Advantage Fit (mesh) | 13/03/2018 | Disclosed in part |
| 18/088 | We kindly request MHRA to provide us access to the RMP/ RMP summary for Neupogen | 09/03/2018 | Disclosed in part |
| 18/089 | Yellow card reports for Raltegravir | 21/03/2018 | Disclosed in full |
| 18/091 | Information about prosecutions by MHRA. | 20/03/2018 | Disclosed in part |
| 18/092 | GMP inspection report for Invidor UK Ltd | 20/03/2018 | Disclosed in part |
| 18/093 | Official policy on use of organisational Facebook or Twitter Accounts | 22/03/2018 | Disclosed in full |
| 18/094 | RMP Viagra Connect 50mg film coated tablets – PL 00165/0392; UK/H/6416/001/DC | 23/03/2018 | Disclosed in part |
| 18/096 | Information on Lariam | 22/03/2018 | Disclosed in full |
| 18/098 | Request for the most recent 300 EMA inspection post inspection letters for GMP/GDP inspections | 27/03/2018 | Disclosed in part |
| 18/101 | Information on falsified or substandard antimicrobials recorded on the Global Surveillance and Monitoring System for SF medical products database | 27/03/2018 | Not held |
| 18/102 | UKPAR for Sulfasalazine 500mg tablets | 01/03/2018 | Disclosed in full |
| 18/103 | PAR for Dexamethasone sodium phosphate Strides 4 mg/ml solution for injection and Dexamethasone phosphate 4 mg/ml Solution for Injection or Infusion | 13/03/2018 | Disclosed in full |
| 18/105 | RMP or the table of safety concerns of Ibuprofen/Paracetamol tablets | 23/03/2018 | Disclosed in part |
| 18/106 | Information whether any companies test people's blood/serum sample after BoNT/A or BoNT/B injection? | 28/03/2018 | Disclosed in full |
| FOI 18/107 | Copy of Change of Ownership application details made between ACTIVASE PHARMACEUTICALS (THR28444/0139) to BELL SONS & CO (DRUGGISTS) LIMITED (THR03105/0002) | 04/04/2018 | Disclosed in part |
| FOI 18/108 | Request details of all trial results with <u>all vaccines</u> that have been done against placebo & not against other forms of vaccine. | 29/03/2018 | Disclosed in part |
| FOI 18/109 | GMP inspection report for Capsugel/ Lonza (previously Encap Drug Delivery) Units 4,5 & 6 Oakbank Parkway Livingston West Lothian EH53 0TH | 12/04/2018 | Disclosed in part |
| 18/110 | A list of meetings held between the MHRA and Cannabis Trades Association (CTA UK) in the last 24 months. | 12/04/2018 | Disclosed in full |

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| 18/111 | Information on NHS Business Services Authority unique data for patients on benzodiazepines, antidepressants and opioid containing medicines given in answer to a Parliamentary Question. | 03/04/2018 | Not held |
| 18/112 | Request for 16th October 2015 MHRA Minutes, standing item 10.1, Human Papillomavirus (HPV) Vaccine - currently redacted under FOIA section 35, Formulation of Government Policy. | 22/03/2018 | Disclosed in full |
| 18/113 | Information about spontaneous suspected Adverse Drug Reaction (ADR) reports for HPV vaccinations received since 2008. | 04/04/2018 | Disclosed in full |
| 18/114 | Information about numbers of complaints about slimming aids. | 05/04/2018 | Disclosed in part |
| 18/115 | Please can you confirm that it is a legal requirement for manufacturers to supply a PSUR to the regulatory authority | 04/04/2018 | Not held |
| 18/117 | Report on AMS Elevates devices implanted at the SEHSCT hospitals between 2012(2), 2013 (1) and 2014 (2). | 15/03/2018 | Disclosed in part |
| 18/118 | Information on when the licences for Paradote Tablets were withdrawn or cancelled; whether the withdrawal / cancellation was at the request of the MA holder or the Licensing Authority ((MHRA); the reason for the withdrawal or cancellation of the MAs. | 09/04/2018 | Disclosed in full |
| 18/119 | Eskazole clinical study report request | 09/04/2018 | Not held |
| 18/121 | Please may I request the figures of all spontaneous ADRs received from 2011-present day, and also reporter type | 13/04/2018 | Disclosed in full |
| 18/122 | I would like to request a copy of the risk management plan for Viagra Connect (UK/H/6416/001/DC). | 11/04/2008 | Disclosed in part |
| 18/123 | HMR enforcement actions | 17/04/2018 | Disclosed in full |
| 18/124 | Information that held about lenalidomide | 10/04/2018 | Disclosed in part |
| 18/125 | PAR Paracetamol oral suspension | 19/03/2018 | Disclosed in full |
| 18/126 | Adverse incident reports on electrical/battery operated hoists | 17/04/2018 | Disclosed in part |
| 18/127 | Please send me the latest PV and GCP Inspection reports for Celgene UK | 20/04/2018 | Disclosed in part |
| 18/129 | A copy of the Public Assessment Reports (UKPARs) for Residerm 1% gel & Zindaclin 1% gel | 22/03/2018 | Disclosed in full |
| 18/130 | Please state the number of abortion pills that had been bought online which were seized by the MHRA for each of the following years:2014-18 | 19/04/2018 | Disclosed in full |
| 18/132 | Courier service procurement information | 28/03/2018 | Disclosed in full |
| 18/133 | A copy of MHRA's assessment of the "NHS 111" app powered by Babylon Health | 27/03/2018 | Disclosed in full |
| 18/134 | ADR information for venom therapy | 24/04/2018 | Disclosed in full |
| 18/135 | what year Cycloporin was licensed for clinical use in the UK (the US FDA licensed it in 1983) | 29/03/2018 | Disclosed in full |
| 18/136 | Use of animals in research by MHRA | 25/04/2018 | Disclosed in part |
| 18/137 | Information on clinical trials on Insulin and High Throughput Screening | 10/04/2018 | Disclosed in full |

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| 18/138 | November 2017 GSK Pharmaceuticals, Vaccines and Consumer Healthcare pharmacovigilance inspection report. | 23/04/2018 | Disclosed in part |
| 18/139 | PAR Hydroxocobalamin injection | 28/03/2018 | Disclosed in full |
| 18/140 | PAR diazepam oral solution | 29/03/2018 | Disclosed in full |
| 18/141 | What pre and post market checks are carried out for pelvic mesh | 23/04/2018 | Disclosed in full |
| 18/142 | Audits or investigations already undertaken or pending which relate to the Pregnancy Prevention Programme for lenalidomide (Revlimid®), manufactured by Celgene | 11/04/2018 | Disclosed in part |
| 18/143 | Licensing information for Thiotepa | 26/04/2018 | Disclosed in part |
| 18/144 | Procurement contract info for MHRA | 25/04/2018 | Disclosed in full |
| 18/145 | SOP for approving marketing authorisations | 24/04/2018 | Disclosed in part |
| 18/148 | Info about feasibility studies have been done by MHRA in collaboration with Public Health England (PHE) or other government or other agency to explore the possibility of undertaking an epidemiological study of the alleged association between HPV vaccine and POTS and CRPS. | 27/04/2018 | Disclosed in part |
| 18/150 | PAR for Clotrimazole 200mg vaginal tablets | 29/03/2018 | Disclosed in full |
| 18/158 | Yellowcard data for medicines and devices | 20/04/2018 | Disclosed in full |