

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>
19/003	Unlicensed supply of Liothyronine 20mg Tablets	02/01/2019	Disclosed in full
19/004	Yellow Card Scheme/Liothyronine	29/01/2019	Disclosed in part
19/005	Use of animals in research by MHRA	01/02/2019	Disclosed in part
19/009	The Day 120 Questions and the applicant's responses & RMP for PL 08553/0514-0515	04/02/2019	Disclosed in part
19/010	Silimed breast implants - biocompatibility tests	31/01/2019	Disclosed in full
19/020	I would like to request the PAR for the change of legal status for simvastatin from POM to BTC	25/01/2019	Not held
19/013	Please can you provide me with copies of these Yellow Card complaints & MHRA decisions, and/or, access to the Yellow Card complaints.	04/02/2019	Disclosed in full
19/014	MHRA updates of clinical trial statuses on EudraCT	31/01/2019	Disclosed in full
19/015	Please provide all clinical trial study reports for product Synacthen Depot 1mg/ml suspension for injection PL 43357/0002	30/01/2019	Not held
19/016	Can I request information under the Act relating to these batches of Lyrica. Can you confirm that where you have said the drugs were released to pharmacies that you mean UK pharmacies and that these would have therefore been prescribed to patients?	25/01/2019	Disclosed in full
19/019	Inspection reports for Mawdsley Brookes and Company Ltd & Polar Speed Distribution Ltd	25/01/2019	Disclosed in part
19/021	Please provide me with current salary details (pay scales by grade) for each grade employed in the department	17/01/2019	Disclosed in full
19/022	yellow card reports for various vaccines	07/02/2019	Disclosed in full
19/023	Please can you provide me with details of any scientific research into the addictive properties of non-benzodiazepene drugs, namely Zopiclone, under the Freedom of Information Act.	08/02/2019	Disclosed in part
19/024	I would like to make a Freedom of Information Request on reports of negative effects of hormonal contraceptive from January 2016 until the time this request is answered	11/02/2019	Disclosed in full
19/025	provide me with the following data on "Reproductive & Breast Disorders" - from Yellow Card - Number of Reactions for each category, e.g. "Breast disorders NEC"	11/02/2019	Disclosed in full
19/026	Liothyronine v Levothyroxine	08/02/2019	Disclosed in part
19/029	Please can I have the data as described in my previous communication pertaining to the active ingredients Melatonin and Rivaroxaban	25/01/2019	Disclosed in part
19/036	Please provide copies of all correspondence between the agency and third parties and any other documentation (including any decisions, rulings or pre-rulings) relating to periodontal products (in the form of chip, film, device, composition, implant, other solid dosage form or in the form of gel) containing octenidine (with or without additional agents),	04/02/2019	Not held

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19/028	including (but not limited to) any such correspondence or documentation relating to Pocket-X Chip or Pocket-X Gel. audits on Sunovion Pharmaceuticals Europe Ltd, Roche Registration Ltd, Bayer PLC & Bayer Healthcare, Mylan and Samsung Bioepis UK Limited	11/02/2019	Disclosed in part
19/037	whether MHRA helped an applicant to secure a licence to enable GC MAF it to be sold in the UK?	05/02/2019	Disclosed in full
19/045	Please will you forward a copy of the reply to a previous request regarding whether Liothyronine and Levothyroxine are or are not substitutes for each other. The previous reference number was GCEP-00131719.	29/01/2019	Disclosed in part
19/031	GDP Inspection Reports for several licensed wholesale distribution sites	12/02/2019	Disclosed in part
19/042	List of all sentinel case folder references for GMP inspections carried out by MHRA since January 2015. List of all sentinel case folder references for GDP inspections carried out by MHRA since January 2015. List of all sentinel case folder references for EMA inspections carried out by MHRA since January 2015 (if not included in the above)	15/02/2019	Disclosed in full
19/043	Does your organisation use agencies? Does your organisation have a centralised temporary staff booking team?	15/02/2019	Disclosed in part
19/046	please provide me with copies of the number of employees of the organisation under 16 years of age, the number of employees of the organisation between 16 - 18 years of age, and the number of employees of the organisation over 18 years of age	14/02/2019	Disclosed in full
19/047	PAR, Clinical and non clinical overview and Risk management and pharmacovigilance activities for Oleunor N7E Emulsion for infusion, Noridem Enterprises Ltd PL 24598/0057:	13/02/2019	Disclosed in part
19/049	RMP for PL 00289/2182-2188	18/02/2019	Not held
19/062	Please could you tell me what forms of Haemotherapy are legally allowed in the UK?	13/02/2019	Disclosed in full
19/050	Please could you provide the data for the last 12 months for import notices i.e the number of notifications and if possible the volume of the following products Pyridoxine (Vitamin B6) injections, Lorazepam 2 mg/ml injections, Isoprenaline injections and Potassium chloride oral controlled release preparations	18/02/2019	Disclosed in full
19/051	inspection reports for all Companies that had major or critical findings please from May 1st 2013 – 30th July 2013	19/02/2019	Disclosed in part
19/054	Specialists disregarding adverse affects risks of methylprednisolone as theoretical	19/02/2019	Disclosed in full
19/056	With reference to the Falsified Medicines Directive (FMD), can you please advise me how many UK community pharmacies, hospital pharmacies and pharmaceutical wholesalers (expressed as a number and a percentage of the expected final total number) have registered to create an account with SecurMed UK for a Requestor role and the number and percentage that have submitted details of their software supplier	12/02/2019	Disclosed in full

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19/057	Bioequivalence reports relating to dabigatran etexilate capsules	21/02/2019	Disclosed in part
19/068	Biomed UK Ltd	14/02/2019	Disclosed in full
19/060	Could we please request the UK specific documentation relating to the RMP, such as the educational materials and communications to healthcare professionals, patient information, and prescription authorisation form to Lenalidomide Sandoz" 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg Hard Capsules (PL 04416/1523-9).	29/01/2019	Not held
19/061	MHRA inspection report of the manufacturing site for MUSE	19/02/2019	Disclosed in part
19/063	Through research I have come across an indicator that suggests that CBD (Cannabidiol) was listed in a 1960's edition of the British Pharmacopeia for therapeutic value. Is this something that you can confirm, as well as how long it was listed as such	26/02/2019	Disclosed in full
19/070	Would you be able to share the details of the relationship between Sigma and Sam Pharma, the status/details of Sam Pharma and confirm that they have been granted the PLPI?		
19/064	I am requesting to be informed of the number of reports received by the MHRA of adverse sexual effects caused by SSRIs	20/02/2019	Disclosed in full
19/065	I am requesting a copy of the following file: 10TH BS FOR FACTOR VIII (Plasma) Code No: 81/547. Box No: HA54	06/03/2019	Not held
19/066	Break-marks on UK liothyronine tablets do not comply with PH.Eur. monograph		
19/069	would want to know if the firm involved have supplied any evidence that this is not the case or if they have only presented evidence for the safety and efficacy of ingestion	04/03/2019	Disclosed in full
19/072	Neo-Cytamen 1000 micrograms/ml solution for injection - Overage confirmation	26/02/2019	Disclosed in part
19/073	Request statistics on the number of children in the UK who are suspected to have died following routine NHS vaccinations over the last 5 years. I would also like to request information on the morbidity rates of children in relation to childhood vaccinations.	25/02/2019	Disclosed in full
19/075	SGS Vitrology Inspection report	07/03/2019	Disclosed in part
19/071	Parallel import licences for liothyronine	08/03/2019	Disclosed in part
19/074	Request a full, comprehensive list of all the vaccines you have discontinued for as far back as your records will allow. I would also like to have an explanation as to why these vaccines have been recalled i.e, adverse reactions, death? Furthermore, i'd like to know how long they were on the market before they were recalled.	08/03/2019	Disclosed in full
19/077	MMR questions	11/03/2019	Disclosed in full
19/081	A Melatonin Immediate release tablet has ever been licensed on the UK market	14/02/2019	Disclosed in full
19/078	If I understand correctly the MHRA have licensed the use of both Sofradex and Otomize? Would I be able to see the test done on these drugs before human use was deemed acceptable.	11/03/2019	Disclosed in full

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19/079	IT information	01/03/2019	Disclosed in full
19/080	I'd like to make a request under the Freedom of Information Act 2000 for all minutes, in full, of the meetings of the core decision-making group of the Expert Working Group on Hormone Pregnancy Tests that took place between 24th April 2017 and 15th November 2017, as well as the minutes of any meetings of the Commission on Human Medicines during that period where the EWG report and conclusions were discussed (in the latter, I am only requesting the minutes of the parts of the meeting where the EWG was discussed – not unrelated matters).	11/03/2019	Disclosed in full
19/082	Inspection report of Ipsen Biopharm	13/03/2019	Disclosed in part
19/083	Clinical and non-clinical overview and risk pv activities for PL 00017/0118	11/03/2019	Disclosed in full
19/084	I would like to know the types and numbers of advanced therapy medicinal products that have been supplied under both the Specials and Hospital Exemption provisions since 2009.	14/03/2019	Not held
19/052	Adrenaline autoinjectors: human factors approach	14/03/2019	Disclosed in part
19/085	originator's Risk management plan	01/03/2019	Disclosed in part
19/086	Can you please provide the most recent submitted risk management plans (RMP) for Baclofen 5mg/5ml Oral Solution	15/03/2019	Disclosed in part
19/087	All conducted and completed GMP Inspections by MHRA in 2017	11/03/2019	Disclosed in full
19/089	Please provide copies of all correspondence from the last 12 months between the MHRA and third parties concerning queries or challenges surrounding the data exclusivity rights attaching to the product Dexdor (active substance Dexmedetomidine) and or the validity of generic marketing authorisations relating to generics of Dexdor	18/03/2019	Disclosed in part
19/090	GcMAF Effects on Cancer and Prosecution of David Noakes	27/02/2019	Disclosed in full
19/091	Statistics of injuries/deaths due to falls from hoists in the healthcare setting from 2014 to present	19/03/2019	Disclosed in full
19/092	How many adverse reactions to using prostatic/ Lupron have been registered under the yellow card scheme and What were all side effects listed under yellow card scheme	13/03/2019	Disclosed in full
19/093	please could you send me, the names and contact details, including email address of any/all person(s) who are involved in the decision making-process for the Procurement of Telecoms and IT Hardware and Services for your organisation. (Eg Procurement, IT, Sustainability roles)	01/03/2019	Disclosed in full
19/094	TVT trials	19/03/2019	Disclosed in part
19/095	Have any studies been done on the risk factors of short term high dose methylprednisolone use? please provide the studies that you used to reach a conclusion that only long term exposure to the drug carries risks?	15/03/2019	Disclosed in full
19/097	Please can you provide a copy of the awarded bid for "Single Sign On".	20/03/2019	Disclosed in full

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19/096	We would like you to release all correspondence between the Medicines and Healthcare Products Regulatory Authority (MHRA) and University Hospitals Plymouth NHS Trust, relating to the Wholesale Dealers Licence inspection undertaken at the Trust on 15th November 2018. This should include the post inspection report, the Trusts's response and any further correspondence between the two	21/03/2019	Disclosed in part
19/098	Statistics of people suffering with liver complications which are linked to the combined oral contraceptive pill	22/03/2019	Disclosed in full
19/100	Adrenaline auto injectors	26/02/2019	Disclosed in part
19/101	What treatments have you approved where Phage Therapy can be used as an alternative to antibiotics?	27/02/2019	Disclosed in full
19/102	Clinical Overview, Nonclinical overview, and Risk management and pharmacovigilance activities	14/03/2019	Disclosed in full
19/104	Regulation 28 Report to Prevent Future Deaths _ Adrenaline Auto-Injectors	19/03/2019	Disclosed in part
19/108	Any evidence to support the claim made against an individual	25/03/2019	Disclosed in part
19/105	Clozapine ADR data	28/03/2019	Disclosed in full
19/106	DETAILS OF THE POST AUTHORISATION SAFETY STUDY (PASS) FOR PFIZER'S OTC VIAGRA CONNECT®	12/03/2019	Disclosed in part
19/107	Module 1.8.2 Risk Management Plan & - Module 2.5 Clinical overview	26/03/2019	Disclosed in part
19/158	Request under the Freedom of Information Act: Wellcome Sanger	28/03/2019	Not held
19/109	request to access study reports pertaining to effects on reproduction and fertility, and developmental toxicity of bupivacaine hydrochloride, which would have been submitted in support of the originator MA application (Marcain, AstraZeneca) in the 1980s	28/03/2019	Disclosed in part
19/126	Ciclesonide - request for Summary RMP	29/03/2019	Disclosed in part
19/116	We would like to obtain the UK PAR for PL 12762/0146 DIAMOX Sodium 500mg Powder for Solution for Injection	08/03/2019	Not held
19/135	TEVA levothyroxine query	02/04/2019	Disclosed in full
19/114	Torbay Pharmaceuticals GMP audit report	15/03/2019	Disclosed in part
19/119	MHRA public assessment report on the "Nicorette 10mg inhalator (PL 15513/0179)	08/03/2019	Not held
19/118	On average how many Trusts fail to meet the MHRA ISO 15189:2012 on first inspection and 2. What is the average rate of non-conformity and which areas are these?	25/03/2019	Not held
19/120	Inventory of records lost in 2006	03/04/2019	Disclosed in full
19/121	Please can you provide me with a list of all the organisations which have accessed the CRPD database and also their purpose for access to the database?	20/03/2019	Disclosed in full
19/123	Please provide details of the clinical research studies for each of the marketing authorisation holders (MAHs) from the Article 31 review of adrenaline auto-injectors	14/03/2019	Disclosed in part

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19/128	Clinical Trial results on Turmeric + Made by and marketed through "Future you health" MLS35	14/03/2019	Not held
19/124	The total number of adverse drug reactions recorded under the Yellow Card Scheme from January 2000 to December 2018 and the number of fatalities in respect of Fexofenadine hydrochloride made by: Sanofi Winthrop Industrie, 30-36 Avenue Gustave Eiffel, 37100 Tours, France	03/04/2019	Disclosed in full
19/125	Electronic copies of 1. The background materials submitted in relation to this product (e.g. parts 2 4 and 5 of the marketing authorisation application dossier) 2. Any assessment of the product (e.g. the Final assessment report or other internal reports)	05/04/2019	Disclosed in part
19/132	How many children have been disabled, neurologically damaged or killed by the MMR vaccine and not been numbered? How many children have been disabled, neurologically damaged or killed by MMR in combination with other vaccine treatments through compound effect?	04/04/2019	Disclosed in full
19/129	Request an electronic spreadsheet, excel or CSV file, of all conducted and completed GMP Inspections by MHRA in 2016? Please include all international including overseas companies	08/04/2019	Disclosed in full
19/130	Request for copies of any MHRA Inspection Reports and IAG/CMT communications with the following license holders since April 1st 2017: Licence Holder MS 44301, CURIUM PHARMA UK LIMITED (previously called Mallinkrodt). 5TH FLOOR, UNIVERSITY COLLEGE HOSPITAL, 235 EUSTON ROAD, LONDON, UNITED KINGDOM, NW1 2BU.	11/04/2019	Disclosed in part
19/134	Follow up to 19/119 - Is the supporting data for the original submission available please? If you don't have access to this could you please direct me to someone that might?	10/05/2019	Disclosed in part
19/139	Zaditen Ketotifen Syrup/Elixir	08/04/2019	Disclosed in full
19/142	would like to know if you can tell me if a trial has been done on vaccinated children comparing them to unvaccinated children and what the rates of illness between these two groups.	09/04/2019	Disclosed in full
19/137	Great Ormond Street's initial application for CTA	26/03/2019	Disclosed in full
19/159	Hydroxychloroquine	12/04/2019	Disclosed in full
19/140	Please provide me with details of falsified medicines that have infiltrated the UK supply chain since 2009	08/04/2019	Disclosed in full
19/143	I would like to request the Pharmacovigilance inspection reports from inspections that have been closed (final inspection reports) between December 2018 and February 2019	08/04/2019	Disclosed in part
19/145	Please find below my amended request for all Pharmacovigilance inspection reports for Companies that had major or critical findings from August 1st 2013 – 31st December 2013	17/04/2019	Disclosed in part
19/146	request_analytical methods_Mefenamic Acid	09/04/2019	Disclosed in part
19/148	I write to enquire as to what information, preferably the latest information, you might be able to furnish me with, regarding this compound (Val 201) and the trial data for past present and future? That can be released?	05/04/2019	Disclosed in full

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19/149	A table to show the number of Yellow Cards reporting the various illnesses for the HPV vaccination and for all other vaccinations (one line item per vaccination) since 2008 and a copy of the annual report by the MHRA to the JCVI on all vaccination reactions	23/04/2019	Disclosed in full
19/150	Under the freedom of information act I would like to request the following information for UK MA approved 15/03/1991– Bupivacaine and Adrenaline 0. 5% w/v / 1:200,000 (Advanz Pharma – Mercury Pharma Int Ltd), PL 02848/0128: SmPC & PIL Clinical Overview Nonclinical overview Risk management plan and pharmacovigilance activities	16/04/2019	Disclosed in full
19/151	Hpv vaccine safety and adverse reactions	16/04/2019	Disclosed in full
19/153	Request for Clonidine tablet - 'Summary of Safety Concern' from Risk Management Plan (RMP)	28/03/2019	Not held
19/155	PAR for Rectogesic 0.4% Rectal Ointment: UK/H/0823/001/MR (UK Licence no: PL 16508/0037 [formerly PL 19075/0003])	01/04/2019	Disclosed in part
19/156	PAR for Voltarol 12 Hour Emulgel P 2.32% Gel (PL 44673/0154)	01/04/2019	Disclosed in part