FOI Ref	Request wording
FOI 23/001	I would like to make a Freedom of Information Request for data around the following points. • All Yellow Card reports from COVID-19 vaccinations for Guernsey in the Channel Islands • The number of suspected fatalities, in addition to the type of adverse reaction. Any other data you may have (i.e. age demographic, date reported etc.) would be much appreciated
FOI 23/002	For the different types of hosting services, can you provide me with the following information: 1. Type of hosting – Dedicated, Co-Location, Cloud Hosting, Other? 2. Who is the supplier of the contract? If possible can you also provide me with the name of the vendor, if applicable? 3. What is the annual contract value for each contract? 4. What type of cloud environment? Private Cloud- a distinct and secure cloud based environment in which only the specified client can operate. Public Cloud - where cloud services are provided in a virtualized environment, constructed using pooled shared physical resources, and accessible over a public network such as the internet. Hybrid- integrated cloud service utilising both private and public clouds to perform distinct functions within the same organisation. 5. What is the original start date of the contract agreement? If there are more than one contract please provide me with the start date for each contract. 6. What is the actual expiry date of the contract agreement? If there are more than one contract please provide me with the expiry date for each contract. 7. When will the organisation plan to review this contract? If there are more than one contract please provide me with the review date for each contract. 8. What is the contract period in years? Please include whether the agreement has any extension periods? 9. What services are provided under the contract? Please do not put hosting information such as web hosting, file storage, hosted application. The more information the better, 10. Can you please provide me with the contract officer responsible for this contract? Complete contact details if possible name, title, contact email and number.
FOI 23/003	Please provide copies of all correspondence relating to the Infected Blood Inquiry or Infected Blood Compensation sent to or received by the below persons (including any attachments) during the period 1st October 2022 - 3rd January 2023.
FOI 23/004	This request is made in respect of the nilotinib hydrochloride monohydrate monograph (No. 2993) as described in the European Pharmacopeia. Specifically, this request relates to the elaboration of monograph 2993 requested by Novartis under the P4 procedure, said elaboration approved at the 161st Session of the European Pharmacopeia Commission on 19-20 June 2018 (the “2018 Elaboration”). The P4 procedure requires that National Pharmacopoeia Authorities (such as BPC) approve and provide feedback on P4 requests. 1. Please provide a copy of monograph 2993 contained in the European Pharmacopeia prior to

	the 2018 Elaboration. 2. Please provide materials submitted by Novartis (and/or its affiliates and/or representatives) in support of the 2018 Elaboration. 3. Please provide copies of correspondence between Novartis (and/or its affiliates and/or representatives) and EDQM and/or BPC relevant to the 2018 Elaboration.
FOI 23/005	Under the provisions of the Freedom of Information Act, 5 U.S.C. 522, I am requesting access to a photocopy of the following documents:(our reference 9378028)MHRA. (2004). "Medicines and Healthcare products Regulatory Agency (MHRA), Working Group on Paediatric Medicines, Review of paediatric data - Monocor (bisoprolol fumarate) (CSM/PMWG 04/3rd MEETING)."If the fee will exceed $75.00 for searching for or copying, please inform me before you fill the request.If all or any part of this request is denied, please cite the specific exemption(s), which you think, justifies your refusal to release the information, and inform me of the appeal procedures available to me under the law.
FOI 23/006	I would be grateful if you would provide details of your current contract covering reprographics/print arrangements under the Freedom of Information Act as follows.1. Number of MFDs (Multi-functional devices) & photocopiers at the Medicines & Healthcare Products Regulatory Agency.2. Name of incumbent.3. Start/end date of contract (if expired, WHEN do you expect to revisit the marketplace).4. Details of any extension options.5. What framework / Route to market used.6. Number of regular/desktop printers (in addition to above).7. Is there a support contract on above, if yes please state start/end date.8. Do you have a Print Room.9. If yes, name of supplier, number of devices and start/end date of contract, also details of any extension options.10. Total annual print/copy volumes including, if applicable your Print Room, for (a) mono (b) colour.11. What Print software do you run.12. Your total annual spend on print.13. Name of person responsible for the running of MFDs and, if applicable, your Print Room
FOI 23/007	1. Would you please provide a URL to a UK Government web site where you have published the missing "Freedom of Information (FOI) responses released by the Medicines and Healthcare products Regulatory Agency (MHRA) for 2022" i.e. those after week commencing 25 April 2022.2. If the MHRA has yet to make the full set of its Freedom of Information (FOI) responses for 2022 (after week commencing 25 April 2022) available to the public:a. please provide the highest level of MHRA Board or Corporate Executive level meeting minute, decision note, memo or similar internal instruction setting out when, why and how the decision was made to withhold further disclosure of FOI responses. b. please provide, as response to this FOI, a zip file containing the missing FOI responses for the period 2 May 2022 to 31 December 2023.
FOI 23/008	I would be obliged if you could provide me with the reason for the cessation of the use of the Astra Zeneca Covid Vaccine in the UK, including all relevant documentation related to this decision. Was yellow card reports of adverse events considered and influential in any way in the making of this decision?

FOI 23/009	I therefore request under the Freedom of information Act that you supply me with the requested information with regard to Steven-Johnson Syndrome cases and the Covid-19 Vaccine from 14th July 2021 to the present day.
FOI 23/010	Please can you inform me of the total number of individuals making yellow card reports regarding COVID vaccines. This is not the same as the number of reports as some individuals may make more than one reports. Please can you further inform me how many of those individuals making reports you have contacted requesting further information
FOI 23/011	Please treat this communication as a request under the Freedom of Information Act 2000.In its weekly, now monthly, summaries of Yellow Card Reporting the MHRA states that “the overwhelming majority of reports relate to injection-site reactions” and “generalised symptoms” that generally “are not associated with more serious or lasting illness”, and that these types of reactions are a “normal immune response” and “tend to resolve within a day or two”. However, it is not revealed what percentage of the Yellow Card reports received are being described as an “overwhelming majority”. Please confirm in respect to the Yellow Card reports received at the date of the latest summary available when answering this request:what categorization MHRA uses for the Yellow Card reports e.g. minor, non-serious, serious, life-threatening, death etc. what percentage of reports were attributed to each category in respect of the reports received and, so far as not answered in response to the above: what percentage of reports were of serious adverse events.what percentage of reports only related to injection-site reactions.what percentage of reports only related to generalised symptoms not associated with more serious or lasting illness.if not split into different categories but are combined in a single category, what percentage of reports only related to injection-site reactions and/or generalised symptoms not associated with more serious or lasting illness.what percentage of reports in the 'overwhelming majority' reports also include reports of reactions that, if made on their own, would not be included within this majority. If the information requested at 1(b) was available to the MHRA at the date of each published weekly, now monthly, summary reports, please provide that underlying information in respect to each published report from the period January 2020 to date.So far as not provided in answer to request 2 above, please answer requests 1 (a) to (g) again in respect to the summary report published at 31 March 2022.If in answer to 1(a) no categorisation is disclosed, what data and analysis is relied on in making the assessmnt as to what reports fit within the “overwhelming majority” so described. I understand that the MHRA has published statements of its assessment that the increased numbers of Yellow Card reports following roll out of the Covid-19 vaccines may be due to certain factors (such as stimulated reporting) but that the increase does not prove a causation by the Covid-19 vaccines. However, the MHRA has not, so far as I am aware, published a statement specifically excluding Covid-19 vaccines as being a reasonably possible cause. I therefore request to know, in relation to reports that are more serious than only ‘relate to injection-site reactions’ or ‘generalised symptoms’ that ‘tend to resolve within a day or two’: Does the MHRA accept that adverse reactions caused by the Covid-19 vaccines (whether directly or as a contributory factor) could be a significant reason for the increase in Yellow Card reports which has coincided with roll out of those vaccines?Has the MHRA at any stage, and if so when, come to a view that adverse reactions caused by the Covid-19 vaccines (whether directly or as a contributory factor) may, in terms, be ruled out as being the reason for the increase in Yellow Card reports which has coincided with roll out of those vaccines? Put another way, is it the MHRA’s assessment that reasons for the increase may be several, but direct or contributory causation by Covid-19 vaccines can be dismissed as playing any significant part in the increase? If the answer to (a) and/or (b) is yes, on what basis is the view reached that causation by Covid-19 vaccines can be so dismissed?Please provide copy of the document(s) in which such a view (or an alternative view) is recorded as being the MHRA's assessment of the above. Please treat this communication as a request under the Freedom of Information Act 2000.Monitoring

	Strategy.I note that the Report of the commission on human medicines expert working group on covid 19 vaccine safety surveillance, published 5 February 2022, records there are four strands to the MHRA's strategy, which combine to address the relative strengths and weaknesses of each form of vigilance:(a) Enhanced passive surveillance – 'observed vs expected' analysis.(b) Rapid Cycle Analysis and Ecological analysis.(c) Targeted active monitoring – Yellow Card Vaccine Monitor.(d) Formal epidemiological studies.In respect to the strand "Rapid Cycle Analysis and Ecological analysis", the statement, published 5 February 2022, notes that ~20% of GP practices in England are registered to it, it is not as real-time at Yellow Card reporting for safety signal detection, and that "as COVID-19 vaccination records (i.e. those given outside of GP surgeries) begin to get updated within GP systems, the MHRA will implement a form of active surveillance known as 'Rapid Cycle Analysis'. (my emphasis). The statement also refers to the "list of pre-defined events of special interest". I request:at what date(s) has the Rapid Cycle Analysis been implemented.in respect of any Rapid Cycle Analysis that been implemented, which have been concluded and when and where can the analysis and/or its conclusions be viewed (please provide copy).please provide copies of the "list of pre-defined events of special interest" in its various iterations at different dates since December 2020 (or otherwise, and preferably, set out the current list including notes of the dates and detail of any amendments to that list i.e. when particular events been added or removed from the list).what are the 'pre-defined events', and within which 'given population cohorts', that have been analysed using ecological analyses since December 2020 (confirming the dates at which commenced and concluded, whether at interim or final stage, and when and where can the analysis and/or its conclusions be viewed (please provide copy)).In respect to strand (d), "Formal epidemiological studies", the statement says."The above three methods are essentially 'signal detection' and 'signal strengthening' tools – i.e. their main purpose is to quickly flag up whether there might be a new, rare side effect and to build the volume of data on safety. They cannot confirm if it is a side effect. Similarly, whilst they can provide some strong evidence to indicate if something is likely to be coincidental, they can not always confirm this. A formal epidemiological study, designed and powered specifically to test a given hypothesis in an unbiased way, is usually necessary to confirm and quantify a suspected rare side effect. These will be undertaken on an ad hoc basis should the need arise based on other vigilance activities."Please confirm what, if any, formal epidemiological studies have been conducted since December 2020, and in respect to which possible or suspected side effects and when.In respect to any such any formal epidemiological studies, confirming the dates at which commenced and concluded, whether at interim or final stage, and when and where can the study or its analysis and/or its conclusions be viewed (please provide copy)
FOI 23/012	Under the Freedom Of Information Act 2000 please supply the following information.(a) Does the MHRA collate and include ADR's for Vaxzevria (Oxford Astra zeneca vaccine) administered outwith the UK in their tally of ADR's for this brand or is the Yellow Card figure made up of UK based ADR reports only?(b) If the answer to (a) is no can you please advise who would have the global figure for ADR's in respect of Vaxzevria to include reports from every country where it is used?(c)Despite the fact that Covishield does not hold a UK PL does the MHRA collate and include Covishield ADR's in the overall tally of ADR's in respect of Vaxzevria?(d) If the answer to (c) is no, could you please explain why not.
FOI 23/013	I would like to request under FOI the current:Risk Management Plan (RMP) for Micafungin (MYCAMINE) , MAH Astellas Pharma
FOI 23/014	Content of AESI Line Listing.xlsx file

FOI 23/015	Could you please tell me why the MHRA receives most of it's funding from pharmaceutical companies?, and if there is a conflict of interest occurring regarding the decisions made in relation to allowing the covid vaccines to be used as an experimental MRNA gene therapy? Am i correct in saying that the covid vaccines are on an experimental trial basis until the end of 2023
FOI 23/016	I would like the data on the side affects thats been reported for the vaccines that may not be listed on the NHS website
FOI 23/017	Please can I request the approved targeted questionnaires for dimethyl fumarate as approved in the current risk management plans for Skilarence (Almirall) PLGB 16973/0039-40 and Tecfidera (Biogen) PLGB 22407/0012-13.The targeted questionnaires are for:Malignancies,Drug-induced liver disease (DILI),Serious infections (other than PML and herpes zoster),Lymphopenia.
FOI 23/018	I would like to request to receive an electronic copy of the following MHRA GMP inspection report under the Freedom of Information Act,MIA(IMP)35718 Insp IMP 35718/876362-0015,Date of inspection 04 February 2022,Name of Company,Quotient Sciences Limited,5 Boulton Rd,Reading,RG2 0NH,United Kingdom,the relevant GMP Certificate was signed on the 14th February 2022 by [S40 name] at the MHRA
FOI 23/019	The index of the complete file in the possession of the MHRA concerning the AstraZeneca COVID-19 vaccine and/ or COVID-19 vaccine ChAdOx1 S [recombinant]. Information helpful to fulfilling the request: ICAN is seeking an index or other listing of all documents concerning the AstraZeneca COVID-19 vaccine in MHRA's possession and that MHRA relied upon to authorize or otherwise approve or license the AstraZeneca COVID-19 vaccine. The index should be a complete list of all documents within any existing biologic/vaccine product file.
FOI 23/020	Please inform me as to whether:1) The AstraZeneca COVID-19 vaccine is still available for administration in the UK.2) If not, why not? In particular, has it been withdrawn and if so, why?
FOI 23/021	How many deaths from adverse vaccine reactions in the last 12 months? Any . Just Vaccine related deaths.
FOI 23/022	These profiles appear to be for specific drugs whereas I was hoping to find combined data for all drugs in that class (SSRIs)
FOI 23/023	I am requesting up to date data on the adverse reactions of all the Covid-19 vaccines that have been given in the UK to date?
FOI 23/024	I am trying to find the IDaps for the MMR vaccine but can't. I want to look at how many reports of deafness or hesring loss have been reported. I've looked under measles, mumps and rubella and vaccines.
FOI 23/025	The following statement is made:"A combined fertility and developmental study (including teratogenicity and postnatal investigations) in rats is ongoing."This statement does not seem to have been updated in 2 years.Can you please tell me:When will results from this study be available?How will the results be made available to the general public?
FOI 23/026	Please disclose, preferably by PDF, a copy of any communications in the past two years to NHS Trusts relating to recording of issues that could be adverse Covid vaccine events as some other reason(s) instead.

FOI 23/027	It has now been over 2 years since the rollout of covid vaccines in the UK but I am unable to find the two year data from any of the phase 3 vaccine trials.Can you please supply me with the reports on the first two years of phase 3 trials. I am particularly interested in deaths and serious adverse events in vaccinated and placebo groups.Can you supply the reports on Pfizer, Astrazeneca and Moderna and Novavax 2 year phase 3 vaccine trials or point me to where these results can be obtained?
FOI 23/028	I would like to request the following data under the FOI act. 1) What is the total number of patients who've had TMJ Implants (jaw) on the NHS? 2) What is the total number of patients who've specifically had Christensen implants in their jaw on the NHS?
FOI 23/029	Please provide a copy of all correspondence between the senior leadership team of the MHRA and Mike Penning MP related to Tenacious Labs or cannabis regulation from 1 September 2022 to date.
FOI 23/030	1. I can see from this publication https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria that Oxford/AstraZeneca COVID-19 vaccine (now known as Vaxzevria) was first granted conditional marketing authorisation on 29/01/2021. Please provide the date this product was first authorised for use in the United Kingdom3. Please provide any date of its expiry4. Please confirm whether it is presently authorised for use in the United Kingdom5. Please provide confirmation that this vaccine has NOT been withdrawn from use6. If this vaccine has been withdrawn from use, please provide any information either requested from or provided by the MHRA in making the decision to withdraw the vaccine.7. As stated in your list of responsibilities (see https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-responsibilities), specifically "helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use" please provide me, as a member of the public, the specific risks that have been identified for the Oxford/AstraZeneca COVID-19 vaccine since the date this product was first authorised for use in the United Kingdom and whether the MHRA feel that these risks outweigh the benefits of taking this vaccine
FOI 23/031	I am making a request for FOI in respect of funding received by MHRA for financial years 2020; 2021 and 2022. Please provide a list of all DONORS and specify individual sums of REVENUE received.
FOI 23/032	we would like to request additional information for “Eylea (aflibercept)”. Requesting document is listed below and please let me know if you need additional information.
FOI 23/033	Do you have an iDAP report for the smallpox vaccine?
FOI 23/034	1. Can you disclose the total amount of adverse reactions including deaths submitted to the Yellow Card scheme for all COVID-19 vaccines administered in Scotland from 8th December 2020 - 14th Jan 2023 ? 2. What percentage of yellow card reports are estimated to be filled out by health professionals ? 3. What is the estimated rate of under-reporting to the Yellow Card scheme?

FOI 23/035	Please provide summary data to date for injuries and deaths reported to the Yellow Card Reporting System and attributed to Covid-19 vaccines. Please provide up-to-date figures for the UK, broken down separately forPfizer, AstraZeneca, Moderna, Novavax and any where the the manufacturer was unspecified. Please break down each individual manufacturer's figures under the following headers: 1. Total reactions 2. Total reports 3. Deaths
FOI 23/036	Please could you confirm for the Moderna BA1 booster - Was the efficacy data referred to above recieved from Moderna prior to approval? -Were either of these reports reviewed prior to approval? --If the reports were not reviewed why not? -If the data was recieved, was it considered as part of the approval process? --If not, why not? -Why is there no reference to the data in the Public Assessment Report?
FOI 23/037	E - cigartte - Yellow card data- I don't have a particular complaint on any product myself (yet!?) but was curious if there are many reported cases. Is there public available information on the number of reported cases and nature of complaints?
FOI 23/038	This email represents a request under the Freedom Of Information Act and is related to a scientific study (described below) involving [S40 name] at the MHRA.The study is "Safety of COVID-19 vaccination and acute neurological events: A self-,controlled case series in England using the OpenSAFELY platform" published in the journal "Vaccine" in 2022.Would you be able to provide :• All reports / preliminary reports related to this study• All versions of the protocol, as the link given in the study is broken and there the document seems to be unavailable
FOI 23/039	Would you be able to provide the list of all epidemiological studies (for example the ones using CPRD and/or OpenSAFELY as data sources, or any other systems available) done on adverse reactions of vaccines, specially HPV vaccines and Covid-19 vaccines ?
FOI 23/040	I am doing a research project investigating call-off contracts in the public sector. I have identified some potential call-off contracts awarded by the Medicines & Healthcare Products Regulatory Agency, but I can't find details of the framework agreements they were awarded from.
FOI 23/041	The Clinical Overview that was submitted in the marketing authorisation application for Ondansetron 8mg/5ml Oral Solution PL 49578/0014
FOI 23/042	Is it possible to obtain data on the time frame of reports for a specific adverse effect from the iDAPs reports? I am looking into the timeframe of reports for neonatal respiratory conditions for pethidine. I can find the timeframe of reports for respiratory, thoracic and mediastinal disorders but I only want to look at a subsection of that system organ class (neonatal respiratory disorders).
FOI 23/043	Provide the test protocol used to ensure that the method of mixing outlined in the Pfizer/BioNTech vaccine Information for UK Healthcare professionals ensured each of the 6 doses withdrawn from a single vial contained the correct amount of active ingredients. Confirm whether any testing was done on mixing prior to approval (yes or no) & if testing was undertaken, the test report. Confirm what testing was undertaken on batches mixed in vaccination centres, what the sampling methodology was & provide an example test report.

FOI 23/044	1. What form do your investigations take, eg do you contact patients or their GP's, coroner's etc 2. What percentage of the reports on adverse reactions and deaths were established to be definitely caused by the vaccines. 3. At what point do you consider withdrawing a medicine or vaccine. I note in the past some have been withdrawn after very few reports of harm. What level of harm would cause you to withdraw the vaccines. 4. Given that there are many recorded yellow card reports what have you done to minimize harm for the future as described on your website.
FOI 23/045	1. Please send the date and time of all meetings or briefings between the MHRA and the Commission on Human Medicines Expert Working Group during 2020/2021 2. Please send the date and time of all meetings or briefings between the MHRA and the COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group during 2020/2021 3. Please send the minutes of all meetings or briefings between the MHRA and the Commission on Human Medicines Expert Working Group during 2020/2021 4. Please send the minutes of all meetings or briefings between the MHRA and the COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group during 2020/2021 5. Please send copies of all letters or emails between the MHRA and the Commission on Human Medicines Expert Working Group during 2020/2021 6. Please send copies of all letters or emails between the COVID-19 Vaccines Safety Surveillance Methodologies Expert Working Group during 2020/2021
FOI 23/046	I would like to know the total number of reports regarding the MMR vaccine, broken down by age, and seriousness of the adverse reaction, and number of reported fatalities, per year going back as far as you have records if possible.
FOI 23/047	Under an FOIA request I would like more information on your authority or lack of (regulatory impotence) on the following:Given recent leaked US Govt Department of Defense[sic] contracts showing that the Pfizer mRNA Convid19 vaccine was developed and delivered under a US Department of Defense 'Medical Countermeasures' programme (thus negating all the regular testing, approval, delivery and regulatory authority oversight), can you confirm a similar medical countermeasures (or similar) authorisation has not been given in the UK? Who is ultimately responsible for the Govt contracts and delivery of these specific mRNA vaccines in the UK?Are the mRNA delivery platforms circumnavigating the usual UK medical authorities in a similar manner, hence your reluctance to intervene in withdrawing the obviously failed, dangerous product, because you have zero authority over a UK MoD or Security Services delivered gene therapy programme?Please show the exact approval and authority chain for the delivery of the mRNA platform and subsequent biologics into the UK. Please also describe the difference between authorisation of a vaccine and a gene therapy product in the UK.Were the MHRA or other approval authorities aware that Fosun, a CCP linked biotech company, was instrumental as a delivery partner along with Pfizer and BionTech in the production of the Pfizer/BionTech mRNA technology? Their name has been redacted in leaked US Govt contracts.
FOI 23/048	I am requesting Vaccine Analysis Print (VAP) for the following shingles vaccines:• Zostavax,• Shingrix.The print must contain information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including 20/01/2023

FOI 23/049	I am aware that there is a contraceptive similar to Nuvaring, the vaginal ring. Annovera, a ring which is replaced annually rather than monthly, and which uses a different kind of estrogen (I believe) to Nuvaring was approved in the US a number of years ago, and is still not available here. Can you tell me when it will be available in the U.K. please?
FOI 23/050	I. What is the current and past regulatory status of "Suprecur 150 micrograms Nasal Spray Solution" (Buserelin), and reasoning therefore? 2. An estimated date by which "Suprecur 150 micrograms Nasal Spray Solution" (Buserelin) will be re-approved/the regulatory issue preventing the sale thereof be resolved, and a summary of the regulatory issues standing in the way of this occurring. 3. The current regulatory status of the related medicine "Synarel 2mg/ml Nasal Spray" (Nafarelin) 4. In the event that "Synarel 2mg/ml Nasal Spray" is also not currently authorised for sale in the UK as of 23rd December 2022, I request details of current and past regulatory status, an estimated date by which such regulatory issues will be resolved, and a summary of the issues standing in the way.
FOI 23/051	Without this information the MHRA would have approved a drug product under Regulation 174 without knowing the identity/fidelity of the active substance in that product. In plain English this would be the first time in the UK's history that a drug product has been approved by the Regulator without the Regulator confirming the active drug substance of that product is what it is claimed to be. I am confident this cannot be the case, but I would welcome an answer to my question, yes or no. Does the MHRA have receipt of the full genomic sequence files for each batch/lot of BNT162b2 that has been approved in the UK?
FOI 23/052	please can I make a Freedom of Information request to be sent copies of all correspondence the MHRA have had so far on this matter. Have you also been in contact with other public sector bodies? I trust the health and safety of patients in this circumstance would take precedence over commercial sensitivities but I do of course understand if certain details need to be redacted before they can be provided in a FOI response. I look forward to receiving the information within 20 working days.
FOI 23/053	I am aware that the CHM in its October 2022 meeting reviewed a presentation assessment on Codeine linctus. would it be possible to attain a copy of the papers presented to the CHM at this October meeting.
FOI 23/054	How much adverse effects have been reported from AstraZeneca batch no PV46676 ? Can you list them please ?Of those reports, how many were spinal strokes ?How many spinal strokes were reported with AstraZeneca being the vaccine ?How many spinal strokes were reported across the vaccines ?
FOI 23/055	Since my previous request for the nucleotide sequence of "Imelasomeran" was rejected, I wish to know the following:What patents apply to the nucleotide composition of the drug substance "Imelasomeran"?
FOI 23/056	Please can you send me copies of the Request for Further Information letters which MHRA sent to Pfizer, AstraZeneca and Moderna during MHRA's assessment of their submissions leading to Temporary Authorisation of each Covid vaccine. If you refuse this request under an FOI Exemption, please provide the following information :a) the document references (inc dates) of those letters.b) how many questions were included in each RFI letter. If you sent no RFI letters *per se* because you conducted so-called Rolling Review,s please can you tell me :c) how many questions/clarifications you asked each of

	those manufacturers.d) in what form the questions were asked (eg email, telephone, in person)
FOI 23/057	Please can you send me MHRA's reply to the following letters from DHSC DepCMO (Prof Van Tam) and Dir/Emergency Preparedness & Health Protection (Emma Reed) to MHRA CEO (Dame June Raine).a) Letter dated 17 November 2020 (ref 201117_Letter to MHRA from DHSC Pfizer R174 authorisation).b) Letter dated 24 November 2020 (ref 20201124 Letter to June Raine AZ R174 Auth).c) Letter dated 24 December 2020 (ref 241220 DHSC letter to MHRA Moderna R174 Auth)
FOI 23/058	You provided me with the RMP and educational material for Ferinject about a month ago. Now I kindly wanted to ask if you could provide me with the specific adverse reaction follow up questionnaire for the same product, Ferinject.These are 4 questionnaires for: use in pregnant women, for hypersensitivity/anaphylactoid reactions, for hepatic events and for infection related events.
FOI 23/059	I write to you to ask for information regarding the MHRA's response to PSSD (post-SSRI sexual dysfunction), how you intend to establish its prevalence and reduce this harm.As I understand it, nothing was done about this devastating side effect of SSRIs until 2019 when the EMA reviewed it. After this, the wording on Patient Information Leaflets (PIL) was changed, although they do not directly mention PSSD nor list all the symptoms of this condition, eg. genital numbness is not on the PIL.I have the following questions:1. Since 2019, what information has been provided to prescribers of SSRIs about the enduring sexual side effects? Was an alert put out?2. What is the process for establishing the prevalence of PSSD?All other side effects of SSRIs have an associated risk, ie. whether it is 'more than 1 in 10' or 'up to 1 in 100', yet with PSSD we have no idea despite over 3 decades of use and millions of prescriptions issued.I note that UK psychiatrists have all but given up on reporting adverse events via the Yellow Card scheme, making fewer than 5 reports in 2021 (FOI 22 1096.pdf). whereas they were making hundreds of reports in the 1990s (FOI 19.473 Table 1.pdf). Given that psychiatrists no longer consider pharmacovigilance part of their job, what other strategies do you have?3. What plans are there to reduce the harms of PSSD in the future? Are their plans beyond the hint on the PIL? Will it ever be called 'PSSD'?4. How does the MHRA intend to speed up the process of recognising harms cause by drugs? Is it acceptable that it took over 28 years to recognise a life-changing side effect of such a popular class of medicines?
FOI 23/060	I would like to know the number of “yellow card” reports by medical professionals and members of the public for each broad drug class received by MHRA for each year from 2010 to the latest year available.Please provide:a) The number of adverse event reports submitted per year by members of the public for each broad drug class.b) The number of adverse event reports submitted per year by healthcare professionals for each type of healthcare profession (as selected by the professional making the report) for each broad drug class.I realise that occasionally an individual adverse event report is duplicated; I am not concerned about this.
FOI 23/061	I would like to make an FOI request of the Medicines and Healthcare products Regulatory Agency (MHRA) for all submissions received from Macfarlan Smith Ltd concerning the UK requirement for codeine concentrated poppy straw for the years 2021 and 2022.

FOI 23/062	Having asked NHS England and the UK Health Security Agency for the information below, they have directed to me to contact your department, as they only partially hold some of the information.Could you please confirm how many of the children that have sadly died with the Strep A infection were inoculated with experimental Covid19 mRNA vaccines?Could you also confirm the percentage of children with confirmed Strep A cases who have also been vaccinated against Covid19, against those infected with Strep A that have not been vaccinated against Covid19?Given MHRA authorisation for the Pfizer vaccine in the 6m to 5yr cohort, a recent FOIA reply from them provided links to authorisation data from EU systems.Could you confirm if the UK (now outside of the EU) still uses the EU EMA system? If not, what UK-based authorisation and monitoring system is used?Given the case fatality rate of less than 0.002% in the 6m to 5yr old cohort, why are you content that children with zero risk from Covid, receive this experimental therapy? Please provide a full list of UK authorisation and monitoring decisions leading to this authorisation.Why do UK authorities still link to Jul 21 papers citing 'very low risk' of myocarditis, when the same EU data base shows 19,191 cases (of myocarditis with 55% reported by healthcare professionals), with 186 deaths? This is far from 'very low risk' and the majority of people diagnosed with myocarditis NEVER fully recover.The same EU data base shows over 3,744 deaths attributed to the Pfizer vaccine alone. Why do UK authorities continue to pedal this toxic, failed product?Given the mRNA platform is being distributed under US Department of Defence rules, prohibiting any investigations into the Pfizer contents, and that the vials remain US DoD property until administered, how does UKHSA and MHRA know that these products are 'safe and effective'? Given they appear to be a bioweapon deployed by the US military, are UK and World health authorities neutered in their powers due to the mRNA NOT being a pharmaceutical product? Are these products issued in the UK under any form of defence contract of foreign government restrictions ?
FOI 23/063	Under the Freedom of Information Act 2000 please provide the following information.(a) Three batches of Covid vaccine 4120z001, 4120z002 4120z003 were imported from the SII for use in the UK in 2021. Could you please confirm whether or not these batches of vaccine underwent testing by NIBSC.(b) In the event that the answer to (a) is no, could you please advise which facility did conduct the relevant batch testing on these 3 batches.
FOI 23/064	Under the Freedom of Information act (FOI), I would like to request the following:names of all the licensed and registered QP's,the status/outcome of most recent NHS inspection/audits,status/outcome of most recent MHRA audit/inspection of Pharmaceutical manufacturing companies,or any pharmaceutical manufacturing companies/hospitals who currently under special measures with the MHRA
FOI 23/065	As a Freedom of Information request, are you able to provide the following information:- What is the total quantity of imported pharmaceuticals that failed UK quality testing in the years 2020, 2021 and 2022? What was the total amount of pharmaceuticals imported to the UK during these years?- What was the total quantity of imported pharmaceuticals from India that failed UK quality testing in the years 2020, 2021 and 2022?- What is the UK's procedure when it identifies a pharmaceutical product that has failed quality testing? Is it destroyed? Will the government notify the country/company that it imported the item from?

FOI 23/066	Thank you for this information. However these are summaries of information and not really a risk : benefit studies or how the MHRA collects the information before the vaccine is approved either for emergency use or approved use. This is the information I am asking for. Also there is an issue with how the values of potential and actual side effects are calculated / estimated and the confidence figure given to such assessments. Additionally,How does the MHRA, in absence of any data, approve for emergency or otherwise, a medicine or vaccine without information, science or data to inform on potential dangers or interactions with other medicines or vaccines? Furthermore, where are the studies about the dangers of such vaccine interactions on people whose immune system is already compromised?It is clear, there is now evidence that shows there is a large increase in myocarditis and pericarditis with increased uptake of these vaccines, yet, the risk is still classed as <1/10000. What is the actual % increased risk and the potential for death caused by continued uptake these boosters / vaccines?How does the MHRA measure the vaccine efficacy? and what are the time periods which this is measured; and why are these limited time periods chosen?, furthermore, if a patient becomes ill with same symptoms of the disease the vaccine is designed to protect against, where is that recorded in these documents and why does this, seemingly, not impact the vaccine efficacy value?Where are the studies of the impacts on fertility with these vaccines for adult, and potential risks to children's ability to have a healthy reproductive system?More importantly, there is a lack of concentration on a targeting approach for the use of these vaccines. Moreover, where are the studies which show that healthy children and adults need(ed) these vaccines in the first place to fight off this virus.Is advising on the correct use of vaccines not part of the MHRA remit?
FOI 23/067	Could you please send me the accounting form for the last ten years please, I would be interested to find out how changes have been made and what particular pharmaceutical companies invest heavily for approvals.Work done by the Commission on Human medicine is contracted out to EAG, which themselves appointed by the NHS, which themselves are overseen by the current political establishment, which are lobbied by the pharmaceutical companies. There is traceability that describes this relationship. It is also my understanding that studies and data to approve medicines and/or vaccines is controlled by this independent scientific process, which has this relationship present. Therefore, how does the MHRA ensure licencing of medicines and vaccines is truly independent, scientifically driven and the data in the studies are accurate?The MHRA is itself funded, via fees, by the pharmaceutical companies whom will make a business decision to cease obtaining funding for medicines / vaccines if their products are not approved with consistent satisfaction to match business models. From a business prospective, it is therefore in the best financial interest of the MHRA to approve the vast majority of medicines / vaccines and not 'rock-the-boat'. How doe the MHRA ensure there is no conflict of interest?
FOI 23/068	Thank you also for your offer of further information, I hereby request the following under the 'Freedom of Information Act 2000': How many Yellow Cards for the covid-19 vaccines included a report of a Coroner's Inquest?How many Yellow Cards for the covid-19 vaccines included a report of a post mortem? How many inquests concerning Covid-19 vaccines have MHRA given evidence to?
FOI 23/069	With regard to a previous FOI request, may I ask for further information, please?1. For the date of the original request, 22 June 2022 and for today's date, 26th January 2023, is the COVID-19 vaccine undergoing trials (as per question 15 in the original email below)?I am content to receive the information in electronic format.

FOI 23/070	In the EMA references you provided there appears to be an over reliance on the data provided by 'the applicant' - ie the very firm you are supposed to be regulating. Given there were concerns with the ALC_0315 'half-life' what further analysis was conducted into this by impartial scientific or medical bodies? Further revelations are apparent on page 46 of the referenced EMA document in that ALC-0159 posted the highest liver concentrations 30 mins post IV injection. Given that under the UK informed consent via the patient safety data sheets supplied with the Pfizer 'vaccination' and other associated MHRA and Pfizer literature, stated the injection stayed within the muscle and did not leave the injection site, does this not disprove that misinformation and both you and Pfizer knew of this fact in early 2021? Regarding the genotoxicity and the ALC excipients not penetrating the cell membrane, thus negating the need for genotoxicity studies, what evidence do you have to support this claim? Please provide non-biased, peer-reviewed studies showing this to be fact.
FOI 23/071	Why was the Oxford/AstraZeneca covid vaccine stopped being given out in the UK? Also why was this done on the quiet?
FOI 23/072	Please could you give me straight and informed answers to the following legitimate questions. I would like to know what the indemnity/ liability clauses are with the vaccines that have been rolled out in the UK?Furthermore I would also like to know who is liable for any adverse side effects that occur.?I would also like to know why Pfizer and the NHS staff administering the doses required full indemnity?
FOI 23/073	“The main efficacy and safety results for the Phase I, II and III trials for all authorised vaccines have been submitted to MHRA, sufficient that these vaccines can be authorised for use in the patient populations stated in the Information for Healthcare Professionals/Summary of Product Characteristics for each vaccine. These studies are currently ongoing to follow-up vaccine recipients to collect additional safety data, in the same way that all clinical trials for new medicines follow up their study subjects after the main results of the study have been reported....The estimated dates for the end of completion of the clinical trials are as follows: AstraZeneca Phase I/II Estimated Study Completion Date: November 15, 2021; AstraZeneca Phase III Estimated Study Completion Date: February 14, 2023 ”A full list, inventory, or manifest of the documents, packages, and data sets *submitted to MHRA in support of the Temporary Authorisation under Regulation 174*. A further list, inventory or manifest of the additional documents, packages, and data sets *submitted to MHRA in support of the Conditional Marketing Authorisation*.A further list, inventory or manifest of additional documents, packages, and data sets that have been *submitted to MHRA in compliance with the post-authorisation measures and obligations specified alongside the CMA*. A further list, inventory or manifest of still outstanding documents, packages, and data sets specified in conjunction with the CMA as *post-authorisation measures and obligations, yet to be submitted to MHRA.
FOI 23/074	I would therefore ask to see your scientific evidence on whether Sars Covid 2 strain has been located in humans.I would also like to see the scientific evidence of each vaccine you supported in confirming that it prevents any human from contracting the virus.
FOI 23/075	Please find below my FOI request regarding malicious emails sent to the department.The date range for the request is for 2022. The data shall include a breakdown by individual departments (e.g. separate departments, agencies, or public bodies within the main government agency), if applicable. Where data isn't available for the entire year, please provide the data and timescale it relates to (e.g. X emails over the last 90 days).1. How many malicious emails have been successfully blocked/detected?2. If possible, please provide a breakdown of figures by malicious email type, e.g. spam, malware, phishing, and ransomware.3. What percentage of malicious emails were opened by staff?4. What percentage of malicious links in the emails were clicked on by staff?5. How many email accounts/employees are there within your department?

FOI 23/076	• A copy of the full clinical study report of the IONA study first published on April 13th, 2002, in The Lancet under the title of “Effect of nicorandil on coronary events in patients with stable angina: the Impact Of Nicorandil in Angina (IONA) randomised trial” authored by The IONA Study Group with a corresponding author Prof H J Dargie. (Dargie HJ et al. Lancet. 2002;359;1269-75.) including any and all protocol amendments that may have occurred during the preparation and during the conduct of the study. • The detailed and complete safety data analysis set of the IONA study published – in part – on April 13th, 2002, in The Lancet under the title of “Effect of nicorandil on coronary events in patients with stable angina: the Impact Of Nicorandil in Angina (IONA) randomised trial” authored by The IONA Study Group with a corresponding author Prof H J Dargie (Dargie HJ et al. Lancet. 2002;359;1269-75.) – if not already contained in toto in the full clinical study report. • Identification and manufacturing information of the version of the 10mg and 20mg tablets used in the IONA study (presumably Ikorel®, Sanofi) and the UK SmPC of the respective nicorandil product used in the study that was in effect at the time of the conduct of the IONA study.
FOI 23/077	
FOI 23/078	I’d be interested primarily in any reports submitted for CareFlow Medicines Management please
FOI 23/079	Telecom - Networks questions
FOI 23/080	FOI on pelvic organ mesh
FOI 23/081	Would you be able to provide all records owned by [s40 name] Epidemiology Department) related to this study ? Including :• The latest version of the protocol if the version 2.0 is not the latest• All reports / preliminary reports / manuscript• All numerical / statistical tables• All correspondences (including emails) associated to those tables, reports or any safety issue discussed in this study
FOI 23/082	1) Please provide the minutes of the referenced EWG meeting on Monday 7th June 2021 where cases of myo/preicarditis were presented. 2) Your previous response to my request of 1st November (main response PDF attached) did not detail the EBGM signal detection procedures requested. To clarify, the EBGM is a mathematical algorithm/procedure. I am requesting a precise definition of the algorithm used, sufficiently detailed that someone could execute the same algorithm on an identical set of data and obtain the same result. Note this does not require original computer code, just the mathematical definition with any controlling input parameters other than the data itself
FOI 23/083	under provisions of the Freedom of Information Act, please provide the minutes of the COVID-19 Vaccine Signal Detection meetings during the period March 1 2021 to June 1 2021.
FOI 23/084	Would you be able to provide the list of all unpublished epidemiological studies involving the MHRA done on adverse reactions of vaccines ? Please note that I only request the list of project Ids / title / status, not the content of those studies.
FOI 23/085	Please can you provide the MHRAs Clinical Assessment Report for this product

FOI 23/086	we would like to obtain copies of the safety data submitted to the Agency or its predecessor agency prior to and necessary for marketing authorisation of Ikorel® (nicorandil) 10mg and 20mg tablets by Aventis Pharma Ltd. (market authorisation holder: Aventis Pharma Limited, Date of first authorisation: 12 August 1992; Market authorization number PL 04425/0327) or any other party sponsoring the submission of data for marketing authorisation of Ikorel® in the UK
FOI 23/087	Can you please search in your database for adverse events for the following product/ search term: https://smokefree.de/ • smoke free app • smoke free 23
FOI 23/088	Presuming that [S40 name] wrote to the BAD as he stated he would, where the BAD duty bound to act on information and or inform the MHRA about [S40 name] correspondence? Did [S40 name] raise concerns about Isotretinoin following the death of [s41 name] given that the expert witnesses were in disagreement about the risks of the Isotretinoin? What action did the MHRA take following [s40 name]'s call for an investigation in 2015/15 and did he order a Prevention of Deaths Order? Has any coroner asked for a prevention of death order?
FOI 23/089	I am requesting a full update to your previous response to FOI 22/982 I would appreciate a full comprehensive report back on all the deaths and serious injuries cause by the covid 19 vaccine in Northern Ireland (exactly the way you answered all my questions in the previous FOI 22/982). Deaths and injuries to be listed by age and vaccine manufacturers
FOI 23/090	Please provide information on all medicinal products that have been approved by MHRA to date and that have been included in the Innovative Licensing & Access Pathway, including both new marketing authorisation approvals and variations to existing approved authorisations. Please provide the following information: product name, strength, pharmaceutical form, name of active ingredient, MA number, name of MA holder, dates of MA/variation submission and approval, date of Innovation Passport approval, approved indication(s). This information is requested under the Freedom of Information Act 2000.
FOI 23/091	Questions on Temporary and Permanent Recruitment Information Request
FOI 23/092	Number of Field Safety Notices - medical devices/IVDs/SaMD
FOI 23/093	1. How many people have been reported as killed by any covid-19 vaccine? 2. How many people have been reported injured by any covid-19 vaccine? 3. Please classify these injuries and mild, medium or severe.
FOI 23/094	1) I still request information on how many CBD food supplement companies, between 31/03/21 and 01/11/22, have been enforced against due to making unproven medical claims. I believe this to be one FOI and not related in any way to the other 3 requests.
FOI 23/095	2) Further to this, I would like to request any emails and files between GW Pharmaceuticals and the MHRA between 01/04/2016 and 01/10/2016 in regards to

	'Cannabinoids' or 'Cannabidiol'. I have altered the dates to accommodate FOI requirements
FOI 23/096	3) Subsequently I would like to re-request any emails and files between the Home Office and the MHRA in regards to 'cannabinoids' and 'cannabidiol', to accomodate FOI requirements I would like to narrow the window down to between 01/04/2016 and 01/10/2016.
FOI 23/097	4) Finally, I would request that all files in regards to the TIGRR report between the FSA and MHRA between 16/06/2021 to 01/11/2022. I have removed the Home Office from this request to aid FOI requirements
FOI 23/098	Are the covid 19 vaccines, in particular Pfizer Moderna and AstraZeneca's, subject to the same rigorous testing and safety checks as other vaccines that don't have an EUA licence ? Also are any of the covid 19 vaccines that the MHRA have given Regulatory approval listed as 'prototypes'
FOI 23/099	post mortem results of covid
FOI 23/100	Disclosure Log - List of FOIA requests answered fully or in part since 1 January 2021 including requests where the MHRA holds no information
FOI 23/101	1. The number of ILAP applications made concerning products that contain psilocybin and/or psilocin. 2. The status of all ILAP applications made concerning products that contain psilocybin and/or psilocin. 3. The number of completed and ongoing clinical trials of psilocybin and/or psilocin containing products registered with the MHRA. 4. All data held by the MHRA pertaining to the toxicology and safety profile of any psilocybin and/or psilocin containing products in healthy and clinical populations submitted to the MHRA.
FOI 23/102	• How many incidents of Topical Steroid Withdrawal have been reported to the Medicines & Healthcare products Regulatory Agency? • How many incident were reported in children? (under 18) • How many incidents were reported in adults? (over 18) • How many incident were reported in people under the age of 35? • Please could you provide me with a list of the topical steroid creams that have been reported and the number of reports of Topical Steroid Withdrawal associated with them? • How many incidents of Topical Steroid Withdrawal were reported to the Medicines & Healthcare products Regulatory Agency between January 2022 and January 2023?
FOI 23/103	I refer to the above subject and to a paper published by MHRA 2 February 2023 setting out a framework for the development of antiviral drugs and monoclonal antibodies. A copy of the paper is attached hereto.I note reference - on page 7 - to evidence that some methods to propagate the virus have led to additional mutations and also reference to pseudo-virus assays. To further clarify the position, I would be grateful if you could arrange to provide me with the following information from MHRA records.*Details of the current MHRA process for approving new antiviral drugs and monoclonal antibodies to ensure safety and efficacy.*

FOI 23/104	please can you tell me how many of the first 1400 yellow card reports relating to COVID vaccinations were followed up, that is that you contacted the person making the report requesting further information.
FOI 23/105	You have defined a set of Conditions of Authorisation for Vaxzevria. I would be grateful if you could provide several of the plans/reports/data you now hold in satisfaction of those conditions. Specifically:1. The final report for a non-clinical study to test in-vitro expression of the S protein of Vaxzevria to elucidate the possible mechanisms of platelet activation after vaccination and to identify the possible triggers.According to your web site (Conditions of Authorisation for Vaxzevria) this document was due publication on 31 July 20212. Submission of a plan in RMP, timelines and protocols to further characterise the thrombosis and thrombocytopenia syndrome associated to the vaccine and elucidate its mechanism, the MAH should conduct suitable clinical studies. These documents were due publication on 31 Aug and 30 Sep 2021.3. 6-month and validated follow-up immunogenicity data of the COV trials to evaluate antibody persistence. This data was due publication on 31 July 2021.4. Updated data from the COV002 study to further evaluate vaccine efficacy against transmission. Due 31 Jan 2022.5. Data on breakthrough cases to investigate potential correlate(s) of protection.5a. This report was due publication on 31 July 2021; both the 27 January and 27 June 2022 updates of your web site page (Conditions of Authorisation for Vaxzevria) showed this publication date.5b. Was this an error in reporting to the public or are you withholding the report? If it was an error and the MAH was authorised to delay publication for at least 11 months, please supply communications and/or minutes of a meeting showing when and how this decision was made.I am requesting the information you hold on AZ Vaxzevria Trial D8111C00004 (UK) apparently referred to in the November 2020 EMA RMP v1 as "ESR 21-21121 [UK] Ph IV Enhanced Active Surveillance"I note a change in Version 4 of the EMA RMP, dated December 2021, removing D8111C00004 (UK) (and D8111R0003(EU) and D8110R00001 (US)) "due to recruitment challenges for study D8111R00003 (EU)" This followed a decision to that effect by the CHMP in November 2021. Though removed as 'requirements' in December 2021, by that date there should have been the following material in place: - Study Design Concept (11 Dec 2020).- Study Protocol (28 Jan 2021),- First interim report Q3 2021.Please provide copies of these documents as well as confirmation that the study began on 8 June 2021 and what organisation led the work. Please confirm whether the trial was terminated and, if so, when. If the trial continued, please confirm what organisation leads the work, what results are (will be) available and when.
FOI 23/106	Please advise what testing was carried out by the MHRA prior to the Covid 19 Vaccinations being approved for use. Additionally, please provide any links to the test data carried out by the MHRA.
FOI 23/107	Can we please ask the same question with the end date of 23.2.23 And 2. For all age ranges please If there is a link to where these resources are available from that would be helpful and save your valuable time
FOI 23/108	1- Stability data reports from Pfizer and MHRA and NHS England 2- Original expiry dates and any extended expiry dates 3-Cold chain logs from arrival in UK Port up to 30 Feb 2022 4 Transport logs , what was the original arrival port and other destinations prior to Salford?
FOI 23/109	I would like to know which are the legal condition imposed for the compassionate use of Remdesivir on hospitalised patient, condition stipulated at the signing of the agreement between the UK government and the Gilead Sciences, Inc. considering that the antiviral Remdesivir received a conditional approval for use. The antiviral Remdesivir could be in any circumstances used on hospitalised patients

	without the informed consent of the patient? knowing that this drug is experimental with no benefit on treating any
FOI 23/110	we would like to obtain a copy of the drug-to drug interaction(DDI) and absorption, distribution, metabolism and excretion (ADME) data (i.e., pharmacokinetic and pharmacodynamic studies) submitted to the Agency around 1992 for marketing approval of Ikorel® 10 mg and 20mg tablets by Aventis Pharma Ltd., UK (now Sanofi, Date of first authorization: 12 August 1992; Market authorization number PL 04425/0327).
FOI 23/111	This email represents a request under the terms of the Freedom of Information Act 2000 and is related to the study "Meningococcal B vaccine: incidence of convulsion following vaccination and compliance with timing of vaccine doses in the UK" done on the CPRD
FOI 23/112	Contact Centre, CRM, and AI & Automation
FOI 23/113	Post-Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine Date of Approval : 04-10-2021 Application Number : 21_000535
FOI 23/114	Please provide me with a copy of an electronic listing (preferably csv format) of all inspections conducted since November 1, 2022. Please include the following fields: case_number, inspection category, site operator number, site operator, inspection site id, site name, address, inspection start date, inspection end date, count of critical deficiencies, count of major deficiencies, count of other deficiencies.
FOI 23/115	Under the Freedom of Information act is it possible to have a redacted copy of the last inspection report for: Surepharm Services Ltd. Bretby Business Park, Ashby Rd E, Bretby, Burton-on-Trent DE15 0YZ
FOI 23/116	Cpap Devices reports - Re NatPSA/2021/005/MHRA
FOI 23/117	For all Yellow Card reports relating to covid-19 vaccines, a) how many have you followed up with colleagues in primary, secondary or tertiary care to request further information? b) how many of these follow ups have gone unanswered from primary, secondary or tertiary care?
FOI 23/118	1. Telephony and UC/ Collaboration a. Please confirm the manufacturer of your telephony system(s) that are currently in place b. When is your contract renewal date? c. Who maintains your telephony system(s)? d. Do you use Unified Communications or Collaboration tools , if so which ones? 2. Microsoft

FOI 23/119	More specifically, please provide the number of reports of adverse reactions in Scotland to the Covid-19 vaccination by the Yellow Card scheme during the period from 6 January 2022 to date (or as close to the present date as is possible). Kindly break the data down into brands of Covid 19 vaccine and dose type (1st dose, 2nd dose and so on).
FOI 23/120	I would like to make a freedom of information request for the following information/data held, stored or utilised in any way by the MHRA. If the MHRA do not have or use such data, please specify.The volume of codeine linctus manufactured for uk market from the year 2000 to 2023 including the following preparations.Bells codeine linctus pl 03105-0063.Care codeine linctus pl 00240-0099.Pinewood codeine linctus pl 04917-0001.Thornton&ross codeine linctus pl 12965-0009.Galcodeine Linctus 2 litre.Any other licensed sugared or sugar free codeine preparation.The volume of codeine linctus obtained by uk wholesalers for uk market from the year 2000 to 2023 including the following preparations.Bells codeine linctus pl 03105-0063.Care codeine linctus pl 00240-0099.Pinewood codeine linctus pl 04917-0001.Thornton&ross codeine linctus pl 12965-0009 Galcodeine Linctus 2 litre Any other licensed sugared or sugar free preparation.The volume of codeine linctus distributed from the wholesalers for uk pharmacy retail market (including hospitals as separate number) from the year 2000 to 2023 including the following preparations.Bells codeine linctus pl 03105-0063.Care codeine linctus pl 00240-0099.Pinewood codeine linctus pl 04917-0001 Thornton&ross codeine linctus pl 12965-0009 Galcodeine Linctus 2 litre Any other licensed sugared or sugar free preparation.The volume of codeine linctus purchased in the uk by the public from retail pharmacies from the year 2000 to 2023 including the following preparations.Bells codeine linctus pl 03105-0063.Care codeine linctus pl 00240-0099.Pinewood codeine linctus pl 04917-0001.Thornton&ross codeine linctus pl 12965-0009 Galcodeine Linctus 2 litre Any other licensed sugared or sugar free preparation.Details (quantitive) of wholesalers or pharmacies referred from any agencies (eg GPHC) to the MHRA regarding erroneous purchase volume of any preparations of codeine linctus. From the year 2000 to 2023.Number of pharmacies referred from any agencies for any investigation (pharmacy standards or fitness to practice) with reference to erroneous codeine preparation ordered or sold via wholesalers between the years 2000 and 2023.Number of pharmacist including superintendents pharmacists referred for any type of investigation split by gender and race for erroneous Codeine Linctus purchases and sales between 2000 and 2023. Please list and link the details of this data as follows;Number of Pharmacist, Responsible Pharmacist or Superintendent, Gender, Race, Quantity of Codeine Linctus Purchased, Quantity of Codeine Linctus Sold, Outcome of Investigation, Details of resulting sanctions following investigation).Number of retail pharmacies registered to purchase and sell codeine Linctus between the years 2000 to 2023 in the UK.Number of retail pharmacies that do not sell Codeine Linctus in the UK between the years 2000 to 2023.Number of adverse events to humans and to what extent, in relation to to the use of specifically Codeine Linctus between the years 2000 to 2023, in the UK.
FOI 23/121	The annual report also shows separate data for "Hospital Doctors" and "Physicians" which I dont understand As a start would you be able to provide annual data from 2010 for all reports by a) doctors according to their declared specialty, including Psychiatry/psychologist, which I appreciate are counted as one specialism? and b) the general public?
FOI 23/122	The number of packs of AndroFeme® 1 (Cream containing 1% w/v (10mg/mL) Testosterone) imported into the UK in 2020, 2021 and 2022.

FOI 23/123	I understand that Livingstone, an online platform by Pharmatelligence Limited/Human Data Sciences, incorporates CPRD data as well as linked hospital data for their users to access directly via the Livingstone platform. Under what license and what terms of use has the CPRD and linked hospital datasets been made available to Human Data Sciences?
FOI 23/124	I am requesting Vaccine Analysis Print (VAP) for the swine flu vaccine Pandemrix. The print must contain information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme.
FOI 23/125	I wish to submit to the organisation a freedom of information request relating to the organisation's ICT contracts, specifically around: 1. contact centre contract(s) 2. inbound network services contract (s)
FOI 23/126	Connectivity and Network Servicesa. Who provides your WAN and internet connectivity and the annual spend on each b. Who provides your SIP trunks and what is the annual spend c. Who provides your WAN services, is this MPLS, SD WAN or Internet, and what is the annual spend d. Who provides your LAN infrastructure and what is your annual spend e. Who provides your WIFI infrastructure and what is your annual spend f. Please confirm the manufacturer(s) of your wired network core and edge switching?
FOI 23/127	would you be able to provide all correspondences (emails, letters, faxes) related to the FOI Request FOI 23/113
FOI 23/128	This email represents a request under the terms of the Freedom of Information Act 2000 and is related to the project described below : Non-specific effects of vaccination in England Application Number : 16_253 done on the CPRD (Clinical Practice Research Datalink) provided by the MHRA with the support of the NIHR involving : [s40] London School of Hygiene & Tropical Medicine (LSHTM) [s40] London School of Hygiene & Tropical Medicine (LSHTM) [s40] London School of Hygiene & Tropical Medicine (LSHTM) [s40] Health Protection Agency - HPA
FOI 23/129	Please provide all data regarding covid vaccines that the MHRA received directly from: Pfizer/BioNTech Moderna AstraZeneca a) at year prior to the annual renewal of the conditional marketing authorisation and b) prior to full licensing being granted.
FOI 23/130	are you going to approve Esaxerenone soon please?

FOI 23/131	Under the 'Freedom of Information Act 2000' I request disclosure of the following relating to the Pfizer-BionTech BNT162b2 and these Comirnaty products: - Comirnaty 30 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0002); - Comirnaty 30 micrograms/dose Dispersion for Injection (PLGB 53632/0004); and - Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0006). 1. All documents up to the product licencing of Comirnaty and ongoing monitoring (studies) relating to the MHRA's assessment of the risk of and/or presence of micro-RNA sequences (miRNA) comprised within the mRNA active ingredient (mRNA genomic sequence).
FOI 23/132	Stesolid rectal tubes 5 mg and 10 mg - PL 20075/0680-81 clinical overview - PL 04543/0364
FOI 23/133	Details of information required: All MHRA pharmacovigilance inspection reports for the period 01 Dec 2021 to 01 Feb 2023 from any company. This can be restricted to those inspections with major and/or critical findings.
FOI 23/134	With regards to the below recently authorised Beclometasone Dipropionate and formoterol fumarate containing product by Lupin Healthcare (UK): • Luforbec 200/6 micrograms per actuation pressurised inhalation solution (PL 35507/0205) In accordance with the FIO Act, I would like to request a copies of the associated Quality Overall Summary (Module 2.3), Clinical Overview (Module 2.5) and Clinical Summary (Module 2.7).
FOI 23/135	I am looking for adverse reactions of the child 6 in 1 vaccine and MMR vaccine reported from 2020-2023 please
FOI 23/136	I would like the organisation to provide me with the following departmental documents around ICT and corporate procurement. Many organisations within your region have different document title names: 1. 2023/24 IT Department Documents ;- these types of documents have detailed information on the department's future plans and strategies. These documents could include: ICT Strategy/Plan, ICT Department Plan, ICT Financial Plan 2. ICT Org Chart ;- with names and job titles 3. Corporate Procurement Strategy that covers 2023/24 and more. For all the documents I have requested, please provide me with the 2023/24 documents, I only want to only receive documents that are live and valid. If the document is a strategic

	plan (e.g. 2020-2025) that covers a set number of years, please provide me with the 2023 version.
FOI 23/137	Pleas provide me with copies of the Ministerial reports on Reg 174a authorisation of vaccines authorised for temporary use and not marketing authorisations for 2021 and 2022
FOI 23/138	In the event that the below triggers a cost exemption, please provide as much information as possible, working down from the top points. - Copies of communication between the MHRA and 'elfbar' between 1 January 2023 and 14 February 2023 - Copies of communication between the MHRA and the UKVIA between 1 January 2023 and 14 February 2023 - Copies of communication between the MHRA and the IBVTA between 1 January 2023 and 14 February 2023 - Copies of communication between the MHRA and 'flavour warehouse' between 1 January 2023 and 14 February 2023
FOI 23/139	I'm writing this email to make a Freedom of Information (FOI) request for "Darzalex (daratumumab)" with PL number "PLGB 12345/0002". Requesting document is listed below and please let me know if you need additional information.
FOI 23/140	I'm writing in regards to receiving information on an originally approved SmPC for DUODOPA, attached, to determine the studies and original indication approved for this drug product. Are you able to assist me with this query, or re-direct me to a more appropriate channel to get this information?
FOI 23/141	My enquiry is regarding SJS/TEN reported cases from all the Covid-19 vaccines from the 14th July 2021 up to the present day, 15th February 2023.
FOI 23/142	Good Morning, I would like to request the clinical trial safety data for the Glaxosmith Klein Infranix hexa 6 in 1 vaccine given to new born babies and Vaxelis 6 in 1 vaccine also given to new born babies. I've searched through your website, the NHS website and the manufacturers website, but cannot find anything related to clinical trials, could you let me know if clinical trials were actually conducted and if so provide the raw data from those trials.

FOI 23/143	Under the 'Freedom of Information Act 2000', I request disclosure of the following, in an anonymised format:a) the number of Yellow Card reports associated with AstraZeneca, batch AB0002. b) Of these reports, i) how many were in relation to a suspected fatal adverse reaction and ii) how many were in relation to heart failure.
FOI 23/144	This email represents a request under the terms of the Freedom of Information Act 2000 and is related to the project described below : Herpes zoster vaccine and the risk of Bell's palsy and Guillain-Barre Syndrome in the UK Date of Approval : 22-05-2019 Application Number : 19_097 done on the CPRD (Clinical Practice Research Datalink) provided by the MHRA with the support of the NIHR involving : [s40 names]
FOI 23/145	I am wanting to know if you have any plans to license Apo Varenicline in the UK? Since Pfizer stopped producing Champix this is the new generic one currently available, unfortunately only in Canada and Australia.
FOI 23/146	Further to FOI 22/817, could you: A: provide updated figures for adverse events for Isle of Man postcodes for ALL brand Covid-19 vaccines to date, and updated DAP attachments for each vaccine to the current date. B: provide the ages of those who reported the adverse events C: provide information on the number of vaccinations (1st, 2nd or booster, etc) of the people reporting, and the time after that the adverse event occurred. D. specify which batch numberper brandwas most reported with an adverse event E. provide the dates isle of man yellowcard information was sent to or requested by the Isle of Man government, any medical services including nobles, manxcare, DHSC and state which department
FOI 23/147	I would like to submit a freedom of information request for copies of MHRA inspection reports carried out on ITH Pharma Ltd from 01/07/2014 to 31/10/2014
FOI 23/148	Could you kindly advise if any adverse events have been reported to the Medicines & Healthcare Products Regulatory Agency in relation to Wismed CC's Medical Device Peditrol (Code URO 041
FOI 23/149	1. A copy of the assessment of conformity produced for [S40 name] cranioplasty plate; 2. A copy of the device registration documentation provided to the MHRA; 3. A copy of the statement produced to comply with the requirements of the UK MDR 2002; 4. Confirmation as to whether an adverse incident was reported to the Medicines and Healthcare Products Regulatory Agency in respect of the cranioplasty plate; and

FOI 23/150	Please could you confirm whether Pfizer Vaccine BNT162b2 complied with the CONDITIONS OF AUTHORISATION UNDER REGULATION 174 in full? Yes or no. Please provide evidence that each of the requirements outlined in this document https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fpublications%2Fregulatory-approval-of-pfizer-biontech-vaccine-for-covid-19%2Fconditions-of-authorisation-for-pfizerbiontech-covid-19-vaccine&data=05%7C01%7CMHRACustomerServices%40mhra.gov.uk%7Cfb389a86081341c32a9208db0fec9aa7%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638121282019528632%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C2000%7C%7C%7C&sdata=6nPeokBkS%2Bo0AqPItJ8k6%2FQqlG%2FaNwndcaHXC%2BGl6w4%3D&reserved=0 was compiled with.
FOI 23/151	I would like this information for the period from 1 April 2021 to 20 February 2023. Contact would primarily include attending or arranging meetings or functions, and responding to correspondence or phone calls. Please break down the information by:• Tobacco company or representative's name• Date of contact(s)• Type of contact (meeting, email, letter, phone call, text/app message or video call, e-card or any other form of electronic communication) • Place of contact, if relevant • Purpose of contact • Outcome of contact, including if no action taken
FOI 23/152	Product: Ciclesonide (Alvesco) - Inhalation aerosol for the treatment of asthma - PL 52811/0007 (80mcg) and PL 52811/0008 (160 mcg) We write with a request for information under the Freedom of Information Act 2000 in respect of any generic or hybrid marketing authorisation applications identifying the above product as the reference medicinal product. Please would you provide the following details in respect of any such generic or hybrid marketing authorisation applications: • date of filing • applicant's name • strengths, dosages and indications (label) • basis of those applications (e.g. whether they are based on in vitro and/or in vivo studies) • procedure being used • status and progress, including any reasons for delays.
FOI 23/153	In early January 2022 The MHRA, NHS England and NHS Improvement told pharmacy led vaccination sites that Pfizer-BioNTech mRNA COVID-19 Vaccines post-thaw expiry dates could be safely extended from 31 to 45 days. Please can you confirm what evidence was used to support the safety of this change to vaccine storage, handling and delivery protocol? Particular in relation to unfolding/unlocking spike proteins. In addition, please can you confirm the following batches were affected by this policy change: FK9712, FN5254, FL9994, FM3802, FN3543, FK0112, FK9706, FH3220,

	FN1664, FF8288, FM3092, FH4751, FK9707, FK0596, FG3712, FK9413, FN4817, FH0114, FF3319, FL1939?
FOI 23/154	let me know if Vertex have made an application with the MHRA to extend their licence to include one year olds ?
FOI 23/156	I am requesting the following information about the consultation on the proposal to make Aquiette 2.5mg Tablets (oxybutynin hydrochloride) available from pharmacies: • Please provide all minutes of meetings held as part of the consultation process since it opened in April 2022; • Please provide a copy of all responses received during the consultation period (23 April 2022 - 13 May 2022)
FOI 23/157	I would like to ask if there is an available RMP/sRMP (approved in UK) for Venofer. Please provide me with the document if possible (or at least please let me know about current list of safety concerns).
FOI 23/158	Covid vaccines safety - follow on to FOI 22/105
FOI 23/159	1a) Is the MHRA maintaining a database of research that has highlighted potential vaccine safety issues? If you do have such a database, can you please share it with me.b)Has the MHRA seen the research below or any other research that highlights potential vaccine dangers?Notes: A number of studies have highlighted potential vaccine safety issues: e.g. here, here, here and here. 2a) Is the MHRA maintaining a database of people in the UK who have suffered health problems after being vaccinated? If you do have such a database, can you please share it with me, with personal details anonymised.b)Is the MHRA in contact with individuals who have suffered health problems after being vaccinated, to give them support and monitor the progression of their health issues?3a) Has the MHRA conducted any clinical research (not statistical) to confirm how many adverse effects reported to the Yellow Card scheme since December 2020 were caused by the vaccines and not just incidental? b)Can you please share all the research from the MHRA's investigations into these vaccine safety issues/adverse effects?(E.g. the UKHSA has a research portal where I can access all UKHSA-funded research)4a) Can you explain how the MHRA reviews post-vaccination fatalities?b)Can you share all these reviews of post-vaccination fatalities since January 2021?Notes: In this document, the MHRA says it undertakes a thorough review of reports with a fatal outcome after vaccination.5a) Does the MHRA believe single studies that have not yet been independently replicated can be relied on to determine vaccine safety and efficacy?Notes: The clinical trials conducted by Pfizer, AstraZeneca, Moderna, Johnson&Johnson, Novavax, and Valneva to my knowledge, are single studies that have not yet been replicated. b)Does the MHRA believe observational studies (not randomised and controlled) can be relied on to determine vaccine safety and efficacy?Notes: In the Yellow Card summary for December 2022, three observational studies are cited as evidence for the safety of the vaccines in pregnancy (footnotes 4,5,6).c) These studies only consider the impact of vaccination on miscarriage, stillbirth, preterm birth. Can you share the evidence that confirms these vaccines won't cause any other health issues over a number

	of years in children born to vaccinated mothers? The placenta theory is often cited as an answer to this question, but can the MHRA confirm that this theory won't be proven wrong in the coming years?6a) Can you please give me a full list of all the types of clinical trial documents that were submitted by Pfizer, AstraZeneca, Moderna, Novartis, Johnson&Johnson, and Valenva to the MHRA for review for the COVID vaccines they produced? Notes: Namely: case report forms, clinical study reports, certificate of analysis, protocol, statistical analysis plan, informed consent form, serious adverse event narratives, electronic individual participant data, investigational medicinal product dossier, investigator's brochure. I can see that the MHRA has published the Public Assessment Report for these vaccines. But I can't see any other data.b)Of these documents (or any others not named here) which ones were reviewed by the MHRA before giving approval to these vaccines?c)Can you tell me when all these documents will be published online by the MHRA?7a) Can you confirm when Phase 4 trials for these six vaccines concluded/are due to conclude?b)Can you share any documents for the trials that have concluded.
FOI 23/160	Under the conditions of Freedom of Information - could I request a copy of the MHRA inspection report carried out on ITH Pharma Ltd on 18th April 2012.
FOI 23/161	I would like to kindly ask you whether you dispose of any information on the list of safety concerns and on additional pharmacovigilance activities or additional risk minimization measures (if applicable) for the medicinal product Zovirax IV by GlaxoSmithKline that is registered in the United Kingdom? Is summary of RMP available for this product?
FOI 23/162	May I please request the following information concerning safety event reporting data, and could you please treat this as a request made under section 1 of the Freedom of Information Act 2000.1. In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 how many notices of a safety issue which meets the applicable definition of an 'emerging safety issue' have been received by the MHRA from Marketing Authorisation Holders for those vaccine products? And of those notices received by the MHRA how many are known to have been received more than 3 working days after the reported date of establishment of that emerging safety issue (i.e. late-filed notices)?2. In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 how many validated signals have been notified to the MHRA by MAHs by means of:(a) a product information and/or RMP variation application or equivalent?(b) inclusion in a PSUR?(c) a standalone signal notification (including any signal also notified in a PSUR but which has been separately notified as an 'important risk')?3. In relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023, on how many occasions has the MHRA been notified of the initiation of a safety referral procedure that affects any such product?4. As part of pharmacovigilance procedures in relation to the Covid vaccine products currently authorised for use in the UK, in each calendar year from 2020 to 2023 on how many occasions has the MHRA received from MAHs notice (of any kind) of a suspected adverse event expressed to have been triggered by one or more members of the public reporting a suspected adverse event via social media?5. In relation to the Covid vaccine products currently authorised for use in the UK, in the period from January 2020 to 2023 on how many occasions has the MHRA commenced either (i) a major safety review or (ii) any other safety review which falls short of a major safety review in response to a new safety signal or to support effective risk minimisation?If it is possible to do so, please provide any or all of the above data broken

	down by reference to each authorised vaccine product; but if it is not possible to break it down in that way, whether as a practical matter or (in your view) as a legal matter, please then nevertheless provide the aggregated data for all such products.
FOI 23/163	With regard to the Emerade adrenaline autoinjector, from the time of its registration/launch in 2014 through to its recent market reintroduction in Oct 2021 (post recall in early 2020), could you tell me if the MHRA has ever received any reports from the marketing authorisation holder (Bausch & Lomb) or any other (previous) MAH, or any complaints from patients or member of the medical or pharmaceutical profession, regarding problems or difficulties with opening or accessing the outer plastic packaging/tube.If so, could you disclose the details of any such report and any consequent changes to the design of the outer packaging, notified to the MHRA by the MAH. This request is made under the Freedom of Information Act 2000.
FOI 23/164	Near real time vaccine safety monitoring for COVID-19 vaccines Date of Approval : 18-10-2020 Application Number : 20_000065 involving : [s40 names] Would you be able to provide all versions of the protocol for this study ?
FOI 23/165	Minoxidil RMP+Risk Minimisation
FOI 23/166	adverse biological effects of vaping are associated with a rise in the reporting of adverse reactions as more people vape, requiring data between 20th May 2016 and 13th January 2022. I have the amalgamated table from page 83 of the Nicotine vaping in England:an evidence update including health risks and perceptions, 2022, but would really like to see a breakdown of adverse reactions by year, to see how and if it has increased? I am aware there is little good evidence of the effects of long term vaping on people who have never smoked, but that it remains a better option for smokers.

FOI 23/167	Details of the prompt actions taken by the MHRA following the Danish health authority suspending the Astra Zeneca vaccine's use for all age groups on 11 March 2021 (pending a detailed analysis) beyond the advice given by Dame June Raine on 18 March 2021. For example, the Danish Ministry sent a letter to every person who had received AZ in the previous 14 days, telling them what symptoms to look out for and when to contact their doctor
FOI 23/168	Case ref 1357 - vaccine adverse reports yellow card
FOI 23/169	we would like to obtain copies of the safety data submitted to the Agency or its predecessor agency prior to and necessary for marketing authorisation of Ikorel® (nicorandil) 10mg and 20mg tablets by Aventis Pharma Ltd. (market authorisation holder: Aventis Pharma Limited, Date of first authorisation: 12 August 1992; Market authorization number PL 04425/0327) or any other party sponsoring the submission of data for marketing authorisation of Ikorel® in the UK. In particular, we would like to obtain copies of the following records in full
FOI 23/170	Documents requesting for freedom of information (FOI) of the product name 'Darzalex'
FOI 23/171	Would you be able to provide all PSURs/PBRERs and monthly reports submitted by the Marketing Authorization Holder of the product "COVID-19 mRNA Vaccine BNT162b2" since the beggining of the roll out in december 2020 ? Would you also be able to provide all PSUR/PBRER rapporteur' assessments if those documents exist
FOI 23/172	Would you kindly advise when Enhertu medicine will be approved in the UK?
FOI 23/173	I hereby submit an official FOI request for information regarding child injuries and deaths from covid vaccines administered in Berkshire.
FOI 23/174	Is the drug gefapixant approved for use in the UK
FOI 23/175	I am seeking records of correspondence TO the MHRA, notifying the agency about suspected or proven overfilled (i.e. exceeding the maximum 2ml permitted by regulation) disposable vape devices, over the last three years (January 2020 to present).I do not require the full correspondence TO the MHRA nor the sender. Just the date of receipt to the nearest month.I also seek correspondence FROM the MHRA to those who have notified it about over 2ml disposable vape devices on the UK market.Further, I am seeking to know what, if any, action the MHRA took in response to those warnings.

FOI 23/176	With reference to your reply, may I request the MHRA release the following documents:1.The FastQ files submitted to the licensing assessment team for their evaluation to support compliance with the 'identity' test parameter associated with BNT162b2 as part of the prior approval process? If this request is refused for any reasons, including confidentiality, I request release of the files in redacted form, and/or documentation confirming the licensing assessment team had receipt of these files.2.Documentation held by the MHRA demonstrating FastQ data are available at batch release & QC testing sites for MHRA to inspect if requested. The MHRA has already confirmed they're not in receipt of these files, however, documentation must exist for the MHRA to confirm such files are available for inspection. I therefore request this documentation. If this request is refused for any reasons, including confidentiality, I request release of documents in redacted form.I would also welcome clarification from the MHRA regarding three key points they made.POINT 1 I wrote."Every single one of those 4,284 nucleotide bases of the BNT162b2 RNA active substance must be aligned in the correct sequence order, starting with the very first base and ending with the final 4,284th base. This sequence is essential to guarantee in-vivo function as designed". The MHRA replied with the statement "This is not fully agreed". I must admit to being extremely surprised by this answer! To reiterate my point and its importance, just one nucleotide mutation could easily render the drug substance useless. For example, at the amino acid level, there are two proline changes in BNT162b2 necessary to fix the S1S2 spike protein in its pre-fusion conformation. A single mutation in either of the two proline codons would more than likely result in the complete loss of pre-fusion conformation and failure of the drug product. Similarly, every single base has been optimised to ensure specific function and a single mutation anywhere has potential to disrupt in-vivo function. How can the MHRA not fully agree that the active drug product should be what it is claimed to be, irrespective of whether it is a biological or small molecule product?POINT 2 The MHRA state"Validation of any proposed analytical methods must be demonstrated as part of the control testing. The routine quality control test methods of the drug substance proposed for release are considered critical to ensure the necessary quality standards are met, but they may not necessarily be the only tests performed on a drug substance. For a complex product like this vaccine, orthogonal techniques and extended characterisation techniques were employed throughout the development of the product, and these were subjected to regulatory evaluation, which also provided additional information about the product with respect to its characteristics."
FOI 23/177	1) I am requesting the total number of suspected deaths from the covid 19 vaccines in Northern Ireland from the start of the rollout to the present day ?Previous figures supplied by yourselves were:Pfizer 12 AstraZeneca 35Moderna *Brand Unspecified 0 2) I am requesting the total number of non-serious and serious including fatal figures in Northern Ireland from the start of the rollout to the present day ?Previous figure supplied by yourselves had a one total figure for Pfizer in table 5 now you have supplied 2 different figures for Pfizer and it is a bit confusing.Please can you supply the information I have requested in the same format as the September 2022 response.Total number of deaths from the start of the rollout until present day by vaccine manufacturers and then a separate box chart whereby these numbers are split into age groups.Total number of serious injuries from these vaccines from the start of the rollout until present day by vaccines manufacturers and then a separate box charts showing same by age group.
FOI 23/178	I would like to submit a request under the Freedom of Information Act (FOIA) regarding all correspondence the MHRA has had directly with Elf Bar. Please could you provide me with the following:A summary of all correspondence from/to ELFBAR in writing or by email between 13th May 2022 and 9th March 2023.A summary of all correspondence from/to IMIRACLE (SHENZHEN) TECHNOLOGY CO., LTD in writing or by email between 13th May 2022 and 9th March 2023.

FOI 23/179	Please provide me with all internal communications, including emails and letters, from the following (Listed below). Please also include MHRA responses to these communications.Matt Hancock Chris Whitty Patrick Vallance
FOI 23/180	I would be grateful for documentary evidence, by return please, that this plan (now being brought forward) predates my request. Please provide proof that the intention to publish predates the date of the request (ie. before 5 January 2023).
FOI 23/181	I am happy to refine the request to the period 1st November 2022 - 1st January 2023.
FOI 23/182	Please can you provide the total number of Adverse Drug Reaction (ADR) reports associated with all COVID-19 vaccinations from the Isle of Man (postcode IM1-IM9) up to the current date.
FOI 23/183	Please disclose all versions of Section 3.2.P.1, Description and Composition of the Drug Product, ever filed with the MHRA for all COVID-19 vaccines . This request covers all such products approved for use in the UK: Moderna, Pfizer/BioNTech, Novavax, AstraZeneca, Janssen, and Valneva.For transparency, please ensure these are provided in fully unredacted form, including Table 3.2.P.1-1, Composition of the Drug Product. The public interest case for this data is to publicly demonstrate compliance with Schedule 8 Part 2 of The Human Medicines Regulations 2012, as concerning the contents of the Summary of Products Characteristics (SmPC). [1] Under Section 14(2) of the FOI Act, a “reasonable interval has elapsed” [2] since my earlier 2021 FOI request [3] to access the composition tables, and so I am now re-requesting these documents and extending the request to all COVID-19 vaccines presently authorised for use by the MHRA.
FOI 23/184	Would you please give an update with regards to Indivior's application to licence Sublocade or RBP-6000 (alternative name is sometimes Subutex Pro) for use in the UK and if these licences have been granted, if not, when are they likely to be granted? If they have been declined, what is the reason for declining the application?Please answer in detail with as much information as you can disclose with regards to these questions.If there are some parts you cannot answer please answer all of the parts you can answer.
FOI 23/185	Request for assessment checklists EU TF mesh.msg.pdf-Deze documenten zijn tot 20 maart 2023 12:11 beschikbaar om te downloaden.
FOI 23/186	We request the following:1. Please confirm the date and value of every unique contract entered into by the Medicines & Healthcare products Regulatory Agency ("MHRA") with Innova Medical Group Inc. between 1 June 2020 and 13 March 2023. 2. Please provide copies of all contracts entered into between MHRA and Innova Medical Group Inc between 1 June 2020 and 13 March 2023. We are aware from the government contracts finder service.
FOI 23/187	I would like to request an electronic copy of GCP Inspection Report (reference INSP GCP 46562/14920539-0001) for the completed GCP inspection of Health Clinics Limited (Care Oncology Clinic), 76 Harley Street, London, W1G 7HH conducted June and July 2021, Reported 14 January 2022 and closed 19 January 2023 based on Freedom of information (FOI) regulations.
FOI 23/188	With reference to the above subject, I request you to kindly provide the most recently submitted risk management plans (RMP) for Sitagliptin/Metformin Hydrochloride 50 mg/850 mg and 50 mg/1000 mg Film-coated Tablets from the company given below: Janumet® 50 mg/1,000 mg film coated tablets - Merck Sharp & Dohme (UK) Limited PL number: PLGB 53095/0036
FOI 23/189	

FOI 23/190	I am sorry for being a nuisance, but it is possible I could have the data on the breakdown of Yellow card adverse reactions to e cigarettes before 26th March? I would be grateful for the yearly breakdowns by body systems of the adverse reactions associated with nicotine containing vapes
FOI 23/191	I am trying to find on your website the adverse reactions data to the most recent HPV vaccine but I am unable to find it. Could you send me a link to it please?
FOI 23/192	1. The original clinical evidence/clinical trials leading to approval of and demonstrating the efficacy of Lithium in the treatment of bipolar disorder 2. The evidence detailing potential side effects of Lithium 3. The most recent review evidence confirming the safety and efficacy of Lithium 4. Any medicines, drugs, interventions and/or procedures refused for the treatment of bipolar disorder 5. Relating to the above point, reasons for refusal to grant any licences
FOI 23/193	I would like to know how many people have reported buying diet pills online - which are fake or have a banned substance within: a) in 2022 b) in 2021 c) in 2020 d) in the past decade e) in the past 20 yearsI understand you have the Yellow Card Scheme which has collected this data.
FOI 23/194	Please could you provide the eleven independent studies that were conducted for the morning sickness drug Debendox. I would also like to know how many of the Hospitals and Universities that were involved in these studies that were conducted in the UK and USA were funded by Merrell Dow Pharmaceuticals.
FOI 23/195	Please provide the following information in accordance with Freedom of Information Act legislation.The first question is specific to Emergency Use Authorisation (EUA) as opposed to the 2012 legislation.Please provide the conditions that are required to be met by the licensing authority that would signal a pause and reappraisal of the associated COVID-19 messenger RNA (mRNA) vaccines approved under Emergency Use Authorisation (EUA).Please provide copies of MHRA's Safety Audits since the rollout of COVID-19 mRNA vaccines approved under Emergency Use Authorisation.Please provide your updated Age Stratification Risk/Benefit Profile of COVID-19 mRNA vaccines approved under Emergency Use Authorisation.Please provide your risk assessment of widely applied vaccination during a respiratory virus pandemic using an imperfect vaccine that does not disrupt transmission or infection.Please provide a copy of the Genotoxicity studies performed on the mRNA COVID-19 vaccines before their approval and rollout.Please provide your risk assessment of frequent mRNA boosters for COVID-19 disease and adverse effects to the hosts immune system, including Endoplasmic Reticulum (ER) Stress and IGG4 Class Switching.Please confirm if any of the vaccines approved under Emergency Use Authorisation against COVID-19 instruct a person's own body to repeatedly manufacture the spike protein. If so, for how long.Please confirm if MHRA have a Vaccine Crisis Communication Manual in the event of an untoward medical occurrence following immunisation against COVID-19, and as a result could potentially create uncertainty and/or erode the public's trust in vaccines and/or vaccination and the authorities delivering them.

FOI 23/196	Under the freedom of information please could you supply the following information.1 The total amount of deaths for people prescribed with midazolam that had Covid19 stated on their death certificate for the period between March 2020 and June 2020.2 the total amount of deaths for people not prescribed with midazolam that had covid 19 stated on their death certificate for the period between March 2020 and June 2020
FOI 23/197	Under Freedom of Information Act, I would like to request the following information: A list of pharmacies that have an active Schedule 1 License
FOI 23/198	Sareum and this molecule. I am just trying to find out what is going on as this CTA was back in November 22. Any information or insight under the freedom of information regarding the delay would be appreciated.
FOI 23/199	Ethigen Ltd Please provide the information reasonably requested.
FOI 23/201	Please could you supply a copy of the Inspection Report arising from the MHRA GMDP Inspection of the following site conducted on 03/08/2022: ALMAC PHARMA SERVICES LIMITED, WOODHOUSE BUILDING, CHARNWOOD CAMPUS, 8 BAKEWELL ROAD, LOUGHBOROUGH, LE11 5RB, UNITED KINGDOM GMP CERTIFICATE NUMBER : UK MIA(IMP) 20782 INSP GMP/IMP 20782/17799871-0008[I]
FOI 23/202	Please can you supply the link the the Yellow Card data for the 6 in 1 baby vaccination adverse reactions
FOI 23/203	▶ Risk Management Plan (RMP) Body (the latest version) ▶ RMP Annex 7, 10, 11, 12 (Template Rev 1) or Annex 4, 6, 7, 8 (Template Rev 2
FOI 23/204	I should be grateful if you could provide me with copies of the Clinical overview for the following product: • Carbocisteine 750 mg/10 ml Sugar Free Oral Solution in Sachet • PL 17509/0074 • MAH: Esteve Pharmaceuticals (formerly Intrapharm Laboratories Limited) • Authorised March 2015
FOI 23/205	Under the freedom of information act I would like to request all clinical trials details relating to Topiramate and Lamotrigine, please can you confirm that you are able to send me this information?

FOI 23/206	Please also provide: - Confirmed number and names of Childhood Vaccines / Immunisations over the last 70 years (by year) and documents confirming or denying any links to autism. - Confirmed Number of Deaths from each of the above viruses and corresponding Immunisations / Vaccines over the past 70 Years. - Confirm whether vaccine-induced antibodies do not provide true immunity whereas natural acquisition of a disease does provide this? If the vaccine-induced antibodies do provide this, please send through signed documentation and studies confirming this? - Do healthy children actually need to have a vaccine / immunisation as their immune system will be doing this? - Confirmation of what Herd Immunity actually is (i.e. which of these options is correct?): o Comes about only due to vaccines o Combination of vaccines and natural immunity (achieved by getting said virus) o Natural immunity only
FOI 23/207	The Commission for Human Medicine established the Isotretinoin Expert Working Group to look at the isotretinoin. The findings and recommendations were reported back to the CHM in late 2021.Under the Freedom of Information Act please could you provide me with a copy of the full report by email.If this is not possible please could you provide me with the details of the recommendations outlined in the report.
FOI 23/208	I write seeking access to the following information under the FOI Act 2000.I am seeking copies of any communication between British American Tobacco and MHRA dated from 16 January 2023 to 6 February 2023. Additionally, I request copies of communication between this date range if the sender or recipient is referred to as the following;-BAT, -BAT PLC,-British American Tobacco PLC, - BAT p.l.c, - British American Tobacco p.l.c, -Nicoventures.If possible within the time and cost limits of the act, please can you also provide any communication to or from MHRA between these dates containing the phrase ‘elfbar’ or ‘elf bar’.If any of this information is already in the public domain, please can you direct me to it, with page references and URLs if necessary. If the release of any of this information is prohibited on the grounds of breach of confidence or commercial sensitivity, I ask that you supply me with copies of the confidentiality agreement and remind you that information should not be treated as confidential if such an agreement has not been signed. If there is a public interest test associated with the exemption, I ask that you take into account the importance of transparency in how tobacco firms interact with regulators.I am seeking copies of any communication sent and received by MHRA between 16 January 2023 and 6 February 2023 which include references to; -Elfbar, -ElfBar, -Elf bar, -Elf Bar, -Shenzhen iMiracle Technology Co. Ltd
FOI 23/209	I would like to request SDTM + ADAM and TFL from any clinical trial data
FOI 23/210	Please could you provide the guidelines for approval of variant covid vaccines as referred to in the JCVI Minutes of the COVID-19 sub-committee Thursday 11 March 2021 (point 15).
FOI 23/211	Freedom of Information request - Important protocol deviations within 7 days after Dose 2 in BNT162b2 clinical trial
FOI 23/212	
FOI 23/213	Please release the following documents relating to the product "Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection".1) The full nucleotide base sequence for "Davesomeran".2) The conditions attached to this Conditional Marketing Authorisation.3) The Public Assessment Report for this approval.4)

	The date and time the application was made.5) The date and time the application was approved.Please provide the documents for 1), 2) and 3) in PDF format if possible.
FOI 23/214	As to the freedom of information act, can you tell me how many adverse reactions there have been to the covid vaccines? I'm particularly interested in neurological adverse effects.
FOI 23/215	Subject: Overhaul of Trial Regulations.I refer to the above subject and attach hereto MHRA Press Release dated 21 March 2023. I have noted the content and would be grateful if you could arrange to provide me with a copy of the "Regulatory Impact Assessment [RIA]" undertaken by MHRA to support the overhaul of trial regulations.
FOI 23/216	I am writing to request the following information.Have you received complaints about weight loss services offered by online medical services linked to pharmacy chains between 2018-2023?How many complaints have you received?What was the source of the complaints (eg, public, healthcare professional)?What was the nature of the complaints?How many of these complaints have the MHRA investigated?What was the outcome of the investigations?
FOI 23/217	Under the Freedom of Information Act, I would like to request the following information: All correspondence between the MHRA and NuVasive, regarding the MHRA's investigation and list of conditions for the Precice IMLL, since the devices recall in January 2021 to present day. All correspondence with equivalent regulatory bodies in the EU or the USA, regarding the approval of the Precice IMLL, since the devices recall in January 2021 to present day.
FOI 23/218	Re: FOIA request - MHRA Managing Medical Devices - Guidance for health and social care organisations - January 2021 On p.5 of the above mentioned MHRA guidance for health & social care organisations, downloadable on GOV.UK it is stated: “The management structure for medical devices should have clear lines of accountability up to board level. These lines of accountability should be extended, where appropriate, to include general practitioners, residential and care homes, community-based services, independent hospitals providing services for NHS patients, managed care providers, Private Finance Initiative (PFI) organisations and other independent contractors. It is important to establish who is accountable, and where there is a need for joint accountability arrangements.” Can you please provide clear and complete information as to how and when, and in which cases, it is deemed appropriate for the said lines of accountability to be extended to include residential and care homes.
FOI 23/219	I request disclosure of the following, in an anonymised format: a) the number of Yellow Card reports associated with AstraZeneca, batch PV46671. b) Of these reports, i) how many were in relation to a suspected fatal adverse reaction and ii) how many individual people made these reports.

FOI 23/220	GDP Guidance note 14 requires wholesalers to obtain evidence that a clinical need exists before a special is supplied.In the period Jan 2021 to Dec 2021 inclusive, can you please provide me with the names of all wholesalers who were given a defficiency in their post inspection letter in relation to their processes for gathering evidence of the clinical need.If this period is too long and exceeds the time limits for FOI requests, i am happy for you to limit it to a period which does satisfy the time limits. Please start the period in Jan 21.Please include the text from the post inspection letter which describes the defficiency in question.
FOI 23/221	Attached is what you list for FSCAs issued after 2020, if I could have something similar for the period of 2007-2020.
FOI 23/222	I request you to kindly provide the most recently submitted risk management plans (RMP) for Procyclidine Hydrochloride 5 mg Tablets from the company given below: Kemadrin Tablets 5mg; MA Holder: Aspen Pharma Trading Limited, Ireland PL 39699/0046
FOI 23/223	We are interested to know the MHRA's Annual Budgets from the UK Government for the last 10 years.
FOI 23/224	Is it possible to provide information relating to the below:I'm order to evaluate the pfizer covid vaccine approval did pfizer submitted information relating to the following:- did pfizer provide data that confirms the vaccine stops transmission of the covid19 virus.- did pfizer provide data that showed the distribution and degradation of the spike protein produced by the mrna.- did pfizer provide pharmacokinetic data for the spike protein.- did pfizer provide data on genotoxicity.- did pfizer provide data on any autoimmune response caused by the vaccine.- can you provide an evaluation report or assessment information that mhra conducted to approve the pfizer vaccine.
FOI 23/225	I would like to request under the freedom of information request protocol all information on the Phizer and Moderna safety and ingredients data. I would also like to request the governments contracts with Pfizer, Moderna, Johnson and Johnson and Astra Zeneca.
FOI 23/226	Under the Freedom of Information Act 2000 I request disclosure of the following: How many coroners' Regulation 28 reports have been issued to the MHRA in relation to any of the Covid 19 vaccines: Pfizer-BionTech BNT162b2 and/or Comirnaty, Moderna and/or Spikevax and Oxford/AstraZeneca.
FOI 23/227	We are writing to you due to the update to the Valproate Pregnancy Prevention Program published in December 2022 where it states:"The CHM has advised that no one under the age of 55 should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment. Where possible, existing patients should be switched to another treatment unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risks do not apply."Therefore our questions are:Based on the statement above and the information on your website concerning the new update, what are the reasons for the CHM and MHRA reaching the conclusion that an update was required?Why did the CHM and MHRA feel it necessary to take it as far a ban on new prescriptions and for men and women up to the age of 55years old.
FOI 23/228	The MHRA Public Assessment Report for Vaxzevria identifies at table 9 the vaccine efficacy as follows:I wish to know the total incidence of first SARS-CoV-2 symptomatic or asymptomatic infection occurring prior to 15 days post dose 2 in participants seronegative at baseline.1. Please provide the numbers broken down between the Control group and the AZD1222 group.2. Please also provide the numbers as between the 2 groups broken

	down as per table 9 above, namely:Symptomatic – Primary,Symptomatic – Non-primary,Asymptomatic
FOI 23/229	The following post-authorization records in the possession of MHRA concerning the Pfizer-BioNTech COVID-19 vaccine1 and/or Comirnaty:1) Cumulative Analysis of Post-Authorization Adverse Event Reports.2) Periodic Safety Update Reports (PSURs).The index of the complete file in the possession of MHRA concerning the Pfizer-BioNTech COVID-19 vaccine1 and/or Comirnaty.Information helpful to fulfilling the request: ICAN is seeking an index or other listing of all documents concerning the Pfizer-BioNTech COVID-19 vaccine in MHRA's possession that MHRA relied upon to authorize or otherwise approve or license the Pfizer-BioNTech COVID-19 vaccine. The index should be a complete list of all documents within any existing biologic/vaccine product file.The following post-authorization records in the possession of MHRA concerning the Moderna COVID-19 vaccine1 and/or Spikevax:1) Cumulative Analysis of Post-Authorization Adverse Event Reports.2) Periodic Safety Update Reports (PSURs).The index of the complete file in the possession of MHRA concerning the Moderna COVID-19 vaccine1 and/or Spikevax.Information helpful to fulfilling the request: ICAN is seeking an index or other listing of all documents concerning the Moderna COVID-19 vaccine in MHRA's possession that MHRA relied upon to authorize or otherwise approve or license the Moderna COVID-19 vaccine. The index should be a complete list of all documents within any existing biologic/vaccine product file.The index of the complete file in the possession of MHRA concerning the Janssen COVID-19 vaccine1 and/or COVID-19 vaccine Ad26.COV2-S [recombinant].Information helpful to fulfilling the request: ICAN is seeking an index or other listing of all documents concerning the Janssen COVID-19 vaccine in MHRA's possession that MHRA relied upon to authorize or otherwise approve or license the Janssen COVID-19 vaccine. The index should be a complete list of all documents within any existing biologic/vaccine product file.The following post-authorization records in the possession of MHRA concerning the Janssen COVID-19 vaccine1 and/or COVID-19 vaccine Ad26.COV2-S [recombinant]: 1) Cumulative Analysis of Post-Authorization Adverse Event Reports.2) Periodic Safety Update Reports (PSURs).The following post-authorization records in the possession of MHRA concerning the Vaxzevria [formerly AstraZeneca] COVID-19 vaccine1 and/ or COVID-19 vaccine ChAdOx1 S [recombinant]:1) Cumulative Analysis of Post-Authorization Adverse Event Reports.2) Periodic Safety Update Reports (PSURs)
FOI 23/230	I have read with interest, following a freedom of information document request, the assessment, by the Australian regulatory authority (the TGA), of the Pfizer Covid 19 mRNA vaccine application assessment (attached).Can you please confirm;1. Was the same Pfizer data utilised by the UK MHRA as the basis to support the aurthorization of the use of the same Pfizer covid 19 vaccinations for UK personnel.2. If this is not the case, what data was utilised by the UK MHRA to support the authorization of the use of the Pfizer covid 19 vaccinations
FOI 23/231	I would like to make an FOI request to ask for MHRA data where misoprostol has been attributed to deaths since the beginning of 2020, when used for abortion, please. If it can also include which abortion provider issued it, such as BPAS or Marie Stopes, that would be helpful too please.
FOI 23/232	I would like to submit an FOI request to know the numbers of vials/packs of intravenous thiamine hydrochloride granted special import licences for supply as an unregistered medicine(ie without full marketing authorisation) during the FY 2022/23.

FOI 23/233	Can I get an extract of all yellow card data reported on the child hood vaccines including - •Diphtheria •tetanus • pertussis (whooping cough) •polio, Haemophilus influenzae type b (Hib) •hepatitis B • Meningococcal group B (MenB) • Rotavirus • Pneumococcal (13 serotypes) • MMR I have been unable to locate and view the data for these on your website.
FOI 23/234	
FOI 23/235	Please would it be possible to have deficiency data from GDP and GMP Inspections carried out in 2020, 2021 and 2022.Ideally the data would be provided in electronic spreadsheet format (Excel or CSV file) similar to how the 2019 data was published on your website: https://www.gov.uk/government/statistics/good-manufacturing-practice-inspection-deficiencies (copy attached).For each inspection we would like to see number of deficiencies of each category (critical, Major, Other) and the GMP / GDP chapter references cited, as well as the type of site inspected e.g., non-sterile, sterile, packaging, importer etc.
FOI 23/236	Please release the specification and/or tolerance for the allowable concentration of dsDNA in all COVID-19 mRNA vaccine products licenced (whether fully or otherwise) by MHRA.
FOI 23/237	We are making a freedom of information request in respect of the ingredients that are used in the weight loss treatments Wegovy, Saxenda and Ozempic. These all include either Semaglutide or Liraglutide, each of which includes PHENOL. Can you please confirm what phenol specifically is included in the ingredients of Semaglutide and Liraglutide. Also, Wegovy, Saxenda and Ozempic have listed in their excipients "phenol". Can you please confirm specifically what phenol is included in these products. We look forward to your acknowledgment and confirmation of when we can expect a response to this request.
FOI 23/238	I am interested in retrieving suspected adverse drug events for acute kidney injury. Thus far, I have only been able to identify this information drug-wise, but not ' event'-wise (i.e., acute kidney disease). I was wondering whether you would be able to guide me to find this information
FOI 23/239	Under the provisions of the Freedom of Information Act 2000, we request the following information:1. Does the MHRA currently receive any funding, or has the MHRA received any funding at any time between January 1960 and March 2023, from any of the following companies, individuals and/or charities:HERBAL RESEARCH COMPANY LIMITED(THE) (00786260).HERBAL RESEARCH INTERNATIONAL LTD (08988771).HRI HERBAL MEDICINE LTD (08811709).JESSUP HEALTH LIMITED (03022591).2. If yes, which company, individual or charity has the MHRA received funding from and when?3. If yes, please specify the nature of the funding (donation, payment for services etc).4. If yes, please specify the amounts received, grouped by year.
FOI 23/240	Could I please receive an electronic copy of the inspection report for all GVP inspections conducted by the MHRA between 01Jan2022 and the 31Dec2022?
FOI 23/241	Under the Freedom of Information Act I request information as follows:1.The number of people in the UK who have reported adverse reactions after receiving a Covid vaccination.2.The symptoms that have been reported as a result of receiving a Covid vaccination.3.The number of deaths that are attributed, or have a link directly or indirectly, to the Covid vaccination.
FOI 23/242	Jeremy Hunt announced that the MHRA would now be sanctioning drugs developed and approved in the USA without wasting time on doing the same thing all over again for use in the U.K.

	Can you tell me when the U.K. will be making Gefapixant available to chronic cough sufferers?
FOI 23/243	I am writing in regarding a freedom of information request which was replied to on 13th Sept 2021 ref 21/1035 regarding graphene oxide which links to 2 fact checks that state Graphene oxide is not used in the Mrna vaccines
FOI 23/244	Under the 'Freedom of Information Act 2000', I request disclosure of the following, in an anonymised format: a) Of the Yellow Card reports associated with Covid-19 vaccine AstraZeneca AB0002, how many were reported by a healthcare professional, of a suspected side effect experienced by a patient. b) of the fatal reports associated with AstraZeneca AB0002, how many had i) a post mortem or ii) a coroner's verdict associating it with the vaccine. c) of the fatal reports associated with AstraZeneca AB0002, how many had pre-existing life-limiting conditions.
FOI 23/245	Please provide a copy of the MHRA GMP Inspection Reports arising from site-based and remote inspections of the following site in the last five years: Fisher Clinical Services UK Limited LANGHURSTWOOD ROAD, HORSHAM, RH12 4QD, UNITED KINGDOM UK MIA(IMP) 18693 / UK MIA 18693 / UK WDA(H) 18693 GMP CERTIFICATE NUMBERS INCLUDE: UK MIA 18693 Insp GMP/IMP 18693/11204-0015[H] UK MIA(IMP) 18693 Insp IMP 18693/11204-0017[I] UK WDA(H) 18693 Insp GMP/GDP/IMP 18693/11204-0009
FOI 23/246	Based on your email dated 7th March, please would you be able to clarify if updates to the below two tables which were provided in FOI 22/982 is what you require? These tables would be updated to include data from the entire length of the vaccination programme up to the date we extract the data from our database. It would also include the bivalent Pfizer/BioNTech and Moderna vaccines.Yes as you have stated above I would like the information supplied in the table format you have shown in your response. Under question 1 and 2 So from the start of the roll out to present day in the same format as the previous foi, the other vaccines from Pfizer and moderna can be displayed separately in a different table. Then separate tables with it broken down by age, I am not too concerned if a star is represented because I know the star represents 1to 5 individuals.

FOI 23/247	Please could you tell me the total number of adverse drug reactions (ADRs) reported to you through the Yellow Card scheme in the 2022 calendar year? In relation to the figures for 2022 could you also provide (i) the number of UK suspected ADR reports received with a fatal outcome, (ii) number of ADR reports received which resulted in prolonged hospitalisation and (iii) the number of reports received which resulted in prolonged hospitalisation AND had a fatal outcome? In relation to the fatal outcomes could you please provide a table showing the ten drugs that were most frequently recorded as having caused such a reaction along with the number of times each one was recorded as having a fatal outcome.
FOI 23/248	
FOI 23/249	(a) Was the licensing of Pluserix MMR progressed under the Clinical Trial Exemption Scheme (11th march 1981)? (b) Was Pluserix MMR provided with a Clinical Trial Exemption Certificate?
FOI 23/250	Copy of the Inspection Report for the Inspection conducted 22nd – 26th November 2021 of Norton Healthcare Ltd., Whitehouse Vale Industrial Estate, Aston Lane North, Preston Brook, Runcorn WA7 3FA, UK.
FOI 23/251	How many Diversity and Inclusion officers did you hire between April 5, 2018 and April 5, 2023? Please state: the full job title of each role, the annual salary of each role, the date of appointment for each role, and a brief description of each role. (For clarity, 'Diversity and Inclusion officer' refers to any job role which has in its title any of the following words: 'diversity', 'inclusion', 'equality', 'wellbeing' and 'EDI'.) - In total, how many Diversity and Inclusion officers do you currently employ? Please state: the full job title of each role, the annual salary of each role, and a brief description of each role. (The definition of 'Diversity and Inclusion officer' is the same as in the previous question.) - Between January 1, 2018 and April 5, 2023, for what period of time has your organisation been a member of the LGBT charity Stonewall? If the membership was terminated, on what date did your membership end? How much did you pay in membership fees and other expenses to Stonewall during the stated period? Please provide a date and reason for each payment Please provide the information in the form of a portable document format (PDF) via email.G261
FOI 23/252	Please could you provide the following data in relation to Pharmacovigilance Inspections of Marketing Authorisation Holders: - Number of inspection findings related to Patient Support Programs - Breakdown by year since 2011, including grading of finding (Critical, Major, Minor)
FOI 23/253	Please could you email me the IDAPs for all the current brands for the vitamin K injection given to new-borns in the UK
FOI 23/254	Please could you email me the IDAPs for each of the childhood vaccines currently on the recommended UK schedule

FOI 23/255	I would like to see copies of all reports of tests/trials and results submitted to MHRA for marketing approval by all manufacturers and suppliers of medication called Mirtazepine (Remeron), including tests/trials and results that were not officially published or released to the general public, and all details concerned. I am particularly interested in all reports of test results that produced adverse effects or side effects from the medication, with more specific interest in side-effects/adverse effects that may include cochlear hair cell damage in the ear, tinnitus, hearing loss, balance problems or symptoms related to ototoxicity, particularly in the ear.
FOI 23/256	Q1 - If the EUA was issued on the 01st December 2020 how can it be based on an assessment of data for the period October 2020 to December 2020? Q2 - How much data was supplied on the 01st December 2020 between the time that the MHRA office opened and the time the EUA was authorised that day? Q3 - How can only 2 months (October 2020 to November 2020) of a trial for a medicinal product that has never before been used in humans and which contains ingredients that have never before been used in humans be deemed as sufficient to give even a marginal or possibly “safe” designation? Q4 - Was there any documentation available from Pfizer prior to 01st December 2020 which was used to base the initial MHRA PAR on and then to “write” it?
FOI 23/257	Could you please send me a copy of the original FOI request which relates to this answer. Could you also please provide me with the details of the person who raised this request.
FOI 23/258	Date submitted to MHRA • Subject • Date response sent • Whether an Internal Review was requested • Whether the case was referred to the ICO I would be grateful if you could, as offered, supply me with this information as soon as possible, please. Please include as much of the same data for 2023 as is readily practicable. Would you also, please, review those 258 cases (for 2021 and 2022) where there was an Internal Review and let me have as much as you can practically provide of the eventual result/outcome, including which exemption may have been relied on.
FOI 23/259	We have contacted DHSC for the above information, but they have asked us to contact Supply Chain Coordination Limited (SCCL). We have now asked by Supply Chain Coordination Limited (SCCL) in their FOIs dated 28th March 2023 to contact MHRA. We would be grateful if you could please provide us the Quality Assurance tests conducted for both contracts dated 16th and 27th April 2020.
FOI 23/260	I would be grateful if you could provide me with copies of all communications held by MHRA relating to the following FOIA requests: 22/931 22/1080
FOI 23/261	Please provide information on the amount of money BIVDA spent on the IVD Roadmap event on Friday the 10th of February 2023. Please provide relevant documents for the same meeting, including invitations, agenda, presentation materials and notes. Please provide a list of attendees to the same meeting.

FOI 23/262	A study of one group of unvaccinated people and the other group consisting of vaccinated people.
FOI 23/263	Is it possible to request a list of all Qualified Persons eligible in the UK, provided in electronic format?
FOI 23/264	1. For each of the years from 2018 to 2022 the number of deaths where Pregabalin has been recorded as the only drug involved.2. For each of the years from 2018 to 2022 the number of deaths where Pregabalin has been recorded as a contributory drug involved.3. For each of the years from 2018 to 2022 the number of deaths where Pregabalin has been recorded as a contributory drug alongside an opioid based drug.4. Provide a detailed list of all concerns relating to the use of Pregabalin in relation to its prescribing with opioids.5. Provide a detailed list of all concerns relating to the use of Pregabalin in relation to its interactions with illegal opioids.6. Provide all information relating to the safety of Pregabalin in relation to its concomitant use with other Central Nervous System (CNS) drugs.7. Provide a short summary of information relating to the approval of Pregabalin for use as a treatment for Generalised Anxiety Disorder.8. Provide a short summary of information relating to the approval of Pregabalin for use as a treatment for chronic neuropathic pain.9. Provide a short summary of information relating to warnings by the manufacturer on its use as a treatment for Generalised Anxiety Disorder.10. Provide a short summary of information relating to warnings by the manufacturer on its use as a treatment for chronic neuropathic pain.
FOI 23/265	I would be grateful if you could provide me with copies of all internal communications held by MHRA relating to FOIA request 23/073
FOI 23/266	I would be grateful if you could provide me with copies of all internal communications held by MHRA relating to FOIA request 23/105
FOI 23/267	Re: Freedom of Information Request (Our Ref: FOI/2023-01/0804)
FOI 23/268	Freedom of Information Request - 8 April 2023
FOI 23/269	Have you since 01/01/2020 conducted any reviews into the use of AI? If so can you publish the findings along with methodology used?
FOI 23/270	Re: Freedom of Information Request
FOI 23/271	Can you confirm how long it should take MHRA to approve a CTA application? Are there there currently unusual problems or delays at MHRA in approving CTA applications? Since July 28 2022 How many applications have been made to MHRA for CTA approval?
FOI 23/272	I am emailing to kindly ask for all Yellow Card reports from COVID-19 vaccinations for the whole of the Channel Islands (Jersey, Guernsey and associated islands). If possible I would like to know the number of suspected fatalities, in addition to the type of adverse reaction. Any other data you may have (i.e. age, demographic, date reported etc.) would be much appreciated.

FOI 23/273	please can you confirm if you received the Phillips Sumika Material Safety Data Sheet in 2008 for full transparency of the nature of the PP product from C.R.Bard and any and all C.R.Bard UK agents and doctors that were supplying hospitals in the UK to implant patients with their PP medical devices.
FOI 23/274	I'm requesting the following information on the Early Access to Medicines Scheme: 1) How many Promising Innovative Medicines (PIM) applications has the MHRA received as part of the Early Access to Medicines Scheme (EAMS) each year between April 2014 and April 2023? a. For each year, how many of these applications have been granted? b. For each year, how many of these applications have been refused? c. For each year, how many of these applications have been withdrawn?
FOI 23/275	I would like to request the public assessment report for licence PL 53886/0025 Dulcolax Adult 5 mg Gastro-resistant Tablets
FOI 23/276	June Raine is on record as stating that 2000 pregnant women who took the injections for covid offered their data. Please can you share the results of this data monitoring?
FOI 23/277	safety of inferior vena cava filters in MRI examinations. Could you do a database query for me for any adverse events with patients with IVC filters during MRI exams covering the period from the 1st of January 2022 to today (12/4/2023)
FOI 23/278	Freedom of Information Request - Importation of Unlicensed Medicines It appears the MHRA have stopped publishing the quarterly summary reports for the importation of unlicensed medicines, with the last one published in Dec 2018, therefore please can I request the following information for the periods 2021 & 2022; • Number of import notifications received. • How many imports did you receive notifications from. • List of exporting countries and number of notifications per country.
FOI 23/279	Documents requesting for freedom of information (FOI) of the product name 'RoActemra'
FOI 23/280	active surveillance of 2000 pregnant women
FOI 23/281	I would like to inquire if there is any information regarding adverse reactions to the excipients arachis oil, peanut or soya oil.
FOI 23/282	Please could you disclose the Public Assessment Report and the Clinical Overview (Module 2.5) for Adaflex (melatonin) tablets marketed by AGB-Pharma AB
FOI 23/283	Hi Is it possible to have information about Yellow Card reports associated with the Shingles vaccine? I have tried to find this information via iDAPs but it doesn't seem to be available. I specifically would like to know about reports of abnormal liver function tests following Shingles vaccination

FOI 23/284	Pursuant to the Freedom of Information Act, we would like to obtain copies of the safety data submitted to the Agency or its predecessor agency prior to and necessary for marketing authorisation of Ikorel® (nicorandil) 10mg and 20mg tablets by Aventis Pharma Ltd. (market authorisation holder: Aventis Pharma Limited, Date of first authorisation: 12 August 1992; Market authorization number PL 04425/0327) or any other party sponsoring the submission of data for marketing authorisation of Ikorel® in the UK. In particular, we would like to obtain copies of the following records in full: • Any study/studies contained in the initial or later/subsequent submission for market authorisation approval for use in chronic angina pectoris patients by the MHRA (or its predecessor agency/UK governmental institutions) related to toxicology testing nicorandil in
FOI 23/285	1. Report on similarity of Lunsumio with Gazyvaro 2. Report on new active substance status of mosunetuzumab
FOI 23/286	contraceptive medicine
FOI 23/287	LUNSUMIO (mosunetuzumab): PLGB 00031/0933-0934 Please provide copies of the following documents concerning the above product: 1. Report on similarity of Lunsumio with Gazyvaro 2. Report on new active substance status of mosunetuzumab
FOI 23/288	Could you please let me know if there have been any more reports of Adverse Events regarding Gefapixant, since November 2021
FOI 23/289	my question is if you can contact you in the following way, are there any other patients with BioNTech heart attack gogus agri sheet weaving high fever vision loss weakness problems
FOI 23/290	Could you please send me any reports you have received on Repevax (pertussis, Polio, diphtheria and tetanus) Also the first vaccines that are administered to new borns in the first year
FOI 23/291	Freedom of Information Request – Desmopressin acetateThis is a request for information pursuant to s.1(1) of the Freedom of Information Act 2000.1) Please indicate if the MHRA has received any marketing authorisation applications for products containing the active ingredient desmopressin acetate since 1 January 2022.2) If the answer to question 1) is yes, please indicate:a) How many such marketing authorisation applications have been received; andb) How many of these have been granted, how many are pending and how many have been refused.
FOI 23/292	Recent evidence on vape regulatory enforcement in the UK - Questions
FOI 23/293	• The number of incidents National Institute for Biological Standards and Control reported to the HSE in the last five years • The nature of each of those incidents (e.g., were workers exposed to pathogens, if so which pathogens, how were the proximate causes of the accident)
FOI 23/294	This email represents a request under the terms of the Freedom of Information Act 2000, would you be able to provide all emails from/to : [s40 names]

FOI 23/295	Under the requirements of the Freedom of Information Act 2000 I am requesting that you send me copies of, or specific and direct electronic links to, each such item of information which has been reviewed by the MHRA Advertising Standards Unit in 2019, 2020, 2021, 2022 and 2023 I am also asking for the MHRA to tell me exactly why the MHRA Advertising Standards and Outreach Unit reviewed each item of information and what sets of regulations, standards or guidelines the Unit used to review each item of information and assess its suitability for dissemination
FOI 23/296	I request disclosure of all data, studies and analyses carried out by the MHRA to examine causes of such deaths as a consequence of the AstraZeneca Covid 19 Vaccination and the “reports being given to the government from the MHRA”, to which the Senior Coroner Andrew Harris refers in the above quote.
FOI 23/297	Would it be possible to tell us whehter you have recevied and application license for ublituximab in relapsing MS?
FOI 23/298	I would like to request the GMP inspection report for the company listed below. Only the covering page, Section A (Inspection Report Summary), and Section D (List of Deficiencies) are requested. Please provide via email, if possible. PACKPHARM LIMITED, UNIT 1, 39 MAHONEY GREEN, RACKHEATH, NORWICH, NR13 6JY, UNITED KINGDOM Certificate Number: UK MIA 13163 Insp GMP 13163/30895848-0002[H] Date of inspection: 29 Mar 2023
FOI 23/299	1. In the last 5 years (between 2018 until to date) a. Were any Certificate of Pharmaceutical Products (CPPs) issued by your health agency for medicinal products containing the active pharmaceutical ingredient, Oxytocin? b. If answer to above is yes, for each individual CPP issued could you share a list of their information as below: i. The year of (CPP) issue ii. The country it was issued to iii. their individual national license numbers iv. their national-approved shelf life and storage conditions (as reported in SmPC sections 6.3 and 6.4)
FOI 23/300	Yes, I would be very happy to accept the data you have available from April 2012 as mentioned below rather than the original request. Do you need me to make a new request or will this email confirmation be sufficient?
FOI 23/301	Can you provide numbers of yellow card reports submitted by london ambulance service or paramedics from London postcodes for each month in the last available year of data
FOI 23/302	When you first gave the Pfizer COVID vaccine it's emergency use licence, did it comply with the legal efficacy percentage of 50%?When you first authorised AstaZenica COVID vaccine, did it comply with the legal efficacy percentage of 50%?As of today, do the Pfizer COVID vaccine and AstraZenica COVID vaccine hit the 50% efficacy threshold required to be authorised as a vaccine?
FOI 23/303	I wish to submit to the organisation a freedom of information request relating to the organisation’s ICT contracts, specifically around: 1. contact centre contract(s) 2. inbound network services contract (s)

FOI 23/304	Please name the person who is in charge of the editorial content on this page https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting Please can you tell me why the incorrect information regarding the number of yellow card reports is drastically under reported despite being updated 8th March 2023 and when this will be updated as it it misleading information?
FOI 23/305	Can you please update this FOI released in April 2022. It's a list of Covid-19 batch numbers with numbers of adverse events and deaths reported relating to each batch number. Can you update the information, providing figures up to April 2023.
FOI 23/306	1) Why was the link disabled? 2) Where can I find the latest versions of the Astra Zeneca data? [please note, NOT the summary, this is of limited use since it's been filtered by the authors]
FOI 23/307	Pending MHRA Filings
FOI 23/308	1. What was the arrangement for procurement of medicines/drugs for Papua New Guinea through the British Pharmacopeia? 2. What sort of processes were involved in this procurement process? 3. When did Papua New Guinea start procuring its medicines/drug supplies through the British Pharmacopeia?
FOI 23/309	1) Total number of yellow card warning reports received in respect of the Advanced Bionics HiRes Ultra and/or HiRes Ultra 3D cochlear devices in the UK which were subject to the voluntary recall mentioned above. 2) Copies of any Public Assessment Reports held in respect of the Advanced Bionics HiRes Ultra and/or HiRes Ultra 3D cochlear devices.
FOI 23/310	Would it be possible to have the following information for Yellow Card Reports from Northern Ireland for the following time periods. From 1/04/2021 to 31/03/2022 and 01/04/2022- 31/03/2023 • Total number of Yellow Card reports submitted from NI for all reporter types • Breakdown of Yellow Card reports from NI by reporter qualification
FOI 23/311	• The duration of time utilising cloud infrastructure.• The criteria used to choose a cloud provider.• The percentage of infrastructures employing cloud services.• The supplier of cloud infrastructures used. (AWS/Oracle/Azure etc.)• Case studies highlighting the successful implementation of the 'Cloud-first' strategy.• The uptime of the cloud infrastructure.• The annual budget over the last five years for IT-managed services• Please provide the percentage spent on cloud-managed services
FOI 23/312	I have a query regarding oplezura ruxolinitb which got EC approval recently. Could you please share any approximate time or news regarding patients in UK can expect about it.

FOI 23/313	We request that the MHRA disclose: a) Whether the market exclusivity for Tecfidera is considered to expire in February 2024 or February 2025; and/or b) Whether the MHRA has granted any generic DMF marketing authorisations with market exclusivity conditions attaching to them and, if so, whether those conditions expire in February 2024 or February 2025. Please note we are only asking for the MHRA to disclose terms of granted (i.e. public) marketing authorisations
FOI 23/314	From page 7 of the MHRA's Agenda for Board Meeting Held in Public 11:00 – 13:30 on Tuesday 19 April 2022: 3.5 An investigational review of LifeVac and DeChoker, two airway clearance devices on the UK market currently subject to marketing restrictions, concluded in March 2022. The outcome of this review is currently being communicated to the manufacturers and shall be published in due course. Please provide me with a copy of the review and all related records including correspondence.
FOI 23/315	I would be grateful if, under the Freedom of Information Act (FOIA), you would be kind to enough to supply me with: • Electronic copies of the a)study protocol, b) investigator brochure (IB), and c) informed consent form (ICF) received by MHRA in relation to the DTX301 Phase 3 study for OTC deficiency (Clinicaltrials.gov: NCT05345171; EudraCT: 2020-003384-25). All appropriately redacted to remove any personal or data protection material.
FOI 23/316	Please disclose [S40 name] letter of resignation
FOI 23/317	Can the following pharmacovigilance & GCP inspection reports be provided for all Companies that had major or critical findings please from April 1st 2022 – 30th June 2022
FOI 23/318	I would be much appreciated if you can provide me with the reported adverse events to you for the following medical devices: .Puraplas 2. Dermal Roller 3.Cannulas 4. PDO Threads”
FOI 23/319	Could you please provide me with the documentation relating to the referral of Calea to the Inspection Action Group in 2010 which should include any inspection reports and correspondence between Calea and the MHRA.
FOI 23/320	I would like to know if there is readily availability for these measure for renal failure and impairment. Otherwise, I was wondering if I could get access to all the Individual Case Safety Reports (ICSR) in some way as done by other counterparts of yours like the FAERS or EudraVigilance (e.g., Oracle BI Interactive Dashboards - DAP (europa.eu), FDA Adverse Events Reporting System (FAERS) Public Dashboard - FDA Adverse Events Reporting System (FAERS) Public Dashboard | Sheet - Qlik Sense). If none of the latter is feasible, I would be interested in knowing whether it would be possible to get similar sheets for the following cases:• Number of adverse events (AE) reported for the drugs (all) reported in the foi 23-238 document attached not associated with ‘renal failure and impairment’

FOI 23/321	❶ Meta-data request - The dates when issues covering “Specials” Drug Importation were on the agenda of the governing body of the MHRA in the last 5 years. ❷ If so please provide the text of the agenda item(s) ❸ Did the MHRA Corporate Plan(April 2021 - March 2024) make any reference or discuss Drug Specials Importation strategy/policy ❹ Meta-data - Dates in 2021 to 2023 when the Unlicensed Imports Team discussed Drug Specials Importation with the MHRA’s generic drugs regulatory approval team.
FOI 23/322	I was hoping you could help me by providing the Risk Management Plan for Viagra Connect since it is authorised in the UK. I am specifically interested in: Part II: Module SVIII Part V: Risk minimisation measures Part VI: Summary of the risk management plan Part VII: Annex 6.
FOI 23/323	Please could you send me the reports for the rest of the vaccinations on the schedule, those being - Hib Men C dtpa/IPV. (4 in 1 pre-school booster) HPV Td/IPV (3 in 1 teenage booster) Men ACWY In addition could you let me know what (if any) the estimated backlog there is in getting these reports on to you system?
FOI 23/324	Recently there have been very concerning news on BBC about deaths linked to Indian Made Cough Syrups particularly for children. Even today there is a report about similar case in Australia and about Eye drops in USA. This can be a serious problem when so many cough syrups are available for over the counter purchase. For the purpose of safety, I would like to know: Are there any Indian Made Cough Syrups in UK market? If yes, who is marketing them?
FOI 23/325	Recently, both sodium hydroxide and hydrochloric acid have been added to the list of excipients in Section 6.1 of the SmPC for Pifzer’s experimental drug for the purpose of pH-adjustment [1]. Neither excipient is listed in Table 2 of Pfizer’s Summary Basis for Regulatory Action (SBRA) [2].You are required to comment on this discrepancy and this recent change to the SmPC. In particular, you should now publicly clarify whether this change in the excipient list applies retrospectively or only from the date these two excipients were added to the SmPC.Disclose all documentation in possession of the MHRA concerning the recent addition of both sodium hydroxide and hydrochloric acid as excipients.
FOI 23/326	1. The testing protocol for this influenza vaccination prior to its use on children? 2. The efficacy of this influenza vaccination in preventing serious illness? 3. The side effects experienced during the testing protocol and use of this influenza vaccination? and 4. What exactly are the genetically modified organisms (GMO) contained within this influenza vaccination?

FOI 23/327	Would you be able to advise whether MHRA are looking to approve mirvetuximab for use in platinum resistant ovarian cancer and, if so, when this is likely to be? This was approved by FDA in November last year: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mirvetuximab-soravtansine-gynx-fra-positive-platinum-resistant
FOI 23/328	current information regarding the beta3 adrenergic agonist Vibegron which has been used in USA to alleviate bladder spasms without significantly affecting blood pressure. Aside from finding out that a licence was applied for last July I cannot find out what progress has been made regarding the possible licencing of the drug and its ultimate appearance in the BNF.
FOI 23/329	We have found out about the success of DCVax and so I'm trying to find out if and when this will be licensed for use in the UK. Could you let me know if this is in the pipeline and if so when it may happen?
FOI 23/330	does your organisation employ any DDaT/IT staff at grade seven within any of the following technologies: - 1. Power Platform 2. Power BI 3. Power Automate 4. SharePoint / SharePoint Online 5. M365 / Microsoft365 / Office365
FOI 23/331	This email represents a request under the terms of the Freedom of Information Act 2000, would you be able to provide all emails from/to : [s40 names]
FOI 23/332	This request is related to the regulatory submission for the Pfizer vaccine, would you be able to provide the Clinical Study Report of the Trial registered as C4591015 and the assessment report done by the MHRA ?
FOI 23/333	We would like to request for the Published Assessment report and information if its Initial application or MA transferred application of the following product under the Freedom of Information Act (FOIA): Fludrocortisone Acetate 0.1 mg Tablets Generics [UK] Ltd. t/a Mylan PL 04569/1813
FOI 23/334	I would like to know all the dates of MHRA licenses for each of the three 52mg LNG-IUDs: mirena levosert and benilexa together with the duration of use for contraception of those licenses. And also whether any of these 3 devices currently have any licence applications pending or under review (together with the stated duration of use for contraception).
FOI 23/335	Please can you provide me a copy of the Public Assessment report associated with the above MA held by Cipla (EU) Ltd. that was approved by the MHRA on 20/03/2023.
FOI 23/336	The number of misoprostol pills seized by the MHRA in each of the following years: 2018, 2019, 2020, 2021, and 2022

FOI 23/337	I am contacting you to request some information namely purporting to the release of information from Public Health England (at the time) to States of Guernsey surrounding the Pfizer BioNtech vaccination in 2021. In detail I would like to know: - the date upon which Public Health England first informed the States of Guernsey of known adverse side effects from the Pfizer Bio-Ntech vaccination that specifically included Pericarditis. And - how this information was communicated to The States of Guernsey.
FOI 23/338	I am writing to request information under the Freedom of Information Act 2000 regarding the number of prosecutions and enforcement actions for the misuse of supply of Tramadol. Specifically, I would like to request the following information: 1. The number of prosecutions undertaken for the misuse of supply of Tramadol between January 1, 2018, to present. 2. The number of enforcement actions undertaken in relation to Tramadol between January 1, 2018, to present.
FOI 23/339	potential call-off contracts awarded by the MHRA, but I can't find details of the framework agreements they were awarded from.
FOI 23/340	To whom it may concern, please treat the following as an FOI request. Please can you provide me with details of all enforcement action taken by MHRA in Scotland in the two financial years (up to March 31 2023). Please give as much details as possible on the enforcement action taken. Please can you provide details of all seizures the MHRA has made in Scotland during the last two financial years (up to March 31 2023). Please give as much details as possible.
FOI 23/341	1. Under the Freedom of Information Act 2000, can you provide the following information: The total number of UK Conformity Assessment (UKCA) certificates issued for medical devices and invitro diagnostic medical devices to date, broken down by group. 2. Under the Freedom of Information Act 2000, can you provide the following information: The total number of medical devices and invitro diagnostics medical devices in the U.K which are registered with the MHRA, including those that are UKAB certified and those that are self-declared to U.K. MDR.
FOI 23/342	Reference is made in the news story to an ongoing clinical trial involving 6,388 children aged 6 months to 5 years and to "common side effects". No reference is made to uncommon side effects. Consequently, I would be grateful if you could arrange to provide me with the following information from MHRA records. 1. Start and end date of the ongoing trial referred to, and 2. A copy of the trial findings used to inform MHRA decision to authorise use of "Spikevax" in infants and children aged 6 months to 5 years.
FOI 23/343	I would like the response to the following information about clinical trials. 1) What is the total number of clinical trial applications that have not yet been reviewed (phase 1-4) 2) What is the longest time from application rec'd to being reviewed (phase 1-4)

FOI 23/344	
FOI 23/345	I want to know about new treatment of vitiligo, FDA approved opzelura.
FOI 23/346	In Section 3.2 of Pfizer's Safety Data Sheet (SDS) for BNT162b2, substances PF-07305885 and PF-07302048 appear as separate ingredients [1]. According to Pfizer's Summary Basis for Regulatory Action (SBRA), SARS-CoV-2 spike glycoprotein mRNA (modRNA) has a per-vial quantity of 225 µg and is the active pharmaceutical ingredient (API) [2]. There is thus no obvious way therefore to map these two ingredients from the SDS to the SBRA.You are required to clarify the distinction between PF-07305885 and PF-07302048. Disclose all documentation in possession of the MHRA concerning these two chemicals, including documentation on their respective exact definitions and the distinction between the two. Disclose all communication between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on these two ingredients.
FOI 23/347	Disclose all internal documentation, including correspondence between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on both the weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA. In addition to this, disclose all internal documentation in possession of the MHRA on these topics, including emails, minutes of meetings and memorandums.
FOI 23/348	1. Has your regulatory body been contacted by the Government with a request for suggestions for post-Brexit regulatory changes? 2. If you have responded to request how many regulatory changes have you proposed. 3. What are those regulatory changes that you have suggested. 4. The number of regulations that relate to your regulatory body which have already been amended or repealed due to Brexit. 5. The titles of these regulations that relate to your regulatory body which have been amended or repealed as a result of Brexit. 6. The number of regulations that relate to your regulatory body which are in anyway under review as a result of Brexit. 7. The titles of these regulations which are under review as a result of Brexit.
FOI 23/349	Are you working with any infectious agents under a Specified Animal Pathogens Order (SAPO)? If yes, what are they? If applicable, what biosecurity level is used during work with PPPs and SAPO infectious agents? Are you currently carrying out any gain of function work, or experiments to enhance the infectiousness of transmissibility of PPPs or SAPO infectious agents? Have you had any incidents of biosecurity lapses, leaks or safety breaches in the past five years? If so, can you list these?
FOI 23/350	Enterprise Application
FOI 23/351	I was wondering if we could get the latest version from innovator RMP (v19.1) in order to be aligned with.

FOI 23/352	For all fatal Yellow Card reports relating to the AB0002 batch of AstraZeneca Covid-19 vaccine (for which, as of 3 Feb 2023, you had 42 reports), a) how many have you followed up with colleagues in primary, secondary or tertiary care to request further information? b) how many follow ups have gone unanswered from primary, secondary or tertiary care? c) how many of these Yellow Card reports were reported by healthcare professionals?
FOI 23/353	1. Please provide a summary of the number of yellow cards submitted to the MHRA, following a suspected adverse reaction to all of the COVID-19 vaccines, for Scotland, from 2020 until present day in May 2023 Please provide:a) Number of cards submittedb) Number of adverse reactions reportedc) Number of serious adverse reactions reported d) Number of fatal events reported from 2020 to May 2023
FOI 23/354	Multi-Functional Devices and printing/scanning services contract(s)
FOI 23/355	I would be grateful if you could provide more information regarding this application. I am aware that the agent/architects are Aleksandra Patarova 16 Melville Street, EH3 7NS.
FOI 23/356	Freedom of Information Request - 20 April 2023
FOI 23/357	M H R A membership of I C M R A
FOI 23/358	1- Can you tell me if any of the COVID-19 vaccines currently in use in the UK are experimental ? 2- Can you tell me if any of the COVID-19 vaccines used in the UK were ever defined as experimental and from which dates were they no longer considered experimental ? 3- From what dates were the COVID-19 vaccines used under EUA licensing ?
FOI 23/359	side effects to numerous medication
FOI 23/360	For all fatal Yellow Card reports relating to the Pfizer monovalent and bivalent Covid-19 vaccine (for which, as of 22 May 2023, you had 903 reports), a) how many have you followed up with colleagues in primary, secondary or tertiary care to request further information? b) how many follow ups have gone unanswered from colleagues in primary, secondary or tertiary care?
FOI 23/361	Medicines Withdrawn for Safety Reasons 2013 to date

FOI 23/362	I am writing to ask that you inform me of the number of times (since 1st January 2020 until the date of your response) that the Information Commissioner has found that the MHRA has breached section 10(1) of FOIA in that it failed to provide a valid response to an FOIA request within the statutory time frame of 20 working days. Please also inform me of the number of times over the same time period that the information commissioner has found the MHRA to be in breach of the FOIA for any reason
FOI 23/363	My request was for copies of, or specific and direct electronic links to (non-pharmaceutical-company) items of information, disseminated on COVID-19 vaccines given a temporary supply and conditional authorisations, which has been reviewed by the MHRA
FOI 23/364	1. Was a [name s40] employed by the Medicines and Healthcare products Regulatory Agency between 20 September and 28 February 2023? 2. If so, please state what position(s) they held between those dates.
FOI 23/365	O365 Licencing Questions:-a.- Which Microsoft O365 do you use eg E3,E5?b.- Do you use the NHS-shared O365 tenant? c.- Do you procure O365 licences through Microsoft Enterprise Agreement (EA) or Cloud Service Provider (CSP). Who is your supplier?d.- When is your licencing renewal date/anniversary for these services?Microsoft Telephony Questionse.- Do you have Microsoft Calling Plans, if so how many licences (users)f.- Do you have other forms of Microsoft Telephony such as Direct routing/Operator connect? How many licences (users) and which supplier?g.- When is your licencing renewal date/anniversary for these services?
FOI 23/366	Please advise whether the MHRA has investigated the complaints/reports submitted by DR CORBYN LTD.
FOI 23/367	I would be grateful if you could provide the following information in relation to the received "marketing authorization application" that is currently under review for "lebrikizumab" (ID4025)? • Is any marketing authorization application for lebrikizumab under review, for the UK? • When was the application submitted and by which company?
FOI 23/368	please can you provide the information below, which appears to be missing from “Section IV CLINICAL ASPECTS” of the above referenced PAR? • What was the total number of male subjects that were enrolled in Study 0683-017? • What was the age-range of the male subjects that were enrolled in Study 0683-017? • The data from how many of these male subjects was used for pharmacokinetic analysis? • For any of the male subjects who did not complete the study / whose data was not used for pharmaceutical analysis, what was the reason in each case for the subject’s data not being used e.g. non-compliance, withdrawal of consent, medical reasons etc.?

FOI 23/369	Please provide all correspondence to and from the MHRA and the below companies between 1st January 2021 and to date: a) Philip Morris International b) British American Tobacco c) Imperial Tobacco d) Gallagher Tobacco/Japan Tobacco International.
FOI 23/370	I request disclosure of the following information for all fatal Yellow Card reports relating to the COVID-19 Vaccine AstraZeneca: a) how many reports from reporters working in primary, secondary or tertiary care have the MHRA followed up to request further information? b) how many of those follow ups for further information have not been unanswered?
FOI 23/371	
FOI 23/372	I would be very grateful if you could send through all pharmacovigilance inspection reports of 2021 related to aARMMS inspections.
FOI 23/373	Freedom of Information Request 13 May 2023
FOI 23/374	[Personal information s40]
FOI 23/375	SSRI effects on test results
FOI 23/376	Earlier this year, health and social care secretary Steve Barclay wrote to you. He asked whether you were getting “value for money from your diversity and inclusion memberships, and if not, consider any steps that you could take to address that”.This included “following the Department [of Health and Social Care]’s example and allowing any associations/subscriptions that you have to lapse or be cancelled”. He set a deadline for 1 May to report back.Please provide a copy of your response to Mr Barclay following this letter. In addition, please also answer the following questions:1. Do you have any diversity and inclusion memberships that you have allowed to “lapse or be cancelled”? This can include before or after Mr Barclay’s letter; 2. If the answer is “yes” to question 1, please disclose: - How many you have/had (under Mr Barclay’s definition of these memberships);- Who each of them were with;- How long the organisation had been subscribed to them; and- How much they cost – both on a per annum and total cost basis
FOI 23/377	Inspection reports for Q1, 3 &4
FOI 23/378	what companies in China and india holder a MHRA manufacturing licence

FOI 23/379	I would like to know, for all fatal Yellow Card reports relating to the COVID-19 Moderna vaccine: i) how many of these Yellow Card reports has the MHRA followed up with healthcare colleagues to request further information? ii) of these follow up requests, how many have gone unanswered?
FOI 23/380	I would be grateful if you could arrange to provide me with the following information from MHRA records. 1. Start and end date of the two clinical trials referred to, and 2. A copy of the trial findings used to inform MHRA decision to authorise use of "SKYCovion" Covid 19 inoculations.
FOI 23/381	Updated Yellow card data for the Isle of Man on Covid-19 vaccines
FOI 23/382	COVID-19 vaccine Yellow Card data for the Isle of Man
FOI 23/383	ICH guideline S1B(R1) on testing for carcinogenicity of pharmaceuticals
FOI 23/384	I was expecting to see the number of yellow cards from NI in the report also. To clarify the number of yellow cards submitted as a separate figure from the number of ADR reports. Would it be possible to have these figures also?
FOI 23/385	Pursuant to the Freedom of Information Act, we would like to obtain copies of the drug-to drug interaction (DDI) data submitted to the Agency at or around 1992 for marketing approval of Ikorel® 10 mg and 20mg tablets by Aventis Pharma Ltd., UK (now Sanofi, Date of first authorization: 12 August 1992; Market authorization number PL 04425/0327). In particular, we would like to obtain a copy of the following records in full: • Any studies contained in the initial or later/subsequent submission for marketing approval for use in chronic angina pectoris patients by the MHRA (or its predecessor agency/UK governmental institutions at the time with the same drug safety, efficacy and approval for human use oversight) related to testing nicorandil for potential drug-to-drug interactions.
FOI 23/386	Copy of numerous inspection reports related to companies
FOI 23/387	Can I please request the Drug Analysis Print (DAP) for the Fluenz Tetra vaccine. In particular, I require information about ENT issues such as tinnitus.
FOI 23/388	I seek data about the first 40 batches of Pfizer authorised and distributed in the United Kingdom including EJ0553, since 2nd December 2020.1. Please provide a list in chronological order of these batch date authorisations including Batch EJ05532. Please show the total dose numbers for each of these batches

FOI 23/389	1. Are Covid19 Jabs/Vaccines are considered Gene Therapy Based products Including Moderna Pfizer and others 2. Have Covid19 Vaccines in Data been studied on side effects with human body with Altitude effects like in Aeroplane on Pilots with these new type Vaccines MRNA lipid nano Particles do MHRA no these types side effects could be caused 3. Did MHRA tell CAA that Covid19 Vaccines are not Gene Therapy products which they are considered by FDA are Gene Therapy Products The screen shot I'll be provided in this email
FOI 23/390	I would like to make a FOI request for any non-clinical information/data you may hold in relation to pindolol?
FOI 23/391	[Personal information s40]
FOI 23/392	I would like to understand whether the change in approach, that Dame June outlines, was a 'top-down' instruction from the DHSC or a 'bottom-up' initiative from the MHRA. If it was 'top-down', I would be grateful if you would provide me with a copy of the letter / communication that instructed this change. If it was 'bottom-up', I would be grateful if you would provide me with the minutes of the meeting where this was discussed and agreed (plus any supporting information that was used to inform that decision), along with any correspondence from the DHSC agreeing to and/or sanctioning this new approach.
FOI 23/393	Documents requesting for freedom of information (FOI) of the product name 'Prolia' ▶ Risk Management Plan (RMP) Body (the latest version) ▶ RMP Annex 7, 10, 11, 12 (Template Rev 1) or Annex 4, 6, 7, 8 (Template Rev
FOI 23/394	I would like to request for Module 2.4, Module 2.5 and Module 5.3.1 submitted for Glycopyrronium Bromide 1 mg & 2 mg Tablets (Kinedexe UK Limited).
FOI 23/395	• Total reactions of Administration Site ADR's • Total reactions of Administration Site ADR's from subcut products • Total reactions of Therapeutic and non-therapeutic effects – Interactions • Total reactions of Therapeutic and non-therapeutic effects – Interactions from subcut products • Total reactions of Therapeutic and non-therapeutic effects - Therapeutic and non-therapeutic responses • Total reactions of Therapeutic and non-therapeutic effects - Therapeutic and non-therapeutic responses form subcut products • Total reactions of Product Issues
FOI 23/396	Please could I request a link to or safety information/Yellow Card Data for Licensed allergan Immunotherapies listed below: • Grazax • Acarizax • Pollinex • Itulazax
FOI 23/397	Can I please have reports on childhood immunisation side effects

FOI 23/398	I would like to see copies of all reports made via Yellow Card Scheme by either doctors or patients relating to side-effects from a medication called Mirtazapine (Remeron), including any reports that were not officially published or released to the general public, and all details concerned.
FOI 23/399	Severals questions on IT services
FOI 23/400	Please can you send me the corresponding standard operating procedure for MHRA's categorisation of Yellow Card (ie "unsolicited") reports of suspected serious adverse events associated with medicines. Please can you also send me the following information for each of the Pfizer, AstraZeneca and Moderna Covid vaccines : a) the number of YC reports of suspected serious adverse events to dateb) the number of YC reports of suspected serious adverse events assessed as i) not related; ii) unlikely related; iii) possibly related, iv) probably related and v) definitely relatedc) the number of YC reports of suspected serious adverse events which have not been assessed for causality
FOI 23/401	please can I ask for the Yellow card report on MMR vaccines in 1 year olds
FOI 23/402	Enquiry re: cardiac devices and intraoperative electrical interference
FOI 23/403	I would like all data and reports the yellow card scheme has on the vaccine 'Bexsero'
FOI 23/404	I am requesting copies of all information held by MHRA relating to the letter sent by [s40 name] to Dr June Raine of the MHRA dated 6th June 2022
FOI 23/405	Under the Freedom of Information Act I am requesting a copy of the final study report for “A post-authorization safety study (PASS) to evaluate the paternal exposure to valproate and the risk of neurodevelopmental disorders including autism spectrum disorders as well as congenital abnormalities in offspring - a population-based retrospective study”, reference EUPAS34201, that was commissioned by the European Medicines Agency and then supplied to the MHRA.
FOI 23/406	1) copies of, or specific and direct electronic links to, each piece of available evidence that the Commission on Human Medicines reviewed for its advice to the MHRA on a possible link between the AstraZeneca Covid-19 vaccine and blood clots, bleeding or low blood platelets. 2) The full and thorough review the MHRA undertook, complete with all sources of available data, concerning blood clots occurring with thrombocytopenia. 3) All updates provided by the MHRA to the COVID-19 Subcommittee of the Joint Committee on Vaccination and Immunisation on the safety of the AstraZeneca Covid-19 vaccination and on-going policy recommendations concerning this product
FOI 23/407	can you please show the break down for the number of fatalities and adverse vaccine reactions for the Covid vaccines (and other medications if possible within cost/time constraints) for each of the members of the CCG and indicate if any victims have applied for compensation under the government scheme if known. Not all ADR’s are reported, please provide any estimates or statements which explain what percentages are reported vs what percentage are unreported for deaths or in general.

FOI 23/408	I would like to request the following information: • What is the reasoning behind asking doctors to throw away almost 999,000 doses of Novavax? • Why were immunologists barred from giving the spare doses to vulnerable people o (i.e., people with conditions listed in the Covid-19 Green Book who had severe adverse reactions to other vaccines that weren't anaphylaxis)? • Why has the government barred Covid vaccines from being available to purchase privately?
FOI 23/409	I am looking into gathering information around the statistics for bed/bed rail related injuries and deaths for 2022 (happy with 2021 if 2022 is not collated). Do you have any advice as to where I can find this information
FOI 23/410	We wish to know the number of MRDCP Reliance route MA applications that are pending for initial assessment with MHRA.
FOI 23/411	I am making a FOI request to ascertain who conferred sovereign status to yourselves
FOI 23/412	We would like to request for the Public Assessment report of the following product under the Freedom of Information Act (FOIA): Betnesol Eye, Ear and Nose Drops Solution 0.1% w/v RPH Pharmaceuticals AB, SwedenPL 36301/0003
FOI 23/413	please provide all master batch records (MBRs) for the clinical supply of Pfizer/BioNTech COVID-19 vaccine BNT162b2. Provide all MBRs prior to and after MHRA granted the Conditional Marketing Authorisation for Comirnaty. In particular, ensure this includes RNA fragment analysis (and DNA fragment analysis, if applicable), and the DNA percentage of the final product.
FOI 23/414	Please may you provide me, in Microsoft Excel or an equivalent electronic format, with a list of invoices that were not paid within 30 days for the last 6 financial years which would feed into the Regulation 113 Notice you are required to publish each year as part of your obligations under The Public Contracts Regulations 2015, with the following information for each invoice (where available): • The name of the Supplier • Supplier email address • Supplier company registration number • Supplier postal address • Supplier telephone number • Supplier website • The date of the invoice • The invoice reference • The gross value of the Invoice • The date the invoice should have been paid by • The actual payment date of the invoice • The total amount of interest liability due to late payment of the invoice • The total amount of interest paid to the supplier due to late payment of the invoice.
FOI 23/415	Under the Freedom of Information Act I am requesting a copy of all correspondence and/ or emails with the European Medicines Agency which discusses either the interim and/ or the final report for “A post-authorization safety study (PASS) to evaluate the paternal exposure to valproate and the risk of neurodevelopmental disorders including autism spectrum disorders as well as congenital abnormalities in offspring - a population-based retrospective study”, reference EUPAS34201.

FOI 23/416	I am requesting a copy of all minutes of meetings of the MHRA and any of its subcommittees which discussed the interim and/or the final reports of "A post-authorization safety study (PASS) to evaluate the paternal exposure to valproate and the risk of neurodevelopmental disorders including autism spectrum disorders as well as congenital abnormalities in offspring - a population-based retrospective study", which was imposed by the European Medicines Agency (reference EUPAS34201).
FOI 23/417	For the use of agencies, please can you confirm if the Medicines and Healthcare Products Regulatory Agency works under, Non-Clinical Temporary and Fixed Term Staff CCS Framework RM6160 and the new CCS Non-Clinical Staffing Framework Agreement RM6277. Please can you confirm the list of agencies that have supplied to the company under the framework through the dates of January 2022 – December 2022. For the same 12-month period, please can you provide the list of agencies that have supplied to you staff outside of the framework CCS Framework RM6160
FOI 23/418	We would kindly like to request the following documents under the Freedom of Information (FOI) Act concerning Hemgenix 1x1013 genome copies/mL concentrate for solution for infusion, PLGB 15036/0160:• Current approved: Risk Management Plan, RMP (eCTD Module 1.8.2 Risk Management System)• Environmental Risk Assessment (eCTD Module 1.6)• Clinical Overview (eCTD Module 2.5)
FOI 23/419	I am looking to capture data that would have prompted the alerts in 2010 and 2014 and compare it to the situation to date. I therefore request the following data broken down by year from 2008-2022. Please provide the data in a spreadsheet. 1. Total annual number of reports about devices used for endometrial ablation 2. Reports broken down by type of complication, including but not limited to: a) uterine wall injury b) wall perforation c) the creation of a false passage 3. Number of reports relating to patients with: a) a retroverted uterus
FOI 23/420	FD8813 please investigate I've seen a spreadsheet suggesting it was
FOI 23/421	1. A copy of the November 17th 2020, letter from the DHSC to the MHRA requesting authorisation, on a temporary basis, of its proposed supply of a vaccine manufactured by Pfizer/BioNTech collaboration, named "COVID-19 mRNA Vaccine BNT162b2", under Regulation 174 of the Human Medicines Regulations 2012, ("the Regulations"). 2. The batch number of BNT162b2 the MHRA granted the TUA for. 3. Which of the two processes BioNTech said in its clinical trials protocols it was using to manufacture BNT162b2 was used to manufacture the specific batch of BNT162b2 that MHRA granted a TUA for? 'Process 1' which was used for small scale manufacturing of product for the clinical trials or process 2 which was used for mass manufacture? 4. It was specified in BioNTech trial protocol that an analysis comparing the reactogenicity and safety of process 1 and process 2 batches (eg comparing the numbers of serious adverse events and deaths) would be conducted. Please provide a copy of the analysis or report produced, received, reviewed or evaluated by MHRA comparing the safety data of the two products.

FOI 23/422	Enquiry on the organizational structure
FOI 23/423	Please can you send me the details of all adverse incidents reported to you within the last 15 years which related to the MRI scanning of fixed orthopaedic implants? If possible I would like this to include the manufacturer and model of the implant(s) and the scanner, the immediate/short term adverse effects, any actions taken, and the details of any long-term follow up with the patient.
FOI 23/424	I would like to request copies of any inert placebo-controlled clinical trials for the current vaccines on the children's recommended vaccine schedule please.
FOI 23/425	We would like to request on the quantity of unlicensed medicine Torbac 5ml ampoules (pack of 10) (Sodium chloride 0.9% with preservative) manufactured by Torbay Pharmaceuticals and distributed by Tor Generics from 2016 until 2023
FOI 23/426	Please share the statistics of the number of reports you have received to the yellow card scheme per year (ideally split by patients and medical professionals), going back as far as you're able
FOI 23/427	could you please share a redacted copy of the innovator RMP - PL 11311/0674 - 0010 Type IB
FOI 23/428	Covid ADR reports
FOI 23/429	• Can you give me a breakdown of the number of instances of substances containing fentanyl have been seized during their attempted illegal importation to the UK in the past 5 years? • Can you give me a breakdown of the number of the instances of substances containing Xylazine being seized during their attempted importation to the UK in the past 5 years?
FOI 23/430	Have there been any reports to the MHRA of heavy PV bleeding (resulting in fainting) one week post hepatitis B vaccination (with Engerix B)?
FOI 23/431	I wish to make a freedom if information request to know what adverse reports you have had from the use of Cyanoacrylate Glue (CAG) used for the treatment of varicose veins. Brands that use this include Venaseal (Medtronic), Venablock (Invamed).
FOI 23/432	1. Please provide the request sent to the CHM for advice on the safety, quality and efficacy of SKYCovion 2. Please provide the advice given to the MHRA by the CHM on the safety, quality and efficacy of SKYCovion 3. Please provide any advice received from the CHM on the impact of any safety issues on the balance of risks and benefits of SKYCovion 4. Please provide evidence of correlates of protection underpinning the decision to infer efficacy from immunobridging
FOI 23/433	1. The formal request received by the CHM for advice on the safety, quality and efficacy of SKYCovion 2. The formal advice provided by CHM to the MHRA on the safety, quality and efficacy of SKYCovion

	3. Representations, reports and other evidence provided as the basis for the advice provided by the CHM on the safety, quality and efficacy of SKYCovion
FOI 23/434	provide me with the independent peer reviewed journals to evidence the scientific legitimacy of the revisions to the ICH guidelines on Good Clinical Practice. provide me with the independent peer reviewed journals on the Innovative Devices Access Pathway (IDAP) to evidence its legitimacy to launch. provide me with the independent peer reviewed journals on the pilot its own genetic 'biobank' to evidence it is scientifically independently peer reviewe
FOI 23/435	I would like to make an FOI request to see Atlas Microbiome Test's DoC
FOI 23/436	If a company submits an MAA for Market Approval and already has completed MIA acceptance and certification requirements, along with PIP certification would MHRA have a public reference that MAA has been submitted and pending review ? Basically what to know if a company has submitted an MAA?
FOI 23/437	Under the provisions of the Freedom of Information Act 2000, we request the following information: 1. In refence to the Determination Notice [s40] 2. Per Point 1 above, in reference to the Notice [s40]
FOI 23/438	Please could you help me with a freedom of information request on the vascular closure device 'Angio-Seal', manufactured by Terrumo? Could you tell me if this device is licensed and CE marked, when this license was granted and what were the associated conditions of safe useage in the NHS, particularly regarding clinician training and conducting pre-operative patient counselling and obtaining explicit patient consent? If the MHRA does not get involved in the formation of the safe operating protocol of new medical devices, who does? Does anybody have the responsibility of enforcing this? Have there been any safety alerts/concerns raised since the license was granted for Angio-Seal Devices and if so, how have these concerns been acted upon?
FOI 23/439	We are also requesting the J+J MHRA inspection report from around 12 months ago. Please could you provide this Inspection Report? Please include non-interventional PASS and aRMMS for this one too
FOI 23/440	request for EWG minutes

FOI 23/441	Answer 3:You said: "Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors." a) Can you tell me how often these analyses were conducted (weekly, monthly) and how many analyses there are in total?b) Please share all these analyses with me. I am not asking for the Yellow Card summaries, but the raw data/analyses that were used to compile the Yellow Card summaries from December 2020-present. The analyses of data mentioned in Answer 1: epidemiology studies, data on national vaccine usage, anonymised GP-based health records, other healthcare data, data from international sources, unpublished studies, and other literature. Answer 4: a) You said: "every report with a fatal outcome is reviewed carefully". Can you confirm whether the MHRA follows-up on and analyses every report of a fatality after vaccination individually? b) These individual analyses of fatalities are the reports that I asked for in my original FOI. Please provide me with the MHRA's analysis of each death. This should amount to over 2,000 reports. I specifically asked for the MHRA's analysis of every fatality, individually, reported to the Yellow Card scheme after COVID vaccination. But you have shared a link to a cumulative summary (the Yellow Card summary). More than 2,000 post-vaccination deaths have been reported to the Yellow Card scheme since December 2020.
FOI 23/442	Just to clarify, the COVID-19 vaccines began to be administered in the UK Dec 8th 2020 starting with Pfizer/Biontech (Comirnaty). I presume PRIOR TO the approval dates (below) the product listed would be considered experimental or under development or an investigational medicinal product ? Pfizer/BioNTech vaccine(Comirnaty) vaccine Dec 21st 2020. Moderna vaccine on 31 March 2021 Janssen Covid-19 vaccine on 28 May 2021 Oxford/AstraZeneca vaccine on 24 June 2021
FOI 23/443	Please provide the number of complaints received by the MHRA, between January 2019 and December 2022, about products containing the herb St. John's wort (Hypericum perforatum L.) that did not, at the time the complaints were received by the Agency, hold a marketing authorisation, a Traditional Herbal Registration or that were considered as "unlicenced". Please group the number of complaints by annual quarter. Please indicate how many of the complaints were submitted to the Agency by commercial entities (i.e. other companies). We are not requesting disclosure of the names or other identification data of the commercial entities. Please format your response in a table titled "Table 1"
FOI 23/444	What studies have been approved in 2022 and 2023 using CPRD data. The webpage is incomplete and is missing months of data for 2022 and entirely missing data for 2023.

FOI 23/445	I would like to request the GMP inspection report for the company listed below. Only the covering page, Section A (Inspection Report Summary), and Section D (List of Deficiencies) are requested. Please provide via email, if possible. BIOPLUS LIFE SCIENCES PRIVATE LIMITED, PHARMED GARDENS, WHITEFIELD ROAD, BANGALORE, IN-560048, INDIACertificate Number: UK GMP 34063 Insp GMP 34063/627590-0003[H]Date of Inspection: 20/03/2023
FOI 23/446	Network Lifecycle 2a. Have you conducted a network refresh in the past 36 months? 2b. If so with which area? (eg Data Centre, Enterprise Networking, Wi-Fi, Security, Collaboration) 2c. Which vendor/technology solution was chosen? 2d. Which reseller/partner delivered the solution? 2e. Who maintains the solution? 2f. When does the maintenance contract expire/renewal date?
FOI 23/447	Please could you provide any information in relation to the screenshot below (MHRA written evidence 1980). In particular, I would like to know if CSM/DHSS did receive funding for a study to be carried out for the morning sickness Debendox, and if so, when was the study undertaken? If a study did take place, what were the results?
FOI 23/448	
FOI 23/449	Documents requesting for freedom of information (FOI) of the product name 'Prolia' ▶ RMP Annex 7, 10, 11, 12 (Template Rev 1) or Annex 4, 6, 7, 8 (Template Rev 2) ▶ PBRER body (the latest one)
FOI 23/450	Please could you tell me if the number of reported issues has increased with flash glucose sensors in the last 3 months compared to the rate a year ago?
FOI 23/451	I am trying to find any information due to Adverse Drug Reactions, and their numbers: spontaneous registration number per year, registrations by specialists number per year, and the most common drugs list.
FOI 23/452	I would be grateful if you could provide a copy of the reports for GMP Inspections carried out at the premises of ERAMOL (UK) LTD, MIA49160/MIA-IMP49160 in 2022 and 2023.
FOI 23/453	

FOI 23/454	We are writing to ask, in relation to any anti-epileptic medications • When taken in pregnancy, has induced gender dysmorphia ever been reported in the offspring? • Has induced gender dysmorphia in offspring, when used in pregnancy ever been reported by the marketing authorization Holder of a) Sodium Valproate b) Carbamazepine c) Topiramate d) Levetiracetam e) Lamotrigine f) Pregabalin g) Phenytoin • If so, which MAHs have reported induced gender dysmorphia and which medication.
FOI 23/455	We are writing from the Independent Fetal Anti-Convulsant Trust (INFACT) to enquire about prescription amounts per year for Anti epilepsy medications in the UK.Therefore we ask:• What is the number of prescriptions given to men in the UK for each year for Valproate from 2015 – 2022• What is the number of prescriptions given to women in the UK for each year for Topiramate from 2015 – 2022• What is the number of prescriptions given to men in the UK for each year for Topiramate from 2015 – 2022• What is the number of prescriptions given to women in the UK for each year for Levetiracetam in 2022• What is the number of prescriptions given to women in the UK for each year for Lamotrigine in 2022
FOI 23/456	1. Please provide the name of the MHRA employee/officer etc who determined the status of those products as medicines. Please also specify what position/role they have in the MHRA. 2. Please provide the name of the MHRA employee/officer etc who contacted Amazon.co.uk and advised them that the products were medicinal. Please also specify what position/role they have in the MHRA. 3. Please specify the date and time when the medicinal status of the products above was decided by the MHRA. 4. Please specify the date and time when the MHRA contacted Amazon.co.uk to advise them that the products were medicinal.
FOI 23/457	[Section 40 personal information]
FOI 23/458	... child health in England and would like to know from what areas the 375 general practices in England for the publication shown below, were taken from. If you could please provide me with a list of towns, villages, and cities that they were taken from and how many practices were in each area, I would then be able to determine what level of deprivation the practices were from.

FOI 23/459	I would like the current data for yellow card reports for each of the different standard vaccines offered to babies up to the age of 2 years old please. Where can I get access to the information on what testing has been undertaken for each of these prior to their approval?
FOI 23/460	With regards to same, would you be able to share the copy of license (UK MIA(IMP) 45317)
FOI 23/461	1. Request for reports submitted which detail any adverse event relating to use of dermal fillers (both hyaluronic acid and non-hyaluronic acid based products).
FOI 23/462	I would like to request some information please. Could you please tell me how many allergy reports in total were made to the yellow card system between 01/10/2020 and 31/05/2023. And also how many of these resulted in a fatality.
FOI 23/463	• How many prescription medications have a Pregnancy Prevention Program? • How long have those prescription medications had their PPP attached? • What is their success rate over their life time?
FOI 23/464	[Section 40 personal information]
FOI 23/465	Freedom of Information request on Anisocoria reports following the AstraZeneca COVID-19 vaccine
FOI 23/466	Freedom of Information request on Eye-related side effects reports following the AstraZeneca COVID-19 vaccine
FOI 23/467	Freedom of Information request on cardiomyopathy reports following the AstraZeneca COVID-19 vaccine
FOI 23/468	Please can you send me copies of all emails from Dame June Raine to the Deputy Chief Medical Officer (England) between 17 Nov 20 and 30 Dec 20 regarding the Temporary Authorisation of the Pfizer and AstraZeneca Covid vaccines.
FOI 23/469	The Risk Management Plans for Pfizer/BioNTech, COVID-19 Vaccine AstraZeneca or COVID-19 Vaccine Moderna are available on the European Medicines Agency (EMA) website at the following links: Pfizer/BioNTech COVID-19 vaccine (known by the EMA under the brand name Comimaty): https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf I am assuming therefore that there is in fact no specific MHRA RMP document since MHRA is following the EMA RMPs. Is this correct?

FOI 23/470	Can the MHRA confirm or deny whether the sale of products intended for human use, which contain any part of the plant St. John's Wort (Hypericum perforatum), otherwise than as traditional herbal medicinal products licenced either under the Traditional Herbal Registration (THR) Scheme or under any other permitted scheme as set out in the Human Medicines Regulations 2012, is prohibited, restricted and/or banned in the UK? 1(a). If the answer to Question 1 above is in the affirmative, can the MHRA confirm that the restriction, prohibition and/or ban on the sale of such products has been publicly and officially communicated to the public at large, that complete details with respect to the restriction, prohibition and/or ban have been and are currently published and available to the public at large, in the form of official documents, and that such documents may be freely accessed by any person and at any time (thus evidencing that the restriction, prohibition and/or ban is valid, in effect and may be appropriately referenced to by any person at any time)? 1(b). If the answer(s) to Question 1 and/or Question 1(a) above is/are in the affirmative, please supply copies of the whole of such documents as described at Question 1(a) above together with the location where they are published. 2. Can the MHRA confirm or deny whether the sale of products classed as food supplements, as defined in Directive 2002/46/EC ("the Food Supplements Directive") and The Food Supplements (England) Regulations 2003, that contain any part of the plant St. John's Wort (Hypericum perforatum) is prohibited, restricted and/or banned in the UK? 2(a). If the answer to Question 2 above is in the affirmative, can the MHRA confirm that the restriction, prohibition and/or ban on the sale of such food supplements has been publicly and officially communicated to the public at large, that complete details with respect to the restriction, prohibition and/or ban have been and are currently published and available to the public at large, in the form of official documents, and that such documents may be freely accessed by any person and at any time (thus evidencing that the restriction, prohibition and/or ban is valid, in effect and may be appropriately referenced to by any person at any time)? 2(b). If the answer(s) to Question 2 and/or Question 2(a) above is/are in the affirmative, please supply copies of the whole of such documents as described at Question 2(a) above, together with the location where they are published
FOI 23/471	Please provide complete formulation specifications and/or requirements, in accordance with relevant UK and retained EU legislation, for products containing any part of the plant St. John's Wort (Hypericum perforatum) in order for such products to be classed as food supplements in the UK in accordance with Directive 2002/46/EC ("the Food Supplements Directive") and The Food Supplements (England) Regulations 2003.Examples of formulation specifications/requirements must include, inter alia, the following:a. the part(s) of plant legally permitted in the formulation of such food supplements;b. for food supplements containing dry, powdered and/or liquid extracts of the plant as active ingredients, the range of Dry Extract Ratio (DER),
FOI 23/472	Freedom of Information Request

FOI 23/473	I would like to make a request under the Freedom of Information Act with regard to 3 batch numbers of Covishield Vaccine. 4120Z001/4120Z002 and 4120Z003 . Were these batch numbers tested by yourselves and if so please could I have the relevant batch certificate for each one . NIBSC or OCABR certification. Dates the batches were tested and findings . If these were not tested before release by yourselves could you tell me where I may get the information from .
FOI 23/474	In relation to its Covid vaccine product authorised for use in the UK, please could you confirm for each calendar year from 2020 to 2023 how many validated safety signals have been notified to the MHRA by Pfizer/BioNTech by means of: (a) a product information and/or RMP variation application or equivalent? (b) inclusion in a PSUR? (c) a standalone signal notification (including any signal also notified in a PSUR but which has been separately notified as an 'important risk')?
FOI 23/475	What are the steps that the Medicines and Healthcare products Regulatory Agency (MHRA) must follow in order to identify the number of complaints received by the Agency about products containing a random herb ‘X’ over a period of 5 years? 2. What is the general cost, in pounds sterling (£/GBP), associated with the process noted at Question 1 above? 3. Is the MHRA able to predict the amount of time required for undertaking the process noted at Question 1 above and/or the cost associated with this process?
FOI 23/476	1. The MHRA has stated that this vaccine was approved “after meeting the MHRA’s required safety, quality and effectiveness standards”. Yet your own guidance document makes clear that there is no efficacy data, and minimal safety data for this vaccine. So what exactly are the required safety, quality and effectiveness standards? 2. As the vaccine is primarily intended for people previously unvaccinated why did you authorise its use for a country like the UK that is highly vaccinated? (see https://wherearethenumbers.substack.com/p/the-new-skycovion-vaccine-more-questions for details) 3. Are you dispensing the vaccine to already vaccinated people in the UK? if so what studies have been performed to show that it is safe and effective to be used in people previously vaccinated with AstraZeneca, Pfizer, Moderna and other vaccine combinations.
FOI 23/477	Please can you confirm the number of Yellow Card reports from the Isle of Man of adverse side effects to covid-19 vaccines since 1st January 2021 to the present date. This request is made under the Freedom of Information Act.
FOI 23/478	If the data are available, I am hoping to collect data on:- The specific wording for the Net Promoter Score question(s) people are asked (e.g., people might be asked if they would recommend the NHS to a friend or to a colleague or somebody else – it’s this type of information I’m interested in across days/weeks/months/years; trusts; different departments within trusts; operations/activities performed etc.)- The individual score people gave (i.e. from the 0-10 scale)- The % of detractors, % of passives, % of promoters for each time the overall NPS score is calculated- The overall NPS score (this calculated by subtracting the % of detractors from the % of promoters)- Any associated qualitative data that might be asked alongside the 0-10 scale- The time period in which individual scores are aggregated (e.g., if the NHS calculates the overall NPS every month, please can I have the specific dates)

FOI 23/479	In responding to a recent request, FOI 23/370, the MHRA revealed: “We actively follow up Yellow Cards of special interest for any information that would benefit in our assessment and encourage all reporters to send relevant updates on their reports." Which would suggest that the MHRA must have some idea of the number of Yellow Card reports of adverse events of special interest it has followed up. So, under the Freedom of Information Act 2000, I resubmit my request for the disclosure of the following information: How many Yellow Card reports of adverse events of special interest has the MHRA followed up?
FOI 23/480	I am writing to inquire about the availability of a new drug called Skyclarys (omaveloxolone), for the treatment of Friedreich's Ataxia in the United Kingdom.
FOI 23/481	[Personal information s40]
FOI 23/482	I am requesting a statement and update upon the continuing use of obsolete tests here in the UK. In order for any tests to be carried out on animals, all institutions are bound by law to submit a project licence. The requirements for regulatory testing is set by yourselves. Ergo you will be fully aware of what the tests are that are going to be used. I specifically would like to know about the Abnormal Toxicity Test and why the MHRA is allowing this obsolete and deleted test to continue to be performed here in the UK.
FOI 23/483	Are NHS Community Wheelchair Services deemed by MHRA “community based organisations that are responsible for the management of medical devices” as per the above MHRA guidance?
FOI 23/484	Has the MHRA consulted the Information Requester’s Terms and Conditions (‘the Terms’), as published on the website www.drcorbyn.co.uk, prior to issuing the Decision to the Information Requester? Q2. If the answer to Q1 above is in the affirmative, has the MHRA, after consulting the Terms, noted that all correspondence in relation to legal and/or regulatory matters must: (i) be directed exclusively to the email address indicated in the Terms as the appropriate channel of communication for such matters
FOI 23/485	Please indicate the reason(s) why the MHRA has not provided the corresponding SKU numbers of the products concerned in the Decision, which is a requirement per the Terms. Q2. Is the MHRA aware that SKU numbers are alphanumeric numbers used by businesses to facilitate the correct and conclusive identification of products for different business purposes, including, inter alia, inventory management and legal/regulatory matters
FOI 23/486	Hi i would like the safety data for all routine child vaccines from birth please
FOI 23/487	sent the paper yellow card report to you on 22/6/2023. Attached below are screenshots of the two pages I sent. Please send confirmation that this report is now logged onto the system. Could you let me know how this report will be processed and any timelines I should expect. Additionally, please send me any current data you have on associated reports of blood disorders following Covid vaccination, in particular lymphoma. If you need any further information please contact me

FOI 23/488	I really need the concrete numbers and if You could share them with me, would be wonderful. I can not find them on page. Could You share with me the numbers as follows in the example (attached file). I need basically this information (from 2012- to 2022): 1. How many Adverse drug reaction reports do You have per year from 2012 until 2022. 2. How many of them are serious/ not serious per year. 3. How many was reported by patients and how many by physicians per year. 4. What are the main top 5 medicines or systems affected by the ADR reports.
FOI 23/489	Can I be provided a copy of the minutes of all meetings by the CHM Sodium Valproate Expert Working Group in 2022 and 2023 to date?
FOI 23/490	How can the MHRA's Communications and Engagement Team and/or the whole of the MHRA predict the amount of time and/or the cost of handling the combined FOI request ref. 23/373, or any FOI request submitted to them, if no action has been taken by them to locate the information requested therein? 1(i) It follows that it would not normally be possible to state with certainty the amount of time, and subsequently the cost, of handling any FOI request if the process of locating the requested information has not been completed or if some steps towards completing the process have not already been taken
FOI 23/491	1. Please indicate whether the MHRA and/or their legal representatives are aware of the 21 June 2023 email in relation to the Cornelius van Baerle Affair. 2. If the response to Q1 above is in the affirmative, why has the MHRA and/or their legal representatives not responded to the 21 June 2023 email promptly and properly to this day?
FOI 23/492	Please can you confirm whether this study of 2000 pregnant women, relating to Covid 19 vaccination, went ahead? If it did go ahead, was there ever an associated report or analysis? Are there raw data from this cohort regarding this study?
FOI 23/493	For the calendar year 2022 could you please tell me i) the number of Adverse Reactions reported relating to dermal fillers ii) could you please provide a complete breakdown of the side effects that the reporters have claimed relating to dermal fillers NOTE: I requested the same data previously for the calendar years 2019, 2020 and 2021. I'd be very grateful if you could provide the details for 2022 in the same format as in the attached.
FOI 23/494	Please share the contract description and number of users for both contracts Please share the annual spend for Salesforce.
FOI 23/495	[Personal information s40]

FOI 23/496	According to this 2 July 2023 tweet https://twitter.com/LifeVacEurope/status/1675496222746877952 LifeVac Europe's UK restrictions have been lifted by the MHRA, (the LifeVac device) can now been freely used by anyone, anywhere to saved [sic] an adult or child/infant as before it was only within care homes and hospitals in the UK.Please provide me with copies of all records associated with the above-described status change approved by your agency including all reviews, reports, and correspondence. If the cost for completing this request exceeds 10£, please notify me before proceeding further.
FOI 23/497	1. Did NIBSC undertake testing of The Batches and if so on what date. 2. Were The Batches tested as 'Covishield' or 'AstraZeneca'? 3. What was the result of the testing? 4. Were The Batches cleared for use in the UK as 'Covishield' or AstraZeneca'?
FOI 23/498	Thank you for the yellow card report for MMR vaccines in 1 year olds, however it is not exactly what I hoped to see. The 3,651 amount of reported ADR ...what time scale is it and what is the amount of children that were vaccinated at that time?
FOI 23/499	Could you please treat my request for the information below as a formal request under the Freedom of Information Act 2000. Could you please give me the following information: (1) The number of Yellow Card reports that mention the term "suicide" OR "suicidal ideation" OR "suicidal risk" for (1) semaglutide and (2) liraglutide (2) Does the MHRA typically formulate reports on such matters? If so, can you please provide them.
FOI 23/500	Numerous inspection reports
FOI 23/501	1. What plans does the MHRA have to improve the range and reach of registers of medical devices? Who will hold (and pay for) these registers? 2. In assessing and registering organisations to become Approved Bodies for the evaluation of medical devices, how will you avoid the obvious conflict of interest which has plagued Notified Bodies in the EU, namely that as Notified Bodies are paid by device manufacturers they have a vested interest in approving a device so that its manufacturer will come back to them in the future?
FOI 23/502	We would kindly like to request an electronic copy of the public summary of the risk management plan (RMP) for PL 16028/0144. According to the published UK Public Assessment Report (UKPAR) for this licensed medicine, a risk management plan was developed to ensure the medicinal product is used as safely as possible.
FOI 23/503	1. Please provide the full name of the person who provided the above-mentioned email response (dated 23 May 2023[s40]). Please also indicate the position held by this person within the MHRA. Q2. [s40] 3. When sending correspondence of such great importance (such as a letter threatening criminal enforcement action), does the MHRA obtain their information about the recipient(s) of the letter from unreliable sources (i.e. 'open source' research) which are unconnected to the governmental organisations that hold accurate records and information?

FOI 23/504	Please can you provide me with information concerning the maintenance of your corporate estate i.e. operational buildings, land and any other property (e.g. investment) and schools, if they are within your jurisdiction. Not any social housing/dwellings.Q1. What type of maintenance management model does your organisation use? E.g. Managed supply-chain, single hard-fm & soft-fm contractor, internal workforce, principal contractor etc.Q2. Can you provide a list of the approved contractors used?Q3. What are the total values of contracts granted?Q4. When do these contracts expire?Q5. What services are provided in each contract?Q6. What procurement method was used? E.g. Open ITT, Framework if so, which one?
FOI 23/505	MHRA recently implemented a new organisational structure. Please can you tell me the effective date of the new organisational structure and send me a copy of the current organisation chart showing SCS1-3 posts, post titles and postholder names, and G6 post titles. Please can you send me a copy of the Programme Business Cases relating to MHRA's Operational Transformation Programme. Please can you send me a copy of any safety impact assessments relating to that Operational Transformation Programme.
FOI 23/506	Please could you disclose the Public Assessment Report and the Clinical Overview (Module 2.5) for Omeprazole (2mg/ml, 4mg/ml) powder for oral suspension marketed by Rosemont Pharmaceuticals Limited
FOI 23/507	A Research Letter by Schmelling et al. was accepted on 26 March 2023 by the European Journal of Clinical Investigation (Schmelling et al., 2023)[1]. Assuming the MHRA are aware of Schmelling et al., 2023 and the conclusion drawn that "the results suggest the existence of a batch-dependent safety signal for the BNT162b2 vaccine, and more studies are warranted to explore this preliminary observation and its consequences," please provide a copy of all internal and external communications relating to this topic and any actions taken by the MHRA as a result of becoming aware of it. If the MHRA are aware of any similar batch-dependent Suspected Adverse Events findings, whether carried within the MHRA or via any other source, please provide details of these and any actions taken by the MHRA.
FOI 23/508	There is considerable public interest in understanding the nature of the data supporting statements made in the PAR that identify specific polymorphism as “essential”. We should be grateful if you would please explain or provide documentation which explains and supports: 1. the basis on which the product has been approved with a PAR that states that “consistent manufacture of the same polymorphic form” is essential 2. which polymorphic form must be manufactured

FOI 23/509	We would like to request a copy of the Public Assessment report (UK PAR) and information if its Initial application or MA transferred application of the following product under the Freedom of Information Act (FOIA) of MHRA: Product name: Renvela® 800 mg film-coated tablets
FOI 23/510	1. Temporary Authorisation of the Pfizer Covid vaccine on 2 December 2020 permitted public use of Batch EJ0553 based, inter alia, on the clinical trials in 2020 defined in Pfizer document C4591001. The vaccine used in the 2020 clinical trials was manufactured using 'Clinical Supply' 'Process 1'. Batch EJ0553 was manufactured in September 2020 using 'Commercial Supply' 'Process 2'.Request 1 : please can you tell me if any human was vaccinated (in UK or elsewhere) using 'Process 2' product prior to 2 December 2020, and if so, when and where. 2. Pfizer amended C4591001 in October 2020 to add, inter alia, at para 9.4 : "The safety and immunogenicity results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing “Process 1” and each lot of “Process 2” will be summarized descriptively. A random sample of 250 participants from those vaccinated with study intervention produced by manufacturing “Process 1” will be selected randomly for the analysis."Request 2 : Please can you send me a copy of Pfizer's report of this. Alternatively, if you exempt its release, tell me the Pfizer reference and date
FOI 23/511	Pharmapac UK Limited - Inspection report
FOI 23/512	could you please send me the following information with regards to the organisation’s Mobile Phones contract. You may have received the same request in the past and this information sent has now expired and I require an update as soon as possible for the following information: If there is more than one provider, please split all the information including the annual average spend, number of connections, duration, contract dates and internal contact details. 1. Network Provider(s) - Please provide me with the network provider name e.g., EE, Telefonica, Vodafone, Three
FOI 23/513	four potential call-off contracts awarded by MHRA, but I can't find details of the framework agreements they were awarded from.
FOI 23/514	Inspection reports for MERCK S.A., ESTRADA DOS BANDEIRANTES 1099, RIO DE JANEIRO, BR-22710-571, BRAZIL Marfleet Analytical Services Limited, Wyke House, Wyke Works, Hedon Road, Hull, HU9 5NL, UNITED KINGDOM
FOI 23/515	Request for future medical device regs consultation response data
FOI 23/516	Under the Freedom of Information Act , please can you forward the response sent to [s40 name]
FOI 23/517	Can you tell me how many adults over the age of 60 have died from RSV (respiratory syncytial virus) in the UK from earliest records available to 2023 seperated by year ?
FOI 23/518	This email represents a request under the terms of the Freedom of Information Act 2000, for the time period from the 1st October 2020 to and including the 31st december 2020, would you be able to provide all emails from/to : [s40 names]

FOI 23/519	a) MHRA quantitative assessment of the "foreseeable benefits" to the younger individuals involved in the trial and those affected by the condition under investigation b) MHRA's assessment of the clinical trial's compliance with UK Law c) a list of any other clinical trials of mRNA Covid vaccines involving trials participants aged 0-17yrs which have been approved by MHRA since 1 January 22.
FOI 23/520	Would it be possible to make another FOI request please? • The total number of all ADR reactions • The total number of all ADR reports • The total number all ADR reactions for subcut products only • The total number all ADR reports for subcut products only
FOI 23/521	1. The exact date of this license change (approximately August 2018) 2. Date of request from MHRA (and/or European equivalent if relevant) to all 28 UK sertraline MAH to update their sertraline PIL in accordance with the license. 3 The timeframe required by MHRA for submission of the updated PIL. 4. The date that MHRA received the updated PIL for each sertraline product from each MA holder. 5. A copy of each updated PIL for each product for each MAH (I will look through them all). 5. The date Marketing Authorisation renewal was issued to each MAH 6. The report provided by each MAH detailing user consultation with target patient groups on the PIL. 7. Details of any testing of communication of suicidal ideation in any context by sertraline MAH.
FOI 23/522	Lipid-related impurity issues for BNT162b2
FOI 23/523	Can you please seek, find and release any internal information in minutes of MHRA meetings, internal & external correspondence etc. that contributed to placing the paragraph below in the MHRA Guidance for health & social care organisation, including care homes, and published in January 2021
FOI 23/524	Betnesol Eye, Ear and Nose Drops Solution 0.1% w/v -Generics [UK] - Assessment reports
FOI 23/525	All inspection, GDP & GMP reports for CALEA UK during 2019
FOI 23/526	I would be grateful if you would provide me with all information which you hold relating to this batch number, including the number, age and ethnicity of recipients; the period of time over which, and the locations in which, this batch number was administered; the dates of its production and distribution; any quality reports; and any reports of adverse effects.
FOI 23/527	Clarification to FOI 23/366