Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
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E14 4PU
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gov.uk/mhra

[redacted]

28 April 2023

FOI 23/225

Dear [redacted]

Thank you for your email.

Please find below answers to the questions you have raised.

Question 1

I would like to request under the freedom of information request protocol all information on the Phizer and Moderna safety and ingredients data.

MHRA response

The MHRA does hold the information requested. Some of this information is available in the public domain (see below). However, we have also determined that some of the information is exempt under Section 12 of the Freedom of Information Act. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information.

Due to the breadth of this request and the potentially very large volume of information involved we ask that you clarify which specific aspects of the safety information for the Pfizer-BioNTech and Moderna COVID-19 vaccines you require, to enable us to provide information of greatest relevance to you.

The MHRA and the European Medicines Agency (EMA) have made available to the public pre- and post-approval safety data for the COVID-19 vaccines. The table below lists these sources of information with links to where they can be located on the internet.

Information on vaccine ingredients is included in the product information for each vaccine. The links to the webpages displaying the product information are given in the second row of the table.

Information source	Description of information	URL / web-link
Details of clinical trial data for the COVID-19 vaccines submitted to EMA and MHRA	- The clinical data for all the authorised COVID-19 vaccines have been published by the European Medicines Agency EMA	Home - Clinical Data Publication - clinicaldata.ema.europa.eu
Details of regulatory approval of Pfizer-BioNTech and Moderna vaccines showing: - Public Assessment Report - Product Information	- The Public Assessment Report explains how the product was assessed and authorised as well as its conditions of use - The product information for healthcare professionals and vaccine recipients includes a list of the recognised adverse effects of the COVID-19 vaccine - Information on ingredients is included in sections 2 and 6 of the Summaries of Product Characteristics and in section 6 of the Patient Information Leaflets	Pfizer-BioNTech: Regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19 Moderna: Regulatory-approval-of-covid-19-vaccine-moderna
Post-approval studies	- Plans for post authorisation studies for COVID-19 vaccines including timelines for completion are included in the Risk Management Plans (RMPs) for COVID-19 vaccines - These RMPs are available on the EMA website as part of the European Public Assessment Reports (EPARs) for these vaccines	Pfizer: Comirnaty | European Medicines Agency (europa.eu) Moderna: Spikevax | European Medicines Agency (europa.eu)
Summary of Yellow Card Reporting for COVID-19 vaccines	- MHRA holds a database of reports of suspected adverse reactions known as Yellow Cards - The Yellow Card scheme is a mechanism by which anybody can voluntarily report any suspected adverse reactions or side effects to the vaccine - It is very important to note that a Yellow Card report does not	Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk) ARCHIVED – Coronavirus vaccine – summary of Yellow Card reporting – GOV.UK (www.gov.uk)

Information source	Description of information	URL / web-link
	necessarily mean the vaccine caused that reaction or event - We ask for any suspicions to be reported, even if the reporter isn't sure if it was caused by the vaccine - Information on safety investigations carried out by the MHRA on these products, including the detection of rare adverse reactions are available in the published summaries of Yellow Card reporting for the primary and booster vaccination campaigns up to the end of August 2022 and the 2022 autumn booster campaign	
Interactive Drug Analysis Profiles (iDAPs)	- The types of suspected adverse reactions being reported to the Yellow Card scheme can be viewed in the form of Interactive Drug Analysis Profiles (iDAPs) - Each iDAP contains a complete listing of all spontaneous suspected adverse drug reactions, or suspected side effects, that have been reported with a particular drug substance or COVID-19 vaccine through the Yellow Card scheme	What is being reported | Making medicines and medical devices safer (mhra.gov.uk)
Drug Safety Update	- This monthly newsletter from MHRA and its independent advisor, the Commission on Human Medicines, has published several articles on COVID-19 vaccine safety	Drug-safety-update
Commission on Human Medicines' meeting minutes	- The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products - CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care	CHM final minutes

Question 2

I would also like to request the governments contracts with Pfizer, Moderna, Johnson and Johnson and Astra Zeneca.

MHRA response
The requested information is not held by MHRA. The MHRA is not responsible for, and does not hold, details of government contracts with pharmaceutical companies.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
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