FOI 24/185 Freedom of Information request - Covid Vaccine

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Fri 22/03/2024 17:57

To:request-1091954-2320e0e2@whatdotheyknow.com <request-1091954-2320e0e2@whatdotheyknow.com>

FOI 24/185

Dear [redacted]

Thank you for your request of 23 February 2024 which asked for:

"1. Evidence of deaths relating to the vaccines.
2. Evidence of illnesses relating to the vaccines.
3. Evidence that the vaccines are safe.
4. Evidence of testing conducted on the Covid 19 vaccines.
5. Evidence of the reason why the booklets were allowed to be blank in the vaccine packs."

We have dealt with your request under the Freedom of Information Act, and we confirm that we hold some of the information requested; we indicate below that for questions 1, 2 and 5 that we do not hold the specific information that you have asked for.

Please see below responses to each of your questions:

1. Evidence of deaths relating to the vaccines.
2. Evidence of illnesses relating to the vaccines.

We first thought it would be helpful to give some context on what the Yellow Card scheme is and subsequently the information we hold. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected Adverse Drug Reactions (ADRs) and incidents in association with medicines, vaccines and medical devices. The scheme is run by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Commission on Human Medicines (CHM), and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. It's vital to note that Yellow Card reports are made based on suspicion and are therefore not conclusive evidence that the medicine or vaccine caused the suspected reaction(s).

Whilst anyone can report their suspicions of a safety concern or incident, a reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. As such, any information provided should not be used to determine incident rates or be taken as proven side effects. A list of the recognised adverse effects of the COVID-19 vaccines is provided in the information for healthcare professionals and the recipient information here.

The MHRA does not hold information on the number of patients that have a COVID-19 vaccine listed as a cause of death on their death certificate, as this falls outside of our remit. The MHRA do not determine causality of individual reports, and this includes reports of fatalities.

You may wish to contact the Office for National Statistics (ONS) here FOI.Team@ons.gov.uk as they may hold this information.

To assist, we can advise that the MHRA hold information around suspected side effects that have been reported to us via the Yellow Card scheme. This information however is exempt from release under Section 21 of the FOIA (Information accessible by other means), as this is already publicly

available.

The MHRA publishes this information in the form of interactive Drug Analysis Profiles (iDAPs) which can be accessed here on the Yellow Card website. You will be able to access a complete listing of all suspected adverse drug reactions (ADRs) that have been reported to the MHRA via the Yellow Card scheme for all of the COVID-19 vaccines. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. You will be able to find information here about the number of reports of suspected ADRs with a fatal outcome on the overview page for each vaccine.

When reviewing the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report to ensure that you do not misinterpret the data. The data shown in these interactive profiles can be very useful in helping to identify possible medicine safety issues. However, this information does not present a complete overview of the potential side effects associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the data shown in the Interactive Drug Analysis Profile alone.

Please be aware that vaccination and surveillance of large populations means that, by chance, some people will experience and report a new illness or events, including fatalities, in the days and weeks after vaccination. The presence of older age groups and chronic underlying illnesses make it more likely that coincidental adverse events, including those with a fatal outcome, will occur, especially given the millions of people vaccinated.

3. Evidence that the vaccines are safe.

For this part of your request, we do hold relevant information, but this question is extremely broad, and we consider that section 12 of the FOIA applies. This is because the time needed to undertake the activities of determining all information within the scope of your request, and locating, retrieving and extracting that information exceeds the 24-hour 'appropriate limit' set out in the FOI Act. We consider that the scope of this question would include all relevant information relating to this subject which would be held throughout the lifecycle of the marketing authorisations of each of the COVID-19 vaccines to the present time. This would require retrieval of 1000s of pages of information and reports held in multiple different locations within the MHRA. To explain this, we've included a link to the Information Commissioner's decision on a similar type of request which also required the retrieval of evidence from multiple areas of the MHRA https://ico.org.uk/media/action-weve-taken/decision-notices/2023/4027614/ic-254831-s5n2.pdf .

Although we are refusing part 3 of your request (and part 4, see below), we provide advice below to assist you in making a new narrowed request; we hope this is useful in explaining the scope of the information that you have asked about and may assist you in identifying a specific topic that you may wish to focus a request on.

All vaccines used in the UK are authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). Each COVID-19 vaccine is only authorised once it has met robust standards of effectiveness, safety, and quality. Links to Public Assessment Reports on data from clinical trials showing the efficacy and safety of the Covid vaccines which were submitted for their authorisation are provided in response to question 4 below.

As with all vaccines and medicines, the safety of COVID-19 vaccines is continuously monitored, and the advice from the MHRA remains that the benefits of vaccination in preventing COVID-19 and serious complications associated with COVID-19 outweigh any currently known side effects in the majority of patients. Information on the characteristics of each vaccine is published by the MHRA on

the GOV.UK website.

Between February 2021 and March 2023 the MHRA regularly published the summary of Yellow Card reporting for COVID-19 vaccines, which provides an overview of the MHRA's safety assessments concerning these products along with the numbers and types of all UK suspected adverse reaction reports we have received for the COVID-19 vaccines, including other relevant information from other studies. The MHRA sought independent advice from the Commission on Human Medicine (CHM) and their Expert Advisory Group on COVID-19 vaccines on specific safety issues. Summary minutes from CHM meetings can be available at Membership - Commission on Human Medicines - GOV.UK (www.gov.uk) and the CHM Annual Reports for 2021 and 2022 are available here: https://www.gov.uk/government/organisations/commission-on-human-medicines .

Periodic safety update reports (PSURs) are pharmacovigilance documents submitted by Marketing Authorisation Holders (MAHs) at defined time points during the post-authorisation phase. The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the risk-benefit balance of the medicinal product taking into account new or emerging information in the context of cumulative information on risks and benefits. For further information about PSURs, please see the Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report available at: Good pharmacovigilance practices | European Medicines Agency (europa.eu). PSURs for COVID-19 vaccines are published by the European Medicines Agency (EMA) under the 'Safety updates' sections of the following links:

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca
https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna

Further, you may also be interested in the International Coalition of Medicines Regulatory Authorities (ICMRA), which includes the MHRA, statement on the safety of COVID-19 vaccines which includes a section of evidence of COVID-19 vaccine safety after use of billions of doses (ICMRA statement on the safety of COVID-19 vaccines | International Coalition of Medicines Regulatory Authorities (ICMRA).

4. Evidence of testing conducted on the Covid 19 vaccines.

When section 12 applies to any part of a request for related information, we follow the Information Commissioner's guidance that whole request may be refused. This question also has a very broad scope, including information held for clinical trials and also for the testing that was undertaken by National Institute for Biological Standards and Control (NIBSC) within the MHRA, and we are therefore refusing this part of your request under section 12. We provide further assistance in the details below that may help you to focus a request on a particular area of testing that you are interested in.

Details of batch testing undertaken by NIBSC is available here. This webpage provides further links to the NIBSC website:
https://www.gov.uk/government/news/independent-batch-release-testing-of-covid-19-coronavirus-vaccines-by-the-nibsc

Data from clinical trials showing the efficacy and safety of the Covid vaccines which were submitted for their authorisation are available through the Public Assessment Reports (PARs) published by MHRA and the European Medicines Agency (EMA). Links to these for Comirnaty (Pfizer vaccines),

Vaxzevria (AstraZeneca vaccines) and Spikevax (Moderna vaccines) are provided below:
https://products.mhra.gov.uk/search/?search=spikevax&page=1&doc=Par&rerouteType=0
https://products.mhra.gov.uk/search/?search=comirnaty&page=1&doc=Par&rerouteType=0
https://products.mhra.gov.uk/search/?search=Vaxzevria&page=1&doc=Par&rerouteType=0
https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax-previously-covid-19-vaccine-moderna
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

Further, data from these clinical trials are publicly available through the EMA Clinical Repository, a link to this is provided below:
https://clinicaldata.ema.europa.eu/web/cdp/home

5. Evidence of the reason why the booklets were allowed to be blank in the vaccine packs.

The Patient Information Leaflets (PILs) authorised by MHRA for Comirnaty (Pfizer vaccines), Vaxzevria (AstraZeneca vaccines) and Spikevax (Moderna vaccines) are published. Links to these are provided below:
https://products.mhra.gov.uk/search/?search=Comirnaty&page=1&doc=Pil&rerouteType=0
https://products.mhra.gov.uk/search/?search=vaxzevria&page=1&doc=Pil&rerouteType=0
https://products.mhra.gov.uk/search/?search=Spikevax&page=1&doc=Pil&rerouteType=0

We hold no information on "the reason why the booklets were allowed to be blank in the vaccine packs." We suggest that you refer this question to either the Department of Health and Social Care (DHSC) or NHS England.

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Appeal rights

If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you 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 a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information

-----Original Message-----
From: [redacted] <request-1091954-2320e0e2@whatdotheyknow.com>
Sent: Friday, February 23, 2024 12:20 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/185 Freedom of Information request - Covid Vaccine

Dear Medicines and Healthcare Products Regulatory Agency,

1. Evidence of deaths relating to the vaccines.
2. Evidence of illnesses relating to the vaccines.
3. Evidence that the vaccines are safe.
4. Evidence of testing conducted on the Covid 19 vaccines.
5. Evidence of the reason why the booklets were allowed to be blank in the vaccine packs.

Yours faithfully,

[redacted]

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For more detailed guidance on safely disclosing information, read the latest advice from the ICO:
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Fhelp%2Fico-guidance-for-authorities&data=05%7C02%7CMHRACustomerServices%40mhra.gov.uk%7C42ba8beaf7884a61c60708dc3469c15e%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638442876056548927%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=KtxN%2FCJDjQARkNrJGrqIXCzLpkcDY4z1f9Hgg9rkyZE%3D&reserved=0
https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whatdotheyknow.com%2Fhelp%2Fico-anonymisation-code&data=05%7C02%7CMHRACustomerServices%40mhra.gov.uk%7C42ba8beaf7884a61c60708dc3469c15e%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638442876056560283%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=7nmrXyBaxY8tVQCNrLFMfVOCx0dUjdC5UEr836BjYWk%3D&reserved=0

Please note that in some cases publication of requests and responses will be delayed.

If you find this service useful as an FOI officer, please ask your web manager to link to us from your organisation's FOI page.
