FOI 24/117 re: URGENT: Spike Protein Concerns and Freedom of Information Request

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

Thu 07/03/2024 12:07

To [redacted]

From: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Sent: 26 February 2024 20:20
To: [redacted]
Subject: FOI 24/117 re: URGENT: Spike Protein Concerns and Freedom of Information Request

Dear [redacted]

Thank you for your email of 29 January 2024, which was sent to our Chief Executive, but which also mentioned the Freedom of Information Act in several places. We note that in response to our acknowledgement of your request, you replied saying "*Thank you for confirming that those elements of the email from 29th January 2024 to* [redacted] *are being handled via FOI. Please confirm that a standard response in relation to the main thrust of the email content will be received from* [redacted] "

We have included directions to some of the ICO's guidance at the end of this email, which advises how to make effective requests for information. We appreciate that this guidance does not quite cover the way you are submitting requests for information alongside general correspondence, but we hope it will be useful nonetheless – the underlying principle of FOIA is that the clearer a request for recorded information is, the less likelihood that a public authority will need to come back to the requester to ask for clarification of the information that is being requested. It is a requirement for a valid request that a clear description of the information sought is provided by the requester. In addition, your own questions are punctuated by 'if necessary' and 'if it helps' – so it would be very helpful if you could review the ICO's guidance with a view to being a little clearer in whether you wish to submit an FOIA request or not.

We note that this issue also arises in your concurrent request, FOI 24/150, and we will write to you about this request separately.

Moving to your email of 29 January 2024 and the questions you asked, for your first question:

> *please can you clarify what activities the MHRA have carried out in relation to understanding the potential harms from the spike protein itself (whether from the virus or vaccine-induced/introduced), including but not limited to requests for further information from the MAHs, requests for additional studies or reviews by MAHs, internal meta-analyses or other reviews of published literature by the MHRA. Please treat this as a Freedom of Information Request if necessary.*

We need to ask you to clarify whether you are seeking recorded information in this request and if so, whether this is for:

- The mRNA vaccines mentioned in the article with which you began your request - **Determinants of COVID-19 vaccine-induced myocarditis**
- Or, bearing in mind that, as you term it, 'potential harms' from 'vaccine-induced' spike protein may apply across COVID-19 vaccines in general, and will form part of our

monitoring of wider safety topics, whether you wish to make this request in respect of all Covid-19 vaccines.
- We note that your second question specifies a type of information for "*for the COVID-19 vaccines since authorisation in the UK"*, but this is not specified for your first question.

We would be grateful for you to provide further details of the specific information you are seeking for this question.

We can advise on certain points where we will not hold recorded information.

- MHRA regulates medicines and is responsible for monitoring the safety of medicines. We do not investigate harms from disease, and therefore we have not carried out any activities to understand potential harms from spike protein *from SARS-CoV-2 itself*. This is not part of our remit.
- The focus of your request appears to be based on the views you have put forward, which you term "*the potential harms from the spike protein itself*". On a very literal reading of this request, we advise that we have not requested marketing authorisation holders to perform additional studies to "*understand the potential harms from the spike protein*", and MHRA has not conducted any "*internal meta-analysis*" in this regard. However, please note that the topic of interest to you may fall within monitoring of wider safety topics. Therefore to assist, we can advise that as part of their pharmacovigilance responsibilities, the manufacturers are obliged to undertake safety monitoring, signal detection, periodic safety reporting and to inform regulators of any new signals for their products.

For details of these studies, please see the Risk Management Plans for the vaccines, which are available on the EMA website:

https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

https://www.ema.europa.eu/en/documents/rmp-summary/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-risk-management-plan_en.pdf

https://www.ema.europa.eu/en/documents/rmp-summary/spikevax-previously-covid-19-vaccine-moderna-epar-risk-management-plan_en.pdf

vidprevtyn-beta-epar-risk-management-plan_en.pdf (europa.eu)

nuvaxovid-epar-risk-management-plan_en.pdf (europa.eu)

We also note that the following COVID-19 vaccines are authorised in the UK, but have not yet been deployed as part of the UK immunisation programme, and this information is also available:

https://www.ema.europa.eu/en/documents/rmp-summary/covid-19-vaccine-janssen-epar-risk-management-plan_en.pdf

Bimervax | European Medicines Agency (europa.eu)

Your second question asks:

> *I would like you to confirm what, if any, current scientific literature (knowledge) the MAHs for COVID-19 vaccines considered post authorisation in relation to the potential harms resulting from the spike protein itself?*

While the first part of this question is more specific, the second part is extremely broad:

If it helps, please provide me with a copy of the PSURs (redacted of any commercial or other sensitive information) for the COVID-19 vaccines since authorisation in the UK from each MAH.

The way you have worded the two parts of the request again creates an issue with regard to a clear description of the information you are seeking – are you asking for one, or the other, or both parts of the request.

This wording means that we are either required to identify/retrieve and then read/search/review all relevant recorded information that may meet the description given of 'scientific literature' or 'knowledge' considered by the MAH in the information we hold which has been provided to us by the MAHs (the FOIA does not cover the knowledge individuals may be aware of, unless this is already held by the public authority in recorded form), or, we take the second part of this question as your request and provide all PSURs, regardless of content. The latter would be a task creating a significant burden in it's own right due to the number of PSURs held by the MHRA, and the size of those documents, each of which would need to be reviewed to remove personal data and any sensitive information.

It is not clear which you wish us to do from the wording you have submitted to us.

To assist, we can explain that the following COVID-19 vaccines are authorised in the UK: Vaxzevria (Oxford-AstraZeneca), Comirnaty (Pfizer/BioNTech), Spikevax (Moderna), JCovden (Janssen), Nuvaxovid (Novavax), VidPrevtyn Beta (Sanofi), SKYCovion (SK Bio), and Bimervax (HIPRA).

As of the time of your request, a total of 24 PSURs have been submitted for these vaccines. Collectively, these documents (reports and appendices) contain tens of thousands of pages and, if this is the part of your request that you wish us to proceed with, we should advise that the burden of reviewing all these documents to identify and remove personal information, and to determine other exemptions, may lead to refusal of the request if this falls to be 'disproportionate'.

Therefore, in the first instance, we would like you to clarify which of the two parts of your second question you wish us to proceed with.

We can provide further advice and assistance in this regard. There are several points you may wish to consider:

- You may wish to continue with a request for the PSURs, so we would advise that you first check the following European Medicines Agency (EMA) publications, as these provide some of the PSURs for the vaccines authorised in the UK, as the UK accepts the EU PSUR format. All COVID-19 vaccines authorised in the EU are here:

  - COVID-19 medicines | European Medicines Agency (europa.eu)

  Specific links for the vaccines are here:

  - AZ: Vaxzevria Vaxzevria (previously COVID-19 Vaccine AstraZeneca) | European Medicines Agency (europa.eu)
  - Pfizer: Comirnaty Comirnaty | European Medicines Agency (europa.eu)
  - Moderna: Spikevax Spikevax (previously COVID-19 Vaccine Moderna) | European Medicines Agency (europa.eu)
  - Janssen Jcovden (previously COVID-19 Vaccine Janssen) | European Medicines Agency (europa.eu) not used in UK

- Novavax Nuvaxovid | European Medicines Agency (europa.eu)
- Sanofi VidPrevtyn Beta | European Medicines Agency (europa.eu)

If you scroll down each page to the 'Safety updates' section, published PSURs are available here. These pages also provide other safety related information. This information may be useful, and we would suggest that after reviewing this, if you wish to continue with a request for PSURs only, you indicate which vaccines and time periods you are interested in.

- Please note, we are aware that the EMA has an intent to publish further PSURs, so we should advise that when a clear request for these is received from you, we will consult with the EMA to determine if the requested information is already intended for publication (in FOIA terms, in this situation, section 22(1) of the FOIA would apply).
- If you do wish to continue with a request for PSURs, we can also advise that a number of these have previously been disclosed in response to FOI requests throughout 2023, concerning Pfizer PSURs number 1-4 and AstraZeneca numbers 1-2. While we will be publishing these responses and disclosures on our website within the next few weeks, if they are of particular interest to you, we could arrange to issue these responses to you in advance of publication.

To conclude, once you have had the opportunity to review the above, we await your clarification in respect of questions 1 and 2 above. We will then progress this as a new request. As noted, we will contact you about FOI 24/150 separately.

The link to the ICO guidance we mentioned is here:

https://ico.org.uk/for-the-public/official-information/how-to-write-an-effective-request-for-information/

Yours sincerely

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

From: [redacted]
Sent: Monday, January 29, 2024 3:48 PM
To: [redacted]
Cc: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: URGENT: Spike Protein Concerns and Freedom of Information Request
Importance: High

Dear [redacted]

A very recently published peer-reviewed research article titled **Determinants of COVID-19 vaccine-induced myocarditis** states the following within its conclusion:

> COVID-19 vaccines induce an uncontrolled expression of potentially lethal SARS-CoV-2 spike protein within human cells, have a close temporal relationship of events, and are internally and externally consistent with emerging sources of clinical and peer-reviewed data supporting the conclusion that COVID-19 vaccines are deterministic for myocarditis, including fatal cases.