FOI 23/621

Dear

Thank you for your request of August 2, 2023, where you asked:

> *"Can you please supply the evidence and science given by Pfizer and AstraZenica [sic] in November & December 2020, that concluded the covid-19 vaccines are perfectly safe for human interaction."*

Given that this is a request for information, 'supply evidence' it is necessary for us to respond in line with the FOI Act. Our response in line with Section 1 (1) a., is information not held. This is because we do not hold information as described in the specific wording of your request that *"Pfizer and AstraZeneca vaccines are perfectly safe for human interaction*."

Below, we explain the types of information we do hold that you may be interested in. We can also explain that all medicines can cause side effects.

All medicines can cause side effects (adverse drug reactions) for vaccine specifically, these side effects are usually mild and short-lived, for example, fever, pain and swelling at the injection site, raised lymph nodes. In many cases these side effects are linked to the intended action of the vaccine i.e. to initiate an immune response, in order for the immune system to be better prepared to recognise the pathogen for which the vaccine is intended, in this case SARS-CoV-2. Nonetheless, some side effects can be serious but such occurrences are usually rare to very rare. Therefore, it is not possible to provide evidence that these vaccines are 'perfectly safe', although, these vaccines are considered to be well-tolerated in most individuals.

Advice and assistance

The Marketing Authorisation Holder (company) submits a dossier of information and data to the MHRA, this is generally separated into 5 modules, see page 7.

Information from the dossier can be requested, but dependent of the volume of information covered we may not be able to process your request, for example, it might be refused due to the time/resource required to locate the information, or it may be refused due to the estimated burden on resources to check that the material can be released and redact exempt information such as personal data. Please also note, there are multiple types of COVID-19 vaccine produced by Pfizer.

If you intend to make a further request please be specific about which vaccine you wish to seek further information about. The EMA also hosts clinical data that was submitted to support these Marketing Authorisations (medicines licenses) on their clinical data repository. You can use the 'create EMA account' function to login to this resource and search for the vaccines which are of interest. Once logged in, click the browse search (fig 1) and select the 'C' in the alphabetical search this should return results for the Comirnaty (Pfizer vaccines), or 'V' for Vaxevria this option should return results for COVID-19 vaccine AstraZeneca.

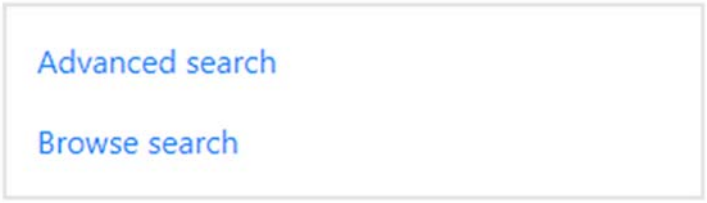

Fig 1.

Public assessment reports
The MHRA produces public assessment reports for new medicinal products authorised after Oct. 2005. This is based on the MHRA assessment report with any commercially or personally confidential information removed, the below reports may be of interest to you. We would suggest reviewing these materials in the first instance. The EMA also host similar reports called EPARs.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1148800/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_PAR_update_Annex_I.pdf

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1112667/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf

We trust that you will find this information of use. Howver, 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 online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow

Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Yours sincerely,

HQA FOI Team