FOI 22/645– consultation of Pfizer documentation

REQUEST
13 April 2022

Under a freedom of information request can the MHRA confirm that they were in possession and had consulted the documents of the recently public released PFIZER DOCUMENTATION that lists known side effects of interest ….before or at the time that the Uk EUA licence was issued.

MHRA RESPONSE
12 February 2023

Dear

Thank you for your email of 13 April 2022. Please accept our apologies for not having responded before now.

You asked MHRA to confirm whether they were in possession of and had consulted the published 'Pfizer documentation' before or at the time that the UK authorisation for this vaccine was granted.

Due to security concerns we have opted not to access the weblink you have provided us with. However, based on similar enquiries it may be that your request relates to the following Pfizer document released by the FDA in late 2021:

https://phmpt.org/pfizers-documents/.

Pfizer provided this report to the FDA (CBER) which summarises post marketing safety data covering the period from the first authorisation for temporary supply on 01 December 2020 (in the UK) up to 28 Feb 2021. Post marketing safety data relates to safety data which is collected after an authorisation has been granted, and includes information such as spontaneous adverse reaction reports. The document makes clear that the list of events from spontaneous reporting included in the report is not a list of side effects. Moreover, the authorisation of the Pfizer/BioNTech vaccine was granted in the UK on 01 December 2020, based on a review of pre-authorisation safety, quality and efficacy data. The UK was the first country in the world to authorise the Pfizer/BioNTech vaccine, so at that time no post-authorisation safety data was available.

Therefore the MHRA was not in possession of this document, however, we will have received the information as part of information Pfizer/BioNTech are obliged to provide to MHRA as part of the GB conditions of the vaccine's authorisation, and this information will have been considered in the context of our ongoing review of the safety of this vaccine. Therefore, the formal FOI response is information not held, in the context that this particular document is not held.

If you have a query about the information provided, please reply to this email.

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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