Medicines & Healthcare products Regulatory Agency

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Canary Wharf
London
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United Kingdom
gov.uk/mhra

[redacted]

20th March 2024

Dear [redacted]

FOI 24/230

Thank you for your Freedom of Information (FOI) request dated 5 March 2024 in which you requested *'the record of internal signal meeting for the week of 05/08/2022'.* You requested an electronic copy to be sent to your email address above. I can confirm the MHRA hold the information you requested.

The MHRA continually monitors safety during widespread use of a vaccine. For the COVID-19 vaccines, we put a proactive strategy in place to do this. We also worked closely with our public health partners in reviewing the effectiveness and impact of these vaccines to ensure the benefits continued to outweigh any possible side effects.

As part of our monitoring role, the MHRA adapted our signal management processes and held dedicated COVID-19 vaccine Signal Detection meetings throughout the pandemic. Following the deployment of the first COVID-19 vaccine in the UK in December 2020, COVID-19 vaccine signal detection meetings were conducted daily for assessors to raise any concerns and potential safety issues. Further into the COVID-19 vaccination programme, the frequency of COVID-19 vaccine signal detection meetings changed once less frequent meetings were considered to be appropriate based on assessment of the evolving safety data.

The COVID-19 vaccine signal detection meetings provided the opportunity to discuss potential safety issues arising from a wide range of information sources, including Yellow Card data and literature articles. Those attending these meetings contributed to the scientific and clinical assessment or had expertise in the areas being discussed. After the meeting, assessors were required to add their assessment comments onto the Agency's signal management system for individual vaccine and adverse event combinations.

Minutes from the signal detection meeting were documented and circulated to the attendees, which included a summary of the key issues raised at the meeting, the discussion around those issues, and any decision to take forward for expert advice. Please find attached the minutes from the COVID-19 vaccine signal detection meeting held in the week of 5th August 2022 as per your request. It is important to note that meeting minutes were variable in content

and length, dependent on the topics presented and discussions conducted. There are also instances where expert advice was sought following further assessment at the COVID-19 Vaccine Benefit Risk Expert Working Group (EWG).

Several acronyms are used within the meeting minutes, which we have defined in Annex 1 at the end of this response to aid your interpretation. Please note that where 'cases' have been referred to within the minutes, this should be interpreted as 'suspected adverse reaction reports' as opposed to cases that have undergone any medical assessment or are considered to meet certain criteria for diagnosis suggesting they have at least a plausible association with the vaccine.

You will notice that some information within the COVID-19 vaccine signal detection meeting minutes provided has been redacted. This information is exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire

SK9 5AF

Annex 1

Acronym	Definition
EWG	Expert Working Group
PRAC	Pharmacovigilance Risk Assessment Committee
MAH	Marketing Authorisation Holder
CHOP	Company perspective, Happenings of note, Our perspective, Product information