Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA
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Canary Wharf
London
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United Kingdom
gov.uk/mhra

26th February 2024

Our Ref: FOI 24/176

Dear [redacted]

Thank you for your Freedom of Information request dated 22nd January 2024, where you requested the Interactive Drug Analysis Profile (iDAP) for the Seqirus UK cell-based quadrivalent influenza vaccine. Please accept my sincere apologies for the delay in response to your request.

Firstly, I would like to inform you that currently our iDAPs are limited to medicines and COVID-19 vaccines data, therefore you will not yet find other routine vaccinations such as the Seqirus UK cell-based quadrivalent influenza vaccine available. The MHRA have begun implementing a new enhanced format of data visualisations. This enables us to provide improvements in format, accessibility and data protection whilst allowing access to more data than has been published previously. The initial phase of this development began with the provision of COVID-19 vaccine data with further plans to include all routine vaccination data, including influenza vaccines, and replace existing iDAPs for medicines this year.

However, further to your request we have conducted a search of our database for all Adverse Drug Reaction (ADR) reports for the Seqirus UK cell-based quadrivalent influenza vaccine. I can confirm that the MHRA have received a total of **299** UK spontaneous suspected ADR reports concerning the Seqirus UK cell-based quadrivalent influenza vaccine, up to and including 22nd February 2024. Please find the attached Vaccine Analysis Print (VAP) for details of the reported reactions to this vaccine, as well as the enclosed information sheet for guidelines on how to interpret the VAP. Please note that the total number of reactions in the table will not be equal to the total number of unique reports as one report may contain more than one reaction.

When considering the attached spontaneous ADR data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have been. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

Please be aware that the VAP provided should not be used as a list of side effects to the Seqirus UK cell-based quadrivalent influenza vaccine, nor should this data to be used to estimate the frequency of side effects or to compare the safety profile of different vaccines. All established undesirable effects for this vaccine can be found listed in section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Patient Information Leaflet (PIL).

I hope the information provided is helpful. 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 Group

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