Medicines & Healthcare products Regulatory Agency

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MHRA Website

[redacted]

Our Ref: FOI2024/00660

25th November 2024

Dear [redacted]

Thank you for your Freedom of Information request dated 28 October 2024, where you stated:

- ***I could not find an IDAP for influenza vaccines, TDaP, or RSV vaccines. Are these available to view, and if so how do I access them.***

MHRA Response

We confirm that we hold the information you have requested.

To firstly provide some clarification around the data available via iDAPs, vaccination data other than COVID-19 vaccines is not currently available in this form. The MHRA have begun implementing a new enhanced format of data visualisations which will enable us to provide access to more data than has been published previously, however, in the initial phase of this development, we have provided only COVID-19 vaccine data with further plans to include all routine vaccination data soon and update the current format for all available medicines' iDAPs.

Further to your request, I can confirm that up to and including 20 November 2024, the MHRA has received:

- **18,293** UK spontaneous suspected adverse drug reaction (ADR) reports associated with all influenza vaccines, with the first report received in October 1951.[1]
- **3,752** UK spontaneous suspected ADR reports associated with the DTaP vaccines, with the first report received in January 1961.
- **555** UK spontaneous suspected ADR reports associated with the RSV vaccines, with the first report received in January 2024.

Further to your request, please find attached the Vaccine Analysis Prints (VAPs) for details of the reported reactions to the above-mentioned vaccines, received through the Yellow Card scheme up to and including 20 November 2024. The attached guidance sheet provides you with further information on how to interpret the print. It is important to note that the total

[1]Data includes both reports concerning live and inactivated influenza vaccines.

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 spontaneous data within this response, 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. 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 or compare the safety profile of different vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

Finally, please be aware that the VAPs provided should not be used as a list of side effects to these vaccines. All established adverse reactions for the available influenza, DTaP and RSV vaccines can be found within section 4 of the Patient Information Leaflets (PILs), available on the MHRA products website.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.