Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

11 January 2023

Dear [redacted]

FOI 22/1193

Thank you for your enquiry dated the 13th of December where you requested Vaccine Analysis Prints (VAPs) for the below vaccines:

- Quadrivalent Influenza Vaccine, egg-grown (QIVe) manufactured by Sanofi Pasteur
- Influvac sub-unit Tetra, Quadrivalent Influenza Vaccine, egg-grown (QIVe) manufactured by Viatris (formerly Mylan)
- Cell-based Quadrivalent Influenza Vaccine (QIVc) manufactured by Seqirus
- Supemtek, recombinant Quadrivalent Influenza Vaccine (QIVr) manufactured by Sanofi Pasteur
- Adjuvanted Quadrivalent Influenza Vaccine (aQIV) manufactured by Seqirus

The MHRA continuously monitors the safety of medicines and 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. Any emerging evidence relating to possible risks associated with vaccines and medicines, is carefully reviewed and, if appropriate, regulatory action would be taken if any serious risks were confirmed.

Please find attached a Vaccine Analysis Print (VAP) for each requested vaccine which contains information on all UK spontaneous suspected ADR reports received through the Yellow Card scheme for that vaccine up to and including 13/12/2022. Please refer to the enclosed information sheet for guidelines on how to interpret the VAPs. Please be advised that due to the way medicines and vaccines are structured in our system we are unable to separate the two Seqirus manufactured vaccines (Cell-based Quadrivalent Influenza Vaccine (QIVc) & Adjuvanted Quadrivalent Influenza Vaccine (aQIV)) into individual VAPs. The combined VAP can be found attached as “Seqirus UK Quadrivalent Influenza Vaccine VAP”.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: MHRA Products | Home for details on the possible side effects of the vaccines.

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When considering the provided spontaneous Adverse Drug Reaction (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. Each year, millions of doses of routine vaccines are given in the UK alone, and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the vaccine. 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 drug, 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. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

I hope the information provided is helpful, but 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,

Vigilance and Risk Management of Medicines Division