Medicines & Healthcare products Regulatory Agency

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

[redacted]

20th February 2024

www.gov.uk/mhra

Dear [redacted]

FOI 24/065

Thank you for your email, where you requested the following:

- Yellow Card reports relating to the vaccine Revaxis. They are not on your site and I've called the manufacturer who confirmed they should be? My daughter is due to have this vaccine tomorrow at school so I'm trying to gather the information to make an informed choice.

- Can you please also advise of the safety of formaldehyde and aluminium hydroxide in this vaccine and how long Revaxis has been administered in the UK?

Further to your request I can confirm we do hold some of the information you have requested. Firstly, please refer to the product information leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: REVAXIS suspension for injection in pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) for details on the known possible side effects of the Revaxis vaccine.

Revaxis has been used in the UK since 2004. The MHRA has received 2418 UK spontaneous suspected adverse reaction reports associated with the Revaxis vaccine up to and including 16th February 2024. Please find attached a Vaccine Analysis Print (VAP) which lists all the reactions reported to the MHRA where the Revaxis vaccine has been suspected. Also attached is a guidance sheet which provides you with further information on how to interpret the print. Whilst information on adverse reaction for all vaccines is not currently available on our website, we are aware this information is valuable and have been working on this, with the aim to have this information accessible on our website later this year.

When considering the attached spontaneous 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 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.

- 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 or vaccine and may be stimulated by promotion and publicity.

Further to your second point, we do not hold this information. However, information about the safety of formaldehyde and aluminium hydroxide in vaccines is available in the Vaccine ingredients section of the University of Oxford's Vaccine Knowledge website which provides independent, evidence-based information about vaccines and infectious diseases.

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

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