Medicines & Healthcare products
Regulatory Agency

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[redacted]

8h May 2024

FOI 24/342

Dear [redacted]

Thank you for your Freedom of Information (FOI) request dated 10 April 2024 where you asked,

"I would like information including all reported adverse effects from 1993-2024 and a Drug Analysis Print on the following vaccines: Infranix hexa 6-in-1 Vaxelis 6-in-1 vaccine"

I can confirm that we do hold the information you have requested. To firstly provide some background, from autumn 2017 a hexavalent (6 in 1) vaccine called Infanrix Hexa, replaced the previously used pentavalent (5 in 1) infant vaccines. In 2022, the UK Health Security Agency (UKHSA) started supplying the vaccine, Vaxelis in addition to Infanrix Hexa for use in the primary immunisation schedule. Vaxelis® is also a hexavalent vaccine and it protects against the same diseases (diphtheria, tetanus, pertussis, polio, Hib and hepatitis B) as Infanrix hexa. Both vaccines are abbreviated to DTaP/IPV/Hib/HepB.

Whilst we have searched our database for the date range requested, I can confirm that the first spontaneous suspected adverse reaction report received for the hexavalent vaccine was in June 2016. Therefore, please find attached a Vaccine Analysis Print (VAP) for the DTPa IPV HiB HepB vaccines. The print contains information on all the UK spontaneous adverse reaction reports received up to and including 30 April 2024. The MHRA have received 702 UK spontaneous suspected adverse reaction reports in association with DTPa IPV HiB HepB vaccines. Of these 702 reports, 656 were reported specifically for the brand Infanrix Hexa and 7 were reported specifically for the Vaxelis brand, the remaining 39 did not provide details of the brand administered.

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Attached is a guidance sheet which provides you with further information on how to interpret the print. As these data do not necessarily refer to proven side effects, you should refer to the product information leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: Home - electronic medicines compendium (emc)

When considering Yellow Card 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 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 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.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Safety and Surveillance Group
Medicines and Healthcare products Regulatory Agency

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The Information Commissioner's Office
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