[redacted]

MHRA
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Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

16th March 2021

Dear [redacted]

FOI 21/181

Thank you for your enquiry dated the 15th February, where you requested information regarding suspected adverse reactions for Infanrix Hexa.

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 drug reaction (ADR) reports received by the Yellow Card Scheme are individually assessed and cumulative information reviewed at regular intervals. The Scheme relies on voluntary reporting of suspected ADRs by health professionals and patients and there is also a legal obligation for pharmaceutical companies to report ADRs for their products. 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.

When considering the below 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.

As this data does not necessarily refer to proven side effects, you should refer to the product information (Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL)) for details on the possible side effects of Infanrix Hexa; https://www.medicines.org.uk/emc/product/2586.

As requested, please find enclosed the Drug Analysis Print (DAP) for Infanrix Hexa. The DAP lists a breakdown of all UK, spontaneous ADRs reported to the MHRA associated with this vaccine. Please note, as it is possible for one report to contain multiple ADRs, the number of ADRs is greater than the number of individual cases. Please refer to the information sheet for guidelines on how to interpret the DAPs.

I hope the information provided is helpful. The MHRA encourages the use of Yellow Card data however wishes to ensure that the data is studied and applied appropriately, and any conclusions/interpretations take into account the above information. For this reason, if you wish to use this information for a publication, we request that you engage with the MHRA during this process and provide a copy of the report.

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, 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
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