Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

5th June 2023

Our Ref: FOI 23/323

Dear [redacted]

Firstly, please accept our apologies for the initial handling of your previous request and thank you for your patience regarding our response to your most recent request dated 4th May 2023. You requested reports relating to the side effects that have been reported for the Hib/Men C vaccine, DTPa/IPV vaccine (4 in 1 pre-school booster), HPV vaccine, Td/IPV vaccine (3 in 1 teenage booster) and Men ACWY vaccine.

Further to your request, please find attached the Vaccine Analysis Prints (VAPs) for details of the reported reactions to the above-mentioned vaccines, up to and including 30th May 2023. The attached Drug Analysis Print (DAP) guidance sheet provides you with further information on how to interpret the prints. It is important to note that the total 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 attached 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 been. 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. 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.

Please be aware that the VAPs provided should not be used as a list of side effects to these vaccines. All established undesirable effects for the Hib/Men C, DTPa/IPV, HPV, Td/IPV and Men ACWY vaccines can be found at the Electronic Medicines Compendium (EMC) website. These are listed in section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Patient Information Leaflet (PIL). Please see the following link for your reference: Home - electronic medicines compendium (emc).

Furthermore, within your request you asked for the estimated backlog in getting these reports onto our system. I can confirm that the MHRA do not have a backlog associated with the processing of ADR reports into our database. For information, under the Human Medicines Regulations (HMR) it is a requirement to process all serious reports within 15 days and all non-serious reports within 90 days.

Please note that the MHRA have begun implementing a new enhanced format of data visualisations. This enables us to provide improvements in format, accessibility and data protection whilst allowing access to more data than has been published previously. The initial phase of this development involves the provision of COVID-19 vaccine data with work currently ongoing to include all routine vaccinations and replace the current iDAPs for medicines later this year.

I hope the information provided is helpful. 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,
Safety and Surveillance Group