Medicines & Healthcare products Regulatory Agency

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

[redacted]

04/01/2024

Dear [redacted]

RE: FOI 23/943

Thank you for your email dated 1st December 2023 where you requested *"Information in relation to severe side effects (including death) and the rates of occurrence"* for the following vaccines:

- Meningitis B
- MMR
- DTaP/IPV/Hib/HepB

I can confirm that up to and including 08/12/2023, the MHRA have received the following number of UK spontaneous suspected adverse reaction reports for each of the requested vaccines:

Vaccine	Total number of reports	Number of serious reports
Meningitis B vaccine	3070	1523
DTaP/IPV/Hib/HepB	690	480
MMR vaccine	8064	4472

To clarify we do not classify reports by severity but instead by seriousness. A suspected ADR report is considered 'serious' on our database if it meets at least one of the following criteria; firstly, whether the original reporter considers the report to be serious whereby they can select based on 6 criteria[1]. Secondly, a reported reaction can be considered serious according to our medical dictionary.

Please find attached Vaccine Analysis Prints (VAPs) which contain information on the reported adverse reactions for each vaccine that have been considered serious as per the

1 *The seriousness criteria for ADR reporting were determined by a working group of the Council for International Organizations of Medical Sciences (CIOMS) and are defined as 6 possible categories which are documented on the Yellow Card. Reporters can select one or more of the following criteria by ticking the appropriate box on the Yellow Card. The criteria are: (1) patient died due to reaction (2) life threatening (3) resulted in hospitalisation or prolonged inpatient hospitalisation (4) congenital abnormality and (5) involved persistent or significant disability or incapacity or (6) if the reaction was deemed medically significant.*

criteria above, as well as the number of reports with a fatal outcome for each vaccine. The attached guidance sheet 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 for details on the possible side effects of these vaccines.

The MHRA cannot provide data for the rates of occurrence of adverse reactions as we do not hold this information. To calculate a reaction rate, two pieces of information are required:

- The first is the number of people receiving the vaccination. Whilst we consider vaccine uptake as part of our analysis of the safety of vaccines, information on the number of individuals administered is not held by the MHRA. This information is held by the UK Health Security Agency (UKHSA).

- The second is the number of individuals who have suffered adverse reactions to a given vaccination. As the Yellow Card scheme is voluntary, 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 Yellow Card data cannot be used to determine the incidence of a reaction or compare the safety profile of different batches of vaccination.

When considering the spontaneous data within this response, 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.

- 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 or compare the safety profile of different vaccines. Reporting rates are influenced by the seriousness of the reaction, their ease of recognition, the extent of use and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines, vaccines during the first one to two years on the market and then falls over time.

We 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
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency