Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

20th February 2024

Dear [redacted]

FOI 24/073, 24/076, 24/077, 24/078, 24/079

Thank you for your emails on 23rd January 2024 where you requested the following:

"Statistics on the number of children who are suspected to have died or experienced severe reactions following routine NHS MenB/MMR vaccine/Pneumococcal vaccine/HibMenC vaccine/6 in 1 vaccine over the past 5 years please."

There are provisions under the FOIA that allow for the aggregation of requests of the same or similar information from a requestor within a 60-day time period. As such, your five requests have been aggregated and a single combined response has been provided below.

It may be helpful to provide firstly some background information to allow interpretation of this data. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected adverse drug reactions (ADRs). The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. There is also a legal obligation for pharmaceutical companies to report serious ADR reports to their drugs. Suspected adverse drug reactions reported to the MHRA via the Yellow Card scheme cannot be considered as attributed to the reported medicine or vaccine as the MHRA encourages reporting of *suspected* ADRs i.e. the reporter does not have to be sure of a causal association between the drug and the reactions – a mere suspicion will suffice. For information on instances where a vaccine has been officially recorded on a death certificate we would advise you to contact the Office of National Statistics, ONS https://www.ons.gov.uk/ who may be able to assist with your enquiry.

Information about the known side effects of medicines and vaccines is included in the Summary of Product Characteristics (SPC) for healthcare professionals and the Patient Information Leaflet, PIL) for patients. The SPC and PIL for vaccines you have requested are available at https://www.medicines.org.uk/emc.

Further to your request, ADR reports are classified as either non-serious or serious. A report is considered serious according to two criteria; firstly, a reported reaction can be considered serious according to our medical dictionary. Secondly, whether the original reporter considers the report to be serious according to 6 criteria[1].

[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

Please see below Table 1, which shows the numbers of serious (excluding fatal) ADR reports in children (patients aged under 18 years, or age group neonate/infant/child) received for the requested vaccines, and the number of ADR reports with a fatal outcome from 1st January 2019 – 12/02/2024. Please note that the sum of reports in the table will not be equal to the total number of unique reports as one report may contain more than one suspect vaccine.

Table 1: UK spontaneous ADR reports in children associated with requested vaccines classified as serious or with a fatal outcome from 01/01/2019-12/12/2024.

Vaccine	Yellow Cards classified as serious (excluding fatal outcome)	Yellow Cards with a fatal outcome
Pneumococcal Conjugate vaccine	346	11
MMR vaccine	685	10
Hib and Men C vaccine	138	1
Men B vaccine	404	10
DTaP/IPV/Hib/HepB	260	11

When considering the spontaneous adverse reaction data detailed above, it is important to be aware of the following points:

- Patient age is not a mandatory field when reporting a Yellow Card and therefore is not always known. Although these vaccines are provided to children as part of the routine immunisation schedule, they may also be given to adult patients in certain clinical circumstances, as such reports where the patient age is unknown have not been included.

- A reported reaction does not necessarily mean it has been caused by the medicine or 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. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

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 this response's date and can be addressed to this email address.

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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.

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Yours sincerely,

FOI Team,
Safety and Surveillance 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