



Medicines & Healthcare products
Regulatory Agency

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gov.uk/mhra

07/02/2024

Dear [REDACTED]

RE: FOI 24/033

Thank you for your email dated 11th January 2024 where you requested information on the following vaccinations under the FOI Act:

1. 6 in one (diphtheria, hepatitis B, Hib (Haemophilus influenzae type b), polio, tetanus, whooping cough (pertussis))
2. Rotavirus
3. MenB
4. Pneumococcal (PCV) vaccine

I can confirm that we hold some of the information requested. We hold information on the numbers of suspected adverse events reported to the MHRA for these vaccines.

I can confirm that up to and including 08/01/2024, 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
6 in one	690
Rotavirus	1547
Meningitis B	3071
Pneumococcal (PCV) vaccine	3045

Please find attached Vaccine Analysis Prints (VAPs) which contain information on the reported adverse reactions for each vaccine, as well as the number of reports with a fatal outcome. 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.

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.

In response to your question regarding number needed to vaccinate, unfortunately we do not hold this information. The UK Health Security Agency (UKHSA) (<https://www.gov.uk/government/organisations/uk-health-security-agency>) may assist you with this information.

Regarding the most up to date research on the safety and efficacy of the vaccinations, Section 21 of the FOI Act states that information which is accessible by other means, such as published research is exempt from disclosure. However, you may find the following resources of use:

- **“Immunisation against infectious disease” (also known as “The Green Book”** (<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>). This publication is available as individual chapters via the Immunisation section of the GOV.UK website. It contains the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK.
- **The EMC website** (<https://www.medicines.org.uk/emc#gref>). This website contains regulated and approved information on medicines and vaccines available in the UK, including summaries of product characteristics (SPCs, which tell healthcare professionals how to use a medicine properly) and patient information leaflets (summaries of the SPC written for patients). Of note, the SPC contains information on the safety profile and efficacy of a medicine/ vaccine. You can access the SPC or PIL for a particular medicine or vaccine using the search function on the EMC website.
- **The Vaccine Knowledge Project** ([Home | Vaccine Knowledge Project \(ox.ac.uk\)](https://www.vaccineknowledgeproject.ox.ac.uk/)). The Vaccine Knowledge Project is a source of independent, evidence-based

information about vaccines and infectious diseases. The Vaccine Knowledge Project is managed by the Oxford Vaccine Group, an academic research group in the Department of Paediatrics at the University of Oxford.

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

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