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

5th February 2024

FOI 24/048

Dear

Thank you for your information request, dated 16 January 2024, where you requested "the figures for measles vaccine deaths and side effects in the UK since 2000 - specifically the MMR vaccine".

Firstly, I thought it would be helpful to give some context on who the Medicines and Healthcare products Regulatory Agency (MHRA) are and what the Yellow Card scheme is. The MHRA is the executive Agency of the Department of Health and Social Care that acts on behalf of the Ministers to protect and promote public health and patient safety, by ensuring that healthcare products meet appropriate standards of safety, quality and efficacy. We keep watch over medicines and devices, and take necessary action to protect the public promptly if there is a problem.

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a vaccine or an adverse medical device incident. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products. In addition to the Yellow Card scheme, there are legal requirements for manufacturers to report problems with their healthcare products to the MHRA.

Whilst anyone can report their suspicions of a safety concern or incident, a reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. As such, any information provided should not be used to determine incident rates or be taken as proven side effects. You should instead refer to the product information which can be found here: MHRA Products Home.



Medicines & Healthcare products Regulatory Agency

The MHRA do not determine causality of individual reports, and this includes reports of fatalities. If you would like to receive certified figures for deaths caused by the MMR vaccine, you may wish to contact the Office for National Statistics (ONS) here FOI.Team@ons.gov.uk as they will hold this information.

Whilst we cannot give certified side effects and deaths, we are able to provide the data around *suspected* side effects that have been reported to us. Based on this and your request I am pleased to confirm that we have received 4,802 UK spontaneous suspected ADR reports for the MMR vaccine from 01/01/2000 up to and including 30/01/2024. Of these 4,802 cases, 40 had a fatal outcome.

Please find the attached Vaccine Analysis Print (VAP) for details of the reported reactions and refer to the enclosed information sheet for guidelines on how to interpret the VAP.

When considering the provided 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 vaccines 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.

The MHRA continuously monitors the safety of medicines and vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. 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.

We hope you find this information useful.



Yours sincerely,

FOI Team, Safety and Surveillance

The Freedom of Information Act only entitles you access to information – the information supplied is subject to Crown copyright, and there are some restrictions on its re-use. For information on the reproduction or re-use of MHRA information, please visit https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information.

If you have a guery about the information provided, please reply to this email

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 you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF