Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Ms Melissa Smith
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MHRA

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www.gov.uk/mhra

24th February 2021

Dear Ms Smith,

FOI 21/129

Thank you for your FOI request dated 2nd February 2021, where you requested the following information:

- *Total number of ADR reports in association with a vaccine between 01/01/2005 and 31/01/21 Of these reports, how many were not serious?*
- *Of these reports, how many were serious?*
- *Total number of ADR reports in association with a vaccine between 01/01/2005 and 31/01/21 in children under the age of 10, between 10 and 18, and in adults 19+.*

The MHRA continuously monitors the safety of 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.

When considering the 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 or events 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 medicines during the first one to two years on the market and then falls over time.

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.

I can confirm we have received a total of 80,182 spontaneous UK suspected ADR reports in relation to vaccines for all ages in respect to the time frame of 01/01/2005 to 31/01/2021. Of these, 47,496 reports were considered serious and 32,686 were classed as non-serious. With regards to seriousness, an ADR 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 whereby they can select based on 6 criteria when filling out a Yellow Card report.

A breakdown by age as requested is provided in Table 1. With regards to the breakdown by age, it is important to note that the age of the patient is not a mandatory field when submitting a Yellow Card report and is therefore not always provided.

Table 1 - UK spontaneous suspected adverse drug reaction reports associated with a vaccine reported between 01/01/2005-31/01/2021, broken down by age.

Patient Age (years)	Number of Reports
<10	14,262
10-18	13,229
19+	47,458
Unknown	5,233

As the data reported to the Yellow Card scheme does not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects of vaccines available in the UK.

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.

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Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines 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
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SK9 5AF