HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Adverse Reaction Reporting to Vaccines – Reminder

Reports of suspected adverse reactions are received by the HPRA from patients/carers, healthcare professionals (HCPs) and Marketing Authorisation Holders (i.e. license holders for a medicine/vaccine) for authorised medicines/vaccines. Reporting suspected adverse reactions to the HPRA is strongly encouraged and healthcare professionals are reminded of this especially during the various vaccination campaigns e.g. the HSE school immunisation programmes.

Information collected through the adverse reaction reporting system is an important method of monitoring medicines/vaccines safety in normal clinical use, by increasing knowledge about known adverse reactions and by acting as an early warning system for the identification of previously unrecognised adverse reactions. Such information is one of the tools used by the HPRA and other regulators in the ongoing safety evaluation of marketed medicines/vaccines. To facilitate monitoring of national experience with medicines/vaccines, reporting of suspected adverse reactions to the HPRA is encouraged and reporters are asked to include as much detail as available to support evaluation.

The HPRA welcome all reports of suspected adverse reactions to vaccines however, not all medication/vaccination errors need to be reported. The error should only be reported to the HPRA if the person experiences a suspected adverse event as a result.

How to report a suspected adverse reaction to the HPRA
The HPRA has an online system for reporting of suspected adverse reactions to medicines/vaccines, with preferred reporting options described below:

- The online system may be accessed via the HPRA website homepage (www.hpra.ie/report)
- The online report form, is also available and can be completed and emailed to medsafety@hpra.ie.
- By email to medsafety@hpra.ie.

To facilitate the most thorough evaluation of suspected adverse reactions, the HPRA requests that healthcare professionals include as much of the following information as possible when submitting a suspected adverse reaction report to a medicine/vaccine. However, please note that non-availability of all this information should not discourage report submission.

- Information on the **person** who has experienced the suspected reaction, including age (or age group) and sex, and any additional available information such as weight/BMI, pregnancy/breastfeeding status, co- morbidities etc.
- A description of the **suspected adverse reaction**, including, time to onset, clinical course and impact on the patient, any treatment administered, and outcome where known.
- Vaccines are classified as biological medicines, therefore EU and national legislation requires clear identification of the product so **brand name** and **batch number** are required.
- The **dose**, if known.
- Relevant **medical history or concomitant conditions** e.g. food allergies, co-morbidities, previous vaccine allergy.
- Any **concomitant medications** (including non-prescription medicines, herbal remedies, or contraceptives).
- **Reporter** (HCP or patient) details.

All adverse reaction reports received will be processed and entered into the HPRA's national pharmacovigilance database. Reports are subsequently sent to EudraVigilance (EV), the European Medicines Agency's (EMA's) database of suspected adverse reactions, where the data are analysed to detect new safety signals. Anonymised data from the EV database are publicly accessible for review at www. adrreports.eu. A privacy notice relating to the processing of personal data collected by the HPRA in relation to adverse reaction reports is available on the HPRA website (www.hpra.ie) under the 'Report an Issue' tab and by clicking on 'Human Medicines Adverse Reaction' or 'COVID-19 Vaccine Adverse Reaction'.

Key Message
- Several options are available to report suspected adverse reactions to medicines/vaccines to the HPRA, with the online reporting option accessible from the HPRA website (www.hpra.ie/report).
- When reporting a suspected adverse reaction to a biological product such as a vaccine, the brand name and batch number should be included.
- Product information (Summary of Product Characteristics and Package Leaflet) for authorised medicines/vaccines is available via the HPRA website using the 'Find a medicine' function on the homepage.

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