HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Adverse Reaction Reporting – 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. Information collected through this system is an important method of monitoring medicines 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. To facilitate monitoring of national experience with medicines and 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.

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)
- A downloadable report form, is also available and can be completed and emailed to medsafety@hpra.ie.
- By email to medsafety@hpra.ie.

In order 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. 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.
- The **brand name** and **dose** of the medicine.
- When a biological medicine, for example a vaccine or insulin, is the subject of the report, then EU and national legislation requires clear identification of the product so **brand name** and **batch number** are required.
- 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'.

Additional Monitoring

EU and national legislation also introduced the concept of additional monitoring, to support prompt identification of any new safety hazards associated with particular medicines. Healthcare professionals and patients are particularly encouraged and reminded to report all adverse reactions associated with the use of these medicines, identifiable by an inverted black triangle on the product information. An explanatory statement is included both in the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for these medicines, together with the symbol:
▼ This medicinal product is subject to additional monitoring

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 medicinal product, the brand name and batch number should be included.
- Medicines subject to additional monitoring are identifiable by a black inverted triangle (▼) accompanied by an explanatory statement in the product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)). All suspected adverse reactions associated with these medicines should be reported.
- Product information (SmPC and PL) for authorised medicines/vaccines is available via the HPRA website using the 'Find a medicine' function on the homepage.

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