HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Adverse Reaction Reporting – Reminder

Key Message

- Reporting suspected adverse reactions supports the ongoing safety monitoring of medicines in normal clinical use, by increasing knowledge about known adverse reactions and acting as an early warning system for identifying previously unrecognised adverse reactions.
- 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).
- Please include as much information as possible to facilitate the most thorough evaluation of suspected adverse reactions. However, please remember that the lack of complete details should not prevent you from submitting your report. At a minimum, it is important that you provide a patient identifier (e.g. age, gender), a suspect medicine, a suspected reaction(s) and your contact information.

Reporting suspected adverse reactions to medicines is important. Healthcare professionals (including doctors, dentists, pharmacists and nurses) are asked to report any suspected adverse reactions observed in their practice to the HPRA's national reporting system.

Information collected through the adverse reaction reporting system is an essential method of monitoring medicines' safety in normal clinical use. It increases knowledge about known adverse reactions and acts as an early warning system for identifying 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.

Whilst reports of any suspected adverse reaction are encouraged, it is of particular importance to report reactions if they relate to:

- Newly authorised medicines
- Vaccines
- Medicines used in pregnancy or breastfeeding
- Reactions experienced in paediatric or elderly populations
- Reports of addiction, dependence or experiencing withdrawal from a medicine
- Reactions experienced following an overdose, misuse or medication error
- Serious reaction to any medicine
- Medicines undergoing additional monitoring. These medicines are easily identified as they have an inverted triangle on their product information, together with the following statement: ▼ This medicinal product is subject to additional monitoring.

How to report a suspected adverse reaction to the HPRA

The HPRA has an online system for reporting suspected adverse reactions to medicines, 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 on the HPRA website hopepage (www.hpra.ie/report). It can be completed and emailed to medsafety@hpra.ie.
- By email to medsafety@hpra.ie.

What to include in suspected adverse reaction reports

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

At a minimum, it is important that you provide a patient identifier (e.g. age, gender), a suspect medicine, a suspected reaction(s) and your contact information. For biological medicinal products which include vaccines, please provide the brand name and batch number, if possible.

Additional information that would be beneficial includes:

- 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 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 (healthcare professional or patient) details.

What happens after the report is submitted?

After you submit a report, it will be assigned a unique number, which will be provided to you. All adverse reaction reports received will be reviewed and entered into the HPRA's national pharmacovigilance database. We may contact you for additional information. 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 concerning 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'.

This section has been supplied by the HPRA for use in MIMS Ireland. However, the HPRA is independent and impartial to any other information contained in this directory.