

Adverse Drug Reaction Reporting - Frequently Asked Questions (FAQs)

1. *What is an Adverse Drug Reaction (ADR)?*

A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

2. *What is a serious ADR?*

A serious ADR is one that is:

- Fatal
- Life threatening
- Causes or prolongs hospitalization
- Causes a congenital abnormality
- Causes disability or incapacity

3. *Which ADRs should be reported?*

The Medicines Authority (MA) encourages reporting of all suspected ADRs.

4. *Who should submit suspected ADR reports?*

Doctors, dentists, pharmacists and other healthcare professionals are all requested to report suspected adverse drug reactions (ADRs).

5. Why should ADRs be reported?

- Tests in animals are insufficiently predictive of human safety;
- In clinical trials patients are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited;
- Information about rare but serious adverse drug reactions (ADRs), chronic toxicity, use in special groups or drug interactions is often incomplete or not available.

6. How can healthcare professionals identify ADRs?

Patients may tell healthcare professionals (HCPs) about symptoms they have experienced since taking a new medicine. However, some ADRs may not be apparent to the patient. HCPs need to be alert to the possibility of suspected ADRs and link signs or symptoms to either current drug therapy or previous therapy. HCPs should be alert for abnormal clinical measurements and laboratory results or when new drug therapy is initiated for purposes of treating the symptoms of an ADR.

7. Do I need to be sure the drug caused the reaction?

No, the reporter need only suspect that the medicinal product may have caused the adverse reaction experienced by the patient. If in doubt, please report.

8. Where should the reports go to?

Forms may be sent **EITHER** to:

- The product's Marketing Authorisation Holder or its local representative **OR**
- The Medicines Authority, Pharmacovigilance Section, Post-Licensing Directorate, 203/level 3, Rue D'Argens, Gzira GZR 1368.



9. From where can I get the reporting form?

Healthcare professionals may either ask the MA (Tel. 23439000, Fax. 23439161) for paper copies of the ADR report cards or may, alternatively, download the electronic version of the form available on the Pharmacovigilance Section of the MA's website at: <http://www.medicinesauthority.gov.mt/phvigilance.htm>

10. What happens to reports once they are submitted to the MA?

ADR reports (as received directly from the HCP or indirectly via secondary reporting by the product's Marketing Authorisation Holder) will be reviewed, evaluated and entered into a database. The cumulative data will facilitate identification of new or emerging safety concerns or new information on recognized adverse effects to be evaluated. The MA will also evaluate information from additional sources such as the medical literature, official company data and international databases to consider their impact on the benefit/risk assessment and thereby allow for proper and timely regulatory action to be taken.

11. Is there a legal obligation to report suspected ADRs?

Yes. The Pharmacovigilance Regulations (Legal Notice 61 of 2006) state that: 'It shall be the duty of doctors and other healthcare professionals to report to the Authority any suspected serious or unexpected adverse reaction to a medicinal product in Malta.'

12. Where can further information about the safety of medicines be found?

Should you require further information you are kindly asked to contact the Medicines Authority, the contact details of which, are supplied below.

Pharmacovigilance Section, Post-Licensing Directorate, Medicines Authority,
203/level 3, Rue D'Argens, Gzira. GZR 1368. Malta.
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