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**Adverse Drug Reaction Reporting
& Pharmacovigilance Guidance Notes
For Healthcare Professionals**

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Issue 3

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BACKGROUND

The Regulation of Medicines in Malta

The mission of the Medicines Authority (MA) is to contribute to the protection of public health in Malta through the regulation of the safety, quality and efficacy of medicines for human use on the Maltese market and to ensure that healthcare professionals and patients have access to information about the safe and effective use of medicines.

Pharmacovigilance

An important aspect of the regulation of medicines in Malta is Pharmacovigilance, which comprises the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicines.¹

The main objectives of pharmacovigilance include early identification of potential safety hazards, evaluation, monitoring and, where appropriate, implementation of regulatory action to maximise benefit and minimise risks associated with medicinal products.

An essential source of new information for the achievement of these objectives, is the notification and reporting of suspected adverse drug reactions (ADRs) which arise following the administration of medicinal products.

Legal basis for National ADR Reporting

The Medicines Act of 2003 provides the regulatory framework for the Medicines Authority (MA) and requires that the MA establishes a national system for the reporting of suspected ADRs occurring in Malta.

¹ WHO definition

Further subsidiary legislation to the Medicines Act for pharmacovigilance activities is published in Legal Notice 61 of 2006. These Pharmacovigilance Regulations 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'.

Establishment of the Reporting System

In May 2004 the MA introduced a national ADR reporting system. This system forms part of an overall Pharmacovigilance system within the MA, which is the primary means of collecting information useful in the safety surveillance of medicinal products. The MA is already receiving and processing ADR reports. By reporting ADRs, healthcare professionals can make a positive contribution to the pharmacovigilance system.

THE IMPORTANCE OF REPORTING ADRS

The Need for Drug Safety Monitoring

Not all hazards can be established before a medicinal product is marketed. Patients, consumers and indeed some healthcare professionals may have expectations that the medicinal products available are “safe” and may be surprised when regulatory action is taken to restrict the use or withdraw medicines as a result of previously unrecognized safety concerns. Information collected during the pre-marketing phase of a medicinal product is inevitably incomplete with regard to the medicinal safety profile because:

- Animal testing is insufficiently predictive of human safety
- Data from clinical trials is limited by their size and duration
- Patients in clinical trials are selected and the conditions of medicinal use differ from those in clinical practice
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available and will only become manifest after the drug is released, maybe after several years.

The Effects of ADRs

All medicines have the potential to cause ADRs. Prevention of ADRs helps to minimise the consequential undesirable effects, primary among which are:

- Increased admissions to hospitals. It is estimated that 2%-6% of all hospital admissions are due to ADRs;
- Increased needs for primary healthcare and an increase in the number of complications during hospitalization in as many as 10% to 20% of patients;
- Fatalities. ADRs constitute up to the 4th commonest cause of death;
- Increases in the length of hospital stays and increases in the cost of patient care;
- Adverse effects on patients' quality of life and their confidence in healthcare;
- Mimicry of disease resulting in unnecessary investigations and/or delay in appropriate treatment.

The Role of Healthcare Professionals

The role of Healthcare Professionals is vital in recording and reporting suspected ADRs in order that regulatory agencies are alerted of emerging safety concerns and thereby facilitating timely and appropriate action.

Advantages of the ADR Reporting System

The advantages of an ADR reporting system are as follows:

- It is an inexpensive method for monitoring the safety of a medicinal product throughout its lifetime
- Reports are based on unbiased observations made by vigilant HCPs
- It is an essential method for detecting signals of rare ADRs
- It remains the primary method of data-collection used in most countries

Participation of Healthcare Professionals is therefore essential for the effective functioning of a pharmacovigilance system.

HOW TO REPORT ADRS

Definitions

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.

Serious ADR

A serious ADR is one that:

- May be fatal
- May be life threatening
- Causes or prolongs hospitalization
- Causes a congenital abnormality
- Causes disability or incapacity

Identification of ADRs

Patients may tell healthcare professionals about symptoms they have experienced since taking a new medicine. However some ADRs may not be apparent to the patient and therefore healthcare professionals need to be alert to the possibility of suspected ADRs and link signs or symptoms to either current drug therapy or previous therapy. Healthcare professionals should be alert for abnormal clinical findings and laboratory results.

Reporting of suspected ADRs

Doctors, dentists and pharmacists and other healthcare professionals are encouraged to report all suspected adverse reactions to the MA. Report cards can be either requested from the MA (Tel. 23439000, Fax. 23439161) or else downloaded from the MA's website at <http://www.medicinesauthority.gov.mt/phvigilance.htm>. ADR reports may then be sent either to the product's Marketing Authorisation Holder (or its local representative) or to the Medicines Authority, 203/level 3, Rue D'Argens, Gzira GZR 1368.

The minimum required details for a valid report are:

- An identifiable reporter (e.g. doctor, pharmacist, dentist)
- An identifiable patient (i.e. initials, age and sex)
- A suspected medicinal product
- A suspected adverse drug reaction

Healthcare professionals should not be discouraged to report if some ADR details are unknown or if in doubt as to whether the reaction observed was due to the drug. Reporters need only suspect that a medicinal product may have caused the adverse reaction. If in doubt, the ADR should always be reported.

Information contained in ADR reports will be entered into a database in an anonymised and secure manner. All personal data will be treated as confidential in conformity with data protection.

OUTCOMES FROM REPORTING

Processing of ADR reports

ADR reports will be reviewed, evaluated, acknowledged and entered into a database. The cumulative data will facilitate identification of new or emerging safety concerns or new information on recognized adverse effects. The MA also evaluates information from additional sources such as world-wide medical literature and international databases.

MA staff will regularly review safety issues internally and with national experts/professional associations. In addition, MA staff will participate in scientific meetings that consider safety issues (e.g. the Pharmacovigilance Working Party Meetings of the European Medicines Agency and other international meetings such as those of WHO).

When a new possible adverse effect is identified (or more information is obtained about a recognized effect) the safety profile of the medicinal product concerned is compared to those of other alternative medicinal products used to treat the same condition and a benefit/risk evaluation is conducted.



Implementation of Regulatory Action

As a result of the evaluation of pharmacovigilance data and consistent with national and European legislation, the MA may take regulatory action to vary, suspend or withdraw a marketing authorisation for a medicinal product if considered appropriate.

Regulatory measures are taken in order to prevent future ADRs and to ensure safer use of medicinal products. Changes made to product information to enhance safety are communicated to healthcare professionals in order to keep them informed. Feedback will be provided to healthcare professionals by means of a Newsletter, which will contain the latest and most important safety information. The Newsletter will be published and distributed at regular intervals throughout the year.

In urgent cases “Dear Healthcare Professionals” letters may be issued to alert healthcare professionals to an emerging safety concern.

The MA will also act as an information service to Healthcare Professionals by providing the latest up-to-date drug safety information.

Further information

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

Medicines Authority
Post-Licensing Directorate
203/level 3, Rue D'Argens
Gzira, Malta
GZR 1368
Tel. (00356) 23439000
Fax. (00356) 23439161
Email: postlicensing.mru@gov.mt



Additional Further Information

Andrews, E. & Mann, R., (2002). *Pharmacovigilance*. West Sussex: John Wiley & Sons.

EU Pharmaceutical Legislation. Available at: <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex>

Medicines Authority. Available at: <http://www.medicinesauthority.gov.mt>

Uppsala Monitoring Centre, World Health Organisation. Available at: <http://www.who-umc.org>