HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

New CPD e-Learning Module on Reporting Suspected Adverse Drug Reactions

A new free e-learning module has been created for all healthcare professionals to learn about the importance of reporting suspected adverse drug reactions (ADRs). This module was created as part of the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action project. The module has received accreditation from the European Accreditation Council for CME (EACCME®). Doctors are awarded 1 EACCME credit (1 hour) upon completion of the 45 minute ADR e-learning module. The SCOPE Joint Action project, in which the Health Products Regulatory Authority (HPRA) participated, aims to support EU member states in the operation of their pharmacovigilance systems which help safeguard public health.

The e-learning module covers important topics relating to the reporting of suspected ADRs, including how to report and what happens to a report once it is made; who can make a report; situations in which a report should be made; and sources of information on ADRs. The e-learning module (hosted on the SCOPE website) can be accessed at http://www.scopejointaction.eu/

There are several options in place for reporting suspected ADRs to the HPRA. These are as follows:

- By following the links (via the 'Report an Issue' tab) to the online reporting options accessible from the HPRA website homepage (www.hpra.ie);
- Using the downloadable report form also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via 'freepost';
- Using the traditional 'yellow card' report, which also utilises a freepost system. 'Yellow cards' are available from the HPRA Pharmacovigilance department on request.
- By telephone to the HPRA Pharmacovigilance section (01-6764971).

Further details on reporting of suspected ADRs to the HPRA can be found on the HPRA website or in a recent article in the 79th edition of the HPRA Drug Safety Newsletter.

Advice to Healthcare Professionals

- Reporting suspected ADRs aids in facilitating continued surveillance of the safety of medicines.
- Reports of suspected ADRs can be made by all healthcare professionals and patients/members of the public to the HPRA.
- A suspicion that a medicine caused a reaction is sufficient to warrant a report.
- Healthcare professionals and patients are particularly encouraged and reminded to report all adverse reactions associated with the use of medicines subject to additional monitoring. These medicines are identifiable by an inverted black triangle and explanatory statement on the product information i.e. the Summary of Product Characteristics (SmPC) and Package Leaflet (PL): ▼ This medicinal product is subject to additional monitoring.

Key Message

- A free e-learning module for healthcare professionals on reporting suspected ADRs is available on the SCOPE website (http://www.scopejointaction.eu/).
- Doctors can earn 1 EACCME credit upon completion of the 45 minute ADR e-learning module.

Further information on the reporting of suspected ADRs and the role of the HPRA is available from www.hpra.ie.

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