HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Adverse Reaction Reporting during 2013

The HPRA continues to place great emphasis on encouraging and promoting the submission of adverse reaction reports associated with the use of medicines from its stakeholders. These reports are important to signal potential safety issues from medicines in use and ultimately assist the HPRA in monitoring the safety of medicines on the Irish market.

As outlined previously in HPRA articles in MIMS Ireland, the revised pharmacovigilance legislation which became effective in July 2012 introduced the concept of additional monitoring for certain medicines (including some for the treatment of diabetes mellitus), enhanced post-authorisation data collection to support prompt identification of any new safety hazards and to allow appropriate regulatory action to be initiated. The European Medicines Agency (EMA) has published a list of medicines subject to additional monitoring which is reviewed and updated as necessary. Certain medicines for the treatment of diabetes mellitus are currently included on the list and are identifiable by an inverted black triangle and an explanatory statement in the Summary of Product Characteristics (SmPC) and Package Leaflet (PL). Healthcare professionals are strongly encouraged to report suspected adverse reactions associated with these medicines, as well as any others on the list.

During 2013, we received a total of 2,835 suspected adverse reaction reports occurring in Ireland from healthcare professionals, members of the public and pharmaceutical companies, indicating a small increase in reporting figures for 2012. A breakdown of the reports by source is outlined below and it is important to note that reports submitted by pharmaceutical companies, will have first been brought to their attention by healthcare professionals, patients and consumers, prior to onward reporting to HPRA. In keeping with experience in other European countries, reporting rates were highest for newly authorised medicines. Reporting rates are influenced by their ease of recognition and may be stimulated by publicity about a particular medicine or reaction. Reporting rates are also influenced by proactive and repeated requests to healthcare professionals to submit reports on certain medicines as part of ongoing post marketing surveillance, as well as other promotional and data collection activities.

Individual case reports are followed up by the HPRA, with feedback information provided to reporters, as appropriate. Relevant, anonymised reports (i.e. serious, suspected cases) notified directly to the HPRA by healthcare professionals or members of the public are forwarded to the appropriate marketing authorisation holders (MAHs) and the EMA within the agreed timeframes and formats. The HPRA also continues to provide anonymised details of reports received to the World Health Organisation (WHO) for inclusion on its international database.

Breakdown of Reports by Source for 2013

Source of Suspected Adverse Reaction Reports	%
Pharmaceutical Company	64
Community Care Doctor	9
General Practitioner	5
Hospital Doctor	4
Hospital Pharmacist	4
Community Pharmacist	4
Nurse	5
Patient/Consumer	1
Other	4

The HPRA greatly appreciates the contribution of busy healthcare professionals in reporting suspected adverse reactions, facilitating the continued surveillance of the safety of medicines. While the time-consuming nature of form-filling and the provision of follow-up information to the HPRA is acknowledged; the collection and evaluation of comprehensive reports is essential to ensure that appropriately detailed case information is available for the continuous surveillance of the safety of medicines. Such reports are essential for the HPRA to ensure that regulatory action/proposals take account of all available data.

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

- By following the links to the online reporting options accessible for the HPRA 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
- By telephone to the HPRA Pharmacovigilance section (01-6764971)

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