



IRISH MEDICINES BOARD

CHANGES TO ARRANGEMENTS FOR DRUG SAFETY NEWSLETTER DISTRIBUTION

In the context of expanding use of electronic media to facilitate prompt and efficient notification of important safety information related to the use of medicines, the IMB intends to discontinue provision and distribution of hard copy versions of the Drug Safety Newsletter (DSN) by post over the coming months and to disseminate it through electronic methods only. This is considered an important and appropriate initiative in the context of increasing use of electronic media and the increased focus on transparency and communication arising from the provisions of the revised pharmacovigilance legislation, which came into effect in July 2012 and was highlighted in the 50th Edition of the Drug Safety Newsletter. These provisions include the prompt publication of reviews and recommendations undertaken at EU level by the newly established scientific committee, which is known as the Pharmacovigilance Risk Assessment Committee or PRAC.

The PRAC mandate covers all aspects of the risk management of the use of medicinal products including the detection, assessment, minimisation and communication relating to the risk of adverse reactions. The PRAC is responsible for providing recommendations to other relevant EMA committees on any question relating to pharmacovigilance activities in respect of medicinal products for human use. Taking the recommendations of PRAC into account, the Committees adopt a final scientific opinion that is legally binding. Information on reviews undertaken by the PRAC, together with recommendations on the outcome of these reviews and proposals for implementation of regulatory action will be highlighted on the IMB website and/or reflected in the IMB Drug Safety Newsletter, as appropriate.

The electronic version of the DSN is in PDF format, thus allowing you to save the newsletter and/or print specific pages. The online version also contains hyperlinks to product information and other documents on the IMB and EMA websites.

To facilitate healthcare professionals, this change in arrangements will be phased in, to allow for provision of email contact details to the IMB and/or registration as a subscriber to the IMB website to receive alerts. It is intended however that by the end of 2013, hard-copy

versions of the DSN will no longer be printed and posted. In the meantime, to ensure that you can continue to receive the DSN, healthcare professionals are requested to:

- Register with the IMB to receive an email alert notifying you that future editions of the newsletter are available online. This may be done by logging on to the IMB website and clicking on to the panel 'Subscribe to our Updates' on the homepage and following the links.

Or alternatively

- Ensure that you are on the IMB mailing list for electronic distribution of the DSN. To do so, please submit your email address, profession (i.e. doctor (G.P./hospital doctor), pharmacist (community/hospital), nurse, dentist etc) and postal address to where you have been receiving a hard copy of the DSN (if relevant) to imbpharmacovigilance@imb.ie or telephone **01 - 6764971** and ask for the pharmacovigilance section to provide your email details, before Monday 30th September 2013

The Pharmaceutical Society of Ireland (PSI) will continue to distribute the DSN to their members as at present and the IMB is liaising with some of the other relevant, professional bodies in Ireland to support additional publication/distribution via their networks. During the interim phase of change over to full electronic distribution, hard-copy versions of the DSN following its publication on the website will continue to be made available.

Key Message

- Hard copy versions of the IMB Drug Safety Newsletter (DSN) will be phased out over the coming months, when electronic versions will become the main method of dissemination.
- Healthcare professionals must register as subscribers to the IMB website, or alternatively provide their email contact details, profession and postal address by 30th September 2013 to continue to receive the IMB Drug Safety Newsletter.