FEBRUARY 2016

HPRA DRUG SAFETY NEWSLETTER

73RD EDITION

In this Edition

Educational materials-optimising the safe and effective use of medicinal products

Medicines use may be complex and ensuring that medicines are used safely and effectively may also be a challenge for those involved in the prescribing, dispensing and using medicines in clinical practice. The HPRA would like to highlight the availability of educational materials and tools for certain medicinal products which should be used to support their rational prescribing and use in clinical practice.

The use of risk minimisation measures to help support the safe and effective use of medicines has evolved over the years. Risk minimisation measures associated with medicinal products are a set of interventions designed to prevent or reduce the occurrence of adverse reactions associated with exposure to a medicine, or to reduce their severity or impact on the patient should such adverse reactions occur.

Risk minimisation measures may consist of 'routine' measures or 'additional' measures.

Routine risk minimisation measures are applicable to all medicinal products and include the product information (i.e. the summary of product characteristics (SmPC), which the basis of information for healthcare professionals (HCPs) on how to use the named medicinal product safely and effectively, the package leaflet (PL), which is primarily aimed at the patient and drawn up in accordance with the SmPC, and the product label), the pack size and design and the legal (prescription) status of the product (e.g. available on prescription only, available through pharmacies, available thorough general sales outlets).

It is usually adequate to address safety concerns relating to medicinal products by these 'routine' risk minimisation measures, e.g. safety warnings and risk minimisation advice, advice on interactions, in the product information (SmPCs for products authorised in Ireland are available through the HPRA website).

However, in some cases, it is considered that 'additional' risk minimisation measures are necessary in order to manage certain key risks and to further optimise the safe and effective use of a medicinal product throughout its lifecycle. The aim of these additional measures is to further support optimal use of a medicinal product in clinical practice by focusing on the most important, preventable risks in a way that does not introduce an undue burden on the healthcare delivery system, HCPs or patients.

Examples of additional risk minimisation measures include direct healthcare professional communications, educational programmes, pregnancy prevention programmes and controlled access systems for certain medicines.

Direct Healthcare Professional Communications (DHPCs) are communications used to convey important safety information to HCPs and to inform them of the need to take certain actions or adapt their practices in relation to a medicinal product. They are all approved by the HPRA and are delivered directly to HCPs by the Marketing Authorisation Holder (MAH) responsible for marketing the product. They also may be disseminated when there is a need to take immediate action or change current practice in relation to a medicinal product, e.g. an important change to the use of a medicine due to the restriction of an indication, a new contraindication, or a change in the recommended dose, due to safety reasons. They may also be distributed when a new product is being launched onto the Irish market in order to highlight specific risk minimisation advice to HCPs. The HPRA also publish all approved DHPCs on the HPRA website and highlight them via our Drug Safety Newsletter (DSN).

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
T: +353 1 676 4971 E: medsafety@hpra.ie www.hpra.ie

Educational materials aim to minimise important risks and maximise the risk-benefit balance of a medicinal product. The content of educational materials supplement the currently authorised product information for the medicinal product to support safe and effective prescribing and use. They are designed to fulfil specific risk minimisation objectives and focus on specific safety concern(s) in order to provide clear statements and concise messages describing actions to be taken in order to prevent and minimise these risks. Educational materials are developed by the MAH for the medicinal product when specifically recommended by a national competent authority (such as the HPRA) and these must be reviewed and approved by the HPRA prior to distribution.

Educational materials may be targeted towards HCPs (e.g. doctors, pharmacists and nursing staff) or patients, or their carers. Examples of educational materials for HCPs include healthcare professional guides, dosing and administration guides, prescriber checklists and monitoring charts. Educational materials directed at patients include patient alert cards, patient guides and patient reminder cards.

Methods for dissemination and the target audience within Ireland (e.g. neurologists, GPs, dermatologists, pharmacists, depending on which group of HCPs is expected to prescribe the product, or which group of HCPs need to be alerted to the risks) are agreed with the HPRA. Currently, the HPRA requires that MAHs distribute educational materials in hard copy to HCPs and/or patients. Distribution may be once-off at launch of a new product or may be periodic over the lifecycle of the medicine in order to ensure that new prescribers and users are reached. These materials may also be made available by the MAH via other modalities, e.g. published on a dedicated website.

To support the wider availability of educational materials relating to medicinal products available on the Irish market, the HPRA recently commenced publication of HPRA approved educational materials for medicines on the HPRA website in agreement with the MAHs who produce them. The materials may be accessed via the HPRA website and downloaded for use, with hard copies requested from the MAH if required.

Educational materials and tools are specific to the medicinal product concerned and there may be minor differences between educational materials produced by different MAHs, even though their medicinal product may contain the same active substance. However, the core messages relating to risk minimisation will be the same.

Educational programmes should be completely separated from any promotional activities.

Pregnancy prevention programmes (PPPs) use educational materials to advise HCPs and patients on minimising pregnancy exposure during treatment with a medicinal product with known or potential teratogenic effects. The scope of such programmes is to ensure that female patients are not pregnant when starting therapy or do not become pregnant during the course and/or soon after stopping the therapy. They may also target male patients when use of a medicinal product by the male partner might have a negative effect on pregnancy outcome.

Pregnancy Prevention Programmes usually consist of guidance in the form of educational materials (e.g. information for HCPs and patients on the teratogenic risk, the actions required to prevent pregnancy, information on how long to avoid pregnancy after treatment is stopped, information for when the male partner is treated). These may be combined with controlled access programmes which are used for a product with a known benefit but which may cause a risk to public health e.g. in the case of drugs which are known to be teratogenic. There may be controlled access at prescribing or dispensing level to ensure that a pregnancy test is carried out, that negative results are verified by a HCP before prescription or dispensing of the medicinal product, that prescription is limited to a maximum of 30 days supply, that patients are counselled in the event of inadvertent pregnancy and that the outcome of the pregnancy is evaluated. Conditions such as specialist prescribers or dispensers or a patient registry may be implemented.

Key Message

- The HPRA has commenced publication of approved educational materials and tools associated with certain medicinal products on the Irish market on the HPRA website.
- It is important that HCPs maintain an awareness of the availability of educational materials relating to medicinal products where additional risk minimisation measures have been recommended.
- HCPs are encouraged to use these educational materials to enhance safe and effective use of medicines in clinical practice and, where applicable, to support discussion of important risk minimisation information with their patients.

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
T: +353 1 676 4971 E: medsafety@hpra.ie www.hpra.ie

Adverse Reaction Reporting-Reminder

The HPRA appreciates the contribution of healthcare professionals in reporting suspected adverse reactions which aids in facilitating the continued surveillance of the safety of medicines. It is recognised and acknowledged that 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 ('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 for 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).

Since July 2012, when revised legislation came into force, patients and consumers across the EU were enabled to directly report any suspected adverse reactions they may have experienced to their national reporting system. Information on this option is available from the HPRA website and the package leaflet that accompanies medicines and has also been highlighted via patient organisations. It is HPRA practice to routinely check all reports received for possible duplicates of cases received from other sources and to collate all relevant information related to case reports, as far as possible.

The revised legislation also introduced the concept of additional monitoring, previously highlighted in the DSN (editions 50 and 53), to support prompt identification of any new safety hazards. Healthcare professionals and patients are particularly encouraged and reminded to report all adverse reactions associated with the use of these medicines, identifiable by an inverted black triangle on the product information. An explanatory statement is included both in the Summary of Product Characteristics (SmPC) and Package Leaflet (PL):

▼ This medicinal product is subject to additional monitoring

The European Medicines Agency (EMA) first published the list of medicines subject to additional monitoring in April 2013 (which is accessible from the HPRA and EMA websites), with an increased focus on reporting of suspected adverse reactions associated with the products concerned. This list is reviewed and updated as necessary, following consideration by the Pharmacovigilance Risk Assessment Committee (PRAC) at its monthly meetings. Medicines remain on the additional monitoring list for a five year period, or until PRAC decide to remove it from the list.

Key Message

- All medicines subject to additional monitoring are identifiable by a black inverted triangle accompanied by an explanatory statement in the product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)). Reports of suspected adverse reactions to these medicines are particularly valuable for regulatory monitoring purposes.
- Healthcare professionals and patients are encouraged to report suspected adverse reactions to the HPRA, preferably using the online reporting option.

Direct Healthcare Professional Communications published on the HPRA website since the last Drug Safety Newsletter

PRODUCT	SAFETY ISSUE
Gilenya (fingolimod)	Risks related to the effects on the immune system
Tarceva (erlotinib)	First line maintenance indication now restricted to treatment of patients whose tumours harbor an EGFR-activating mutation

Correspondence/Comments should be sent to the Pharmacovigilance Section, Health Products Regulatory Authority, contact details below.

Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
T: +353 1 676 4971 E: medsafety@hpra.ie www.hpra.ie

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority