HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

The Importance of Product Information for Medicines

The HPRA would like to remind healthcare professionals of the importance of regular review and monitoring of product information for medicines, to support awareness of relevant updates/changes which may affect prescribing, dispensing, administration or monitoring practices. It is also important that patients and care-givers, as appropriate, are made aware of the information contained in the Package Leaflet (PL) and should be encouraged to read it prior to and during their treatment.

The product information is comprised of the Summary of Product Characteristics (SmPC) and the PL. These documents are issued when a medicine is first licensed for use and are reviewed and updated as necessary throughout the lifetime of a medicine, to reflect the current state of knowledge of the medicine and the risks associated with its use. The SmPC is mainly intended for use by healthcare professionals and SmPCs for all medicines currently authorised in Ireland are accessible on the HPRA website (www.hpra.ie) via the 'Find a Medicine' search function. The PL reflects the more comprehensive information described in the SmPC, but is required to be presented in an abbreviated and easy-to-read format for patients. The majority of PLs are also accessible from the HPRA website, with work on-going to complete this option to facilitate access to all PLs as soon as possible. Marketing Authorisation Holders (MAHs) are also required to ensure that current copies of the product information are included when medicines are supplied to pharmacies.

The SmPC provides the basis of information for healthcare professionals to use a medicine safely, effectively and in the most appropriate manner. It is also a legal document, agreed between the HPRA/EMA (European Medicines Agency) and the relevant pharmaceutical company. The format and content of the SmPC is laid down in EU/national legislation and regulatory guidance documents. Use of a medicine outside the conditions/recommendations described in the SmPC falls under the responsibility of the healthcare professional.

It is important to note that the SmPC is not intended to provide general advice on the treatment of particular medical conditions. On the other hand, specific aspects of the treatment related to use of the medicine, or its effects may be mentioned. Similarly, general advice on administration procedures is not included, but any advice specific to the medicine concerned will be included, if appropriate.

The PL is drawn up in accordance with the SmPC and is subject to user-testing to ensure its ease of readability by patients/consumers. It plays an essential part in supporting the safe and effective use of a medicine by a patient. Consequently, it is important that a PL is provided each time a product is dispensed. Patients and care-givers should be encouraged to read the current version of the PL that accompanies their medicine(s) and to discuss any relevant concerns with a healthcare professional involved in their care.

Key message

- Product information (SmPC and PL) is available for medicines currently authorised in Ireland from the HPRA/EMA websites (accessible from www.hpra.ie) as well as from the relevant MAHs.
- The current versions of the product information should be consulted regularly to ensure medicines are are used in the safest and most effective manner.
- Patients should be encouraged to read the PLs provided with their medicines and to discuss any concerns with a relevant healthcare professional.

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