HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA commences publication of educational materials and tools for medicines

In December 2015, the HPRA commenced publication of approved educational materials and tools for medicines on its website (www.hpra.ie).

Educational materials are additional risk minimisation measures that are intended to promote the safe and effective use of the medicinal product. While the approved product information (the Summary of Product Characteristics (SmPC), Package Leaflet (PL) and product labelling) provides all relevant information for medicinal products, educational materials focus on one or more specific safety concerns related to use of a particular medicinal product so as to provide clear information on these specific risks and describe concisely what actions are required to prevent and minimise such risks.

Educational materials may be intended for healthcare professionals (e.g. doctors, pharmacists and nursing staff) and/or patients and care-givers. For example, educational materials may outline what a doctor needs to consider before prescribing a medicine for their patient, or what specific monitoring (e.g. regular blood tests) is required while their patient is on that medicine. Likewise, educational materials may help in reminding patients about important safety information that they need to be aware of before and during treatment with a medicine so that they use the medicine safely and effectively. They may also provide advice to patients on when to seek medical advice. Examples of educational materials for healthcare professionals include healthcare professional guides, dosing and administration guides, prescriber checklists and monitoring charts. Examples of educational materials directed at patients include patient alert cards, patient guides and patient reminder cards.

Educational materials are produced and distributed by the Marketing Authorisation Holder (MAH i.e. license holder) of the medicinal product and are specific to that medicinal product. They are not required for all medicines but rather are provided if it is considered that they will aid in optimising the safe and effective use of the product. The need for educational materials is agreed with the HPRA and may be decided at the time of approval of the medicinal product or at a later time in the lifecycle of the product.

Only educational materials which have been reviewed and approved by the HPRA are included on the list published on the HPRA website. These materials are published with the agreement of the MAH responsible for producing them and may be downloaded for use by healthcare professionals and patients. Please note the HPRA does not provide hard copies of these materials. If hard copies are required, the relevant MAH for the medicinal product should be contacted.

Currently available, approved educational materials are located on the HPRA website (under Medicines-Safety Information-Educational Materials for Medicines). Further information in relation to educational materials may be obtained by contacting the HPRA Vigilance Department at medvigilance@hpra.ie

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