

Guide to

Submission of Educational Tools and Materials

1 INTRODUCTION

Educational tools and materials are additional risk minimisation measures for a medicinal product and will be specified as a requirement in the Risk Management Plan (RMP) or Annex II of the Conditions of Marketing Authorisation. Educational materials and other risk minimisation tools intended for healthcare professionals or patients must be assessed at national level by the Health Products Regulatory Authority (HPRA) prior to their approval for distribution in Ireland.

A clear distinction is made between risk minimisation tools requiring approval and other informational materials that are intended for promotional purposes (i.e. that are not the subject of a RMP). Only educational materials which are included in an EU-RMP or which are a condition of the marketing authorisation require HPRA approval.

The Vigilance Assessment section of the Human Products Monitoring department is responsible for the national assessment and approval of educational materials and tools. The HPRA retains autonomy in deciding the appropriateness of national educational materials and tools in accordance with the key elements agreed at EU level and outlined in the EU-RMP. It also retains autonomy in deciding the national applicability of measurement of effectiveness studies due to differences in healthcare delivery systems across member states or where extrapolation of results of such studies conducted in other member states would not be considered to be representative nationally.

2 CONSIDERATIONS FOR PREPARATION AND IMPLEMENTATION OF EDUCATIONAL TOOLS AND MATERIALS

Guidance on the principles for development and implementation of additional risk minimisation measures, including educational materials and tools, as well as the evaluation of the effectiveness of risk minimisation measures is available in GVP module V –Risk Management Systems and GVP module XVI – Risk minimisation measures: selection of tools and effectiveness indicators.

Where educational materials and tools are considered necessary for generic products based on safety concerns related to the active substance, the materials should be aligned with those for the reference medicinal product.

In addition, educational materials and tools for distribution in Ireland should contain details of the medicinal product's 'additional monitoring' status if applicable as well as wording encouraging the reporting of adverse reactions. Please see the 'Guide to Additional Monitoring Requirements and Statements Encouraging Reporting of Adverse Reactions' at www.hpra.ie.

3 SUBMISSION TO HPRA

The applicant should submit proposed educational tools in electronic format to medvigilance@hpra.ie together with:

- A. Cover letter briefly outlining the context for submission of educational materials.
- B. The completed 'Submission of Risk Minimisation and Educational Materials by Marketing Authorisation Holders' form available at www.hpra.ie. The following points should be addressed by completion of the form:
 - Rationale for and objectives of educational materials;
 - Brief description of tools proposed;
 - Key elements of content;
- C. The draft educational materials:
 - Whenever possible, the documents should be submitted in pdf format, in order to guarantee their readability and the pertinence of the visual aids;
 - In order to optimise the efficiency of the assessment and review process, the documents should also be submitted in a modifiable text format (Word);
 - For visual or audiovisual documents, apart from the submission of the CD-Rom or DVD, a typed text indicating the scenario, describing or representing the image and transcribing the audio must be attached.
- D. Proposed communication plan:
 - Setting, timing, timelines for distribution, target audience, changes to previously agreed distribution plans (if applicable), coordination with other MAHs (if applicable), quality control methods to ensure distribution lists are kept up to date.
- E. Evaluation plan:
 - Details of plan for evaluation of effectiveness of tools (process and outcomes including milestones) where applicable.
- F. Reference documents:
 - Annexes I to III of the marketing authorisation (with relevant version of the SmPC/package leaflet);
 - Annexes of the RMP describing the minimisation tools;
 - Copies of literature references mentioned in the documents;
 - Other supporting data accompanying the submission.

Submissions must be made at least three months prior to product launch to facilitate assessment of the educational tools and materials and any subsequent revisions.

The HPRA may require the applicant to submit new draft documents if the initial assessment concludes that the documents are not in accordance with the requirements for educational materials.

During the assessment procedure, the HPRA may send comments to the company. A case reference number will be provided and should be quoted in all subsequent correspondence.

The final documents must be provided to the Vigilance Assessment section in electronic format.

4 UPDATES

Following a major variation of the marketing authorisation (with an impact on key elements of the educational materials) or following an update of the RMP, updated educational materials should be submitted to the HPRA and will follow the same assessment process.

The application should be submitted both in pdf and Word formats. The Word format should have any changes to previous materials tracked (and justification of the modification, for example, by including a cross-reference to the variation procedure. Include the HPRA case reference number if known).

In case of major modifications to the document (paragraphs added, moved or major rephrasing), it is recommended to format it as a three-column table (original text, modified text and justification of modification).

The modification of formats, models or following a minor marketing authorisation variation (for example modification of a section of the SmPC without an impact on the body text of the document) should only be provided for information.

In case of submission of an updated document, the applicant should specify the distribution procedures planned, and highlight any changes to previously agreed distribution plans.

5 CONTACT DETAILS

Please send electronic submissions or queries to medvigilance@hpra.ie.

HPRA
18 June 2014