

29.10.2025

## **Instructions for preparing additional risk minimisation materials for a medicinal product**

### **1 General**

Additional risk minimisation measures (aRMM) included in the risk management plans (RMP) for medicinal products often include additional risk minimisation materials, such as training materials, instructions for physicians and patients, patient cards, checklists, etc. In this document, these will be referred to as 'risk minimisation material'. The instructions given in the current version of GVP module XVI on the content, layout, and publication of materials, such as on websites, must be followed:

[https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-xvi-risk-minimisation-measures-rev-3\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-xvi-risk-minimisation-measures-rev-3_en.pdf)

### **2 Submission of material**

Versions of the national risk minimisation materials included in the risk management plan to be disseminated in Finland are to be sent for review to Fimea to the TURVA e-mailbox at [TURVA@fimea.fi](mailto:TURVA@fimea.fi).

The material is reviewed before the product is introduced to market.

In addition to the actual risk minimisation material, the following is requested to be submitted:

- Cover letter with contact information. The cover letter indicates the regulatory procedure which has led to the need for the educational material or other risk minimisation material. The cover letter also includes a plan for the dissemination of the material, indicating at least the dissemination method, time point when dissemination is anticipated to start and the frequency of further disseminations, and the target population.
- The most recent approved summary of product characteristics (SmPC) and package leaflet (PL)

- The most recent approved version of the RMP, including annexes, which indicate the purpose and key elements of the risk minimisation material.

When updating the risk minimisation material, the cover letter indicates the reason for the update. Any changes to the original material should be clearly marked.

If the material is distributed to patients, the delivery must include versions in both Finnish and Swedish.

### **3 Content, layout, publication and distribution of the material**

Risk minimisation material should focus on key risk information and be consistent with the approved summary of product characteristics and the package leaflet. It should not be a summary of the SmPC or the package leaflet, being instead limited primarily to the key information contained in Annex 6 of the RMP.

Risk minimisation material is intended to highlight risks information and risk minimisation measures, and to support or monitor compliance with these measures.

The risk minimisation material of a generic or biosimilar product containing the same active substance must be as consistent as possible with the material of the reference product.

Risk minimisation materials for the same active substance should be kept as similar as possible to promote patient safety, deliver a consistent message and avoid confusion in the target audience. For this reason, marketing authorisation holders are encouraged to produce joint material.

Risk minimisation material may not contain any direct or indirect marketing information or illustrations, nor should it be combined with any materials intended for sales promotion.

It is not considered sales promotion to refer to a medicinal product by its trade name in the material. However, this should be done with caution.

#### **3.1 Layout**

Fimea requests marketing authorisation holders to add the medicine safety information symbol to risk minimisation materials intended for health care professionals. The symbol is requested to be added to new material, and to previously approved material when the material is updated for another reason.



There are no requirements for the location or size of the symbol, but in each material intended for health care professionals, it should appear at least once and preferably on the first page. The symbol can be downloaded from Fimea's [media bank](#).

In general, logos of the marketing authorisation holder (MAH) and/or product should be avoided. As a rule, logos are considered to be sales promotion elements. If there is a justifiable reason for the use of the logo, the justification should be stated in the cover letter.

The final layout version of risk minimisation material should be submitted to Fimea for review before the material is distributed to the agreed target groups.

### **3.2 Publication and distribution**

Fimea will publish the written risk minimisation material in PDF format on its website. The material includes the version number and Fimea's approval date (mm/yyyy). If the material is not to be published before introduction to the market, the marketing authorisation holder is asked to inform Fimea thereof by sending a notification to Fimea's TURVA mailbox.

Electronic distribution of risk minimisation material is permitted, but printed versions must be available on request. The Fimea website may not be the sole electronic distribution channel. If the material is distributed through the marketing authorisation holder's website, links/QR codes should lead directly to the material in question.

The marketing authorisation holder makes sure to only distribute the latest approved version of the material. The material is distributed to approved target groups to their personal postal address or email, or both. In addition to personal addresses, the material can also be distributed to health care units and pharmacies.