25.01.2017

Instructions for the preparation of product-specific risk minimisation material

The risk management plans (RMP) for medicinal products often include additional risk minimisation materials (educational materials, instructions for physicians and patients, patient charts, checklists etc.). Instructions regarding the layout, format and publication of such materials e.g. on websites are provided in GVP module XVI addendum 1:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/12/WC500198761.pdf

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. The review of the material must be completed before the product is introduced to the market, if so required by SPC Annex II.

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

- Cover letter with contact information. The cover letter must indicate the regulatory procedure which has led to the need for the educational material or other risk minimisation material. The cover letter should also include 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. For new marketing authorisations, the cover letter should also provide an estimate of the date of introduction to the market, or the start date of the product's marketing.
- The most recent approved summary of product characteristics (SPC) and package leaflet (PIL)
- The most recent approved version of the RMP, including annexes, which indicate the purpose and key elements of the risk minimisation material.

Similarly, when updates to risk minimisation material are delivered, the cover letter should indicate the reason for the update. Any changes to the original material must be clearly marked.

If material is disseminated to patients, Swedish versions must also be submitted.

Risk minimisation material should focus on key risk information and be consistent with the approved summary of product characteristics and the package leaflet. Risk minimisation material may not contain any promotional illustrations or information, nor should it be combined with any materials intended for sales promotion.

The final layout version of the risk minimisation material must be submitted to Fimea for review before dissemination.

Fimea will publish the written risk minimisation material in PDF format on its website. The material must be marked with Fimea's approval date. If the material is not to be published before introduction to the market, the marketing authorisation holder must inform Fimea thereof by sending a notification to Fimea's TURVA mailbox.

25.01.2017

The marketing authorisation holder should ensure that only the latest agreed version is disseminated.

Risk minimisation materials for the same active substance should be kept as similar as possible, in order to deliver a consistent message and avoid confusion in the target audience. Marketing authorisation holders are therefore encouraged to share the content of their educational material(s) upon request from other marketing authorisation holders.

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