Additional risk minimisation measures (aRMM)

Submission of educational materials

General requirements

State Agency of Medicines (SAM) reviews, amends (if required) and approves educational materials in case these are part of additional risk minimisation measures (aRMM) set as condition regarding to the safe and effective use of the product. That means materials of

- Centrally authorised products for which aRMM educational materials are set as a condition in EC decision Annex II D or prepared according to Risk Management Plan which are approved within assessment report.
- Mutually recognised, decentrally or nationally approved medicinal products for which aRMM educational materials are prepared according to Risk Management Plan which are approved within assessment report.

SAM does not review or approve any educational material which is prepared by the Marketing Authorisation Holder (MAH) on its own initiative. Such materials are considered to be as advertising of medicinal products.

In case MAH on its own initiative considers necessary to apply aRMM (including educational materials to Health Care Professionals (HCP) or patients) to guarantee safe use of the medicinal product, Risk Management Plan must be amended in advance and variation submitted. Only after approval of the variation such materials are considered as part of the marketing authorisation.

Submission of educational materials to SAM

Before distributing aRMM materials to HCPs or patients MAH is requested to submit to SAM English final versions (as PDF files) and Estonian versions as word files (*according to article 78[5] § 9 of Medicinal Products Act).*

aRMM educational materials must be sent to e-mail **pharmacovig@ravimiamet.ee**

To guarantee fast and smooth process

- On the e-mail *Subject* line MAH should write "**Name of the medicinal product**", "**aRMM", "initial"** OR "**repeated**" (that helps to clarify are Estonian materials sent to SAM for the first time for approval or are they amendments/updated of previously approved materials)
- In the letter MAH should clarify what are the grounds of submission of these materials (condition of marketing authorisation (in Annex II D or in approved RMP)

- In case repeated submission MAH should clarify when materials where approved last time and what are main amendments/changes. All amendments/changes must be done in tracked version.

In addition the following must be submitted:

- **Communication plan** (to whom materials are meant, distribution plan, in case of repeated materials the clarification how the recall/disposal will be organised)
- **Estonian speaking contact** *(according to article 4§ 4 of Regulation of the Ministry of Social Affairs no 26).*

Other important requirements

Educational materials must not contain advertising elements (no product logo or unrelated pictures)

Every separate material must have version umber.

After approval of educational materials as word (doc) files, MAH must submit final version as pdf file. If required, SAM may propose amendments to the final pdf file.

Black triangle – in case the product is in the list of medicinal products under additional monitoring (see http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142453.pdf), the warning must be included in aRMM materials. Black triangle must be on the cover/first page and explanation in the footer:

▼ Käesoleva ravimi suhtes kohaldatakse täiendavat järelevalvet. See võimaldab kiiresti tuvastada uut ohutusteavet. Tervishoiutöötajatel palutakse teavitada kõigist võimalikest kõrvaltoimetest www.ravimiamet.ee kaudu.

Timelines of review/approval of the aRMM materials

Materials will be reviewed and feedback given to MAH within 2 weeks:

- First-time materials
- Previously agreed format or lay-out changes significantly
- Significant substantive changes (new warnings)
- Changes in the communication plan

- **Materials will be reviewed and feedback given to MAH within 5 days:**

- Repeated materials (with no significant changes)
- Non-significant substantial changes (specification of warnings, revision of mistakes)
- Final version as pdf file.