5.08.2020

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.

Educational materials should be drafted, submitted and disseminated in accordance with the Guideline on good pharmacovigilance practices Module XVI Addendum I – Educational materials https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices.

Submission of educational materials to SAM

Before dissemination of aRMM materials to HCPs or patients MAH is requested to submit to SAM English final versions (as pdf files) and Estonian versions as ***.docx** 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**", "**active ingredient(s)", "aRMM", "initial"** OR "**repeated**" (that helps to clarify are Estonian materials sent to SAM for the first time for approval or are they amendments/updates 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, the grounds of the changes and what are the main amendments/changes. All amendments/changes in Estonian versions must be done using tracking function.

Always the following must be submitted:

- **Communication plan**
    - To whom material/information is meant (if addressed to HCPs the, speciality should be specified; if individual physicians, by name)
    - Dissemination method (either by name, through a professional society, hospital department, hospital pharmacy, etc)
    - Planned dissemination date; in case of repeated materials the clarification how the recall/disposal of previous version will be organised).

    The communication plan must be adapted to the Estonian local situation.

- **Estonian speaking contact** *(according to article 4 §4 of Regulation of the Ministry of Social Affairs no 26).*
  Note: Name of the contact person is required to SAM, not to be presented on the materials – see also section "Recommendations"

  SAM assumes that the Estonian-speaking contact person appointed by the MAH is aware of the additional risk minimisation measures implemented for the medicinal product (including the dissemination of the materials, training of HCPs, valid version of the materials, etc).

<u>Dissemination of materials</u>

MAH must ensure that every HCP of the target group receives aRMM educational materials / gets the training.

If MAH transmits aRMM materials to target group (i.e prescribers) via e-mail through professional societies, the cover letter must contain clear request that the society must send a confirmation letter to the MAH regarding dissemination of the aRMM materials. In case confirmation is not received within sensible time, the MAH shall re-contact the society for delivery of materials. In case the dissemination of educational materials via society is not feasible, the materials should be disseminated to target group by other means (e-mail, postal mail or direct contact). For comparison the MAH may use the list of healthcare professionals which can be found on Health Board website: the Register of healthcare professionals - http://mveeb.sm.ee/Tervishoiutootajad/?

The MAH must keep records of the target group given in the communication plan (to whom aRMM materials were disseminated / who got the training and when).

(according to point 11, article 2 § 78[3] of the Medicinal Products Act - GVP Module XVI point XVI.B.6: *„The marketing authorisation holder should ensure appropriate version control of the risk minimisation tools in order to ensure that all healthcare professionals and patients receive up-to-date risk minimisation tools in a timely manner and that the tools in circulation are consistent with the approved product information. To this purpose the market authorisation holders are encouraged to*

keep track of the receipt of any risk minimisation tools. These records may be subject to audit and inspection.")

In certain cases, in agreement with the MAH, the materials may be disseminated by the SAM.

Other important requirements

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

The MAHs logo may be included once together with the MAHs contact details.

After approval of educational material as *.docx file, MAH must submit designed material in pdf-format. SAM may request amendments to the designed material.

Materials must have a **version number;** this must be added to the new / revised material at the latest when sending the final file in pdf format. The SAM will approve the file of the material(s) with version number in pdf format or video file.

When distributing a **revised version of the materials**, the HCP should be reminded that the previous version has expired and should be destroyed.

Frequency of dissemination of materials - The frequency of dissemination specified in the RMP or in the Annex II of the Marketing Authorisation must be followed. If the frequency of re-dissemination is not specified, materials must be disseminated when they are revised / modified or at the request of the SAM.

Video material as a risk minimisation measure – video in English and written scenario in Estonian must be submitted for review. After approval, the video will be linked to the Register of medicinal products from the MAHs website or from YouTube channel (SAM can upload the video to the SAMs YouTube channel).

Audio material as a risk minimisation measure for visually impaired patients must correspond in content to the approved patient material. After approval, the audio file will be linked to the Register of medicinal products from the MAHs website or from YouTube channel (SAM can upload the audio file to the SAMs YouTube channel).

Patient safety card, which is part of the Product Information and is included in the package, must be submitted as a pdf file to SAM before launch of the product in Estonia. The pdf file will be added to the Register of medicinal products. If SAM grants exemption from language requirement of the labelling (i.e foreign language package is allowed) for a product with patient safety card in the package, the inclusion of Estonian language patient safety card /dissemination of the card should be agreed with SAM prior applying for the exemption.

Black triangle – in case the product is in the list of medicinal products under additional monitoring (see EMA website), 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.

Recommendations

Contact details - The aim of the contact details presented in the material is to give the HCP of the target group the opportunity to subscribe further copies of the materials or to report adverse drug reactions. Healthcare professional should get response to the request in Estonian language. Contact details of the Marketing Authorisation Holder should be presented as phone number or general e-mail address of the MAH (local affiliate etc), they should not contain name of the person.

Materials aimed to train patients should contain advice to talk to their doctor for further information. Contact details of the Marketing Authorisation Holder in the Patient material should be the same as in the Package Leaflet.

The templates of the cover letters to the society or directly to the prescribers are presented in Annexes 1 and 2.

By sending educational materials electronically via society's e-mail, pharmacovig@ravimiamet.ee as CC should be added.

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)
- Designed material in pdf-format.

Submission of the material with final design as pdf file and reference to SAMs website

Approved materials with final design in pdf-format should be sent to the State Agency of Medicines prior to dissemination to target groups. SAM publishes materials on the website.

Annex 1

Cover letter to Societies

Subject: Riskivähendamise meetmed ravimi {ravimi nimetus} ({toimeaine}) kasutamisel

Sisu: Lp ... Selts

Palun edastage allolev teave seltsi liikmetele:

{Ravimi nimetus} ({toimeaine, näidustus}) müügiloa hoidjale {müügiloa hoidja nimetus} on müügiloa saamise tingimuseks seatud kohustus tagada riskivähendamise meetmena teabematerjal ravimit väljakirjutavale arstile / patsiendile. Teabematerjal aitab parandada teadlikkust {riski kirjeldus (lühikirjeldus on leitav ravimiregistris)} riski osas.

Materjalid saab lisada e-kirjale ravimiregistrist lingi pealkiri (sellele klikkides avaneb materjal pdf dokumendina)

Olenevalt materjalidest võiks edasine tekst olla järgmine:

Palun tutvuge materjaliga. Ravimi määramisel kasutage kontrollnimekirja (kui on nt kontrollnimekiri vms).

Uuendatud materjali korral tuleks lühidalt välja tuua, mis on muutunud võrreldes eelmise versiooniga.

Ravimit välja kirjutades tuleb patsiendile riski selgitada ja anda juhend või meeldetuletuskaart. (kui on patsiendile mõeldud materjal, siis täpsustage materjali)

Täielik teave ravimi kohta on leitav ravimi omaduste kokkuvõttest – viide

Palun saatke kinnitus, kui kiri on seltsi liikmetele edastatud.

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Annex 2

Cover letter to HCP

Subject: Riskivähendamise meetmed ravimi {ravimi nimetus} ({toimeaine}) kasutamisel

Sisu: Lp dr ....

{Ravimi nimetus} ({toimeaine, näidustus}) müügiloa hoidjale {müügiloa hoidja nimetus} on müügiloa saamise tingimuseks seatud kohustus tagada riskivähendamise meetmena teabematerjal ravimit väljakirjutavale arstile / patsiendile. Teabematerjal aitab parandada teadlikkust {riski kirjeldus (lühikirjeldus on toodud ravimiregistris} riski osas.

Materjalid saab lisada e-kirjale ravimiregistrist lingi pealkiri (sellele klikkides avaneb materjal pdf dokumendina)

Olenevalt materjalidest võiks edasine tekst olla järgmine:

Palun tutvuge materjaliga. Ravimi määramisel kasutage kontrollnimekirja (kui on nt kontrollnimekiri vms).

Uuendatud materjali korral tuleks lühidalt välja tuua, mis on muutunud võrreldes eelmise versiooniga.

Ravimit välja kirjutades tuleb patsiendile riski selgitada ja anda juhend või meeldetuletuskaart. (kui on patsiendile mõeldud materjal, siis täpsustage materjali)

Täielik teave ravimi kohta on leitav ravimi omaduste kokkuvõttest – viide

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History of changes

Time	Content of the main changes
14.03.2018	New section added - **Submission of the material with final design as pdf file and reference to SAMs website**
28.02.2018	**General requirements** - Educational materials should be drafted, submitted and disseminated in accordance with the Guideline on good pharmacovigilance practices Module XVI Addendum I – Educational materials. In section **Submission of educational materials to SAM** wording has been changed: Communication plan and Estonian speaking contact should always be submitted: In section **Communication plan** the dissemination via e-mail through professional societies has been specified. New section added – **Recommendations**
08.06.2018	**Submission of educational materials to SAM** – sections **Communication plan** and **Estonian speaking contact** have been amended **Recommendations** – section **Contact details** has been amended New **Annexes 1 and 2 –** cover letter templates
27.02.2019	Text in **annexes 1** and **2** has been amended as from now on the educational materials are in the register of medicinal products, not in the separate table
5.08.2020	**Communication plan:** specified the submission details, the Estonian-speaking contact person **Dissemination of materials:** in certain cases SAM can disseminate the materials **Other important requirements**: specified the details regarding the inclusion of the version number in the materials, the destruction of the previous version when disseminating the new version, the frequency of distribution of the materials, regarding the video and audio materials and patient safety card, regarding MAHs logo **Recommendations:** contact details of the MAH in the Patient material should be the same as in the Package Leaflet. Text in **annexes 1** and **2** has been amended to include a requirement in the cover letter to indicate changes compared to previous version of the materials