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Information for marketing authorisation holders
15.04.2013.

Submission of educational materials stated in the risk minimisation plan to the State Agency of Medicines and their approval

Normative documents

- 22nd January 2013 Cabinet of Ministers Regulation No. 47 "Procedure for Pharmacovigilance" (hereinafter - Regulation No. 47).
- 8th March 2005 Cabinet of Ministers Regulation No. 175 "Regulations for Manufacture and Storage of Prescription Forms, as well as Writing Out and Storage of Prescriptions" (hereinafter - Regulation No. 175).
- COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 of 19 June 2012 on the performance of the pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
- Regulation (EC) No 726/2004 of the European Union and of the Council of 31st March 2004 laying down the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (hereinafter - Regulation No. 726/2004).
- European Commission Volume 9A Guidelines on Pharmacovigilance for Human Use of the Rules Governing Medicinal Products in European Union, Part IV, Guidelines for Marketing Authorisation Holders and Competent Authorities on pharmacovigilance Communication, Direct Healthcare Professional Communications (*http://ec.europa.eu/health/files/eudralex/vol-9/pdf/vol9a_09-2008_en.pdf*).
- Good pharmacovigilance practice guidelines.

When submitting the educational materials developed by the marketing authorisation holder to the State Agency of Medicines (hereinafter - SAM), SAM invites marketing authorisation holders to comply with the following requirements:

1. The marketing authorisation holder shall regularly update the risk management system and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products. The marketing authorisation holder shall submit the established risk minimisation measures to the State Agency of Medicines for approval (*Regulation No. 47, Article 15.8*).

2. The marketing authorisation holder shall ensure the availability of the developed materials for risk minimisation measures approved by the State Agency of Medicines to the physicians entitled to prescribe the appropriate medicinal product (*Regulation No. 175, Article 34*^{4})

3. The marketing authorisation holder shall ensure that the provided information is objective, it should not be misleading (*Regulation No. 47, Article 19; Regulation No. 726/2004, Chapter 3, Article 24(5)*)

When developing the educational materials, marketing authorisation holders are asked to take into account the following:

- The content of the educational materials shall be completely compliant with the approved product information effective in the member state, that is, the summary of product characteristics and the package leaflet.

- The educational materials regarding safety issues of medicinal products shall not include any kind of information (images, slogans or statements) that could be considered as an advertisement or that the competent authority considers to be promoting prescription, supply, marketing or use of medicinal products.

- The implementation of educational programs shall not be associated with measures promoting prescription, use or marketing of medicinal products.

- The contact information of patients and healthcare professionals obtained by the marketing authorisation holder within the educational program shall not be used by the marketing authorisation holder in medicinal product advertising measures.

- When developing the materials for risk minimisation measures the marketing authorisation holder shall comply with the lexical, grammatical and stylistic standards of the literary language and terminology in order to ensure effectiveness and high quality of the risk minimisation communication.

- All educational materials intended for healthcare professionals (physicians or pharmacists) and patients shall be submitted to SAM in Latvian together with the original document in English.

Procedure for submission of documents

Submission of draft educational materials to SAM

The following documents shall be submitted electronically by forwarding them to these e-mail addresses: Inese.Studere@zva.gov.lv and Lolita.Smate@zva.gov.lv:

- draft educational materials in Latvian;

Please note that when preparing educational materials in Latvian the marketing authorisation holder shall ensure correct materials compliant with linguistic requirements and with the appropriate medical terminology used in these materials.

- copies of documents on which the educational materials are based upon and being submitted for approval;

For example, EC decision, requirements of the marketing authorisation or risk minimisation measures included in the risk management plan of the marketing authorisation holder or other.

- educational materials in English;

- the updated version of summary of product characteristics and package leaflet.

The cover letter must indicate:

- justification for developing and submitting educational materials,
- list of documents included in the set of educational materials (indicating precise title and number of pages),
- target audience and distribution plan of the educational materials in Latvia,
- indicate, if the format and content, as well as the target audience and distribution plan of the educational materials was discussed with, for example, scientific associations, professional associations or healthcare specialists (physicians or pharmacists),
- if specific distribution requirements have been stated, please also indicate how the marketing authorisation holder shall ensure them in Latvia (for example, requirement to ensure cooler bags, etc.).

Approval of educational materials

The marketing authorisation holder shall continue the discussion regarding the content and format of the project for educational materials in Latvian, as well as the distribution plan and target audience by e-mail communication or via telephone or during SAM working hours, previously coordinating the time of visit with the competent expert:

- During the approval of educational materials SAM may ask the marketing authorisation holder to consult with terminologists, linguists, medical and pharmaceutical professional associations, as well as separate specialists in order to clarify or verify:
    - ✓ terminology compliance,
    - ✓ comprehensibility and perceptibility of the information,
    - ✓ whether the information is compliant with the medical and laboratorial possibilities available in Latvia;
- The SAM expert may ask the marketing authorisation holder to submit additional information or materials, if necessary.

Submission of <u>final version</u> of educational materials to SAM

The following documents shall be submitted in paper format:

- The original of the final version of educational materials approved by SAM;
- The cover letter should indicate:

- ✓ the marketing authorisation holder submits the final version of educational materials after discussing the draft educational materials with a SAM expert (indicate, if during the approval process the educational materials were discussed also with other organisations or persons);
- ✓ list of documents included in the set of educational materials;
- ✓ SAM approved list of target audiences and distribution plans for educational materials in Latvia.

In case of uncertainties, please contact the Adverse Drug Reactions Monitoring Department, phone No. 67078442, e-mail Lolita.Smate@zva.gov.lv; Inese.Studere@zva.gov.lv .

Confirmation of SAM approval of educational materials

SAM will inform in writing the submitter of educational materials regarding the approval of educational materials by sending out a letter.

Publishing information regarding approval of educational materials on SAM website

In accordance with Article 34^4 of the 8th March 2005 Cabinet of Ministers Regulation No. 175 "Regulations for Manufacture and Storage of Prescription Forms, as well as Writing Out and Storage of Prescriptions" the information regarding SAM approved educational materials shall be published on SAM website www.zva.gov.lv section "List of risk minimisation educational materials for medicines".