PHV-7 SÚKL requirements for the production, content and distribution of educational materials targeting healthcare professionals and patients

Valid since: 25.4.2014

The guideline elaborates the terms and lays down the conditions for providing data and documents to the State Institute for Drug Control (SÚKL) in the area of the production, content and distribution of educational materials targeting healthcare professionals and patients.

Related regulations:

Act No. 378/2007 Coll., on pharmaceuticals and on amendments to some related acts (Act on Pharmaceuticals), as amended

Act No. 95/2004 Coll., concerning the conditions for receiving and recognition of basic qualification and specialist qualification for performing the medical profession of physician, dentist and pharmacist

Decree No. 228/2007 Coll., on marketing authorization of medicinal products

Guideline on Good Pharmacovigilance Practices (GVP), Module I, V, XV, XVI

Acronyms and Abbreviations

SmPC	Summary of Product Characteristics
PIL	Patient Information Leaflet
GVP	EU Guideline on good pharmacovigilance practices
SÚKL	State Institute for Drug Control
EMA	European Medicines Agency
PRAC	Pharmacovigilance Risk Assessment Committee
CMDh	Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human
CHMP	Committee for Medicinal Products for Human Use
EU	European Union
EM	educational material
MP	medicinal product
RMP	Risk Management Plan for a medicinal product

1. Definitions of Terms

- **educational materials targeting a healthcare professional -** important message for healthcare professionals communicated in order to augment the information in the SmPC, relating to the actions and measures necessary for safe use of the medicinal product and to reduce the probability of the occurrence of adverse reactions associated with exposure to a medicinal product, to minimize risks and thus improve the benefit/risk balance. The requirement to create and distribute the EM is imposed through a decision by the EMA, CMDh or a national medicine agency (SÚKL) or through a proposal by the marketing authorization holder for an action for minimizing risks. The objectives and content of the EM are described in detail in the Risk Management Plan (RMP).
- **educational materials for patients –** important message for patients and/or their carers communicated in order to augment the information in the PIL relating to the actions and measures necessary for the safe use of the medicinal product and to reduce the probability of the occurrence of adverse reactions associated with exposure to a medicinal product in order to minimize risks and thus improve the benefit/risk ratio. The requirement to create and distribute the EM is imposed through a decision by the EMA, CMDh or a national medicine agency (SÚKL) or through a proposal by the marketing authorization holder for an action for minimizing risks. The objectives and contents of the EM are described in detail in the Risk Management Plan (RMP).
- **healthcare professional** - pursuant to Act No. 95/2004 Coll.

2. Content of educational material for healthcare professionals

The aim of the production and distribution of the EM is to deliver specific recommendations to physicians and/or other healthcare professionals to highlight selected safety concerns and thus ensure protection for the health of the patient and other persons who are in direct contact with the product and also to minimize the risks arising from the character, indication and way of use of the active substance.
The content of the educational material should be fully aligned with the currently approved product information for a medicinal product.
The format of the educational material should be appropriate to the message to be delivered.

The topics communicated through the EM can be intended for more recipients, i.e., for physicians with different specialties, pharmacists and/or other healthcare professionals, and can address more than one safety concern.

Marketing authorization holders for the same active substance/ combination of active substances should be required by SUKL to have educational materials with as similar as possible layout, content, colour and format.

The information in the EM should have clearly defined scope and should include unambiguous statements, be as brief and apposite as possible, with content not going beyond the basic scope of the topic, and the content of the EM should not be unnecessarily diluted by including information that is not immediately relevant to the safety concern and that is adequately presented in the SmPC. The content may include recommendations relating to dosage, contraindications, management of critical situations and how to manage adverse reactions, measures relating to specific groups of patients, treatment management including special administration procedures, dosing of the medicinal product and monitoring of patients, or important information that needs to be given to the patient before, during or upon completion of the treatment.

The EM should not duplicate the currently approved SmPC. The aim of EM is to warn of possible risks arising in relation with the use of a medicinal product, and to describe measures to minimize these risks. It always should refer the reader to the SmPC.
To distinguish the EM from a range of other printed materials relating to promotional activities, the EM must be marked as standard in the upper left corner of the first page of the EM with a clearly visible red coloured headline < *Edukační materiály* > [Educational materials]. The font for this headline must be significantly larger than the font for the following text. It must be clearly and distinctly separated from other text, headings and other graphical elements. If the EM is distributed in a form other than written text, the respective data carrier must be labelled appropriately.
This labelling must also be on the envelopes or packaging in which the EM is distributed.
This labelling may be used exclusively for educational materials whose form, content and way of distribution have been approved by SÚKL.

The following text on the page must be the name of the related active substance, and/or medicinal product. Education material´s title, meaningfully reflecting the scope of the message, has to be placed below.

Education material related to an active substance which is a subject to additional monitoring must conspicuously contain this information on the first page in the following way:

< ▼ *Tento léčivý přípravek podléhá dalšímu sledování. To umožní rychlé získání nových informací o bezpečnosti. Žádáme zdravotnické pracovníky, aby hlásili jakákoli podezření na nežádoucí účinky.* >

(▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.)

All EMs shall contain a reminder of the need and how to report adverse reactions.

Preferably in the following form:

<Jakékoli podezření na závažný nebo neočekávaný nežádoucí účinek a jiné skutečnosti závažné pro zdraví léčených osob musí být hlášeno Státnímu ústavu pro kontrolu léčiv.

Podrobnosti o hlášení najdete na: http://www.sukl.cz/nahlasit-nezadouci-ucinek

Adresa pro zasílání je Státní ústav pro kontrolu léčiv, oddělení farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.

Pokud se hlášení týká biologického léčiva, je třeba doplnit i přesný obchodní název a číslo šarže.

Tato informace může být také hlášena společnosti....„

(Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected or unexpected adverse reactions to State Institute for Drug Control (SÚKL).

Details of the reporting of adverse reactions are available at: http://www.sukl.cz/nahlasit-nezadouci-ucinek

The correspondence address is the State Institute for Drug Control, Pharmacovigilance Department, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.

If the report applies to a biological medicinal product, the precise trade name and batch number should be indicated.

The information can also be reported to the company....")

The reporting to SÚKL shall always be mentioned before all other ways and recipients of the reporting.

Marketing authorization holders for generics are required to have educational material with as similar as possible content, form and graphical layout as the EM for original products.

The EM must not contain:

- promotional elements, either direct or veiled (e.g., logos, product brand colours)
- pictures and images not related to the management of those risks requiring additional minimisation measures (they are permitted only if they are in close relation to the material content, e.g., appropriate site of application, etc.)
- graphs and tables that do not directly relate to the safe use of the product
- content that is not in close relation to the intended message
- heading or name of product on the front page in red
- references to literature that does not directly relate to the EM content

The form of EM that has been already approved by SÚKL before the issue of this *Guideline* shall be modified in line with this Guideline at the time of a next update of EM. The changes shall be submitted for approval to SÚKL as well.

It is recommended that healthcare professionals, experts and related medical societies are consulted on the design and wording of the EM.

3. Content of Educational Materials targeting patients

The aim of the production and distribution of EM to patients should be to communicate important safety information to increase the awareness of patients and their carers of these facts and therefore ensure the safe and effective use of the medicinal product, protect the patients' health as well as the health of other persons in direct contact with the medicinal product, and minimise risk.

The form of the educational materials should be adequate to the intended message.

The content of the EM shall always be in line with currently approved PIL.

The EM can address more than one safety concern.

Information in the EM should have a clearly defined scope and should include unambiguous statements, and be as brief and apposite as possible, with content not going beyond the basic scope of the topic, while the content of the EM should not be unnecessarily diluted by including information not immediately relevant to the safety concern and that is already presented in the SmPC.

The EM should be written in lay-language, and it is recommended to avoid the use of medical terms and foreign terms in order to maximise the comprehensibility of the message.
All the communicated information should be appropriately formulated with regard to any sensitive information and its impact on the patient (e.g., further progression of a disease, pregnancy, adverse reactions).

The contents may, e.g., include recommendations related to the correct administration of MP (dosing, quantity, application site, etc.), contraindications, adverse reactions, early recognition of the likelihood of development or occurrence of adverse reactions, and a description of how to manage such situations, including an unambiguous statement about when immediate medical care should be sought. The EM should also contain important information to be discussed with the physician before, during or after completion of the treatment.

If appropriate, a diary for posology or diagnostic procedures or other important activities that need to be carried out and recorded by the patient would be a part of the patient's educational materials to ensure that any steps required for the effective use of the product are adhered to.

The EM should not duplicate the currently approved PIL. The aim is to warn of possible risks arising in connection with use of the medicinal product and a description of measures to minimise the risks; however, they should contain a recommendation to read the PIL and, if any doubts or questions arise, discuss them with the attending physician or pharmacist.

Patient´s education material related to an active substance which is a subject to additional monitoring must conspicuously contain this information on the first page in the following way:

<▼Tento přípravek podléhá dalšímu sledování. To umožní rychlé získání nových informací o bezpečnosti. Můžete přispět tím, že nahlásíte jakékoli nežádoucí účinky, které se u Vás vyskytnou. >

(▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.)

Each EM shall contain a reminder of the need and how to report adverse reactions.

Preferably in the following form:

<Jakékoli podezření na závažný nebo neočekávaný nežádoucí účinek a jiné skutečnosti závažné pro zdraví léčených osob musí být hlášeny Státnímu ústavu pro kontrolu léčiv.

Podrobnosti o hlášení najdete na: http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek

Adresa pro zasílání je Státní ústav pro kontrolu léčiv, oddělení farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.

Pokud se hlášení týká biologického léčiva, je třeba doplnit i přesný obchodní název a číslo šarže.

Tato informace může být také hlášena společnosti....„>

*(*Any suspected serious or unexpected effects or other facts important for health of the treated persons should be reported to the State Institute for Drug Control.

Details of the reporting of adverse reactions are available at http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek

The correspondence address is the State Institute for Drug Control, Pharmacovigilance Department, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.

If the report applies to a biological medicinal product, the precise trade name and batch number should be mentioned.

The information can be also reported to the company....")

If the information is submitted in a different way, reporting to SÚKL shall always be mentioned before all other ways of reporting.

4. Patient alert card

The aim of this tool should be to ensure that special information regarding a patient's past and current therapy, medical procedures and safety concerns and risks arising from, e.g., the concomitant use of several medicinal products leading to life threatening interactions with other therapies, the teratogenic character of the active substance, increased risk of bleeding etc.is held by the patient at all times and reaches the relevant healthcare professional as appropriate.

The information should include:

- the need to carry the card at all the times and present it at any visit to a physician or therapeutic or diagnostic procedure.
- the key information related to the diagnosis and treatment that might affect any urgent or non-urgent medical decisions
- the contact data of the patient and/or his carer
- the contact data for the attending physician or the facility where the patient is undergoing treatment

The card should be of an appropriate size enabling it to be carried, e.g., in a wallet.

5. Submitting the educational material for approval

Drafts of educational material should be sent via e-mail to: farmakovigilance@sukl.cz.

- the e-mail should clearly state the reason for the preparation of the EM, including the legislative material (CMDh decision, EU referral, an amendment to SmPC etc.) along with documents demonstrating the change
- along with the original in English (if it exists)
- in MS Word format so that any comments can be inserted in the form of comments and revisions
- the translation into Czech must be of high quality
- before sending, it is necessary to verify that recommendations contained in the material are applicable to Czech medical practice
- unless mentioned otherwise, EM should be submitted for approval at least 2 months before the planned launch of the medicinal product, or 2 months before the distribution of the updated material in the case of planned actions. If it is necessary to prepare and distribute an educational material for already marketed products, EM submission for approval is subject to the scheme of the national agency or European Medicines Agency based on whose decision the obligation to prepare and distribute the EM arose
- the e-mail must include a proposal of the distribution plan that further specifies the way, time schedule and target groups of the distribution

6. Approval of the educational material

On the basis of the submitted data the SÚKL will send, within a reasonable time, its opinion on the content and the way of distribution of the EM. SÚKL is not responsible for the quality of the language or whether or not the material is up to date. Once the content is agreed, the marketing authorization holder will send a proposal for the graphical layout of the material in PDF format. The final form of the educational material depends on the agreement between the marketing authorization holder and the SÚKL Pharmacovigilance Department.

After the approval of the material, the marketing authorization holder will send the approved final version in PDF format along with the precise date of distribution and a description of the way of distribution and a consent with the publication of the EM on the SÚKL website. If the marketing authorization holder does not desire publication, it should communicate its reason sufficiently in advance to the SÚKL Pharmacovigilance Department.

If the marketing authorization holder finds some grammatical mistakes once the EM have been approved, it can correct them without a need for an additional approval of those corrections.

7. Distribution

Any educational programme must be strictly separated from promotional and advertising activities.

The distribution of educational materials for healthcare professionals should be primarily and specifically targeted at the affected healthcare professionals and should be direct without any other mediator (e.g., distributors of medicinal products). Other forms of distribution can be implemented only after approval by SÚKL.

The distribution of educational materials for patients is implemented indirectly via healthcare professionals.