PHV-7 version 1

SÚKL requirements for the development, content, and distribution of educational materials targeting healthcare professionals and patients

Effective date: 13 March 2019

The guideline provides detailed definitions of terms and stipulates conditions governing the submission of information and source documents to the State Institute for Drug Control (SÚKL) in the area of development and distribution of educational materials targeting healthcare professionals and patients.

The Guideline is being issued on the basis of and in compliance with the provision of Section 91, paragraph 4 of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, and Guideline on Good Pharmacovigilance Practices (GVP), Module I, V (rev. 2), X, XV, XVI, Addendum to Module XVI.
The Guideline is legally binding.

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 Authorisation of Medicinal Products

Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts

Act No 40/1995 Coll., on Advertising Regulation

Decree No. 228/2008 Coll., on Marketing Authorisation of Medicinal Products, as amended

Guideline on good pharmacovigilance practices (GVP), Module I, V, X, XV, XVI, Addendum to Module XVI.

Directive No 198/2013 of the European Parliament and of the Council

Abbreviations:

CAP	Centrally authorised product
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures
DC	Decentralised procedure
EM	Educational materials
EMA	European Medicines Agency
EU	European Union
GVP	Guideline on good pharmacovigilance practices
MA	Marketing Authorisation
MP	Medicinal product
MRP	Mutual recognition procedure
PIL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee
RMP	Risk management plan
SmPC	Summary of Product Characteristics
SÚKL	State Institute for Drug Control

1. Definitions of terms

- **Educational materials targeting healthcare professionals** – an important communication for healthcare professionals, distributed in order to reduce risks and hence improve the risk/benefit ratio of the respective medicinal product. The materials supplement, specify or broaden information on the pharmaceutical contained in the SmPC that are relevant to the procedures and measures necessary for the safe use of the medicinal product and for the prevention of adverse reactions thereto or to mitigate their consequences. The obligation to develop

and distribute EM is imposed on the basis of a decision adopted by EMA, CMDh or the national drug agency (SÚKL), or on the basis of the marketing authorisation holder´s proposal for measures to mitigate risks. The objective and content of EM shall be described in detail in the Risk Management Plan (RMP).

- **Educational materials for patients** – an important communication for the patients supplementing, specifying or broadening information about the medicinal product contained in the PIL. The materials concern procedures and measures necessary for the safe use of the medicinal product and for the prevention of adverse reactions thereto or to mitigate their consequences, so as to improve the risk/benefit ratio of the medicinal product. The obligation to develop and distribute EM is imposed on the basis of a decision adopted by EMA, CMDh or the national drug agency (SÚKL), or on the basis of the marketing authorisation holder´s proposal for measures to mitigate risks. The objective and content of EM shall be described in detail in the Risk Management Plan (RMP).
- **Patient Alert Card** – an important communication for the patient or healthcare professionals on the medicinal product taken by the patient, on procedure(s) completed by the patient in relation with the use of the medicinal product, and on situations where certain safety risks could develop (e.g. possible interactions, teratogenic nature of the active substance, increased risk of adverse reaction incidence, etc.). The obligation to develop and distribute a Patient Alert Card shall be described in detail in the Risk Management Plan (RMP).

2. Content of educational materials for healthcare professionals

The reason for EM development and distribution is to alert doctors or other healthcare professionals, as appropriate, of important safety information, and hence ensure the protection of the health of the patient as well as other persons coming into direct contact with the medicinal product and, furthermore, to minimise the risk implied by the nature, indication, and use of the active substance.

The EM development should be always based upon the currently effective version of the SmPC. The form of the EM has to be adequate to the intended message.

The topic communicated through EM may be addressed to various recipients, i.e. doctors of various specialities, pharmacists, or other healthcare professionals, as appropriate, and may pertain to more than one safety problem.

The content may, for instance, include recommendations relevant to dosage, contraindications, managing critical situations and adverse reactions, measures relevant for specific patient groups, description of treatment, including specifications regarding the method of use, medicinal product posology, and patient additional monitoring, or important information that the doctor has to communicate to the patient before, during, or after treatment.

Messages contained in the EM should be clear, brief, as apt as possible, and not exceeding the basic scope of the topic. The purpose of the EM must not be distorted by the addition of other, redundant information which already forms part of the SmPC.

The EM should not be a duplicate of the currently effective SmPC. They must always include an invitation to study the SmPC, which should be ideally worded as follows:

> *<Aktuálně platný SmPC lze vyhledat na webových stránkách Státního ústavu pro kontrolu léčiv v sekci Databáze léků na adrese http://www.sukl.cz/modules/medication/search.php.>*
>
> *<The currently effective SmPC is available from the website of the State Institute for Drug Control under the Medicines database section at http://www.sukl.cz/modules/medication/search.php.>*

The inclusion of this recommendation cannot be considered a fulfilment of the MA holder´s obligation to distribute the SmPC to doctors, where such condition has been stipulated by the marketing authorisation.

To distinguish the EM from a number of other printed matter and promotional brochures, as a standard, the cover page of the EM has to show the words <Educational materials> in the left upper corner, in a clearly visible format in red colour. The font size of these words has to be significantly bigger than the font size of the other text. These words have to be clearly and visibly distinguished from other texts, titles and other graphic elements. Where the EM are to be distributed in a form other than written text, it is necessary to place this indication on the label of the relevant media in a suitable manner.
This indication must be also shown on the envelope or packaging in which the EM is distributed.

This indication may be used solely for EM the form, content, and method of distribution of which have been approved by SÚKL.

Furthermore, the active substance/active substance combination to which the communication pertains, or the name of the medicinal product, if appropriate, must be specified. Below the name of the medicinal product, the EM title shall be provided, which shall effectively represent the content thereof.

A description of the method of adverse drug reaction reporting must form part of any EM, ideally worded as follows:

> *<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, odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.>*
>
> *<Any suspected serious or unexpected adverse reaction and other facts relevant for the health of patients must be reported to the State Institute for Drug Control.*
>
> *For reporting details, please refer to: http://www.sukl.cz/nahlasit-nezadouci-ucinek.*
> *The mailing address is: Státní ústav pro kontrolu léčiv, odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.>*

This method of reporting to SÚKL must be always provided prior to other reporting methods, such as an invitation to report to the MA holder:

> *<Tato informace může být také hlášena společnosti....>*
> *<This information may be also reported to (company)....>*

In case EM concerning a medicinal product under additional monitoring are distributed to healthcare professionals, this fact shall be distinctly shown on the title page, in the following manner:

> *<▼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 under additional monitoring. This will facilitate rapid collection of new safety information. Healthcare professionals are kindly asked to report any suspected adverse reactions.>*

One side of the printed black triangle must be 0.5 cm.

Where the EM concern a biological product, the following shall be also included:

a) Warning of the need to report the batch identification number and the trade name of the product in case an adverse reaction is reported, ideally worded as follows:

   <Je třeba doplnit i přesný obchodní název a číslo šarže. Tato informace může být také hlášena společnosti....>

   <It is necessary to provide also the exact trade name and batch number. This information may be also reported to (company)....>

b) Warning that the name of the medicinal product and batch number must be clearly noted in the patient´s documentation.

Where SÚKL does not require joint EM for an active substance, where the name(s) of medicinal products are not specified, then the EM developed for generic products must be, in terms of their purpose, content, form as well as graphic representation, as similar to the EM for the original product as practicable.

Each version of the EM should be appropriately identified in the bottom part of the title and last page of the EM,

i.e. version number and date of approval by SÚKL, ideally in the following format:

<*Verze: xx*>
<*Schváleno SÚKL: xx/20xx*>
<*Version: xx*>
<*Approved by SÚKL: xx/20xx*>

EM must not contain:

- any direct or indirect elements of advertising nature (including logos, colour combinations associated with a logo or product, etc.);
- photos or images not directly associated with the safe use of the product (images are allowed only if illustrating the content of the material, such as possible injection application sites, etc.);
- graphs and tables which are not directly associated with the safe use of the product;
- content not closely related to the intended message;
- title or name of the product on the title page in red font;
- references to any literature not directly associated with the content of the EM.

It is advisable to consult doctors of the respective speciality and professional societies when developing EM.

EM for healthcare professionals with professional and specialised qualification required for the performance of the medical profession of a doctor, dentist and pharmacist may, in exceptional cases, be approved solely in the English language. This shall be always assessed and approved by SÚKL with a view to the specific circumstances of the case in question.
EM for healthcare professionals defined by Act No 96/2004 Coll. on Non-Medical Healthcare Professions, should always be drafted in the Czech language.

3. Content of educational materials for patients

The reason for developing and distributing EM for patients is to communicate important safety information in order to increase the patient and patient carer awareness of these facts, and thus ensure the safe use of medicinal products, protection of the health of the patient and other persons coming into direct contact with the product, and to minimise risks.
The EM form must be adequate to the intended message.
When drafting the EM, it is always necessary to rely on the currently effective version of the PIL. EM may address several important safety concerns.

The message of EM for patients should be clear, brief, and as apt as possible, and their content should not exceed the basic scope of the topic and purpose of the EM and must not be confounded by additional, indirect information already contained in the PIL.
The language used must be comprehensible for lay persons and the use of specialised terms and foreign words must be reduced to a minimum in order to convey as straightforward a message as possible.
Any messages should be worded appropriately with a view to possible sensitive information and their impact upon the patient (e.g. further disease progression, pregnancy, adverse reactions, etc.).

The content may, for example, include recommendations pertaining to the administration of the medicinal product (dosage, quantity, application site, etc.), contraindications, adverse drug reactions, early recognition of (potentially) arising adverse reactions, and a description of recommended procedure to resolve these situations, including a clear recommendation on the situation under which it is necessary to immediately seek urgent medical assistance. Furthermore, the EM should contain important information to be discussed with the doctor before, during or after completion of the treatment.

If appropriate, a diary for posology or diary of other scheduled check-ups with the doctor or other diagnostic procedures could form an appropriate and important part of the patient's educational materials to ensure and

emphasise the necessary cooperation on the part of the patient throughout the entire therapeutic process.

EM should not be a duplicate of the currently effective PIL. They shall always include an invitation to study the PIL and emphasise the necessity to consult the treating doctor or pharmacists in case of any doubt or concerns regarding treatment.

It is advisable to include the following text:

<*Tento přehled nežádoucích účinků není úplný a je třeba se seznámit i s možnými dalšími nežádoucími účinky, jejichž výčet naleznete v Příbalové Informaci pro pacienta. Příbalová informace pro pacienta (PIL) je distribuována v každém balení léčivého přípravku a lze jí také vyhledat na http://www.olecich.cz po zadání názvu léčivého přípravku pod zkratkou PIL.*>

<*This overview of adverse drug reactions is not complete and it is necessary to familiarise yourselves with other potential adverse reactions the list of which is available from the Patient Information Leaflet. The Patient Information Leaflet (PIL) is distributed in each package of the medicinal product and it may be also found at http://www.olecich.cz under the abbreviation PIL if you enter the name of the medicinal product.*>

The inclusion of this recommendation cannot be considered a fulfilment of the MA holder´s obligation to distribute the PIL to patients, where such condition has been stipulated by the marketing authorisation. In such a case the distributed EM shall include also the adequate number of copies of the currently effective PIL.

A description of the method of adverse drug reaction reporting shall form an integral part of any EM and shall be ideally worded as follows:

<*Pokud se u Vás vyskytne kterýkoli z nežádoucích účinků, sdělte to svému lékaři nebo lékárníkovi. Stejně postupujte i v případě jakýchkoli nežádoucích účinků, které nejsou uvedeny v příbalové informaci. Nežádoucí účinky můžete hlásit také přímo prostřednictvím národního systému hlášení nežádoucích účinků.*
Podrobnosti o hlášení najdete na: http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek.
Adresa pro zasílání je Státní ústav pro kontrolu léčiv, odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.>

<*Should you experience any of the adverse reactions, please tell your doctor or pharmacist, and do so also in case of any adverse reactions that are not described in the Patient Information Leaflet. You can also report adverse reactions directly, via the national adverse drug reaction reporting system.*
For details regarding reporting, please refer to: http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek.
The mailing address is: Státní ústav pro kontrolu léčiv, odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.>

This method of reporting to SÚKL must be always specified prior to other reporting methods, such as a request to report to the MA holder:

<*Tato informace může být také hlášena společnosti....*>
<*This information may be also reported to (company)....*>

In case EM on medicinal products under additional monitoring are distributed to patients, this fact shall be stated on the title page, in a distinct manner and worded as follows:

<▼*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 product is under additional monitoring. This will facilitate rapid collection of new safety information. You can contribute by reporting any adverse reactions that you experience.* >

One side of the printed black triangle must measure 0.5 cm.

Where the report concerns a biological product, the following warning on the necessity to report also the batch identification number shall be also included, ideally worded as follows:

<*Je třeba doplnit i přesný obchodní název a číslo šarže. Nahlášením nežádoucích účinků můžete přispět*

k získání více informací o bezpečnosti tohoto přípravku.>

<*It is necessary to provide also the exact trade name and batch number. By reporting adverse drug reactions you can contribute to the collection of further information on the safety of this product.*>

Each EM version should be identified as appropriate in the bottom part of the title and last page of the EM, i.e. version number and date of approval by SÚKL, ideally in the following format:

<*Verze: xx*>
<*Schváleno SÚKL: xx/20xx*>

<*Version: xx*>
<*Approved by SÚKL: xx/20xx*>

4. Patient Alert Card

The reason to develop and distribute Patient Alert Cards is to inform the doctor and other healthcare professionals about the medicinal products taken by the patient, the procedure(s) completed by the patient in association with the use of the medicinal products, and situations that could imply safety risks (e.g. potential interactions, teratogenic nature of the active substance, an increased risk of adverse reaction incidence, etc.).

The content of the communication must include:

- the necessity to carry the Patient Alert Card with oneself at all times and to present it on any visit to a doctor or a therapeutic or diagnostic procedure;
- key information regarding diagnosis and treatment that could affect any urgent as well as non-urgent medical decisions;
- contact details of the patient or their carer, if appropriate;
- contact details of the treating doctor or workplace where the patient is treated.

Where no other materials for patients have been created, the content of the Patient Alert Card shall also include a description of the adverse reaction reporting method (an abbreviated version may be used), an invitation to study the SmPC or PIL, according to the purpose of the card in question, and the symbol of inverted black triangle together with the declaration of additional monitoring, if relevant for the concerned medicinal product.

The size and quality of material of the Patient Alert Card must be adequate to ensure that the Card may be easily carried by the patient (e.g. in a purse) in the long run.

5. Submission of educational materials for approval

Proposed EM shall be sent by e-mail to the following address: farmakovigilance@sukl.cz.

The content of the e-mail with the proposed EM must include:

- the reason why the EM have been developed, including legislative source materials (decision of CHMP, CMDh, EU referral, change to SmPC, etc.) together with documents evidencing such change;
- the English original of the proposed EM (if it exists);
- the proposed EM in the Word format so as to be able to insert comments in the form of mark-ups;
- the text of the presentation in the Word format, if the EM assume the form of a presentation (e.g. PowerPoint);
- anticipated EM distribution date;
- draft Distribution Plan which shall specify the method of distribution, time schedule, distribution target groups, and the number of relevant healthcare professionals to whom the EM are to be distributed (for specimen Distribution Plan, please refer to the annex hereto).
    - Using a separate dated document called “Distribution Plan”, the applicant shall describe the proposed method, date, and scope of distribution (individual medical specialties, method of initial distribution, repeated Distribution Plan (timelines and method of redistribution, means of

identifying further need for EM, etc.).

- SÚKL may also request the distribution list of individual workplaces where distribution is to be carried out, including other additional details (such as the number of copies per workplace, number of doctors to whom EM is to be delivered, etc.). In compliance with the GDPR, SÚKL does not require itemised lists with the names of doctors or other healthcare professionals.

Before sending the e-mail with the proposed EM it is necessary to check whether the recommendations contained in the materials are applicable to the Czech medical practice.

The proposed EM should be provided to SÚKL for approval at least 2 months prior to the planned placement of the medicinal product onto the market or prior to the sending of updated EM for marketed medicinal products, unless stipulated otherwise (e.g. another time schedule). If it is necessary to prepare and distribute new EM for marketed medicinal products, their submission for approval shall be governed by the approved scheme of SÚKL or EMA on the basis of whose decision the obligation to develop and distribute EM has arisen.

Submission for approval is required also for the Patient Alert Card distributed in medicinal product packages whose Czech text has already been approved as part of the marketing authorisation procedure (this applies particularly to medicinal products authorised via centralised procedure), where, however, the format, appearance and possible distribution method are still subject to approval by SÚKL. Following assessment, SÚKL may request secondary distribution method of the Patient Alert Card via doctors, particularly in those cases where the patient does not come into direct contact with the medicinal product packaging (e.g. in case of medicinal products administered by infusion), and hence it is not adequately ensured that the patient will indeed get the Patient Alert Card.

For the purposes of a cover letter which is to be attached by the MA holder to the shipment or which is the subject of e-mail communication with the doctor or another healthcare professional, SÚKL has developed a template which forms an annex hereto and which may be used by the MA holder at their discretion. The purpose of the cover letter is the description of reasons why the EM has been developed and what its objectives are.

SÚKL considers the information contained in the EM public data intended to minimise risks which are not subject to the MA holder´s copyright. For this reason, the MA holder is advised not to include any data considered thereby to be copyright-protected or their business secret to the EM.

SÚKL requires that the materials be submitted for approval also in case where the MA holder is aware that the medicinal product may be reimbursed as per Section 16 of Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, or in those cases where the MA holder, in compliance with Section 3, paragraph 6(b) of Decree No 228/2008 Coll., on Marketing Authorisation of Medicinal Products, as amended, applies for the placement of individual batches of a medicinal product the labelling of which is not in the Czech language (so called foreign-language batch) onto the market.

6. Approval of educational materials

With a view to the submitted source materials, SÚKL shall, within a reasonable timeline, provide its opinion on the content and methods of distribution for the EM. SÚKL is not responsible for the linguistic quality and up-to-datedness of the materials. Once the content is approved, the MA holder shall send the proposed graphical representation of the materials in the PDF format. The final form of the EM is subject to agreement between the MA holder and SÚKL´s Pharmacovigilance Department.

Following EM approval, the MA holder shall send the approved final version, in its final graphical form, in the PDF format together with the exact date of distribution and approved Distribution Plan. Should the MA holder identify grammatical errors, they may correct them without having to have these corrections further approved.

7. Distribution of educational materials targeting healthcare professionals

Distribution must always include all doctors who could in practice prescribe the medicinal product in question, as set forth by the conditions and obligations associated with the marketing authorisation of the medicinal product. In justified cases, this concerns also doctors who could prescribe or use the medicinal product beyond the scope of

approved indications (so called off-label use).
Distribution must not be limited by the MA holder solely to doctors or other healthcare professionals among whom the product is actively promoted or who are visited by specialised company representatives.
In case of distribution of some EM, it is necessary to include also the concerned pharmacies, such as hospital pharmacies or pharmacies with specialised workplaces, among the distribution groups.

Any educational program must be completely separated from promotional activities.

Primary distribution method in terms of fulfilment of obligations set forth by the marketing authorisation of the medicinal product in question

The primary (i.e. main) distribution method must be proposed in the Distribution Plan and approved by SÚKL. The primary distribution of EM for healthcare professionals must ensure targeted outreach to the concerned healthcare professionals and must be carried out directly, i.e. via post, electronic communication, or specialised representatives. A specialised representative shall mean a person who acts as an agent of the pharmaceutical company of the MA holder, is adequately qualified, and will provide the target expert with any information as necessary.
SÚKL considers EM to be materials of non-advertising nature, hence obviously not serving for the purposes of promoting the prescribing, deliveries, sale, dispensing or consumption of human medicinal products. Their purpose is, in particular, to notify of, alert of, and provide information regarding warnings associated with human medicinal product safety concerns.
Distribution of EM by the MA holder´s specialised representatives shall not be considered advertising. Its separation from promotional activities must be preconditioned by the fact that upon EM hand-over by the company´s specialised representative, a clear and straightforward statement is made to the effect that these are materials intended solely to safeguard risk minimisation measures.
EM cannot be handed over together with advertising materials. EM hand-over must be clearly separated in time as well as verbally so as to convey the clearly different purpose of the EM from that of advertising materials.
It must be clearly stated that the meeting does not concern promotional purposes as referred to under the Act on Advertising Regulation.

Distribution of EM may be outsourced with specialised agencies preparing or organising the distribution proper via post or e-mail which is contracted to ensure the provision of EM directly to the hands of the concerned healthcare professional. The MA holder must, thereafter, receive an assessment (process indicators) of distribution effectiveness from the company, which shall be archived by the former for the purposes of e.g. audits or pharmacovigilance inspections. Distribution, however, cannot be carried out via another agent (e.g. a distributor of pharmaceuticals).

Secondary distribution method (web platforms, mobile applications, videos)

In addition to the primary distribution method, other distribution channels may be also made use of as so called secondary distribution method in order to provide complex information about the medicinal product to healthcare professionals. Not always do the secondary distribution methods have to be approved by SÚKL. Nevertheless, the websites/web platforms or mobile applications may not be labelled as approved by SÚKL. The indication of approval may be shown solely on the EM or those secondary distribution methods which were specifically approved by SÚKL.

For the purposes of approval of secondary distribution methods, SÚKL requires, in particular, the following:

- specially created websites which are not linked to the websites of the MA holder and which do not contain any link or click-through to the MA holder´s website;
- for access to the content of the EM it is not possible to request that, in addition to the declaration of whether the user is or is not a healthcare professional, the user should log in and/or enter any other identification data;
- possibility to download the EM in a common no-editable format (such as PDF);
- it is not possible to prohibit making of copies and sharing of the EM from this website;
- a short and easy-to-remember website address;
- absence of any advertising elements.

SÚKL is not responsible for the business terms and conditions of such websites and its approval of the content of

the website does not imply that it agrees with the text and content of the business terms and conditions provided by the MA holder on such websites.

If the MA holder is the owner of websites which are not only educational in nature, SÚKL shall not prevent the publication of approved EM on these websites (with the possibility to download the EM in a non-editable format, such as PDF). This concerns a secondary distribution method which, however, is not approved by SÚKL, and hence should not form part of the Distribution Plan.

SÚKL encourages any activities of the MA holder aimed at obtaining information about the effectiveness of the educational program on the basis of data obtained from these very websites. This purpose and intension, however, has to be clearly stated on the websites.

The hand-over of EM to healthcare professionals at professional events (e.g. medical congresses) is also permissible as a secondary distribution method, if carried out in order to provide complex information about the medicinal product outside the scope of promotional activities. Such events, however, must not be events associated with the placement of a new medicinal product on the market (so called launch symposia).

Making use of various digital channels, such as websites, social media, specialised web interfaces or mobile applications for the distribution of EM is permissible provided the aforementioned conditions are met. The recipient of the EM must be clearly specified (patient/healthcare professional) and the non-promotional nature of EM provision ensured. Furthermore, the provided information must be up-to-date so as to avoid any confusion on the part of healthcare professionals as well as the general public. If the MA holder publishes EM, they shall be obliged to arrange for the publication of updated versions, no later than within one month of the approval of the change by SÚKL.

SÚKL recommends to avail also of other EM distribution routes, such as publication on the websites of professional associations.

8. Distribution of educational materials for patients

The distribution of EM for patients shall be carried out by the MA holder indirectly via healthcare professionals, e.g. a doctor will hand the EM or Patient Alert Card over to each patient whom he/she begins to treat with the particular product.
SÚKL recommends to avail also of other distribution routes, such as publication on the websites of patient organisations.

The MA holder should inform the doctor about possible ways of re/ordering EM for patients, e.g. via specialised representatives, in writing or by phone from the MA holder´s non-promotional unit (medical or pharmacovigilance department).

9. Active ways to establish the need for educational materials and redistribution

The MA holder must, particularly with a view to their own data on the consumption of the concerned medicinal product, estimate the adequate need for each doctor and their future need, in particular with regard to the EM for patients, and must continue to actively assess this need, either via their specialised representatives or by directly asking the doctors (by phone, e-mail). Doctors must not be required to print the EM for patients and other target groups themselves. It is not possible to transfer the entire responsibility for notification of the need for additional EM to the doctors, either. Such responsibility may be taken over by a doctor only after a signature of a written contract with the MA holder.

A specialised representative’s question on the need to provide more EM for doctors and their patients is not considered an act of promotion. Alternatively, mass distribution repeated in adequate time intervals and scheduled in advance may be employed. Such repeated mass distribution must form part of an approved Distribution Plan.

10. Joint development and distribution of educational materials

Holders of marketing authorisations of medicinal products containing the same active substance/combination of active substances should cooperate in the development and distribution of joint EM, i.e. to create EM of uniform content, graphic layout, format, without company logos, and stating only the active substance/combination of active substances.

In case there are several MA holders who have medicinal products with the same active substance and who have identical or very similar obligations regarding EM development and distribution or any other measures to minimise risks (in particular, but not limited to medicinal products legally based on Art. 10(1), 10(3), and 10(4) of Directive 2001/83/EC), SÚKL usually requires all of these MA holders to develop and distribute joint EM.

Joint EM development

These EM shall be developed for a particular active substance/combination of active substances without giving the names of individual medicinal products. There may be a space reserved for the entry of the name of the medicinal product upon hand-over to the patient or his/her carer within the EM; this concerns primarily Patient Alert Cards. The method of providing the names of medicinal products depends on the specific situation and is subject to agreement with SÚKL.

The following courses of action may be applied:

1) Educational materials for the original medicinal product have already been approved in compliance with this Guideline.

- The previously approved text shall be used and amendments in terms of deleting the name of the original medicinal product and its replacement with the name of the active substance/combination of active substances shall be made.
- The title of the EM shall be amended so as to clearly reflect that they are applicable to all medicinal products with the same indication(s) containing the same active substance/combination of active substances.
- SÚKL shall inform the representative of the original medicinal product on the receipt of application for EM approval for a product with the same active substance/combination of active substances and on the decision regarding joint EM development.
- SÚKL shall ensure the sharing of contact information among the concerned MA holders.
- Where there are several MA holders entering the market, their representatives shall appoint a contact person for further communication with SÚKL from amongst themselves. Such contact person shall thereafter represent all of the parties involved, including the representative of the original medicinal product(s), unless he/she is the contact person.
- The appointed contact person shall get the approved EM from SÚKL´s website. In case of problems with editing in the PDF format, the contact person may request these EM from the MA holder of the original medicinal product. SÚKL suggests that the MA holder of the original medicinal product provide the materials without unnecessary delay.
- If necessary and having regard to the up-to-datedness of the previously approved EM, SÚKL may request further text and format amendments thereof.

2) There are no approved EM for the original product or generic products, or there are several approved educational materials

- SÚKL shall inform the representatives of MA holders of the necessity to develop joint EM.
- SÚKL shall ensure the sharing of contact information among the concerned MA holders.
- The representatives of MA holders shall appoint a contact person for further communication with SÚKL from amongst themselves. Such contact person shall thereafter represent all of the parties involved, including the representative of the original medicinal product(s), unless he/she is the contact person.
- The representatives of MA holders shall draft a joint EM proposal which shall be submitted by the contact person to SÚKL for assessment.
- SÚKL shall provide its opinion on the submitted joint EM proposal.
- On the basis of this opinion, the representatives shall then prepare the final joint EM proposal which shall be submitted by the contact person to SÚKL for approval.

The following course of action is usually common for both categories:

Typically, the text shall not give the names of individual medicinal products or MA holders´ contact addresses. This ensures that in case another medicinal product is placed onto the market or any of the products is no longer distributed, it will not be necessary to update and redistribute the EM.

Instead, the EM shall encourage healthcare professionals to study the SmPC and find the MA holder´s contact data in the SmPC of the respective medicinal product, ideally by including the following text:

> *<Aktuálně platný SmPC lze vyhledat na webových stránkách Státního ústavu pro kontrolu léčiv v sekci Databáze léků na adrese http://www.sukl.cz/modules/medication/search.php. Kontaktní údaje jednotlivých držitelů rozhodnutí o registraci léčivých přípravků obsahujících (vložit název účinné látky/látek) lze nalézt v části Kontakty, která se objeví po kliknutí na název léčivého přípravku.>*

> *<The currently effective SmPC may be obtained from the website of the State Institute for Drug Control under the database of medicinal products section at http://www.sukl.cz/modules/medication/search.php. Contact data of individual holders of marketing authorisations of medicinal products containing (enter the name of the active substance(s)) are available from the Contacts sections, which will come up if you click on the name of the medicinal product.>*

The procedure for PIL retrieval and an invitation to study the PIL for patients or their carers shall be handled likewise, ideally using the method outlined under chapter 3 (Content of educational materials for patients).

In case only some of these medicinal products are under additional monitoring, the declaration thereof shall be modified as follows:

For healthcare professionals:

<Některé z léčivých přípravků obsahujících (název účinné látky/látek) podléhají následnému sledování, což je vyznačeno přítomností symbolu obráceného černého trojúhelníku na balení a textech doprovázejících léčivý přípravek následujícím způsobem: ▼ Tento léčivý přípravek podléhá dalšímu sledování. To umožní rychlé získání nových informací o bezpečnosti.

Žádáme zdravotnické pracovníky, aby hlásili jakákoli podezření na nežádoucí účinky.>

<Some of the medicinal products containing (name of the active substance/s) are under additional monitoring, which is indicated by the symbol of a black inverted triangle on the packaging and in the texts accompanying the medicinal product as follows: ▼ This medicinal product is under additional monitoring. This will allow for rapid collection of new safety information.

Healthcare professionals are kindly asked to reports any suspected adverse reactions.>

For patients:

<Některé z léčivých přípravků obsahujících (název účinné látky/látek) podléhají následnému sledování, což je vyznačeno přítomností symbolu obráceného černého trojúhelníku na balení a textech doprovázejících léčivý přípravek následujícím způsobem: ▼ 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.>

<Some of the medicinal products containing (name of the active substance/s) are under additional monitoring, which is indicated by the symbol of a black inverted triangle on the packaging and in the texts accompanying the medicinal product as follows: ▼ This medicinal product is under additional monitoring. This will allow for rapid collection of new safety information. You may contribute by reporting any adverse reactions that you experience.>

Joint EM distribution

The distribution of new, i.e. joint EM shall be organised by all of the parties involved. MA holders are advised to

submit a joint Distribution Plan referred to under chapter 5 (Submission of educational materials for approval). SÚKL shall not be involved in negotiations on how the costs of the development and distribution of joint EM will be shared.

The provision of additional joint EM as needed shall then be safeguarded by each MA holder individually as per the approved method further detailed in the Distribution Plan.

Should the parties involved fail to achieve consensus, SÚKL shall announce the date and venue of a joint meeting via its website or e-mail, at least 14 days in advance. The results of the joint meeting regarding the content and appearance of joint EM shall then be required by SÚKL for all holders of marketing authorisations of the concerned medicinal products. It is in the interest of the MA holders to arrange for their representatives to attend the meeting. Failure of any of the MA holders' representatives to attend the meeting shall not constitute grounds for postponing the meeting or for non-applicability of its conclusions.

Following the EM approval, such EM shall be considered the only ones effective within the territory of the Czech Republic for all of the concerned medicinal products. This will automatically result in the revocation of previously approved EM and these EM shall not be allowed to be further distributed.

3) In case of placement of another medicinal product onto the market which is subjected to the same obligation implied by its marketing authorisation, and existence of joint EM, the joint approved EM shall be applied in the following manner:

- The MA holder shall submit the information on planned placement onto the market (at least 2 months in advance) together with the current version of the approved joint EM published on SÚKL´s website, or shall provide the exact wording of their title, version number, if applicable, and the date of their publication.
- The holder shall submit the proposal of their own Distribution Plan or the joint Distribution Plan will be shared therewith, if applicable (e.g. containing timelines for scheduled repeated mass distribution).
- SÚKL shall thereafter provide its opinion on the proposed distribution method. In most cases of this type, the course of action consisting solely of the provision of further joint EM by specialised representatives whenever necessary shall be recommended. Nevertheless, in justifiable cases only, SÚKL may require mass distribution based on the conditions set forth by the marketing authorisation.

11. Change of content or termination of distribution of educational materials

With a view to assessment of the EM effectiveness, the MA holder may arrive at a conclusion that, according to their analysis, the information conveyed has been sufficiently incorporated in the current medical practice within the territory of the Czech Republic and that its further communication to doctors is no longer needed. With a view to this finding, the MA holder may ask SÚKL for EM content reduction or termination of EM distribution within the territory of the Czech Republic. In case of medicinal products authorised solely via the national procedure, it is necessary to request that this obligation be lifted within the scope of submission of application for variation to marketing authorisation and submission of a RMP update. Where medicinal products authorised via MRP/DCP or centrally authorised medicinal products are concerned, SÚKL may authorise limited or suspended distribution solely within the territory of the Czech Republic.

The application must be appropriately justified by the MA holder, providing the opinion of clinical experts from the field in question, or members of professional associations stating that the information has already been implemented in current medical recommendations (particularly the Czech Medical Association of Jan Evangelista Purkyně) or in textbooks. Furthermore, it is necessary to present evidence that doctors are aware of these facts and routinely adhere to these procedures (e.g. internal recommended therapeutic procedures at individual workplaces, absence of adverse drug reaction reports, evidence in reports and articles), or results of post-authorisation safety studies of EM effectiveness.

The application (except for the application for RMP variation requesting the lifting of the obligation to develop and distribute EM), together with any documentation, shall be submitted to the following address: farmakovigilance@sukl.cz. The subject of the e-mail message shall clearly state that this is an application for limited EM distribution and the name of the concerned medicinal product.

It is advisable to discuss possible conditions and requirements on the part of SÚKL prior to the submission of the application. Applications for RMP variation requesting the lifting of the obligation to develop and distribute EM, together with any documentation, shall be submitted to the following address: posta@sukl.cz.

With regard to the obligation to assess the effectiveness, established by GVP, SÚKL may require that upon each update of EM for doctors carried out more than 5 years of the first distribution of the EM, the MA holder submit effectiveness evaluation and justify further need therefor in respect of each key element separately, taking into account particularly the following facts:

- the quantity and severity of adverse drug reaction reports relevant for the given risk within the territory of the Czech Republic;
- incorporation into clinical guidelines and recommended medical procedures applied within the territory of the Czech Republic;
- incorporation into approved procedures in specialised hospital centres (centres of biological treatment, transplantation centres, oncological centres, etc.);
- written opinion of experts from the field in questions on the up-to-datedness of the EM text;
- results of studies focused upon the assessment of EM effectiveness conducted within the territory of the EU with a special emphasis upon results (if available) from the Czech Republic.

In case that as a result of a variation to marketing authorisation (MRP/DCP + CAP), the obligation to implement further risk minimisation measures has been lifted, it is necessary to advise SÚKL´s Pharmacovigilance Department to this effect (farmakovigilance@sukl.cz) no later than within 1 month of approval of the variation to marketing authorisation. The same advice has to be made in case of planned termination of medicinal product marketing in the Czech Republic or its outage, as much in advance as practicable (at least 1 month).

In case the obligation to implement further risk minimisation measures is lifted or significantly changed in respect of centrally authorised medicinal products, such measure shall be applied to any other medicinal products with identical EM (identical active substance/combination of active substances, identical or similar risks), unless SÚKL requests otherwise. The concerned MA holders shall be advised to this effect by e-mail sent to the contact addresses of qualified persons for pharmacovigilance provided to SÚKL by the MA holder.