**Instructions to applicants**

**Submission of educational materials**

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I - Conditions for submission of Educational Materials

All educational materials for medicinal products for human use intended for implementation in Portugal must be previously agreed with INFARMED, I.P.

The Marketing Authorisation Holder (MAH) or its Representative must submit its **first proposal of educational material(s)** to Infarmed for assessment prior to the availability of the medicinal product and regardless of the reimbursement status.

The MAH/Representative must also submit to Infarmed an **updated version of the educational material(s)** for assessment every time that:

- important changes to the risk and/or the need for new risk minimisation measures are identified;

- changes in the key messages and/or the content of the educational material(s) are agreed at the European Union (EU) level and/or by national competent authorities;

- there are changes in relevant contact information, including for reporting of adverse reactions.

The proposal should only be submitted after the conclusion of the procedure in which these measures are agreed – such as the publication of the European Commission (EC) Decision (in case of new marketing authorisations (MA)), the notification of approval of a variation to the MA (e.g., CHMP positive opinion), the approval of the Risk Management Plan (RMP), whether initial or updated, or within the scope of a referral – as the request will only be validated afterwards.

**Note:**

- The educational materials “Patient cards” that are included in the packaging are excluded from the scope of these “Instructions to applicants”, as they were already assessed within the context of the respective procedures for review/approval of the medicinal product information (Summary of Product Characteristics (SmPC), Patient leaflet (PL), labelling).

- In the case of parallel distribution of medicinal products, and in accordance with the available guidance on the EMA website, (<https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/parallel-distribution>), the parallel distributor is required to liaise with the MAH and Infarmed to discuss the requirements applicable to the educational materials that must be met before distributing the medicinal products.

II – Establishment of consortium

In cases where the educational materials concern medicinal products with the same active substance(s) from several MAHs, it is strongly recommended that a single consistent message be sent to healthcare professionals and/or patients/users/individuals. The MAHs are encouraged to collaborate to prepare and disseminate joint educational materials in Portugal, covering all applicable active substance(s)-containing medicinal products.

Upon becoming aware of the need to implement educational materials, the MAHs/Representatives of the involved medicinal products should establish a consortium in a timely manner and submit a joint proposal to Infarmed, via the email at [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt).

In cases where the prior establishment of a consortium is not feasible, the MAHs/Representatives of the involved medicinal products should contact Infarmed by email [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt), expressing their willingness to join a consortium and allowing the sharing of their contact information with other MAHs/Representatives.

Infarmed will then share the contacts with all MAHs/Representatives, requesting the appointment of a main contact point for the consortium and the submission of a single proposal for the educational materials and implementation plan.

It is recommended that the MAH of the reference medicinal product act as the contact point. If not possible, another MAH/Representative should take the lead, ideally the one with the largest market share in Portugal.

**Note**: The establishment of a consortium is always the preferred option. Even if such a consortium was not feasible in the 1st version of the educational materials, it may be formed at a later stage of the review process. The inclusion of a new MAH in an existing consortium is also possible, as long as there is previous agreement among the relevant MAHs.

III – Application instructions

The request shall be addressed to the Directorate of Risk Management for Medicines (Direção de Gestão do Risco de Medicamentos – DGRM), via email at [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt), according to the following instructions:

III. a) Information to be provided in the email

* + Information on the MAH/Representative or the main contact point and other MAHs of the consortium, including contact point’s name and email;
  + In the case of a consortium, confirmation from each MAH/Representative delegating responsibility to the MAH/Representative acting as the main contact point for the consortium (email sent to [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt) following the initial submission of the joint proposal);
  + Framing of the request (e.g.: EC Decision, approved RMP, assessment report identifying the need for these measures);
  + Detailed description of the implementation plan for the educational materials in Portugal, including:

- **Target population(s)** (for medical doctors, specialties should be stated);

- **Dissemination method** (e.g. paper, email, meeting/training, in hand, during a medical appointment, or when dispensing the medicinal product in the pharmacy, etc.);

- **Date** when dissemination is anticipated to start and **frequency of further disseminations**.

**Note**: In the case of a newly authorised medicinal product, distribution should occur before it is made available to patients, regardless of the method of availability and reimbursement status.

III. b) Annexes to be provided in the email

* A copy of the approved RMP, Annex IID of the EC Decision, and/or any other document that supports the implementation of the proposed educational materials, as along with the product information in Portuguese (SmPC/PL). In the case of reviewing existing educational materials or introducing new educational material due to an updated RMP, the respective supporting documents **should have the changes highlighted (track changes mode)**.
* Working documents (Word version) containing the proposed texts in Portuguese (in very exceptional cases, duly justified and with the agreement of Infarmed, another language may be allowed, e.g., for complex materials intended for a restricted and highly specialized group of healthcare professionals, or in case of urgency in distribution prior to the start of any modality of availability of a medicinal product with an already granted MA). In the case of an update of the educational materials, the working documents **must have the changes highlighted (track changes mode)**.
* Proposed graphic versions (PDF, PowerPoint, video, website layout, etc.) reflecting the intended final layout, which will be properly adapted once agreed upon with Infarmed. These versions may not be available in Portuguese, as their purpose is to assess the graphic layout and ensure that there is no advertising content.
* Power of attorney whenever the applicant is different from the MAH.

**Notes:**

- The files cannot exceed 600 MB

- Allowed formats are:

- Office documents (Excel, Word, PowerPoint);

- Adobe Acrobat documents (PDF);

- Images (JPEG, PNG, GIF);

- Videos (MKV, FLV, AVI, MOV, QT, WMV, MP4, MPG, MPPEG, M2V, M4V e OGG)

- If the size of the files exceeds the allowed size for email, the proposal should be submitted via a secure online platform (e.g., Eudralink).

IV – Assessment criteria related to the format and content of Educational Materials

The main reference documents to be used in the preparation of educational materials are the RMP (specifically Part V and Annex 6), the SmPC/PL, Annex IID for centrally authorised medicinal products or Annex IV for nationally, mutual recognition or decentralized authorised medicinal products included in a referral or Periodic Safety Update Report (PSUR) single assessment procedure. Additionally, the principles described in GVP XVI must also be considered.

The educational material(s) should have an appropriate content and layout.

On the 1st page:

* Invented name of the medicinal product followed by the active substance in parentheses; in cases where the educational materials are common to medicinal products from several MAHs, it may be necessary to agree with Infarmed on a simplification, also taking into account the size of the material itself. In any case, the name of the medicinal product should not be larger than the title of the document.
* If the medicinal product is under additional monitoring, the corresponding symbol (black inverted triangle) must be included next to the invented name or active substance, along with the explanatory sentence (which may be abbreviated to “This medicinal product is subject to additional monitoring.” - please see GVP Module X).
* If the educational materials do not apply to all indications or presentations of the medicinal product, information regarding the indication, pharmaceutical form, strength, route of administration or other differentiating element must be included.
* The document’s title should be concise, clearly identifying its purpose and the target population (e.g., checklist for prescribers, patient card, guide for the patient/caregiver, guide for prescribers, guide for pharmacists, etc.).
* Logos of the MAH and medicinal product should be avoided; if really needed (properly justified), they must not contain advertising/promotional content and should appear only once in each proposed document (either on the first or the last page). Note that if included on the first page, the logo should not be larger than the document’s title. In this case, if medicinal product´s logo already includes the name of the medicinal product and the name of the active substance in portuguese, there is no need to duplicate these references on the first page.
* The version number agreed with Infarmed and the date (e.g.: Versão X, mm\_yyyy) should be placed at the bottom of each sheet of the educational material (if the type of educational material does not allow this, e.g., a video or audio, this information should appear at the beginning and/or end).

On the remaining pages:

* Educational materials should be as concise as possible to facilitate reading/use; if the educational material is extensive (e.g., addressing several risks), an introductory summary of the key messages should be added, and an index may be included.
* A statement should be included explaining that the educational materials fulfil a condition for the safe use of the medicinal product and were developed in agreement with Infarmed. It should also clearly summarise the risks addressed that aimed to be minimized with these materials. Key messages should be easily identified (e.g., through colours, font size, bold or italic text, shapes, etc.)
* Avoid simply transcribing the SmPC/PL; instead, the message should be rephrased for better understanding and/or be complemented with relevant data for the effectiveness of these additional risk minimisation measures (e.g. charts, diagrams, bullet points, etc.).
* Include the approved indication using the exact wording of section 4.1 of the SmPC, or section 1 of the PL for patient educational materials. In exceptional cases (e.g., when multiple therapeutic indications exist or space is limited – e.g., patient card), a generic reference to the indications may be used, directing readers to section 4.1 of the SmPC or section 1 of the PL for details.
* The use of promotional language or mentions, direct or implicit, are not allowed (avoid expressions such as "we are pleased to submit" or "you will find an innovative form of treatment").
* The scope of information should be limited to the key messages agreed in the RMP or the EC Decision. Additional information, such as efficacy data, safety comparisons with other medicinal products, or statements implying that the medicine is well tolerated or that adverse reactions occur with a low frequency should not be included. However, in certain circumstances, Infarmed may allow the inclusion of efficacy data or other SmPC/PL content (with reference to the corresponding section) if duly justified by the MAH.
* A statement encouraging the reporting of any suspected adverse reactions and the contacts for reporting in Portugal (NCA and MAH) should also be included, taking into account the size of the material (e.g., patient card may only include a link to Portal RAM and the MAH’s phone number). MAHs must provide a Portuguese phone number.
* References, hyperlinks or Quick Response (QR) codes to websites are not allowed, except in specific cases: links to Infarmed or the European Medicines Agency (EMA) websites where the SmPC and/or PL are publicly available, websites already approved at European level by the EMA’s *Working Group on* *Quality Review of Documents* (QRD), or dedicated websites for educational materials dissemination, as agreed with Infarmed (see section V – Utilization of Websites). Direct QR codes linking to the educational materials are also allowed.
* The medicinal product should be identified by the invented name or, in cases when the materials refer to more than one medicinal product, the active substance name should be used instead. References to the invented name should be limited to the strictly necessary and must not contain registered trademark symbols (®, ™).
* Mentions to other medicinal products outside the scope of educational material are not allowed.
* The information must be structured to highlight the key messages according to their relevance and to facilitate readability (e.g., it should have sufficient white/empty spaces – margins, spaces between columns and paragraphs, etc. – and a format distinct from a SmPC/PL).
* Images and/or graphics presentations of the information should only be used when text alone is insufficient to adequately convey key messages of the materials (e.g., to illustrate the proper use of the medicinal product through a specific device), and there must be harmony among these elements and the text. They may also be included in the materials for patients/caregivers to encourage the use and facilitate understanding of the messages.
* Bibliographic references are only allowed if they contain critical information related to risk minimization that is not available in the SmPC/ PL and are properly justified.
* Educational materials must contain a reminder to carefully read the SmPC/PL on Infarmed’s website (Infomed – <https://extranet.infarmed.pt/INFOMED-fo/>) and/or, for centralized medicinal products, on EMA’s website (<https://www.ema.europa.eu/en/medicines>), in cases where the Infomed link to the SmPC/PL is not functional (e.g., the name of the medicinal product ends in “e” in English and “a” in Portuguese).

V – Utilisation of Websites

The MAH may publish the educational materials on a specifically dedicated website, provided that the following conditions are met:

* The website address must be provided to Infarmed. If the website is still not yet developed, a mockup with all its content must be submitted for assessment (working document outlining the intended layout, and the text for the legal pages).
* The method of website dissemination to the target population (how the website will be disclosed to healthcare professionals and/or patients and whether it will serve as the main or additional means of distributing e educational materials) should be agreed with Infarmed.
* A statement must be submitted to Infarmed confirming that the website content is consistent with the agreed materials, and ensuring that, after the Infarmed’s agreement with the website, it will remain available as long as the educational materials are required. Any further changes to the website must be previously agreed with Infarmed.
* The specific website should only include educational materials agreed with Infarmed, with no references to other documents or websites/pages or weblinks, except for relevant documents such as the SmPC, PL and RMP of the medicinal product. Links to legal documents (e.g., privacy policy, terms and conditions of use, etc.) must pertain solely to the website itself, and the content of these legal documents should be submitted to Infarmed and be limited to the minimum information required, taking into account the purpose of the site.
* All content on the dedicated website should be in Portuguese or, in exceptional cases, duly justified and with the agreement of Infarmed, in English.

**Note:** If a website for mobile technology has already been approved at EU level by CHMP or CMDh, the MAH may propose to Infarmed the inclusion of its corresponding QR code in the educational materials.

VI – Agreement and Dissemination of Educational Materials

The MAH/Representative or the main contact point of the consortium must wait for Infarmed’s agreement with the educational materials, which will be communicated via email at [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt).

During the assessment procedure, Infarmed may request additional information or amendments to the proposed versions.

By default, Infarmed will consider a maximum timeframe of 60 days for the assessment of educational materials. This period may vary, depending for instance on the kind and number of the requested educational materials, and/or the quality of the submitted drafts.

After reception of the email informing about the agreement with the educational materials, the final versions, with their identification of the version number and the date (e.g. Versão X, mm\_yyyy), must be sent by the MAH/Representative or the main contact point of the consortium to the email [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt).

Educational materials will be available on Infarmed’s website (in the fold(s) of the medicinal(s) product(s), available at Infomed - <https://extranet.infarmed.pt/INFOMED-fo/>), on the date agreed with Infarmed for the beginning of dissemination, except if the MAH/Representative or the main contact point and/or other MAHs of the consortium express their disagreement duly justified, until that date via email to [info.seguranca@infarmed.pt](mailto:info.seguranca@infarmed.pt).

Additionally, Infarmed will provide safety alerts related to the educational materials, through the integration of the health technology alert service (*Serviço de Alertas de Tecnologias de Saúde* - *SATS*) with the Health Technology Information Transfer system (*Cedência de Informação de Tecnologias de Saúde* - *CITS*), to entities with a protocol for the transfer of information with Infarmed, so that safety alerts can be integrated into the various electronic prescribing and dispensing systems for medicinal products, Infomed and National Health Service (*SNS*) applications, as applicable.