

ANSM RECOMMENDATION FOR THE SUBMISSION OF GOOD-QUALITY TRANSLATION IN THE CONTEXTE OF AN APPLICATION FOR A MARKETING AUTHORISATION (MA), MA VARIATION, OR RENEWAL FOLLOWING A MUTUAL RECOGNITION OR DECENTRALISED MA PROCEDURE

Scope of application



In order to comply with the regulatory deadlines for notifying decisions following an application for:

- a marketing authorisation (MA)
- an MA variation (including those submitted via worksharing)
- a renewal

following a mutual recognition procedure (MRP) or decentralised procedure (DCP), the French National Agency for the Safety of Medicines and Health Products (ANSM) issues recommendations on the quality and compliance of translations submitted by MA holders.

Applicants/MA holders are reminded that they must submit the French translation of the final approved texts of the Summary of Product Characteristics (SmPC), the package leaflet and the labelling, at the end of the mutual recognition or decentralised procedure.

This translation must be carried out in accordance with:

- the present ANSM recommendations
- the CMDh recommendations “*Best Practice Guide on the submission of high-quality national translations*”:
<https://www.hma.eu/human-medicines/cmdh/procedural-guidance/general-info.html>
- the EMA guideline “*EC Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use*”:
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en

How to submit a translation



All information is available on the ANSM website under the heading “Traduction” and can be accessed via the following link:

<https://ansm.sante.fr/page/modalites-de-soumission-pour-une-amm>

A. LIST OF DOCUMENTS TO BE PROVIDED

1. **Translation compliance statement** for the annexes of the marketing authorisation (MA) (resulting from a mutual recognition or decentralised procedure), for any initial MA application, MA variation application (including those submitted via worksharing) or renewal, duly completed, including as an annex the “List of items expected from the holder in response to their request (text in red)”

The compliance statement must be provided in Word format, accompanied by a fully scanned version, dated and signed by the MA holder or the Responsible Pharmacist (or the Pharmacist delegated by the Responsible Pharmacist for the purpose of signing this statement) within the operating pharmaceutical establishment, where the operation is carried out on behalf of the holder pursuant to Article R. 5124-2 3° of the French Public Health Code.

Important:

The compliance statement must be signed after the approval date of the European procedure.

2. The complete set of the **4 consolidated MA annexes**, in French: Summary of Product Characteristics (Annex I), Annex II, labelling (Annex IIIA) and package leaflet (Annex IIIB), compliant with the style sheet in force. Where applicable, use the latest version approved by ANSM, in secured format.
3. **Proof of end of procedure from the RMS, with all its attachments**, in particular:
 - a. Approval letter (EOP letter)
 - b. Final approved English text
 - c. Final assessment report (FAR, FVAR or FRAR), where applicable
4. **ANSM's approval regarding the name of the product**: email received from the assessor in charge of the procedure. For initial MA applications, in the absence of documentation confirming the name accepted in France, the translation of the MA application cannot be submitted and must be postponed. Where applicable, the ANSM assessor who handled the procedure should be contacted to obtain this documentation.

B. WHEN TO SUBMIT THE DOCUMENTS

Within 7 calendar days of finalisation of the European procedure, regardless of the procedure, including type IA and IB variations.

C. HOW TO SUBMIT THE LES DOCUMENTS

Documents must be submitted by email only to the following address:
Ueurop@ansm.sante.fr

To facilitate the process, please write in French and use a standardised subject and body for the email, as follows:

Subject: Translation – Initial MA application *or* MA variation application *or* MA renewal application (delete as appropriate) – Full procedure number – Name of the product line

Body of the message:

1. List of attachments in the message, with the format of each attachment:
 - a) Translation compliance statement, dated and signed, with its completed annex (scanned)
 - b) Translation compliance statement, with its completed annex (Word format)
 - c) Proposed translation (complete consolidated version, 4 MA annexes) in the format of the style sheet in force
 - d) Proof of end of procedure from the RMS, with all attachments, in particular:
 - Approval letter (EOP letter)
 - Final approved English text
 - Final assessment report (FAR, FVAR or FRAR), where applicable
 - e) Where applicable, ANSM's approval regarding the name of the product
2. Contact details of the file contact for all correspondence, as well as the holder's generic email address

Applicants must also pay particular attention to the following points:

- **one email** per product range (or per CIS product code) and per procedure
- **one compliance statement** per product range (or per CIS product code)

- as many translation proposals as there are CIS codes, even where the approved English text was a single “combined” text covering all strengths and pharmaceutical forms.

If it appears that the documents sent do not comply with these recommendations, the application will not be processed and must be entirely renewed by a new submission to be sent to Ueurop@ansm.sante.fr, taking into account the elements of non-compliance indicated in the e-mail sent by ANSM.

In this case, the notification period will be suspended and the responsibility for the delay incurred will be attributable to the MA applicant, until a new complete and compliant submission is received.

Quality criteria for the translation of “product information”



1. GENERAL

To ensure the quality of the translation of the “product information” and its compliance, the MA applicant or holder must check certain fundamental points. A complete translation of the texts into French must be provided, and the wording must be clear and appropriate.

These fundamental aspects will be assessed against the following criteria:

- Compliance with the English texts adopted at the end of the procedure
- Compliance with the “format of the document”
- Use of appropriate and adapted scientific terminology (see below section 4)
- Use of terminology consistent with the French translation of the current reference frameworks
- Use of terminology consistent with that already adopted for other products (reference medicinal product, other medicinal product containing the same active substance, product belonging to the same therapeutic class) (see below section 5)
- Use of the ANSM glossary of terms and phrases suited to medicine users

2. COMPLIANCE WITH THE ENGLISH TEXTS ADOPTED AT THE END OF THE PROCEDURE

At the end of each procedure, the MA applicant or holder must ensure that the translation submitted to ANSM faithfully reflects the entirety of the adopted texts and is clearly written, with no omissions or additions.

In the event of discrepancies between the approved English text and the proposed French translation, justification is requested in the compliance statement in the section provided for this purpose (“Justifications for any deletions, modifications or additions to the approved English texts”)

3. COMPLIANCE WITH “FORMAT OF THE DOCUMENT”

The translation must be submitted as a Word document and must comply with the current version of the ANSM style sheet and its drafting recommendations, available on the ANSM website under the heading “Documents de référence / Recommandations / Recommandations relatives à la rédaction des projets d’annexes de l’AMM accessible” via the link:

<https://ansm.sante.fr/documents/reference/recommandations-relatives-a-la-redaction-des-projets-dannexes-de-lamm>

Important:

The adopted English texts (common texts) may have “multiple” labelling, which is not an option in the case of the ANSM style sheet. The wording of Annex IIIA of the translation should be adapted to comply with the format of the ANSM style sheet (translation proposals with “multiple” labelling are considered as non-compliant documents)

4. USE OF APPROPRIATE AND ADAPTED SCIENTIFIC TERMINOLOGY

a) Prerequisites

The MA applicant or holder must ensure that the translation is carried out by a person whose native language is preferably French and who has professional knowledge of the relevant therapeutic area, in particular observing the following rules:

- Use of appropriate and adapted scientific terminology
- Use of clear and appropriate language, particularly for the patient package leaflet, taking into account the results of the patient leaflet readability test
- Use of terminology consistent with the French translation of the reference sources in force (cited in this document – see below)
- Use of the standard wording set out in the various sections of the MA annexes:
[Product-information \(QRD\) templates - Human | European Medicines Agency \(EMA\)](#)
- No “word-for-word” translation
- No translation prepared using translation software

b) In the pharmaceutical sections of the MA

◆ Names of substances

Translations of the names of active substances and excipients must comply with the French version of the guidelines:

- for substances listed in the European Pharmacopoeia: the French version of the European Pharmacopoeia;
- for substances not listed in the European Pharmacopoeia: the French version of the International Non-proprietary Name (INN) recommended by the World Health Organization (WHO) or, in the absence of such a name, their common usual name;

- for herbal substances and preparation: the name of the plant and of the plant part used, in French, followed by the Latin scientific name in parenthesis according to the two-word system.

◆ **Pharmaceutical forms, routes of administration and packaging**

For the translation of pharmaceutical forms, routes of administration and packaging to be mentioned in the dedicated sections of the SmPC, package leaflet and labelling, reference should be made to the French version of the “Standard Terms” of the European Pharmacopoeia.

The list of “Standard Terms” is available online at the following link:

<https://standardterms.edqm.eu>

Regarding “Patient-Friendly Terms” sometimes appearing in brackets after the pharmaceutical form in the MA annexes: where no French translation is available on the European Pharmacopoeia Standard Terms website, these “Patient-Friendly Terms” will not be included in the French version of the annexes.

◆ **Special storage precautions**

For the translation of the special storage precautions to be mentioned in the appropriate sections of the SmPC, package leaflet and labelling, reference should be made to the French version of Appendix III to the QRD templates (Appendix III to the Quality Review of Documents templates for human medicinal products):

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-qrd-templates-humanht>

◆ **Score line in the product name**

Where scoring is demonstrated in the pharmaceutical dossier (standard sentence <*The tablet can be divided into equal doses.*> mentioned in SmPC section 3) and is justified by the posology, the term “sécable” should be mentioned in the pharmaceutical form appearing in the name of the medicine in SmPC section 1 and in the other “product name” sections of the package leaflet and labelling.

It should be noted that for non-scored generic products of scored reference products, a specific warning will appear in the generic medicines directory when the product is entered in the corresponding generic group: “A scored generic product should be dispensed where the posology requires a fraction of a tablet.”

c) In the clinical sections of the MA

◆ **Fertility, pregnancy and lactation**

The information in SmPC section 4.6, Fertility, pregnancy and lactation, should be written taking into account the standard statements defined in Annex I of the QRD template, available online at the following link:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-grd-templates-human>

◆ **Adverse effects**

The information in SmPC section 4.8, Adverse Reactions, must be written taking into account the standard wording defined in Annex II of the QRD template, available online at the following link:

<https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-grd-templates-human>

and in compliance with the current version of the MedDRA terminology (Medical Dictionary for Regulatory Activities terminology), available online at the following link:

<https://www.meddra.org>

◆ **Excipients with known action or effect**

The translation of information relating to excipients with known action or effect should be in accordance with the French version of the latest version in force of the guideline “*Excipients in the label and package leaflet of medicinal products for human use*”, published by the European Commission as part of the “*Notice to Applicants*” (Volume 3B), available online at the following link:

<https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human-use>

d) Other sections of the MA:

◆ **Names and addresses of the various stakeholders**

Regarding the names and addresses of the various stakeholders listed in the annexes (manufacturer responsible for batch release, operator) should be consistent with the wording of the manufacturing authorisations.

For national transfer of ownership applications linked to an EU name change, translations must be submitted at the end of the procedure, and the parallel application must be noted in the annex table. This will ensure the synchronised notification of the two related variations.

◆ **Conditions of prescription and supply**

These must be mentioned in the dedicated sections at the end of the SmPC, in Annex II and in the labelling. The proposed French wording must comply with the entries listed in the current version of the ANSM style sheet.

◆ Conditions of the MA and obligations of the MA holder (Annex II)

The MA holder must ensure that the information contained in these sections complies with any conditions or obligations imposed on it by the competent authorities during the procedure, as well as any commitments made during that procedure.

For generic products, this information must generally be aligned with that of the reference products.

◆ Section F. “QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS” of Annex II

The qualitative and quantitative composition in excipients must be expressed consistently with the active substance composition given in SmPC section 2 (i.e. if the active substance composition in the SmPC is expressed per 1 mL or 1 g of finished product, the excipient composition in this section must also be expressed per 1 mL or 1 g of finished product; if the active substance composition in the SmPC is expressed per x mL or x g of finished product, the excipient composition in this section must also be expressed per x mL or x g of finished product).

5. USE OF TERMINOLOGY CONSISTENT WITH THAT ADOPTED FOR OTHER PRODUCTS (reference product, other product containing the same active substance, product belonging to the same therapeutic class)

The MA applicant or holder should take into account the French terminology recently adopted for the reference medicinal product, or for medicinal products containing the same active substance or belonging to the same therapeutic class, or for herbal medicinal products complying with the same monograph developed by the HMPC and published by the EMA.

In addition, where the reference product has recently undergone a European harmonisation procedure in accordance with Article 30 of Directive 2001/83/EC, the “product information” of generic MAs must be brought into line with the texts appearing in the European Commission decision adopted at the end of the procedure.

As a reminder, where information protected under the intellectual property rights of the reference product must be removed for generic, biosimilar or hybrid products, this must be clearly specified and justified when the translations are submitted, in the compliance statement.