Agence nationale de sécurité du médicament et des produits de santé

ANSM RECOMMENDATIONS FOR THE SUBMISSION OF TRANSLATIONS IN THE CONTEXT OF AN APPLICATION FOR A MARKETING AUTHORISATION (MA), MA VARIATION OR RENEWAL FOLLOWING A MUTUAL RECOGNITION OR DECENTRALISED PROCEDURE

Scope of application

In order to comply with the regulatory deadlines for notification of decisions following an application for a:

- marketing authorisation (MA)
- MA variation
- renewal

following a mutual recognition procedure (MRP) or a 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 proposed by MA holders.

MA holders/applicants are reminded that they must submit the French translation of the final approved texts of the Summary of Product Characteristics (SPC), package leaflet and 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 recommendations of the CMDh "*Best Practice Guide on the submission of high-quality national translations"* accessible via the link: https://www.hma.eu/90.html
- the EMA's "*EC Guideline on the Readability of the labelling and Package Leaflet of Medicinal Products for Human use*" accessible via the link: https://ec.europa.eu/health/documents/eudralex/vol-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

- **Statement of compliance of the translation** of the annexes of the marketing authorisation (MA) (resulting from a mutual recognition or decentralised procedure), for any application for an initial MA, a variation or renewal, duly completed, including as an appendix the "Summary list of the sections modified since the last text communicated by the ANSM".

The statement of compliance (*engagement de conformité des traductions*) to be completed is available on the ANSM website under the heading "*Traduction*" and can be accessed using the link above. An annotated version of the statement of compliance is also available, in English and French, as a guide only for filling in the various sections.

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

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

- **All four annexes of the MA in ONE Word document**, in French: Summary of product characteristics (Annex I), Annex II, labelling (Annex IIIA) and package leaflet (Annex IIIB) and in accordance with the current ANSM style sheet, for each dosage

Important:
Respect the format of the document (see below, section C. RESPECT THE "FORMAT OF THE DOCUMENT")

- **End of procedure approval email from the RMS with all attachments**

- **If applicable*, a copy of the ANSM approval for the name of the medicinal product**

*For initial MA applications or MA variation applications relating to a name change.

Important:
In the absence of proof mentioning the name accepted in France (received during the validation phase or during the procedure or, failing that, by email from the ANSM evaluator), the translation of the MA application cannot be submitted and will have to be postponed.
If necessary, the ANSM assessor who has followed the procedure may be contacted to obtain this proof. Upon receipt, the proof of approval of the name should be attached when submitting the translation.

- **Proposed translation of commitment(s) made at the end of the procedure, where applicable**

B. WHEN TO SUBMIT DOCUMENTS

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

Important:
For applications for transfer of ownership or change of operator at national level, associated with a change of name of the medicinal product, translations will have to be submitted after finalisation of the European procedure for the change of name.

C. HOW TO SUBMIT DOCUMENTS

Documents must be submitted **by e-mail 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:

Sample submission message

Subject of the message:
Traduction – AMM initiale et/ou Modification ou Renouvellement (supprimer les options inutiles) - Numéro de procédure complet - Dénomination de la gamme
(Translation - Initial MA and/or MA Variation or Renewal (delete unnecessary options) - Full procedure number - Name of the product line)

Body of the message:

- File Code (CIS Codes)
- Name of the medicinal product or range
- Full procedure number
- Date of approval of the procedure
- List of attachments in the message with the format of attachments (see section A):
    - Statement of compliance of the translation, dated and signed, with appendix completed (digitised/scanned)
    - Statement of compliance of the translation, with appendix completed (Word format)
    - Proposed translation on the full consolidated version; all 4 annexes of the MA in the current style sheet format, for each dosage
    - End of procedure approval email from the RMS (forwarded, with all attachments)
    - If applicable, a copy of the ANSM approval of the name of the medicinal product
    - Where appropriate, proposed translation of commitment(s) made at the end of the procedure.
- Contact details for all correspondence and generic email address of the holder.

Applicants should also pay particular attention to the following:

- one e-mail per procedure and per medicinal product/CIS or per product line (same procedure)
- there should be the same number of translation proposals as there are medicinal product/CIS, even though the approved English text includes all strengths and dosage forms (*"combined"*).

Non-compliant documents

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"

A. GENERAL

In order to ensure the quality of the translation of the "product information" and its compliance, the applicant or MA holder must check certain fundamental points. They must provide a full translation of the texts in French and ensure that the writing is clear and appropriate.

These fundamental aspects will be assessed through the following criteria:

- Compliance with the English texts adopted at the end of the procedure
- Respect of the "format of the document"
- Use of appropriate and adequate scientific terminology (see below section D)
- Use of terminology in line 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, medicinal product belonging to the same therapeutic class) (see below section E)
- Use of the ANSM lexicon of terms and expressions suitable for users of medicines

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

At the end of each procedure, the applicant or MA holder must ensure that the translation submitted to the ANSM is faithful to the entirety of the texts adopted and written clearly, without omission or addition.

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

In the particular case of withdrawal of patented indications, the applicant must submit a translation of the complete annexes and highlight the deleted paragraphs (they may be highlighted or crossed out).

C. RESPECT THE "FORMAT OF THE DOCUMENT"

The translation must be submitted in Word format and must comply with the current version of the ANSM style sheet and its drafting recommendations, available on the ANSM website under the heading "Proposals for MA/registration annexes (SPC, labelling, package leaflet)" (*Propositions d'annexes AMM / enregistrements (RCP, notice, étiquetage)*) 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).

D. USE APPROPRIATE AND ADAPTED SCIENTIFIC TERMINOLOGY

Prerequisites

The applicant or MA holder must ensure that the translation is carried out by a person whose mother tongue is preferably French and who has professional knowledge of the therapeutic area concerned, in particular by complying with the rules defined below:

- Use of appropriate and adapted scientific terminology
- Use of clear and appropriate language in particular for the patient information leaflet, taking into account the results of the patient information leaflet readability test
- Use of terminology in line with the French translation of the current standards (and quoted in the document - see below)
- Use of the standard phrases listed in the current version of the ANSM style sheet
- No word-for-word translation
- No translation using translation software

Pharmaceutical sections of the MA

Names of substances

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

- for substances listed in the European Pharmacopoeia: French version of the European Pharmacopoeia;
- for substances not included in the European Pharmacopoeia: the French version of the international non-proprietary name recommended by the World Health Organization (WHO) or, in the absence of such a name, their usual non-proprietary name;
- for herbal substances and preparations: name of the plant and 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 the pharmaceutical forms, routes of administration and packaging to be mentioned in the dedicated sections of the SPC, package leaflet and labelling, reference should be made to the French version of the European Pharmacopoeia Standard Terms.
The list of Standard Terms is available on the internet via the link:
https://standardterms.edqm.eu/
Concerning the “Patient-Friendly Terms” sometimes appearing in brackets after the pharmaceutical form in the annexes to the MA: in the absence of a French translation on the European Pharmacopoeia's 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 SPC, package leaflet and labelling, reference should be made to the French version of Appendix III to the Quality Review of Documents templates for human medicinal products. this is available on the internet via the link:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates-human

Score line in naming
Where tablets have been designed with a score line for division as demonstrated in the pharmaceutical dossier, the approved SPC shall state :
<*The tablet can be divided into equal doses*.> in section 3.
In this case, the term "*sécable*" should be included in the SPC under heading 1 in the name of the medicinal product and under heading 3 in the pharmaceutical form, as well as in the corresponding sections of the package leaflet and labelling.

Clinical sections of the MA

Fertility, pregnancy and lactation
The information in section 4.6 of the SPC for Fertility, Pregnancy and Lactation, should be written taking into account the standard statements defined in Appendix I of the QRD template, which can be consulted on the internet using the link :
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates-human#appendices-section

Adverse effects
The information in section 4.8 of the Adverse Reactions SPC should be written taking into account the standard wording defined in Appendix II of the QRD template, which can be consulted on the internet using the link:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/product-information-templates-human#appendices-section
and in compliance with the updated version of the MedDRA terminology (Medical Dictionary for Regulatory Activities terminology) available on the internet at the following link: https://www.meddra.org/

Excipients with a known action or effect
The translation of the information on excipients with a known action or effect should be in accordance with the latest French version of the annex 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"* document (volume 3B) which can be consulted on the internet via the following link: https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human

Other sections of the MA

Names and addresses of the various stakeholders
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.

Prescription and dispensing conditions (PDC)
These should be mentioned in the appropriate sections at the end of the SPC, in Annex II and in the labelling. The proposed French wording must comply with the wording listed in the current version of the ANSM style sheet.

Conditions of the MA and obligations of the MA holder (Annex II)
The marketing authorisation holder must ensure that the information contained in these sections is consistent with any conditions or obligations imposed by the relevant authorities during the procedure and with any commitments made during the procedure.
For generic products, this information will generally have to be aligned with that of the reference product.

Section F. "QUALITATIVE AND QUANTITATIVE COMPOSITION OF EXCIPIENTS" from Annex II
The qualitative and quantitative composition of excipients shall be expressed in a manner consistent with the composition of the active substance in section 2 of the SPC.
For example, if the composition of active substance in the SPC is presented as "Per x mL or x g of finished product", the composition of excipients in this section will also be expressed as "Per x mL or x g of finished product".

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

The MA holder or applicant should take into account recently adopted French terminology for the reference medicinal product or 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, when the reference product has recently undergone a European harmonisation procedure in accordance with Article 30 of Directive 2001/83/EC, the "product information" of marketing authorisations for generics must be brought into line with the texts contained in the European Commission decision adopted at the end of the procedure.

As a reminder, where information protected by intellectual property rights is to be removed, this must be clearly specified when submitting the translations in the compliance undertaking, see above under B. COMPLIANCE WITH THE ENGLISH TEXTS ADOPTED AT THE END OF THE PROCEDURE