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Procedure Management and Business Support

Practical information on translations for referral procedures (human)

Introduction

A linguistic review of product information in all EU languages is performed after adoption of CHMP opinions / CMDh position/agreement to ensure high quality and consistent product information.

Such product information linguistic review is part of the Commission Decision-Making Process (DMP) as outlined in Articles 9 and 10, and Articles 34 and 35 of Regulation (EC) No 726/2004, as well as in Articles 20 and 23 of Regulation (EC) No 1234/2008, as applicable.

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Table of contents

1. The linguistic review process for Referral procedures

1.1. Introduction

This section presents the translation process of referral procedures of the following Annexes to the CHMP Opinion / CMDh position/agreement:

- Annex I (Translated by MAH/applicant).
  List of products concerned by the procedure;
- Annex II (Translated by the Translation Centre based in Luxembourg)
  Scientific conclusions and grounds for the maintenance, variation, suspension, revocation or refusal of renewal of the marketing authorisations subject to conditions;
- Annex III (Translated by MAH/applicant).
  Full Product Information or amendments to be included in the relevant sections of the summary of product characteristics or the labelling or package leaflet, if applicable;
- Annex IV (When applicable - translated by the Translation Centre based in Luxembourg)
  Conditions of the marketing authorisation
- Annex V (When applicable – translated by the Translation Centre based in Luxemburg)
  Timetable of the implementation of the CMDh agreement

The translations of all or some of these Annexes and the linguistic review of Annex III (if applicable) in all EU languages is performed after adoption of CHMP Opinion/CMDh position/agreement.

The translations are required in the following 22 languages: Bulgarian (BG); Croatian (HR); Czech (CS); Danish (DA), German (DE); Greek (EL); Spanish (ES); Estonian (ET); Finnish (FI); French (FR); Hungarian (HU); Italian (IT); Lithuanian (LT); Latvian (LV); Maltese (MT); Dutch (NL); Polish (PL); Portuguese (PT); Romanian (RO); Slovak (SK); Slovenian (SL); Swedish (SV).

If Norway (NO) and Iceland (IS) are involved in the referral procedure (i.e. NO and IS are included in the Annex I at the Opinion stage) the Annex I and III have to be translated in NO and IS as well, unless NO and IS authorities give their written confirmation that the translations are not required even though they are involved in the procedure.

1.2. The translations process

1.2.1. The preparation of the translation process

In view of the short timeframe for finalisation of the translations and in order to optimise the quality of the translations, MAH/applicants are strongly advised to prepare for the translation process well in advance in the pre-opinion / position/agreement stage.

In case of a referral procedure where several MAHs/applicants are involved, the EMA will contact the MAHs during the procedure in order to organise the work-sharing related to the translation process[1].

[1] Please NOTE: If you are involved in such procedures with multiple MAHs/applicants, and you have not been contacted directly by the EMA to discuss the translations process, you are NOT required to provide any translations.

1.2.2. During the translation process

After the CHMP opinion or CMDh position/agreement, the MAH/applicant has to provide the translations of the adopted Annex I and Annex III in all EU languages (including Icelandic and Norwegian – if applicable) according to the timelines provided by the Agency:

- Day 5 (5 days after opinion/ position /agreement) — Translations of the adopted Annex I (list of products) and Annex III (when applicable - SmPC, labelling and package leaflet text) in EN and in all other EU languages (including Icelandic and Norwegian, when applicable) are to be provided electronically (in one Eudralink package) to the Member States Contact Points for Translations and to the EMA's procedure secretary.

- Day 19 (19 days after opinion/ position /agreement) — Member States will send linguistic comments on the SPC, labelling and package leaflet to the MAH/applicant by e-mail with a copy to the EMA's procedure secretary.

- Day 22 (22 days after opinion / position /agreement) — The MAH/applicant will implement the required changes, compile the translations and send it back to the European Medicines Agency.
  In case of disagreement between the member state and the MAH/applicant, the EMA will not interfere in the translation process at this stage. Disagreements should be solved directly with the concerned NCA.
  In order to facilitate and accelerate the check of the implementation of the Member States' comments, the MAH/applicants should indicate in "QRD Form 2" for each language if all comments have been implemented or not. In the latter case, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts.

1.2.3. After the translation process

Once the translations are received from the MAH/applicant, the Agency will check if all Member States' comments have been implemented.

a) In case of a CHMP opinion or a CMDh position (by majority) from the CMDh, the Agency will compile the Annexes in all languages and send the final copies to the Commission, members of the Standing Committee and the MAH/applicant at Day 27 (27 days after opinion).
Following receipt of the final compiled translations, the Commission will start the 22-day Standing Committee consultation, addressing only legal and public health matters (which means in principle no further linguistic review) (for timelines, please see appendix 1).

b) In case of a CMDh agreement (by consensus), the Agency will compile the Annexes in all languages, send the final copies to the National Competent Authorities and the full set of annexes will be published on the EMA website (for timelines, please see appendix 2).

1.3. Translations in practice

1.3.1. Translation of Annex I

Following the PRAC recommendation (if applicable), the MAH/applicant involved in the translation process should proceed with the translations of the Annex I (list of products approved concerned by the procedure).

- For translations of Annex I QRD templates for each language should be used Home>Regulatory>Human Medicines>Product Information>Product information templates>Mutual-recognition, decentralised and referral procedures
- Make sure that the title page is adjusted in accordance with the adopted English text and that all the brackets (i.e <>) are taken out in the title.
- The translations have to follow the Annex I exactly as adopted by the CHMP / CMDh. The Annexes SHALL NOT be updated at this stage.
- Translate the entire Annex I in all official EU languages, except information in the following columns: Marketing Authorisation Holder, applicant (as applicable) and (invented) name (*see figure 1*).
- Keep the alphabetical order as per the English version (*see figure 1*).

Figure 1: example of translation of Annex I

English original:

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand 2 mg - Tabletten	2 mg	Tablet	Oral use
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels Belgium	Atacand	2 mg	Tablet	Oral use
Bulgaria	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand	8 mg	Tablet	Oral use
Cyprus	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand	4 mg	Tablet	Oral use
Czech Republic	AstraZeneca UK Ltd., Macclesfield, Cheshire, United Kingdom	Atacand 4 mg	4 mg	Tablet	Oral use
Denmark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand	4 mg	Tablet	Oral use

German translation:

Follow the order of English version:

Mitgliedsstaat EU/EWR	Inhaber der Zulassung	Phantasiebezeich-nung	Stärke	Pharmazeutische Darreichungsform	Art der Anwendung
Österreich	AstraZeneca Österreich GmbH., Schwarzenbergplatz 7, A-1037 Wien, Austria	Atacand 2 mg - Tabletten	2 mg	Tablette	Zum Einnehmen
Belgien	NV AstraZeneca SA Egide Van Ophemstraat 110 B-1180 Brussels, Belgium	Atacand	2 mg	Tablette	Zum Einnehmen
Bulgarien	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand	8 mg	Tablette	Zum Einnehmen
Zypern	AstraZeneca AB, S-151 85 Södertälje, Sweden	Atacand	4 mg	Tablette	Zum Einnehmen
Tschechische Republik	AstraZeneca UK Ltd., Macclesfield, Cheshire, United Kingdom	Atacand 4 mg	4 mg	Tablette	Zum Einnehmen
Dänemark	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund, Denmark	Atacand	4 mg	Tablette	Zum Einnehmen

1.3.2. Translation of Annex III

- The structure of the English Annex III has to be strictly followed and should be exactly translated as per the adopted English version (i.e.: full product information or only amendments to the relevant sections of the product information).
- For translations of Annex III QRD templates for each language should be used

  Home>Regulatory>Human Medicines>Product Information>Product information templates>Mutual-recognition, decentralised and referral procedures
- Make sure that the title pages are adjusted and all brackets (i.e <>) are taken out in the title.
- Don't leave sections out, don't update the Annex III, e.g. the sections [to be completed on a national level] simply to be translated as 'to be completed on a national level'.

In order to facilitate and accelerate the check of the implementation of the Member States' comments, the MAHs/applicants should indicate in "QRD Form 2" for each language if all comments have been implemented or not. In the latter case, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts.

2. The linguistic review process for Article 20 of Regulation (EC) No 726/2004 procedures or for CAPs when involved in Article 31 Pharmacovigilance or Article 107i of Directive 2001/83/EC

2.1. Introduction

This section presents the translation process for the centrally authorised products (CAPs).

Annexes translated by the MAH:

1. Annex A : All authorised presentations of the product (if applicable)
2. Product information composed of:
   - Annex I: Summary of product characteristics
   - Annex II:
     - Manufacturer of the biological active substance and manufacturers responsible for batch release (as applicable)
     - Conditions or restrictions regarding supply and use
     - Other conditions and requirements of the marketing authorisation
     - Conditions or restrictions with regards to the safe and effective use of the medicinal product
     - Specific obligation to complete post authorisation measures for the conditional marketing authorisation or for the marketing authorisation under exceptional circumstances (as applicable)
   - Annex III: Labelling and Package Leaflet

3. Annex related to the art.127a[2]: conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

Annexes translated by the Translation Centre based in Luxembourg:

- Scientific conclusions and grounds for the opinion

2.2. The translation process

For procedures affecting the product information of CAPs, only the EN language version needs to be provided with the responses to the List of Questions. Translations of the adopted product information in all other EU languages (including Icelandic and Norwegian) are to be provided electronically (in one Eudralink package) to the Member States Contact Points for Translations by Day +5 (i.e. 5 days after adoption of the opinion) and copy to the procedure secretary. Translations of the revised Annex A only need to be sent to the Procedure secretary by Day +5, if applicable.

The following checks will apply:

Check by	When	Who	Scope
QRD/CHMP 'Member State'	Day +5 to +19	Member States	Detailed review of highlighted changes in all translations
PIQ	Day +25 to +27	Agency	Review of implementation of Member States comments

Comments will be sent directly by the Member States to the MAH at the latest by Day +19, with a copy to the Procedure secretary.

The MAH will send the final translations in Word format in clean and tracked changes, incorporating the Member States' comments, as well as in PDF format (clean only), electronically to the Procedure secretary by Day +25.

The Agency will check if all Member States' comments have been implemented before sending the final translations to the Commission. In order to facilitate and accelerate the check of the implementation of the Member States' comments, the MAH should indicate in "QRD Form 2" for each language if all comments have been implemented or not. In the latter case, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts.

Poor quality translations or a poor implementation of Member States' comments or absence of a completed QRD Form 2 may lead to a delay in transmission to the Commission.

Following receipt of the final compiled translations, the Commission will start the 22-day Standing Committee consultation, addressing only legal and public health matters (which means in principle no further linguistic review) (see appendix 3).

3. Implementation & follow-up

Since the process is based on a single linguistic check of the translations and especially since specific timeframes are set, a full commitment from all parties involved is required. In particular,

[2] Note: when Annex related to the art.127a is required, it needs to be provided to the EMA as a separate zip file from the Product Information

MAH/applicant will have to commit to provide good quality translations and to comply with Member States' comments.

If a translation is considered to be of unacceptable poor quality, the Member State concerned will inform the MAH/applicant and the Agency within 3 days of receipt of the translation. The Agency will inform the MAH/applicant of the poor quality of the translations and the transmission to the Commission will be delayed until receipt of the amended translation (which would be expected within 1 week). A revised timetable will then be prepared.

MAHs/applicants are also strongly advised to liaise directly with the Member States in case of disagreement with any of the comments made or in case further clarification on some comments is required, and to reflect the outcome in "QRD Form 2".

In addition, MAHs/applicants are reminded that in case the complete product information is part of the Annex III, it should be presented in strict compliance with the QRD Convention (e.g. format, layout, margins)

The Agency will monitor the quality of the translations, the review by the Member States and industry's compliance with Member States' comments as part of the Performance Indicators.

4. Useful reference documents

- QRD Convention:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf

- QRD Human Product Information Templates:

http://www.ema.europa.eu/htms/human/qrd/qrdtemplate.htm

- QRD Human Product Information Template with explanatory notes:

Home>Regulatory>Human Medicines>Product Information>Product information templates

- QRD Human Referral Templates:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp&mid=WC0b01ac0580022c59#section2

- QRD Human Referral Template with explanatory notes:

http://www.hma.eu/uploads/media/QRD_annotated_template_CMDh.pdf

- Annex I Human referral Template in all languages:

Home>Regulatory>Human Medicines>Product Information>Product information templates>Mutual-recognition, decentralised and referral procedures

- List of Member States Contact Points for Translations (with guidance on the sending of product information to Member States):

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004437.pdf

- QRD Reference Documents (on terminology and style):

Home>Regulatory>Human Medicines>Product Information>QRD reference documents and guidelines

- User guide on the preparation of PDF versions of the product information:

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004182.pdf

- EC Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008

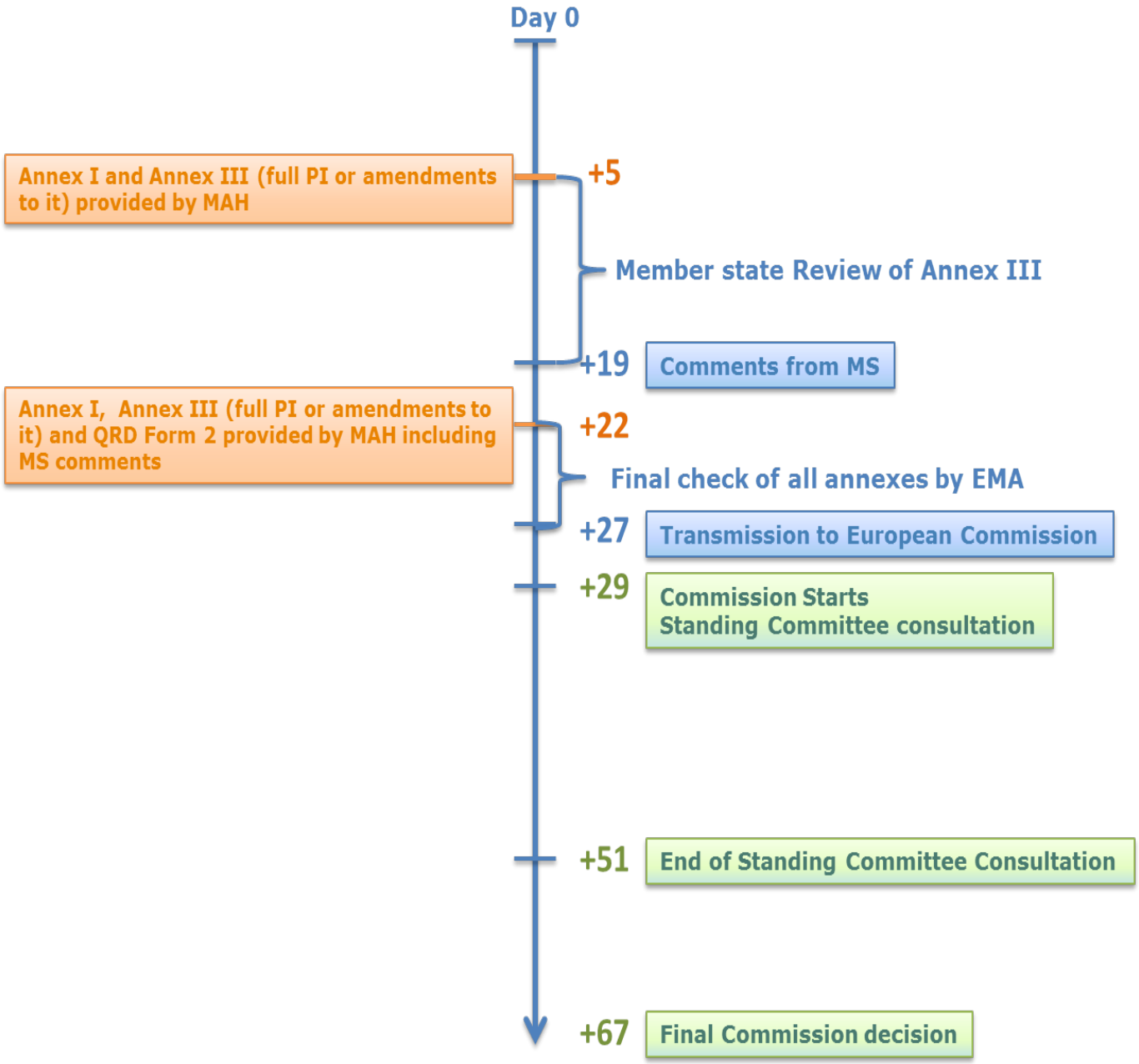
http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/betterreg/pharmacos/procedural_guideline_adopted.pdf

- PIQ/QRD Pre-opinion Review of Product Information for Referral Procedures and Article 29

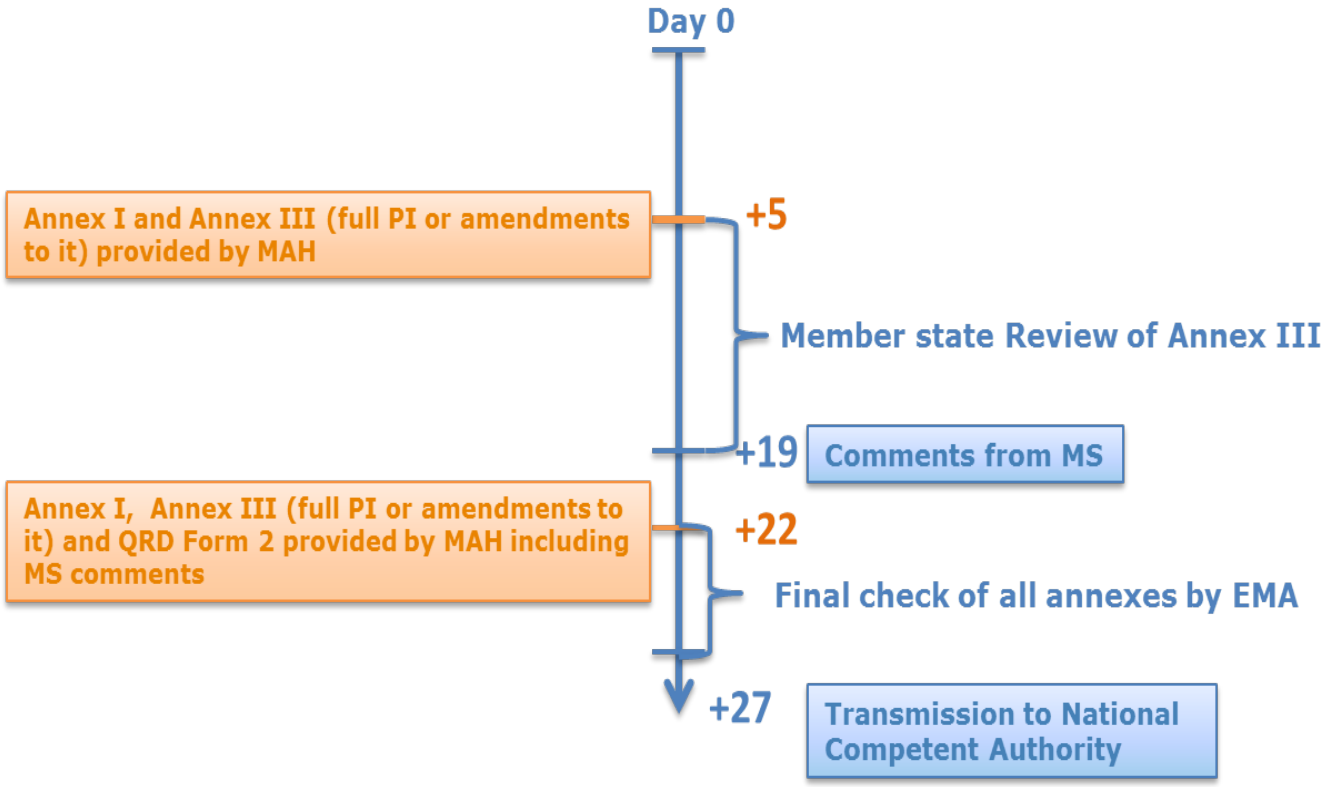
  Paediatric Procedures

http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500002739.pdf

Appendix 1 – Timeline in case of a CHMP Opinion or a CMDh Position (by majority)



Appendix 2 – Timeline in case of CMDh agreement (by consensus)



Appendix 3 – Timelines for Article 20 procedures, Article 31 pharmacovigilance or article 107 i of Directive 2001/83/EC involving CAPs