EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

The linguistic review process of product information in the centralised procedure

Human medicinal product applications

Contents

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1. Introduction

In order to ensure high quality and consistent product information (PI) of centrally authorised products (CAPs) in all Member States, a linguistic review of the PI[1] will be performed at different stages of the procedures, depending on the type of application: pre-opinion review of the English product information (EN PI), and/or post-opinion review of the translations in all EU languages.

Such post-opinion 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.

The timeframes apply to initial marketing authorisation applications as well as to relevant post-authorisation procedures. The timeframes refer to calendar days, not working days. For applications that have been reviewed by the CHMP in an accelerated assessment, the timeframes may be shortened on a case-by-case basis, depending on the urgency by which the European Commission's Decision will need to be adopted.

This document presents the product information review process within the DMP timeframes and provides details on its practical implementation for the pre-opinion review of the EN PI and the post-opinion review of the translations in all EU languages. The review of the information provided via a mobile technology is not included in this document and is described in the Guidance document on mobile scanning and other technologies.

2. Pre-opinion labelling review of the English product information

At submission and during assessment, only the EN PI is submitted and reviewed. Applicants may provide a combined Summary of Product Characteristics (SmPC) and/or package leaflet text for different strengths of the same pharmaceutical form; detailed guidance is available in the Policy on combined Summaries of Product Characteristics (SmPCs). Different pack-sizes of the same strength can be presented in one labelling text. Further guidance on the presentation of product information is available in the QRD annotated EN template and QRD Convention.

Where applicants consider to also market a combined printed package leaflet, a detailed justification for such a combined package leaflet will have to be included in the dossier at submission or at the latest at Day 121 and sent in parallel to the Agency via QRD@ema.europa.eu. The justification should take into account the QRD guidance as published in the Compilation of QRD decisions on stylistic matters.

2.1. New marketing authorisation applications

The following process is in place for new marketing authorisation applications, as illustrated in the timelines (Annex 1), except for generic/biosimilar/hybrid/informed consent applications, for which there is no pre-opinion labelling review of the EN PI.

The EN PI submitted by the applicant at the start of the procedure will be subject to the following checks:

[1] Annex I Summary of Product Characteristics (SmPC), Annex II Conditions, Annex III Labelling & Package Leaflet and Annex related to article 127a and Annex IV (when applicable)

Who	When	Scope
Agency	Day 10	Detailed review of the **EN PI** to ensure compliance with current standards (e.g. QRD templates), consistency with the SmPC Guideline and other relevant guidelines, and also to highlight claims in need of further substantiation
Agency/QRD members/PCWP[2]/ EMA medical writers	Day 140	
Agency	Day 210	Final check of the Opinion EN PI to ensure all previous comments have been correctly addressed

The labelling review comments will be incorporated into the review of the PI performed by the rapporteur, and a single set of comments will be sent to the applicant as part of the list of questions at Day 120. All the comments included in the reviewed PI are to be taken into account when submitting the revised EN PI as part of the answers to the list of questions at Day 121.

Upon receipt of the revised EN PI at Day 121, the Agency will review the implementation of the labelling review comments by the applicant and will circulate the revised EN PI to all QRD members as well as to representatives of Patients' and Consumers' Organisations and the EMA medical writers for comments (via written procedure) by Day 140.

In exceptional cases where, as a matter of urgency (e.g. pandemic crisis), if a full QRD pre-opinion review (performed by Member States) is not possible, the Agency may consider a labelling review performed solely by the Agency.

The Day 140 labelling review comments will be incorporated into the review of the PI performed by the rapporteur, and a single set of comments will be sent to the applicant as part of the Day 157 set of documents.

All the comments are to be taken into account when submitting the revised EN PI as part of the answers to the list of outstanding issues at Day 181, or before opinion if no list of outstanding issues is adopted. The Agency will check if all labelling review comments have been implemented before the opinion is adopted.

2.2. Line extensions

The following process is in place for line extensions, as illustrated in the timelines (Annex 1).

The EN PI submitted by the applicant at the start of the procedure will be subject to the following checks:

Who	When	Scope
Agency	Day 140	Detailed review of the **EN PI** to ensure compliance with current standards (e.g. QRD templates), consistency with the SmPC Guideline and other relevant guidelines, and also to highlight claims in need of further substantiation

[2] Patients' and Consumers' Working Party

Agency	Day 210	Final check of the Opinion EN PI to ensure all previous comments have been correctly addressed

The Day 140 labelling review comments will be incorporated into the review of the PI performed by the rapporteur, and a single set of comments will be sent to the applicant as part of the Day 157 set of documents.

All the comments are to be taken into account when submitting the revised EN PI as part of the answers to the list of outstanding issues at Day 181, or before opinion if no list of outstanding issues is adopted. The Agency will check if all labelling review comments have been implemented before the opinion is adopted.

In case of a grouped submission including a line extension, the same principles as for the pre-opinion review of a line extension will apply.

2.3. Renewals

The following process is in place for 5-year renewal procedures, as illustrated in the timelines (Annex 2), except for generic/biosimilar/hybrid/informed consent renewal applications, for which there is no labelling review of the EN PI. Annual renewals do not undergo a labelling review unless major changes occur in the EN PI.

The EN PI submitted by the applicant at the start of the procedure will be subject to the following checks:

Who	When	Scope
Agency	Day 30	Detailed review of the **EN PI** to ensure compliance with current standards (e.g. QRD templates), consistency with the SmPC Guideline and other relevant guidelines, and also to highlight claims in need of further substantiation
Agency	By Opinion	Final check of the Opinion EN PI to ensure all previous comments have been correctly addressed

3. Post-opinion linguistic review for initial marketing authorisations and line extensions

Following the adoption of a positive CHMP opinion, applicants will provide the translations in all other EU languages[3] of the final adopted EN PI, Annex IV and Annex related to article 127a (if applicable), to the Agency at the latest 5 days after the CHMP opinion (Day 215). In view of the short timeframe for finalisation of the translations, and in order to optimise the quality of the translations, applicants/marketing authorisation holders (MAHs) are strongly advised to initiate the translation process well in advance of the opinion (e.g. after Day 180).

In those cases where an English PI is adopted with separate SmPCs/PLs, the use of combined SmPCs/PLs for different strengths of the same pharmaceutical form is encouraged for all languages in

[3] All EU languages including English, Icelandic and Norwegian. Details on the handling of the Icelandic and Norwegian PI annexes are given in the Pre-authorisation guidance Q&A.

order to facilitate the linguistic review. However, in these cases, the SmPCs/PLs for all languages will need be separated at the end of the linguistic review process in line with the adopted English PI.

Applicants will send the translations together with the QRD Form 1 to the Agency (qrd@ema.europa.eu) by Day 215. The Day 215 submission package should be presented in compliance with the Day 215 Checklist.

The following checks will apply:

Who	When	Scope
Member States (QRD members)	Day 215-229	Detailed review of all translations
Agency	Day 235-237	Review of implementation of Member States' comments

Each translation will be subject to one Member States' linguistic review, co-ordinated by the national QRD member. QRD members will send their comments directly to the applicant with a copy the Agency (Product Shared Mailbox) at the latest by Day 229, together with the overall feedback on the quality of the translations indicated in the QRD Form 1.

The applicant will send the final translations with tracked changes, incorporating the Member States' comments, in Word format[4], as well as in clean Word and PDF format (see also User guide on how to generate PDF versions of the product information – human) together with the QRD form 2 to the Agency (qrd@ema.europa.eu) with a copy to the Product Shared Mailbox by Day 235. The Day 235 submission package should be presented in compliance with the Checklist. For initial applications containing a new active substance, the applicant will also be asked to provide the translations of the International non-proprietary name/common name of the active substance in the official languages of the European Union, plus Irish language, in a tabulated format ('INN table').

The Agency will check if all Member States' comments have been implemented before sending the final translations to the European Commission (EC). In order to facilitate and accelerate the check of the implementation of the Member States' comments, the applicant must submit the QRD form 2 where they indicate for each language if all comments have been implemented.

Where comments have not been fully implemented, the applicant should provide a justification for the appropriate language(s) stating why certain comments are not reflected in the final PI. Such justification(s) and/or alternative proposals should be discussed and agreed with the relevant Member State(s) before submitting final translations to the Agency.

Poor quality translations, poor implementation of Member States' comments, or absence of a completed QRD form 2 may lead to a delay in transmission to EC (see also section 6).

Following receipt of the final translations from the Agency, the EC will start the 22-day Standing Committee consultation, addressing only legal and public health matters, which means in principle no further linguistic review.

[4] Word documents to be submitted in Microsoft Word 2007 file version ('.docx' files)

4. The linguistic review process for post-authorisation procedures

Detailed practical information regarding PI submission is available under Post-Authorisation Guidance on the Agency's website.

Where a linguistic review is considered necessary, the same general principles as for the post-opinion linguistic review for initial marketing authorisation applications will apply, as outlined in the section above.

4.1. Type II variations

For Type II variations affecting the product information, only the EN PI needs to be provided at submission.

For procedures starting on a weekly basis, the linguistic review will continue to follow the monthly review cycle, starting five days after the conclusion of the next applicable CHMP plenary meeting. The monthly linguistic review will consolidate all variations affecting the product information annexes concluded during that month. For more information on Type II variations starting on a weekly basis or following a monthly timetable, please consult the Post-authorisation guidance.

For the post-opinion linguistic review, the MAH will send the translations to the Member States Contact Points for Translations by Day +5 (i.e. 5 days after adoption of the Opinion) with a copy to the Agency.

Each translation will be subject to one Member States' linguistic review, co-ordinated by the national QRD member. QRD members will send their comments directly to the MAH with a copy the Agency at the latest by Day +19.

The MAH will send the final translations with tracked changes in Word format, incorporating the Member States' comments, as well as in clean Word and PDF format (see also User guide on how to generate PDF versions of the product information – human) together with the QRD form 2 to the Agency by Day +25. The Day +25 submission package should be presented in compliance with the Checklist.

The tracked changed product information files must include the statement containing the procedure number(s) and may be published on the EMA website as part of the product EPAR page.

The Agency will check if all Member States' comments have been implemented before sending the final translations to EC. In order to facilitate and accelerate the check of the implementation of the Member States' comments, the applicant should submit the QRD form 2 where they indicate for each language if all comments have been implemented.

Where comments have not been fully implemented, the applicant should provide a justification for the appropriate language(s) stating why certain comments are not reflected in the final texts. Such justification(s) and/or alternative proposals should be discussed and agreed with the relevant Member State(s) before submitting final translations to the Agency.

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 EC (see also section 6).

Commission Decisions on Type II variations shall be adopted without a Standing Committee procedure. Consequently, there will be no further revision of the translations of the Annexes after Day +27.

For procedures that will have a Commission Decision adopted within 12 months, the translations submitted at Day +25 will be considered as final. However, if it is necessary to make (minor) amendments to the Annexes, all official language versions of the Annexes will be sent to the MAH.

Following receipt of the final translations from the Agency, EC will start the Decision adoption process for variations listed in Article 23(1a)(a) of Regulation (EC) No 1234/2008.

For **urgent 30-day Type II variations**, in particular for safety issues, the MAH will have to send the translations to the Member States upon validation of the Type II variation.

The linguistic review will take place in parallel to the scientific assessment in order to accelerate the final approval of the Type II variation. Such cases will have to be discussed and agreed with the Agency before the start of the procedure.

In case the procedure affects only Annex II, deletions or minor changes to the EN PI, no post-opinion translation timetable may be considered on a case-by-case basis.

4.2. Type IA/IB variations

In case the Type IA/IB variation affects the PI, the complete set of Annexes is to be provided in all languages as part of the variation notification. The revised PI should be provided in Word tracked changed format.

As changes to the PI resulting from Type IA/IB variations are expected to be minimal, no check on the correct implementation of the variation changes in the EN language version will be performed by the Agency during the procedure.

For **Type IA variations**, no linguistic review of the PI in all other EU languages will be performed and the MAH will be responsible for ensuring the correctness of the translations.

For **Type IB variations** affecting the PI, as laid down in Art. 2(5) and Art. 3(2) of Commission Regulation (EC) No. 1234/2008, a linguistic review of the PI in all other EU languages will, in general, be required. The linguistic review will take place in parallel to the scientific assessment, and the same process as for type II variations will apply (see section 4.1)

4.3. Grouping

MAHs may choose to group the submission of several types of procedures affecting the same marketing authorisation. Such grouped submissions will follow the linguistic review process according to the highest procedure included in the group, e.g. a grouped submission of a line extension and Type II variation will follow the review of a line extension, or a grouped submission of a Type II variation and a Type IB variation will follow the review of a Type II variation.

However, in the EN PI **all** the changes from the procedures involved in the grouping will have to be incorporated in tracked changes. In this example, the submitted EN PI will include the changes from the line extension and the changes from the Type II variation.

For the post-opinion linguistic review, the same principles as for a line extension (see section 3) or for a Type II variation (see section 4.1) will apply, as appropriate. However, the MAH will submit the EN PI and all translations in tracked changes highlighting **all** the changes from the procedures involved in the grouping.

4.4. Worksharing variations (including at least one centrally authorised product)

MAHs may choose to submit the same Type IB or Type II variation, or the same group of variations affecting several authorised human medicinal products, which may not only include centrally authorised products (CAP) but also nationally authorised products (NAPs) from the same MAH in one submission. Line extensions are excluded from worksharing.

The linguistic review process described below only applies to CAPs as part of the worksharing procedure.

Worksharing submissions follow a 60- or 90-day timetable. For worksharing procedures including only type IB variations, the linguistic review will take place at Day +5 after the next available start date as published in the submission dates of Type IB variations requiring linguistic review.

At submission, for **all medicinal products** involved in the worksharing procedure, the EN PI in tracked changes must be provided.

However, for the post-opinion linguistic review, considering that the same change(s) should in principle apply to all CAPs involved in the worksharing submission, the linguistic review will only be performed on **one** set of annexes of **one CAP** involved in the worksharing. If the changes differ for the products involved in the worksharing procedure, the linguistic review will be performed on the product containing most of the changes. The MAH will submit only **one** set of translations for **one CAP** involved in the worksharing and the same principles as for a Type II variation will apply (see section 4.1).

Upon finalisation of the linguistic review, the MAH will correctly implement the same amendments in all the other CAPs, as appropriate. The MAH will send the final translations of **all medicinal products** involved in the worksharing procedure with tracked changes in Word format, incorporating the Member States' comments, as well as in clean Word and PDF format together with the QRD form 2 to the Agency by Day +25.

4.5. Article 61(3) Notifications

The complete set of Annexes is to be provided in all languages as part of the Art. 61(3) Notification submission. The revised PI should be provided in Word tracked changed format.

For Art. 61(3) with **minimal changes to PI** (e.g. minor editorial changes, alignment to QRD statements, etc.), no linguistic review of the PI in all other EU languages will be performed and the MAH will be responsible for ensuring the correctness of the translations.

For Art. 61(3) with **extensive changes to PI**, as laid down in Art. 2(5) and Art. 3(2) of Commission Regulation (EC) No. 1234/2008, a linguistic review of the PI in all other EU languages will, in general, be required. The linguistic review will take place in parallel to the scientific assessment, and the same process as for type II variations will apply (see section 4.1)

4.6. Annual re-assessment and Renewals

In case the Annual Re-assessment or Renewal affects the SmPC, Annex II, labelling and/or package leaflet, only the EN PI needs to be provided at submission.

For the post-opinion linguistic review, the same principles as for a Type II variation will apply (see section 4.1).

4.7. Referral procedures

Only the EN language version of SmPC, labelling and/or package leaflet, or parts thereof as applicable, needs to be provided during the procedure.

For the post-opinion linguistic review, the same principles as for a Type II variation will apply (see section 4.1).

Following receipt of the final translations of all applicable annexes from the Agency, the EC will start the 22-day Standing Committee consultation, addressing only legal and public health matters (which means in principle no further linguistic review).

For more details on the post-opinion linguistic review for both CAPs and NAPs involved in referral procedures, please refer to the information provided here.

4.8. PSUSAs and PASS results (107q)

For the post-opinion linguistic review, the same principles as for a Type II variation will apply (see section 4.1).

For more details on the post-opinion linguistic review for both CAPs and NAPs involved in PSUSA and PASS procedures, please refer to the information provided in the Post-authorisation guidance.

5. Generic, hybrid, biosimilar and informed consent new applications

The same general principles as for the post-opinion linguistic review for any new marketing authorisation application apply to generic, hybrid and biosimilar applications (see section 3). However, if another procedure for the reference product has been concluded at the same time, both procedures will follow a parallel linguistic review. In such a case, the Agency will send the highlighted English version of the final PI of the reference product to the applicant of the generic/biosimilar/hybrid application. As soon as the linguistic review for the reference product has been completed, the Agency will also send those translations to the applicant of the generic/biosimilar/hybrid product and request updated translations within 2 days.

In case another procedure for the reference product has been concluded at least one month or two months before, and no information has been published on the Agency's website, the Agency will proactively send the translations validated by the Member States to the applicant of the generic/biosimilar/hybrid product.

Where the existence of usage patent(s) leads to differences in SmPC/PL compared to the reference medicinal product, this should be indicated accordingly in the QRD form 2.

Apart from the specific sections of the product information that differ from the reference medicinal product (e.g. quality part), the product information annexes (in all other EU languages, including Icelandic and Norwegian) of the generic/biosimilar/hybrid applications should follow the respective approved product information annexes of the reference product. Format changes to the generic/biosimilar/hybrid SmPC in comparison to the reference medicinal product's SmPC are acceptable as long as the content remains consistent. The current QRD template and the SmPC guideline should be applied to the generic/biosimilar/hybrid SmPC as far as possible, if the relevant information is available (for details on the general principles regarding the SmPC information for a generic/biosimilar/hybrid product refer to relevant QRD guidance). Only the English product

information should indicate with tracked changes those sections which differ from the reference product.

For **informed consent applications**, no post-opinion linguistic review of the product information annexes will be performed, and the applicant/MAH will be responsible for ensuring compliance of the translations with the respective linguistic version(s) of the reference medicinal product.

6. The linguistic review process for small and medium-sized enterprises (SMEs) new applications

For the pre-opinion review, the same general principles as for the pre-opinion review of initial applications apply (see section 2).

For the post-opinion linguistic review, the same general principles as for an initial marketing authorisation application apply (see section 3), with the following exceptions:

- The SME applicant will provide **only** the English, Norwegian and Icelandic PI translations, together with the QRD Form 1 to the Agency.
- For **all other EU languages**, as part of the incentives offered to SMEs according to Article 11 of Regulation (EC) No 2049/2005, the Centre de Traduction (CdT) will provide translations of the adopted EN PI, on behalf of the SME applicant[5]. The Agency will coordinate the linguistic review between the Member States and the CdT.

Upon request, the SME applicant can take over the responsibility for the translation of certain EU languages and/or request the opportunity to comment on certain EU languages during the Member States review.

7. 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, industry will have to commit to providing good quality translations from a reputable provider specialised in medical terminology and to comply with Member States' comments. If a translation is considered to be of unacceptably poor quality, the Member State concerned should inform the applicant/MAH and the Agency within 3 days of receipt of the translation. The transmission to the Commission will be delayed until receipt of the amended translation (which would be expected to arrive within 1 week) and its subsequent linguistic check.

Applicants/MAHs 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 the QRD form 2.

In addition, applicants/MAHs are reminded that product information should be presented in strict compliance with the QRD Convention (e.g. format, layout, margins) and the User guide on how to generate PDF versions of the product information - human.

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 Key Performance Indicators.

[5] The SME incentive only applies to new applications; for post-authorisation procedures the general principles apply

8. Useful reference documents

Agency Linguistic review webpage:

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/linguistic-review-human

QRD Convention:

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/quality-review-documents-qrd-convention-be-followed-european-medicines-agency-qrd-templates_en.pdf

QRD Human Product Information Template with explanatory notes:

https://www.ema.europa.eu/en/documents/template-form/qrd-product-information-annotated-template-english-version-104_en.pdf

QRD Human Product Information Templates in all languages:

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

QRD Human Product Information ATMP Templates in all languages:

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

Annex A Human Template in all languages:

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

Annex related to the art.127a Human Template in all languages:

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

Annex IV conditional positive Human Template in all languages:

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

Annex IV exceptional circumstances positive Human Template in all languages:

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

Annex IV standard positive Human Template in all languages:

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

QRD Human Referral Templates:

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

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

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/member-states-contact-points-translations-review_en.pdf

QRD Reference Documents (on terminology and style):

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-reference-documents-guidelines-0

Relevant Human Guidelines (e.g. SmPC Guideline) and Notes for Guidance:

https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/how-prepare-review-summary-product-characteristics#scientific-guidelines-with-smpc-recommendations-9701

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

https://www.ema.europa.eu/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-human_en.pdf

Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products:

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF

EC Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products:

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:017:0001:0044:en:PDF

European Medicines Agency post-authorisation procedural advice for users of the centralised procedure:

https://www.ema.europa.eu/en/human-regulatory/post-authorisation

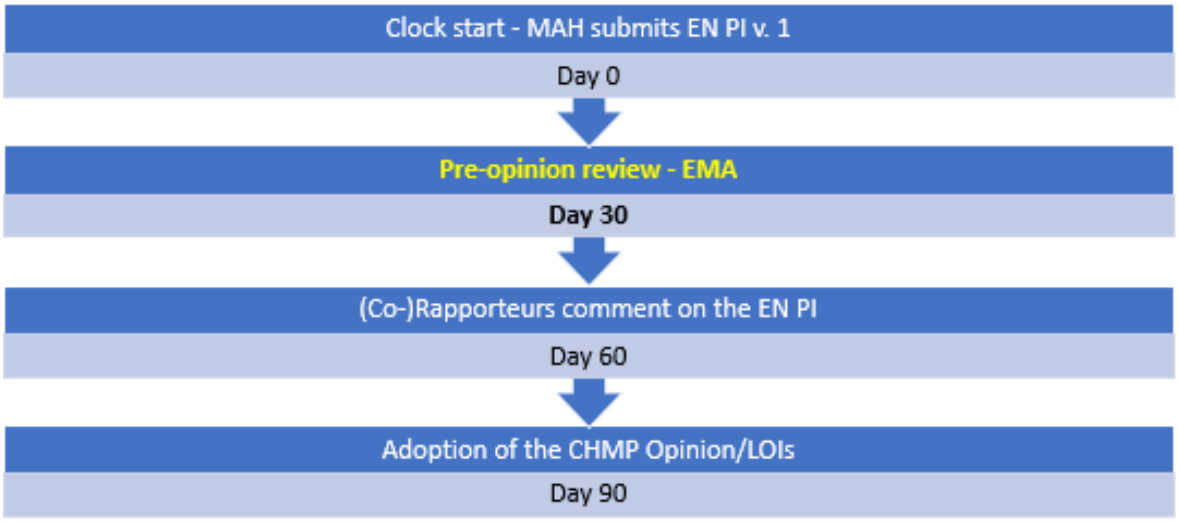
Submission dates of Type IB variations requiring linguistic review:

https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/submission-dates/procedural-timetables

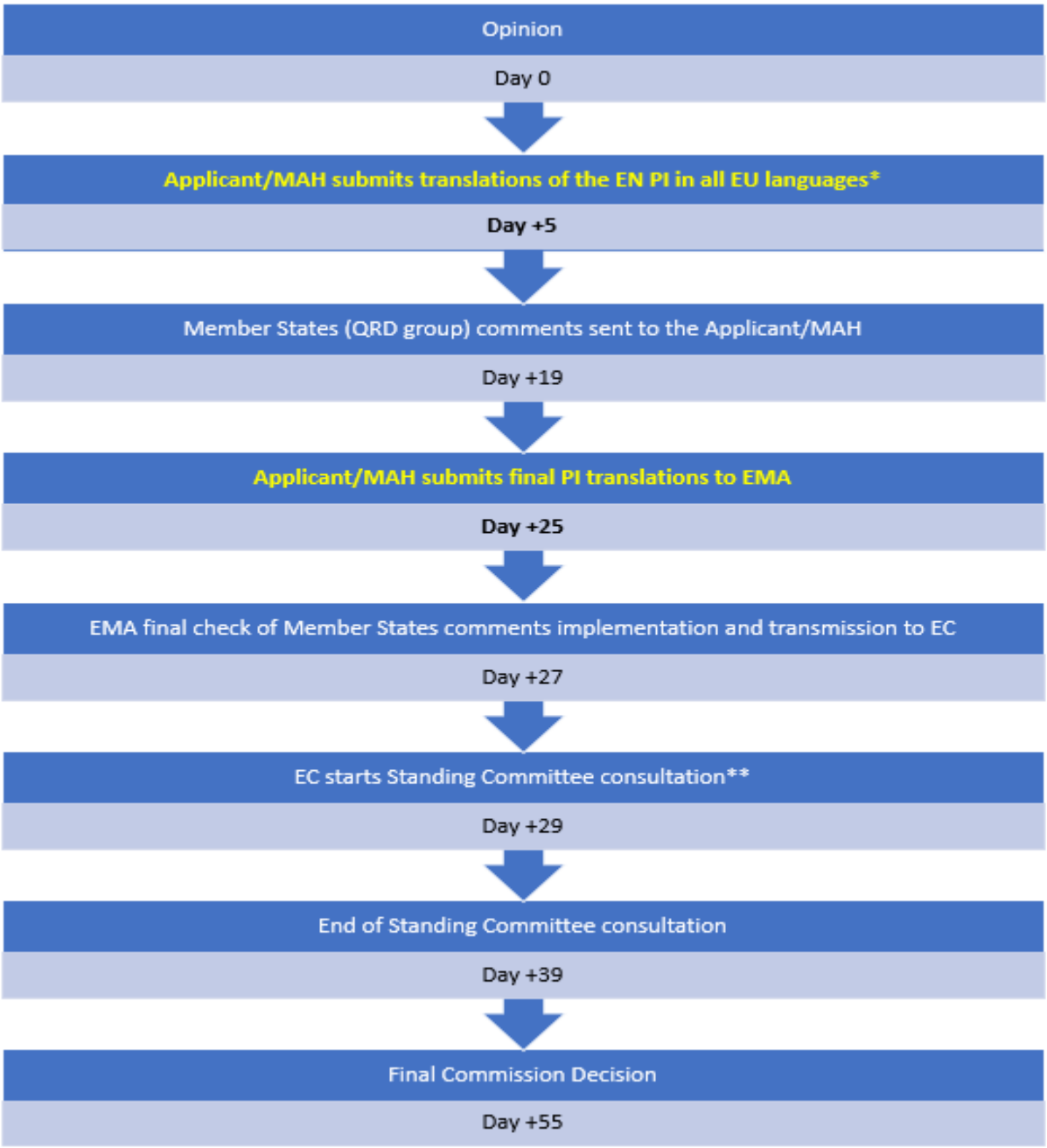
Annex I: Pre-opinion review timelines (EN PI only) for Initial Applications and Line Extensions

*not applicable to line extensions

Annex 2: Pre-opinion review timelines (EN PI only) for Renewals



Annex 3: Post-opinion linguistic review timelines (translations)



* For initial applications and line extensions the applicant/MAH sends translations to the EMA only (grd@ema.europa.eu); for all other post-authorisation procedures the MAH sends translations directly to the Member states contact points for translations

** Where applicable