EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Operational procedure on

The linguistic review process of product information in the centralised procedure - veterinary

1. Introduction

A linguistic review of product information[1] in all EU languages is performed after the adoption of CVMP Opinions to ensure high quality and consistent product information of Centrally Authorised Products (CAPs) in all Member States.

Such post-opinion 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.

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.

This document presents the product information linguistic review process within the DMP timeframes and provides details on its practical implementation.

2. The linguistic review process for new applications and extensions

The following process has been put in place for New Applications and Extensions, as illustrated by the attached timelines (Annex 1):

*The Linguistic Review Process of Product Information in the Centralised Procedure – Veterinary and related timetables have been updated to include: new requirements from Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human and veterinary medicinal products; information on the handling of urgent pre-opinion review(s) for exceptional cases (e.g. Pandemic crisis); a new section to cover the linguistic review process for Small and Medium-sized Enterprises (SMEs) new applications; information about the linguistic review for Informed consent new applications; clarification about Member States' comment(s) not implemented. The e-mail address for MAH/MSs to send translations/comments has been updated to "vet.translations@ema.europa.eu". Changes have also been made to reflect the new Agency corporate identity launched on the 8th of December 2009.

[1] Annex I Summary of Product Characteristics (SPC), Annex II Conditions, Annex III Labelling & Package Leaflet, Annex IV (when applicable)

At submission and during assessment, only the English language version (EN) of the product information is submitted and reviewed (see section 2.1 "pre-opinion"). Applicants may provide a combined Summary of product characteristics (SPC) and package leaflet text for different strengths of the same pharmaceutical form. Different pack-sizes of the same strength can be presented in one labelling text.

Further details on the presentation of product information text is available in the QRD Annotated EN template.

Translations of the agreed product information in all EU languages (including Icelandic and Norwegian) are to be provided after adoption of the CVMP EN opinion for linguistic review (see section 2.2 "post-opinion").

The standard timetable for provision of translations to the European Medicines Agency (hereinafter referred to as "Agency") is presented in Annex 2.

For applications which have been assessed by the CVMP in an "accelerated manner", the timeframes for the pre-opinion activities (see section 2.1.) may be adjusted accordingly, depending on the urgency by which the European Commission's Decision will need to be taken.

In exceptional cases where as a matter of urgency (e.g. pandemic crisis) a full QRD pre-opinion check (performed by Member States) will not be possible, the Agency may consider to only perform a PIQ Technical check (performed by the Agency).

2.1 Pre-opinion

The EN version of the product information will be subject to the following checks:

Check by	***When***	**Who**	**Scope**
Technical PIQ[2]	Day 70-100	Agency	Detailed review of the **EN** text
Agency/QRD	Day 121-165	Agency/QRD	Detailed review of the **EN** text

The Technical PIQ comments will be attached as an annex to the scientific comments and sent to the applicant as part of the list of questions at Day 120. Both types of comments are to be taken into account when submitting the revised EN product information as part of the answers to the list of questions at Day 121.

With regards to the Technical PIQ comments, applicants are requested to clarify in "PIQ" (Annex 7) if and why certain comments were not taken into account.

Upon receipt of the revised EN product information at Day 121, the Agency will review the implementation of the Technical PIQ comments by the applicant and will forward the revised EN product information to all QRD members for comments (via written procedure) by Day 155.

The Agency will send a compilation of the written QRD comments to the applicant at the latest by Day 155 (see also attached timeline).

When applicants are requested to provide additional EN versions (e.g. in preparation of an oral explanation at Day 181 or before adoption of the final opinion), these texts will not be subject to any

[2] Product Information Quality review group

formal linguistic review. However, applicants should inform the Agency if and why certain QRD comments were not taken into account. The Agency will check if all PIQ and QRD comments have been implemented before the opinion is adopted.

2.2. Post-opinion

Marketing Authorisation Holders (MAHs) should send the translations of the final EN product information annexes to the Agency at the latest by Day +5 after the CVMP opinion.

A correctly separated SPC and package leaflet per pharmaceutical form, containing all pack-sizes related to the pharmaceutical form concerned must be provided. The SPC and package leaflet can include all the strengths for each pharmaceutical form.

Translations of the adopted product information and Annex A[3] (list of products) in all other EU languages (including Icelandic and Norwegian[4]) as well as "QRD form 1" (Annex 8) are to be provided electronically (in one Eudralink package) to the Agency (qrd@ema.europa.eu)[5] by Day +5. In view of the short timeframe for finalisation of the translations and in order to optimise the quality of the translations, MAHs are strongly advised to initiate the translation process well in advance during the Pre-Opinion stage (e.g. after Day 155).

The following checks will apply:

Check by	***When***	**Who**	**Scope**
QRD 'Member State'	Day +5 to +19	Member States	Detailed review of all translations
PIQ	Day +25 to +27	Agency	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 MAH and copy to the Agency (qrd@ema.europa.eu) at the latest by Day +19 after the CVMP opinion together with an overall feedback on the quality of the translations - "QRD form 1" (Annex 8).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments in word format, as well as a PDF Format (clean), electronically to the Agency (qrd@ema.europa.eu) by Day +25.

Further details on the presentation of product information text are available in the QRD Annotated EN template.

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" (Annex 9) 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. 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.

[3] The EN version of Annex A is prepared by the Agency. MAHs will have to provide all other EU languages (including Icelandic and Norwegian). However, no linguistic review of Annex A is required.
[4] Details on the review of the Icelandic and Norwegian language versions are given in the Guidance document on Iceland and Norway.
[5] To obtain a Eudralink account, which allows for a secure e-mail service with the Agency, contact: eudralink@ema.europa.eu.

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 (see also section 5).

Following receipt of the final translations from the Agency, 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 applications which have been reviewed by the CVMP in an "accelerated assessment" procedure, the timeframes for the various post-opinion activities may be shortened on a case-by-case basis, depending on the urgency by which the Commission Decision will need to be taken.

3. The linguistic review process for post-authorisation procedures

Detailed practical information regarding product information submission (paper and/or electronic versions) is available in the Agency Post-Authorisation Guidance on the European Medicines Agency Website.

The same general principles as for the post-opinion linguistic review of New Applications apply, as illustrated by the attached timelines (Annex 3).

The standard timetable for provision of revised translations to the Member States/Agency, which will be adopted by the CVMP, is presented in Annex 4.

3.1. Type IA/IB variations

In case the Type IA/IB variation affects the product information Annexes, the complete set of Annexes is to be provided electronically in all languages on CD-ROM/DVD as part of the variation notification or via Eudralink. The revised Annexes should be presented with all proposed changes 'accepted' (so-called 'clean' version).

As changes to the product information resulting from Type IA/IB notifications are expected to be minimal, no linguistic review on the correct implementation of the variation change in the EN language version will be performed by the Agency during the procedure.

For **Type IA variations**, no linguistic review of the product information Annexes in all other EU languages (including Icelandic and Norwegian) will be performed and the MAH will be responsible for ensuring the correctness of the translations.

For **Type IB variations**, as laid down in Art. 2(5), and Art. 3(2) of Commission Regulation (EC) No. 1234/2008 and affecting the product information, a linguistic review of the product information annexes in all other EU languages (including Icelandic and Norwegian) will, in general, be required.

The linguistic review will take place in parallel to the scientific assessment (see Timetable template in Annex 4). Translations of the product information in all 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 validation**) and copy to the Agency (vet.translations@ema.europa.eu).

Comments will be sent directly by the Member States to the MAH at the latest by Day +19 (i.e. 19 days **after validation**), with copy to the Agency (vet.translations@ema.europa.eu).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments in Word format, as well as in PDF format (clean), electronically to the Agency (vet.translations@ema.europa.eu) by Day +25 (i.e. 25 days **after validation**). Translations of the

revised Annex A only need to be sent to the Agency (vet.translations@ema.europa.eu) (i.e. 5 days **after validation**), if applicable.

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" (Annex 9) 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. 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.

3.2. Type II variations

For Type II variations affecting the product information, only the EN language version needs to be provided at submission. 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 CVMP Opinion) and copied to the Agency (vet.translations@ema.europa.eu). Translations of the revised Annex A only need to be sent to the Agency (vet.translations@ema.europa.eu) by Day +5, if applicable.

The following checks will apply:

Check by	***When***	**Who**	**Scope**
QRD '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 after the CVMP opinion, with a copy to the Agency (vet.translations@ema.europa.eu).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments, in Word Format, as well as a PDF format (clean), electronically to the Agency (vet.translations@ema.europa.eu) by Day +25 after the CVMP opinion.

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" (Annex 9) 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. 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 the Commission (see also section 5).

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 after the CVMP opinion.

Following receipt of the final translations from the Agency, the Commission will start the Decision adoption process.

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 (see Timetable template in Annex 4). Such cases will have to be discussed and agreed with the Agency before the start of the procedure.

3.3. Grouping

MAHs may choose to group the submission of several Types of procedures of the same Marketing Authorisation. Such grouped submissions will follow the linguistic review process according to the highest procedure included in the group:

Grouping examples:

a) Extension + Type II variation => will follow the linguistic review process of an Extension.

- Pre-opinion: The same principles as for the pre-opinion linguistic review of an Extension apply, as illustrated by the attached timelines (Annex 1). However, in the EN language version **all** the changes from the procedures involved in the group will have to be incorporated in track changes. In this example, the submitted EN language version will include changes from the Extension + changes from the type II variation.
- Post-opinion: The same principles as for the post-opinion linguistic review of an Extension apply, as illustrated by the attached timelines (Annex 1). However, at Day +5 after the CVMP opinion, the MAH will submit the English and all other EU languages product information Annexes (including Icelandic and Norwegian) in tracked changes highlighting all the changes from the procedures involved in the group.

  The MAH will send the final translations with tracked changes, incorporating the Member States' comments in Word format, as well as PDF Format (clean), electronically to the Agency (qrd@ema.europa.eu) by Day +25 after the CVMP opinion.

b) Type II + Type IB variation => will follow the linguistic review process of a Type II variation

- Post-opinion: The same principles as for the post-opinion linguistic review of a Type II variation apply, as illustrated by the attached timelines (Annex 3). However, at Day +5 after the CVMP opinion, the MAH will submit the English and all other EU languages product information Annexes (including Icelandic and Norwegian) in tracked changes highlighting all the changes from the procedures involved in the group. In this example, the English and all other EU languages product information Annexes (including Icelandic and Norwegian) will include changes from the Type II variation + changes from the Type IB variation.

  The MAH will send the final translations with tracked changes, incorporating the Member States' comments in Word format, as well as PDF Format (clean), electronically to the Agency (vet.translations@ema.europa.eu) by Day +25 after the CVMP opinion.

The submission dates for Type IB variations requiring linguistic review (as published on the Agency website) are not applicable for type IB variations submitted as part of a group.

3.4 Worksharing including at least one centrally authorised product (CAP)

MAHs may choose to submit the same Type IB or Type II variation, or the same group of variations affecting more than one CAP from the same MAH in one submission. Extensions are excluded from worksharing.

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

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; 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.

Upon finalisation of the linguistic review, it will be up to the MAH to correctly implement the same amendments in all the other CAPs, as appropriate.

- For worksharing submissions including a type II variation:

  At submission and for **all products** involved in the worksharing procedure, the EN language versions (with track changes) of the Product Information are to be provided.

  However, post-opinion, only **one** set of Annexes (EN + translations in all other EU languages, including Icelandic and Norwegian) for **one CAP** is 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 CVMP opinion) with copy to the Agency (vet.translations@ema.europa.eu).

  Comments will be sent directly by the Member States to the MAH at the latest by Day +19, with a copy to the Agency (vet.translations@ema.europa.eu).

  The MAH will send the final translations of **all products** involved in the worksharing procedure, with tracked changed, incorporating the Member States' comments in Word format, as well as in PDF Format (clean), electronically to the Agency (vet.translations@ema.europa.eu) by Day +25 (i.e. 25 days after adoption of the CVMP opinion). Translations of the revised Annex A only need to be sent to the Agency (vet.translations@ema.europa.eu) by Day +5, if applicable.

- For Worksharing submissions including **only** type IB variations:

  At submission and for **all products** involved in the worksharing procedure, the EN language versions (with track changes) of the Product Information are to be provided.

  The linguistic review will only be performed on one set of Annexes (EN + translations in all other EU languages, including Icelandic and Norwegian) for **one CAP**. The linguistic review will take place in parallel to the scientific assessment and will follow the principles as outlined in section 3.1 for Type IB variations

The submission dates for Type IB variations requiring linguistic review (as published on the Agency website) are not applicable for type IB variations included in a worksharing submission. Worksharing submissions follow 60 or 90 day timelines.

The standard timetable for provision of revised translations to the Member States/Agency, which will be adopted by the CVMP, is presented in Annex 4.

3.5. Annual re-assessment and renewals

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

During the scientific assessment, a detailed pre-opinion review of the EN product information will be performed by the Agency (PIQ) and QRD members. PIQ/QRD comments will be sent to the MAH by Day 75. When providing a revised EN version for adoption of the opinion, the MAH should inform the Agency if and why certain PIQ/QRD comments are not taken into account.

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 and copied to the Agency (vet.translations@ema.europa.eu).

The following checks will apply:

Check by	***When***	**Who**	**Scope**
QRD/CVMP '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 Agency (vet.translations@ema.europa.eu).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments in Word format, as well as in PDF format (clean), electronically to the Agency (vet.translations@ema.europa.eu) 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" (Annex 9) 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. 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 the Commission (see also section 5).

Following receipt of the final translations from the Agency, 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).

In case the Annual Re-assessment or Renewal affects only Annex II, none or a shorter post-opinion translation timetable may be considered by the Agency on a case-by-case basis.

3.6. The linguistic review process for referral procedures

The same general principles as for the post-opinion linguistic review of New Applications apply, as illustrated by the attached timeline (Annex 5):

Only the EN language version of SPC, labelling and/or package leaflet needs to be provided at submission[6].

[6] For referrals according to Art 35 (2), this may be limited to specific parts of the product information only.

Translations of the adopted Annex I (list of products) and Annex III (SPC, labelling and package leaflet text) 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 (= 5 days after adoption of the CVMP opinion) and copied to the Agency (vet.translations@ema.europa.eu).

The following checks will apply:

Check by	***When***	**Who**	**Scope**
QRD/ 'Member State'	Day +5 to +19	Member States	Detailed review of all translations
PIQ	Day +22 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 Agency (vet.translations@ema.europa.eu).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments, electronically to the Agency (vet.translations@ema.europa.eu) by Day +22.

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" (Annex 9) 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. 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 the Commission (see also section 5).

Following receipt of the final translations of the product information (Annex III), Annex I (list of products), Annex II (scientific conclusions) and Annex IV (conditions) from the Agency, 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).

The standard timetable for provision of translations to the Member States/Agency, which will be adopted by the CVMP, is presented in Annex 6.

4. The linguistic review process for generic, hybrid biosimilar and informed consent new applications

The same overall decision-making and linguistic review process will apply to generic, hybrid, biosimilar and Informed consent applications as for any new marketing authorisation application.

However, for generic applications the EN version of the product information will only be subject to a PIQ Technical check (performed by the Agency) both by Day 100 and by Day 155. A QRD pre-opinion check (performed by the Member States) will not be required.

For hybrid and biosimilar applications a normal QRD pre-opinion check (performed by the Member States) will be performed.

For informed consent applications only a PIQ Technical check will be performed by the Agency by Day 60.

The same general principles as for the post-opinion linguistic review for any new marketing authorisation application apply. Where there are differences in SPC/PL compared to the reference medicinal product, this should be indicated accordingly in the e-mail when sending translations to the Agency.

Apart from the specific sections of the product information (e.g. Quality part) that differ from the reference medicinal product, the product information annexes (in all other EU languages, including Icelandic and Norwegian) of the generic, hybrid and biosimilar applications should follow the respective approved product information annexes of the reference product. 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 in all other EU languages (including Icelandic and Norwegian) will be performed and the MAH will be responsible for ensuring compliance of the translations with the respective linguistic version(s) of the reference medicinal product.

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

The same general principles as for the pre-opinion linguistic review of New Applications apply, as illustrated by the attached timeline (Annex 1).

However, at Day +5 after the CVMP opinion, the Centre de traduction (Cdt) will provide translations of the adopted product information and Annex A (list of products) in all other EU languages (**excluding** Icelandic and Norwegian) electronically to the Agency, on behalf of the SME in question.

The SME applicant will provide the English adopted product information together with the Norwegian and Icelandic translations and Annex A (list of products) as well as "QRD form 1 (Annex 8).

Upon request, the SME applicant can have the possibility of taking over responsibility for the translation of certain EU languages and/or request the opportunity to comment on certain EU languages during the Member States review (for details on the procedure to request responsibility for translation and/or opportunity to comment please refer to SOP/EMA/0100).

The Agency will provide translations of the adopted product information and Annex A (list of products) as well as "QRD SME-Cdt Form 1" (Annex 10) electronically to all Member States (including Iceland and Norway).

Each translation will be subject to one Member State's linguistic review, co-ordinated by the national QRD member. QRD members will send their comments directly to the Agency (qrd@ema.europa.eu) at the latest by Day +19 together with an overall feedback on the quality of the translations and the "QRD SME-Cdt Form 1" (Annex 10).

The Cdt will send the final translations with tracked changes, incorporating the Member States' comments, in Word format as well as clean documents and the "QRD SME-Cdt Form 2" (Annex 11), electronically to the Agency (qrd@ema.europa.eu) by Day +25.

The SME applicant will provide the Norwegian and Icelandic final translations with tracked changes, incorporating the Member States' comments, in Word format, as well as in PDF format (clean),

together with the "QRD form 2" (Annex 9), electronically to the Agency (qrd@ema.europa.eu) by Day +25.

The timetables for provision of translations which will be adopted by the CVMP are presented in Annex 12 and Annex 13.

6. Implementation and 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 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 a revised timetable will be prepared.

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 "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).

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.

7. Useful reference documents

- QRD Convention:
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf
- QRD Veterinary Product Information Templates:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d9b0
- QRD Veterinary Product Information Template with explanatory notes;
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005257.pdf
- Annex A Veterinary Template in all languages
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000185.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058002d9b0#section1
- 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):
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000253.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008af8a
- Relevant Veterinary Guidelines (e.g. SPC Guidelines) and Notes for Guidance:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000253.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008af8a
- Guidance document for industry, with regard to the extension of the Centralised Procedure, Referral procedures, Parallel Distribution/Import and Pharmacovigilance Requirements to Iceland and Norway:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000028.jsp&mid=WC0b01ac0580022716

- 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

http://ec.europa.eu/health/files/eudralex/vol-1/reg_2008_1234/reg_2008_1234_en.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
- 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

http://ec.europa.eu/health/files/eudralex/vol-2/c17_1/c17_1_en.pdf

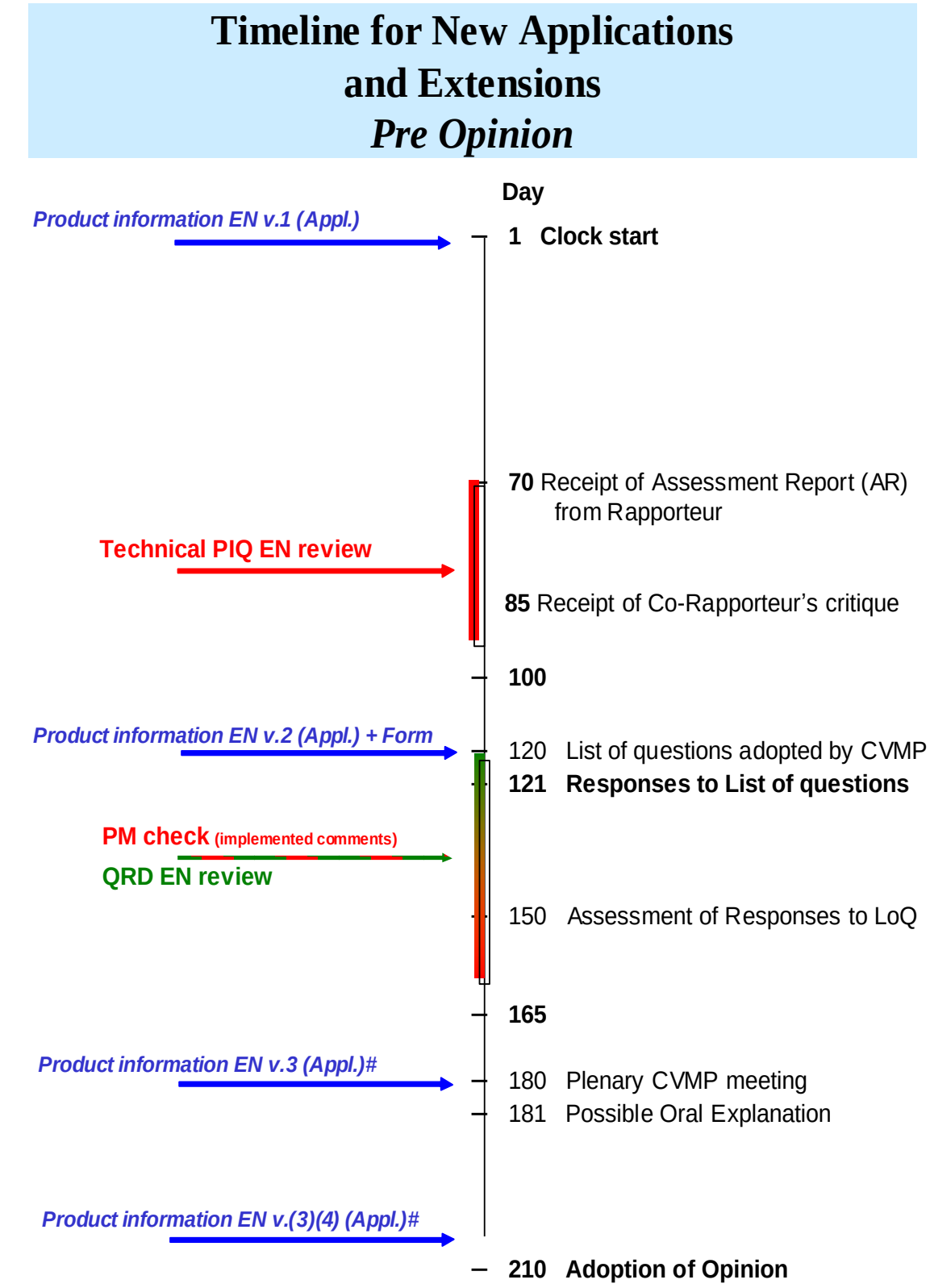
- PIQ/QRD Pre-opinion Review of Product Information for Referral Procedures and Article 29 Paediatric Procedures

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

- Translation of product information for SME applicants of the centralised procedure

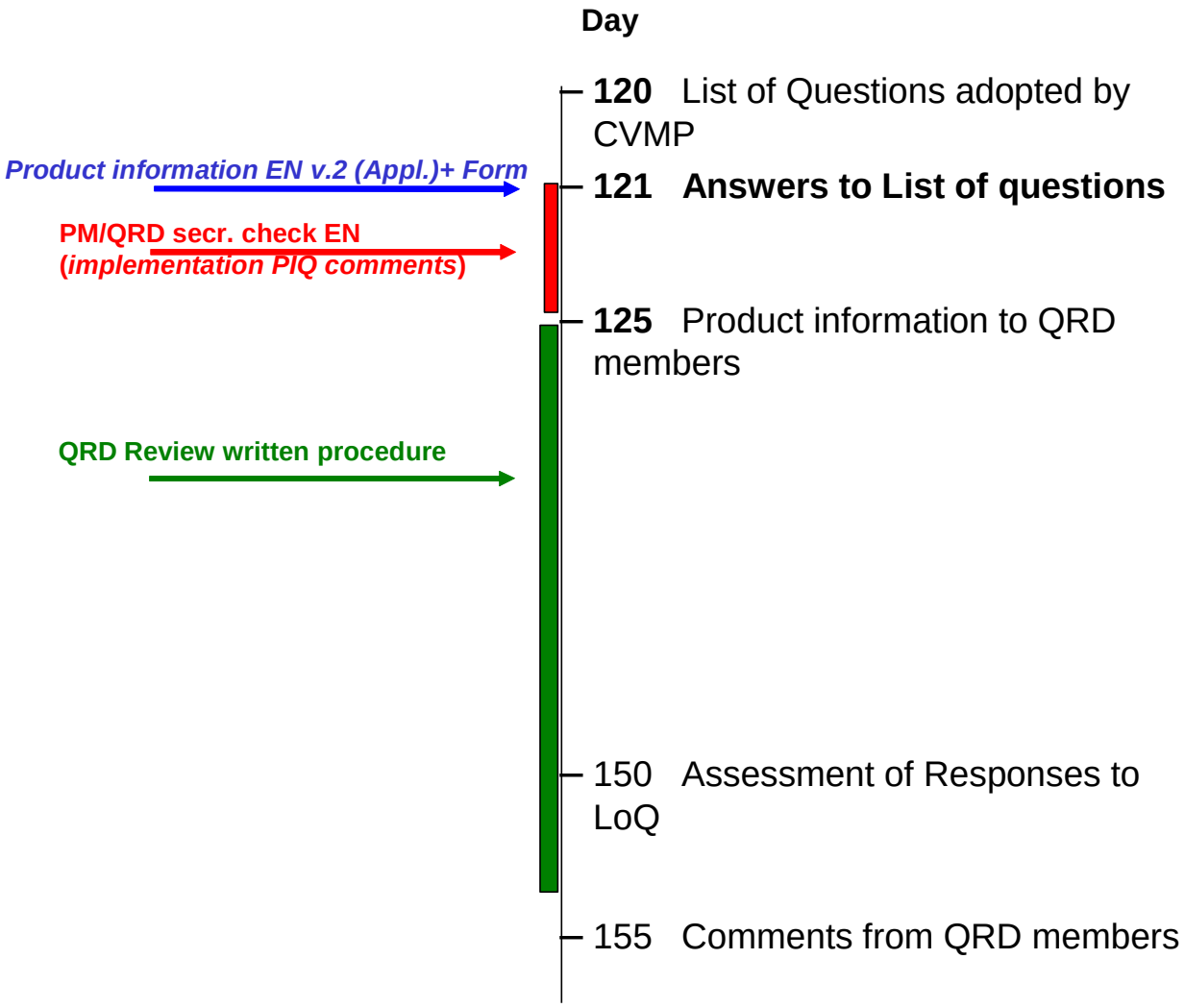
http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2010/06/WC500093989.pdf

Annex 1 – Timeline for new applications and extensions

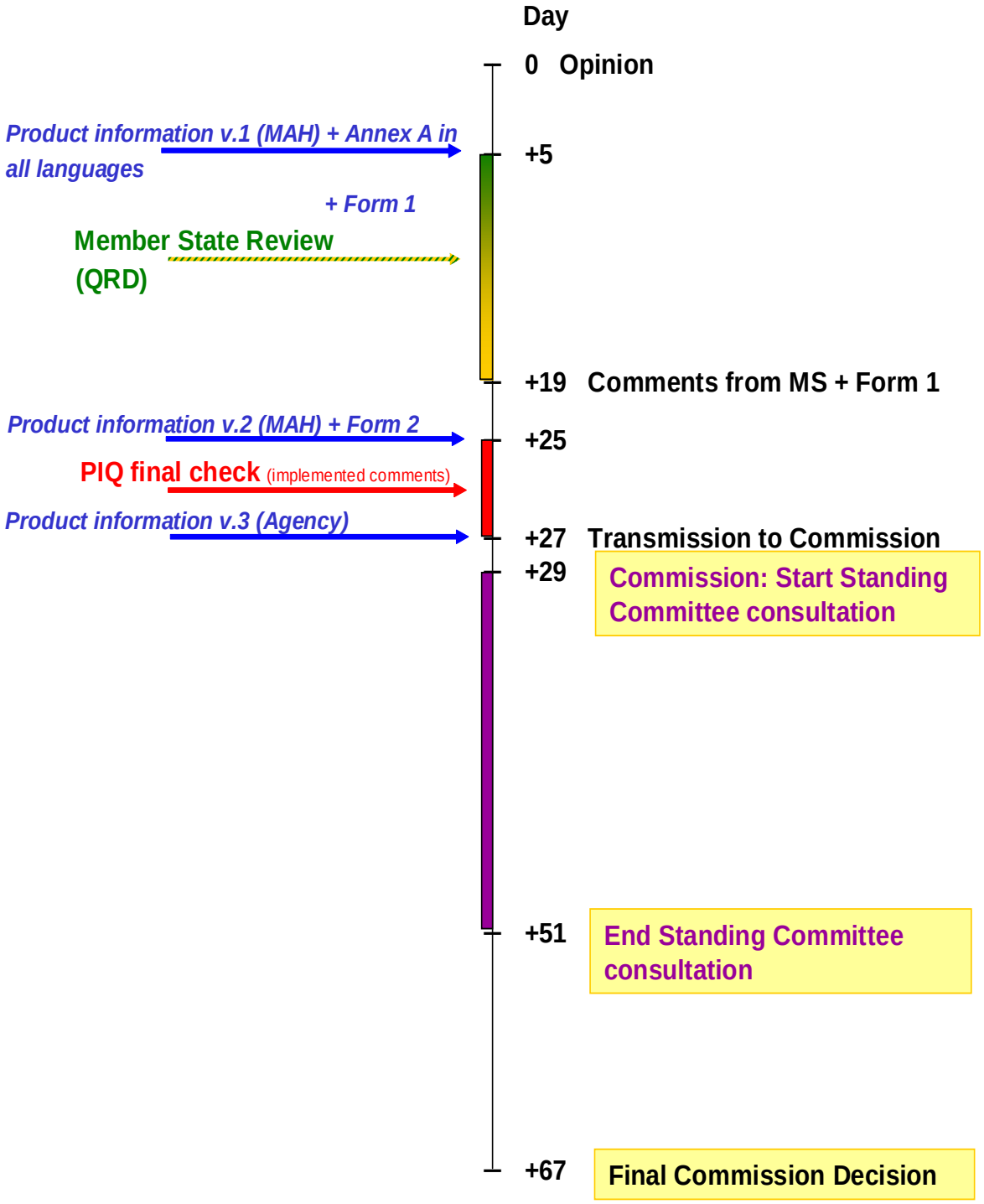


version not subject to linguistic check

Timeline
for Review of Product Information
Pre Opinion –AGENCY/QRD Review of EN



Timeline for New Applications and Extensions *Post Opinion*



Annex 2 – Timetable for new applications and extensions

Timetable for the finalisation of the CVMP opinion & Annex A, Annex I Summary of Product Characteristics, Annex II and Annex III Labelling and Package Leaflet <and Annex IV♣> in all EU Languages

PRODUCT EMEA/V/C/XXX/

The applicant will provide the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <(and Annex IV)> and Annex A° in all EU languages (incl. EN◇, NO and IS) to the Agency (+QRD Form# 1) by e-mail§ (qrd@ema.europa.eu) or on CD Rom:		<Text> *(5 days after opinion)*
Member States will send linguistic comments on the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <and Annex IV> to the applicant by e-mail§ with a copy to the Agency (qrd@ema.europa.eu) together with QRD Form# 1, by:		<Text> *(19 days after opinion)*
The applicant will implement the required changes, compile the translations* and send these to the Agency (+ QRD Form# 2) by e-mail§ (qrd@ema.europa.eu) or on CD Rom, by:		<Text> *(25 days after opinion)*
Agency will compile the EN Opinion and Annexes in all languages and send final copies to the Commission, Members of the Standing Committee and the applicant, by:		<Text> *(27 days after opinion)*

<♣ Annex IV relates to "conditions or restrictions with regard to the safe and effective use to be implemented by Member States" (when applicable)>

◇ For generics/hybrid/biosimilar applications the English product information should indicate those sections which differ from the reference product.

° Annex A is to be provided as a separate word document per language

Downloadable at the European Medicines Agency Website (Website)

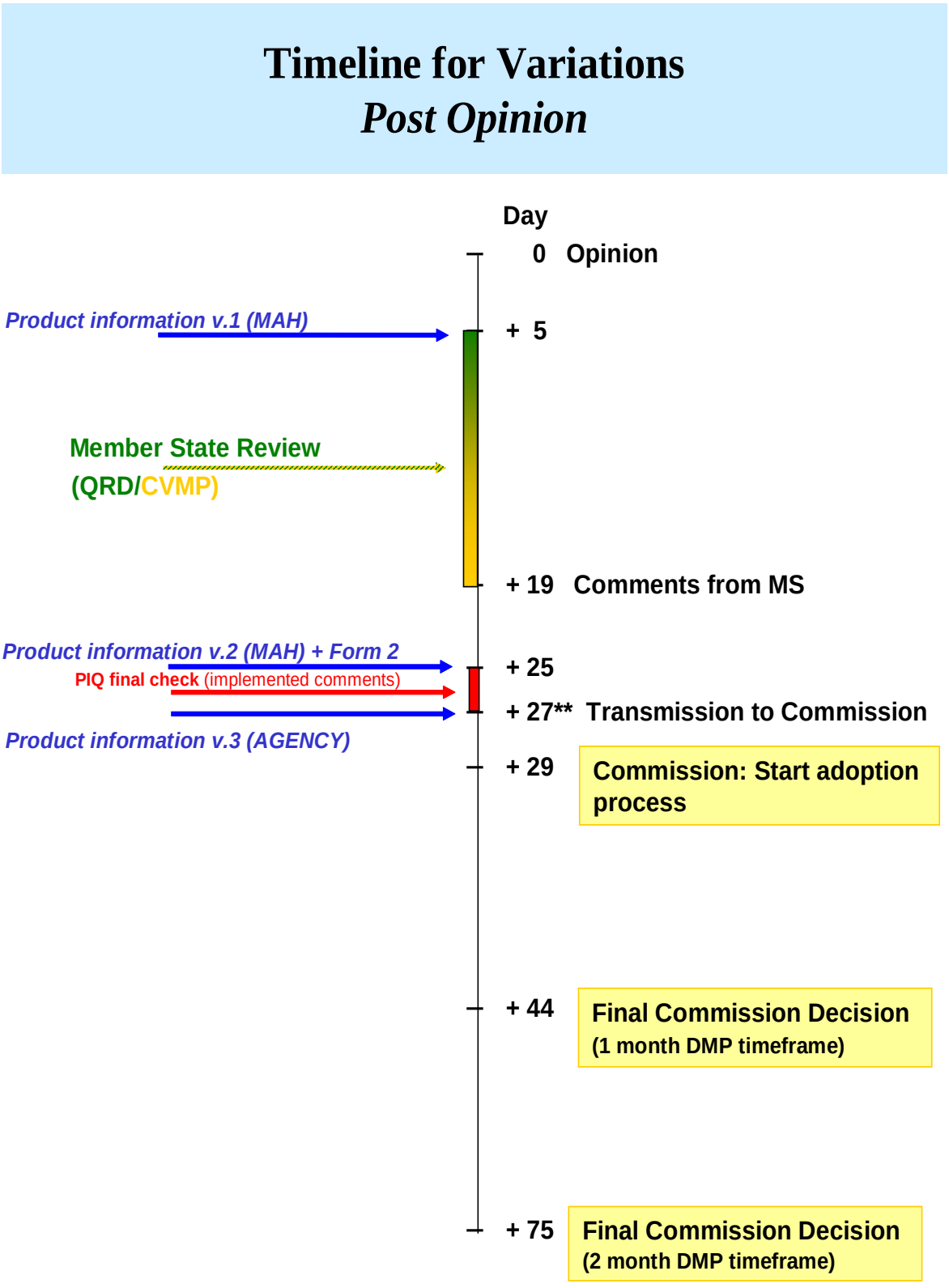
§ The e-mail title should clearly specify the (invented) name of the medicinal product, the Procedure number and the Day in the procedure to which the translations relate (e.g. Day 215)

* The final product information i.e. Annex I, II, IIIA and IIIB must be submitted electronically as one clean PDF file for each official EU language (incl. EN, NO and IS) together with the word files highlighted with tracked changes (see also the User guide on the preparation of PDF versions of the product information). The translations must be accompanied by the completed check list.

Annex IV (when applicable) must be presented as a separate PDF document with "IV" removed from the title page together with the word files highlighted with tracked changes. All translations should be numbered as **ONE** document, starting with "1" (bottom, centre) on the title page of Annex I and Annex (IV) when applicable.

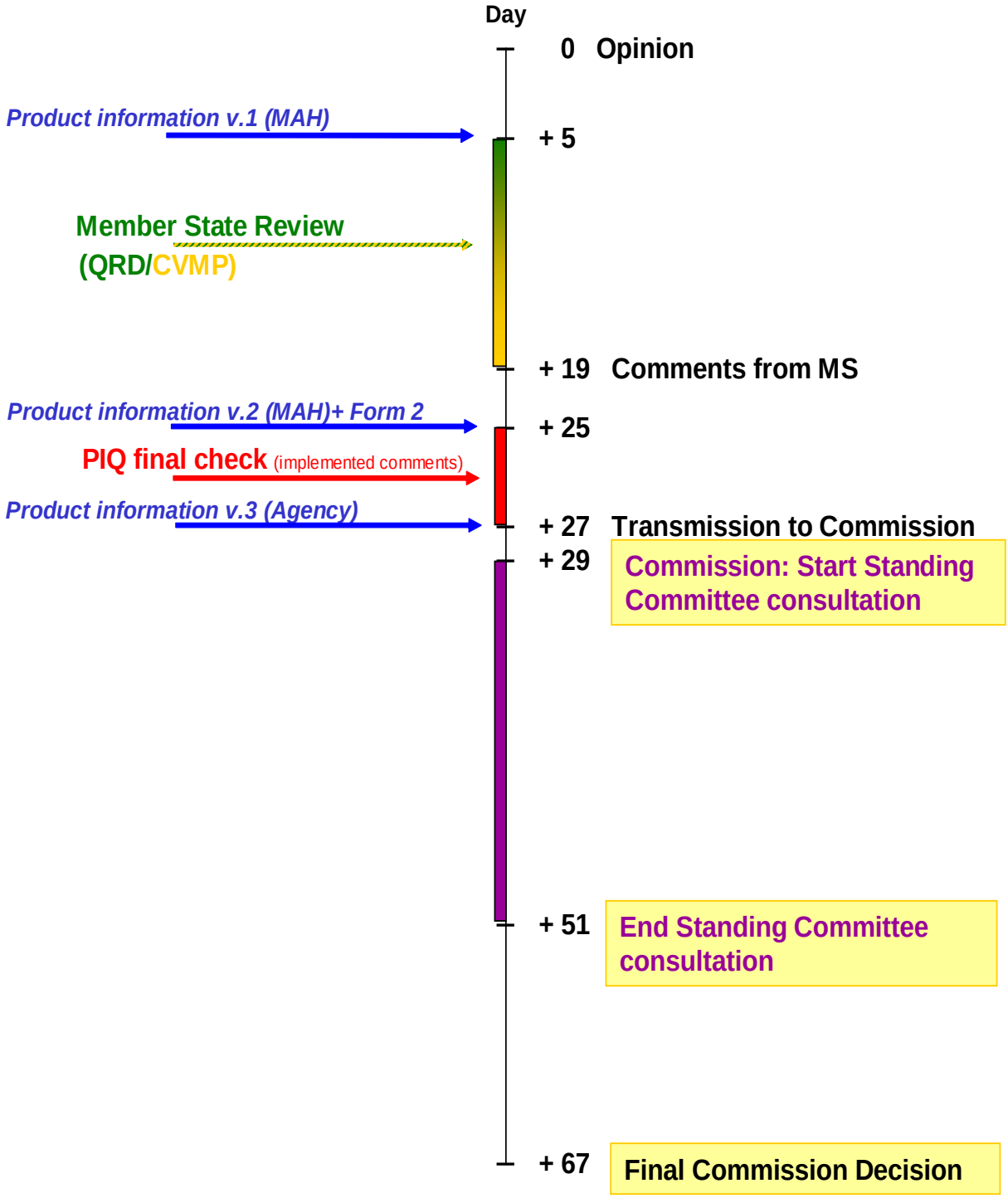
The Annexes should be presented in strict compliance with the QRD Convention.

Annex 3 – Timeline for type II variations, renewals, annual re-assessments



** Although, the legal timeframes foresee +30 or +60 days for the Final EC Decision, the Agency will adhere to the current linguistic timeframes and provide the final Annexes in all languages to EC by Day +27

Timeline for Renewals/Annual Re-Assessment
Post Opinion



Annex 4 – Timetable for type II variations, renewals, annual re-assessments

Timetable for the finalisation of the CVMP opinion & Annex A *(if amended)*, Annex I Summary of Product Characteristics, Annex II and Annex III Labelling and Package Leaflet <and Annex IV♣> in all EU Languages

<PRODUCT> EMEA/V/C/XXX/

The MAH will provide the product information◇ <and Annex IV> in all EU languages (incl. EN, NO and IS) to the Member States by e-mail§, with a copy to the Agency (vet.translations@ema.europa.eu). <The MAH will provide the revised Annex A° in all EU languages to the Agency (vet.translations@ema.europa.eu)>, by:		<Text> *(5 days after opinion)* *(5 days after validation)*$
Member States will send linguistic comments on the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet+ <and Annex IV> to the MAH by e-mail§ with a copy to the Agency (vet.translations@ema.europa.eu)>, by:		<Text> *(19 days after opinion)* *(19 days after validation)*$
The MAH will implement the required changes, compile the translations* and send these to the Agency (+ QRD Form# 2) by e-mail§ (vet.translations@ema.europa.eu), by:		<Text> *(25 days after opinion)* *(25 days after validation)*$
The Agency will compile the EN Opinion and the Annexes in all languages and send final copies to the Commission, Members of the Standing Committee[7] and the MAH, by:		<Text> *(27 days after opinion)* *(within 5 days after opinion)*$

<♣ Annex IV relates to "conditions or restrictions with regard to the safe and effective use to be implemented by Member States" (when applicable)>

[7] For information only for Type II variations, as Commission Decisions on Type II variations shall be adopted without a Standing Committee consultation procedure.

◇ The full set of annexes i.e. Annex I, II, IIIA, IIIB and IV (when applicable) must be submitted electronically for each official EU language as one word document (highlighted with tracked changes) per language. All translations should be numbered as **ONE** document, starting with "1" (bottom, centre) on the title page of Annex I.

§ The e-mail title should clearly specify the (invented) name of the medicinal product, the procedure number and the Day in the procedure to which the translations relate (e.g. Day +5)

$ For urgent 30 day Type II variations and Type IB variations requiring linguistic review.

° The revised Annex A, where applicable, is to be provided as a separate word document per language.

+ For Type II variations and Annual Re-Assessments and annual renewals (conditional MA): check of highlighted changes only.

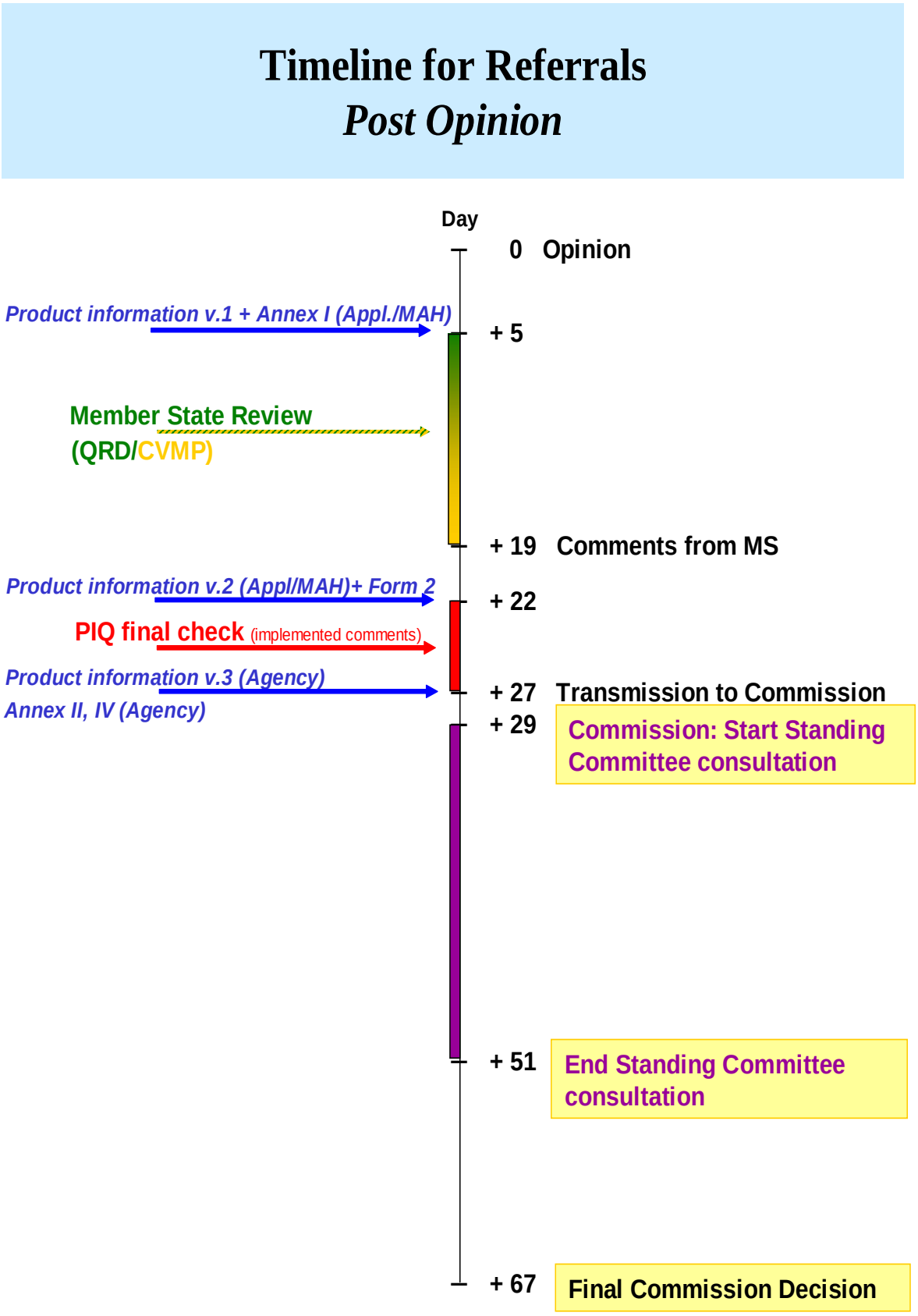
Downloadable at the European Medicines Agency Website (Website)

* The final product information i.e. Annex I, II, IIIA and IIIB must be submitted electronically as one clean PDF file for each official EU language (incl. EN, NO and IS) together with the word files highlighted with tracked changes (see also the User guide on the preparation of PDF versions of the product information). The translations must be accompanied by the completed check list

.

Annex IV (when applicable) must be presented as a separate word document with "IV" removed from the title page. All translations should be numbered as **ONE** document, starting with "1" (bottom, centre) on the title page of Annex I and Annex (IV) when applicable. The Annexes should be presented in strict compliance with the QRD Convention.

Annex 5 – Timeline for referrals



Annex 6 – Timetable for referrals

Timetable for the finalisation of the CVMP opinion & Annex I, Annex III Summary of Product Characteristics, Labelling and Package Leaflet in all EU Languages

<PRODUCT>

EMEA/V/A-xx/XXX

The MAH will provide the product information* and Annex I in all EU languages (incl. EN, NO and IS) to the Member States by e-mail[§], with a copy to the Agency (vet.translations@ema.europa.eu),by:		XXX *(5 days after opinion)*
Member States will send linguistic comments on the Summary of Product Characteristics, Labelling and Package Leaflet to the MAH by e-mail[§] with a copy to the Agency (vet.translations@ema.europa.eu),by:		XXX *(19 days after opinion)*
The MAH will implement the required changes, compile the translations* and send these to the Agency (+ QRD Form[#] 2) by e-mail[§] (vet.translations@ema.europa.eu), by:		XXX *(22 days after opinion)*
Agency will compile the EN Opinion and the Annexes in all languages and send final copies to the Commission, Members of the Standing Committee and the MAH, by:		XXX *(27 days after opinion)*

[#] Downloadable at the European Medicines Agency Website

[§] The e-mail title should clearly specify the (invented) name of the medicinal product, the Procedure number and the Day in the procedure to which the translations relate (e.g. Day +5)

* Annex I and III (clean and highlighted with tracked changes) must be submitted electronically for each official EU language as one combined word document per language, presenting the Annexes in the following order:

Annex I

all SPCs

all Labelling

all PLs

The order of the strengths and pharmaceutical forms within Annex III should follow the order of the Annex I.

All translations should be numbered as **ONE** document, starting with "1" (bottom, centre) on the title page of Annex I. The Annexes should be presented in strict compliance with the QRD Convention.

Annex 7 – PIQ form

PIQ Form:
For applicants when submitting revised English product information to the European Medicines Agency

DAY 121

(Applicant to complete by day 121 and include in the answers to the list of questions)

Product Name	:	
Application Number	:	
Applicant Name & Address	:	
Details of applicant's contact person ***(Name, tel, fax & E-mail)***	:	

All Technical PIQ comments implemented	:	**EN** ☐

Tick the box if appropriate

If not, a justification should be provided stating why certain comments are not reflected in the revised version. Please indicate, as presented below, the document (SPC, Annex II, labelling or package leaflet) and section to which the disputed comment relates together with an alternative proposal.

- SPC

Section Title & Paragraph	Comment	Alternative proposal

Annex 8 – QRD form 1

QRD Form 1:
For Member States' product information check

DAY 229

(Applicant to complete Section 1 and to send to the Agency by Day 215)
(MS to complete Section 2 and to send to applicant and Agency by Day 229)
(NO and IS to send to applicant and Agency upon finalisation of the check)

SECTION 1:

Application Details (to be completed by the applicant):

Product Name	:	
Application Number	:	
Grouping submission		Yes☐ No☐
Applicant Name & Address	:	
Details of contact person for translations (Name, tel, fax & E-mail)	:	
Rapporteur and Co-Rapporteur	:	
Product Team Leader / Project Manager	:	
Extensions ONLY	:	*<Provide here a short description of the differences between the already authorised presentations and the new extension (e.g. indicate sections amended)>*

SECTION 2:

Product information check (to be completed by Member States):

Language :	**BG**	**CS**	**DA**	**DE**	**EL**	**ES**	**ET**	**FI**	**FR**	**HU**	**IS**	**IT**
	LT	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**	

Details of MS contact for translations check :	
Total checking time (hours) :	

	YES	**NO**
Assisted by CVMP member and/or assessors :		
Assisted by other staff members :		
Assisted by Standing Committee member :		

	VG	**G**	**A**	**UN***
Overall quality of translation :				
• **SPC** :				
• **Annex II**				
• **Labelling** :				
• **Package Leaflet** :				
• **Annex IV (if applicable)**				

(VG=Very Good; G= Good, A = Acceptable; UN=Unacceptable)

* If unacceptable, return translation **within 3 days** to the applicant (copy Agency) and include an explanation in the box below.

The translation was unacceptable because:

Nature of comments:

	M	**S**	**F**
Missing words or sentences :			
Scientific incorrect translations (e.g. terminology) :			

Inaccuracies (incorrect translations – incl. spelling, punctuation, grammatical mistakes)				
Editorial, stylistic changes (e.g. rephrasing)	:			

(M=Many; S=Several; F=Few)

Any other comments (e.g. formatting problems):

Date of completion of form	:	

Annex 9 – QRD form 2

QRD Form 2:
For applicants when submitting revised translations to the European Medicines Agency

DAY 235 / DAY + 25

(Applicant to complete by Day 235 and send to QRD Secretariat)
(Applicant to complete by Day +25 and send to PTL/PM secretary)
(Only one form to be completed for all the languages)
(Only one form to be completed for Worksharing and grouping submissions)

SECTION 1:

(to be completed by the applicant)

Product Name	:	
Application Number	:	
Worksharing submission		Yes☐ No☐
Grouping submission		Yes☐ No☐
Applicant/MAH Name & Address	:	
Details of contact person for translations ***(Name, tel, fax & E-mail)***	:	
Worksharing submission ONLY	:	*<Confirm here that changes implemented to this CAP will be implemented in all CAPs included in the worksharing submission>*

All Member States' comments implemented :

BG	CS	DA	DE	EL	ES	ET	FI	FR	HU	IS	IT
LT	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**	

Tick the appropriate box for each language as follows:

✓ - Comments received and implemented
X - Comments received, not all implemented
NC- Confirmation received that there are no comments on the translation for this procedure
n/a – No comments received from MS

If not, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts. Please indicate, as presented below, for the language(s) concerned the document (SPC, Annex II, labelling or package leaflet) and section to which the disputed comment relates together with an alternative proposal or an indication of how the issue has been resolved. Justification(s) and/or alternative proposals should be discussed and agreed with the relevant Member State(s) **before** submitting final translations to the Agency.

If comments have been discussed and agreed/revised with the Member States, a copy of any relevant correspondence should be attached to this form.

{LANGUAGE}

- SPC

Section Title & Paragraph	Comment	Alternative proposal or how was the issue resolved?

SECTION 2:

(to be completed by Procedure Secretary):

	New Application	Line extension	Renewal	Annual Re-assessment	Art.61.3 Notifications
Type of procedure					
	Referral	**Type II Variation 30 Days**	**Type II Variation 60-90 Days**	**Type IB Variation**	**USR**
	Generic Application				

Opinion date or Start of procedure[8]	
Deadline for providing linguistic comments :	
Form completed by :	

	BG	CS	DA	DE	EL[9]	ES	ET	FI	FR	HU	IS	IT
Check performed by MS* :												

	LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV
Check performed by MS* :											

*MSs who have sent comments or sent an e-mail confirming they have no comments on the translation have to be ticked:

✓ - Comments received

- **Delay in MS comments?** If yes, provide country name and number of days delayed.

[8] Start of procedure for 30-Days Type II Variations, Type IB Variations and USRs only; opinion date for all other procedures. *(only one form to be completed per procedure, even if (multiple) comments may be received at different stages)*

[9] New applications are checked by Cyprus, all other procedures are checked by Greece.

- **Delay in transmitting translations to EC?** **Yes O** **No O**
  If yes, provide further details in "Any other feedback"
- **Any other feedback?**

Annex 10 – QRD SME-Cdt form 1

QRD SME-CdT Form 1:
For Member States' product information check

DAY 229

(MS to complete Section 2 and to send to the Agency by Day 229)

SECTION 1:

Application Details (to be completed by the Agency):

Product Name	:	
Application Number	:	
Grouping submission		Yes☐ No☐
Applicant Name & Address	:	
Details of contact person for translations (Name, tel, fax & E-mail)	:	**EMA QRD SECRETARIAT** qrd@ema.europa.eu ONLY IF TRANSLATION **UNACCEPTABLE**: CdT client.coordination@cdt.europa.eu
Rapporteur and Co-Rapporteur	:	
Product Team Leader / Project Manager	:	
Extensions ONLY	:	*<Provide here a short description of the differences between the already authorised presentations and the new extension (e.g. indicate sections amended)>*

SECTION 2:

Product information check (to be completed by Member States):

Language :

BG	CS	DA	DE	EL	ES	ET	FI	FR	HU	IS	IT

LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV

Details of MS contact for translations check :	
Total checking time (hours) :	

	YES	NO
Assisted by CVMP member and/or assessors :		
Assisted by other staff members :		
Assisted by Standing Committee member :		

	VG	G	A	UN*
Overall quality of translation :				
• **SPC :**				
• **Annex II**				
• **Labelling :**				
• **Package Leaflet :**				
• **Annex IV (if applicable)**				

(VG=Very Good; G= Good, A = Acceptable; UN=Unacceptable)

* If unacceptable, return translation **within 3 days** to CdT (client.coordination@cdt.europa.eu) with a copy to the Agency (qrd@ema.europa.eu) and include an explanation in the box below.

The translation was unacceptable because:

PLEASE MAKE SURE THAT THE SUBJECT/TITLE OF THE E-MAIL YOU WILL SEND TO CDT INCLUDES THE FOLLOWING INFORMATION:

Member State linguistic review for <EMEA/H/C/xxx><language> -UNACCEPTABLE

Nature of comments:

		M	S	F
Missing words or sentences	:			
Scientific incorrect translations (e.g. terminology)	:			
Inaccuracies (incorrect translations – incl. spelling, punctuation, grammatical mistakes)				
Editorial, stylistic changes (e.g. rephrasing)	:			

(M=Many; S=Several; F=Few)

Any other comments (e.g. formatting problems):

Date of completion of form	:	

Annex 11 – QRD SME-Cdt form 2

SME-CdT QRD Form 2:
For CdT when submitting revised translations to the European Medicines Agency

DAY 232

(CdT to complete by Day 232 and send to QRD Secretariat)
(Only one form to be completed for all the languages)
(Only one form to be completed for Worksharing and grouping submissions)

SECTION 1:

(to be completed by the CdT)

Product Name	:	
Application Number	:	
Worksharing submission		Yes☐ No☐
Grouping submission		Yes☐ No☐
Applicant/MAH Name & Address	:	
Details of contact person for translations ***(Name, tel, fax & E-mail)***	:	**CdT** client.coordination@cdt.europa.eu
Worksharing submission ONLY	:	*<Confirm here that changes implemented to this CAP will be implemented in all CAPs included in the worksharing submission>*

All Member States' comments implemented :

BG	CS	DA	DE	EL	ES	ET	FI	FR	HU	IS	IT

LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV

Tick the appropriate box for each language as follows:
✓ - Comments received and implemented
X - Comments received, not all implemented
NC- Confirmation received that there are no comments on the translation for this procedure
n/a – No comments received from MS

If not, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts. Please indicate, as presented below, for the language(s) concerned the document (SPC, Annex II, labelling or package leaflet) and section to which the disputed comment relates together with an alternative proposal or an indication of how the issue has been resolved. Justification(s) and/or alternative proposals should be discussed and agreed with the relevant Member State(s) **before** submitting final translations to the Agency.

If comments have been discussed and agreed/revised with the Member States, a copy of any relevant correspondence should be attached to this form.

{LANGUAGE}

- SPC

Section Title & Paragraph	Comment	Alternative proposal or how was the issue resolved?

SECTION 2:

(to be completed by Procedure Secretary):

	New Application	Line extension	Renewal	Annual Re-assessment	Art.61.3 Notifications
Type of procedure					
	Referral	**Type II Variation 30 Days**	**Type II Variation 60-90 Days**	**Type IB Variation**	**USR**
	Generic Application				

Opinion date or Start of procedure[10]	
Deadline for providing linguistic comments :	
Form completed by :	

	BG	CS	DA	DE	EL [11]	ES	ET	FI	FR	HU	IS	IT
Check performed by MS* :												
	LT	**LV**	**MT**	**NL**	**NO**	**PL**	**PT**	**RO**	**SK**	**SL**	**SV**	
Check performed by MS* :												

*MSs who have sent comments or sent an e-mail confirming they have no comments on the translation have to be ticked: ✓ (= Comments received)

- **Delay in MS comments?** If yes, provide country name and number of days delayed

- **Delay in transmitting translations to EC?** **Yes O** **No O**
  If yes, provide further details in "Any other feedback"

- **Any other feedback?**

[10] Start of procedure for 30-Day Type II Variations and USRs only; opinion date for all other procedures.
(only one form to be completed per procedure, even if (multiple) comments may be received at different stages)
[11] New applications are checked by Cyprus, all other procedures are checked by Greece.

Annex 12 – Timetable for SMEs new applications - Cdt

SME Timetable for the finalisation of the CVMP opinion & Annex A, Annex I Summary of Product Characteristics, Annex II and Annex III Labelling and Package Leaflet <and Annex IV♣> in all EU Languages

<PRODUCT>

EMEA/V/C/XXX

The CdT* will provide the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <(and Annex IV)> and Annex A° in all EU languages (excl. NO and IS〃) to the Agency by:		<Text> *(5 days after opinion)*
The Agency will provide the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <(and Annex IV)> in all EU languages to Member States (excl. NO and IS〃) together with QRD:SME-CDT Form 1#, by:		<Text> *(5 days after opinion)*
Member States (excl. NO and IS〃) will send linguistic comments on the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <and Annex IV> to the Agency by e-mail§ (qrd@ema.europa.eu) together with QRD:SME-CDT Form 1#, by:		<Text> *(19 days after opinion)*
The Agency will forward the linguistic comments to the CdT by e-mail§ (client.coordination@cdt.europa.eu), by:		<Text> **(AM)** *(20 days after opinion)*
The CdT will implement the required changes, compile the translations* and send these to the Agency together with QRD: SME-CDT Form 2# by e-mail§ (qrd@ema.europa.eu), by:		<Text> *(22 days after opinion)*
The Agency will compile the EN Opinion and Annexes in all languages and send final copies to the Commission, Members of the Standing Committee and the applicant, by:		<Text> *(27 days after opinion)*

<♣ Annex IV relates to "conditions or restrictions with regard to the safe and effective use to be implemented by Member States" (when applicable).>

* Centre de traduction des organes de l'Union européenne (Translation Centre)

° Annex A is to be provided as a separate word document per language

〃NO and IS translations are provided and handled by the applicant. A separate CVMP Timetable should be prepared and adopted.

§ The e-mail title should clearly specify the (invented) name of the medicinal product and the country

Downloadable at the internal QRD Website (The Intranet)

*At Day 232, the Annexes (clean and highlighted with tracked changes) must be submitted for each official EU language as separate documents per language as follows:

- all Annexes I, followed by Annex II, all Annexes IIIA and IIIB, in one document

All translations should be numbered as **ONE** document, starting with "1" (bottom, centre) on the title page of Annex I and Annex (IV) when applicable. The Annexes should be presented in strict compliance with the QRD Convention.

Annex 13 – Timetable for SMEs new applications - applicant

Timetable for the finalisation of the CVMP opinion & Annex A, Annex I Summary of Product Characteristics, Annex II and Annex III Labelling and Package Leaflet and <Annex IV♣> in EN, IS and NO

<PRODUCT>

EMEA/V/C/XXX

The applicant will provide the product information <and Annex IV> and Annex A° in EN◇, NO and IS to the Agency (+QRD Form# 1) by e-mail§ (qrd@ema.europa.eu) or on CD Rom:		<Text> *(5 days after opinion)*
IS and NO will send linguistic comments on the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet <and Annex IV> to the applicant by e-mail§ with a copy to the Agency (qrd@ema.europa.eu) together with QRD Form# 1, by:		<Text> *(19 days after opinion)*
The applicant will implement the required changes, compile the translations* and send these to the Agency (+ QRD Form# 2) by e-mail§ (qrd@ema.europa.eu) or on CD Rom, by:		<Text> *(25 days after opinion)*
The Agency will compile the EN Opinion and Annexes in all languages and send final copies to the Commission, Members of the Standing Committee and the applicant, by:		<Text> *(27 days after opinion)*

<♣Annex IV relates to "conditions or restrictions with regard to the safe and effective use to be implemented by Member States" (when applicable)>

◇ For generics/hybrid/biosimilar applications the English product information should indicate those sections which differ from the reference product

°Annex A is to be provided as a separate word document per language

Downloadable at the European Medicines Agency Website (Website)

§ The e-mail title should clearly specify the (invented) name of the medicinal product, the procedure number and the Day in the procedure to which the translations relate (e.g. Day 215)

* The final product information i.e. Annex I, II, IIIA and IIIB must be submitted electronically as one clean PDF file for each NO and IS together with the word files highlighted with tracked changes (see also the User guide on the preparation of PDF versions of the product information). The translations must be accompanied by the completed check list.

Annex IV (when applicable) in a separate document with "IV" removed from the title page

All translations should be numbered as ONE document, starting with "1" (bottom, centre) on the title page of Annex I and Annex (IV) when applicable. The Annexes should be presented in strict compliance with the QRD Convention.