



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Evaluation Division

The linguistic review process of product information in the centralised procedure – human

1. Introduction

A linguistic review of product information¹ in all EU languages is performed after the adoption of CHMP 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):

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 (SmPC) 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.

Where applicants consider to also market a combined package leaflet, a detailed justification for such a combined package leaflet will have to be included in the application at submission or at the latest at

* The Linguistic Review Process of Product Information in the Centralised Procedure – Human has been updated with a revised Annex 6 ‘Submission of Day +25/235 final product information annexes’, which replaces Annex 7 and combines the ‘QRD Form 2’ and ‘Day 235/+25 Checklist’. Several amendments and improvements have been made to the ‘QRD Form 2’.
¹ Annex I Summary of Product Characteristics (SmPC), Annex II Conditions, Annex III Labelling & Package Leaflet and Annex 127a and Annex IV (when applicable)



Day 121. The justification should take into account the QRD guidance as published in the "[Compilation of QRD decisions on stylistic matters](#)".

Further guidance 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 for linguistic review after adoption of the CHMP EN opinion (see section 2.2 "post-opinion").

For applications which have been reviewed by the CHMP in an "accelerated assessment" procedure, 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) is not possible, the Agency may consider to only perform a Technical Labeling Review (performed solely by the Agency).

2.1. Pre-opinion

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

Who	When	Scope
Agency Technical Labeling Review	Day 10	Detailed review of the EN text to ensure compliance with current standards (e.g. QRD templates), consistency with SmPC guideline and other relevant guidelines, and also highlight claims in need of further substantiation
Agency/QRD/PC WP ² /EMA medical writers	Day 140	

The Technical Labeling Review comments will be incorporated into the scientific comments; a single set of comments will be 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.

Upon receipt of the revised EN product information at Day 121, the Agency will review the implementation of the Technical Labeling Review comments by the applicant and will forward the revised EN product information to all QRD members for comments (via written procedure) by Day 140 as well as to representatives of Patients' and Consumers' Organisations and the EMA medical writers (see also attached [timeline](#)).

The Day 140 Technical Labeling Review comments will be incorporated into the scientific comments and a single set of comments will be sent to the applicant as part of the Day 150 set of documents.

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 outstanding issues at Day 181, or before opinion if no list of outstanding issues is adopted. The Agency will check if all Technical Labeling Review comments have been implemented before the opinion is adopted.

² Patients' and Consumers' Working Party

2.2. Post-opinion

Marketing Authorisation Holders (MAHs) should send the final EN product information to the Agency at the latest by Day 215.

A correctly separated SmPC and package leaflet per pharmaceutical form, containing all pack-sizes related to the pharmaceutical form concerned, must be provided. The use of combined SmPCs for different strengths of the same pharmaceutical form is encouraged for all languages after the adoption of the opinion when the SmPCs are completely identical, except for the few strength-specific details (e.g. if the indications are different for the different strengths, the SmPCs cannot be combined). For different strengths not meeting the criteria above, a separate SmPC per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned will have to be provided after opinion.

The process to request a combined PL for different strengths is a separate one, independent from the use of a combined SmPC. Only upon CHMP agreement (on a case-by-case basis and following QRD consultation), the package leaflet does not need to be separated per strength after adoption.

Translations of the adopted product information, Annex IV and Annex 127a (if applicable), and Annex A³ (list of products) in all other EU languages (including Icelandic and Norwegian⁴) as well as "[QRD Form 1](#)" (Annex 5) are to be provided electronically (in one Eudralink⁵ package) to the Agency (qrd@ema.europa.eu) by Day 215. The Eudralink package should be presented in compliance with the [Day 215 Checklist](#) (Annex 4). 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 in the Pre-Opinion stage (e.g. after Day 180).

The following checks will apply:

Who	When	Scope
QRD 'Member State'	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 MAH and copy the Agency (Product Shared Mailbox) at the latest by Day 229 together with an overall feedback on the quality of the translations - "[QRD Form 1](#)" (Annex 5).

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 (in one Eudralink package)

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) by Day 215. When the name of the medicinal product is composed by the INN + name of MAH, the applicant should ensure that the name in the Annex A translations is consistent with the translations of the name in the Product Information, as stated in Annex I Summary of Product Characteristics, section 1. NAME OF THE MEDICINAL PRODUCT. No linguistic review of Annex A is required, however, if any changes occur during the linguistic review, the revised Annex A in all EU languages should be provided together with the final translations by Day 235.

⁴ Details on the handling of the Icelandic and Norwegian PI annexes are given in the Pre-submission guidance Q&A.

⁵ To obtain a Eudralink account, which allows for a secure e-mail service with the Agency, contact: eudralink@ema.europa.eu

to the Agency (qrd@ema.europa.eu) with a copy to the Product Shared Mailbox by Day 235. The Eudralink package should be presented in compliance with the [Day 235 Checklist](#) (Annex 6).

A separate SmPC and package leaflet per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned must be provided (for combined SmPCs and combined package leaflet see above.) 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 6) 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 6).

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 that have been reviewed by the CHMP in an "accelerated assessment" procedure, the timeframes for 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 is available in the Agency Post-Authorisation Procedural Advice 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 2).

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 as part of the variation notification or via Eudralink. The revised Annexes should be provided in Word format (changes highlighted).

As changes to the product information 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 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. 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) with a copy to the procedure assistant and Product Shared Mailbox.

Translations of the revised Annex A only need to be sent to the procedure assistant with a copy to the Product Shared Mailbox by Day +5 (i.e. 5 days after validation), if applicable.

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 (Product Shared Mailbox).

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 (in one Eudralink package) to the procedure assistant by Day +25 (i.e. 25 days after validation) with a copy to the Product Shared Mailbox. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

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 "[ORD Form 2](#)" (Annex 6) 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 Opinion) with a copy to the procedure assistant and Product Shared Mailbox.

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](#).

Translations of the revised Annex A only need to be sent to the procedure assistant with a copy to the Product Shared Mailbox by Day +5, if applicable.

The following checks will apply:

Who	When	Scope

QRD 'Member State'	Day +5 to +19	Detailed review of highlighted changes in all translations
Agency	Day +25 to +27	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 (Product Shared Mailbox).

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 (in one Eudralink package) to the procedure assistant with a copy to the Product Shared Mailbox by Day +25. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

The Agency will check if all Member States' comments have been implemented before sending the final translations to the Commission, where applicable. In order to facilitate and accelerate the check of the implementation of the Member States' comments, the applicant should indicate in "[QRD Form 2](#)" (Annex 6) 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 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, the Commission 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.

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 tracked 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 215, 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 in PDF format (clean), electronically (in one Eudralink package) to the Agency (qrd@ema.europa.eu) with a copy to the Product Shared Mailbox by Day 235. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

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 2). However, at Day +5, the MAH will submit the product information in English and all other EU languages (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 (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 in PDF format (clean), electronically (in one Eudralink package) to the procedure assistant with a copy to the Product Shared Mailbox by Day +25. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

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

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**.

Worksharing submissions follow a 60- or 90-day timetable.

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 tracked 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 Opinion) with a copy to the coordinating assistant and Product Shared Mailbox.

Translations of the revised Annex A only need to be sent to the coordinating assistant by Day +5, if applicable.

Comments will be sent directly by the Member States to the MAH at the latest by Day +19, with a copy to the Agency (Product Shared Mailbox).

The MAH will send the final translations of **all products** involved in the worksharing procedure, with tracked changes, incorporating the Member States comments in Word format, as well as in PDF format (clean), electronically (in one Eudralink package) to the coordinating assistant with a copy to the Product Shared Mailbox by Day +25 (i.e. 25 days after adoption of the Opinion). The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

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

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

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](#).

3.5. 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 language version needs to be provided at submission.

During the scientific renewal assessment, a detailed pre-opinion review of the EN product information will be performed by the Agency, QRD members and representatives of Patients' and Consumers' Organisations. Technical Labeling Review comments will be sent to the MAH by Day 75. When providing a revised EN version for adoption of the opinion, applicants should inform the Agency if and why certain Technical Labeling Review 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 with a copy to the procedure assistant and Product Shared Mailbox.

The following checks will apply:

Who	When	Scope
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QRD/CHMP 'Member State'	Day +5 to +19	Detailed review of (highlighted changes in) all translations
Agency	Day +25 to +27	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 (Product Shared Mailbox).

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 (in one Eudralink package) to the procedure assistant with a copy to the Product Shared Mailbox by Day +25. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

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 applicant should indicate in "[QRD Form 2](#)" (Annex 6) 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 6).

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 the Annex II, no 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 (incl. Article 29 paediatric procedures)

The same general principles as for the post-opinion linguistic review of New Applications apply, as illustrated by the attached [timeline](#) (Annex 3):

Only the EN language version of SmPC, labelling and/or package leaflet needs to be provided at submission⁶.

During the scientific referral assessment, a detailed pre-opinion review of the EN product information may be performed on an ad-hoc basis by the Agency and QRD members. Technical Labeling Review comments will be sent to the MAH by Day 30 (for details on the different Referral procedures please refer to [SOP/EMA/0073](#)). When providing a revised EN version for adoption of the opinion, applicants should inform the Agency if and why certain Technical Labeling Review comments are not taken into account.

Translations of the adopted Annex I (list of products) and Annex III (SmPC, 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

⁶ For referrals according to Art 31 (2), this may be limited to specific parts of the product information only.

+5 (i.e. 5 days after adoption of the Opinion) with a copy to the procedure assistant and Product Shared Mailbox.

The following checks will apply:

Who	When	Scope
QRD/ 'Member State'	Day +5 to +19	Detailed review of all translations
Agency	Day +22 to +27	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 (Product Shared Mailbox).

The MAH will send the final translations with tracked changes, incorporating the Member States' comments, as well as in clean format in Word, electronically (in one Eudralink package) to the procedure assistant with a copy to the Product Shared Mailbox 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 applicant should indicate in "[QRD Form 2](#)" (Annex 6) 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 6).

Following receipt of the final translations of the product information (Annex III), Annex I (list of products), Annex II (scientific conclusions) and Annex 127a (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).

3.7. The linguistic review process for PSURs and PSUSAs

The CHMP Opinion or CMDh position on a PSUR procedure recommending variation to a Marketing Authorisation includes the following annexes:

- Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation;
- Amendments to the product information and, for centrally authorised products, the full product information (Summary of Product Characteristics, Labelling and Package Leaflet, in English);
- Condition to the Marketing Authorisation, if applicable.

The CHMP Opinion on a PSUSA procedure consists of the following annexes, as applicable:

- Annex A of CAPs;
- Annex B for CAPs: includes Annexes I, II, III and IV (scientific conclusions) for each CAP;

- Annex C for NAPs: includes Annex I (scientific conclusions), Annex II (amendments to the product information) and, as applicable, Annex III (conditions to the marketing authorisation).

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, with a copy to the procedure assistant and Product Shared Mailbox. The following checks will apply:

Who	When	Scope
QRD/CHMP 'Member State'	Day +5 to +19	Detailed review of translations
Agency	Day +25 to +27	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 (Product Shared Mailbox).

For CAP holders, 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 (in one Eudralink package) to the procedure assistant by Day +25 with a copy to the Product Shared Mailbox. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

The Agency will check if all Member States' comments have been implemented before sending the final translations to the Commission by Day +27.

For NAP holders, EMA will forward them Annex I and, in case CAPs are included in the PSUSA, the final agreed PI translated by the CAP MAH in all EU languages (including NO and IS) by Day +25.

The NAP MAH(s) will send Annex II in all languages (prepared by using the translated PI, if available), and Annex C in the agreed EU languages in Word format, as well as in PDF format (clean), electronically (in one Eudralink package) to the procedure assistant with a copy to the Product Shared Mailbox by Day +27. The Eudralink package should be presented in compliance with the [Day +25 Checklist](#) (Annex 6).

The Agency will compile the Annexes for the NAPs in all EU languages and send final copies to the Commission by Day +27.

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 Technical Labeling Review (performed by the Agency) by Day 180. A Labeling pre-opinion Review (performed by the Member States) will not be required.

For hybrid and biosimilar applications a Technical Labeling pre-opinion Review will be performed by the Agency and Member States.

For informed consent applications only one Technical Labeling Review 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. 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 product information of the reference product to the applicant of the generic/hybrid application. As soon as the linguistic review for the reference product has been completed, EMA will also send those translations (including Icelandic and Norwegian) to the applicant of the generic/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, EMA will proactively send the translations validated by the Member States to the applicant of generic/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 1](#) (Annex 5).

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. Format changes to the generic, hybrid or biosimilar's 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, hybrid or biosimilar SmPC as far as possible, if the relevant information is available (for details on the general principles regarding the SmPC information for a generic/hybrid/biosimilar 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 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, in the post-opinion phase, as part of the incentives offered to SMEs according to Article 11 of Regulation (EC) No 2049/2005 at Day 215, the Centre de Traduction (CdT) will provide translations of the adopted product information, Annex IV and Annex 127a (if applicable) 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 electronically (in one Eudralink package) the English adopted product information annexes and Annex A (list of products), Annex IV and Annex related to the Art. 127a (if applicable), together with the Norwegian and Icelandic translations as well as "[QRD Form 1](#)" (Annex 5)

to the Agency (grd@ema.europa.eu) with a copy to the Product Shared Mailbox by Day 215. The Eudralink package should be presented in compliance with the [Day 215 Checklist](#) (Annex 4).

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 as well as "[QRD Form 1](#)" (Annex 5) electronically to all Member States (including Iceland and Norway) at Day 215.

Each translation will be subject to one Member State linguistic review, co-ordinated by the national QRD member. QRD members will send their comments directly to the CdT with a copy to the Agency (Product Shared Mailbox) (or to the applicant for IS & NO) at the latest by Day 229 together with an overall feedback on the quality of the translations "[QRD Form 1](#)" (Annex 5).

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 Form 2](#)" (Annex 6), electronically (in one Eudralink package) to the Agency (grd@ema.europa.eu) by Day 235.

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 the English, Norwegian and Icelandic final translations in PDF format (clean), together with the "[QRD Form 2](#)" (Annex 6), electronically (in one Eudralink package) to the Agency (grd@ema.europa.eu) with a copy to the Product Shared Mailbox by Day 235. The Eudralink package should be presented in compliance with the [Day 235 Checklist](#) (Annex 6).

6. 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 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).

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) and the [User guide on the preparation of PDF versions of the product information](#).

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.

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 Human Product Information Templates:

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

QRD Human Product Information Template with explanatory notes:

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

Annex A Human Template in all languages:

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

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

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

Annex IV conditional positive Human Template in all languages:

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

Annex IV exceptional circumstances positive Human Template in all languages:

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

Annex IV standard positive Human Template in all languages:

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

QRD Human Referral Templates:

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

Annex I Human referral Template in all languages:

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

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_000254.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008c34c

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

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000254.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058008c34c

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

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004716.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:

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/health/files/eudralex/vol-2/c323_9/c323_9_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:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:017:0001:0044: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

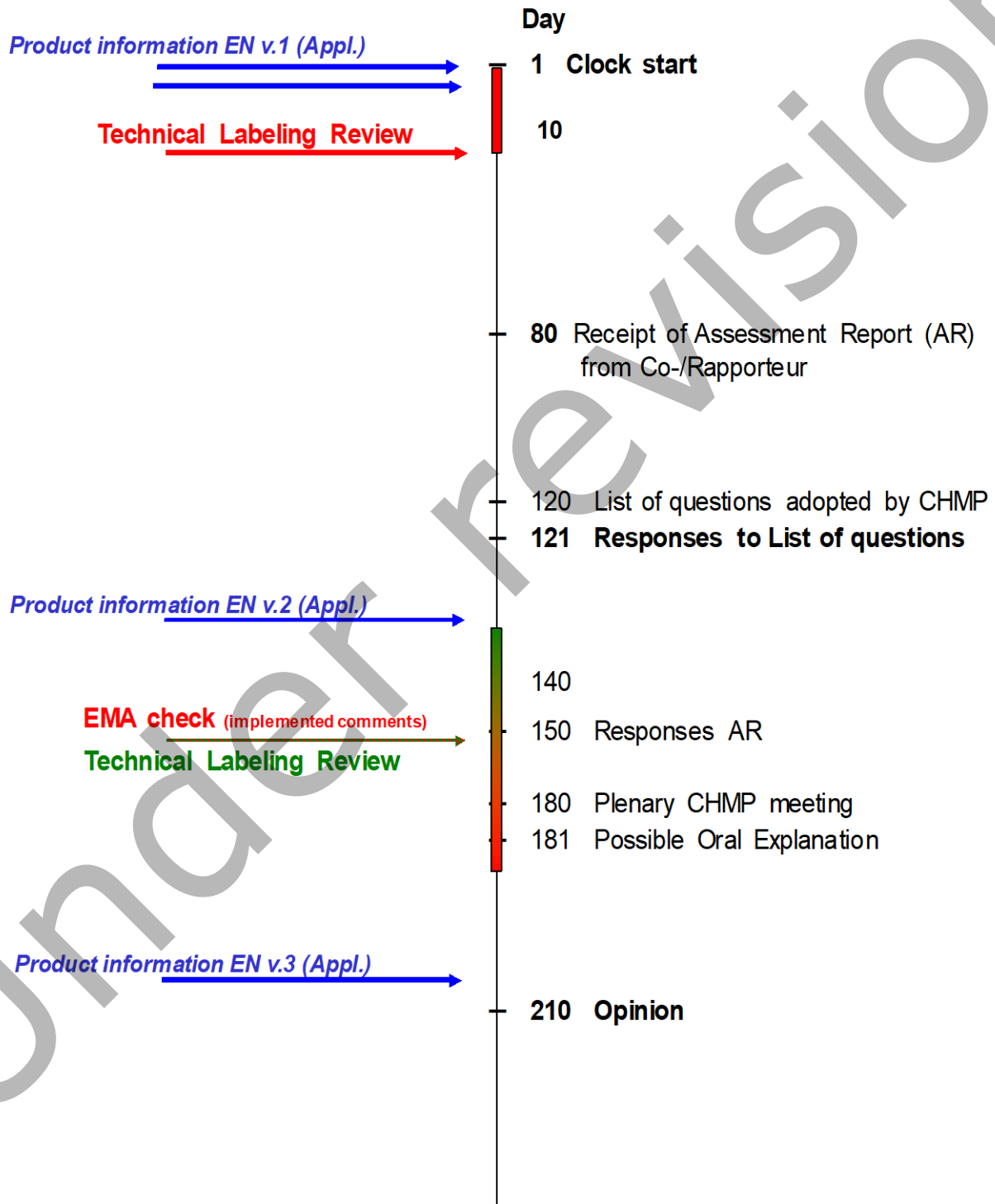
European Medicines Agency post-authorisation procedural advice for users of the centralised procedure

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003981.pdf

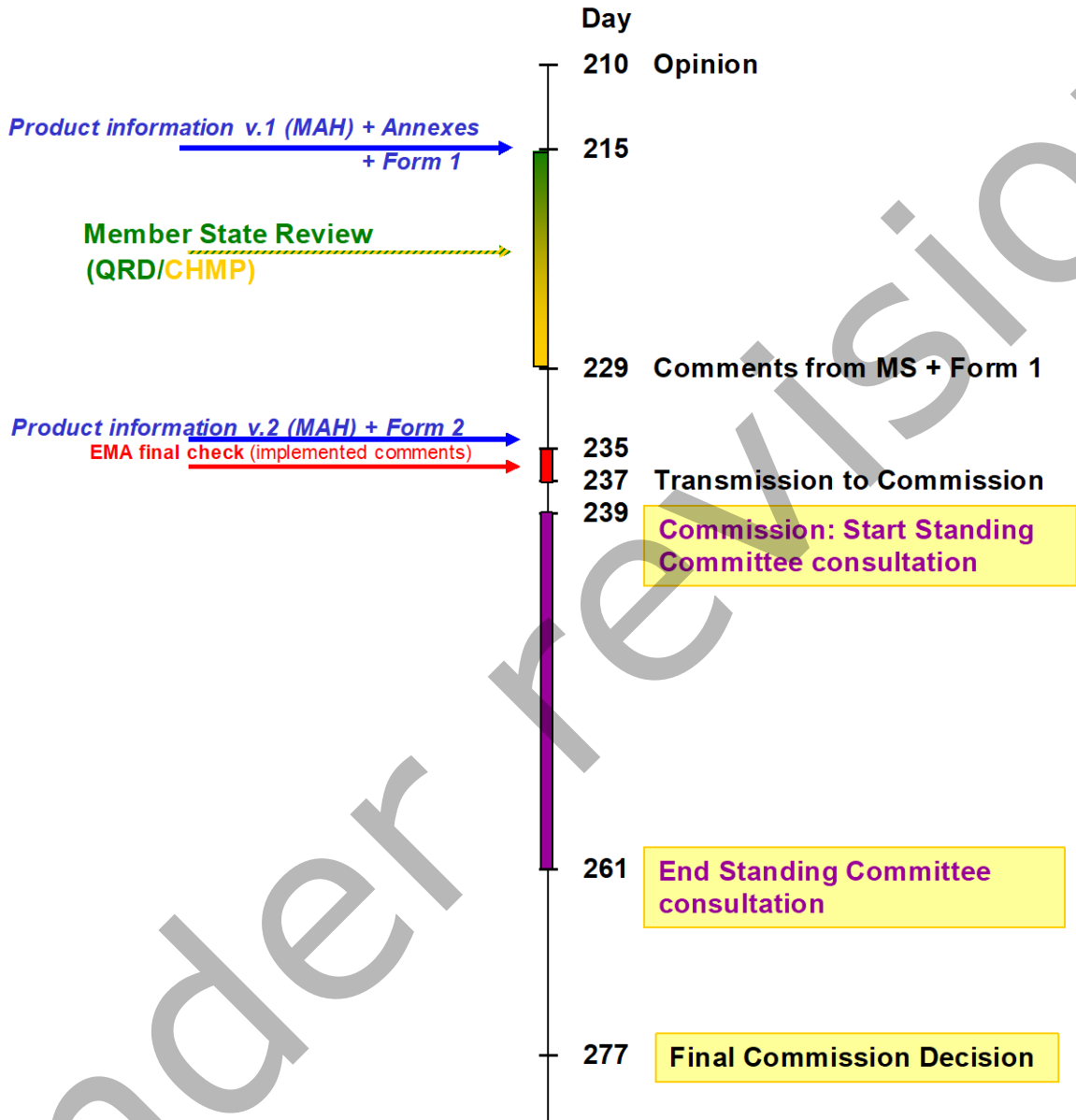
Submission dates of Type IB variations requiring linguistic review

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000330.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05803d8b9c

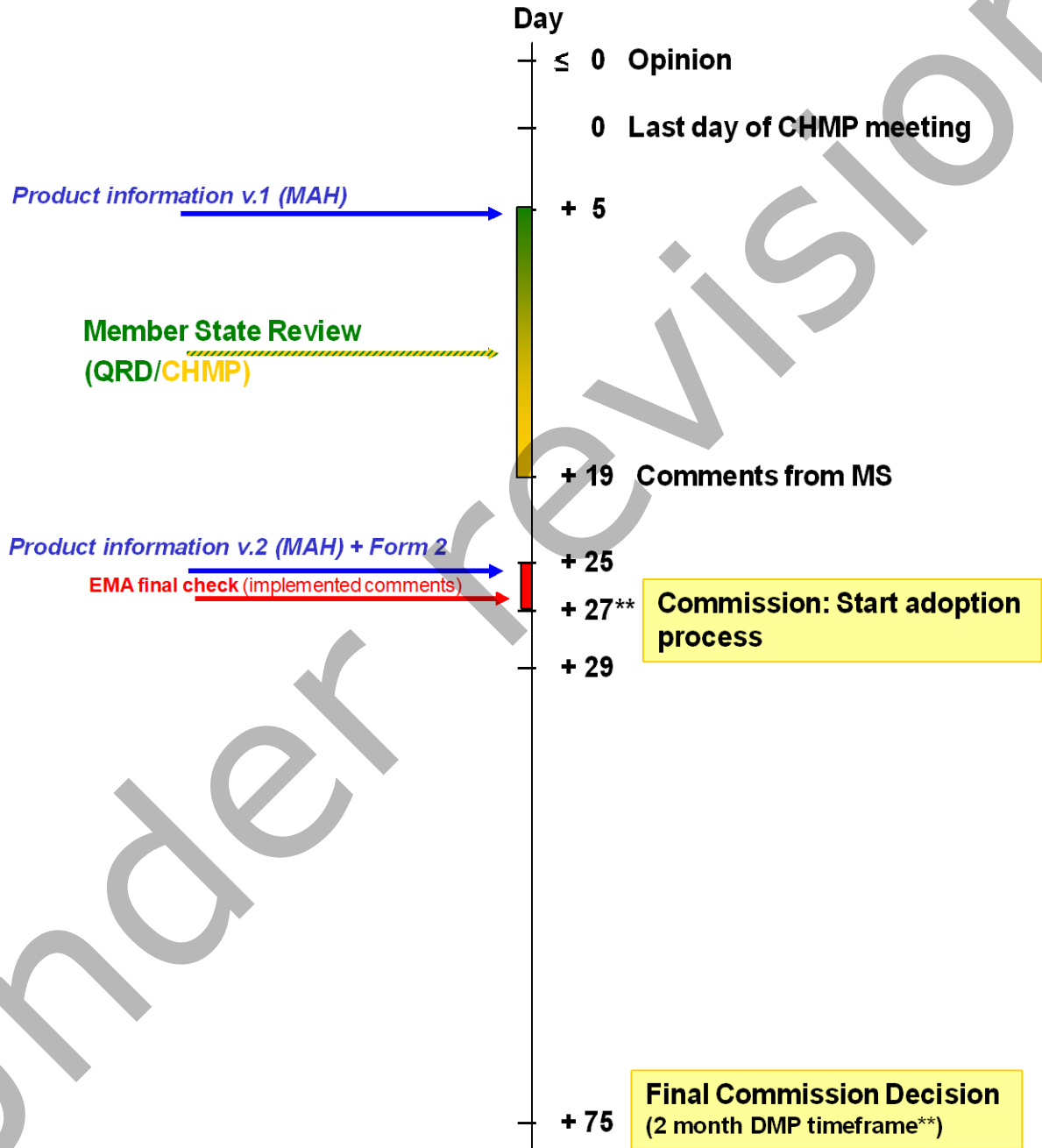
Timeline for New Applications and Extensions *Pre Opinion*



Timeline for New Applications and Extensions *Post Opinion*

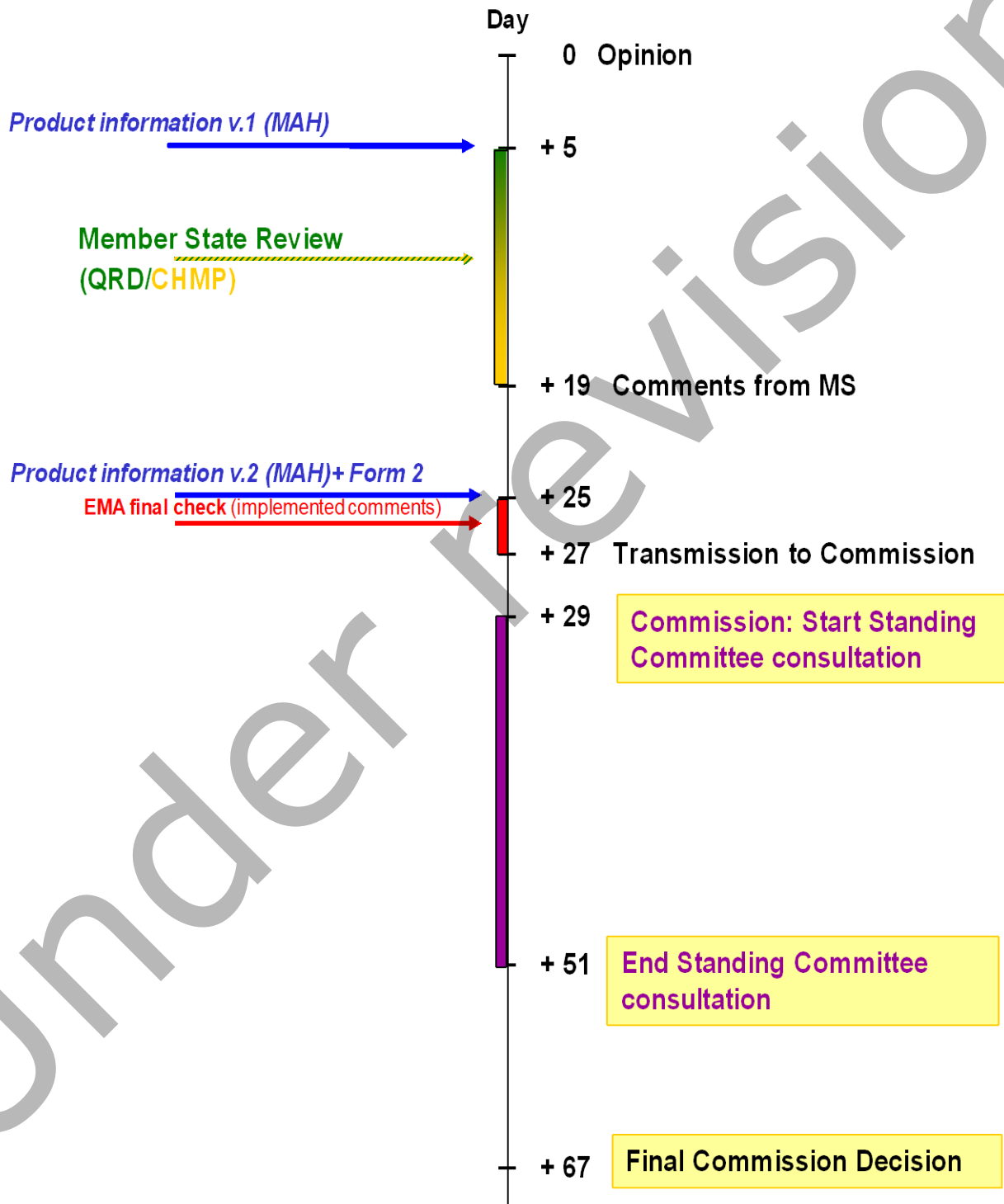


Timeline for Variations *Post Opinion*



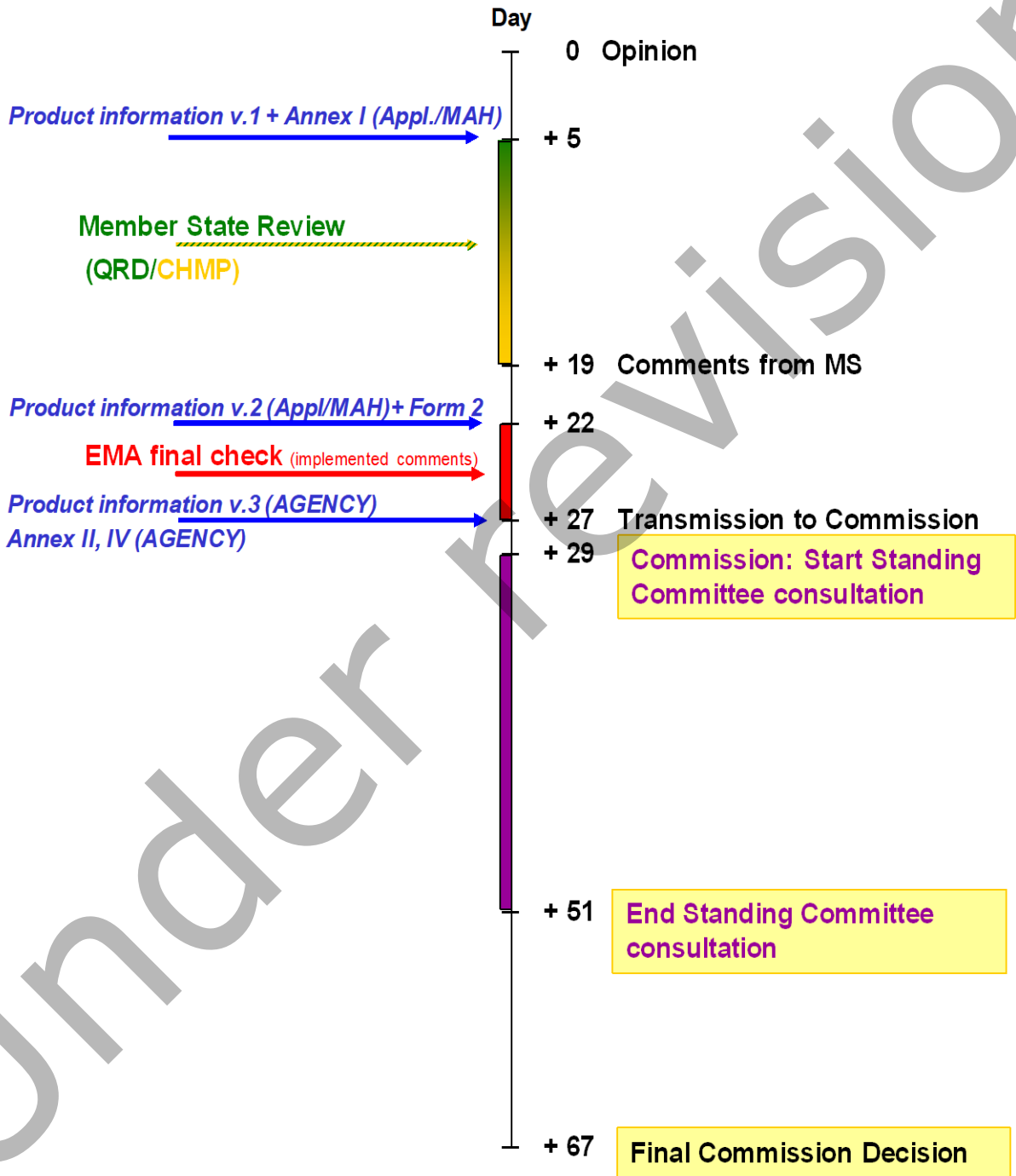
** applicable only to Type II variations listed under Art. 23.1a(a) of Commission Regulation (EC) No 1234/2008

Timeline for Renewals/Annual Re-assessment *Post Opinion*



Under revision

Timeline for Referrals *Post Opinion*



Annex 4 – Day 215 Checklist

Checklist for the submission of Day 215 product information annexes for a post-opinion linguistic review

For initial marketing authorisations and line extension applications the applicant/MAH should submit the Day 215 product information annexes for a post-opinion linguistic review in one Eudralink message to the European Medicines Agency (grd@ema.europa.eu) with a copy to the Product Shared Mailbox

Subject title: <Product name> - <procedure number> - Post-opinion review - Day 215 submission by applicant

For the submission of the full set of annexes, i.e. Annex I (SmPC), Annex II, Annex IIIA (labelling) and Annex IIIB (package leaflet) and Annex IV (if applicable) together with Annex A, Annex 127a (if applicable) in all EU languages, the applicant/MAH confirms that they have prepared the submission files in accordance with the following checklist:	
The QRD Convention published on the Agency's website was followed for the preparation of the Word source files	<input type="checkbox"/>
<i>For multiple applications submit only ONE SET of files with a declaration that the same QRD comments will be implemented for the other product(s) at day 235</i>	
For initial applications: Full set of annexes are provided in WORD CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <PRODUCT NAME> day 215 PI all languages	<input type="checkbox"/>
For generic/hybrid/biosimilar initial applications: Full set of annexes are provided in WORD CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <PRODUCT NAME> day 215 PI all languages	<input type="checkbox"/>
In addition to this, a separate English PI is provided indicating sections which differ from the reference product in tracked changed mode (not highlighted)	<input type="checkbox"/>
For line extension applications: Full set of annexes are provided in WORD TRACKED CHANGED files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <PRODUCT NAME> day 215 PI all languages	<input type="checkbox"/>

Annex A is provided as separate WORD CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <PRODUCT NAME> day 215 Annex A all languages	<input type="checkbox"/>
Annex 127a (if applicable) is provided as separate WORD CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <PRODUCT NAME> day 215 Annex 127a all languages	<input type="checkbox"/>
The QRD Form 1 is attached as WORD file with section 1 completed in all parts	<input type="checkbox"/>
Email address of applicant's translations coordinator(s) and email address of the EMA Product Shared Mailbox for the receipt of the Member States QRD comments are correct	<input type="checkbox"/>
The Eudralink package has an expiry date of no less than 30 days	<input type="checkbox"/>

Submit the Eudralink package to QRD@ema.europa.eu with a copy to the Product Shared Mailbox⁷

⁷ You may receive a **Delivery notice** from the Product Shared Mailbox; this is an automated reply and you may consider it as receipt of your email. It should therefore be disregarded and no additional steps should be taken to resend the package.

Annex 5 – 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	:	<input type="text"/>
Application Number	:	<input type="text"/>
Worksharing submission	:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Grouping submission	:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Applicant Name & Address	:	<input type="text"/>
Details of contact person for translations	:	<input type="text"/> (Name, tel, fax & E-mail)
Rapporteur and Co-Rapporteur	:	<input type="text"/>
Procedure Manager/EPL	:	<input type="text"/>
PI differences (for extensions and	:	<input type="text"/> <Provide here a short description of the differences between the already authorised presentations and the new extension (e.g. indicate sections amended)>

generics only):

< Where the existence of usage patent(s) leads to differences in SmPC/PL compared to the reference medicinal product, this should be indicated here>

Comments to be sent to

<email address for applicant's translations coordinator(s)> with a copy (cc) to the Agency <Product Shared Mailbox>

SECTION 2:

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

Language	BG	CS	DA	DE	EL	ES	ET	FI	FR	HR	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)

Assisted by CHMP member and/or assessors

	YES	NO

Assisted by other staff members

Assisted by Standing Committee member

Overall quality of translation

- SmPC
- Annex II
- Labelling
- Package Leaflet
- Annex IV (if applicable)

	VG	G	A	UN*

(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:

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	S	F
:			
:			
:			
:			

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

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

Date of completion of form

:

Annex 6 – Submission of Day +25/235 final product information annexes (QRD Form2 and Checklist)

Submission of Day +25/235 final product information annexes

QRD Form 2

For applicants/MAHs when submitting revised translations to the European Medicines Agency

Product Name:

Click here to enter text.

Full Application Number:

Click here to enter text.

Applicant/MAHs contact details for translations:

Click here to enter text.

Click here to enter text.

Click here to enter text.

Member States' comments implementation

Select the appropriate answer from the drop down box for each language as follows:

- YES** Comments received and implemented
- NO** Comments received, not all implemented
- NC** Confirmation received that there are no comments on the translation for this procedure
- n.a.** No response received from Member State

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

Applicant/MAH confirms that ALL Member States have provided comments.

YES NO*

***If 'NO', contact the procedure assistant prior to submitting the files to cross-check comments received by the European Medicines Agency.**

The following Member States DID NOT provide comments:

[Click here to enter text.](#)

Deadline for Member States comments:

[Click here to enter text.](#)

Delay in Member States comments? Provide country name and number of days delayed:

[Click here to enter text.](#)

Justification of non-implementation of comments

If not all comments implemented, 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 (SmPC, 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.

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}

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

{LANGUAGE}

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

{LANGUAGE}

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

{LANGUAGE}

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

Checklist

The following files should be submitted in one Eudralink message to the European Medicines Agencyⁱ with a copy to the Product Shared Mailboxⁱⁱ at Day +25 / 235

Subject title: <Product name> - <procedure number> - Post-opinion review - Day <+25 or 235> final submission by MAH /applicant

For the submission of the full set of annexes, [i.e. Annex I (SmPC), Annex II, Annex IIIA (labelling) and Annex IIIB (package leaflet) and Annex IV (if applicable)], Annex A, Annex 127a (if applicable) in all EU languages, the applicant/MAH confirms that they have prepared the submission files in accordance with the following checklist:	Tick to confirm check
The QRD Convention published on the Agency's website was followed for the preparation of the Word source files	<input type="checkbox"/>
The User guide on how to generate PDF versions of the product information published on the Agency's website was followed for the preparation of the PDF files	<input type="checkbox"/>
The PDF versions in all EU languages are identical to the Word source files	<input type="checkbox"/>
Track changes and comments have been 'accepted' (not simply switched off) and coloured or highlighted text does not appear in the PDF versions (except for sections referring to Appendix V)	<input type="checkbox"/>
The marketing authorisation dates of first authorisation (dates for different presentations to reflect the date of the first authorisation) and latest renewal, if any, are correct and indicated in section 9 of the SmPC, as appropriate	<input type="checkbox"/>
Revision dates do not appear in section 10 ('Date of revision of the text') of the SmPC	<input type="checkbox"/>
Revision dates do not appear in section "this leaflet was last approved on" of the package leaflet	<input type="checkbox"/>
Pictures in the SmPC and package leaflet display correctly and do not overlap with the text. They appear in the correct order and references made to picture numbers in the text are correct. The entire text in pictures was translated into the respective EU language	<input type="checkbox"/>
There are no blank pages or unexpected blank spaces (note: half empty pages are acceptable if they occur in connection with tables or pictures)	<input type="checkbox"/>
There is no text in the header of the pages	<input type="checkbox"/>
Only page numbers appear in the footer of the pages, starting with '1' (bottom, centre) on the title page of Annex I, and the format is font Arial 8	<input type="checkbox"/>

<p>Full set of annexes are provided as an integrated document in WORD TRACK CHANGED files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <i><PRODUCT NAME> day +25 (235) PI tracked all languages</i></p> <p>Full set of annexes are provided in PDF CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 PDF files) named as <i><PRODUCT NAME> day +25 (235) PI PDF all languages</i></p> <p>PDF files follow the naming convention ema-combined-h-xxx-<language code> and bookmarks and document properties are added</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p>Annex A (if applicable)** is provided as separate document with the cover page 'Annex A' removed in PDF CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 PDF files) named as <i><PRODUCT NAME> day +25 (235) Annex A PDF all languages</i></p> <p>PDF files follow the naming convention h-xxx-AA-<language code> and document properties are added</p> <p>**Where additional changes to the day +5/215 files have been made, submit full set of revised Annex A in WORD TRACK CHANGED files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <i><PRODUCT NAME> day +25 (235) Annex A word tracked all languages</i></p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p>Annex 127a (if applicable) is provided as</p> <p>separate document with '127a' removed in WORD TRACK CHANGED files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <i><PRODUCT NAME> day +25 (235) Annex 127a all languages</i></p> <p>separate document with '127a' removed in PDF CLEAN files in all EU languages (incl. EN, NO & IS) in one ZIP folder (containing 25 word files) named as <i><PRODUCT NAME> day +25 (235) Annex 127a PDF all languages</i></p> <p>PDF files follow the naming convention h-xxxx-Art127a-conditions-<language code> and document properties are added</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<p>Separate WORD file with the completed table of International non-proprietary/Common name of the active substance translations in all languages (if applicable and requested in the Day 210 letter to MAH)</p>	<input type="checkbox"/>
<p>Completed QRD Form 2 and Checklist for the submission of Day +25 / 235 final PI annexes</p>	<input type="checkbox"/>
<p>The Eudralink package has an expiry date of no less than 30 days</p>	<input type="checkbox"/>

Submit the Eudralink package to the Agency with a copy to the Product Shared Mailbox

Confirmed by: [Click here to enter text.](#)

Date: [Click here to enter text.](#)

ⁱ Contact email address as per the adopted CHMP Timetable

ⁱⁱ You may receive a **Delivery notice** from the Product Shared Mailbox; this is an automated reply and you may consider it as receipt of your email. It should therefore be disregarded and no additional steps should be taken to resend the package.