Submission of Day +25/235 final product information annexes (human and veterinary)

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

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

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 StatesDID 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}

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| **Section Title & Paragraph** | **Comment** | **Alternative proposal or how was the issue resolved?** |
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{LANGUAGE}

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| **Section Title & Paragraph** | **Comment** | **Alternative proposal or how was the issue resolved?** |
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{LANGUAGE}

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

The following files should be submitted in one Eudralink message to the European Medicines Agency [[1]](#endnote-1) with a copy to the Product Shared Mailbox[[2]](#endnote-2) at Day +25 / 235

Please be reminded that in accordance with **Union data protection requirements**, no personal data should be included in the annotated PIs. This applies to the English version and all the translations. Please submit annotated PIs in an anonymised format (i.e. names of the reviewers removed from the track-changes). If you do not wish to do so, please ensure that the individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant.

**EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder.**

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

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| **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](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005091.pdf) published on the Agency’s website was followed for the preparation of the Word source files |[ ]
| The User guide on how to generate PDF versions of the product information [human](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004716.pdf) / [veterinary](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/02/WC500101956.pdf) published on the Agency’s website was followed for the preparation of the PDF files |[ ]
| The PDF versions in all EU languages are identical to the Word source files |[ ]
| 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) |[ ]
| 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 |[ ]
| Revision dates do not appear in section 10 (‘Date of revision of the text’) of the SmPC |[ ]
| Revision dates do not appear in section “this leaflet was last approved on” of the package leaflet |[ ]

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| 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 |[ ]
| There are no blank pages or unexpected blank spaces (note: half empty pages are acceptable if they occur in connection with tables or pictures) |[ ]
| There is no text in the header of the pages |[ ]
| 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  |[ ]
|  |
| **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 *<PRODUCT NAME> day +25 (235) PI tracked all languages*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 *<PRODUCT NAME> day +25 (235) PI PDF all languages*PDF files follow the below naming convention and bookmarks and document properties are added**ema-combined-h–xxx-<language code>** *(for human procedures)* **ema-combined-v–xxx-<language code>** *(for veterinary procedures)* | [ ] [ ] [ ]  |
| **Annex A** (if applicable)\*\* is provided as separate document with the cover page/title ‘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 *<PRODUCT NAME> day +25 (235) Annex A PDF all languages*PDF files follow the below naming convention and document properties are added **ema-other-h-xxx-aa-<language code>** *(for human procedures)* **ema-other-v-xxx-aa-<language code>** *(for veterinary procedures)*\*\*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 *<PRODUCT NAME> day +25 (235) Annex A word tracked all languages* | [ ] [ ] [ ]  |
| *(for human procedures only)* **Annex 127a** (if applicable) is provided asseparate 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 *<PRODUCT NAME> day +25 (235) Annex 127a all languages*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 *<PRODUCT NAME> day +25 (235) Annex 127a PDF all languages* PDF files follow the naming convention **ema-other-h-xxx-a127a-<language code>** and document properties are added | [ ] [ ] [ ]  |
| 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) | [ ]  |
| Completed **QRD Form 2** **and Checklist for the submission of Day +25 / 235 final PI annexes** |[ ]
| The Eudralink package has an expiry date of **no less than 30 days** |[ ]

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

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Confirmed by: Click here to enter text. Date: Click here to enter text.

1. Contact email address as per the adopted CHMP/CVMP Timetable [↑](#endnote-ref-1)
2. 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. [↑](#endnote-ref-2)