QRD Form 2 - veterinary

For applicants/MAHs when submitting the final 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 reply received from Member State

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| BG | CS | DA | DE | EL/CY | ES  | ET | FI | FR | HR | HU | IS[[1]](#footnote-1) |
| 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 a reply *(with or without comments).*

 YES [ ]  NO\* [ ]

**\*If ‘NO’, contact the procedure coordinator prior to submitting the files to cross-check if the missing comments were received by the European Medicines Agency.**

The following Member StatesDID NOT provide a reply:

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.

**Were there any comments relating to the English product information, which require amendment in other languages?**

 YES [ ]  NO [ ]

**If yes: Have all the languages been amended accordingly?**

 YES [ ]  NO\* [ ]

*\*If no, please provide further details below*

Justification of non-implementation of comments

If not all Member State comments have been 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 (SPC, Annex II, labelling or package leaflet) and section to which the disputed comment relates together with an alternative proposal.

If comments were not implemented, but have been discussed and agreed and/or revised in agreement with the Member State(s), it is not necessary to list these; however, the MAH should be able to provide a copy of any relevant correspondence in case of queries.

In case of comments affecting the English language version, which require changes in other languages, the changes should be listed, and the EMA scientific support coordinator informed, as soon as possible. If required, these changes should then also be made in the other languages, and confirmation provided that all the relevant languages have been checked by Member States and amended accordingly. The standard timelines might be modified in this case.

{LANGUAGE}

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| **Section Title & Paragraph** | **Comment** | **Alternative proposal** **unresolved issues** |
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|  |  |  |

{LANGUAGE}

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| --- | --- | --- |
| **Section Title & Paragraph** | **Comment** | **Alternative proposal unresolved issues** |
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Checklist

Final files to be submitted in one Eudralink message to the European Medicines Agency [[2]](#endnote-1) with a copy to the Product Shared Mailbox[[3]](#endnote-2)

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 > final submission by applicant/MAH**

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| **For the submission of the full set of annexes, [i.e. Annex I (SPC), Annex II, Annex IIIA (labelling) and Annex IIIB (package leaflet)] 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](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/quality-review-documents-qrd-convention-be-followed-european-medicines-agency-qrd-templates_en.pdf) was followed for the preparation of the Word source files |[ ]
| The [User guide on how to generate PDF versions of the product information-veterinary](https://www.ema.europa.eu/documents/regulatory-procedural-guideline/user-guide-how-generate-pdf-versions-product-information-veterinary_en.pdf) 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  |[ ]
| Revision dates do not appear in section 9 (‘Date of the last revision of the SPC’) of the SPC*For post-authorisation procedures:*The date of the first authorisation is correctly indicated in section 8 (‘Date of first authorisation’) of the SPC | [ ] [ ]  |
| Revision dates do not appear in section “this leaflet was last approved on” of the package leaflet |[ ]
| Pictures /pictograms in the SPC 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[[4]](#endnote-3) TRACKED CHANGED files in all EU languages[[5]](#endnote-4) in one ZIP folder (containing 25 word files) named as *<PRODUCT NAME> day +25 PI tracked all languages*Full set of annexes are provided in WORD CLEAN files in all EU languages in one ZIP folder (containing 25 word files) named as *<PRODUCT NAME> day +25 PI clean all languages*Full set of annexes are provided in PDF CLEAN files in all EU languages in one ZIP folder (containing 25 PDF files) named as *<PRODUCT NAME> day +25 PI PDF all languages*PDF files follow the below naming convention and bookmarks and document properties are added**ema-combined-vprocedure number-product name-<variable part>-language code**[[6]](#endnote-5) | [ ] [ ] [ ] [ ]  |
| Separate WORD file with the completed table of **International non-proprietary/Common name of the active substance** translations and pharmaceutical form in all languages (if applicable and requested in the Day 210 letter to MAH) | [ ]  |
| Completed [**QRD Form 2** **and Checklist**](https://www.ema.europa.eu/documents/template-form/qrd-form-2-checklist-submission-day-25-files-veterinary_en.docx)for the submission of 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. Comments from Iceland are expected only for those products that are marketed in Iceland [↑](#footnote-ref-1)
2. Contact email address as per the adopted CVMP Translations Timetable [↑](#endnote-ref-1)
3. 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)
4. Word documents to be submitted in Microsoft Word 2007 file version ( ‘.docx’ files) [↑](#endnote-ref-3)
5. All EU languages plus English, Icelandic and Norwegian [↑](#endnote-ref-4)
6. For further details on the file naming convention and the relevant specifications that apply, please refer to the Annex 2 of Chapter 2 from the Implementation Guide on veterinary medicines

product data in the UPD ([VET EU IG](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/eu-implementation-guide-ig-veterinary-medicines-product-data-chapter-2-format-electronic-submission_en.pdf)) [↑](#endnote-ref-5)