



## 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](mailto:grd@ema.europa.eu)) with a copy to the Product Shared Mailbox<sup>1</sup>

**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 III A (labelling) and Annex III B (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

*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*

**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

**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

In addition to this, a separate English PI is provided indicating sections which differ from the reference product in tracked changed mode (not highlighted)

**For line extension applications:**

Full set of annexes are provided 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 215 PI all languages



<b>Annex A</b> 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 < <i>PRODUCT NAME</i> > <i>day 215 Annex A all languages</i>	<input type="checkbox"/>
<b>Annex 127a</b> (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 < <i>PRODUCT NAME</i> > <i>day 215 Annex 127a all languages</i>	<input type="checkbox"/>
<b>The QRD Form 1</b> 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 <b>no less than 30 days</b>	<input type="checkbox"/>

Submit the Eudralink package to [QRD@ema.europa.eu](mailto:QRD@ema.europa.eu) with a copy to the Product Shared Mailbox<sup>1</sup>

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<sup>1</sup> 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.