

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 (qrd@ema.europa.eu) with a copy to the Product Shared Mailbox¹

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.

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

(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 <u>ORD Convention</u> 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 <i>PRODUCT NAME> day 215 PI all languages</i>	
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 <i>PRODUCT NAME></i> 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</product>	
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 <i>PRODUCT NAME> day 215 Annex A all languages</i>	
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</product>	
The QRD Form 1 is attached as WORD file with section 1 completed in all parts	
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	
The Eudralink package has an expiry date of no less than 30 days	

Submit the Eudralink package to ${\underline{\tt QRD@ema.europa.eu}}$ with a copy to the Product Shared ${\tt Mailbox^1}$

¹ 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.