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Human Medicines Evaluation Division

Implementation plan for the revised QRD templates v9.1

The European Medicines Agency and the Quality Review of Documents (QRD) Group have revised the Human Product Information templates.

This revision comes after 2 years of experience with the previous QRD template issued as a result of the implementation of the new pharmacovigilance legislation, and it is based on the feedback received from various sources, e.g. National Competent Authorities, Pharmaceutical Industry, Patients and Consumers groups.

The revised QRD template has introduced new guidance for 1) the acceptance of combined SmPCs for different strengths of the same pharmaceutical form, 2) the dates to be recorded in section 9 of the SmPC (i.e. date of first authorisation and date of latest renewal), 3) the text to be included in Annex II, and 4) the list of local representatives in the package leaflet as a result of the revised EC Guideline on the packaging information of medicinal products for human use.

Implementation timelines

It is recommended to implement the revised QRD template v9.1 as soon as possible, but not later than 2 years following the publication date, for medicinal products with regulatory activity, and no later than 3 years for medicinal products with no regulatory activity.

The following documents are provided:

- A “Clean Annotated QRD template”;

- A “Highlighted Annotated QRD template”, presenting all changes made to the previous version (v9);

- “QRD templates” in all EEA languages, clean versions in MS Word.

Details of the implementation of the revised QRD templates

1) For ongoing initial marketing authorisation applications via the centralised procedure

Applicants should comply with the revised QRD template as early as possible and at the latest by Day 181 of the procedure (e.g. at Day 121 or at Day 181).

Considering the time constraints, new marketing authorisation applications with a CHMP opinion scheduled within 2 months following the publication of the revised QRD templates will not be required to adjust to the new version.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5515
Send a question via our website www.ema.europa.eu/contact

2) For new marketing authorisation applications via the centralised procedure

Applicants should comply with the revised QRD template at the time of submission.

However, any new marketing authorisation application with scheduled submission within 2 months following the publication of the revised QRD templates will be allowed to comply with the revised QRD template at Day 121 of the procedure.

3) For existing marketing authorisations granted via the centralised procedure

Applicants are encouraged to use the first upcoming regulatory procedure affecting Product Information Annexes (e.g. Line Extension, Variation, etc.) to comply with the revised QRD template.

At the occasion of the renewal of the marketing authorisation, applicants should bring the Product Information Annexes in line with the revised QRD template.

For products with no regulatory activity, MAHs are advised to update their Product Information Annexes according to QRD template v9.1 within 3 years following the date of publication of the QRD template. On a case by case basis, further extension may be considered.

Article 61(3) notifications and Variations not affecting the Product Information Annexes should not be used for this purpose.

Applicants/MAHs are advised to discuss the consequences of the implementation of this guidance for their product(s) with their Procedure Manager.