EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Implementation plan for the centralised procedure: QRD template v.8.1

The Quality Review of Documents (QRD) Group, the CMDv and the CVMP have revised the veterinary product information (PI) templates. This revision comes after 4 years of experience with the previous version. The template for each EEA language, as well as an annotated template in English (clean and tracked changes), are available on both the EMA and CMDv websites. A separate implementation plan is published on the CMDv website for MRP/DCP/purely-national MAs.

1) For new initial marketing authorisation (MA) applications via the centralised procedure:

Applicants should comply with PI template v.8.1 at time of submission. However, any veterinary medicinal product with a submission scheduled within 2 months of publication of PI template v.8.1 will be allowed to comply during the course of the procedure, see section 2.1 below.

2) For ongoing applications via the centralised procedure:

a. Ongoing initial MA applications

Any initial MA application already submitted at the time of publication of PI template v.8.1 should switch to it during the course of the procedure, preferably using existing time-points in the procedure when a submission of documents is foreseen (e.g. Day 121 responses to questions) and, at the latest, by Day 181. This applies even if no specific questions are asked on the draft product information during the MA application procedure.

However, considering the time constraints, new MA applications with a CVMP opinion scheduled within two months of the date of publication of PI template v.8.1 will not be required to adjust to the new version (unless the applicant wishes to do so). In this case, alignment with PI template v.8.1 should take place post-authorisation, see section 3 below.

b. Ongoing post-authorisation applications

Marketing Authorisation Holders (MAHs) with post-authorisation applications ongoing at the date of publication of PI template v.8.1 who wish to switch to it before the end of the procedure should request this on a case-by-case basis using the email address: vet.applications@ema.europa.eu. Where it is possible to switch within an ongoing post-authorisation affecting the PI, this is strongly encouraged.

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3) For existing MAs granted via the centralised procedure:

MAHs should align the PI with template v.8.1 at the next post-authorisation procedure affecting the PI (e.g. variation, line extension) and at the latest by the time of renewal of the MA (if applicable).

Applicants/MAHs wishing to discuss the consequences of PI template v.8.1 for their product(s) may submit any questions to their nominated EMA project manager for initial MA applications or, for post-authorisation procedures, to vet.applications@ema.europa.eu