Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

14 November 2012
EMA/CMDv/708985/2012

Implementation plan for MRP / DCP – Quality Review of Documents veterinary product information template version 8

The European Medicines Agency, the veterinary coordination group (CMDv) and the Quality Review of Documents (QRD) Group have revised the veterinary product information templates.

This revision is due to a QRD/CMDv harmonisation exercise, resulting in one common template to be used for centralised, mutual recognition (MRP) and decentralised procedures (DCP).

The QRD group took this opportunity to also implement some changes to improve the text in all the templates. The template for each European language, as well as an annotated template in English, are available on both the EMA and CMDv websites. A separate implementation plan has been published for centrally-authorised products.

Details of the implementation of the revised product information templates

1) For ongoing initial marketing authorisation applications via MRP / DCP:

Considering the time constraints, ongoing MR/DC procedures ending in November and December 2012 will not be required to adjust to the new version unless the applicant wishes to do so. For MR/DC procedures ending in January 2013 onwards, applicants should now comply with the product information template v.8 as soon as possible.

2) For new marketing authorisation applications via MRP / DCP:

As from January 2013, applicants should comply with the product information template v.8 at time of submission.

However, any veterinary medicinal product with scheduled submission between now and 1 January 2013 will be allowed to switch to the new templates during the course of the MR/DC procedure.

3) For existing marketing authorisations granted via MRP / DCP:

Marketing Authorisation Holders (MAHs) are encouraged to use the first upcoming regulatory procedure (e.g. extension, type II variation, etc.) affecting product information to comply with template v.8.

At the occasion of a renewal of the marketing authorisation, applicants should align the product information with template v.8.

All type IA variations and type IB variations not affecting the product information, should not be used for this purpose of switching to the new templates.

Applicants/MAHs are advised to discuss the consequences for their product(s) by submitting any questions to their Reference Member State for MRP/DCP or to the relevant national competent authority for purely-national marketing authorisations.