



Mandate of the CMDv *ad hoc* working group on validation

BACKGROUND

The Veterinary Coordination Group (CMDv) has been established in accordance with Article 31.1 of Directive 2001/82/EC as amended. The tasks of the CMDv include the provision of guidance on the administrative aspects of procedures for Marketing Authorisations in the Mutual Recognition (MRP) and Decentralised Procedures (DCP).

In the beginning of 2012 the CMDv discussed the simplification of procedures for granting a MA in the context of the review of the veterinary pharmaceutical legislation. In previous CMDv meetings, validation was already discussed with stakeholders, especially the additional national requirements. Validation is a crucial point for both the applicant and for RMS and CMS; consequently the CMDv wishes to organise a forum for discussion on validation with the objective to harmonise and simplify the process.

Therefore CMDv decided to create an *ad hoc* working group on validation.

MANDATE

The mandate of the CMDv *ad hoc* working group on validation will be to improve the validation phase in MRP/DCP with the development of a standard checklist and associated guidance on its criteria.