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Veterinary Medicines Division

Exceptions to the VNeeS format

Applicable to CP, MRP, DCP, NP[1]

There are no exceptions to VNeeS format. Applicants are asked to note the following with regard to part 2 of the dossier in CTD format.

With the coming into force of the revised VNeeS guideline version 2.4[2], as of 1 July 2016 the CTD format of quality documentation inside a veterinary dossier is allowed by the VNeeS specification and therefore is no longer considered an exception to the VNeeS format. This technical provision is without prejudice to the specific requirements of the receiving competent authorities, which are described below.

Submissions for veterinary dossiers in eCTD format cannot be accepted by regulatory authorities.

However, in certain specific cases, (parts of) the quality dossier could be accepted by regulatory authorities in CTD format based on NeeS (Note: not eCTD) provided that a correlation table between the CTD format sections used and the appropriate sections in the Annex I/NtA format is provided. An example for such a correlation table can be found here.

CTD (NeeS) format for the quality part of the dossier may only be used for a veterinary submission:

• For an active substance master file (see pre-submission guidance on the EMA website)

• For product applications for limited markets where the quality data has already been submitted and assessed for a human medicinal product (see "Quality data requirements for veterinary medicinal products intended for minor uses or minor species", EMEA/CVMP/QWP/128710/2004).

• For the whole quality part, if acceptable for both rapporteurs and the Agency (for CP), or agreed with the Reference Member State (MRP/DCP) prior to submission of the application. In such cases, the remaining CVMP members (for CP) / or Concerned Member States (for MRP, DCP) would also accept the CTD format for the quality part.

Please also refer to the CMDv document on CTD format acceptance.

For e-submission with both NtA and CTD folders, the CTD part should not be submitted outside the VNeeS submission, i.e. files and folders from a NeeS (CTD) structure should be incorporated into the

1 Centralised Procedure (CP), Mutual Recognition Procedure (MRP), Decentralised Procedure (DCP), National Procedure (NP).
2 Version 2.4 of the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product is published on the EMA eSubmissions website veterinary: http://esubmission.ema.europa.eu/tiges/vetesub.htm

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VNeeS structure. More specific technical guidance is provided in the revised VNeeS guideline version 2.4.

Note: Should you find any other exceptions preventing 100% compliance with the VNeeS format, please discuss this directly with the regulatory authority concerned and motivate this in the cover letter accompanying the dossier.

The regulatory authority should liaise with the Veterinary Harmonisation Group accordingly.