13 April 2012
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Veterinary Medicines and Product Data Management

Procedural announcement: E-submissions

Electronic submissions for veterinary medicinal product or MRL applications

Background

Since January 2010, the Agency has accepted electronic submissions for applications for veterinary medicinal products or MRLs. Such applications should be submitted in line with the Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product ("e-submission guideline"). Taking into account that this procedure of submitting electronic dossiers was new and that both regulatory authorities and applicants had to adjust their internal procedures to comply with e-submission requirements, the Agency accepted up to now dossier submissions not fully in line with these requirements. The electronic submissions are sent as CD or DVD, particularly initial applications, but updates of dossiers and responses to list of questions or post-authorisation applications are often submitted via EudraLink/e-mail. These EudraLink/e-mail submissions are not always sent via a central address, which may cause delays or inconsistencies in archiving.

Requirements as of 1 June 2012

As of 1 June 2012, only submissions that are fully compliant with the requirements of the e-submission guideline will be accepted by the Agency, as internal procedures will be streamlined, requiring that only technically valid applications can be further processed. Technical validity will be based on the "VNeeS checker", which can be downloaded free of charge from the Belgian or French agencies' websites (links are provided under: http://esubmission.ema.europa.eu/tiges/vetesub.htm).

EudraLink / e-mail submissions must be addressed to the central generic email address vet.applications@ema.europa.eu with a copy to the product specific mailbox (if known). In future, EudraLink submissions/e-mails addressed to individual staff members will not be understood as official submissions, but merely as a copy or additional information to the project manager or other contact person.

Applicants are therefore reminded to ensure that:

- Only applications 100% in line with the "VNeeS" checker should be submitted.
- They check their e-dossiers prior to submission, using the VNeeS checker. This check is strongly recommended and if 100% compliance is not achieved for reasons outside the influence of an applicant (e.g. deviations in regard to different formats outlined in the NtA and the e-submission guideline), a justification should be added to the letter covering an application.

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- In case they wish to attach the technical validation report created by the VNeeS checker tool, they should only save it under the “add-info” folder.
- Any electronic submission (CD/DVD or EudraLink/email) has to be correctly labelled, indicating at least the following: product name, procedure number, and – as required - procedure stage (e.g. response to questions)
- Any submissions via EudraLink/e-mail should only be addressed to vet.applications@ema.europa.eu, with a copy to the product specific mailbox (if known). Submissions via EudraLink/e-mail addressed to individual staff members will not be understood as official submissions, but merely as a copy or additional information to the project manager or other contact person.
- The EMA Gateway is at present only to be used for Human submissions and not for Veterinary submissions.

It is recommended to submit e-dossiers to the Agency one week in advance of the “recommended submission date” to ensure that only technically valid applications will be available on time. This includes initial marketing authorisation applications or MRL submissions, as well as post-authorisation procedures, or submissions during an on-going procedure (e.g. responses to the LoQ or LoOI).

More details on e-submissions for veterinary medicinal products or MRLs are available on the website of the TIGes Veterinary subgroup: http://esubmission.ema.europa.eu/tiges/vetesub.htm.