Information ÚSKVBL for the applicant and marketing authorisation holders of the veterinary medicinal products relating to electronic submission of the marketing authorisation dossier

Veterinary medicinal agencies of the European union accept applications and marketing authorisation dossier in electronic format since 01/01/2010. System of electronic submission "e-Submission" has been established with the aim of facilitation and harmonisation of the submission of the applications and marketing authorisation dossier in EU member states in order to streamline the marketing authorisation procedures.

ÚSKVBL applies electronic submission of application form (**e-AF - Electronic Application Form**) as well as marketing authorisation dossier (**e-Dossier**) for all types of the marketing authorisation procedures: centralised, mutual recognition, decentralised and national, further for post-marketing authorisation procedures and also for ASMF / MRL procedures. E-Submission is used by the following marketing authorisation procedures: new marketing authorisation, renewal of the marketing authorisation and type I and II variations. For other procedures on the national level are kept the current application word forms - e.g. parallel import application, withdrawal application, marketing authorisation transfer application.

With the view of the submission system optimalisation, the exact rules are set to fix up e-Submission system in itself. Common and only acceptable format is veterinary format of the marketing authorisation dossier (**VNeeS format - Veterinary Non-eCTD Electronic Submission**). The above format is mandatory for use for all types of marketing authorisation procedures, including national procedures, since 01/01/2019. Specific structure of VNeeS folders enables general and obvious identification of the marketing authorisation dossier.

Technical validation of the marketing authorisation dossier is based on the fulfilment of the defined criteria set in VNeeS validation form (**VNeeS Validation Checklist**).

Automatic validation control system (**VNeeS Checker**) is used for the verification of the technical quality and for the processing of the technical validation of the marketing authorisation dossier in the framework of validation phase. Checking through VNeeS Checker should be

standardly used by the applicant and marketing authorisation holders for verification if the application/marketing authorisation dossier is submitted in compliance with the required parameters and by national veterinary medicinal agencies for examination of the completness and validity of the submitted application/marketing authorisation dossier.

All bodies using e-Submission should follow documents specifying requirements and conditions for e-Submission which are published at e-Submission website in order to facilitate the handling of the electronic submission to all parties involved. For the purpose of preparing and publishing of the relevant documents there was established a special working subgroup - subgroup for harmonisation of the electronic submission of the veterinary medicinal products (**Veterinary Harmonisation Group - VHG**
). It is working group of EMA experts and is composed of representatives of competent agencies and institutions of EU member states, EMA representatives and representatives of pharmaceuticals industry. Functioning of this subgroup is focused on develpment and implementation of standards for electronic data and electronic information submission in context of european marketing authorisation procedures for veterinary medicinal products. The applicants and marketing authorisation holders can fully use e-Submission system in Czech republic using the most preferable way through Common European Submission Platform (CESP) or through Eudralink, eventually through hard media (CD, DVD).

On the ground of the regular updates of the appropriate e-Submission documents mentioned above it is highly recommended to check the above documents before the respective electronic submission of the marketing authorisation dossier to ensure e-Submission is submitted in valid version and is performed in line with valid requirements.

Documents and information regarding e-Submission are available at EMA website:

http://esubmission.ema.europa.eu/
http://esubmission.ema.europa.eu/tiges/vetesub.htm

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