25 November 2016
EMA/715059/2016
Veterinary Medicines Division

# Common Repository for all veterinary submissions in the centralised procedure – statement of intent

In February 2014 the European Medicines Agency (EMA) introduced the Common Repository for Human Centralised Procedure submissions, enabling all National Competent Authorities (NCAs) to access and retrieve eCTD format Centralised Procedure submissions for Human Medicinal Products in compliance with the HMA eSubmission Roadmap.

The HMA eSubmission Roadmap foresees in its vision the use of the Common Repository for all Centralised Procedure submissions to the NCAs, including veterinary submissions, albeit without a specified delivery timeframe on the part of veterinary submissions.

The Common Repository enables the Marketing Authorisation Holders to submit EMA coordinated applications only once to the EMA and hence removing the need to send CDs/DVDs or CESP submissions to individual Member States. The provision of the submitted dossiers to the Member States takes place electronically between the EMA and the NCAs. With Common Repository in place, the submissions sent to EMA via eSubmission Gateway/Web Client are considered delivered to all NCAs' representatives and alternates. This currently applies to all types of Human Centralised Procedure eCTD format submissions, including PMF submissions and ASMF submissions.

The Common Repository enables the National Competent Authorities to search, browse and download submissions. The solution allows for 2 main modes of operation; a Web User Interface and an Application Programming Interface. Further information is available in the published Q&A document on the Common Repository page of the eSubmission website.

In 2016, EMA has held preliminary discussions with its technical provider for an extension of the current Common Repository to non-eCTD format submissions including NeeS, VNeeS, as well as non-structured submissions. Such technical extension should be achievable via a change request for the Common Repository.

The EMA plans to be in a position to offer the Common Repository to NCAs involved in authorisation of Veterinary Medicinal Products in the Centralised Procedure in the future (implementation planning is in progress), with a draft implementation timeframe by the end of 2017.

***Related information***

- Common Repository website

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- EMA Common Repository: Questions and answers relating to practical and technical aspects of the implementation
- eSubmission Gateway and Web Client
- eSubmission Registration