Mandatory use of Common Repository for all human Referral submissions – Statement of Intent

The EMA's strategy for the electronic submission of applications aims to improve efficiency and streamline processes for all stakeholders.

The use of the Common Repository for all human Referral submissions will become mandatory on 1st December 2017.

From 1 December 2017, the use of Common Repository for Referral submissions will replace the use of CESP and CD/DVD for sending the Referral submissions to the National Competent Authorities (NCAs). All human referral submissions sent to the EMA will be considered delivered to all NCAs representatives and alternates.

Submissions for all referrals should be made via EMA eSubmission Gateway/Web Client only. Additional copies should not be submitted **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. More information on the Common Repository can be found here.

Background

The introduction of the Common Repository in February 2014 enabled all NCAs to search, browse and download centralised procedure eCTD submissions for human products including ASMF and PMF submissions. The use of the Common Repository for Human Centralised Procedure submissions is mandatory since July 2015 and all NCAs are using the Common Repository as their only source of Centralised Procedure submissions in compliance with the HMA eSubmission Roadmap.

The introduction of Common Repository has significantly reduced the time required for receiving and validating incoming applications and ensures continuous and immediate access to up-to-date dossiers. It has also significantly reduced the number of submissions sent by the applicants/MAH thereby reducing time and costs related to submissions.

The EMA is currently working on an extension to the Common Repository for all Veterinary submissions. It is expected that the Veterinary submissions will be available in the Common Repository before the end of Q4 2017. EMA will subsequently expand the Common Repository to contain all other remaining submission types for EMA coordinated procedures. Timelines for the upcoming releases will be communicated closer to the time.

Related information

- [Common Repository](#)

- [eSubmission Gateway and Web Client](#)