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Information Management Division

Mandatory use of Common Repository for EMA coordinated submissions for human medicinal products – 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 EMA coordinated procedures will become mandatory on 1st September 2018.

- PMF (Plasma Master File, previously under home) – eCTD format
- ASMF (Active Substance Master File, previously under home) – eCTD format
- Signal Detection – eCTD format & NeeS format. This type is connected to the connected to the EPITT database (European Pharmacovigilance Issues Tracking Tool). This is only for DCP/MRP. A NAP in a single member state is not under the lead of EMA and thus outside the scope of the CR
- PASS 107 NAPs – eCTD format & NeeS format. This is only for DCP/MRP. A NAP in a single member state is not under the lead of EMA and thus outside the scope of the CR
- Work Sharing NAPs – eCTD format & NeeS format (NAP = National authorized Product)
- Ancillary devices – unstructured (set of docs in PDF format)

From 1 September 2018, the use of Common Repository for above submissions will replace the use of CESP and CD/DVD for sending the submissions to the National Competent Authorities (NCAs). All mentioned submissions sent to the EMA will be considered delivered to all NCAs representatives and alternates.

Submissions for EMA coordinated procedures 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

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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.

Related information

- Common Repository
- eSubmission Gateway and Web Client