



## Annex 5 to the eSubmission Roadmap on the mandatory use of the Common Repository for EMA led procedures

Adopted by the eSubmission expert group on 15.06.2018

# 1. Background

The [HMA eSubmission Roadmap](#) published on the EMA website describes the current situation of eSubmission in the European Union and the issues that will be addressed in the near future. The roadmap includes a number of initiatives such as dossier formats, portal solutions and application forms. The roadmap also describes the mandatory use of the Common Repository (CR) for Centralised Procedure submissions in the human and veterinary domains. This annex 5 describes the transitioning to the mandatory use of the CR.

## Common Repository

The current [CAP Dossier Requirements](#) for Human submissions and the [CVMP dossier requirements](#) for Veterinary submissions elaborate details on the requirements on dossier format and addresses for the provision of copies of the submission sequences sent to EMA for the Centralised Procedure applications/procedures. The CR removes the need to provide each National Competent Authority (NCA) with a copy of the submission by allowing all NCAs access to all submissions received for the procedure types supported by the CR. This means that the applicant/MAH will only send a submission to the EMA via the eSubmission Gateway/Web Client which will be technically validated where possible, uploaded and made available to all NCAs through the CR.

The NCAs have permanent and immediate access to search, view and download all submission sequences either using manual web interface or an automated API (Application Programming Interface).

The objective and vision is to reduce the administrative burden for Regulatory Authorities and Industry and to support the timely availability of the submissions within the network.

For **submissions for Human Medicinal Products**, a stepwise approach has been developed to deliver the vision, as follows:

- Step 1: 1 July 2015. Use of the CR is mandatory for all NCAs for all eCTD Submissions in the context of Centralised Procedures
- Step 2: 1 December 2017: Use of the CR is mandatory for all human Referral submissions
- Step 3: Since 8 March 2018 submissions of the following types are supported by the CR and its use will be mandatory starting as of 1 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 EPITT database (European Pharmacovigilance Issues Tracking Tool). This is only for DCP/MRP. A NAP (Nationally authorised Product) 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
  - Ancillary devices – unstructured (set of docs in PDF format)

As a further step, the CR will be merged with the PSUR Repository to further streamline the NCA access to all types of submissions.

For **submissions for Veterinary Medicinal Products** the following approach has been developed to deliver the vision:

- Step 1: The CR was extended to include all veterinary submissions of the following types: centralised procedures, ASMFs, MRLs and Referrals. The statement of intent was published on 25 November 2017.
- Step 2: Available options since 19 March 2018 according to the information published in "Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency and to members of the Committee for Medicinal Products for Veterinary use (CVMP)", EMA/466102/2007:

Option I: NCAs are ready to receive veterinary submissions via CR

Applicants send their dossier via EMA gateway, submitted dossier is made available via CR, for CVMP members no further submission via any other channel is necessary, as they will receive the dossier via CR.

Option II: NCAs are not yet ready to receive veterinary submissions via CR

Applicants send their dossier via EMA gateway, submitted dossier is made available via CR. For CVMP members, additional submission via the recommended channel is necessary, as they will not receive any submissions via CR.

- Step 3: The use of the CR by NCAs to retrieve veterinary submissions of the above specified types will be mandatory from 1 June 2018, removing the need for the applicants to send copies of the submissions to individual Member States.

## 2. General Concepts

NCAs have two ways of downloading documentation from the CR:

- Download individual documents (using http protocol) Tool: Web User Interface (Browser)
- Download full dossier (using BitTorrent protocol) Tool: CR API Client

The Web User Interface is available to the NCAs via Eudranet. Two types of roles are available for access:

- Anonymous User, with rights to search, view and download individual documents
- Administrator with rights to search, view and download individual documents and full submissions.

The Web User Interface is compatible with Lightweight Directory Access Protocol (LDAP) and can therefore use the Eudra Common Directory user registry. In practice this means that the registered users of the CR do not need a separate account to connect to the CR but can use their Eudra user account.

The CR API client is available through Eudranet together with a JAVA based client tested and developed for automatic download by the Spanish Agency (AEMPS). Should you wish to receive this client, please send an email to [edossier@aemps.es](mailto:edossier@aemps.es).

For Human procedures, the Web User Interface is not intended to be an eCTD viewer. Investments for a separate eCTD viewer tool should not be needed as the CP submissions can be downloaded

using an API Client and reviewed with National eCTD Review Tools. Each NCA should have its own eCTD viewer to review national and MRP/DCP eCTD submissions and it is foreseen that it is used also for centralised procedure dossiers when needed.

For further information please see the [Q&A document](#).

### 3. Operational aspects

User and password requests can be addressed to EMA IT Service Desk (<https://servicedesk.ema.europa.eu/>). Up to 3 administrator users is recommended per NCA. The number of anonymous user is not limited per NCA. Administrators are authorised to manage NCA APIs and BitTorrent based download of sequences whereas anonymous users can only browse the CR and download single documents.

The Common Repository Maintenance Group collects and evaluates change requests and once approved, coordinates their implementation and releasing into production. Change requests can be addressed to EMA IT service desk (<https://servicedesk.ema.europa.eu/>).

If a National Competent Authority downloads the submissions using the CR API it is useful to know that:

- BitTorrent clients can be set up to move the submissions from human or veterinary domain once downloaded to a different folder. This action can be used as a signal to know that the sequence has been completely downloaded.
- For eCTD sequences you can use the eu-regional.xml, this file contains all the metadata needed to identify the submission and can be used to import the downloaded sequences automatically in your local repository. For eCTD sequences, it is possible to access and download a specific document via http using the relative path associated with the document in the eCTD backbone files eu-regional.xml or index.xml

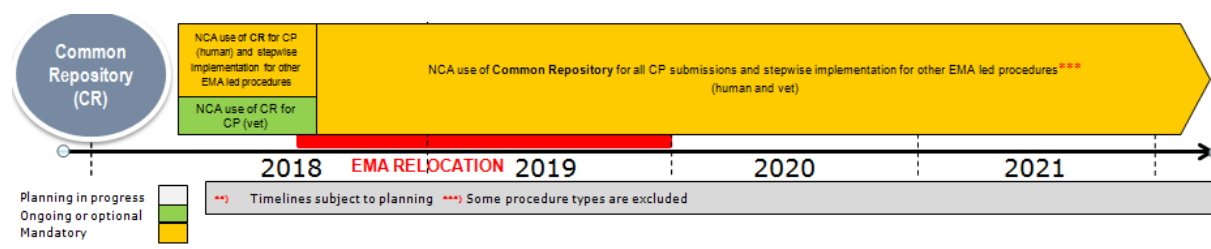
### 4. Benefits of using the Common Repository

- Simplification of submission channels: All Centralised Procedure submissions in all formats are sent via the eSubmission Gateway / Web Client removing the need to send separate copies to NCAs and hence reducing the number of submissions sent by the applicants/MAHs, thereby reducing time and costs related to submissions.
- One way of submission transmission: there will no longer be a need to create CDs/DVDs as all submissions are sent through a portal.
- Reduction in the need to archive and store non-relevant submissions in the NCAs: The NCAs download and store only those submissions of which they wish to have local copies in their national systems (for majority of NCAs this means retrieving only dossiers for procedures where they are a Rapporteur or Co-Rapporteur).
- Continuous and immediate access to up-to-date dossiers of centralised procedures or EMA led procedures by all NCAs
- Automated downloads from the CR using an API can be scheduled removing need for manual access to the repository.
- Submissions are technically validated where possible at the point of receipt before upload to the CR.

## 5. Availability of the Common Repository

The CR was launched on the 28 February 2014 and is now available to all NCAs via the Eudraportal. Once the use of the CR becomes mandatory for a specific procedure, individual submissions to NCAs for that procedure are not needed any more. The implementation towards the mandatory use of the CR by the NCAs will be organised via existing change management activity dealt with by EMA with close collaboration with the NCAs.

### 5.1. Timelines



### 5.2. Next steps

Milestone	By
Use of Common Repository mandatory for Veterinary submissions of the following types: centralised procedures, ASMFs, MRLs and Referrals.	1 June 2018
Use of Common Repository mandatory for Human submissions of the following types: <ul style="list-style-type: none"> <li>o PMF (Plasma Master File, previously under home) – eCTD format</li> <li>o ASMF (Active Substance Master File, previously under home) – eCTD format</li> <li>o Signal Detection – eCTD format &amp; NeeS format. This type is 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</li> <li>o PASS 107 NAPs – eCTD format &amp; 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</li> <li>o Work Sharing NAPs – eCTD format &amp; NeeS format</li> <li>o Ancillary devices – unstructured (set of docs in PDF format)</li> </ul>	1 September 2018

### **5.3. Guidance Notes, useful links and contacts**

- All information, including relevant guidance, Q&A and workaround documents, is available under: [http://esubmission.ema.europa.eu/central\\_repository.HTML](http://esubmission.ema.europa.eu/central_repository.HTML)
- [The acceptable usage policy](#) defines a set of rules for the Common Repository users, which give direction how to use the CR system in an optimal way, leading to good system response times, high reliability and an efficient use of the available IT resources
- EMA will provide assistance to NCAs as needed.

For any query please contact the EMA IT service desk: <https://servicedesk.ema.europa.eu>