EMA Common Repository: Questions and answers relating to practical and technical aspects of the implementation

This question and answer document aims to address the frequently-asked questions and provide guidance regarding technical and practical aspects of the European Medicines Agency's Common Repository.

Contents

Objectives of the Common Repository

1. What is the Common Repository?

The Common Repository is a solution that is hosted at the data centre of the EMA. It is implemented within the context of the introduction of electronic submissions, as part of the human centralised procedure for the marketing authorisation of medicinal products in the European market. It contains the entirety of eCTD electronic submissions.

The Common Repository is accessed via client software which is a custom development for the review of electronic submissions in eCTD format. The entire system is called European Review System (EURS).

The solution allows for 2 main modes of operation: the Web User Interface and the Application Programming Interface (API) (see question 6 for further details).

The use of the Common Repository became mandatory on 1 July 2015.

2. What is the advantage of using the Common Repository?

There are many advantages to the introduction of the Common Repository. The solution provides:

- The facility for electronic storage and distribution of a variety of application dossiers and documents – no more unnecessary environmental and administrative burden of duplicating CDs and DVDs
- Better support for version control of submissions and sequences. The risk of different (and potentially outdated) versions of dossiers being processed or reviewed is eliminated
- Faster distribution of documents in line with business deadlines. There is no need for multiple copies of a single dossier to be submitted to all NCAs in each Member State
- Unlike the CESP or eSubmission Gateway/Web Client which are transfer mechanisms, the Common Repository makes the submissions permanently available to Member States and can thereby reduce the need for NCAs to keep their own national copies of all Centrally Authorised submissions (the NCAs might only wish to download to their own local repositories copies of submissions that they are (Co)Rapporteur/Peer Reviewer).

With the introduction of the Common Repository, the EMA assures that only eCTD submissions which have passed the technical compliance checks by the EMA are made available to the NCAs.

3. Which types of application can be retrieved from the Common Repository?

The first phase of the Common Repository (CR) project was established to identify an effective way to provide access for National Competent Authorities to Centralised Procedure application dossiers (initial MAA and post-authorisation activities) for human medicines. Currently only Centralised Procedure eCTD applications are stored in the EMA's Common Repository, but it is the intention to use the CR in the future also for other procedure and document types.

4. Who is the Common Repository for?

The Common Repository is for use by NCAs and the EMA. The pharmaceutical industry benefits from the use of the Common Repository indirectly. Now that the use of the Common Repository is

mandatory for all NCAs the applicants/MAH will no longer need to send copies of the Centralised Procedure submissions to NCAs. The applicants/MAHs should submit their Centralised Procedure submissions to EMA only via eSubmission Gateway/Web Client. No separate submissions are to be sent to any NCAs on CD/DVD or via CESP.

Please see the details on 'Dossier requirements for CAPs' document on EMA website.

5. Is the Common Repository only able to receive submissions sent via the eSubmission Gateway / Web Client?

The Common Repository contains *all* eCTD Centralised Procedure submissions. It is mandatory to use the eSubmission Gateway/Web Client for Centralised Procedure submissions to the EMA.

6. Is the Common Repository available for use by the Pharmaceutical Industry?

The Common Repository is for use by NCAs and the EMA. When eCTD Centralised Procedure submissions are sent to the EMA they are automatically loaded in to the Common Repository. Pharmaceutical Industry colleagues do not require direct access to the Common Repository.

The key users are members of the European Medicines Regulatory Network, who are normally not working from the EMA premises and who need secure access over the Internet to the Centralised Procedure submissions provided by the Pharmaceutical Industry to the EMA. These are Member States (MS) staff, Rapporteurs, Co-Rapporteurs, Peer Reviewers and other CHMP, PRAC and CAT members.

The pharmaceutical industry benefits from the use of the Common Repository indirectly as they no longer need to send copies of the Centralised Procedure submissions to NCAs. Please see the details in the 'Dossier Requirements for CAPs' document on EMA website.

Modes of operation

7. What is the difference between the Web User Interface and the Application Programming Interface (API)?

Web User Interface
There are two different ways to access the Common Repository via the Web User Interface;

- The anonymous (unregistered) user can search and browse through all the dossiers stored in the EMAs Common Repository. They can also view and download single files (size limitations may apply) in the Common Repository.

- The Administrator (registered user) can search and browse through all the dossiers and view single files (size limitations may apply) in the Common Repository. The Admin user can also download full submission sequences to be permanently stored by the NCAs. Up to 3 Administrator users can be added for each NCA.

It is possible to fully operate the Common Repository by using the Web User Interface with Administrator rights. The Administrator user can select a start date and create at that start date a complete national copy of all the CR information which shall be maintained in its national repositories.

Once the initial copy has been created, NCAs will then be able to retrieve regularly information about any new eCTD submission, which has been sent to the EMA as part of the Centralised Procedure. In

order to maintain their national CR copy, NCAs will choose which of the new Centralised Procedure submissions shall be downloaded into their national environment.

This mode provides a basic view without the option for extended queries such as searching within specific time intervals. The Web User Interface does not require specific software and it's an easy to use, free solution for the NCAs.

Application Programming Interface (API)

In order to use the Common Repository via the API, the NCAs need to obtain software either by developing this or purchasing from a relevant vendor. It should be noted that EMA does not offer an automation tool and that EMA does not provide an end to end solution via API.

The Application Programming Interface is based on the concept that NCAs will build a copy of the EMA's Common Repository within their national repository. This national copy may contain 100% of EMA's Common Repository files, but it may also contain only a subset of the centrally held information. The EMA provides the NCAs with the description of an open application programmable interface (API) to the Common Repository for searching, downloading and browsing/viewing.

It is expected that NCAs, which have decided to operate using the API, will select a start date and will create at that start date a complete national copy of all the CR information which shall be maintained in its national repositories.

Once the initial copy has been created, NCAs will then be able to retrieve regularly information about any new eCTD submission, which has been sent to the EMA as part of the Centralised Procedure. In order to maintain their national CR copy, NCAs will choose which of the new Centralised Procedure submissions shall be downloaded into their national environment.

Using the Common Repository via the API will enable the NCAs automate the retrieval of submissions from the repository.

A summary of the main features is shown below:

Feature / Requirement	Web User Interface- Anonymous User NCAs have the possibility to search and browse	Web User Interface- Administrator User NCAs have the possibility to search, browse and download	Application Programming Interface (API) - NCAs build a copy of the EMA's Common Repository within their national Repository.
Aligned with the latest EMA submissions due to fully automated functionality			✔
NCAs build a copy of the EMA's Common Repository		✔	✔
Search and browse through all the dossiers stored in the EMAs Common Repository and view single files	✔	✔	✔
Download single documents	✔	✔	✔
Download sequences		✔	✔
Define extended queries such as searching within specific time intervals			✔
Basic query capabilities	✔	✔	✔
Access to 100% of EMA Common Repository	✔	✔	✔

Acceptable submission formats and size limitations

8. What file formats are able to be submitted to the Common Repository?

Submissions received in eCTD format will be loaded in to the Common Repository.

9. Is there a size limit for submissions stored in the Common Repository?

There is no storage limit.

10. Is there a download limit for submissions stored in the Common Repository?

There is a 100MB limit for individual downloads when logged in as an anonymous user. There is no limit for downloads requested by users logged in as an Administrator.

Connection and registration process

11. How can NCAs gain access to the Common Repository?

The Common Repository Web User Interface with the user login is available via your web browser.

NCAs can connect via the EMA's Virtual Private Network (VPN), Eudranet. They do not need to install any client software; the website is used as the interface. This website can show all dossiers from the *Centralised procedure*, uploaded at EMA and made available for download by *Torrent*. The website provides access to the Web User Interface as an anonymous or Administrator user with each having different access rights.

12. Our NCA would like multiple users, is this possible?

Yes, the Common Repository has been designed to allow multiple users.

13. What is the difference between an "Anonymous" user and an "Administrator" user of the Web User Interface?

An anonymous user can search and browse complete dossiers and download single documents. An Administrator user can search, view and download complete sequences.

14. Can NCAs only view submissions for which they are the Rapporteur or Co-Rapporteur?

No, all NCAs can have access to all submissions contained in the Common Repository.

Technical questions

15. Do NCA's need access to other EMA systems to enable the Common Repository to work?

NCAs are required to connect to Eudranet in order to access the Common Repository. Connectivity to other EMA systems is not required.

16. Do NCAs need an external software provider in order to connect to the Common Repository?

The use of an external provider for access to the Application Programming Interface (API) is at the discretion of individual NCAs. The Web User Interface is available via a secure URL to all NCAs.

17. Are NCAs restricted to download content from the Common Repository at specific times?

The CR Access Manager located at the EMA will contain a traffic shaping function, which will limit the download capacity to 20% of the EMA's available Internet bandwidth between 8 am and 8 pm, UK time on EMA working days. After 8 pm and before 8 am in the morning as well as on weekends and during

EMA holidays 80% of the bandwidth will be made available for NCA downloads of CR information over EudraNet.

18. Which browser is supported for use with the API?

The EMA support Internet Explorer 8 and Firefox 16.

19. Is there a way to detect configuration issues experienced when trying to connect to the Common Repository?

The EMA has created a diagnostic tool that can assist NCAs in the detection of configuration issues when it is not possible to connect to the Common Repository. The tool runs in a "silent mode" which requires no human interaction for collecting the test results of the network configuration.

The diagnostic tool is accessible via a designated URL and requires Java 6 to be installed. A user guide providing details of the main functionality and set-up information is available upon request.

General questions

20. Is the Common Repository a secure system?

All communication is over EudraNet. EudraNet is a virtual private network (VPN) between the NCA's and the EMA using the IPsec protocol with 3DES encryption. All EudraNet users have signed up to a security policy which stipulates that each NCA and the EMA are responsible for the security in their own domain.

21. Common Repository availability and mandatory use?

The Common Repository was launched on 28th of February 2014. A selected number of NCAs participated in an initial enhanced support phase. From 1 July 2015 the use of Common Repository became mandatory for all NCAs.

22. What is the cost of the Common Repository for NCAs?

There is no cost to access the Web User Interface, however; the cost of configuring the Application Programming Interface will depend on the requirements of individual NCAs.

23. Will industry continue to submit the CHMP/PRAC copies via CESP or will the members also have access to the repository?

As the use of the Common Repository is now mandatory, all Centralised Procedure eCTD submissions to all NCAs are now done via the Common Repository. The applicants/MAHs submit to EMA via the eSubmission Gateway/Web Client (the use of these tools is mandatory for all Centralised Procedure submissions) and these submissions are subsequently technically validated and uploaded to the Common Repository where they are permanently available for all NCAs. The NCAs then retrieve relevant submissions from the repository and make them available to their assessors, the same way

they would make them available if a CD/DVD or CESP package would have been received. The applicants/MAHs only submit once to EMA and no further copies to NCAs are required.

It should be noted that submissions sent via CESP for MRP/DCP and/or National Procedures are not made available via the Common Repository.

24. How will the NCAs access the Working documents provided together with the eCTD submissions now that Common Repository is in use? Are the working documents distributed via the Repository

The working documents are currently not available via the Common Repository. They are sent to NCAs via an automated email once received via the eSubmission Gateway/Web Client. The applicants should continue sending the Working documents to EMA together with eCTD submissions.

25. Are the PSUR Single Assessment submissions available via the Common Repository?

The current release of the Common Repository only contains Centralised Procedure eCTD submissions, including PSURs for Centrally Authorised Products. Submissions related to PSUSA procedures will be made available via the PSUR Repository which was launched in January 2015. The use of PSUR repository will become mandatory in June 2016.

Glossary

Definitions, Acronyms, and Abbreviations

Additional definitions, acronyms, and abbreviations:

Term	Definition
EURS:	European Review System
eCTD:	electronic Common Technical Document
CR:	Common Repository
NR:	National Repository
NCA:	National Competent Authority
EMA:	European Medicines Agency
ECD:	Eudra Common Directory
Eudra:	European Union Drug Regulatory Authorities
EMRN:	European Medicines Regulatory Network
VPN:	A virtual private network (VPN) is a secure network that uses primarily public telecommunication infrastructures, such as the Internet, to provide remote offices an access to a central organizational network. There are two types of VPNs; remote access VPNs and site to site VPNs. Remote access VPNs are for individual users who are not in a fixed location - remote or roaming users. Site to site VPNs are for multiple users in a fixed location - like regional offices. EudraNet is a site to site VPN
Applicant	A pharmaceutical company or its agent that is submitting

	information in support of an *application*
Centralised Procedure	The centralised registration procedure for the authorisation and maintenance of medicinal products in the European Union. There are 4 types of procedures that operate within the EU – The eSubmissions via the Gateway is only dealing with the Centralised Procedure
Submission	A single set of information and/or documents supplied by the applicant as a part of, or the complete, Application. In the context of eCTD, this is equivalent to '**sequence**'

Contact us

To register or if you have any further non-technical questions that are not adequately addressed by this document, please forward your query or comment to eSubmission@ema.europa.eu