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PSUR Repository: Frequently Asked Questions (FAQ)

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FAQs from NCA

1. What is the PSUR Repository?

The PSUR Repository delivers a secure electronic submission point for Marketing Authorisation Holders (MAH) streamlining the Periodic Safety Update Report (PSUR) submissions for the pharmaceutical industry.

It acts as a common storage place for PSURs, PSUR Assessment Reports (ARs), comments and final outcomes, with a secure access for NCAs and the European Commission. The PSUR Repository supports both, the PSUR Single Assessment Procedure (PSUSA) and the single, pure NAP procedures where the active substance is only authorised in one Member State.

2. How can I access the PSUR repository?

You must register with the Agency to use the PSUR repository. Once registered you will need your user name and password to log into the repository using a web browser and navigate to https://psur-repo.eudra.org/psur-ui

3. Do NCAs need an external software provider in order to connect to the PSUR Repository?

No.

The Agency has tested the system with Internet Explorer 9+.
The system also works with more recent versions of Firefox and Chrome, though it has not been fully tested with all of these browsers.

4. Are NCAs restricted to download content from the PSUR Repository at specific times?

The aim is ensure the repository is available at all times. However, there will be times when the software needs to be updated and access to the repository may be limited. Such updates will take place out of standard EMA office hours and the network will be notified well in advance of any downtime.

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

Yes, the PSUR Repository has been designed to allow multiple users. The repository has been configured based on an average of 30 users per NCA. This means that some agency will use less and some will need more. Based on your needs and justification the repository can be configured accordingly.

6. What user roles are available for use with the repository?

There are two roles:

Reviewer – can search and download documents only

Contributor – In addition the reviewer access this role can also upload documents to the repository.

You must specify the type of user for whom you are requesting access and this must be done at the time of registrations.

7. How long does it take for NCAs to register for the PSUR Repository?

The registration process can take up to 20 working days.

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

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

9. Will there be an API for PSUR repository?

There are plans to develop an API for the PSUR repository similar to the API for the Common Repository. Further announcements will be made on the eSubmissions website.

10. Is there a size limit for submissions stored in the PSUR Repository?

There is no storage limit.

11. Do NCAs have to pay a fee to register for the PSUR repository?

No. There no fees to the NCA for registering and using the PSUR repository.

12. Why can't I upload an assessment report

Please ensure that you are logged in using the correct role. If you cannot see the "upload" option next to the "search" option at the top of the browser screen then you are logged in as a "Reviewer". Only "Contributor" role has permissions to upload documents to the PSUR Repository.

Please ensure that you are using one of the supported browsers, IE 9+, Firexfox and Chrome.