

PSUR Repository – procedures for single, pure nationally authorised products (NAPs) - Invitation to submit all PSURs to the Repository

The PSUR repository is now available and it offers a secure electronic submission point for Marketing Authorisation Holders (MAH), streamlining Periodic Safety Update Report (PSUR) submissions for the pharmaceutical industry. It will act 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) as governed by the EURD list and the single, pure NAP procedures, where the active substance is not included in the EURD and may only be authorised in one Member State.

Since January 2015, the EMA has been piloting single assessment PSUR procedures in the repository. After a successful independent audit confirming that the repository has reached the required functionality, the EMA Management Board has announced that mandatory use of the repository will commence on 13th June 2016.

The EMA has also announced that the repository will, from 11th February 2016, enter a switch-on phase. This is a phase of simulated mandatory use and allows National Competent Authorities (NCAs) and MAHs to upload PSURs, assessment reports and comments via the repository and takes advantage of the enhanced notification system offered by the repository.

The NCAs will continue receiving nationally authorised NAP PSURs locally until the mandatory use (June 2016).

The switch-on phase will allow for further learning and preparation for the mandatory use of the system for both MAHs and NCAs. Therefore during the switch-on phase (i.e. from 11th February 2016) the CMDh would like to invite MAHs for pure national products to submit their PSURs and any related supplementary information to the repository.

MAHs should note that prior to submission to the PSUR repository, product data in the Article 57 database should be checked to ensure that products are correctly entered and will hence be available in the PSUR repository.

MAHs are also reminded that PSUR submissions both to the PSUR repository and NCAs must be structured electronic submissions, i.e. eCTD or NeeS. PSURs submitted as pdf documents cannot be uploaded into the PSUR repository, and will entail follow up with the relevant MAH.

Additional information on the repository and guidance on how to register can be found on the EMA's PSUR repository web pages: http://esubmission.ema.europa.eu/psur/psur_repository.html

Users should report any issues they may have with the system through the PSUR repository mailbox psurrepository@ema.europa.eu. When communicating issues, please copy the relevant NCA contact.