EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Periodic Safety Update Report (PSUR) repository mandatory use: questions and answers

Information for marketing authorisation holders (MAHs) on changes to the submissions of PSURs for human medicines

1. What is the PSUR repository?

The PSUR repository is a common storage place for PSURs, regulators' PSUR assessment reports, comments and final outcomes. National Competent Authorities (NCAs) have direct, secure access to the repository. More information on the PSUR repository can be found here: http://esubmission.ema.europa.eu/psur/psur_repository.html.

2. How are PSUR submissions changing?

From 13 June 2016, it is mandatory for all MAHs in the European Union (EU) to submit PSURs for human medicines directly to the PSUR repository. This means that companies must use the repository as a single point for all submissions and should no longer submit PSURs to NCAs directly.

The PSUR repository is mandatory for both centrally and nationally authorised medicines whether they follow the EU single assessment or a purely national assessment procedure. The PSUR repository is intended for PSURs for human medicines only.

3. After 13 June 2016, what happens if a PSUR is not submitted to the PSUR repository?

PSURs that have not been sent to the PSUR repository are considered as not submitted and will not be assessed. PSURs not sent to the PSUR repository will not fulfil the MAH's legal obligation to submit PSURs.

4. How do I submit a PSUR?

All PSURs are submitted to EMA's PSUR repository using the eSubmission Gateway/Web Client: http://esubmission.ema.europa.eu/esubmission.html

In order to submit a PSUR to the PSUR repository via the eSubmission Gateway /Web Client all users must register using the self-registration functionality. PSURs must be submitted as an Electronic Common Technical Document (eCTD) or non-eCTD electronic submission (NeeS). PSURs submitted in any other electronic format cannot be uploaded into the PSUR repository and will be rejected.

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Information on the repository, guidance on how to register and multimedia tutorials for MAHs on how to submit a PSUR, as well as on the correct structured electronic formats, can be found on EMA's PSUR repository web pages here: http://esubmission.ema.europa.eu/psur/psur_repository.html

5. What steps do I have to take before I can submit a PSUR to the PSUR repository?

Prior to submission to the PSUR repository, MAHs must ensure that the information on their authorised medicines is entered correctly in the Article 57 database. This is a legally binding requirement from the EU pharmaceutical legislation.

The PSUR repository product selection is connected to the Article 57 database. If a product has not been correctly included in this database, it will not be displayed in the PSUR repository.

More information about the submission of information on medicines in the Article 57 database is available here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0

6. Who can I contact to help me with my queries on PSUR repository?

Users can contact EMA to send their questions or report any issues they have with the PSUR repository and/or the eSubmission Gateway/Web Client to the EMA Service Desk portal: https://servicedesk.ema.europa.eu.