8 June 2016
EMA/383311/2016
Media and Public Relations

# Single, central platform now mandatory for all periodic safety update reports

## PSUR repository facilitates information exchange on the safety of human medicines authorised in the EU

As of 13 June 2016, all periodic safety update reports (PSURs) for human medicines authorised in the European Union (EU) must be submitted to the PSUR repository, which has been developed by the European Medicines Agency (EMA) in close collaboration with EU Member States and the industry.

The PSUR repository is a single, central platform for PSURs and related documents to be used by all regulatory authorities and pharmaceutical companies in the EU. It was introduced by the EU pharmacovigilance legislation to facilitate the exchange of information on the safety of authorised medicines between regulators and pharmaceutical companies.

Marketing authorisation holders must now use the repository as a single point for all submissions and should no longer submit their PSURs to NCAs. The eSubmission Gateway is available on the eSubmission website.

The PSUR repository provides an important simplification for marketing authorisation holders allowing them to send all PSURs to a single recipient. It also facilitates the assessment of the reports by ensuring that NCAs, EMA and its scientific committees have timely and secure access to all relevant documents.

In June 2015, EMA's Management Board gave the green light for the use of the repository following an independent audit that confirmed that the tool meets the agreed functional specifications.

Since the initial release of the PSUR repository in January 2015, EMA has been supporting companies and NCAs to ensure they are ready to use this new tool. The system has been implemented using a phased approach and feedback from users has been taken into account to improve the system.

Guidance, interactive training sessions and links to all relevant documents have been made available on EMA's eSubmission website. More information on how to submit a PSUR through the repository can be found in a questions-and-answers document published today.

PSURs are reports providing an evaluation of the benefit-risk balance of a medicine. Marketing authorisation holders must submit PSURs at defined time points following a medicine's authorisation. PSURs include the results of all studies carried out with this medicine, both in its authorised and unauthorised uses.

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EMA uses the information in PSURs to determine if there are new risks identified for a medicine or whether the balance of benefits and risks of a medicine has changed. It can then decide if further investigations need to be carried out or can take action to protect the public from the risks identified, for example by updating the information provided for healthcare professionals and patients.