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EudraVigilance system downtime – impact on PSUR Repository and the eAF

The European Medicines Agency (EMA) will launch a new and improved version of EudraVigilance, the European information system of suspected adverse reactions to medicines that are authorised or being studied in clinical trials in the European Economic Area (EEA).

Following the EMA Management Board confirmation and announcement in May 2017 that the database has achieved full functionality, the **new version of EudraVigilance will go live on 22 November 2017** with enhanced functionalities for reporting and analysing suspected adverse reactions. The public health benefits from the new system and operational benefits for stakeholders and regulators will provide a robust basis for pharmacovigilance and signal management activities for years to come.

The go-live plan outlines a set of detailed, sequenced tasks and activities required to launch the new EudraVigilance production system including the migration of more than 11 million Individual Case Safety Reports (ICSRs) and associated data and the decommissioning of the current (legacy) EudraVigilance system as regards the ICSR reporting and processing functionalities. To allow for a smooth transition from the current to the new EudraVigilance system, a cutover (**downtime**) period of 10 business days i.e. from **8 to 21 November 2017** is required.

During the scheduled downtime it will not be possible to amend product data in Article 57. This will impact the **PSUR Repository** as the product selection for the PSUR submissions is linked to Art. 57. It will not be possible to update/amend product data for the creation of the XML delivery files during this downtime period. The EMA therefore strongly recommends that MAHs with a PSUR submission date falling during the scheduled downtime (8 to 21 November 2017) carefully review the list of products available through the PSUR Repository xml delivery file user interface to ensure availability of the products included in the relevant procedures and make plans to create the xml delivery file and **submit** their **PSUR prior to the 8 November**.

Alternatively if an earlier submission cannot be accommodated MAHs are nevertheless encouraged to review the availability of products and correctness of the entries in the XML delivery file. The MAHs should contact the EMA service desk to request a late submission ID in order to submit initial PSUSAs after the due date. There is no need to request late submission ID for subsequent submissions, such as responses.

This will also impact eAF use as the substance selection for the Initial MAA is linked to EXVDMP. It will not be possible to update substance data for the creation of eAF dataset during this downtime period. The EMA strongly recommends that MAHs, with a MAA date falling during the scheduled downtime (8 to 21 November 2017), carefully review relevant data and ensure that the required substances are available via the eAFs.

Related information: EudraVigilance | eSubmission - PSUR Repository | EMA Service Desk portal

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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