Technical Note on the planned EudraVigilance downtime from 8 to 21 November 2017
IT systems impacted and steps to follow

This technical note describes the IT systems including EudraVigilance, which will be impacted by the planned downtime from 8 to 21 November 2017 and provides further instructions to Member States, applicants, marketing authorisation holders and sponsors of clinical trials.

1. EudraVigilance (Human) system and XEVMPD (Art.57 database)

Key components of EudraVigilance will not or will only be partially available from 8 to 21 November 2017. These are as follows:

- The **EudraVigilance registration system will be unavailable**. Registrations of new organisations or users and updates to existing users should be submitted in a timely manner **by 15 October 2017** so they can be processed by EMA before the registration system becomes unavailable on 8 November 2017.

- **EVWEB, the application for electronic reporting of individual case safety reports (ICSRs) for authorised medicinal products and suspected unexpected serious adverse reactions (SUSARs)** for products subject to investigation in clinical trials in the EEA **will not be available** to users of competent authorities, marketing authorisation holders and sponsor of clinical trials in the EEA.

- **XEVMPD (Art.57 database)** will not be available for the **electronic submissions of data on medicines (Article 57)**. This applies to new entries and updates to existing entries, which should be completed where possible, prior to the 8 November 2017. Where this is not possible, the data submission should take place as of 22 November 2017.

- **Signal management by NCAs and EMA will be impacted to a small extent**, as the current EVDAS will be kept operational but with the dataset not refreshed daily during the downtime.

The adrreports.eu portal (www.adrreports.eu) website for the general public and healthcare professionals will remain live.

The reporting by patients and healthcare professional to national Competent Authorities (NCAs) and to marketing authorisation holders (MAHs) in the EEA will not be impacted.

To facilitate the transition from the current to the new EudraVigilance system, the EMA's pharmacovigilance business team in consultation with the Pharmacovigilance Risk Assessment Committee (PRAC), the Clinical Trials Facilitation Group (CTFG) and the EudraVigilance Expert Working Group have prepared the **EudraVigilance go-live plan**. **This plan describes the business processes impacted and outlines the alternative arrangements that need to be planned for by national competent authorities, marketing authorisation holders and sponsors of clinical trials during the downtime**. The plan also reiterates the **mechanisms in place to notify any emerging safety issues** by marketing authorisation holders and sponsors of clinical trials to Member States and the EMA. Related information: EudraVigilance change management.

2. EudraVigilance Veterinary

Key components of EudraVigilance Veterinary will not or will only be partially available from 8 to 21 November 2017. These are as follows:

- The **EudraVigilance registration system will be unavailable**. Registrations of new organisations or users and updates to existing users should be submitted in a timely manner **by 15 October 2017** so they can be processed by EMA before the system becomes unavailable on 8 November 2017.

- **EVWEB, the application for electronic reporting of suspected adverse reactions related to veterinary medicinal products will not be available** to users of Competent Authorities and marketing authorisation holders in the EEA.

- The **electronic reporting of suspected adverse reactions** related to veterinary medicinal products **by gateway organisations will be possible** for reports having occurred in **Germany**, **Spain** or the **UK only**.

- **Signal management by NCAs and EMA will be impacted to a small extent**, as the EudraVigilance Veterinary data warehouse will be kept operational. However, the data in the data warehouse will not be refreshed during the downtime.

The reporting by veterinarians and health professionals to national Competent Authorities and marketing authorisation holders in the EEA will not be impacted.

Related information: EudraVigilance Veterinary -Login

3. PSUR Repository

PSUR submission will not be affected. However, due to the unavailability of the XEVMPD (Article 57 database) from 8 to 21 November 2017, the **PSUR Repository** will be affected by the downtime as the product selection for the PSUR submissions is linked to XEVMPD (Article 57) data.

- **It will not be possible to update/amend product data in the XEVMPD (art.57 database) for the creation of the XML delivery files during this downtime period.**

The EMA strongly recommends that MAHs, with a PSUR submission date falling during the scheduled downtime, 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. MAHs should create the xml delivery file and **submit** their **PSUR prior to the 8 November 2017,** where applicable. Alternatively, if an earlier submission cannot be accommodated, MAHs are encouraged to review the availability of products and correctness of the entries in the XML delivery file user interface. The MAHs should contact the EMA service desk to request a late submission ID to submit initial PSURs

after the due date. There is no need to request late submission ID for subsequent submissions, such as responses.

4. eAF

The eAF will remain available. However, due to the unavailability of the XEVMPD (Article 57 database) from 8 to 21 November, the use of **eAF** will be affected as the substance selection for an initial marketing authorisation application is linked to the XEVMPD (Article 57 data).

- **It will not be possible to update substance data in the XEVMPD (art.57 database) for the creation of the eAF dataset during this downtime period**.

The EMA strongly recommends that MAHs with a marketing authorisation application date coinciding with the scheduled downtime (8 to 21 November 2017), carefully review and update relevant data beforehand.

Related information: eSubmission

5. EudraCT database and EudraCT data warehouse

The EudraCT database and EduraCT data warehouse will remain available. However, due to the unavailability of XEVMPD (Article 57 database) from 8 to 21 November 2017 and other EudraVigilance components as outlined under point 1, the EudraCT database and EudraCT data warehouse will be affected.

- For protocol data and the registration of substance data in the XEVMPD (Article 57 database) as part of the preparation of the clinical trial application, entries should be completed prior to the 8 November 2017. Where this is not possible the data submission should take place as of 22 November 2017.

- The EudraCT data warehouse used by NCAs and EMA will be impacted to a small extent. It will be kept operational but with the dataset not refreshed during the downtime (in particular the reports on protocol data and the SUSAR monitoring reports).