LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la Santé - Division de la Pharmacie et des Médicaments

Followed by :
Anne-Cécile Vuillemin, , Pharmacovigilance Responsible Person
Edwige Chokoté, Clinical Research Associate
Direction de la Santé, Division de la Pharmacie et des Médicaments
pharmacovigilance@ms.etat.lu

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Communication regarding the electronic transmission to the Direction de la Santé, Division de la Pharmacie et des Médicaments, of suspected unexpected serious adverse reactions (SUSARs) having occurred in interventional clinical trials

According to Directive 2001/20/CE[1] and Regulation 536/2014/UE[2] repealing Directive 2001/20/EC, sponsors of interventional clinical trials must report all suspected unexpected serious adverse reactions (SUSARs) occurring in these trials in Luxemburg to the Direction de la Santé, Division de la Pharmacie et des Médicaments (DPM).

The DPM has implemented a system of electronic exchange of suspected adverse reactions via the WebTrader module of the EudraVigilance web application (EVWEB). The DPM reminds all sponsors of interventional clinical trials of their obligation to report all SUSARs electronically as Individual Case Safety Reports (ICSRs), in full compliance with the ICH E2B(R2) or E2B(R3)/M2, with all medical information coded with the MedDRA dictionary. As of 30th of June 2022, only the E2B(R3) will be accepted.

The following rules are applicable:

Sponsors of interventional clinical trials approved in Luxemburg must report electronically, according to the timelines laid down in the European and national legislation, as follows:

- SUSARs occurring in Luxemburg to the EudraVigilance Clinical Trials Module (**EVCTM**) **only**, with the receiver identifier **EVCTMPROD**;

[1] Directive 2001/20/EC of 4 April on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

[2] Regulation (EU) No 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

- SUSARs occurring outside Luxemburg, including SUSARs occurring outside of the European Economic Area (EEA), to **EVCTM**. SUSARs occurring outside Luxemburg must be reported according to the requirements of each Member State of the EEA (for SUSARs occurring in the EEA) and of the EMA (for non-European SUSARs).

The European Medicines Agency (EMA) has granted the DPM access to the EudraVigilance database, allowing the DPM to download the cases directly.

Reporting obligations are considered fulfilled when the reporting of SUSARs having occurred in Luxemburg has been made to EVCTM.

Regarding the detailed guidance on electronic reporting, sponsors must follow the requirements of the « *Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ("CT-3")* ».

The DPM does not require from sponsors of clinical trials already in production with EVCTM to perform additional testing for the electronic transmission to the receiver identifier **DPM**.

Save exceptional circumstances, reporting to the DPM other than reporting to EVCTM are not accepted. Sponsors of clinical trials who do not report electronically yet, must implement electronic transmission of SUSARs according to the rules and procedures for transmission to Eudravigilance, including tests with the EMA, as applicable. For detailed information, please follow this link :
https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance/eudravigilance-how-register

Please note that any previous recommendation concerning SUSAR reporting, such as reporting by email or any other communication channel, is obsolete and replaced by this guidance.

Should you have any practical question, please contact us at
pharmacovigilance@ms.etat.lu

Please accept, Madam, Sir, our respectful regards.

Dr Anna Chioti
Chief of Division
Division of Pharmacy and Medicines