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

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

Followed by :
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Communication regarding the electronic transmission to the Direction de la Santé, Division de la Pharmacie et des Médicaments, of spontaneous reports and individual case safety reports (ICSRs) from non-interventional clinical trials

According to Community legislation (Directive 2001/83/EC[1] and Regulation (EC)[2] No 726/2004 as amended), Marketing Authorisation Holders (MAH) of medicinal products, independently of the authorisation procedure, must report in an expedited manner:

- Serious adverse reactions occurring in the European Economic Area (EEA) or in third countries (out of the EEA) to the EudraVigilance Post-Authorisation Module (**EVPM**), with the receiver identifier **EVHUMAN,** no later than 15 calendar days from the date the information was received.
- Non-serious adverse reactions occurring in the EEA to **EVHUMAN,** no later than 90 calendar days from the date the information was received.

In addition, any suspicion of transmission of an infectious agent via a medicinal product is considered as a serious adverse drug reaction and must be reported no later than 15 calendar days from the date the information was received.

Save exceptional circumstances, these reactions must be transmitted 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 European Medicines Agency (EMA[3]) has granted the DPM access to EudraVigilance, allowing the DPM to download cases directly.

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[1] Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use

[2] Regulation (EC) No 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[3] EMA: European Medicines Agency

Reporting obligations are considered fulfilled when the reporting of ICSRs having occurred in Luxemburg to EVPM has been performed.

MAHs are informed by this communication that, as of the 3rd of February 2020, all cases reported to EudraVigilance by the DPM have, as the second part of the « Sender's Safety Report Unique Identifier » (C.1.1 in EB(R3) and A.1.0.1 in E2B(R2)) and of the « Worldwide Unique Case Identifier » (C.1.8.1 in E2B(R3) and A.1.10.1 in E2B(R2)) completed as **ALMPS** (and no longer AFSSAPS).

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