EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2013
EMA/573249/2013

Communication on reporting of suspected adverse reactions occurring in the European Union by Competent Authorities in Member States to the World Health Organization

The EU pharmacovigilance legislation adopted in 2010 requires the European Medicines Agency (EMA) to make available promptly all reports of suspected adverse reactions that occurred in the European Union (EU) to the World Health Organization (WHO)[1].

De facto, this provision of reports should occur to the Uppsala Monitoring Centre (UMC), which acts as the WHO Collaborating Centre for International Drug Monitoring.

While the legislation came into force on 1 July 2012, the provision of reports of suspected adverse reactions that occurred in the EU from the Agency to the UMC will start after a successful audit of enhanced EudraVigilance functionalities[2].

In the interim, Competent Authorities in EU Member States continue their reporting to the UMC in accordance with the guidelines on "Good Pharmacovigilance Practices (GVP): Module VI – Management and reporting of adverse reactions to medicinal products" published on the Agency's website.

[1] Article 28c of Regulation (EC) No 726/2004
[2] Article 24(2) of Regulation (EC) No 726/2004

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