Electronic Reporting of Individual Case Safety Reports (ICSRs) originating in Romania

Starting with 22 November 2017, in accordance with European legislation regarding pharmacovigilance of medicinal products for human use, Regulation (EC) 726/2004 as amended, and Directive 2001/83/EC as amended, transposed into national legislation regulating medicinal products, Law 95/2006 on healthcare reform, Title XVIII, The medicinal product, as amended, irrespective of medicinal product authorisation procedure, the following requirements apply for Marketing Authorisation Holders (MAHs) for all serious and non-serious adverse reactions occurring within the European Economic Area (EEA) and brought to their attention by a healthcare professional or patient:

- individual Case Safety Reports (ICSRs) reporting requirements for Marketing Authorisation Holders (MAHs) shall be in accordance with relevant EU guidance included in the revised Guideline on good pharmacovigilance practices - Module VI Management and reporting of adverse reactions to medicinal products, the latest revision. This revision is published on the EMA website.
- serious valid ICSRs originating in Romania shall be submitted directly by the marketing authorisation holder to the EMA EudraVigilance database Post-Authorisation Module (with the Message/Batch Receiver Identifier: EVHUMAN) within 15 days from the date of report receipt;
- non-serious valid ICSRs originating in Romania shall be submitted directly by the marketing authorisation holder to the EMA EudraVigilance database Post-Authorisation Module (Message/Batch Receiver Identifier: EVHUMAN) within 90 days from the date of report receipt;
- submission to the EudraVigilance database shall be done electronically in the ICH E2B (R2) or the ICH E2B (R3) format.

As of 22 November 2017, MAHs will no longer receive regulatory cases directly from the National Agency for Medicines and Medical Devices (NAMMD). Cases will be made available to MAHs by the EMA via the EudraVigilance system in the ICH E2B (R3) format. For more information, please see the EudraVigilance section on the EMA website.

This is in line with the principle of centralised reporting of suspected adverse drug reactions to the EMA EudraVigilance database as introduced by EU pharmacovigilance legislation.

This letter supersedes all previous documents describing NAMMD requirements for ICSRs electronic transmission and shall be in force as of 22 November 2017.