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Electronic Reporting of Spontaneous Individual Case Safety Reports (ICSRs) and reports from non-interventional clinical trials to the Romanian National Agency for Medicines and Medical Devices (NAMMD)

In accordance with entry into force of the new European legislation regarding pharmacovigilance of medicinal products for human use, Regulation (EC) 726/2004 as amended, and Directive 2001/83/EC as amended, transposed as required into national legislation regulating medicinal products, **Law 95/2006 on healthcare reform, Title XVII, The medicinal product** as amended, irrespective of authorisation procedure of medicinal product, Marketing Authorisation Holders (MAHs) shall promptly report 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, to the Competent Authority of the Member State in whose territory the incident has occurred, if required.

Save in exceptional circumstances, such reactions shall be communicated electronically as Individual Case Safety Reports (ICSRs), in full compliance with the ICH E2B(R2)/(M2) and Community guidelines, and using the coding MedDRA of medical information.

Following transposition of these requirements into **Law 95/2006 on healthcare reform, Title XVII – The medicinal product**, as amended, the National Agency for Medicines and Medical Devices (NAMMD) hereby informs on use of an electronic data exchange system for suspected adverse reactions through the webtrader component of the EudraVigilance Web Application (EVWEB). Therefore, the following rules apply for transmission of spontaneous reports and reports from non-interventional trials:

- Reports of suspected serious adverse reactions and of any suspected transmission via a medicinal product of an infectious agent originating in Romania, shall be electronically transmitted to the NAMMD, within 15 days, using the message receiver identifier **NMA.**
- Reports of suspected non-serious adverse reactions originating in Romania shall be electronically transmitted to the NAMMD, within 90 days, using the message receiver identifier **NMA.**
- All literature cases transmitted to the NAMMD shall be accompanied by submission of copies of literature articles provided in PDF format and sent via email to farmacovigilenta@anm.ro.
- Reports of suspected serious adverse reactions and of any suspected transmission via a medicinal product of an infectious agent originating in another EEA country and associated to products authorised through mutual recognition procedure or decentralised procedure or subject of a referral procedure, and for which Romania is the Rapporteur or the Reference Member State, shall be transmitted to the NAMMD with the message receiver identifier **NMA**. This is in addition to regulatory reporting obligations as applicable in the Member State on whose territory the suspected serious adverse reaction has occurred.

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- Reports of suspected serious adverse reactions and of any suspected transmission via a medicinal product of an infectious agent originating in the territory of a third country (non-EEA country) shall only be transmitted electronically to the EudraVigilance PostAuthorisation Module (EVPM), using the message receiver identifier **EVHUMAN**. Because third country cases are made directly available via the EudraVigilance, they do not need reporting to the NAMMD. Copies of literature articles related to suspected serious adverse reactions reportable to the EVPM shall be provided in PDF format and sent via email to the EVLIT@ema.europa.eu.

MAHs are reminded that:

- ✓ For electronic transmission, the NAMMD uses the Eudravigilance Webtrader, therefore MAHs need no compatibility test with the NAMMD. The NAMMD does not require MAHs already in production with the EVPM to perform additional tests for electronic transmission of spontaneous reports and reports from non-interventional trials. MAHs intending to start electronic transmission shall initially inform the NAMMD by email to roxana.stroe@anm.ro and camelia.lazar@anm.ro.
- ✓ In case of system failure, switch is advised to alternative reporting means (e.g. via fax: +40213163497 or email: adr@anm.ro), accompanied by NAMMD notification of occurrence of failure at the sender's site. Receipt of such reports is acknowledged. If the problem is resolved and electronic reporting is restored, the NAMMD shall be informed and the E2B electronic version of the report shall be submitted to the NAMMD.

Electronic retrospective reporting of ICSRs (backlog management)

MAHs are requested to retrospectively report ICSRs in electronic format:

- With use of "backlog" instead of "ichicsr" in the ICH M2 message header identifier M1.1 „Message type". The field value is case-sensitive and shall be reported in lower case. To exclude such reports from expedited reporting compliance checks, retrospectively transmitted ICSRs need to be clearly flagged as "backlog".
- To the NAMMD, as regards suspected serious adverse reactions and any suspected transmission via a medicinal product of an infectious agent, originating in Romania as of 01 January 2007. This refers to ICSRs not already transmitted electronically to the NAMMD or the EVPM. All "backlog" messages shall be addressed to the NAMMD using the message receiver identifier **NMA**. Prior to initiation of retrospective transmission, initial testing with the NAMMD is required. Transmission to the NAMMD may be performed via the EVWEB or via physical media in line with the applicable ESTRI recommendations (floppy disks, CD-R, DVD).

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- To the EVPM, as regards suspected serious adverse reactions and any suspected transmission via a medicinal product of an infectious agent, originating outside the EEA, not already transmitted electronically to the EVPM. All "backlog" messages shall be addressed to the EVPM using the message receiver identifier **EVHUMAN**. Prior to initiation of transmission of "backlog" messages, basic tests needs to be conducted with the EMA and a transmission timeline agreed.

This letter supersedes all previous documents describing NAMMD requirements for ICSR electronic transmission and shall be in force as of 01 August 2014.

Marius SAVU, M.D.,

President of the National Agency for Medicines and Medical Devices, Romania