



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections and Human Medicines Pharmacovigilance Division

Reporting requirements of marketing authorisation holders in the EU regarding suspected adverse reactions occurring with medicinal products they donate outside the EU to public health programmes against neglected tropical diseases

Clarifications have been requested from the European Medicines Agency (hereinafter referred to as the Agency) by the World Health Organization (WHO) as regards reporting requirements for marketing authorisation holders in the European Union (EU) as regards suspected adverse reactions occurring with medicinal products they donate outside the EU to public health programmes against neglected tropical diseases.

Marketing authorisation holders in the EU in this context are physical or legal entities holding a marketing authorisation in the EU for a medicinal product they donate outside the EU, irrespective of differences in dosage forms and/or product information.

The following clarifications are provided:

Based on Article 107(1) of Directive 2001/83/EC, marketing authorisation holders in the EU have the legal obligation to record and report to competent authorities in the EU Member States and the Agency all suspected adverse reactions, occurring in the EU or in third countries, which are brought to their attention.

Therefore, any suspected adverse reaction brought to the attention of a marketing authorisation holder for a medicinal product they have donated outside the EU should be recorded and reported by the marketing authorisation holder to the relevant competent authorities in the EU.

In accordance with the legal requirements set out in Directive 2001/83/EC and Regulation (EC) 726/2004 and as further detailed in the EU guidelines on good pharmacovigilance practices, marketing authorisation holders who donate medicinal products outside the EU to public health programmes against neglected tropical diseases should, for medicinal products they have donated to the programmes:



(1) report to EU competent authorities, as individual case safety reports by means of EudraVigilance, serious suspected adverse reactions which occur outside the EU in these public health programmes and which are brought to the attention of these marketing authorisation holders;

(2) report to EU competent authorities, by means of summary tabulations and discussion in the periodic safety update reports, non-serious adverse reactions which occur outside the EU in these public health programmes and which are brought to the attention of these marketing authorisation holders.

Further guidance on (1) and (2) is provided in Modules VI and VII of the EU guidelines on good pharmacovigilance practices.

The above clarifications are based on the EU legislative framework and good pharmacovigilance practices, which were endorsed by the EU regulatory network.