

Circular No: P09/2008
July 2008

Re: Requirements for submission of E2B(M) Individual Case Safety Reports (ICSRs) to the Medicines Authority

To all Marketing Authorisation Holders (MAHs) and Sponsors of Clinical Trials

This Circular repeals Circular P02/2007 on the above-captioned subject matter.

In line with Directive 2001/83/EC as amended, Regulation (EC) 726/2004 and the Pharmacovigilance Regulations 2006 (Legal Notice 61 of 2006), MAHs are obliged to report to the Medicines Authority suspected serious adverse reactions (expected and unexpected) occurring in Malta and suspected serious and unexpected adverse reactions occurring in the territory of a third country (non-EU/EEA).

Based on these requirements, ICSRs concerning suspected serious adverse reactions originating in Malta should be transmitted electronically to the Medicines Authority with the message receiver identifier ADM. Parallel reporting of ICSRs in paper format is not required. Moreover, MAHs are requested to submit ICSRs concerning suspected serious and unexpected adverse reactions occurring in the territory of a third country (non-EU/EEA) to EudraVigilance only with the message receiver identifier EVHUMAN. It is worth noting that ICSR submission to EVHUMAN encompasses reporting to the Agency and to all the Member State authorities (including the Medicines Authority) in line with the requirements of the Directive and Regulations mentioned in the preceding paragraph.

Directive 2001/20/EC and the Clinical Trials Regulations 2004 (Legal Notice 490 of 2004) instruct sponsors of clinical trials to report to the Medicines Authority suspected unexpected serious adverse reactions (SUSARs) arising from clinical trials conducted in Malta and from multi-centre clinical trials which include Maltese centers. Thus, SUSARs arising from clinical trials conducted in Malta and from multi-center clinical trials which include Maltese centers, should be submitted electronically by the sponsor to the EudraVigilance Clinical Trial Module (EVCTM) using message receiver identifier EVCTMPROD. It is worth noting that SUSAR submission to EVCTM encompasses reporting to the Agency and to all the concerned Member State authorities (including the Medicines Authority) as per the requirements of Directive 2001/20/EC.

Post-Licensing Directorate
Medicines Authority