



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

August 2012

Subject: MedDRA version control

In the context of the electronic reporting of Individual Case Safety Reports (ICSRs), the EudraVigilance Expert Working Group (EV-EWG), the committee overseeing the practical implementation of the electronic reporting of ICSRs in the Community, would like to remind all stakeholders that they should follow the recommendations of the MedDRA Maintenance Support Service Organisation (MSSO) regarding the switch to a new MedDRA version as outlined below: *"A new release version of MedDRA should become the reporting version on the first Monday of the second month after it is released. To synchronize this event over the three ICH regions, the MSSO recommends midnight GMT, Sunday to Monday, for the switchover", for example:*

MedDRA v15.0	Monday 7 May 2012
MedDRA v15.1	Monday 5 November 2012
MedDRA v16.0	Monday 6 May 2013

The stated change over date and time need to be adhered to consistently by all stakeholders to avoid any disruptions with regard to the electronic exchange of ICSRs. MedDRA subscribers who are able to quickly update and validate their systems with each release of MedDRA should recognise that if they submit ICSRs using the updated MedDRA version prior to the receiving party, which has not switched to the updated version, the transmitted ICSRs may be rejected.

In practice this means that the switch can be performed as of Friday night UK time, until the cut off time 12.01 a.m. UK time Monday morning. During this time it is recommended that no ICSR is sent as otherwise the receiver(s) may reject it.

Yours sincerely,

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