



PRESS RELEASE

Lisbon, Portugal, ICH MedDRA[®] Management Board Meeting

ICH MedDRA Management Board Endorses
Blue Ribbon Panel Recommendation for a 27th SOC

Lisbon, 9 November 2014 – The ICH MedDRA Management Board met in Lisbon, Portugal on 8-9 November 2014.

27th System Organ Class (SOC)

The Board endorsed the Blue Ribbon Panel's recommendation for the addition of a 27th SOC in MedDRA to accommodate terms related to product quality concepts. The planned implementation date is March 2016 for MedDRA Version 19.0. The MSSO will engage in discussions with users regarding the details of this new SOC.

MSSO Subscription Rates

The Board is pleased to announce that there will be no increase in MedDRA subscription rates for 2015. This is the result of continued growth of MedDRA subscribers throughout the world – currently numbering over 4,000 organisations – and increased efficiencies to contain costs of maintenance and development of the terminology.

Special Licences

The Board received an update on the status of special licences granted to regulatory authorities which support low revenue organisations to use MedDRA for reporting requirements. There is now a total of over 1,000 organisations worldwide benefitting from special licences. Further information is available on the MedDRA website and is also referenced in a new MedDRA Factsheet – *Accessing MedDRA*.

ICH M1 Points to Consider

The ICH M1 Points to Consider Working Group will be meeting at EMA in London on 10-12 November 2014 to discuss refinements to the coding of medication errors, off label use, and other related concepts in MedDRA, and to provide support to the EU medication errors project.

Standardised MedDRA Queries (SMQs)

The Board acknowledged the significant efforts of the Council for the International Organization of Medical Sciences (CIOMS) SMQ Working Group and renewed the Memorandum of Understanding between ICH and CIOMS for a further year of development of new SMQs. The Board noted that there are now 96 SMQ topics in use.

The next scheduled meeting of the Board will be on 6-7 June 2015 in Fukuoka, Japan.

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