

PRESS RELEASE

**MedDRA® Management Committee Meeting
Geneva, Switzerland, 11-12 November 2017**

MedDRA Management Committee Takes Further Steps to Support MedDRA's use as a Global Standard

Geneva, 30 November 2017

Geneva, Switzerland, November 2017 – The MedDRA Management Committee met in Geneva, Switzerland on 11-12 November 2017. Ms. Sophie Sommerer (Health Canada, Canada) was appointed as Chair with the unanimous support of the Committee to serve until November 2018.

Subscription Rates

The Committee is pleased to announce that there will be a further reduction in MedDRA subscription rates for lower revenue MSSO subscribers in 2018, following on from the rate reduction that was already implemented for all MSSO subscribers in 2017. Details will be available on the MedDRA website.

This reduction is a reflection of the continued success of MedDRA as a global standard in public health. With over 5,000 subscribing organisations in more than 110 countries, the costs of maintaining and developing the terminology can be distributed over a wider base, whilst still providing the same high standard of tools and services to MedDRA users.

Efforts to Assist the Global Uptake of MedDRA

Reducing subscription rates is just one of the steps being taken by the Committee to assist the global uptake of MedDRA. Training and support are considered key to ensuring MedDRA's smooth implementation. So far in 2017, MSSO has provided free training to over 3,000 participants through webinars, as well as face-to-face training which is now being conducted in multiple locations worldwide, including Brazil, Canada, China, Europe, Mexico, Russia and the United States.

In Geneva, the Committee was pleased to announce plans to commence local support in several countries and regions where the demand for training and support in the local language is increasing. This includes Central America and the Republic of Korea, starting in 2018, and China from 2019. Furthermore, in recognition of local language needs, the Committee is pleased to announce plans to add Korean and Russian MedDRA translations to the current portfolio of 11 MedDRA languages.

The Committee is also welcoming of coordination with the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre) in supporting countries transitioning from WHO-ART to MedDRA for pharmacovigilance activities. Two representatives from the MedDRA Management Committee participated in a preconference workshop on MedDRA held in Uganda on 6 November, ahead of the 2017 WHO Annual Meeting of Representatives of the National Pharmacovigilance Centers (NPCs). The Committee also noted that the MSSO and the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre) held a successful joint MedDRA/WHODrug meeting in Beijing, China in September 2017.

ICH M1 Points to Consider

Recognising the importance of guidance in ensuring the use of MedDRA in a standardized way, the Committee noted the efforts of the ICH M1 Points to Consider (PtC) Working Group in supporting MedDRA's global uptake. The Working Group met in Geneva on 13-15 November to complete the first draft of a companion document to the PtC documents. This document will provide more detailed guidance, examples, and "Questions and Answers" on topics of regulatory importance. The first edition of the companion document will address data quality issues and medication errors, and is expected to be available in 2018.

Standardised MedDRA Queries (SMQs)

The Committee acknowledged the significant work 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. One new SMQ Dehydration will go into production in March 2018 for MedDRA Version 21.0.

ISO Certification

The MSSO reported that it has held ISO certification since 2003 and is now compliant with the new ISO 9001:2015 standard as of August 2017 following successful completion of an audit. ISO 9001:2015 certification has also been achieved successfully by the JMO.

Other Activities

The Committee was also updated on other important initiatives and developments. The MSSO reported on its participation in the Innovative Medicines Initiative's WEB-RADR (Recognising Adverse Drug Reactions) project and the development and testing of a set of "patient friendly terms" in MedDRA to support direct patient reporting of adverse events through mobile applications and web portals. The patient friendly term list and an explanatory document are expected to be available in 2018 and will be published on the MedDRA website.



The next scheduled meeting of the Committee will be on 2-3 June 2018 in Kobe, Japan.

For further information, please contact:

ICH Secretariat

Chemin des Mines 9

1202 Geneva, Switzerland

Tel: +41 22 338 3206

E-mail: PressRelease@ich.org - Websites: www.ich.org / www.meddra.org