



**MedDRA
Maintenance and Support
Services Organization
Annual Report
2010**

1 MedDRA As An ICH Product

MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and The World Health Organization, and is chaired by the IFPMA. See page 10 for a list of the individual Management Board members.

2 MedDRA MSSO Mission

The MedDRA Maintenance and Support Services Organization (MSSO) is tasked with two functions:

- Establish and maintain a mechanism for international support and development of the MedDRA terminology
- Foster the use of MedDRA worldwide through communication, education, and services

The goal of the MSSO is to maintain MedDRA as a stable, consistent terminology to suit the needs of regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing; and for data entry, retrieval, evaluation, and presentation.

3 Highlights for 2010

3.1 Subscription and Subscription Rates

The year 2010 was a year of continued growth and development of MedDRA for the MSSO. MedDRA had 2782 subscribing organizations worldwide by the end of 2010 (2611 in 2009). Of the 2782 worldwide subscribers, 2264 were MSSO subscribers (2108 in 2009) and 518 were JMO subscribers (503 in 2009). The 2264 MSSO subscribers represent a 7% growth in subscribers in 2010 over 2009 (10% the year before).

Figure 3-1 depicts the distribution of MSSO subscribers by region. Figure 3-2 provides the number of new MSSO subscribers (422) in 2010 (412 in 2009) by each region.

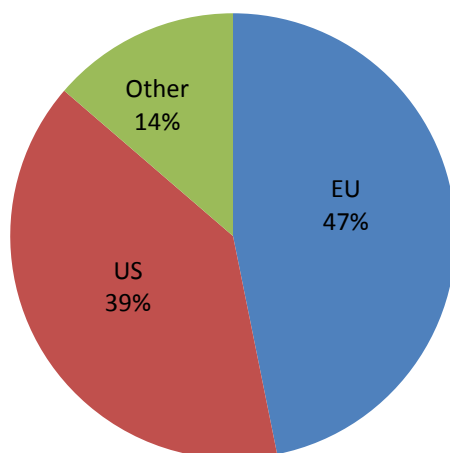


Figure 3-1. MedDRA MSSO Subscribers (2264)

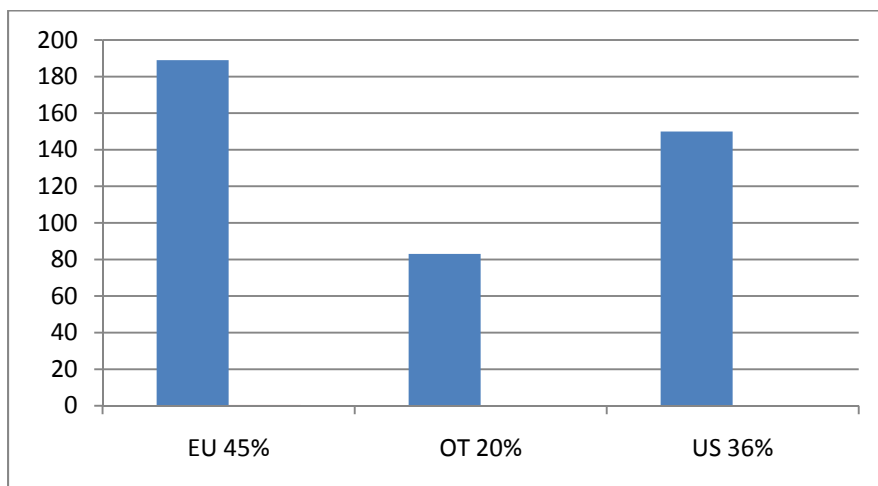


Figure 3-2 New MSSO Subscribers (422) in 2010

At the end of 2010, the Board approved the MSSO's proposal for no changes in subscription rates from 2010 for 2011 (see Table 3-1). For the sixth year in a row, subscription rates have either fallen or remained unchanged.

The 2011 rates are as follows.

Subscription Level	2010/2011
Basic	\$0
Core 0 (< \$1M)	\$190
Core 1 (\$1-10M)	\$804
Core 2 (\$10-500M)	\$5,529
Core 3 (\$500M – 1B)	\$11,600
Core 4 (\$1B – 5B)	\$47,600
Core 5 (> \$5B)	\$62,850
Developer	\$2,990
Regulatory Authority	\$0

Table 3-1. 2010 and 2011 Annual Subscription Rates (in US Dollars)

3.2 Major Development of MedDRA Terminology

In 2010, the MedDRA terminology including translations and SMQs continued to grow and evolve. A summary of major additions and modifications in the 2010 releases of MedDRA are listed in Table 3-2.

Activity	Version	Initiator
Microorganism test terms*	13.0	Regulatory authority
Device related terms including new HLGs and HLTs*	13.0	Users, device experts
3 new SMQs	13.0	CIOMS SMQ Working Group
ASHT II terms	13.1	Alerting System for Chemical Health Threats (ASHT II) project, funded by the European Union Public Health Programme, for use in the Rapid Alert System for Chemical Incidence (RAS-CHEM).
2 new SMQs	13.1	CIOMS SMQ Working Group

Table 3-2. Highlights in v13.0 and v13.1

* Some of the effort for these tasks was performed in 2009.

Chinese Translation

After the IFPMA received the MedDRA Chinese translation from Pfizer, the MSSO updated the translation from MedDRA v7.1 to MedDRA v12.1. In a cooperative effort with MedDRA users, the translation was verified and found to be of good quality. The MedDRA Chinese translation was made available to users on 15 September 2009.

Unlike EU translations, an additional fee is required to access the MedDRA Chinese translation. The MedDRA Management Board decided that the Chinese translation fee would not change from the 2009 rates in 2010. Table 3-3 provides the 2010 MedDRA Chinese translation subscription fees and those for 2011.

Subscription Level	2010	2011
Basic	\$100	\$50
Core 0 (< \$1M)	\$100	\$50
Core 1 (\$1-10M)	\$100	\$50
Core 2 (\$10-500M)	\$500	\$150
Core 3 (\$500M – 1B)	\$1,000	\$300
Core 4 (\$1B – 5B)	\$2,000	\$600
Core 5 (> \$5B)	\$3,000	\$850
Developer	\$1,500	\$450
Regulatory Authority	\$0	\$0

Table 3-3. 2010 and 2011 Chinese Translation Subscription Fee (in US Dollars)

Hungarian Translation

The Hungarian translation of MedDRA was started in the first half of 2010 after IFPMA received the initial translation performed by the National Institute of Pharmacy in Budapest, Hungary. The National Institute of Pharmacy translated the MedDRA LLTs and PTs (over 65,000 terms) through MedDRA v10.0. The MSSO's initial effort was focused on the translation of the user documentation (e.g., MedDRA Introductory Guide, SMQ Introductory Guide). The remaining MedDRA terms (i.e., those added to MedDRA after v10.0 and the hierarchy terms) were translated after the documentation. This translation will be made available to users in 2011 with the v14.0 release of MedDRA (March 2011).

SMQs

Five new SMQs were added in 2010 bringing the total number of production SMQs to 84.

Continuing a review of SMQs with all narrow or all broad PTs, the MSSO – with input from the CIOMS SMQ Working Group – changed the scope of selected terms in three SMQs and in certain sub-search SMQs thereof: SMQ *Dementia*, SMQ *Gastrointestinal perforation, ulceration, haemorrhage or obstruction*, and SMQ *Oropharyngeal disorders*.

Microorganism Identification Terms

The MSSO received a proposal from a regulatory authority to add additional microorganism identification test terms to SOC *Investigations* for MedDRA v13.0.

The proposal included approximately 120 new PTs and 197 new LLTs, and it included the movement of existing PTs and LLTs. The new terms describe laboratory confirmation of a microorganism when there is no documented infection. These new terms facilitates the monitoring of contamination of biologics, medical devices, food supply, etc.

Device-related Terms

MedDRA has been developed to support reporting in relation to drug-device combination products. In response to subscriber's requests, the MSSO conducted a device-related term review with the help of industry volunteers to enhance the hierarchical groupings of device related terms in MedDRA. New device related HLGTS and HLTs were added in MedDRA v13.0 to SOC General disorders and administration site conditions where HLGTS Product quality issues is linked. Existing device-related groupings and terms in SOC Injury, poisoning and procedural complications were moved to the appropriate new device-related structure. In addition, 58 new terms were added. Subscribers may submit change requests via the MSSO change request process for needed device-related concepts that are not yet represented in the terminology.

ASHT II Terms

MedDRA was selected by the Alerting System for Chemical Health Threats (ASHT II) project, funded by the European Union Public Health Programme, for use in the Rapid Alert System for Chemical Incidence (RAS-CHEM). One of the ASHT II project goals is to incorporate a harmonized terminology of symptoms and syndromes to signal the possible release or exposure to toxic chemicals. MedDRA will be used to improve information sharing, analysis and reporting of events between health professionals from poison centers and national public health officials.

The majority of concepts needed by the ASHT II project were already in MedDRA. The ASHT II project members requested the addition of a set terms that were not in MedDRA. After a review by the MSSO, a total of 95 changes were made for MedDRA v13.1 which includes 20 new PTs, 69 new LLTs, 5 moved terms and an additional link for an existing PT.

3.3 Significant MSSO Activities

MedDRA Web-based Browser

The MedDRA Web-based Browser (WBB) was launched on 12 January. By the end of January, over 400 MSSO subscribers had accessed the new tool. Three webinars were provided to users to give an overview of the functions of the WBB, and these were attended by over 328 users. The volume of Help Desk issues related to the WBB has been at a reasonable level.

MSSO MedDRA Training

The MSSO continues its effort to train subscribers and regulatory authorities on MedDRA. Webinars were added to the free MedDRA training program in 2009. During 2010, the MSSO provided free MedDRA training to 876 people. Of this number, 191 individuals were from regulatory authorities representing the following countries/regions: ASEAN countries (attendees from Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, and Vietnam), Canada, Croatia, EU, and the United States.

The 876 trainees include attendance at 4 free subscriber webinars which were well received by MedDRA users. The MSSO plans on continuing to provide webinars in 2011 on a variety of topics.

MedDRA in China

There were a series MedDRA related activities conducted in China in May 2010. Together with representatives from the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK and the US Food and Drug Administration (FDA), the MSSO met with staff at the State Food and Drug Administration Adverse Drug Reaction Center (SFDA ADR) in Beijing. Topics discussed included the ADR process in China and UK, an overview of MedDRA, and use of MedDRA in drug safety analysis in the US and UK.

The MSSO also chaired a session on the use of MedDRA in safety signal detection from regulatory and industry perspectives during the DIA-China Annual Meeting with speakers from MHRA, US FDA, and Pfizer.

The MSSO also conducted MedDRA free training on coding and safety data analysis and also held a user group meeting in Beijing. The courses and user group meeting were both well attended.

The MSSO met with the pharmacovigilance group of the R&D-based Pharmaceutical Association Committee (RDPAC) – an industry association representing 39 multinational companies – to update them on recent MedDRA initiatives. The MSSO also met representatives of the China ICH Research Group who study and translate ICH guidance and provide SFDA with recommendation on ICH initiatives.

Pharmacogenomic Terms

The MSSO worked with pharmacogenomic experts at the European Medicine Agency (EMA) and discussed the potential to add more of these types of terms to MedDRA. This topic was initially presented at the June 2010 Pharmacogenetic Working Party (PGWP) meeting. A subset of experts from this group provided input regarding existing pharmacogenetic terms in MedDRA. The PGWP later provided feedback on the development of new terms to add to MedDRA. The

initial set of pharmacogenomic terms – based on research by the MSSO and with input from the PGWP – will be implemented in MedDRA v14.1 (September 2011).

SMQ Survey

In early 2010, the MSSO launched a second SMQ survey (the first one had been in 2006 – 2007) whose goals were: to assess the extent and ways in which SMQs are currently used; to identify impediments to SMQ use; and to solicit suggestions to improve the utility of SMQs. There were nearly 300 responses from MSSO and JMO subscribers. Some of the conclusions reached by the survey were that there continues to be a need for SMQ training; technical challenges for use are still present, especially for algorithmic SMQs; and there is a wish to have SMQs in SAS format. For this last item, the MSSO began to engage the SAS Institute to determine a way to address this desire.

MedDRA in the ASEAN Region

In March 2010, the MSSO participated in a MedDRA training workshop for the Association of Southeast Asian Nations (ASEAN) organization in Kuala Lumpur, Malaysia. Other participants were Dr. Sonja Brajovic of FDA and Dr. Christina Winter of Glaxo SmithKline. The workshop was very valuable for establishing contacts in ASEAN, and trainees had very positive follow-up comments and questions.

MSSO ISO Certification

In August 2010, the MSSO passed an independent audit for compliance with the ISO 9001:2008 standard for Quality Management Systems. The ISO certification reinforces to MedDRA users, through an independent third-party, that the MSSO operates an effective quality management system that delivers a quality product.

3.4 Outlook and Goals for 2011

The MSSO looks forward to continued growth and development in 2011. There are several development efforts planned for 2011 that are intended to continue and enhance the MSSO's support for MedDRA users. The following is a list of the planned development efforts:

- Put more SMQs into production and support their implementation by MedDRA users
- Provide the MedDRA Hungarian translation
- Update WebCR to provide more functions to MedDRA users
- Develop the MedDRA Versioning Analysis Tool
- Conduct a Blue Ribbon Panel meeting on proposed revisions to the Neoplasms SOC

- Coordinate MedDRA development activities with the MedDRA Expert Panel
- Enact a more “proactive” approach to MedDRA maintenance and gather input for broad changes from users
- Continue implementing a broader and more comprehensive free MedDRA training program for regulators and subscribers, and respond to requests for training from ICH Global Cooperation Group members beyond the ICH regions
- Continue proactively seeking feedback from regulatory authorities on MedDRA translations
- Continue to produce – and increase the number of – scientific papers on MedDRA

MedDRA Management Board and the Senior Members of the MSSO

The individual members of the MedDRA Management Board (as of the end of 2010) are listed with their organizational affiliation.

Dr. Matus Ferech - European Commission

Dr. Sabine Brosch - European Commission (Alternate)

Dr. Christina Winter – EFPIA

Dr. Barry Arnold – EFPIA (Alternate)

Mr. Barry Hammond – EFPIA (Alternate)

Dr. John (Jake) Kelsey - FDA

Dr. Marthe Bryant-Geneviev – FDA (Alternate)

Ms. Heather Sutcliffe – Health Canada

Dr. Christopher Turner – Health Canada (Alternate)

Mr. Morell David – MHRA

Mr. Daisaku Sato – MHLW

Dr. Daisuke Tanaka – MHLW (Alternate)

Ms. Izumi Oba – MHLW (Alternate)

Mr. Yo Tanaka– JPMA

Dr. Paul Lagarenne – PhRMA

Ms. JoAnn Medbery – PhRMA (Alternate)

Dr. Odette Morin – IFPMA

Dr. Dawn Ronan – IFPMA (Alternate)

Dr. Lembit Rägo – WHO Observer

Mr. Osamu Handa – JMO

Mr. Reiji Tezuka (Alternate)

Mr. Patrick W. Revelle – MedDRA MSSO

Dr. Patricia Mozzicato – MedDRA MSSO (Alternate)

Dr. Anna C. Zhao-Wong – MedDRA MSSO (Alternate)

The MedDRA MSSO team is international in nature with team members who were educated in Canada, Germany, Spain, China, India, UK, and the United States. In addition to the MSSO Medical Team, the MSSO has an ongoing partnership in Japan with the MedDRA Japanese Maintenance Organization (JMO). The following is a list of the senior staff members and their role in the MSSO.

Patrick Revelle, Director

Anna Zhao-Wong, M.D., Ph.D., Deputy Director and Manager of MedDRA Terminology Development and Services

Patricia Mozzicato, M.D., Chief Medical Officer

Brian O'Hare, Manager of Terminology Maintenance

Eva Beate-Rump, M.D., Medical Officer Germany

Tomás Moraleda Garcia, M.D., Medical Officer Spain

Savian Nicholas, M.D., Medical Officer USA

Nandini Mehrotra, M.D., Medical Analyst

Judy Harrison, M.D., MSSO Consultant

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