



**MedDRA  
Maintenance and Support  
Services Organization  
Annual Report  
2007**

### MedDRA MSSO Mission

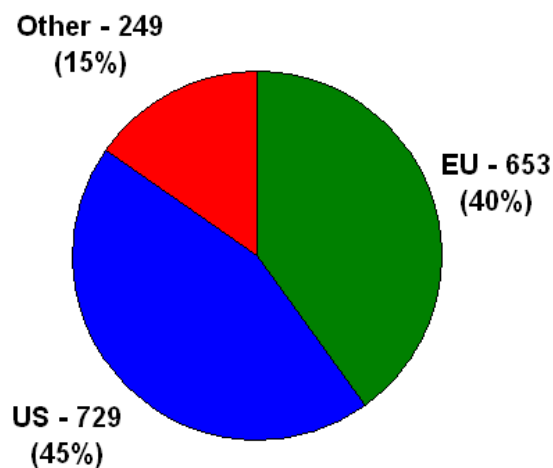
The MedDRA Maintenance and Support Services Organization (MSSO) is tasked with two functions:

- 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

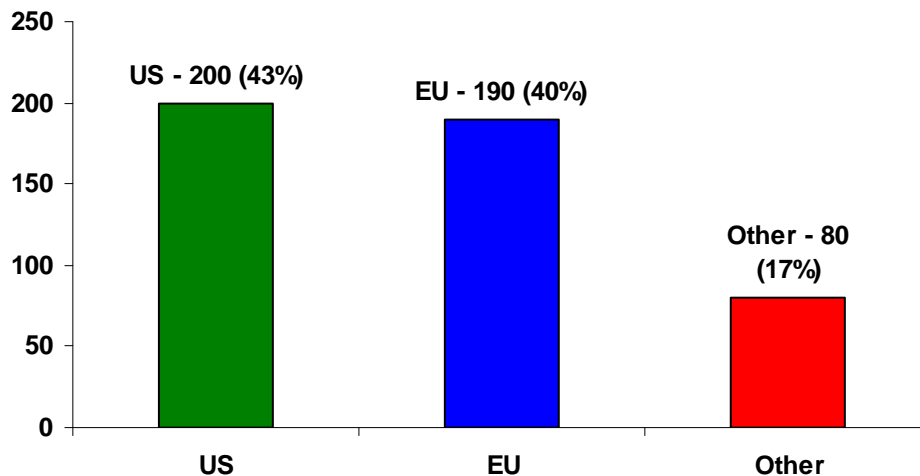
The goal of the MSSO is to maintain the MedDRA terminology as a stable, consistent terminology to suit the needs of regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing; and for data entry,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

### Highlights for 2007

During 2007, the MSSO experienced a year of continued growth and development of MedDRA. The number of worldwide MedDRA subscribers was 2,099 by the end of 2007. Of the 2,099 worldwide subscribers, 1,631 were MSSO subscribers and 468 were JMO subscribers. The 1,631 MSSO subscribers represent a 33% growth in subscribers in 2007 over 2006. Figure 1 depicts the distribution of MSSO subscribers by region (number of subscribers and overall percentage). Figure 2 provides the number of new MSSO subscribers (470) in 2007 by each region.



**Figure 1 - MedDRA MSSO Subscribers (1631)**



**Figure 2 - Number of new MSSO subscribers (470) in 2007 by region**

The development of MedDRA continued as well. In 2007, the MSSO initiated several efforts to ensure MedDRA evolves to meet the needs of the subscribers. The following sections provide a description of the significant MedDRA activities in 2007.

**Standardised MedDRA Queries (SMQs)** -The SMQ working group, formed under the auspices of the Council for International Organizations of Medical Sciences (CIOMS), is charged with development and initial testing of SMQs. As members of this working group, MSSO personnel participated in the development and maintenance of SMQs. In 2007, the MSSO added 27 new SMQs for use by subscribers bringing the total number of production SMQs to 55.

In addition, the MSSO implemented an SMQ survey and received 161 responses from over 100 organizations for the survey. The survey was to assess the extent and ways in which SMQs are currently utilized, to identify impediments to SMQ use, and to solicit suggestions to improve the utility of SMQs.

**Subscription Rates** - The Board approved the reduction for Core 1 (\$850 down from \$1,177, 28% reduction) and a 5% reduction for Core 2 (\$5,850 down from \$6,159). In addition, the MSSO has removed fees for European Union translations.

**Web Download of MedDRA Releases** – During 2007 the MSSO completed the transition from CD-ROM distribution of MedDRA to be completely web-based. This has been well received by subscribers since it allows immediate access to the latest version of MedDRA.

**MSSO MedDRA Change Request (WebCR)** - The MSSO has completed the initial prototype of the change request submission software tool that will allow MedDRA subscribers to enter change requests via a web-based form instead of sending a spreadsheet to the MSSO through email. The MSSO has involved several MedDRA users to review and provide feedback on this new tool. The MSSO plans to put WebCR in production in 2008.

**MedDRA Expert Panel** - The MSSO organized an external MedDRA expert panel to provide feedback to the MSSO on MedDRA development ideas and provide a mechanism to review contested change requests.

**Improvements to MedDRA's Hierarchy** – The MSSO implemented the Blue Ribbon Panel recommendations on the abuse-dependence terms and revised MedDRA's hierarchy to remove multi-axial HLTs in cumulative data output to improve MedDRA's utility in statistical analysis.

**MSSO MedDRA Training** - The MSSO continues its effort to train individuals on MedDRA. During the year 2007, the MSSO has provided MedDRA training to 944 people. The MSSO also trained 292 individuals from regulatory authorities, representing the following countries: Canada, Cyprus, Denmark, Germany, Greece, Hungary, Ireland, Lithuania, Slovenia, Spain, and the United States.

**MSSO and Non-ICH Countries** - The MSSO traveled with IFPMA and a MedDRA Management Board member to China to participate in two workshops (18 June – 22 June). The workshops, coordinated by Chinese SFDA and Health Canada, were entitled “Pharmaceutical Quality Workshop 2007” and were held in Shanghai and Chengdu. The MSSO provided an Introduction to MedDRA presentation and responded to questions from the audience. The MSSO sees this meeting as an initial step in the process of introducing MedDRA to China, and we look forward to furthering this effort.

**Additional Medical Device Terms in MedDRA** - The MSSO coordinated efforts with the FDA's Center for Devices and Radiological Health (CDRH) to discuss the status of the device terminology they have developed. The MSSO will continue this coordination and review CDRH terms for potential inclusion in MedDRA.

**Implementation of MedDRA in Vigibase** - The MSSO, in conjunction with IFPMA, supported the WHO (Uppsala Monitoring Centre (UMC)) effort to implement MedDRA in Vigibase. The goal is to extend the current Vigibase system to support the input of MedDRA-coded data and provide all output (e.g., reports) in MedDRA and WHO-ART<sup>®</sup>. This extension of Vigibase will be put into production in 2008.

**MedDRA Language Offerings** - The MSSO expanded its language offerings to include the Czech translation.

**Scientific Papers on MedDRA** - The following are papers written by MSSO staff on MedDRA during the 2007 year.

Mozzicato, P. Standardised MedDRA Queries: Their Role in Signal Detection. *Drug Safety* 2007, 30(7): 617-619

Bo, QY, Xiong, NN, Zou, JD, Jiang, M, liu, F, and Zhao-Wong, A. Internationally agreed medical terminology: Medical Dictionary for Regulatory Activities. *Chin J Clin Pharmacol Ther* 2007 May; 12(5).

### **Outlook and Goals for 2008**

The MSSO looks forward to continued growth and development in 2008. The MSSO has several development efforts planned for 2008 that are intended to continue MedDRA's support for users. The following is a list of the planned development efforts:

- Implement more SMQs and support the implementation of SMQs by subscribers
- Update the MedDRA Chinese translation and make it available to subscribers
- Provide the web-based change request entry tool to subscribers
- Upgrade the MSSO desktop MedDRA Browser
- Explore the implementation of MedDRA for non-ICH regions (e.g. China)
- Coordinate MedDRA development activities with the MedDRA Expert Panel
- Implement a broader and more comprehensive free MedDRA training program for regulators and subscribers
- Continue to produce – and increase the number of – scientific papers on MedDRA

### **MedDRA Management Board and the Senior Members of the MSSO**

The activities of the MedDRA MSSO are overseen by the 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. The individual members of the MedDRA Management Board are listed with their organizational affiliation.

Dr. Peter Arlett – European Commission  
Dr. Barry Arnold – EFPIA  
Dr. Christina Winter – EFPIA (Alternate)  
Mr. Barry Hammond – EFPIA (Alternate)  
Dr. Andrea G. Feight – FDA

Dr. Robert Wise – FDA (Alternate)  
Ms. Heather Sutcliffe – Health Canada  
Dr. Christopher Turner – Health Canada (Alternate)  
Mr. Morell David – MHRA  
Mr. Kenji Kuramochi– MHLW  
Dr. Tetsuya Kusakabe– MHLW (Alternate)  
Dr. Tatsuo Kishi – MHLW (Alternate)  
Mr. Yo Tanaka– JPMA  
Dr. Paul Lagarenne – PhRMA  
Ms. Janet Jenkins-Showalter – PhRMA (Alternate)  
Dr. Odette Morin – IFPMA  
Dr. Dawn Ronan – IFPMA (Alternate)  
Dr. Lembit Rägo – WHO Observer  
Dr. Mary Couper – WHO Observer (Alternate)  
Mr. Yasuo Sakurai – JMO  
Mr. Shigeki Tsuda – JMO (Alternate)  
Mr. Patrick Reville – MedDRA MSSO  
Dr. Patricia Mozzicato – MedDRA MSSO (Alternate)

The MedDRA MSSO team is also international in nature with team members who were educated in Germany, Spain, China, India, 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 Reville, Director  
Jim Mundell, Manager of Terminology Maintenance  
Patricia Mozzicato, M.D., MSSO Chief Medical Officer  
Eva-Beate Rump, M.D., Medical Officer Germany  
Tomás Moraleda Garcia, M.D., Medical Officer Spain  
Anna Zhao-Wong, M.D., Ph.D., Manager of MedDRA Terminology Development and Services  
Nandini Mehrotra, M.D., Medical Analyst  
Maya Nair, M.D., Medical Analyst  
Judy Harrison, M.D., MSSO Consultant  
Marvin Meinders, D.V.M., M.P.V.M., Medical Officer USA

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