

**MedDRA® MSSO International User Group Meeting
Osaka Japan – 12 November 2003**

The agenda for the meeting was as follows:

1. MSSO Overview of Activities
2. JMO Overview of Activities
3. US FDA – Regulatory Update
4. EU EMEA – Regulatory Update
5. JP MHLW – Regulatory Update
6. Coffee Break
7. Points to Consider Update
8. CIOMS/MSSO Data Analysis
9. Panel Discussion

1. MSSO Overview of Activities, Patrick Revelle

Mr. Revelle presented an overview of the activities engaged by the MSSO. In the area of transparency, the MSSO has made efforts to make MedDRA and the maintenance process known and understood by the user community so they understand our decision process of why things are either included or excluded from the terminology. In that effort, MedDRA 6.1 was recently released in September and MedDRA 7.0 is scheduled for release March 2004. As a part of the transparency process the MSSO has started to post rejected terms which are these terms submitted by subscribers that the MSSO has chosen not to implement are being posted to make people aware of previously submitted requests and the rationale as why terms have been rejected.

The plans for changes to MedDRA have been posted for subscribers so that they can be aware of those plans before the MSSO implement them. The MSSO recently started the MedDRA forum on the website which allows for subscribers to post comments or questions to be viewed or responded to by other MedDRA subscribers. The MSSO does monitor and provide some responses to the comments or questions posted but the majority of the responses come from the subscribers themselves.

In the area of stability without stasis, both the MSSO and the JMO are always concerned about how quickly the terminology is expanding or changing both have tried to tread the fine line between accepting changes and then slowing the growth to ensure only appropriate changes are made to the terminology. The area in which have had a significant number of changes made and anticipate more changes to occur is within the Investigation SOC. In the recent MedDRA release, there are a significant number of edits done to the NOS terms (not otherwise specified) and modified terms, both done in an effort to make MedDRA more consistent and accurate within the terminology.

The Blue Ribbon Panel was another method for the MSSO to gather expert recommendations to help form policy and guidance on specific issues. During the initial meeting, the expert panelists came from the US, Europe and Japan, from both from regulatory authorities and industry, to ensure the MSSO incorporate all aspects from all sides into the development of these concepts. The MedDRA subscribers were able to attend the meeting, however, only as observers. The focus of the meeting was on the consistency of the maintenance activities and the recommendations from the panel were written up and provided to the Management Board for review and approval before implementing. Once approved, the recommendation results will be made available to subscribers. The MSSO plans for future blue ribbon panel will be to hold two meetings annually and the panel expert groups will change based on the topic to be discussed, with members represented by the three regions and from both regulatory and industry.

Another activity involving the MSSO is development of a new concept called Standardized MedDRA Queries (SMQs), which is a joint effort with CIOMS under a co-development agreement. This started out as two separate efforts that were working on the same topic, with the MSSO developing the MedDRA Analytical Groupings (MAGs) and the CIOMS working on the Standardized Structure Queries (SSQs). The co-development agreement calls for a two-year collaborative process to produce the initial implementation of SMQs, which will be owned by the IFPMA and maintained by the MSSO for distribution with each MedDRA release. The maintenance of the SMQs will be a part of the change request process as part of the MedDRA subscription.

The final activity relates to the translation of MedDRA. Currently French, German and Portuguese translation of the terminology is available to the PT level. Recently, the Spanish and Dutch translation of the terminology has been added to English and Japanese version of the terminology, both of which is available to the LLT level. A recent policy change approved by the Management Board will affect the EU translations, where MedDRA EU LLT translation will be revised to allow for duplicate translations. Currently only the Spanish and Dutch translations are affected because they are completed to the LLT level. MedDRA/J will not be affected by the policy change.

The meeting continued with presentations from the following:

- JMO Overview of Activities - Mr. Yasuo Sakurai, JMO
- US FDA – Regulatory Update – Dr. Andrea G. Feight, FDA
- EU EMEA – Regulatory Update – Dr. Sabine Brosch, EU
- JP MHLW – Regulatory Update – Ms. Tomiko Tawaragi, MHLW
- Points to Consider Update – Dr. Toni Piazza-Hepp, FDA
- CIOMS/MSSO Data Analysis – Mr. Patrick Revelle, MSSO

The briefing slides for these presentations can be found on the web site.