

**MedDRA® MSSO International User Group Meeting
Prague, Czech Republic – 9 March 2004**

The agenda for the meeting was as follows:

1. Opening Remarks
2. Regulatory Update
3. E2b ICSR Experience
4. Networking break
5. Update on Standardised MedDRA Queries (SMQs)
6. MedDRA and Modifiers
7. Question & Answer Session

The MedDRA MSSO User Group meeting was held in Prague, Czech Republic on 9 March 2004. Speakers included members of the MSSO, Dr. Sabine Brosch of EMEA and Dr. Erik Malte Rasmussen of Leo Pharmaceuticals.

1. Mr. Patrick Revelle, Director of the MSSO, opened the meeting with an overview of the recent developments for MedDRA and the MSSO including a summary of changes for version 7.0 of MedDRA, MedDRA's recent growth rate, the status of MedDRA subscriptions worldwide, and the announcement of a recently revamped MSSO website.
2. Dr. Sabine Brosch gave an overview of the Eudravigilance system at the EMEA. She described MedDRA's mandatory use in pharmacovigilance post-authorization activities in the European Community including a review of the fields in the E2b format that requires the use of MedDRA. Dr. Brosch also provided a statistical overview by MedDRA System Organ Class (SOC) of the coded adverse reactions and indications reported to the Eudravigilance system. She next gave an overview of the Eudravigilance Data Warehouse project including MedDRA's role therein. Next, Dr. Brosch described MedDRA's role in the Eudravigilance Web Application for small and medium size enterprises (SMEs), which supports the ability of these types of companies to perform electronic ICSR reporting using MedDRA by means of new MedDRA licensing categories. Finally, Dr. Brosch gave an overview of the evolving Eudravigilance Clinical Trial module for electronic reporting of suspected unexpected serious adverse reactions (SUSARs).
3. Dr. Erik Malte Rasmussen spoke about how E2b compliance, including the use of MedDRA, has been achieved at Leo Pharma. He described the commercially available tool used to track, import and send E2b

messages. He stressed the importance to always supply in the message the “verbatim” term, the LLT and the PT (as needed).

4. Networking Break
5. Dr. Patricia Mozzicato of the MSSO presented an update on the progress of Standardised MedDRA Queries (SMQs) including a description of the cooperative agreement for the development of SMQs between CIOMS and the MSSO. She provided a definition of a SMQ, gave an overview of the data elements and file of SMQs, and descriptions of broad versus narrow scope, SMQ algorithms and SMQ hierarchy. She next described the various phases (Phase I, II and post-production) of SMQ testing and maintenance.
6. Dr. Tomas Moraleda Garcia of the MSSO gave an overview of a possible future approach to integrating modifier terms (e.g. acute, bilateral, acquired) into MedDRA. He described a possible classification system for modifiers and described also the potential implications of modifier terms in the E2b message. Finally, Dr. Moraleda outlined the next steps that the MSSO will take to move the modifier proposal forward including a MSSO authored paper, circulation of this paper to the MedDRA Management Board and the user community, and coordinate with the Points to Consider and E2b working groups. He also asked the attendees to continue to think about the benefits and challenges involved with this potential change to MedDRA.
7. After a Question and Answer session, the meeting was adjourned.