

Agenda for Blue Ribbon Panel meeting

Location: AstraZeneca, Zoetermeer, the Netherlands

Date/time: 16 March 2005, 09h00 – 15h00

Moderators: Patrick Revelle, Director, MedDRA MSSO; Patricia Mozzicato, Medical Officer USA

09h00 – 10h30

- I. Opening Remarks
 - a. Site logistics
 - b. Introduction of panel members
 - c. Background and issue
 - i. Purpose of product labeling
 - ii. MedDRA's intended uses
 - iii. Role of a terminology in labeling
 - iv. MedDRA's current organization and the potential impact on labeling
 - v. MedDRA user community's interest in this topic
 - d. Roles and responsibilities
 - i. Panelists
 - ii. Observers
 - iii. Moderators
- II. General Principles and the Three-Tiered System: Discussion of MSSO recommendations
 - a. Manufacturer's label – use of MedDRA terms; evaluation of expectedness
 - b. Prescribing information – logical groupings and natural language
 - c. Patient/consumer information – MedDRA terms not applicable

10h30 – 11h00

Refreshment break

11h00 – 12h30

- III. Legacy labels and related topics: Discussion of MSSO recommendations
 - a. Integrating new MedDRA information
 - b. Label conversion

12h30 – 13h30

Lunch

13h30 – 15h00

- IV. Review of MSSO's Recommendations
 - a. Revisions/expansions as needed based on BRP discussions

- V. Summary and conclusions

(Meeting concludes)