

MedDRA and Product Labeling: Best Practices

On 16 March 2005, the MSSO conducted a Blue Ribbon Panel meeting held in Zoetermeer, the Netherlands. For this meeting the topic was MedDRA and Product Labeling. The MSSO prepared a document entitled [MedDRA® and Product Labeling: “Best Practices” Recommendations](#) for the meeting.

The panelists included the following:

- Ineke Crijns (Medicines Evaluation Board, the Netherlands) – Representing EU Regulators
- Yasuo Sakurai (JMO) – Representing Japanese Industry and MHLW
- Melissa Truffa (FDA) – Representing FDA
- Reinhard Fescharek (Bayer) – Representing EU Industry
- Leander Fontaine (Wyeth) – Representing US Industry
- Patricia Mozzicato (MSSO) – Chair for the meeting

There was an active discussion between the panelists and the observers. The observers included a wide range of disciplines (e.g., Biostatisticians, Drug Safety, Clinical Development, and Regulatory Affairs representatives).

The MSSO will work with the panelists to revise the “Best Practices” recommendations and present the revised document to the MedDRA Management Board at the next meeting in Brussels in May 2005. If approved by the Management Board, the document will be posted on the MSSO Web site.

¹ The FDA panelist was not able to attend the meeting.