



# The Role of the MedDRA Management Board

Vienna, Austria

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MedDRA® is a registered trademark of the International Federation of  
Pharmaceutical Manufacturers and Associations (IFPMA)



# Discussion Points

- Responsibilities
- Membership
- Representative discussion points and actions



# A Few Definitions

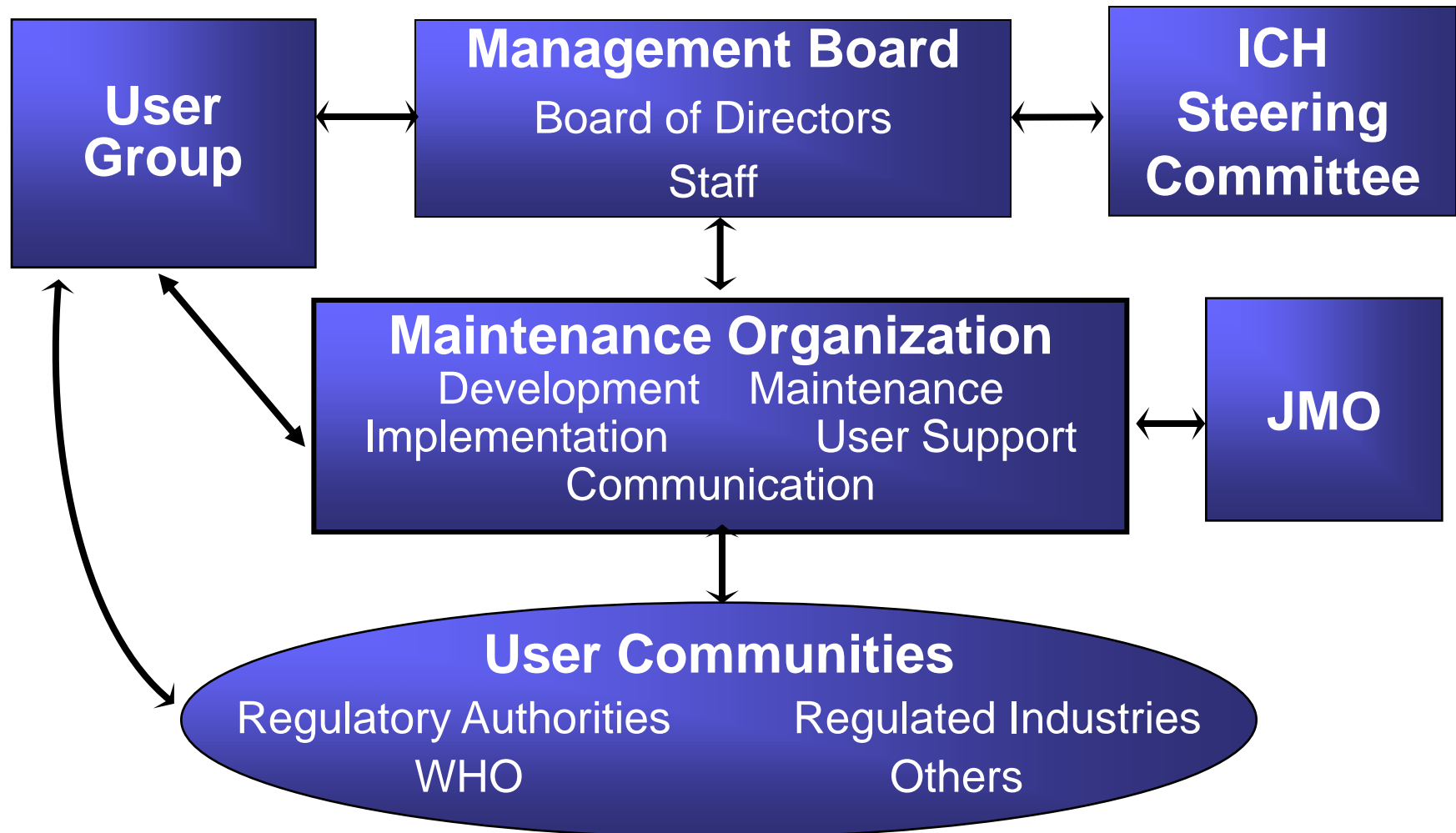
- International Conference on Harmonisation (ICH)
  - Developed MedDRA
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
  - Acting as a trustee for ICH, owns MedDRA
  - Contracts for the maintenance organization (MSSO)



# A Few Definitions (cont)

- MedDRA Management Board consists of one member each from
  - IFPMA Secretariat
  - EC, EFPIA, MHLW, JPMA, FDA, PhRMA, MHRA UK, and Health Canada
    - 'Alternates' also identified
  - WHO (participates as an observer)
- Appointed by ICH Steering Committee

# Maintenance Organization Structure





# Purpose and Responsibilities

- Major responsibilities
  - Oversee financial and technical operations of the MSSO
    - Examples: Review MSSO costs, review and approve plans for significant changes to MedDRA
  - Ensure the continued development and viability of MedDRA
  - Ensure MSSO is meeting the needs of users
    - Meets performance measures associated with change requests (i.e., initial response, final disposition of change requests)
    - Provides high quality medical decisions



# Board Members

- European Commission
  - Peter Arlett
- MHRA
  - Morell David
- EFPIA
  - Barry Arnold
  - Christina Winter (Alternate)
  - Barry Hammond (Alternate)
- FDA
  - Andrea G. Feight
  - Robert Wise (Alternate)
- PhRMA
  - Paul Lagarenne
  - Janet Jenkins-Showalter (Alternate)
- MHLW
  - Masanobu Yamada
  - Tetsuya Kusakabe (Alternate)
  - Tatsuo Kishi (Alternate)
- JPMA
  - Yo Tanaka
  - Takayoshi Ichikawa (Alternate)
- Health Canada
  - Heather Sutcliffe
  - Christopher Turner (Alternate)
- IFPMA
  - Odette Morin
- WHO Observer
  - Lembit Rägo
  - Mary Couper (Alternate)



# Representative Discussion Points

- MedDRA subscription rates
  - The Board worked with the MSSO to reduce 2006 and 2007 subscription rates
  - MedDRA has become a standard with a substantial number of worldwide users
  - The costs of maintenance are shared by all users based on the annual turnover (revenue)



# Representative Discussion Points (cont)

Subscription Level	2005 Price	2006 Reduction	2006 Price	2007 Reduction	2007 Price	Reduction from 2005 Rates
Basic	\$3,377	85%	\$507	100%	\$0	\$3,377
Core 0	\$3,825	80%	\$765	74%	\$200	\$3,625
Core 1	\$7,825	80%	\$1,576	25%	\$1,177	\$6,648
Core 2	\$13,506	40%	\$8,104	24%	\$6,159	\$7,347
Core 3	\$25,887	40%	\$15,532	21%	\$12,270	\$13,617
Core 4	\$69,782	20%	\$55,826	10%	\$50,243	\$19,539
Core 5	\$92,292	20%	\$73,834	10%	\$66,451	\$25,841
Developer	\$5,629	30%	\$3,940	20%	\$3,152	\$2,477

- Significant reductions started in 2006 with emphasis on lower revenue subscribers

# Representative Discussion Points (cont)

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- 2007 continued the reduction with a no-cost subscription for Basic users (non-profit/non-commercial use)



# Representative Discussion Points (cont)

- SMQ development
  - Board reviews the status of SMQ development
  - Board has final approval for SMQs to be put into production
- Blue Ribbon Panels
  - Board reviews and approves BRP panel recommendations



# Representative Discussion Points (cont)

- MedDRA development areas
  - Board reviews and approves MSSO proposals for MedDRA development
    - HLT/HLGT review and improvement
    - NOS implementation
    - Medication errors
    - Device terms



# Representative Discussion Points (cont)

- MSSO Business Plan
  - Board reviews and approves and annual update of the MSSO Business Plan
    - Links MSSO activities (both normal maintenance and development activities) to a financial budget



# Discussion