

Update on GMDN

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Outline

Role of global nomenclature

GMDN Agency

GMDN System

Translations

Recent events

New Governance model

Next Steps



Role of Global Nomenclature

- Single nomenclature for GHTF's regulatory model
- Provides generic descriptors for medical devices
- Used in exchange of information among regulators



GMDN Agency

- Created in 1991 to meet the requirements of the EC
- Incorporated as a UK company in 2004
- System used by regulators and industry



GMDN Agency Structure

- Board of Trustees (3 members)
- Maintenance Agency Policy Group (MAPG)
- MAPG Core Group
- Expert Group



GMDN System

- Based on ISO 15225
- System of coded descriptors to identify medical devices
- Over 10,000 preferred terms
- Preferred term
 - Code, term name, definition, product category



GMDN System (cont.)

- Examples of Search categories:
 - Product category
 - Clinical specialty
 - Device invasiveness
 - Device use-frequency
 - Device materials
 - Device sterility



Translations

- EU in 26 languages—ongoing
- Russia—ongoing
- Brazil—Portuguese complete
- Mexico—Spanish complete
- China—near completion



Recent Events

- GHTF proposed governance model
- Accepted by trustees in April, 2009
- Transition to new model underway



New Governance Model

- Expanded International Board of Trustees
- GMDN Members Group
- Policy Advisory Group



Expanded International Board of Trustees

- 6 board members
 - 2 GHTF governments
 - 1 AHWP
 - 1 GHTF Industry
 - 2 Existing trustees



Members of the Agency

- 12 members
 - 6 Trustees
 - 6 Others



Policy Advisory Group

- 5 GHTF government representatives
- 5 GHTF industry representatives
- 5 AHWP representatives
- 1 WHO representative



New Board of Trustees Next Steps

- First meeting in early July
- Approve nominees for GMDN members
- Approve nominees for PAG
- Develop implementation plan for governance
 - Strategic plan, charter, business plan
- Analyze funding mechanisms



Future Activities

- Training programs on GMDN System
- Meeting of the new Policy Advisory Group



Goal for GHTF

- *Globally accepted and sustainable nomenclature system*

