ASIAN HARMONIZATION WORKING PARTY

STG Nomenclature Update

Lindsay Tao, Co Chair

15th AHWP Annual Conference,
Riyadh, Saudi Arabia

Goal and Role of Nomenclature

- Single globally accepted and sustainable nomenclature system
- Provides generic descriptors for medical devices
- Used in exchange of information among regulators
- Supports patient safety

Primary User of Nomenclature

- Regulatory bodies
- Competent authorities
- Manufacturers
- Distributors of medical devices
- Conformity assessment bodies
- Notified bodies

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AHWP Guiding Principle on Nomenclature:

- 14th AHWP Annual Conference in HK

- Support a single global nomenclature
- Support GHTF's efforts on global harmonization as in the AHWP mission statement
- Ask for more seats at GMDN to voice out AHWP's interests
- Seek detailed requirements on nomenclature regarding fees, governance, database, response time, development and future use of the system
- Member economics make their own decision on adopting a particular nomenclature system
- In evolving situation, member economics are recommended to make cautious decision based on up-to-dated and sufficient information and assessment

STG Nomenclature Progress

- AHWP Chair participated Special GMDN board of Trustee meeting which was held in the conjunction with AHWP TC and GHTF SC meeting in May 2010 in Singapore
- AHWP re-emphasized its position at this meeting on:

  Request of increasing AHWP voice by additional representatives at BOT, addressing issues on fees, National License, and etc.
- Two AHWP representatives were nominated to GMDN BOT: China SFDA and Singapore HSA
- AHWP representative participated GMDN BOT meeting in Oxford in September, 2010
- 5 PARTICIPANTS from AHWP to be nominated as proposed in AHWP TC Meeting in Singapore:
  - 1 from each of the following members - CHINA, MALAYSIA,SAUDI ARABIA,SINGAPORE,SOUTH KOREA

GHTF Progress on Nomenclature

- Proposed change on GMDN Governance Structure in 2009
- Participation of GMDN governance change
  - Discussion with WHO, GS1 and other agencies were underway in order to explore possible collaboration opportunities and free access
  - Recommendations for improvement
- GHTF Website statement re use of GMDN
- GHTF SC members agreed the website statement re use of GMDN in Nov 2010

GHTF Progress on Nomenclature

- GHTF Website statement re use of GMDN

- GLOBAL NOMENCLATURE SYSTEM

One of the key elements in working to achieve a globally harmonised approach to the regulation of medical devices is the use of a single nomenclature system that is readily available globally for regulatory purposes. The members of the GHTF are committed to having a single global nomenclature system for medical devices.

The nomenclature of a medical device facilitates its progression through the entire product life cycle. The use of a single system would enable consistency in classification and identification, the consistent capture of product information across manufacturers, sponsors, distributors and in the clinical setting, for example, in hospitals. It would streamline medical device recalls, adverse event reporting and postmarket surveillance and monitoring.

The GMDN is a system of internationally recognised coded descriptors used to generically identify medical devices, which is now being utilised by many of the world's medical device regulators and industry. **The GHTF therefore endorses the GMDN coding system as the preferred nomenclature system for regulatory purposes for medical devices and will continue to work to ensure its effective governance and availability.**

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GMDN Improvements

- Total of 17, 642 Preferred terms (half are IVD)
- IT upgrades to accommodate translated terms
- Quarterly GMDN Newsletter
- Translations
  - EU (25 languages)
  - China (Mandarin)

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Thank You