STG Nomenclature & UDI

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Scope

- The purpose of a single nomenclature
- History of nomenclature in AHWP
- AHWP Requirements on Medical Device Nomenclature
- Achievement of STG nomenclature
- On-Going Working with GMDN
- UDI Update
- Next step

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The Purpose of Single Nomenclature

- To provide a consistent platform for regulators
  - Pre-market
  - Post-market

- To facilitate international trade and avoid the need of coding devices

- To be used in purchasing, inventory control, and other applications

- Can be used for the upcoming UDI

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History of nomenclature in AHWP

- In 2008, Issue raised on fees, governance structure, and etc after Singapore and HK use of GMDN. AHWP STG was established

- In 2009, New governance structure was proposed by GHTF

- In 2010, AHWP requested one additional seat at Board of trustee at GMDN

- In 2011, Finalize nomination of AHWP representatives to GMDN
  - Board of Trustee: Singapore HSA and Chinese SFDA
  - Policy advisory group: China, Korea, India, Singapore, Saudi Arabia

- Since then, AHWP participated GMDN BOT and PAG meetings

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AHWP Requirements on Medical Device Nomenclature

Resolution passed on requirements of medical device nomenclature in Nov. 2009 annual conference:

1. Charge:

    1)   Charging mechanism and method

    2)   Affordability.

    3)   Free of charge to all users

2.   Governance:

    Have the power to speak and manage when needed

AHWP Requirements on Medical Device Nomenclature

3. Database:

    1) Access to the updated copy

    2) Have right to continue the use, distribution and development of the database

4. Response Time:

    1) Replies to questions within one week

    2) Replies to new codes creation within two weeks

5. Developments:

6. Further Use of the System: Cover other applications i.e. UDI

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Achievement of STG nomenclature

- **Got agreement from GMDN agency on providing free access and free training to AHWP regulators**

- AHWP representatives active participate GMDN reform in order to meet AHWP requirements on nomenclature

- Establish linkage and work with WHO on medical device nomenclature issue

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On-Going Working with GMDN

- Funding and sustainability:

  – GMDN and IHTSDO (International Health Terminology
    Standards Development Organization) announced
    Collaborative Efforts in Sept. 2011.

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On-Going Working with GMDN

- GMDN Database :
  - Development of SOP and Regulatory Use of GMDN manual to clarify:
    - GMDN Scope
    - New Term Development
    - Obsolete of terms
    - The function of GMDN
    - The relationship between GMDN and UDI
    - GMDN Structure:
    - GMDN coding
    - Regulatory use of GMDN at different phase, especially pre-market, Product coding during the clinical testing phase
    - Translations of GMDN Terms
    - Education

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On-Going Working with GMDN

- GMDN development:

  - EC has made a Decision on the introduction of a formal system of Medical Device adverse incident reporting called EUDAMED in May 2011. This uses the GMDN as the generic device identifier

  - FDA required GMDN in its UDID in proposed draft UDI rule which is expected to publish soon

  - Membership in Latin America and Asia Pacific:
    - Mexico, Peru, Vietnam joined GMDN as new members,
    - Brazil, Columbia, Singapore, Saudi Arabia, Korea renewed GMDN membership this year.
    - Turkey
    - **Now it is free to all regulatory agencies**

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UDI Update

- AHWP representative joined GHTF ad hoc working group in 2009

- Participated GHTF UDI guidance document drafting

- Contributed to the GHTF UDI guidance document

- GHTF UDI final guidance document was published in Sept. 2011

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UDI Update

- The fundamental concepts of a global UDI System :

  - The UDI and UDI Carrier are based on global standards(e.g. GS1, or HIBIC)

  - A UDI applied to a medical device anywhere in the world should be able to be used globally to meet the UDI requirements of any regulatory authority

  - National or local identification numbers should NOT be a substitute for UDI

  - Regulatory Authorities should not specify how to modify these standards

  - The UDI Database core elements should not be modified

  - The UDI Database should use the HL7 SPL for data exchange

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Next Step

- Nomenclature:

  – Continue participation of nomenclature work at GMDN, GHTF(IMDRF) and WHO, provide AHWP comments

  – Follow up with AHWP economy and nominate economy regulator contact to GMDN to establish free access and training if needed

- UDI

  – Coordinate with GHTF UDI experts and organize in-depth training whenever possible

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ASIAN HARMONIZATION
WORKING PARTY

THANK YOU!