Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Summary Report
from STG Nomenclature

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13th AHWP Meeting
NEW DELHI, INDIA, 5-6 November 2008

STG(N) Work Progress

- 11 January 2008:
  - Agreed in teleconference to work on two existing nomenclature systems, UMDN and GMDN

- 3-4 March 2008:
  - ECRI and GMDN Agency invited for presentations on UMDN and GMDN systems respectively during AHWP meetings at Kuala Lumpur (GHTF, WHO participating)

Findings at KL Meeting

	GMDN	UMDN
Technical Merit	Excellent	Excellent
Future Development	Good	Satisfactory
Popularity	Authorities	Hospitals +WHO + less authorities
Governance	Fail	Excellent
Long-term Commitment	Fail	Excellent
Charges	Fail	Excellent (Free)
Sustainability	Fail	Good
Impact on Trade	Expensive	Admin impact
Impact on governments	Impossible to implement	No impact

STG(N) Work Progress

- April 2008
  - Participated in GHTF Ad Hoc Working Group on GMDN Governance
    - a model with **13 trustees including 2 AHWP representatives in an International Board of Trustees proposed**
    - comments from AHWP economy members consolidated **including charging mechanism**

Charge Mechanism

Country	GDP* (US$M)	Optimistic Estimate (if all AHWP members join)	Pessimistic Estimate (if few members join)
World	54,311,608		
GHTF+AHWP	45,219,754	EUR 600,000	EUR 720,000
European Union	16,830,100	EUR 223,311	EUR 267,973
United States	13,843,825	EUR 183,687	EUR 220,425
Japan	4,383,762	EUR 58,166	EUR 69,799
Canada	1,432,140	EUR 19,002	EUR 22,803
Australia	908,826	EUR 12,059	EUR 14,471
China	3,250,827	EUR 43,134	EUR 51,760
India	1,098,945	EUR 14,581	EUR 17,498
Korea	957,053	EUR 12,699	EUR 15,238
Indonesia	432,944	EUR 5,745	EUR 6,893
Chinese Taipei	383,307	EUR 5,086	EUR 6,103
Saudi Arabia	376,029	EUR 4,989	EUR 5,987
South Africa	282,630	EUR 3,750	EUR 4,500
Thailand	245,659	EUR 3,260	EUR 3,911
Hong Kong, China	206,707	EUR 2,743	EUR 3,291
Malaysia	186,482	EUR 2,474	EUR 2,969
Singapore	161,349	EUR 2,141	EUR 2,569
Phillipines	144,129	EUR 1,912	EUR 2,295
Vietnam	70,022	EUR 929	EUR 1,115
Brunei Darussalam	12,386	EUR 164	EUR 197
Cambodia	8,604	EUR 114	EUR 137
Lao PDR	4,028	EUR 53	EUR 64
Total	45,219,754	600,000	720,000

STG(N) Work Progress

- August 2008
  - Diverse views received from AHWP economy members

- September 2008
  - Sent letters to GMDN Agency & ECRI for
    - trial license;
    - long term commitment relating to the use, charge, maintenance and future development

STG(N) Way Forward

- To be discussed in the TC Meeting at New Delhi in November, 2008

- Where we will go?!

UMDN/GMDN Differences

Mapping between nomenclatures

UMDN	GMDN
- Main purpose is for purchase system, not based on Risk Management Regulation - International standard nomenclature for medical device since 1971 7,500 terms for medical device and 8,000 for biomedical terms - Non hierarchical numeric code - Linked to 39 categories	- GMDN was developed to meet the identified needs of the European Commission to establish a generic-level nomenclature in support of the European Medical Device Directives - There were 6 contributing nomenclatures in the development of GMDN - International standard nomenclature for medical device since 2001 8,000 terms for medical device and 10,000 for biomedical terms 16 categories + new ……

GMDN Principles

- Creation of a single nomenclature system
- The 6 contributing nomenclatures were:
  - ECRI – UMDNS
  - NKKN – Norway
  - JFMDA/MHLW – Japan
  - FDA – Pro-codes etc
  - EDMA – for IVDs
  - ISO9999 – Aids for the Disabled

GMDN Search Function

- These "Collective Terms" allow the search process to use headers such as:
  - Clinical Specialities
  - Device Applications
  - Device Attributes
  - Device Invasiveness
  - Device Materials
  - Device Power/Operation
  - Device Sterility
  - Device-Use-Frequency
  - General Device Descriptive Terms
- The GMDN Navigator: 1000+ Collective Terms, and in searching for a specific 'P'— Generic Term and Code

Mapping between nomenclature

- GMDN

  - At all stages of the GMDN development there has been participation by USFDA.

  - In 2001, ECRI withdrew its participation in the development process although there were some 800 UMDNS terms that were accepted.

  - In the current, much expanded, list of GMDN terms a mapping is shown to terms from other nomenclatures when this is appropriate.
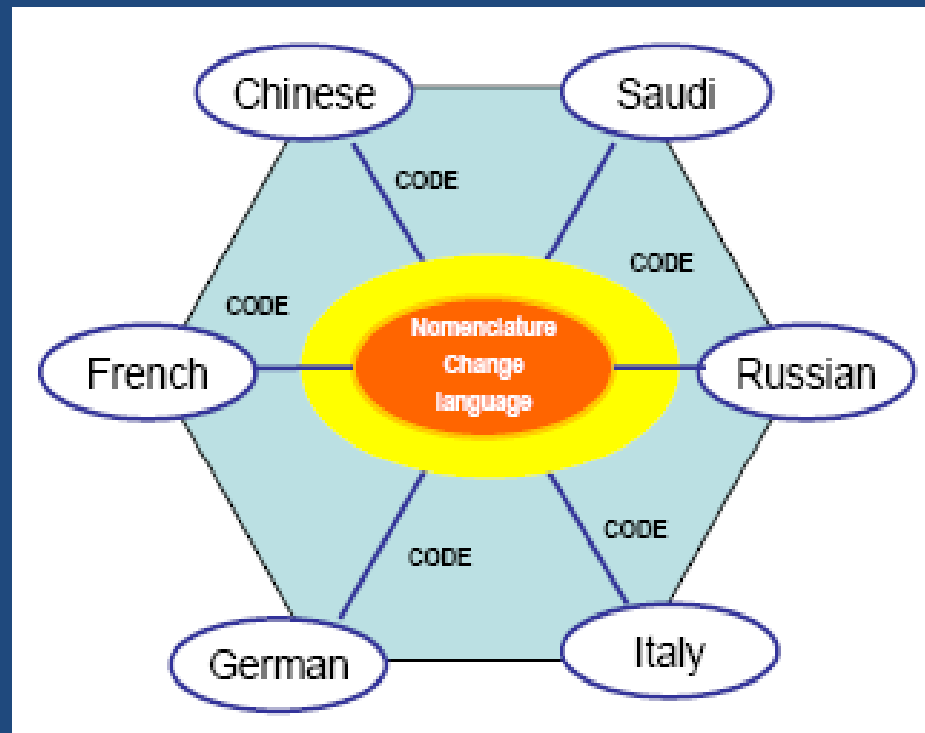
Some points from comparisons

- Establish on different purpose: Purchase or Surveillance

- Different on hierarchical directory structure

- Same words, but not same on the definition of terms base on risk

- Different on term code system

- Hundred-percent mapping between GMDN and UMDN is impossible

How Nomenclature works
on Post Market Surveillance & Vigilance or in Recall Procedure?

- Use Nomenclature as a language changing platform for: **(1) Tracing Device**, **but not only; (2) Purchasing program**

How Nomenclature works
on Post Market Surveillance & Vigilance or in Recall Procedure?

Example 1: Cardiac valve prosthesis

- An implantable synthetic substitute for the natural heart valve. This device is **typically used to treat acquired or congenital valvular diseases**; various configurations exist, e.g., **caged ball, tilting disk, or bileaflet.** The device may be constructed from **various materials**, e.g., silicone rubber, Stellite, Teflon, polypropylene, Dacron or pyrolitic carbon. For **biological heart valves** see the appropriate generic device group.

How Nomenclature works
on Post Market Surveillance & Vigilance or in Recall Procedure?

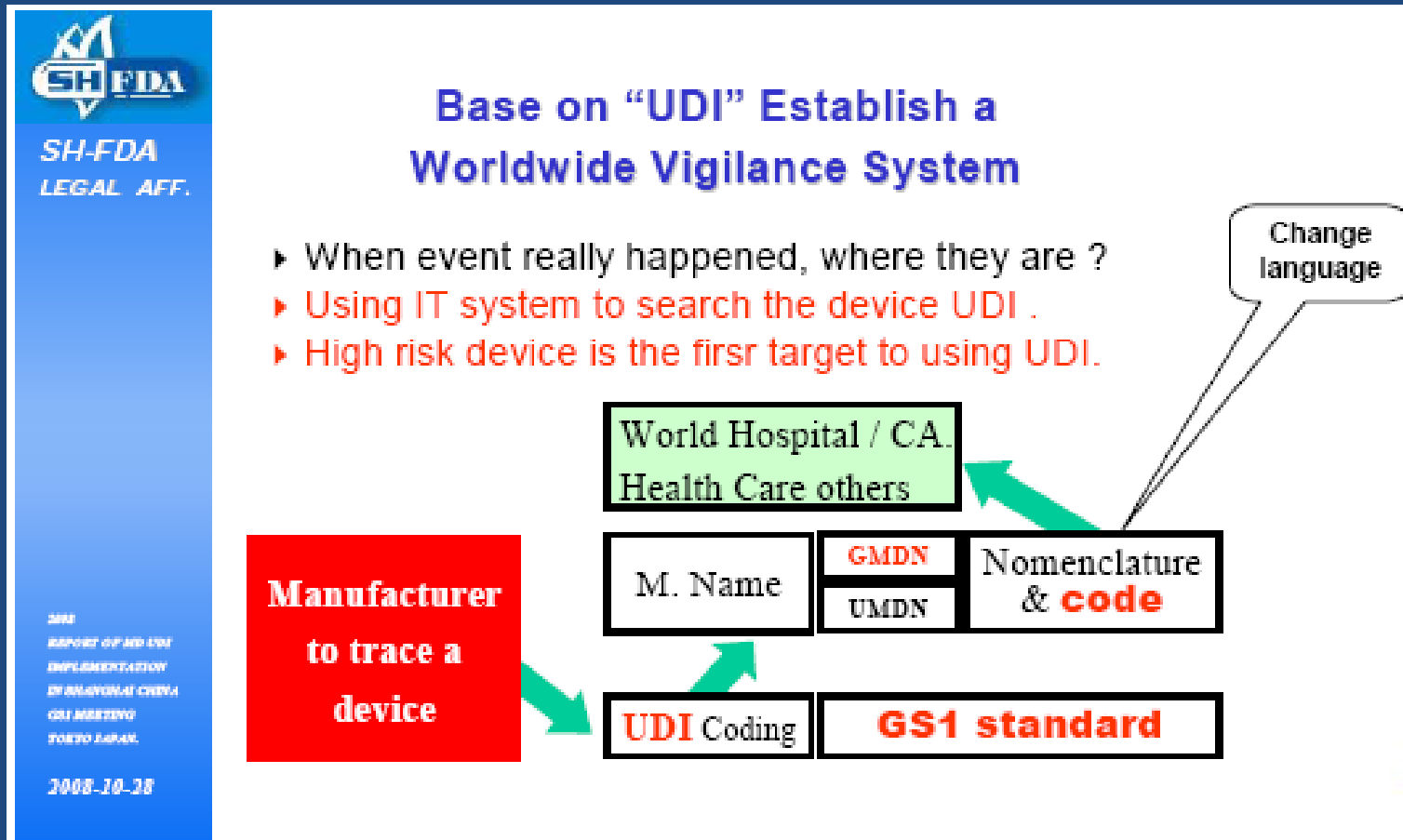**Example 2:** CAD/CAM unit, orthopaedic

- **A complex software based equipment for computer-aided design (CAD) and computer-aided manufacturing (CAM) of custom-made implantable prostheses**, e.g., total hip replacement femoral stems. The custom-made prostheses are typically used intraoperatively in a total joint replacement procedure allowing for optimal fit of an implant to specific patient's bone anatomy.

Nomenclature + UDI
on Post Market Surveillance & Vigilance or in Recall Procedure?

- **Nomenclature works with UDI for Device Traceability**

Summary Report from STG Nomenclature

- All the members of AHWP is aware the purpose of GHTF to establish an independent and single nomenclature system to enhance the efficiency of post market surveillance and traceability of MD. AHWP TC recognize the efforts and would like to support this direction.

- To achieve the consensus and work out feasible plan, AHWP TC STGN propose each member economy continue to study and compare the two systems (UNDM and GNDM) and achieve conclusion which is suitable for implementation.

Summary Report from STG Nomenclature

- AHWP TC STGN will actively participate in the discussions with GHTF and WHO and urge GHTF and WHO to make clear decisions on the guidance of a worldwide nomenclature system. STGN will continue to represent AHWP to focus on three areas:
  - user fee
  - management mechanism
  - sustainability

Thank you for your attention!