Stakeholders' Informal Consultation on Nomenclature for Medical Devices

Department of Essential Health Technologies

Health Systems and Services

WHO Headquarters, Geneva, Switzerland
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List of Abbreviations

ADG       Assistant Director General
AHWP      Asian Harmonization Working Party
ATC       Anatomic Therapeutic Chemical
CENETEC  National Center for Health Technology Excellence (Mexico)
CPG       Clinical Practice Guideline
CMMS      Computerized Maintenance Management System
DDD       Defined Daily Dose
DIM       Diagnostic Imaging and Medical Devices
EHT       Essential Health Technologies
EU        European Union
EUDAMED   European Databank on Medical Devices
FDA       Food and Drug Administration (United States)
GHTF      Global Harmonization Task Force
GIHT      Global Initiative on Health Technologies
GMDN      Global Medical Device Nomenclature System
HSS       Health Systems and Services
HTM       Health Technology Management
ICD       International Classification of Diseases
ICPS      International Classification for Patient Safety
iHTP      Integrated Healthcare Technology Package
IHTSDO    International Health Technology Standards Development Organization
INN       International Nonproprietary Name
ISO       International Organization for Standardization
MOH       Ministry of Health
PAHO      Pan American Health Organization
PSM       Medicines Policy and Standards
QSM       Quality Assurance and Safety: Medicines
SNOMED    Systematized Nomenclature of Medicine – Clinical Terms
TGA       Therapeutic Goods Administration (Australia)
TS        Technical Specification
UDI       Unique Device Identification
UMDNS     Universal Medical Device Nomenclature System
UN        United Nations
UNSPSC    United Nations Standard Products and Services Code
WHA       World Health Assembly
WHO       World Health Organization
WIPO      World Intellectual Property Organization
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Executive Summary

A Stakeholders' Informal Consultation on Nomenclatures for Medical Devices was held at World Health Organization (WHO) Headquarters in Geneva, Switzerland on 23-24 March 2011. The objectives of the meeting were to:

- Update all participants on recent evolutions of current nomenclatures and the organizations managing them, needs for nomenclatures, the Unique Device Identification initiative, the results of WHO baseline country survey on medical devices with respect to nomenclatures, as well as recommendations from the Global Forum on Medical Devices in September 2010.

- Share experience of use of nomenclatures by regulators and health technology managers from countries.

- Present a number of strategic options for WHO's policy with the aim to achieve a single medical device nomenclature.

An informal advisory panel presented details on existing nomenclature systems for medical devices, discussed the need for and purpose of medical device nomenclatures, and worked together to devise an action plan on how to move forward. The participants included external experts, WHO staff members from Headquarters and regions, representatives from national organizations in charge of managing medical devices, regulators, procurement specialists, medical device maintenance specialists, umbrella organizations for manufacturers of medical devices, non-governmental organizations, and international organizations.

The first day consisted of presentations on WHO naming systems in health care, naming systems for health technologies, regulatory needs for medical device nomenclature, nomenclature needs for management purposes, and the future of nomenclature systems, and unique device identification (UDI). Working group sessions were held on the second day to discuss steps for nomenclature mapping or harmonization, options for WHO consideration, and incorporation of UDI and to develop an action plan.

The meeting resulted in a set of proposals/commitments to be completed in the next 6-months and to be discussed again at the next meeting in September, 2011.
1. Introduction

1.1 Importance of Nomenclatures for Medical Devices

Health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation and attainment of internationally agreed health-related development goals, including those contained in the Millennium Declaration. Having a nomenclature system in place for health technologies, specifically medical devices, facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers. Such standardization is currently used in some regulatory systems but is also a prerequisite for inventory management and databases for maintenance of equipment.

Several naming systems for medical devices exist and each is used by a different group of professionals depending on the needs of that particular group. The systems have different purposes, such as maintenance, procurement, accounting, stock keeping, regulatory affairs (product registration for marketing authorization), adverse medical device event reporting, and customs operations.

The number of systems in existence can make it difficult to communicate between individuals, organizations. As such, it is important that a unified nomenclature system be put into a place that can be used globally and is the primary reason for bringing the stakeholders together for this consultation meeting.

1.2 Background and Supporting Resolutions

A consultation on the role of WHO in the integration of health technologies in national systems held at WHO/HQ on 7-9 February 2007 resulted in the following recommendations:

- Review, with help of external experts, existing medical device nomenclature systems and adapt one universal system, including a glossary of terms, updated if necessary, and recommend this one system
- Provide guidance on its use
- Advocate to Member States to use this recommended medical device nomenclature system
- Encourage industry to cooperate in standardizing the nomenclature

This led to the World Health Assembly (WHA), at its 60th session, to request the Director-General through resolution 60.29 Health Technologies (Annex 1): "to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of… a standardized glossary of definitions relating to health technologies in particular medical devices".

As a result of this resolution, WHO launched the Global Initiative on Health Technologies (GIHT) which aims to impact the burden of disease and ensure effective use of resources by providing tools and guidance on assessing current technologies in countries, setting technology standards, selecting appropriate technologies, as well as managing and maintaining procured technology resources in a sustainable way. One deliverable of the GIHT is to make available a WHO recommended nomenclature for medical devices.
A first meeting regarding medical device nomenclatures was held in January 2008. Health technology experts, specialists in medical device nomenclatures and stakeholder representatives, including regulators, industry and standardization organizations and professional organizations formulated the following recommendations:

- The development of another nomenclature system should not be considered
- A joint working group to be established with ECRI, Global Medical Device Nomenclature (GMDN) Agency and other organizations that manage/develop nomenclatures. WHO to serve as facilitator of the working group
- The mapping needs to be done by the working group to develop the "single" or "consolidated" nomenclature system
- Clarification should be made as to the intended use and intended users of the nomenclature
- The end product, that is the "single" or "consolidated" nomenclature system, should be managed by WHO. Any details particular to the owner of the nomenclature system shall remain as property of the individual organization that owns the specific nomenclature, such as the GMDN and the Universal Medical Device Nomenclature System (UMDNS)

This second informal consultation is meant to continue this discussion and bring forward a plan of action for implementation of a unified globally applicable nomenclature system.
2. The Consultation

The informal consultation on nomenclatures for medical devices was held at WHO Headquarters in Geneva Switzerland on March 23-24, 2011. It was attended by 27 representatives from different sectors of medical devices: government representatives, medical device manufacturing industry, regulatory agencies, nomenclature agencies and organizations, international organizations, United Nations (UN) agencies, and representatives from other WHO offices and organizations involved in medical device nomenclatures.

The consultation objectives were to:

- Update all participants on recent evolutions of current nomenclatures and the organizations managing them, needs for nomenclatures, the Unique Device Identification initiative, the results of WHO baseline country survey on medical devices with respect to nomenclatures, as well as recommendations from the Global Forum on Medical Devices in September 2010.

- Share experience of use of nomenclatures by regulators and health technology managers from countries.

- Present a number of strategic options for WHO's policy with the aim to achieve a single medical device nomenclature.

2.1 Programme of Work

A. Opening Remarks: Dr Carissa Etienne, WHO, Assistant Director General, Health Systems and Services (ADG/HSS)

The ADG/HSS, Dr Etienne, noted the importance of the meeting for the advancement of health systems. WHO will continue to promote norms and standards in health technologies, and to strengthen this component within the WHO Health Systems Building Blocks and within the programme of work in quality of care and patient safety. Lack of common nomenclature represents a challenge for health systems and services managers. Thus, it is important to have common terminology for access, regulation and use of medical devices. Two of the key recommendations from the First WHO Global Forum on Medical Devices held in 2010 specifically address this issue, and these recommendations need to be framed within the broader aspect of access to care.

B. Background Information: Mr Bjorn Fahlgren & Mrs Adriana Velazquez, WHO, Diagnostic Imaging and Medical Devices Unit, Essential Health Technologies Department, Health Systems and Services (HSS/EHT/DIM)

In January 2008, a meeting on nomenclatures was organized by WHO whereby it was recommended that a new system not be developed, that a joint working group be established and a mapping be carried out. At present, there are at least two international nomenclatures systems; however there is an opportunity to move towards a single nomenclature system during this consultation.
WHO articles 1, 2, 21 and 23 provide clear mandate for the organization to be developing standards in pharmaceuticals and similar products in international commerce, as well as to work in nomenclature areas. Resolution WHA60.29 also calls on WHO to work with Member States and Collaborating Centres on technical documents including standards and a glossary of definitions. It also urges Member States to move towards harmonization, to implement tools for prioritization, and to work on standards and norms. In 2008, WHO received a grant from the Gates Foundation to review policy and regulatory practices within countries, including information on nomenclature systems in use within countries. The first baseline country survey on medical devices was globally launched in March 2010 to collect basic information on: policy, regulations, procurement, technical specifications, maintenance resources, inventories and nomenclature systems of medical devices. The review indicated a broad mix of nomenclature systems (UMDNS, GMDN, nationally developed) in the countries used either for regulatory processes and/or procurement with 51% of countries not having any nomenclature system for medical devices.

During the First WHO Global Forum on Medical Devices, a series of recommendations were issued on the role of medical devices in health service delivery, on regulatory issues, on management, but of particular reference for WHO, to support free access to nomenclature systems, and for WHO to urge industry to tag medical devices with nomenclature references. Based on these recommendations and because nomenclature is critical not only from a regulatory perspective, but also from a management perspective, in procurement, maintenance, in the development and application of clinical practice guidelines and in the use of medical devices, WHO is seeking to provide guidance to health professionals.

2.2  WHO Recommended Naming Systems in Health Care

A. International Nonproprietary Names (INN) for drugs: Dr Raffaella Balocco, WHO

International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. They are used in almost all Member States. Each INN is a unique name that is globally recognized and is public property, hence they cannot be registered as trade-mark and can be used freely. A nonproprietary name is also known as a generic name.

The INN Programme is located within the Medicines Policy and Standards department/ Quality Assurance and Safety: Medicines team (PSM/QSM), and collaborates with the WHO Quality Safety and Standards (QSS) unit and the INN Advisory Group on biologicals to name biological substances. Interested parties include national regulatory authorities, trademark authorities, research-based industry, pharmacopoeias, European Commission, World Intellectual Property Organization (WIPO), etc. Recent progress is being made in linking INN with the Anatomic Therapeutic Chemical/Defined Daily Dose (ATC/DDD) system (pharmacological nomenclature system). Access to INN data and information is possible thanks to the INN Extranet Mednet, the INN web interface (restricted to INN experts and applicants) and the INN Global data hub.
B. **WHO International Classification of Diseases (ICD-10): Dr Bedirhan Ustun, WHO**

ICD is a classification of mortality, but also for monitoring morbidity and quality of care, and adverse events in health services. Linked with the ICD are the International Classification of Functioning Disability and Health, and International Classification of Health Interventions. ICD-11 is focusing on a coherent classification of mortality, morbidity, primary care, clinical care, research, public health, etc. It will serve as an international and multi-lingual reference standard, integrated with electronic health records. WHO is working with SNOMED to ensure synergies in the development of classification.

C. **The International Classification for Patient Safety (ICPS): Dr Iciar Larizgoitia Jauregui, WHO**

The conceptual framework of ICPS contemplates the analysis of the incident, the detection of the problem, mitigating factors, outcomes and ameliorating actions. A web-based collaborative authoring tool is being developed for the classification system, which will be pre-populated by WHO.

### 2.3 Naming Systems for Health Technologies

A. **Global Medical Device Nomenclature (GMDN): Mr Mark Wasmuth**

The GMDN follows the Global Harmonization Task Force (GHTF) model, to facilitate exchange of information between manufacturers, regulators and healthcare providers. The data is structured according to ISO15225. The GMDN Agency was established in 2005, and to date over 19,000 Preferred Terms have been defined. The GMDN has a Board of Trustees and a Policy Advisory Group (with a focus on manufacturers / regulators). GMDN categories extend beyond traditional medical devices (e.g. laboratory equipment, complementary therapy). In November 2010 the GHTF endorsed the GMDN as the preferred nomenclature system for regulatory purposes. The United States Food and Drug Administration (FDA) will use the GMDN for its Unique Device Identification (UDI) system and the European Commission has noted that the GMDN presents the best practice for information exchange. The GMDN membership scheme enables manufacturers to maintain the currency of their GMDN data set. The GMDN is available in 28 languages.

B. **UMDNS (Universal Medical Device Nomenclature System): Ms Vivian Coates**

ECRI has developed and maintained the UMDNS since 1971. ECRI conducts applied research and provides consultancy and published reports on medical devices, health technology assessment and patient safety. UMDNS is continuously maintained as a core activity of ECRI. UMDNS has more than 26,000 terms, 9,000 are preferred terms, and more than 17,000 entry terms. There are 2,340 licensee organizations in more than 100 countries. It is being used by ministries of health, regulatory agencies, by the United States Department of Defense, device manufacturers, private health providers, and thousands of hospitals in medical devices management and procurement and in ECRI’s own tools used worldwide for health technology management and patient safety. UMDNS is linked to ICD and SNOMED through the Unified Medical Language System, embedded in the WHO iHTP (Integrated Healthcare Technology Package) software tool and in many third-party commercial software applications for managing and procuring health
technologies. It is a formal, polyhierarchical system for organizing device-related information. There is a related database on manufacturers and suppliers. UMDNS is free of charge for government, hospital, manufacturer and supplier use, however a fee may be charged for e-commerce and commercial software companies.

C. ISO/TS 19218 naming of medical devices: Mr Leighton Hansel

Technical committees of the International Organization for Standardization (ISO) developed the “ISO/TS 19218” naming system for medical devices, which specifies requirements for a coding structure for describing adverse events related to medical devices. It is a mechanism for coding and data exchange between regulators on adverse events. It can also be used by end users, but does not include pre-market or clinical studies. Original coding is based on coding developed by the FDA, and is being developed through GHTF working groups, the process having been initiated in 2003. The number of adverse events reported relating to medical devices is growing, particularly by the FDA. Codes are being used by regulatory authorities, with different degrees of ‘granulation’ expected.

D. SNOMED CT of IHTSDO: Prof. Martin Severs

The International Health Technology Standards Development Organization (IHTSDO) presented its strategic position on Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), which goes beyond regulatory use. There is a willingness and commitment to move towards harmonization. It has 15 member countries, with a further 8 countries in discussion. Management is separated from Governance. The vision is to enhance human healthcare, improve care and facilitate accurate sharing of clinical and related health information. Stakeholders include governments, industry, clinical bodies and individuals. SNOMED CT is made available through a single form end-user license. Only Members, who are countries, can translate without IHTSDO Management Board approval, but IHTSDO produces translation guidelines. SNOMED CT is a terminology, the Systemized Nomenclature of Medicine, organized and structured in a logical manner. It is broken into concepts, descriptions, and relationships. There are more than 380,000 concepts, and about 1,000,000 terms. It is embarking on a major upgrade of its medical device content, especially over the next year, with 32 projects over the next 5 years. The use cases are based on clinical practice and recording use cases, and supporting patients with long term conditions. It is important to link the medical device with procedures and the patient record to facilitate linkages between systems not only to support good accurate and timely clinical regulation but also as importantly to support safety use cases, clinical audit, and research as well as administrative use reporting. The IHTSDO is committed to working with medical device regulators, WHO and medical device nomenclatures recommended by both industry and regulators.

2.4 Regulatory Needs for Medical Device Nomenclature

A. Therapeutic Goods Administration of Australia: Dr Larry Kelly

The representative from the Australian Therapeutic Goods Administration (TGA) presented on the pre- and post-market regulatory uses of GMDN, with specific focus on device information and manufacturer information. At the point of market entry, a risk based approach is used in device classification in which broad terms are employed for low risk devices and the more specific preferred terms (with a unique product identifier) are used for high risk devices. The
level of pre-market assessment undertaken by TGA is aligned with the risk of the product. In addition TGA uses the GMDN for verifying that manufacturers have undergone a conformity assessment procedure appropriate to the devices produced at the nominated site. The GMDN is also used for post-marketing surveillance. For example, the GMDN can be used to group products that have a shared characteristic for the purposes of product reviews or recalls.

B. European Commission: Ms Susanne Hoeke

From the European Commission perspective, the Commission began to look at the issue during harmonization of legislation in the early 1990s. The results of this discussion led to the creation of the GMDN. Thereafter EUDAMED (European Databank on Medical Devices) was developed originally based on GMDN to facilitate analysis of data on devices, manufacturers and post-marketing use. EUDAMED is in process of implementation, where Member States will be required to enter information as of May of this year. From the legal perspective, medical device directives do not expressively require GMDN; however GMDN is referenced in several guidance documents. The ‘EUDAMED Decision’ allows use of GMDN but also other internationally recognized nomenclature. The principle challenges in relation to GMDN include language, governance and access. The Commission has tendered GMDN translation into 20 community languages, and the governance issues are being resolved (with the Commission chairing the GMDN Policy Advisory Group).

C. Asian Harmonization Working Party: Mr Wang Bao Ting

The representative from the Asian Harmonization Working Party (AHWP) noted the importance of the nomenclature issue from a patient safety, regulatory, procurement and management perspective. The AHWP established a committee to review the issue of naming medical devices and concluded that the naming system should support government regulation and manufacturer registration. Whatever naming system is adopted should be done so with caution, and with a focus on patient safety. AHWP is committed to working with the WHO and the development of a unified naming system through consensus.

D. Industry Perspectives: Ms Janet Trunzo

AdvaMed, acting as industry representative for GHTF, indicated support for the principle of having a single nomenclature system, namely the GMDN system (as developed for the GHTF Regulatory Model), not only to facilitate registration but also post-marketing surveillance. Attributes of such as system should include the use of generic terms, quality control to maintain updates, expertise to create and define new terms appropriately, be widely accepted by stakeholders, be translated into necessary languages and have an effective governance structure. The industry considers that the GMDN meets this criteria; it is supported by the GHTF regulators and industry, and has long term sustainability and future direction.

In discussion, the issue surrounding developing codes for new technologies within the framework of the GMDN is resolved given the time necessary for the development of a medical device.
2.5 Nomenclature Needs for Management Purposes

A. Clinical Engineering Department, MOH Ghana: Dr Nicholas Adjabu

The representative from the Ministry of Health (MOH) Ghana highlighted the importance of nomenclature for medical devices from the health technology management perspective, particularly in large health care systems with networks of care providers and institutions. Personnel at each facility need to identify products by common codes for inventory management purposes, as well as reporting of adverse events. A common nomenclature facilitates communication between health care managers, vendors and consumers.

B. Lists of medical devices for healthcare facilities, procurement or reimbursement in clinical practice guidelines: Ms Elsa Arellanes Jarquin

CENETEC, part of the Ministry of Health of Mexico, has been a WHO Collaborating Centre since 2009. It produces information regarding medical devices, such as technical specifications and general technological information. It has developed over 300 clinical practice guidelines (CPGs) using evidence-based methodologies. One-hundred of these CPGs were used by consultants for a WHO project that began in November 2009 to develop lists of medical devices by clinical procedure based on CENETEC’s information. The main medical devices needed to fulfil each procedure were identified and coded using UMDNS and GMDN. The linkage of the CPG with the codification of medical equipment is critical to ensure efficient use of resources, facilitate procurement and reimbursement and help in better decision making.

C. Current Situation in the Eastern Mediterranean Countries: Dr Adham Ismail and Dr Iyad Mobarek

The Eastern Mediterranean Region is diverse in the sense that it comprises high, middle and low income countries. Dr Ismail explained that the WHO regional office is focusing on policy support, access to essential devices, quality and safety, management and use, where nomenclature is a cross-cutting and basic component of all areas of action. Nomenclature systems are virtually non-existent in low and middle income countries of the region. Much has to be done to promote the concept of a unified nomenclature that will enable countries to have adequate medical devices information systems and to compare the medical device situation between countries with the same economic conditions. In summary, this element is important if the work programme is to effectively move forward.

Jordan was presented as a case-study using UMDNS. Dr Mobarek explained the Computerized Maintenance Management System (CMMS) developed in Jordan and how UMDNS codes were helpful in building the system. He emphasized the importance of CMMS in assessing medical equipment needs at the primary, secondary or tertiary levels. He pointed out that though the nomenclature system relied on UMDNS codes at its inception, local engineers made huge modifications to the codes at later stages to cope with their dynamic needs. The result was a successful CMMS system - with nationally developed nomenclature codes for its medical devices - that has the following features: ability to be linked centrally, high-speed communication between concerned parties (“paperless technology”), functional assessment of medical devices through performance indicators, and complete and accurate inventory of available spare parts.
2.6 Future Developments of Nomenclatures: Unique Identification Systems

A. Global Harmonization Task Force: Dr Larry Kelly

The representative from TGA (Australia) and the Global Harmonization Task Force highlighted the importance of developing a global Unique Device Identification (UDI) system. GHTF guidance aims to avoid prescriptive country-specific requirements regarding the core elements of the UDI system (device identifier, UDI carrier, and UDI database). Characteristics of the UDI were presented including guidance for the UDI system (assignment of UDI following international medical device identification standards). The device identifier (static information about the device and certain safety related properties e.g. 'contains latex') and production identifier (variable information such as batch or serial number) must be individually identifiable. It is envisaged that a global approach to UDI will improve all aspects of medical device management and use including regulatory, procurement and clinical, thereby enhancing patient safety.

B. United States Food and Drug Administration: Mr Jay Crowley

The FDA noted that the identification of devices naming processes is in fact a continuum. GMDN is a high level description but is not connected to a specific device (GMDN cannot be used to recall a device), and UDI is related to specificities of a product that does not capture other aspects of the naming systems. Identification Standards are being used in different ways, and in fact efforts are on-going to fix various issues at one time. The UDI brings a host of benefits, in particular in product recalls, but must also facilitate examination of the class of products by using the GMDN system (e.g. is there a problem with a product or a class of products?). Approaches are being developed to have two barcodes representing the UDI on all medical devices - one with the device category/identifier, and the second with information on the manufacturer, serial or batch number and other product specifications, or alternatively one large barcode with all information present. At present however the approach is not standardized and barcodes are not available yet at the user/provider level.

C. Representative of the European Commission: Ms Susanne Hoeke

The European Union (EU) is also developing a EU UDI and have similar thoughts to those presented by the FDA and the ad hoc GHTF working group. Basic requirements will be introduced in the revision of medical devices directives in the first quarter of 2012. Databases will have to be compatible (with the global database and with EUDAMED).

D. Representatives UNSPSC: Mr Ted Haas and Mr Steve Arens

In a presentation on the United Nations Standard Products and Services Code (UNSPSC), a representative of GS1 USA commented that the code set is multi-domained, whereby there are 56,000 codes in 50 domains. A project is under way to match codification with ATC, and thereafter work will commence on medical devices, and it is expected that more than 16,000 medical devices will be coded (however they are not similar to GMDN or UMDNS). A new segment in medical services will be coded in the future. UNSPSC is open to collaborating with other actors.
2.7 Technical Discussions

In the discussion, it was noted that different systems are in operation in a number of developing countries, and that possibilities do exist to find commonality at the collective term level. However it was noted that there is a continuum of systems, and as such a serious of mappings need to be carried out to find a common framework for integration. With respect to the UDI, it was noted that the US, EU and China are developing UDI systems and there is a possibility that each system is not compatible. There is therefore the need for WHO to support a single global UDI system to ensure standardization across countries; alternatively there could be a UDI system with an adaptor to ensure comparability and integration across systems.

It was also noted that there is a possibility that terminology is not clear: are we discussing nomenclature, name or class of products? Also is UDI proprietary (given that it relates to a specific product (proprietary name and batch details))? In addition does the UDI for a given product allow us to distinguish from another product with different specifications?

As basis for the discussion for the working groups, the chair summarized a number of key points:

- The regulatory environment is a catalyst, which can be used to build on, but it is not the only factor to be considered;
- What system is sufficiently transparent and science based that will allow us to implement a coherent system?

2.8 Breakout Sessions

The participants at the meeting split into two working groups: one with representation from countries, regulators and UN agencies and the other with naming agencies and industry. Both groups discussed future steps in terms of (1) mapping and harmonization of all existing codes, and (2) UDI and nomenclature future trends. The outcomes of the working groups focused on future possible solution and options, which could include:

- One system becoming the sole nomenclatures system (although not truly a feasible option)
- Future harmonization whereby the two primary nomenclature systems work together to review and develop single codes for medical devices
- Separate systems with maps that clearly link and/or integrate the systems.

In addition the participants noted that the UDI was a new and important element in the discussion, and that there are possibilities that the UDI could be used to generically describe a medical device (equivalent to the GMDN or UMDNS) with either an additional code (either integrated into a single code, or presented as a separate code) relating to the specific product. There is a clear preference from the industry, GHTF, FDA and GMDN Agency for the development of a UDI that builds on the GMDN system, however for UMDNS stakeholders, this represents a challenge.

WHO (EHT/DIM) identified the need to move towards a nomenclature and classification system that would be of benefit to the developing countries, that would facilitate the registration and surveillance of medical devices, and would facilitate the selection of a core or essential list of medical devices. Diverging nomenclature systems do not support effective health technology
management (HTM) solutions. WHO requires a solution that is cost effective, specifically the solution MUST:

**Support:**
- WHO Classifications
- Medical Device Regulation
- Personal Health Care (including medical records)
- Supply Chain Management including recalls

**Have:**
- A governance and management system

**Be:**
- Financially sustainable in a fair and equitable manner

**Resist:**
- The development of any new coding system

**Enable:**
- The rational development and harmonization of existing coding systems (GMDN, UMDNS, UDI etc.).
3. Recommendations

Discussion was held on whether the focus should be on developing a single system for the generic naming of devices or a unified identification system that provides unique product references, possibly also including a generic naming system which would be linked to other existing coding systems.

Mapping between the two existing nomenclature systems could represent an intermediary step as a possible future step towards convergence of the systems. Another suggestion was an umbrella system that provides a 3–4 digit preliminary code linking existing systems. However, it is necessary to be clear on whether we are discussing nomenclature, or classification. Perhaps a higher level classification that establishes linkages between the two systems is sufficient. There needs to be a degree of high level terms to support regulation, but there also needs to be coherence between the systems and sufficient coding to support clinical practice.

The following proposals/commitments were made for the following six month period which will move the discussion forward:

- Two naming agencies (ECRI and GMDN Agency) return to their Boards / Trustees with a view to making available information to facilitate a mapping exercise, and to a move towards convergence in the future. Each agency will report back.

- WHO will clarify the road map, raise the issue with the Classification Network to determine opportunities, discuss with patient stakeholders, raise it with the IHTSDO stakeholders, discuss the UDI database with the FDA, discuss their respective databases with ECRI and GMDN with a view to creating a possible model, and evaluate the utility of a high level tabular list for medical devices.

- ECRI suggests working with WHO to see what mapping can be done with ICD-11, and to work with IHTSDO on a similar issue.

- WHO will provide information to Member States on both systems and review possibilities to provide free access.

- IHTSDO will engage with the GMDN agency, create a SNOMED CT mode, develop high level terms within a year, and work with the GHTF and regulators on this process.

- The EU will report to Member States, including on the process for the implementation of the EU/UDI, and request feedback.

- WHO will identify focal points (national regulatory agencies and HTM) within countries and promote the principles of nomenclature use for medical devices (for regulators and health technology managers).

- FDA will report back on advances with UDI.
Annex I. Programme of Work

**Day 1** 23 March 2011

08:00 Participants Registration (badges at the main entrance of WHO)

09:00 Opening remarks  
*Dr Carissa Etienne*

09:20 WHO institutional mandate for work on nomenclatures, summary report and recommendations from the Informal Consultation on Nomenclatures and Glossaries for Health Technologies Medical Devices in 2008,  
*Mr Björn Fahlgren*

09:30 Resolution WHA 60.29, Country survey data and recommendations from the Global Forum on Medical Devices,  
*Mrs Adriana Velazquez Berumen*

09:40 Discussion

**WHO recommended naming systems in health care**

09:50 International nonproprietary names for medicines,  
*Dr Raffaella Balocco*

10:00 International classification of diseases,  
*Dr Bedirhan Ustun*

10:10 International Classification for Patient Safety,  
*Dr Iciar Larizgoitia Jauregui*

10:20 Discussion

**10:30** Coffee break

**Naming systems for health technologies**

10:50 Presentation of the GMDN and the GMDN Agency,  
*Mr Mark Wasmuth*

11:05 Presentation of the UMDNS and the ECRI Institute,  
*Ms Vivian Coates*

11:20 Presentation of the ISO standards for naming of medical devices,  
*Mr Leighton Hansel*

11:35 Presentation of SNOMED clinical healthcare terminology,  
*Professor Martin Severs*
11:50 Discussion

12:15 **Lunch**

**Regulatory needs for a medical device nomenclature**

13:30 Therapeutic Goods Administration of Australia, *Dr Larry Kelly*

13:45 European Commission, *Ms Susanne Hoeke*

14:00 Asian Harmonization Working Party, *Mr Wang Bao Ting*

14:15 Industry perspective, ADVAMED, *Ms Janet Trunzo*

**Nomenclature needs for management purposes**

14:30 Clinical Engineering Department, Ministry of Health, Ghana, *Dr Nicholas Adjabu*

14:45 Lists of medical devices for health care facilities, procurement or reimbursement and reference in clinical practice guideline, CENETEC *Ms Elsa Arellanes Jarquin*

15:00 Current situation in the Eastern Mediterranean Countries, *Dr Adham Ismail and Dr Iyad Mobarek*

15:15 Discussion

15:30 **Coffee Break**

**Future developments of nomenclatures - Unique identification systems**

16:00 Global Harmonization Task Force, *Dr Larry Kelly*

16:15 United States Food and Drug Administration, *Mr Jay Crowley*

16:30 Representative for the European Union, *Ms Susanne Hoeke*

16:45 Discussion

17:00 **Adjourn**

17:15 **Reception - Main Restaurant (WHO HQ)**
Day 2  24 March 2011

09:00  Summary of day one by the Rapporteur

09:15  Introduction to break out sessions - Presentation of characteristics to evaluate. Possible scenarios and options, Björn Fahlgren

09:20  Working groups

Group 1: Room M 505
Regulators, national technology managers, and UN organizations

Group 2: Room M 605
Nomenclature agencies, industry and WHO

Questions to answer for both groups

- Steps for nomenclature mapping or harmonization
- UDI and nomenclature future trends

10:30  Coffee break

11:00  Working groups (continued)

12:30  Lunch

13:30  Presentations by working groups

14:10  Discussion

15:15  Coffee Break

15:30  Summary by the Rapporteur

16:30  The way forward and closing of the meeting, Chair
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Stakeholders' Informal Consultation on Nomenclatures for Medical Devices

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Health technologies¹

The Sixtieth World Health Assembly,

Having considered the report on health technologies;²

Recognizing that health technologies equip health-care providers with tools that are indispensable for effective and efficient prevention, diagnosis, treatment and rehabilitation and attainment of internationally agreed health-related development goals, including those contained in the Millennium Declaration;

Understanding that health technologies in particular medical devices represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies in particular medical devices that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently;

Acknowledging the need for Member States and donors to contain burgeoning costs by establishing priorities in the selection and acquisition of health technologies in particular medical devices on the basis of their impact on the burden of disease, and to ensure the effective use of resources through proper planning, assessment, acquisition and management;

Noting the need to expand expertise in the field of health technologies in particular medical devices;

1. URGES Member States:

(1) to collect, verify, update and exchange information on health technologies in particular medical devices as an aid to their prioritization of needs and allocation of resources;

(2) to formulate as appropriate national strategies and plans for the establishment of systems for the assessment, planning, procurement and management of health technologies in particular medical devices, in collaboration with personnel involved in health-technology assessment and biomedical engineering;

¹ The term “health technologies refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives”.

² Document A60/26.
(3) to draw up national or regional guidelines for good manufacturing and regulatory practices, to establish surveillance systems and other measures to ensure the quality, safety and efficacy of medical devices and where appropriate participate in international harmonization;

(4) to establish where necessary regional and national institutions of health technology, and to collaborate and build partnerships with health-care providers, industry, patients' associations and professional, scientific and technical organizations;

(5) to collect information that interrelates medical devices, which deal with priority public-health conditions at different levels of care and in various settings and environments, with the required infrastructure, procedures and reference tools;

2. REQUESTS the Director-General:

(1) to work with interested Member States and WHO collaborating centres on the development, in a transparent and evidence-based way, of guidelines and tools, including norms, standards and a standardized glossary of definitions relating to health technologies in particular medical devices;

(2) to provide support to Member States where necessary in establishing mechanisms to assess national needs for health technologies in particular medical devices and to assure their availability and use;

(3) to develop methodological tools to support Member States in analysing their health technologies in particular medical devices needs and health-system prerequisites;

(4) to provide technical guidance and support to Member States where necessary in implementing policies on health technologies, in particular medical devices especially for priority diseases, according to different levels of care in developing countries;

(5) to work jointly with other organizations of the United Nations system, international organizations, academic institutions and professional bodies in order to provide support to Member States in the prioritization, selection and use of health technologies in particular medical devices;

(6) to establish and update regularly an evidence and web-based health technologies database to serve as a clearing house which will provide guidance on appropriate medical devices according to levels of care, setting, environment, and intended health intervention, tailored to the specific needs of country or region;

(7) to provide support to Member States with vulnerable health-care systems so as to identify and put in place appropriate health technologies in particular medical devices that facilitate access to quality services in primary health care;

(8) to report on implementation of this resolution to the Executive Board and the Sixty-second World Health Assembly through the Executive Board.

Eleventh plenary meeting, 23 May 2007
A60/VR/11