Global Medical Device Nomenclature – GMDN

Governance Document

As agreed to in GMDN MAPG plenary on: 2008.12.03

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Abbreviations:

AGM	annual general meeting
AHWP	Asian Harmonization Working Party
BSI:	British Standards
CEN:	European Standards Organisation
EC:	European Commission
ET:	Expert Team
GHTF:	Global Harmonization Task Force
GMDN:	Global Medical Device Nomenclature
ISO:	International Standards Organisation
MAS:	Maintenance Agency Secretariat
MHLW	Ministry of Health, Labor and Welfare
PAG:	Policy Advisory Group
TGA:	Therapeutic Goods Administration
WHO:	World Health Organization

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1. **Introduction**

The GMDN Agency has very successfully developed GMDN. At this point regulators and industry alike are looking at GMDN to become the single unified nomenclature system used worldwide.

This success requires changes to the GMDN governance in order to meet the increased needs of both regulators and industry. These changes need to ensure long-term sustainability, governance and transparency.

This Governance document introduces a number of changes in order to move to a governance model that is aimed at ensuring decisions taken by the Agency are mindful of the needs of the international regulatory community.

The changes described here will address in particular the governance of the GMDN Agency. The changes aim at providing a more broadly-based international and representative board of trustees, whilst recognizing the role and experience of the current three trustees and ensuring the necessary continuity of the operations. To this end three trustees are intended to be added to the current three trustees.

The changes in governance also aim at ensuring a stronger involvement of stakeholders in the ongoing policy development of the Agency. This is achieved by giving the current Maintenance Agency Policy Group (MAPG) a more representative membership, clearer policy advisory, rather than technical, tasks and a more formal recognition. (To be known as the Policy Advisory Group.)

It is recognized that in a second step the business model will need to be assessed. As a transitional measure, the current license fee based funding system will remain in place. However, a revised business and licensing model will be developed, overseen by the Board, with a view to it being implemented within 12 months and no later than 2 years.

The transitional governance arrangements will be reviewed by the Board of Trustees and the Policy Advisory Group at the end of two years, to determine whether there is a need to revise any aspects of the governance model.

Note
Funding for participation in meetings (GMDN related) can only be considered for contracted persons.

2. Background

The Global Medical Device Nomenclature (GMDN) was developed, from 1991 to 2001, to meet the requirements for a globally acceptable nomenclature system to provide unique generic descriptors for medical devices, suitable for regulatory and healthcare purposes on a global basis.

Requirements by the European Commission to develop a standard for the structure to be used for the nomenclature, funding and mandate for the standards activity provided by the European Commission, and following this, the development of the initial data file through the GMDN Project, have been the major activities that created the GMDN.

It is noted that the initial GMDN data file was created with reference to the contents of the following nomenclature systems and where appropriate the preferred terms, as selected from any of these nomenclatures, was incorporated. The nomenclatures were:

ECRI – UMDNS nomenclature
EDMA nomenclature
FDA - CDRH nomenclature
ISO 9999 nomenclature
Japanese – MHLW/JFMDA nomenclature
Norwegian – NKKN nomenclature

3. Purpose

The GMDN is intended for the following purposes:

- To give a common generic descriptor for medical devices having similar features, characteristics and intended use.
- To be used in the exchange of data between regulatory bodies to in particular facilitate market surveillance and follow-up of adverse incidents.
- To be used for the exchange of data in the healthcare community.

4. The legality of GMDN placement and governance

By resolution of CEN BT "2000 – RESOLUTION BT 17/2000 (47BT: item 3.5)" the responsibility for the maintenance of GMDN was given to a selected Maintenance Agency through BSI who accepted that this responsibility is passed to the appropriate body formulated and now legally constituted as GMDN Agency (a non-for-profit company established under UK law). The GMDN Agency is based on the Articles of Association of the GMDN Agency and the Memorandum of Association of 10 February 2005.

The legal placement and governance of the GMDN is based on the following:

4.1 Document GMDN(99) Draft N 124 Rev2

1999, Document GMDN(99) Draft N 124 Rev2, from the GMDN Project Council to Comité Européen de Normalisation / European Committee for Standardization (CEN) – *Proposals for*

the rules of procedure for the Maintenance Agency of the forthcoming EN/report and ISO/technical report "Global Medical Device Nomenclature", hereinafter referred to as *"Rules of Procedure"*, is the document that defines the setting up of a GMDN Maintenance Agency and has been used by the **GMDN Maintenance Agency Policy Group to govern the GMDN Agency activities.**

NOTE 1: This document – **GMDN(99)12Rev2** – states in section 7.3 "The electronic database file: The MAS will market to users the GMDN data and updates as an electronic file. The file may be made available under licence agreement on readily accessible storage media (e.g. a CD-ROM), through a password-protected web-site or equivalent source."

NOTE 2: The document – **GMDN(99)12Rev2** is superseded by this present governance document.

4.2 RESOLUTION BT 17/2000

2000 – RESOLUTION BT 17/2000 (47BT: item 3.5)

Subject: Maintenance Agencies: *BT,*
- considering its **Resolution BT 146/1994** about guidelines for Maintenance Agencies (MA);
considering the request from CEN/TC 257/SC1 "Nomenclature for medical devices" for such a MA on GMDN "Global Medical Device Nomenclature" which is based on EN ISO 15225 "Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange";
noting the involved cooperation with ISO on this subject and a possible coordination of the MA with ISO/TMB;
allocates the MA responsibility for this GMDN to BSI;
agrees that the GMDN "Global Medical Device Nomenclature" is developed as a CEN-ISO (Technical) Report, first to be approved by BT, then to be maintained by the MA and approved regularly by CEN/TC 257/SC1.

This resolution was applicable as of 2000-04-05

5. Structure of GMDN governance

5.1 The GMDN Agency

5.1.1. Roles of the Agency

The main role of the GMDN Agency is in accordance with its Memorandum of Association as follows:

- To carry out the functions of a Maintenance Agency to develop and maintain the "Global Medical Device Nomenclature" for medical devices.

- To meet the needs identified by the European Commission when developing the European Directives on Medical Devices to establish a nomenclature for medical device generic descriptors which will meet a global need for identification purposes.

This identification will facilitate exchange of regulatory data and assist in identification of medical devices for commercial purposes.

- To ensure that the GMDN meets the needs of regulatory bodies, industry and other users as the primary reference and working generic nomenclature for the exchange of regulatory information.

- To ensure that the GMDN is constructed with reference to European and international standards indicating the structure of such a medical device nomenclature.(e.g. ENISO 15225)

- To be responsible for adding, amending and archiving terms and definitions for medical devices and to assign codes as required to provide easy identification. Such codes will be consistent so that all translated versions of the nomenclature will carry an identical code for each generic or other term as specified in GMDN

- To liaise with standards bodies (e.g. CEN, CENELEC, ISO, IEC) to be aware of current standards on medical device nomenclature (including any additional levels of identification e.g. collective terms, identification of particular attributes, links to other nomenclatures as appropriate).

- To co-ordinate and link with appropriate organisations concerning translation of GMDN into other languages.

5.2 GMDN Agency Members

The original three Trustees are the first "Members" of the Agency (Article 26 of the Articles of Association of GMDN Agency).
This change in governance which affects the new model will be the nomination of 9 new GMDN Agency "Members" of the company known as the GMDN Agency.
It is foreseen to enlarge the current number of 3 trustees by adding 3 of these members (making 6 trustees in total).
The total number of "Members" is thus 12 (including 6 trustees).
Nominations to fill vacancies as "Members" shall ensure the democratic principles of GMDN Agency, by spreading the selection of the acceptable candidates from amongst a broad range of regions/countries/organisations/manufacturer-associations/experts, so as to prevent potential undue dominance by any one or more of such bodies.
GHTF, AHWP,WHO, Trade Associations and Regulatory bodies from different regions of the world should be represented in the list of members.

5.2.1 GMDN Agency Trustees

The trustees have statutory duties under UK law. The role of the trustees is to govern and direct the operations of the GMDN Agency. Fiduciary responsibility for the GMDN Agency rests with them, hence they approve the Agency budget, ensure the accounts fairly represent the company's financial position and performance, monitor and evaluate adequacy of internal controls, and oversight an audit plan, including the selection of an external auditor.

The trustees also make strategic decisions, implement rules governing the reporting and procedural operation of the GMDN entity and give directions on the operations of the Agency to ensure that the decisions taken by the Agency will overall meet the needs of the international regulatory community.

The trustees will not be involved in the day-today operational management of the GMDN MA.

It is foreseen to enlarge the current number of three trustees by an additional 3. The composition of the 6 trustees is at this point envisaged as follows:

2 nominees of GHTF governments
1 industry nominee
2 existing trustees
1 member of AHWP

The Chairman of GMDN Agency Board of Trustees is appointed by the Trustees

The members of the Agency will pass a resolution requiring due consideration of the advice of the Policy Advisory Group (PAG).

Trustees will be appointed for terms of three years, with an option for renewal. Trustees will normally meet four times a year (quarterly), but additional meetings can be required.

Meetings of trustees may be held by teleconferences or videoconferences as well as face to face, but must be minuted. Minutes will be maintained by an employee of the GMDN MA, under the supervision of the CEO.

5.3 The Policy Advisory Group (PAG)

The PAG will be the key policy advisory body of the GMDN Agency. It will not be a technical advisory group. It will be a representative Group, bringing together representatives of international governments, global industry, and WHO as PAG members. The PAG will be created under the Articles of Association [via formal rule made under clause 61 of the Articles of Association], thus formalising the establishment and important role of this advisory group.

The key role of PAG will be to provide advice to the Board of Trustees on matters of relevance to the satisfactory maintenance of the GMDN, including:

- ways to ensure that the GMDN meets International requirements of regulatory bodies, industry and other users as the primary working nomenclature for exchange of regulatory information;
- new and emerging international needs for nomenclatures.
- means of ensuring that developing technologies are monitored and incorporated as appropriate.

The PAG deals with policy, not with operational or technical details.

According to the Articles of Association, unless otherwise specified, the trustees manage the Agency and the trustees may exercise all the powers of the Agency. In order to ensure that the views of the Policy Advisory Group are duly taken into consideration a direction will be given

by special resolution that the trustees must take due account of the opinions of the Policy Advisory Group.

The composition of the Policy Advisory Group is as follows:

5 representatives of the GHTF founding governments (US, Canada, Japan, Australia and Europe)
5 representatives of the Asian Harmonization Working Party (governments)
5 industry representatives (nominated by industry)
1 representative of the World Health Organization (WHO)
nominated representatives of other regions of the world

Trustees shall add representatives to the PAG as needed.

Observers may also participate in meetings of the Policy Advisory Group (PAG), including the Chief Executive Officer (CEO) and management team experts and technical specialists as required, at the invitation of the Chair of the PAG. Other users of GMDN will also be invited as observers to share their experiences.

The PAG will meet normally 2 times a year, but more frequent meetings may be required in the transition phase.

The PAG will elect a Chair from within its membership for two year terms, which will not offer an option for renewal. This will ensure the Group has a representational nature.

5.4 The Chief Executive Officer (CEO)

Day to day management is handled by the Chief Executive Officer. The CEO oversights and directs the work of the GMDN Maintenance Agency staff/contractors and experts. Responsibilities will also include:

- Managing the Agency Budget
- Communication with users, government bodies, hospitals, etc.
- Receiving all proposals for changes to the GMDN data file.
- Advising users regarding the application of the GMDN.
- Maintenance of an efficient communication between the Agency and its stakeholders.
- Encouraging and assisting in the translation of the GMDN to other languages.
- Actively promoting the use of the GMDN to all parts of the globe.
- Organization of PAG and Board meetings.

The CEO will have responsibility for ensuring the engagement of appropriately skilled experts to the staff of the GMDN Maintenance Agency, including IT and nomenclature experts.

The CEO will also have the capacity to establish working groups as deemed necessary by the Board of Trustees in order to deal with issues that arise. Examples of such issues could include:

- To ensure that the GMDN is constructed in compliance with the standard, EN ISO 15225.
- To ensure that further developments of GMDN, e.g., introduction of the GMDN Navigator, are fully enacted.
- To ensure that new developing technologies are monitored and incorporated as appropriate.
- To establish and co-ordinate with appropriate organisations for translation of the GMDN into other languages, to facilitate its international use.

NOTE 1

Establishment of the GMDN Agency

In order to carry out the tasks as mandated by CEN to the MAPG and BSI, a registered company to deal with secretarial and financial matters had to be established. The Mandate from CEN indicates that the Secretariat (MAS) should be chosen through a tendering process. No appropriate candidate was, however, identified. Henceforth, at the GMDN plenary meeting at BSI on 13. and 14. May 2004, London, the conception of GMDN setting up its own MAS was discussed and a preliminary budget prepared.

To avoid further delays a Work Group Meeting, held at BSI in London on 31. January and 1. February 2005, was called. There it was agreed, based on the discussion in the May 2004 meeting, to immediately set up a company limited by guarantee to be named "GMDN Agency". The Chair was asked to elaborate a memorandum in accordance with legal rules, and to include a preamble with reference to the MAPG's mandate and the decisions by CEN BT.

The GMDN was thus formally constituted as "GMDN Agency" and with Company Number 05392271. This being a company limited by guarantee (a non-for-profit company/ ASQL), and as such, acknowledged to carry out the tasks identified, and in accordance with the framework indicated in the "*Rules of procedure*" for the maintenance of the GMDN.

To form the GMDN Agency as a non-for-profit company three natural persons were needed to sign up as trustees. Messrs *Philippe Verdonck, Jacob Nordan* and *Maurice Freeman* volunteered as all were able to sign up without lengthy procedures involving formalities and permission by employers. The Trustees are subject to a number of legal duties which are set out in the Commissioners' publication CC3 "*Responsibilities of Charity Trustees*".

At its first annual general meeting (AGM), held at Radley on 22. May 2006, UK, the three trustees decided to resign and re-elect themselves for this duty until the Agency was fully operative and before their places could be made available other possible candidates by vote.

According to "*Articles of Association of* GMDN *Agency*" the Agency may, in addition to *trustees*, consist of *members*, subject to an approval by the trustees. All members will have a vote at the general meetings, both Annual or extraordinary.

GMDN AGENCY
(Not-for-profit UK Company)
ORGANISATIONAL CHART

TOTAL NUMBER OF MEMBERS – 12
GMDN AGENCY "MEMBERS"
(INCLUDES 6 TRUSTEES – SEE BELOW)

INTERNATIONAL BOARD OF TRUSTEES
(meets 4 times per year)
- 2 GHTF representatives (3 year term)
- 2 existing trustees (3 year term)
- 1 AHWP (3 year term)
- 1 Industry (3 year term)

Elect Chair

Policy Advisory Group
(meets twice per year)

Rotating Chair – to be elected by Group members (2 year term)

- 5 reps of the GHTF founding Governments (US, Canada, Japan, Australia and Europe)
- 5 reps of AHWP (governments)
- 5 industry reps (nominated by industry
- 1 rep of WHO

Plus observers as required:

e.g. CEO, Management team experts, etc.

GMDN MAINTENANCE AGENCY

OPERATIONAL MANAGEMENT

EXECUTIVE MANAGER/CEO

MAINTENANCE AGENCY SERVICES

EXPERT TEAM
TERM DEVELOPMENT
TECHNICAL GROUP

CORE GROUPS
AS REQUIRED

IT SERVICES
SOFTWARE DEVELOPMENT

SECRETARIAL & ACCOUNTS SERVICES

PUBLIC RELATIONS
SEMINARS
EDUCATION