Regulator's Use of GMDN
GMDN Policy Advisory Group (PAG)
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The consistent international use of a single device nomenclature offers numerous benefits. It allows regulators to streamline their national processes and efficiently share information about medical devices with stakeholders, including other regulators. For industry it avoids the need of coding devices according to a variety of different nomenclatures or classification systems.

GMDN was developed to describe medical devices at a generic level to support a wide variety of regulatory purposes. GMDN is based on ISO 15225 'Medical devices - Quality management - Medical device nomenclature data structure', whose scope is "to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. by regulatory authorities, manufacturers, suppliers, health care providers and end users."

This use document was prepared by GMDN's Policy Advisory Group (PAG) and suggests how regulatory authorities can utilize the GMDN to support both national processes and global information exchange.

There are a number of regulatory processes that can be supported through the use of GMDN, including:

- Registration of Manufacturers and other Parties and Listing of Medical Devices (GHTF/SG1/N065:2010).
- Medical Devices Post Market Surveillance:
    - Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2-N54R8:2006).
    - National Competent Authority Report Exchange Criteria and Report Form (GHTF/SG2/N54R8:2006)
- Unique Device Identification (UDI) System for Medical Devices (GHTF/AHWG-UDI/N2R3:2011).
- Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N40:2006).

GHTF reference documents can be found at www.imdrf.org

Registration of Manufacturers and other Parties and Listing of Medical Devices
The collection of identifying information on manufacturers, importers, and distributors ('Registration') and the types of medical devices marketed by those parties ('Listing') are fundamental elements of regulatory control. Medical device listing provides information on medical devices supplied to a particular market. The use of GMDN for device listing provides a foundation for device identification to support a number of other regulatory processes.

Medical Devices Post Market Surveillance
With the relationship established in Registration and Listing between individual manufacturer's devices and their appropriate GMDN term, this information can be used for post-market surveillance to aggregate, analyze and monitor incidents and

establish trends. This information can also be used to supports active market surveillance, allowing regulators to target audits to specific groups of devices as follow-up to trends observed in vigilance data. Regulators can also use this information to identify manufacturers of a specific device type when a safety concern is identified.

Unique Device Identification (UDI) System for Medical Devices
The UDI System will require the label of most medical devices to have a consistent, unambiguous and standardized identifier. UDI will be a foundational element for a host of public health benefits, including more efficient and effective device recalls, improved device post-market surveillance, and global track and trace systems. The Global UDI Database (UDID) will contain basic identifying information and other essential information. In order to support the development and use of the UDID, the GMDN term can be used as the generic device descriptor, which allows stakeholders to organize information and identify similar devices.

There are a number of principles that should guide the use of GMDN:

1. Use the most recent version of GMDN
The early versions of the GMDN data file were distributed on CD-ROM. Since September 2005, the GMDN has been updated and only available in real time through the on-line GMDN Database. To facilitate appropriate data sharing, the GMDN Agency now produces semi-annual releases (January 1 and July 1) to allow regulators to manage and update their internal systems and to facilitate translations.

New terms and revisions to existing terms will continue to be made available immediately via the on-line database. Regulators are encouraged to either use the on-line database or the most recent semi-annual version. The use of older versions of GMDN or creating national adaptations limits the benefits of a single GMDN data set and is discouraged.

2. Use of the GMDN codes
GMDN is a polyhierarchical system consisting of Preferred Terms (PTs) and Collective Terms (CTs). PTs are flat and linked to CTs (device attributes and high-level terms) which are used to create polyhierarchies. The most detailed generic descriptor is the PT and is the most appropriate level of coding for individual device identification. However, some regulators may choose to use broader categories (such as description by CTs) for certain devices or purposes. For example, a listing by PT may be required only for higher risk class devices, while CTs may be used for lower risk classes. If a manufacturer has coded their devices based on PTs, they can easily roll-up their GMDN data to higher level CTs.

3. Manufacturers' responsibility to assign the code
In many jurisdictions the manufacturer has the responsibility to select and assign the appropriate PTs to their devices. This is more efficient than having multiple regulatory jurisdictions encoding the same device and allows the manufacturer to use the same code in different jurisdictions. However, regulatory authorities are encouraged to review and validate the terms provided by the manufacturer. If regulators identify inconsistencies in the use of PTs in different jurisdictions, you are encouraged to bring these to the GMDN Agency’s attention for resolution.

More importantly, manufacturers should be encouraged to identify the appropriate GMDN PT early in the device's development process. This allows sufficient time to resolve any inconsistencies and, if necessary, for the development of a new term or modifications to an existing term or definition in order to avoid unnecessary delays in marketing a new device.

4. Obsolete terms

PTs are occasionally made obsolete when there is a need to provide a more granular structure. For example, there was originally only one term for cardiovascular stent. As new technologies emerged, the original stent term was made obsolete – and replaced by terms for bare metal, drug eluding, and absorbable. As terms are made obsolete, regulators should have processes in place for the manufacturer to update the term used to the most current appropriate term.

5. Translations of GMDN Terms

GMDN is maintained by the GMDN Agency in English. Many regulators are translating GMDN for their national purposes, and the semi-annual version releases are intended to support this activity. The Agency also provides for uploading the translations into the GMDN Database to improve the access and consistency of the GMDN translations. If possible translations should include not only the term names, but also the definitions.