Use Cases of the GMDN

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Background

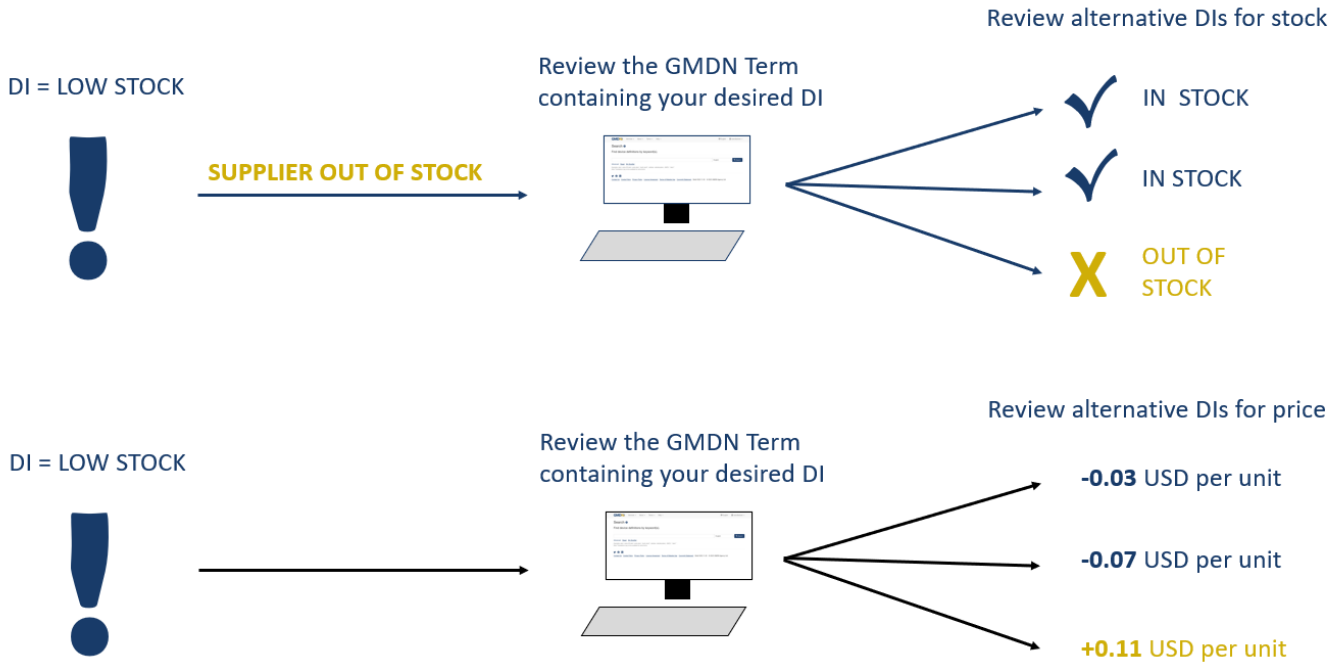
The Unique Device Identifier (UDI) is a standardised identifier for medical devices, existing in the form of an alphanumeric code. The code consists of 2 components, the Device Identifier (DI) which corresponds to the proprietary name of a device, as it is produced and sold by a specific Manufacturer, and the Production Identifier (PI) which corresponds to production details such as lot number, expiration date and individual unit serial number.

The Global Medical Device Nomenclature (GMDN) is an internationally recognised, methodically devised system of medical device nomenclature and terminology, used to group individual, proprietarily named medical devices (DIs) under generic names which are descriptive of their shared concepts and attributes. The following article has been written to explain use cases of the GMDN and highlight where each use case fits into the dataflow of the medical device industry.

All UDI codes used as examples are fictional and any similarity to active codes is coincidental.

Procurement and Tendering

When alerted to a DI shortage the inventory manager can contact the supplier to order that exact DI, reducing the risk of human error associated with procurement. While this system is extremely beneficial to the procurement process, it has its limitations; for example, if the desired DI is out of stock or has been discontinued, the UDI alone cannot identify alternatives. In this same situation, GMDN Terms can provide an easily accessible list of alternative DIs with similar attributes and intended uses. The GMDN Term to which the desired device is assigned will likely (except for novel devices) have a range of alternatives for the user to review (demonstrated below).



In this way GMDN Terms function similarly to a comparison website, allowing the user to review devices from different Manufacturers and find the correct device at the best price. This process also stands to benefit

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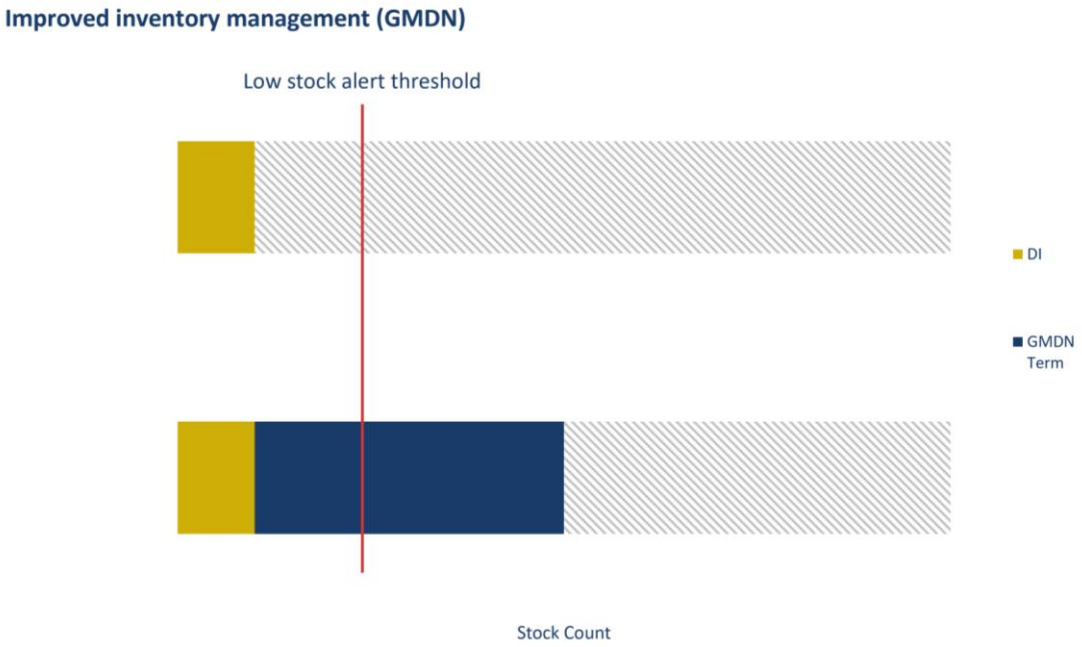
Manufacturers by functioning as a marketplace, providing exposure for their devices; incorrect GMDN Term assignment would cause Manufacturers to miss out on this opportunity.

Inventory management

Use of the UDI makes inventory management far less arduous than without it, facilitating input scans and stock alerts. Tracking inventory with GMDN Terms expands on the latter, allowing users who use a range of DIs for the same function (e.g., users who purchase devices from a range of suppliers) to track stock of similar devices. As shown in the figure below, when only using the UDI the inventory manager would receive an alert to inform them there is a shortage of a specific DI, prompting them to place an order for the DI. If that user happened to use a range of DIs for the same purpose, for example they obtain stock from multiple suppliers, the use of UDI would not alert them of the stock of these other devices.



Post market surveillance

Continuous monitoring of medical device real world evidence (RWE) throughout the lifetime of a device provides for more effective regulation and often forms part of the regulatory framework. Information regarding usage, efficacy, and risk, associated with a particular DI is collected from sources such as electric health records (EHR) and device registries to facilitate the clinical evaluation process. This data, unlike that collected in a clinical trial, represents the efficacy of a device exactly as it is used by clinicians, removing the risk of sample bias. This data could be represented as follows:

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However, as alluded to earlier, the DI doesn't necessarily provide the whole picture. Devices which have the same intended use and similar technologies, but that are produced by different Manufacturers have different DI's. This means clinical evaluation of a DI monitors the efficacy of a device as produced by a specific Manufacturer, and not the efficacy of a device 'type'. In the example below we are looking at Cardiac resynchronization therapy implantable pacemakers.

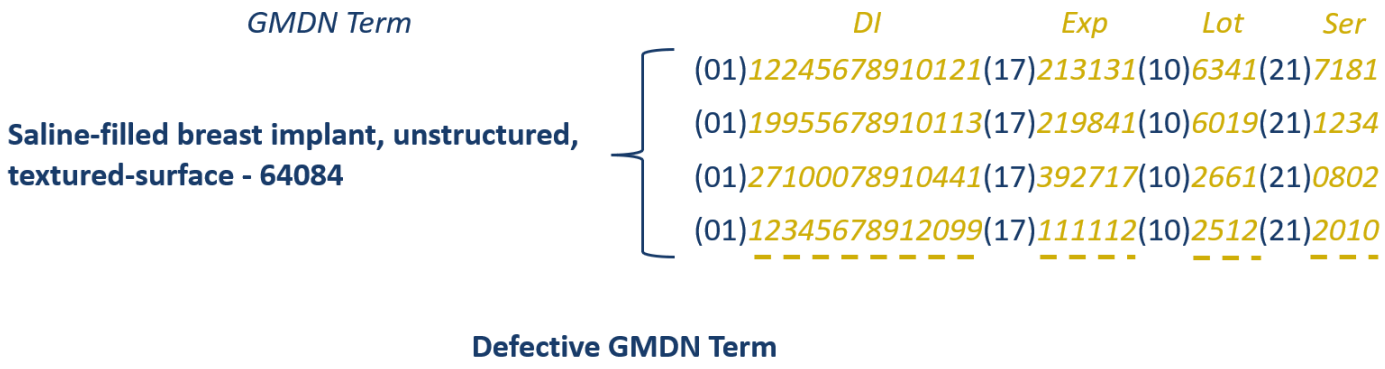
Utilisation of the UDI alone doesn't allow for evaluation of the efficacy of this type of pacemaker, only of the specific make and model of pacemaker associated with DI 00855547005410. As shown below, by using GMDN Terms for post market surveillance a comprehensive dataset can be created for the analysis of a device type by collating registry data and EHRs for all DIs assigned to a specific GMDN Term, increasing the sample size, and improving the statistical significance of the analysis.

Safety signal detection

As you may know, comparison of UDI codes associated with a particular issue, can highlight whether the issue is restricted to a single lot or whether it is an issue with that DI as a whole.

Use of the GMDN expands on this function, in the case of similar devices from different Manufacturers with a common issue, by facilitating comparison of DIs within a Term. The figure below displays UDI HRIs of devices with different DIs but a common issue.

Reviewing these devices as part of a GMDN Term as opposed to as individual DIs flags the whole Term and alerts users to the fact that devices associated this Term may be more prone to malfunction, poor performance or unexpected side effects.



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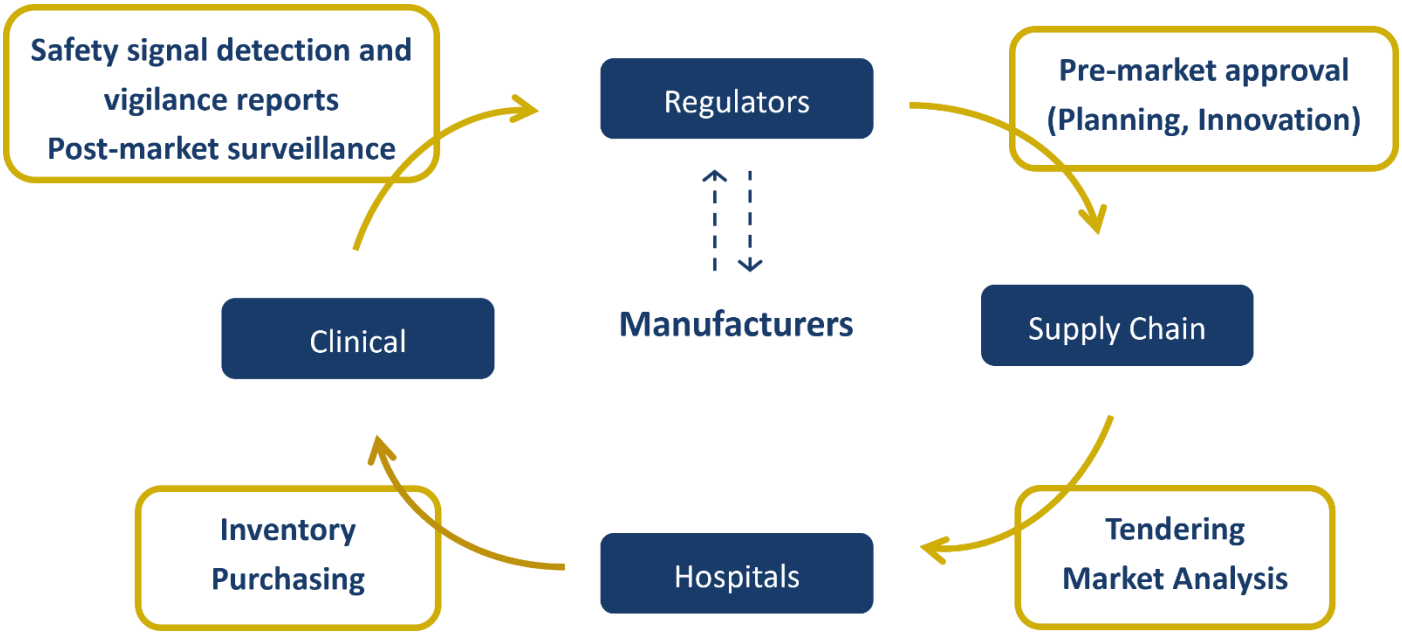
Summary

So how can the GMDN work for you? The schematic below represents where each GMDN use case fits into the dataflow of the medical device industry. The whole process centres around Manufacturers, they produce the devices and the rest of the cycle wouldn't work without them. Manufacters are what we refer to as 'Assigners'; they are responsible for assigning their device to the correct GMDN Term, setting the cycle of use cases in motion.

The GMDN Term is included in the Manufacturer's premarket application to Regulators. Following approval, group purchasing organisations (GPOs) and other segments of the supply chain can use GMDN Terms for tendering and market analysis. GPOs then supply the hospitals with stock to equip their clinicians, where GMDN Terms are used to monitor inventory and inform their purchasing habits to save time and money. RWE regarding device usage (patient groups, efficacy, side effects) is collected from clinical users in the form of EHRs and registry data to be used by Regulators for safety signal detection and vigilance reports, and for post-market surveilance, to gain information impossible to obtain through clinical trials.

By collating these records acording to GMDN Term, Regulators can evaluate efficacy and safety of device types and use their findings to inform policy changes, making it easier to ensure only safe and effective devices remain on the market.



As highlighted throughout this piece, UDI implementation serves as a foundation, in both structure and function, which the GMDN extends. Implementations are at various stages by national Regulators around the world, the longest being that by the US FDA, functional for 10 years, and Turkey, fully functional for 1 year.

Other countries are either at a feasibility stage or are implementing a phased approach based on risk class and are at different stages, including Australia (TBD), Singapore (~2028), Saudi Arabia (~2024) and the EU (~2028) among others.

The increasing uptake of UDI regulation and data collection, combined with increasing adoption of the GMDN as the naming and grouping standard, allows more users in more regions to benefit in the ways described above and serves to bring us closer to global harmonisation for medical device regulation and availability.

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