Product Classification in Healthcare

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Executive Summary

The purpose of this document is to provide an overview of the global classification and nomenclature landscape in healthcare and to offer guidance. This is intended for those who are investigating options for classifying products in the healthcare sector.

Product classification and nomenclature in the global healthcare sector is quite complex for many reasons. There have been discussions within the GS1 Healthcare community for many years regarding the potential to standardise product classification by providing a global standard, such as other industries have done with GS1's Global Product Classification (GPC).

In the past, GS1 has surveyed the global healthcare community via the GS1 Member Organisations, to better understand the current status and developments as they relate to the use of classification and nomenclature systems. In late 2014 and early 2015 we again surveyed the global community in an effort to determine leading trends and practices. While the survey results do not point to a clear trend or use of one single system over another, there are some general observations and recommendations which can be offered. Table 1 provides a listing of various purposes for classification based on the responses to our surveys.

It should be noted that there is a subtle but specific distinction which should be made between classification and nomenclature. This document offers a simple differentiation intended to assist in the evaluation of the systems listed in Table 2.

While most people will agree that a single global classification standard is desirable, it is very impractical and perhaps even impossible to migrate the hundreds of thousands of users (i.e. hospitals, manufacturers, regulators) from the current systems they use to a single global standard. This is further evidenced by the recent regulations that have mandated specific systems. For this reason the Global Data Synchronisation Network (GDSN) enables the

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communication of any of the classification or nomenclature systems associated with a specific product in the network.

This paper provides an overview of the systems currently used across the world and a listing of the business reasons why products are classified. This document can serve as a reference tool in the process of determining which system Trading Partners may choose to use.

Current Situation

There currently there are over 20 different Classification and Nomenclature systems used across the world for the classification of products in the healthcare sector. Classification and Nomenclature systems serve different purposes. A simple distinction between a Classification systems and a Nomenclature system is as follows:

- **Classification** –A form of cataloguing, or identifying, products and can be defined as a process for grouping products into categories based on an understanding of the essential properties and relationships between them. A classification system is used to group like products such as Medical Devices, versus Pharmaceutical Drugs. Example classification systems are UNSPSC, GPC, eClass and ATC among others.

- **Nomenclature** – A system with rules to name individual items. A nomenclature system is used to provide common descriptions to products which have the same performance characteristics and thereby can be substituted for each another (i.e. two syringes, with differing product descriptions from two different manufacturers which are designed for the same purpose or use).

Classification and Nomenclature systems are usually developed for specific purposes, such as tariff code harmonization by the World Customs Organisation, Anatomical Therapeutic Chemical (ATC) classification by the World Health Organization (WHO) and more general purposes such as purchasing and spend analytics or regulatory purposes such as Global Device Nomenclature (GMDN) used by the U.S. FDA for their Unique Device Identifier (UDI) regulation. The GMDN is also required by regulators in many countries for regulatory submission purposes.

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There are many business reasons why products need to be classified. A survey of the global healthcare community has identified specific reasons why people use classification systems. The order of the systems listed below is based on the original survey of the global healthcare community when asked why they classified products.

Business Process	Definition
Spend Analysis	**Spend Analysis** is the process of collecting, cleansing, classifying and analysing expenditure data with the purpose of reducing procurement costs. Spend analysis can provide answers to such questions as: • What was bought? • Who bought it? (requisitioner, buyer, department, location) • From whom did we buy it? • When was it bought? • How much did we pay for it?
Financial Analysis	**Financial Analysis** refers to an assessment of the viability, stability and profitability of a business or business unit, as a basis for making business decisions. Based on the results, management may decide to: • Continue or discontinue a part of its business; • Make or purchase certain materials in the manufacture of its goods; • Buy or lease certain equipment used in the production of its goods; • Issue stocks or negotiate a bank loan to increase its working capital; • Make decisions regarding investing or lending capital. Financial analysis deals with issues such as profitability, cash flow, liquidity and sustainability.
Procurement (Sourcing, Acquisition)	**Procurement** is the business process of obtaining goods and services—from requisition through payment. It commonly involves • purchase planning • standards determination

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	• specifications development • supplier research ("discovery") and qualification • value analysis • financing • price negotiation • purchasing (PO, Acknowledgement, Invoice…) • supply contract administration • inventory control and stores • disposals and other related functions
Strategic Sourcing	**Strategic sourcing** is an institutional procurement process that continuously improves and re-evaluates the purchasing activities of a company. The steps in a strategic sourcing process are: • Assessment of a company's current spend (see Spend Analysis) • Assessment of the supply market (who offers what?) • Development of a sourcing strategy (where to buy what, while minimizing risk and costs) • Identification of suitable suppliers • Negotiation with suppliers (products, prices) • Implementation of new supply structure • Track results and restart assessment (continuous cycle)
Tendering (Request for Quotation (RFQ), Request for Proposal (RFP), Call for Bids)	**Tendering** is a process by which a company seeks prices and terms for a particular product or service to be provided under a contract. The sealed offers themselves, typically including company information, a description of the proposed product or service, and a price quote, are known as tenders or bids. Tendering is often mandated and regulated in the public sector.
Enterprise Resource Planning (ERP)	**Enterprise Resource Planning** (ERP) is an information system designed to coordinate all the resources, information, and activities needed to complete business processes such as order fulfilment or billing. ERP systems come in

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	many different forms, most including multiple modules for various business processes.
Materials Management Information System (MMIS)	**Materials management** is the branch of logistics that covers the acquisition of supplies, quality control of the purchasing process, and the standards involved in ordering, shipping, receiving, and warehousing those supplies. Most large US healthcare providers operate MMIS. It is common usage to refer to MMIS as a subset of ERP systems.
Asset Management	**Asset Management** is the practice of managing the whole lifecycle of an organization's assets, both physical and non-physical. Asset lifecycle includes design, construction, commissioning, operating, maintaining, repairing, modifying, replacing and decommissioning/disposal. Examples of physical assets include buildings and capital equipment. Examples of non-physical assets include IT assets, network configurations, software, digital asset, electronic media and data.
Category Management (Merchandising)	**Category Management** refers to where a large company manages groups of products as separate business units responsible for their own inventory turns, profit, etc. It also refers to where a manufacturer and a retailer collaborate to develop a marketing strategy for a group of products. Also (merchandising) refers to activities aimed at increasing inventory turns, such as special offers, bundling, free samples and displays.

Table 1

In 2009 GS1 Healthcare recommended the creation of two overarching Bricks in the GS1 Global Product Classification (GPC) standard which provide a very high level classification of the two major product groups in healthcare, while enabling the adoption of the Global Data Synchronisation Network (GDSN) in Healthcare. A decision was also taken by GS1 Healthcare to not develop further classification granularity for GPC within the healthcare sector. The rationale for this decision is that there is no desire on the part of the global healthcare

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community to migrate to a single classification system globally from many systems currently in use. In some cases, it is not possible to migrate to a single system because regulations may require the use of a particular system.

Subsequently, an extension of these two bricks was approved. The two additional bricks allow for the separation of device and pharmaceutical items intended for human use and consumption from those specifically designed for animal welfare (veterinary).

Therefore the GPC standard currently consists of four main Bricks (classification codes), one for Medical Devices, one for Pharmaceutical Drugs, Biologics and Therapeutic Nutritionals, one for Veterinary Medical Devices, and one for Veterinary Pharmaceutical Drugs, Biologics and Therapeutic Nutritionals, plus an additional 135 Bricks which had been previously developed mostly for the retail industry, which includes retail pharmacies, prior to the 2009 GS1 Healthcare recommendation.

For a list of the GPC Brick codes which may be used for healthcare products visit the GS1 website.

Support for Other Classification Systems

In addition to the GPC system as the mandatory classification for GTINs in the GS1 Global Registry, the Global Data Synchronisation Network (GDSN) provides support for other classification systems. This feature allows for the use of various classification systems outside the GDSN, as needed in specific countries, sectors or as required by trading partners.

Classification systems, such as UNSPSC, CLADIMED, eClass, NHS e-class and others are identified within the GDSN by using the "Additional Classification Agency" attribute. This function provides structured identification and management of a relationship-specific classification system.

The GDSN attributes for additional classification systems are listed below.

- additionalClassification
  - additionalClassificationAgencyName

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- additionalClassificationCategoryCode
- additionalClassificationCategoryDescription

As adoption of global standards increases in healthcare globally, stakeholders in many countries turn to GS1 for a recommendation on a classification system to adopt for their local market. Because the decision was made not to fully developed GPC for healthcare, GS1 and its Member Organizations are unable to make a specific recommendation.

In late 2014 GS1 conducted a survey of the global healthcare community in order to get a more current understanding of the classification landscape. The survey results highlight the considerable complexities which exists in this area and that no one system, or few systems, emerge as the clear leader across the board. In fact, the results further validate the original understanding of why it is impractical and perhaps impossible to migrate to single system globally.

Below is a listing of the various Classification and Nomenclature systems used in healthcare and the declared purpose for each system. It should be noted that some of these systems, such as MedDRA and SNOMED, are also used for medical terminology classification or indications and diagnosis and as such may be attached to the product's data in addition to other systems.

System	Definition/Description	Maintenance Agency	Website	Declared Purpose
AHFS	American Hospital Formulary Service and Pharmacologic Therapeutic Classification - classification allows the grouping of drugs with similar	American Society of Health-System Pharmacists	http://www.ahfsdruginformation.com/pt-classification-system.aspx	Clinical: The mission of AHFS Drug Information® (AHFS DI®) is to provide an evidence-based foundation for safe and effective drug therapy.

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	pharmacologic, therapeutic, and/or chemical characteristics			
ATC	Anatomical Therapeutic Chemical Classification - active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties	WHO Collaborating Centre for Drug Statistics Methodology (WHOCC)	http://www.whocc.no/atc/structure_and_principles/	Research: The purpose of the ATC/DDD system is to serve as a tool for drug utilization research in order to improve quality of drug use.
ClaDiMed	Classification des dispositifs médicaux is the classification for medical device used in France and Belgium	ClaDiMed association	http://www.cladimed.com/english-version/	Modelled after the ATC, to provide a generic nomenclature for healthcare providers and device suppliers.
CMDR	Canadian Medical Device Regulations (CMDR) Preferred Name Code (PNC) The *Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices* is intended to assist manufacturers in	Health Canada's Therapeutic Products Directorate	**CMDR** is found at the following locations two locations (**part 1**): http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-1.html#s-1. (**part 2**)	Regulatory: To aid device manufacturers in registering products with regulatory agency prior to sale in Canada.

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	confirming the classification of medical device products after application of the Classification Rules for Medical Devices set out in Schedule 1 of the *Medical Devices Regulations*.		http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-5.html#s-32. **PNC** is found at http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/keyword_motscles2-eng.php	
CND	Classificazione Nazionale dei Dispositivi medici (CND) - Italian classification system for medical devices	Ministero della Salute Dipartimento dell'Innovazione Direzione generale dei farmaci e dei dispositivi mediciUfficio III, Viale della Civiltà Romana, 700144 Roma	http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=328&area=dispositivi-medici&menu=classificazione	Assessments of adverse events, transparent procurement processes by the national health system.
CPV	Common Procurement Vocabulary (CPV) establishes a single	The Office for Official	http://simap.europa.eu/codes-and-nomenclatures/co	The CPV establishes a single classification system for public procurement aimed at

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	classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of procurement contracts	Publications of the European Communities (OPOCE)	des-cpv/codes-cpv_en.htm	standardizing the references used by contracting authorities and entities to describe the subject of procurement contracts.
DM&D	The NHS Dictionary of Medicines and Devices (dm+d) contains unique identifiers (codes) and associated textual descriptions for representing medicines and medical devices in information systems and electronic communications.	The dm+d Programme Board is chaired by the Director of Medicines, Pharmacy and Industry Group, Department of Health.	http://www.dmd.nhs.uk/index.html	…a more integrated and safer healthcare system…interoperability, opportunities for comparison and reducing variation, enhancing patient safety. The dm+d uses SNOMED-CT codes throughout to classify pharmaceuticals. They have also created a dm+d SNOMED-CT UK Drug extension which defines the relationships between SNOMED-CT identified concepts This webinar provides an overview introduction at https://isd.hscic.gov.uk/trud3/user/guest/group/0/pack/6/subpack/71/releases
eCl@ss	Standardized Material and Service Classification and Dictionary - cross-industry product data	eCl@ss Association (http://wiki.eclass.eu/wiki/	http://www.eclass.de/eclasscontent/standard/search.html.en	…cross-industry product data standard for classification and clear description of products and services. …procurement, controlling and

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	standard for classification and clear description of products and services	The_eCl@ss_ association)		distribution…company-wide process data management as well as engineering.
(GIVD) (previously known as EDMA)	Global In Vitro Diagnostic Classification for medical devices	European Diagnostic Manufacturers Association (EDMA)	http://www.edma-ivd.eu/index.php?page=Global-IVD-Classification	… to support the collection and analysis of market statistics.
USC	Uniform System of Classification (USC) - provides logical groupings of pharmaceutical products considered to compete in the same or similar markets	IMS Health Pharmaceutical Action Committee	http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/Health%20Services%20Research%20Network/USC_Classiification_Process_2011.pdf	The USC provides logical groupings of pharmaceutical products considered to compete in the same or similar markets; each category provides the manufacturer a solution to determine the market share for their product(s), as well as their competitors.
GMDN	Global Medical Device Nomenclature -To give a common generic descriptor for medical devices having similar features, characteristics and intended use for exchange of data between regulatory bodies.	GMDN Agency	https://www.gmdnagency.com/	The main purpose of the GMDN is to provide health authorities and regulators, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single generic naming system that will support patient safety. The GMDN is used for: - Data exchange between manufacturers, regulators and healthcare authorities

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				- Exchange of post-market vigilance information - Supporting inventory control in hospitals - Purchasing and supply chain management The work was mandated by the European Commission in order to provide the necessary tool to carry out the implementation of the Medical Devices Directive, including the European databank for medical devices, Eudamed.
GPC	Global Product Classification - A system that gives a common language for grouping products in the same way	GS1	http://www.gs1.org/gdsn/gpc	GPC is the mandatory classification system for the GS1 Global Data Synchronization Network (GDSN). GPC gives buyers and sellers a common language to group products the same way globally to ensure effective data synchronization in the Global Data Synchronization Network (GDSN). GPC enables the following processes: - Item Registration - Subscription - Validation - Search - Publication/Subscription Match

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HCPCS	Healthcare Common Procedure Coding System - a standardized coding system for describing the specific items and services provided in the delivery of health care	Centers for Medicare and Medicaid CMS	http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/MedHCPCSGeninfo/	Used by healthcare providers in claims for reimbursement. Required by Medicare and Medicaid, also used for private insurance payers. Mostly procedures (healthcare services provided to patients), but also covers supplies that are reimbursable.
ICPS	World Health Organization (WHO) International Classification for Patient Safety Note: Code still under development	WHO Patient Safety Drafting Group	http://www.who.int/patientsafety/implementation/taxonomy/en/	a conceptual framework for reporting and classifying incidents, understanding the patient safety domain and learning
MedDRA	Medical Dictionary for Regulatory Activities – standardized international medical terminology for regulatory communication in the registration, documentation and safety monitoring of medical product	ICH has contracted a Maintenance and Support Services Organization – MSSO - to maintain, develop and distribute MedDRA	http://www.meddra.org/	…medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans. …for use in the registration, documentation and safety monitoring of medical products both before and after a product has been authorized for sale. Products covered by the scope of MedDRA include pharmaceuticals, biologics, vaccines and drug-device combination products.

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NAPCS	North American Product Classification System Identify, define, and classify the final products and services produced and transacted by reporting units within each industry	US Census Bureau, jointly with like agencies of Canada and Mexico	http://www.census.gov/eos/www/naics/index.html	The long-term objective of NAPCS is to develop a market-oriented, or demand-based, hierarchical classification system for products (goods and services) that (a) is not industry-of-origin based but can be linked to the NAICS industry structure, (b) is consistent across the three NAICS countries, and (c) promotes improvements in the identification and classification of service products across international classification systems, such as the Central Product Classification System of the United Nations.
NHS eClass	The National Health System (NHS)-eClass is a bespoke classification system for products and services, managed by the English NHS. The purpose of NHS-eClass is to facilitate the accurate analysis of expenditure.	NHS-eClass was operated for the English NHS by NHS PASA but is now administered by NHS Shared Business Services.	http://www.nhseclass.nhs.uk/	NHS-eClass was designed to support the accurate and standardized classification and cataloguing of products and services, and to enable a more detailed analysis of NHS non-pay expenditure below the TFR3 level thereby facilitating improved contracting focus. In the first instance the classification is for members of the NHS Finance and Procurement Community Secondly, other recognised user would include the NHS trading partners:

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				- NHS Services and Solutions provider - NHS Supply Chain - Suppliers to the NHSOther public sector procurement organisations i.e. OGC NHS-eClass is mapped to the UNSPSC and TFR/NCA (National Chart of Accounts) classifications.
Product Code Classification Database	The Product Classification Database contains medical device names and their associated product codes. The name and product code identify the generic category of a device for FDA and provides the regulatory class of the group.	FDA - Food and Drug Administration Center for Devices and Radiological Health	http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051637.htm	…developed by the Centre for Devices and Radiological Health (CDRH) in support of its mission. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.
SHPA	Society of Hospital Pharmacists of Australia Note: Does not appear have a code system at this time. In 2003 a position paper referenced GS1 and indicated SHPA	SHPA The Society of Hospital Pharmacists of Australia	http://www.shpa.org.au/	

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	would monitor for systems to consider.			
SNOMED	The Systematized Nomenclature of Medicine (SNOMED) CT® (Systematized Nomenclature of Medicine- Clinical Terms – controlled coded clinical terminology for use in electronic health records	IHTSDO® (International Health Terminology Standards Development Organisation	http://www.ihtsdo.org/snomed-ct/	SNOMED CT contributes to the improvement of patient care by underpinning the development of Electronic Health Records that record clinical information in ways that enable meaning-based retrieval. This provides effective access to information required for decision support and consistent reporting and analysis. Patients benefit from the use of SNOMED CT because it improves the recording of EHR information and facilitates better communication, leading to improvements in the quality of care.
UMDNS	Universal Medical Device Nomenclature System – nomenclature and computer coding system for medical devices	ECRI Institute	https://www.ecri.org/Products/Pages/UMDNS.aspx?sub=Management%20Tools,%20Guidelines,%20Standards,%20and%20Nomenclature	The purpose of UMDNS is to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases.
UNSPSC	United Nations	Managed by	www.unspsc.org	The UNSPSC offers a single

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	Standard Products and Services Code® (UNSPSC®) is an open, global, multi-sector standard for efficient, accurate classification of products and services	GS1 US for the UN Development Programme (UNDP)		global classification system that can be used for: - Cost-effective procurement optimization - Full exploitation of electronic commerce capabilities Typically used by purchasing organizations for spend analysis

Table 2

Recent Developments

Since the introduction of the UDI regulation by the U.S. FDA requires Global Medical Device Nomenclature (GMDN), it has become more prominent and the use of this system has increased. Additional growth can be expected if other medical devices regulators also require it for their regulations.

The United Nations Standard Products and Services Code (UNSPSC) has significantly developed its code set for both Medical Devices and Pharmaceutical products among other categories. This is in response to user demand for additional classification coverage. Many countries now require its use as part of national government procurement programmes.

General Recommendation

As previously stated, product classification in the healthcare sector is complex for many valid reasons. However, there are some general practices and principles one must keep in mind when making a recommendation on which system to use. Below are a few factors to consider.

- **Regulation**: Confirm if there is a particular regulation which mandates a specific system in the target country or region. For example, the U.S. FDA requires that every manufacturer of medical devices assign a GMDN code to their product sold in the US, when they register their product and master data in their Global UDI Database (GUDID). It is important to be aware of current regulations and their requirements. GS1 maintains

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a Public Policy database which contains information on regulations around the world which impact the healthcare sector -- http://healthcare.gs1.org/pp/

- **Business Purpose for classification**: Certain classification systems have been designed for specific purposes. Business functions such as Spend Analysis, Procurement and Category Management may require different classification systems. For example, the Common Procurement Vocabulary (CPV) establishes a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of procurement contracts. The table 2 above contains a listing of systems used in healthcare including their declared purposes. This table is intended to provide a centralized resource to aid in your research.

- **Product type**: Systems such as GMDN, GMDNS and ATC have been designed for specific product types such as medical devices and pharmaceuticals. Therefore these systems have a specific declared product type and serve very specific functions and are not interchangeable.

- **National recommendations**: Verify with the local GS1 Healthcare User Group to see if they have agreed or if they recommend a particular classification system nationally. For example GS1 Healthcare US recommends the use of UNSPSC for the classification of products in the US market. Note that regulations will override commercial recommendations.

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