
GS1 Standards in healthcare: raising the bar on patient safety and supply chain efficiency

ABSTRACT

Patient safety, supply chain security, traceability and efficiency in Healthcare are currently at the forefront of government regulatory and industry concerns around the world. As a result, numerous, and often incompatible solutions are being (or have been) proposed to the national and international supply chain stakeholders and, in some cases, adopted in preference to global standards. The cost of diverse government regulations, proprietary services and incompatible solutions being offered to stakeholders has made it clear that there is a need to define and increase adoption of open, global standards. This is the mission of GS1 Healthcare.



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Challenges and opportunities in the healthcare supply chain

Patient safety initiatives across the world tackle the challenges in the Healthcare supply chain, including the reduction of medication errors, the fight against counterfeiting, optimised post-market surveillance, etc.

More than 30% of all adverse drug events are preventable and appear to be consequences of medication errors¹. Adverse events from medication errors represent a significant problem for Healthcare worldwide, as indicated by several studies in different countries. An Adverse Event Study in one country indicated that 9.3% of hospital stays incurred a serious adverse event, with medication errors being the main cause (37.4% of such events)². The implementation of automatic identification systems, up to the point-of-care, has proven to significantly reduce medication errors; for example, the Veterans Affairs Medical Center in Topeka, U.S.A., has reported that bar coding reduced its medication error rate by 86% over a nine-year period³.

Counterfeit Healthcare products are in the first place a risk to public health. It is almost impossible for patients and dispensing Healthcare professionals to spot the fakes. Healthcare products are supplied through complex,

multi-echelon global supply chains that currently lack transparency, making it vulnerable to infiltration by counterfeiters. The introduction of a unique identification for each and every pack, where appropriate, will enable traceability and authentication systems with readily available technology. This will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain, or at least, make it uneconomic.

Other patient safety initiatives are related to improving post-market surveillance and adverse event reporting, product recalls, disaster preparation, treatment documentation, etc.

Reducing costs and increasing supply chain efficiency will contribute to keeping soaring Healthcare costs under control. Diverging country requirements for supply chain data further complicate an already complex production, packaging and distribution system and add risk and cost. Manual systems and processes in hospitals are unable to efficiently and safely handle the constant change that occurs with supplies and pharmaceuticals. Standardised automatic identification and traceability systems will simplify and improve accuracy in a number of supply chain processes from production to point-of-care or point-of-sale.

Welcome to the world of GS1 Standards

Open, technology-independent standards permit full interoperability and compatibility. End users are not locked into proprietary solutions and R&D resources can be freed up for other added value developments once standards have been adopted.

GS1 Standards are not only open and technology-independent, but also truly global, which is vital in supply chains that often cross borders.

First of all, the GS1 System of Standards incorporates a set of Identification Keys. These are numbers identifying products and services and providing access to information held in computer files. These numbers are:

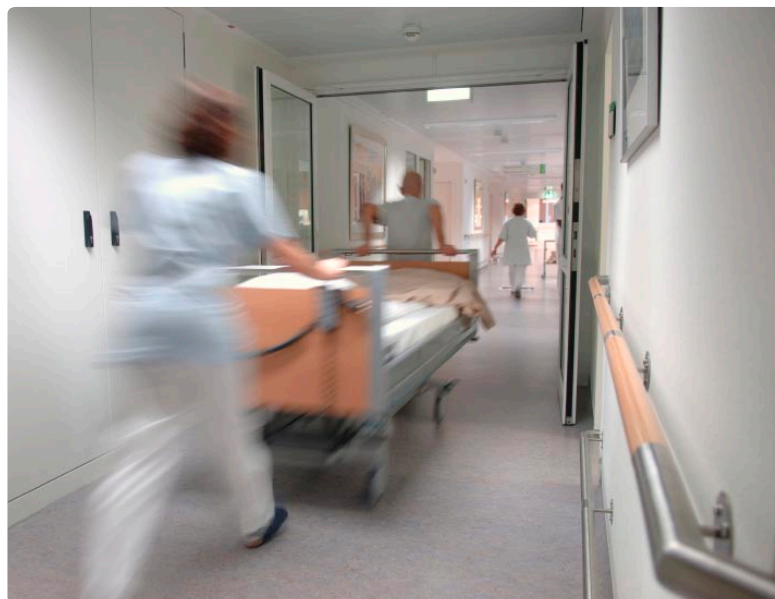
- Unique: every variant of an item is allocated a separate unique number;
- Non-significant: they identify an item but contain no information about it;
- International: GS1 Identification Keys are unique across all countries and all sectors;
- Secure: GS1 Identification Keys are fixed length, numeric and include a standard check digit

At the heart of the GS1 System is the GTIN (Global Trade Item Number) Identification Key. These numbers are allocated by the manufacturer, according to the GTIN Allocation Rules and include; a GS1 company prefix assigned to a company by GS1, an item reference assigned by the company and an automatically generated check digit. GS1 has published specific Healthcare GTIN Allocation Rules, due to the complex needs of the industry.

The GS1 System also incorporates a number of other Identification Keys, including GLN (Global Location Number), SSCC (Serial Shipping Container Code) and GRAI (Global Returnable Asset Identifier).

GS1 Identification Keys can then be carried on any type of data carrier, a GS1 bar code (linear or 2-dimensional) or an EPCglobal Radio Frequency Identification (RFID) tag, on the specific product or packaging.

The GS1 Global Data Synchronisation Network (GDSN), built around the Global Registry and GDSN-certified data pools, provides a powerful environment for secure and continuous synchronisation of accurate product and location data.



GS1 eCom (Electronic Data Interchange) provides global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners.

GS1 Traceability Standards provide a powerful tool kit for implementing traceability to enable full actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale or point-of-care, to ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

GS1 Fast Facts:

- User-driven standards organisation
- Member organisations in 108 countries
- 2,000 employees supporting 1.2 million companies
- 6 billion 'beeps' per day, based on GS1 Standards, make it the most widely used system of supply chain standards

A voluntary, global Healthcare user group

GS1 Healthcare is a voluntary, global Healthcare user group bringing together all related Healthcare stakeholders. Members range from leading pharmaceutical and medical device manufacturers, healthcare providers, distributors and Group Purchasing Organisations (GPOs), governmental and regulatory bodies and associations including the U.S. FDA, Public Health Agency Canada and Eucomed.

The mission of GS1 Healthcare is to bring together experts in Healthcare to develop and implement global standards to successfully enhance patient safety and supply chain efficiencies.

GS1 Healthcare is now widely recognised as an open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in Healthcare for patient safety, supply chain security and efficiency, traceability and accurate data synchronisation.

Healthcare suppliers advance global supply chain standards

Confronted with diverging country specific product identification requirements and developing traceability requirements, suppliers were instrumental in establishing the global Healthcare user group in 2004-2005. Many leading suppliers are members of the global Healthcare user group and actively drive global standards development and adoption at a global level.

At a global level, current supplier members include (dd. April 2009); Abbott, Alcon, Amgen, Baxter, B. Braun, Boston Scientific, Bristol-Myers Squibb, Cook, Covidien, Edwards Lifesciences, Fresenius Kabi AG, GlaxoSmithKline, Johnson & Johnson, King Pharmaceutical, Medtronic, Merck & Co., Novartis Pharma, Pall Medical, Pfizer, Purdue Pharma, Sakura Seiki, Schering-Plough, and Smiths Medical.

At a national level, many more suppliers are member of a GS1 Member Organisation and are involved in national initiatives to drive adoption and implementation of GS1 Standards in the Healthcare supply chain.

Also other stakeholders, such as distributors, retailers, and logistics providers have been involved. Global members include; CVS, Cardinal Health, DHL Exel Supply Chain, and McKesson.

Healthcare providers advance global supply chain standards

Leading Healthcare providers and Group Purchasing Organisations (GPOs) worldwide are endorsing GS1 Standards and are paving the way for sector-wide adoption.

Some notable examples are:

In the U.S.A.

- AHRMM, a professional membership group of the American Hospital Association serving more than 4,000 active members
- Amerinet, a GPO serving more than 2,200 acute care and 25,000 alternate care health systems members
- Novation, a GPO serving 2,500 members of VHA Inc. and the University HealthSystem Consortium (UHC) and nearly 12,000 members of Provista, LLC
- Premier Inc., a GPO serving more than 2,000 hospitals and 53,000-plus other healthcare sites
- SMI (Strategic Marketplace Initiative): 32 healthcare provider members, including for example Duke University Health System, Johns Hopkins Health System, Mayo Clinic, Sisters of Mercy ~ ROI, SSM Health Care, University Kentucky HealthCare, and Yale New Haven Health System

In Austria

- Orthopädisches Spital Speising GmbH, Vienna (Vinzenz Gruppe) and Wiener Krankenanstaltenverbund are members of the global Healthcare user group

In Canada

- CareNET, a not-for-profit organisation comprised of over 450 hospitals across Canada
- HealthPro, a GPO serving 485 hospitals
- MedBuy, a GPO serving more than 350 Healthcare facilities

In Chile

- Cenabast, the Supply Center for the Ministry of Health in Chile

In France

- UNIHA, a network of 32 university hospitals and 22 large hospitals

In Germany

- Comparatio Health, a GPO comprised of 6 university hospitals
- EK UNICO, a GPO comprised of 13 university hospitals, including 300 special clinics and more than 240 institutes

In Hong Kong

- Hong Kong Hospital Authority, a statutory body managing 40 public hospitals, 48 specialist clinics and 75 general clinics

In Japan

- Tokyo Medical University, Kanto Medical Center and Nagoya University Hospital, etc.

In the Netherlands

- NFU (the Dutch Federation of University Medical Centre), comprised of 8 university medical centres
- Erasmus MC Hospital Rotterdam and Universitair Medisch Centrum Groningen are members of the global Healthcare user group

In Switzerland

- Geneva University Hospitals are members of the global Healthcare user group

In the U.K.

- The Department of Health best practice guidance Coding for Success recommended that both industry and the NHS adopt the GS1 System of coding standards. Over 175 NHS hospitals have registered for GS1 UK membership.

GS1 Healthcare advocates global harmonisation

Global standards will enable all stakeholders to efficiently and effectively comply with various identification, traceability and product catalogue requirements. To this end, GS1 Healthcare user groups (local and global) aim to be a neutral and trusted source for governmental bodies, regulators and associations for all related matters. Some notable examples are:

- Providing input to the European Commission for the legislative proposals to ensure safe, innovative, and accessible medicines currently being developed

- Providing input to the Global Harmonisation Task Force (GHTF), U.S. FDA, the European Commission, and others, on the adoption of GS1 Standards for Unique Device Identification (UDI)
- Providing input to the Italian Ministry of Health who is currently reviewing the 'Bollino' system
- Providing input to the Turkish Ministry of Health to ensure full compliance with GS1 Standards
- Providing input to the WHO Technology work group of IMPACT (Anti-Counterfeiting Taskforce)
- Provided input to the Japanese Ministry of Health, Labour and Welfare, resulting in revised bar code guidelines for medical devices in line with GS1 Standards
- Provided input to the UK Department of Health resulting in the 'Coding for Success' programme
- Provided input to the Public Health Agency of Canada resulting in the GS1 Standards-based vaccine bar coding project
- Provided input to the EFPIA project for coding and identification of pharmaceutical products
- Provided input to the Australian National eHealth Transition Authorities (NeHTA) resulting in endorsement of GS1 Standards
- Provided input to the California Board of Pharmacy for ePedigree requirements to comply with GS1 Standards

GS1 Healthcare will continue to promote global supply chain standards and invites all stakeholders to join the user group, either at national or global level.

For more information about GS1 Healthcare, visit www.gs1.org/healthcare

REFERENCES

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