Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GHWP Liaison Member Updates for GS1

Chiara Bernini

Senior Manager Public Policy Healthcare

GS1

GS1 is a global standards organisation

Neutral and not-for-profit

User-driven and governed

Global and local

Inclusive and collaborative

GS1 standards help

Product information

Sustainability

Traceability

Authentication

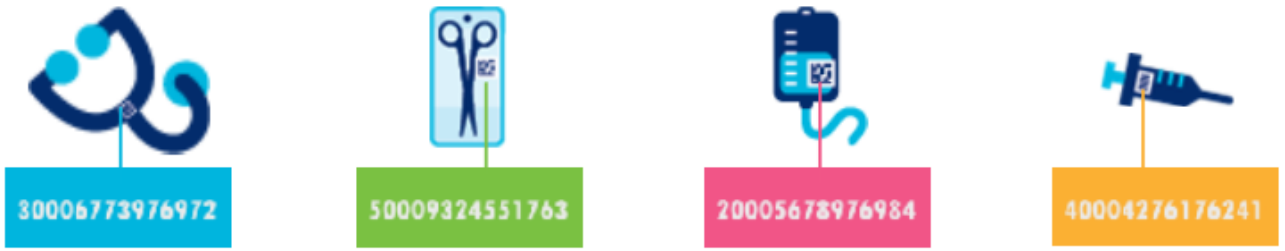
Trust

Interoperability

UDI: what is it?

Unique Device Identifier (UDI)

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the **unambiguous identification of a specific medical device on the market.**



UDI scope

Regulated medical devices

Pharmaceuticals

The definition of regulated medical devices varies from jurisdiction to jurisdiction (hence from country to country).

Do not confuse

	Standardisation of the global unique identifier	Risk-based **classification** of medical devices	**Nomenclature** code
Enabled by	Organisations such as GS1	National competent authorities	Organisations such as Global Medical Device Nomenclature Agency
Example	GTIN	Class 3 medical devices under EU MDR	GMDN nomenclature EMDN (under dev.)

GS1 role in UDI across the world

GS1 is supporting the IMDRF and is a Liaison Member to the GHWP … supporting global harmonisation

Mandated by ANMAT for traceability of certain devices in Argentina

99% of medical devices identified with GTIN in Japan

MHLW Annual Survey, 2012

£3 million on average saved each year in every NHS hospital in England

Lord Carter interim report, 2015

UDI issuing agency/entity in China, EU, Saudi Arabia, South Korea, Singapore, U.S.A. – and more to come

91,8% of devices identified with GTIN in Turkey

Turkish National Drug and Medical Device Databank (TITUBB)

GS1 standards also used for identification of medical devices in Netherlands, Qatar, UK …

GS1 provides support to regulators as they develop and implement their UDI requirements

The need to align on a global UDI framework

- UDI is very beneficial - it is crucial that regulators around the world align and ensure consistency when setting-up regional or national UDI system

➢ This will ensure :
  - highest levels of patient safety beyond borders
  - harmonised identification systems for medical devices globally

The challenge of global implementation

- Multiple UDI-DIs for the same model of device
- **Different UDI Triggers**
- Impact of multiple standards for UDIs (one per issuing agency) on cost and time to implement in healthcare
- Different positions on the UDI carrier
- Differing codes / values for data fields in the UDI databases
- Different nomenclatures
- Exceptions
- Etc

This can create regulatory and administrative burden and can undermine successful implementation from manufacturers to healthcare providers.

GSMP HC GTIN Allocation Rules Updates MSWG

- New regulations, new business processes and new requirements have risen that require clarifications within the Healthcare GTIN Allocation Rules for it to maintain its value in the identification of items and in the broader implementation of GS1 standards in the healthcare industry.

- The revision will make the rules easier to use and help companies better understand situations where healthcare specific rules apply.

Why UDI? Patient safety and traceability

REGULATOR

- market surveillance, along across borders
- identification and documentation of devices placed on the market and used in hospitals
- customs control and fight falsified devices
- others: insurance, price control, tender requirements, inventory management

HOSPITAL

- electronic health records
- purchasing, inventory, invoicing
- safety alerts and fields safety corrective actions (FSCA)
- no relabelling and less medical errors

MANUFACTURER

- compliance with regulations and tender requirements
- costs optimisation
- data synchronisation and processes efficiency

Contact Details

Chiara Bernini
Senior Manager Public Policy Healthcare
GS1 Global Office, Brussels

chiara.bernini@gs1.org
GS1.org/healthcare