Position paper: GS1 and IDMP

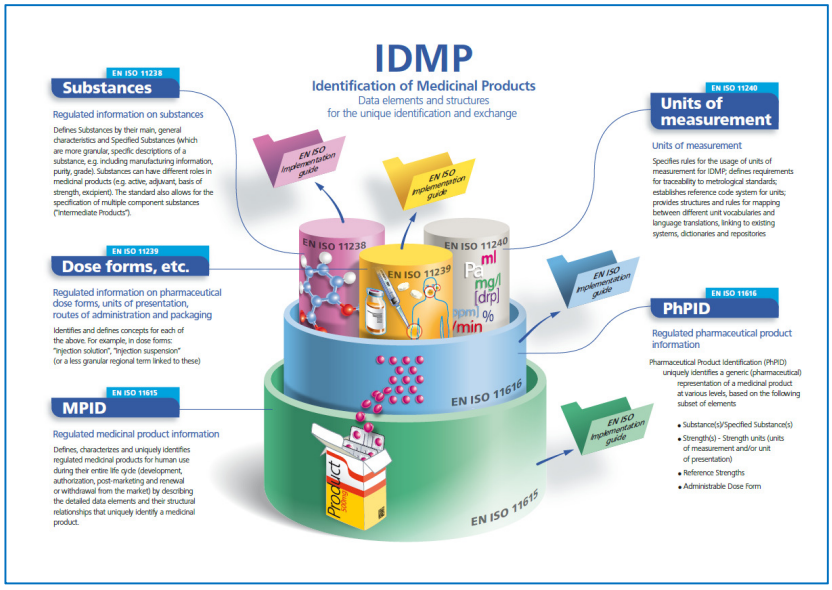
This position paper presents the vision of GS1 Healthcare regarding the regulatory initiative "Identification of Medicinal Products (IDMP)". It demonstrates the complementary relationship between GS1 standards and IDMP, as well as how both impact a safer supply chain and ultimately safer care. It is meant to support an understanding of how GS1 and IDMP complement each other.

Positioning IDMP

Regulatory requirements for marketing authorisation include the submission of master data describing a medicinal product. Historically, a vision was developed within the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) for increased interoperability across the world. At one point in time, ICH decided to task the ISO technical committee *ISO/TC 215 Health informatics* to deliver the standards that would make ICH's vision, IDMP, a reality.

What is IDMP

IDMP is a set of ISO standards, including their implementation guides (technical specifications), which enable unique structuring and identification of master data which can be used globally. It is built upon HL7 (Health Level Seven® International) messaging standards[1] that are used to transmit information from Marketing Authorisation Holders to their regulatory body.



[1] HL7 is a standard developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

The regulatory benefits are numerous and include:

- harmonised identifiers around the globe that enables more efficient adverse event reporting;
- information exchange between regulators becomes more secure by reducing the mapping tables.

For Marketing Authorisation Holders, IDMP standardises product information to be transmitted and shared with the regulators, thus reducing mapping tables and individualized specific formatting. It includes the utilization of GS1 Global Trade Item Numbers (GTINs) as the regular link between marketing authorisation, supply chain identifiers and traceability.

For the supply chain, it is expected that:

- manufacturers will have a single way to manage their master data, for commonality between the Global Data Synchronisation Network (GDSN) and IDMP (e.g. pharmaceutical form, route of administration, unit of measurement),
- clinicians will have a single channel for access to information via regulated medicinal product master data, impacting prescription, dispensing and adverse event reporting,
- supply chain security will be improved by the consistent use of identical master data

In summary, IDMP supports regulatory and clinical processes and is complemented by GS1 identification standards for supply chain processes.

IDMP and GS1

IDMP is a detailed data model for medicinal products with a global scope; it currently involves primarily European Union and USA, but is going to be adopted by number of other regulators. It uses the concepts of *pharmaceutical product* and *medicinal product*. These concepts differ from the terms used in the supply chain. In explanation:

The unique identification of a *pharmaceutical product*[2] allows linking *medicinal product* master data regardless of the jurisdiction and the marketing authorisation holder. A *pharmaceutical product* is the combination of substances, quantities, pharmaceutical form, etc., which is common to one or many *medicinal products*. Marketing authorisations are issued by the competent authorities according their legislation. When it comes to the identification of the physical trade item packaging hierarchy, the data model provides a placeholder for the GS1 Global Trade Item Number (GTIN).

This flexible approach enables linking supply chain identification (via GS1 Standards) with IDMP, even for packaging levels which might not be regulated (such as with a tertiary packaging level item) or for multi-country packaging.

GS1 and IDMP

The GS1 system of standards includes the Global Data Synchronisation Network (GDSN), which enables trading partners to exchange product master data in a standardised way. The GDSN specifications accommodate the IDMP defined value sets, such as pharmaceutical dose form or units of measures (for medicinal products, e.g. millilitre, millimole, microgram, etc.). Consequently, data consistency will be enhanced which increases efficiencies when medicinal products are supplied,

[2] See graphic above, *pharmaceutical product* is defined in EN ISO 11616

dispensed, prescribed and administered, as well as when an adverse event has to be notified, research about recalled medicinal product has to be undertaken, etc.

IDMP, GS1 and the fight against falsification of medicinal products

The fight against falsification is aided by the precise identification of medicinal product packages (using GTIN and attributes such as a serial number) which must reference master data. This master data provides appropriate information about the medicinal product being considered. A perfect illustration will be the link between IDMP and the European Medicines Verification system that will allow the pharmaceutical industry to leverage one trusted source to configure the EMVS. This will reduce drastically the collection / configuration and maintenance effort and will improve the usage of consistent master data.

The combination of master data (such as IDMP identifiers) and supply chain identifiers (GTIN, lot/batch and serial number) is not only key to fight the falsification of medicinal products, but also by scanning the barcode and aggregating or processing the encoded data, future expectations for healthcare processes, efficient deliveries & transaction data accuracy can be met. Pharmacovigilance or even pharmacoepidemiology can also be further supported.

Who is GS1

GS1 is a neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain standards system in the world. GS1 standards improve the efficiency, safety and visibility of supply chains across multiple sectors. With local Member Organisations in over 110 countries, GS1 engages with communities of trading partners, industry organisations, governments and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 standards. (more information is found at: www.gs1.org).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.

References

GS1 Healthcare GTIN Allocation Rules:
http://www.gs1.org/sites/default/files/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

HL7 International: www.hl7.org

ICH: www.ich.org

ISO TC 215: http://isotc.iso.org/livelink/livelink/open/tc215

WG6 : www.isotc215-wg6.team

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