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## **Position paper: GS1 and ISO 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 ISO IDMP for both medicinal products with marketing authorisation<sup>1</sup> and investigational medicinal products<sup>2</sup> subject to clinical trials. ISO IDMP promotes a safer and more secure supply chain to better support health and care. Ultimately, this position paper is meant to facilitate understanding of how GS1 and ISO IDMP complement each other.

### **Positioning ISO IDMP**

Regulatory requirements for investigational and authorised (i.e., marketed) medicinal products 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 international interoperability. In 2007, ICH identified certain Standard Development Organisations (SDOs), which included ISO technical committee *ISO/TC 215 Health informatics*, to deliver the standards that would make ICH’s vision, IDMP, a reality.

### **What is ISO IDMP**

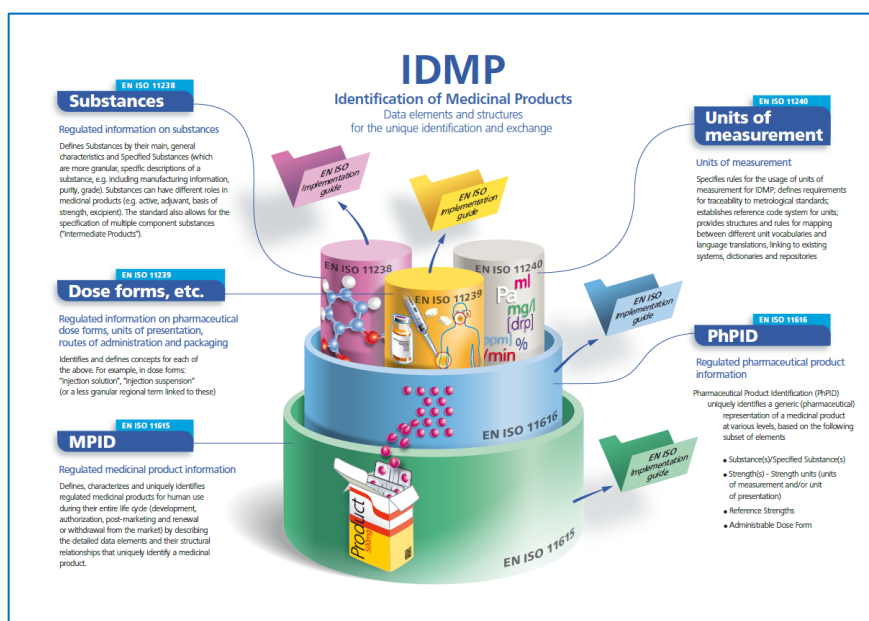
IDMP is a set of ISO standards, including their implementation guides (technical specifications), which enable unique structuring and identification of data which can be used globally. It is built upon HL7 (Health Level Seven® International) messaging standards<sup>3</sup> that are used to transmit information from Marketing Authorisation Holders to their regulatory body. Likewise, ISO IDMP is used to transmit information from Clinical Trial Sponsors to relevant regulatory bodies.

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<sup>1</sup> Pharmaceutical product or combination of pharmaceutical products that may be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions (ISO 11615, § 3.1.50)

<sup>2</sup> Pharmaceutical product or combination of pharmaceutical products or placebo(s) being tested or used as a reference in a clinical trial (3.1.11), including products already with a marketing authorisation (3.1.40) but used or assembled (packaged) in a way different from the authorised form, used for an unauthorised indication, or used to gain further information about the authorised form (ISO 11615, § 3.1.31)

<sup>3</sup> 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 adopting common semantics and value sets.

For Marketing Authorisation Holders, ISO IDMP standardises product information to be transmitted and shared with the regulators, by using common semantics and value sets. It includes the utilisation 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 common semantics and value sets between the Global Data Synchronisation Network (GDSN) and ISO IDMP (e.g. pharmaceutical form, route of administration, unit of measurement),
- clinicians will benefit of a consolidated set of information, including the relevant ISO IDMP identifiers, semantics and value sets, beside additional assets such as SNOMED CT for example, to process selection, prescription, dispensing and adverse event reporting,
- supply chain security will be improved by the consistent use of identical data.

For clinical trial sponsors, ISO IDMP is likewise used to standardise the product information transmitted and shared with regulators. With the clinical trials sector moving to use of GTIN for identification of investigational products packages, similar to the commercial environment the GTIN becomes the link between IDMP, supply chain processes and traceability information.

In summary, ISO IDMP supports regulatory (including clinical trials) and clinical processes and is complemented by GS1 identification standards for supply chain processes.

## ISO IDMP and GS1

ISO IDMP is a detailed data model for medicinal products with a global scope; it currently involves primarily European Union and USA, with adoption/implementation under review by a number of



other regulators<sup>4</sup>. It uses the concepts of *pharmaceutical product* and *medicinal product*. These concepts differ from the terms traditionally used in the supply chain. In explanation:

The unique identification of a *pharmaceutical product*<sup>5</sup> allows linking *medicinal product* data regardless of the jurisdiction and the marketing authorisation holder or clinical trial sponsor. A *pharmaceutical product* is the combination of substances, quantities, pharmaceutical form, etc., which is common to one or many *medicinal products*. Marketing authorisations and approved clinical trial applications are issued by the competent authorities according to their legislation. When it comes to the identification of the physical trade item packaging hierarchy, the data model provides the placeholder for the GS1 Global Trade Item Number (GTIN as “Data Carrier Identifier”).

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) for multi-country packaging or for investigational medicinal products.

## GS1 and ISO 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 ISO 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, 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.

## ISO 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 drastically reduce 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.

## IDMP and clinical trials

There is a necessity to capture standardised information about investigational medicinal products as part of clinical trials. There is also the need to accurately identify the packaged investigational medicinal product for supply chain purposes.

Reliance on IDMP to provide the foundational data vocabulary for investigational products is increasing, evidenced by the European Medicine Agency clinical trial portal and database

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<sup>4</sup> See : [IPRP – International Pharmaceutical Regulators Programme](#)

<sup>5</sup> See graphic above, *pharmaceutical product* is defined in EN ISO 11616

incorporating IDMP for example. Reliance on the GTIN as the identifier for the investigational medicinal products is also increasing, as seen by implementation of these standards by clinical trial sponsors, contract manufacturers, logistics providers, trial sites, etc.

Together these identifiers will contribute to innovative products moving through the regulatory process effectively.

## About 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](http://www.gs1.org)).

## About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefits to all stakeholders. Global members of GS1 Healthcare members include more than 120 leading healthcare organisations worldwide.

Follow us on Twitter: @GS1Healthcare

View the GS1 Healthcare website: [www.gs1.org/industries/healthcare](http://www.gs1.org/industries/healthcare)

## References

GS1 Healthcare GTIN Allocation Rules:

[http://www.gs1.org/sites/default/files/docs/gsmg/healthcare/GS1\\_Healthcare\\_GTIN\\_Allocation\\_Rules.pdf](http://www.gs1.org/sites/default/files/docs/gsmg/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)

HL7 International: [www.hl7.org](http://www.hl7.org)

ICH: [www.ich.org](http://www.ich.org)

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

For more information contact Christian Hay : [christian.hay@gs1.org](mailto:christian.hay@gs1.org)

