The Global Language of Business

ISO/TS 16791:2014

Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers

Overview

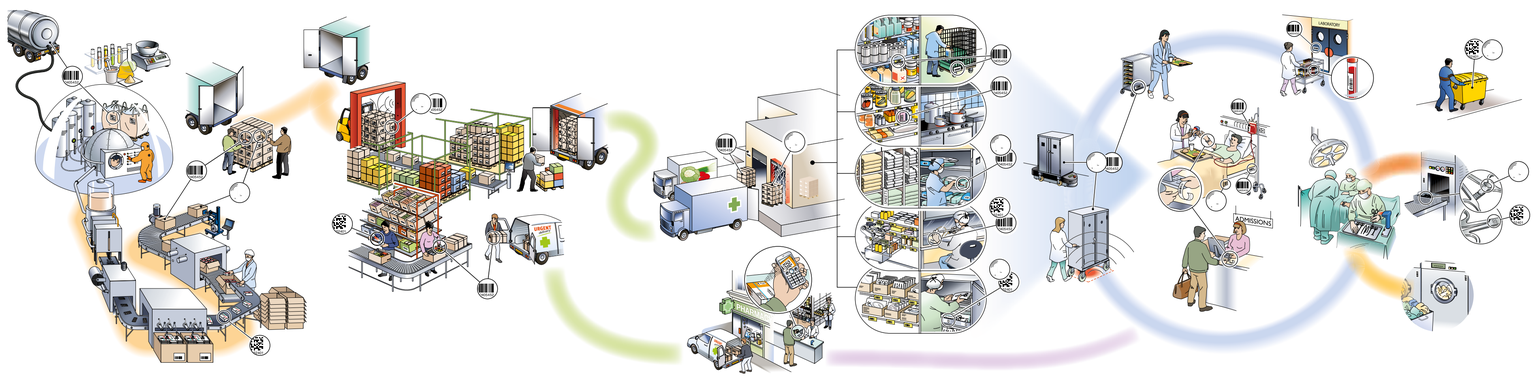
This Technical Specification (TS) provides the link between the major regulatory initiatives (IDMP: Identification of Medicinal Product, and ICSR: Individual Case Safety Report). Both initiatives are going to be implemented across the world along the next 10 years and the supply chain.

The link provides guidance to regulatory affairs about supply chain processes and needs. That's why the TS includes good practices regarding product identification in the context of various processes and use cases to support the normative content. GS1 standards are used for product identification, including processes such as Master Data Management (GDSN) or Event Tracking (ECPIS).

Some use cases

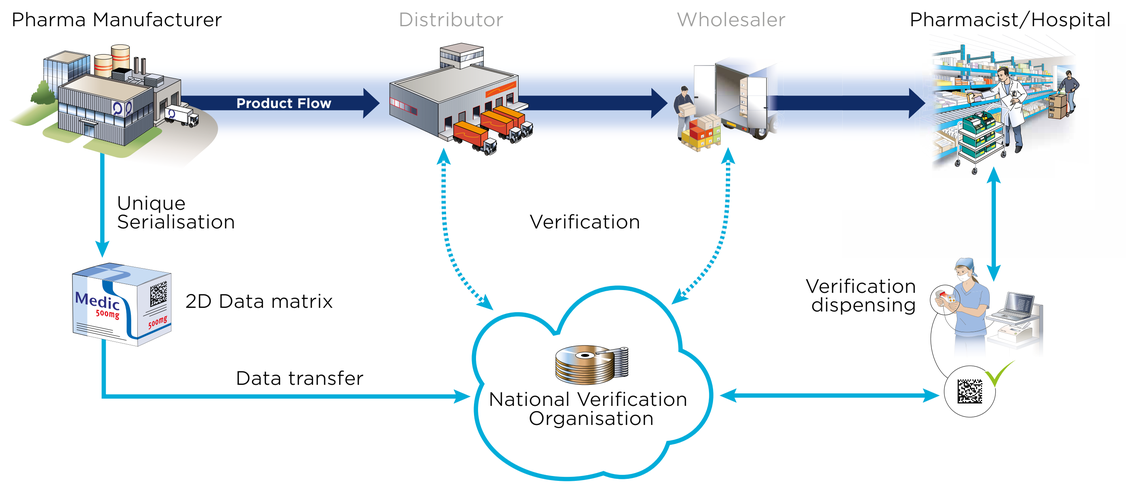
Traceability

From the simplified product tracking between 2 supply chain actors, the TS provides guidance for repackaging, compounded preparations or reconstitution



Fight against falsification of medicinal products

Using serialisation as a mean for product authentication (process chosen in Europe), or as a mean for supply chain integrity (process based on EPCIS, ISO/IEC 19987), both with a particular attention to master data management



Improving patient safety at point of care

Medicinal product identification at primary package level

Who worked on this Technical Specification?

Experts from ISO Technical Committee 215, Working Group 6 have been engaged in this work. There were representatives from manufacturers, regulators, hospital experts and GS1 MO from 9 countries engaged to the development of the document. Project leader was Gary Hartley, GS1 New Zealand.

What comes next?

To ensure that the document remains up-to-date and globally relevant ISO/TS 16791:2014 has been the subject of a systematic review. Through this process, national standards bodies review the document and its use in their country (in consultation with their stakeholders) to decide whether it is still valid, should be updated, or withdrawn. The result was the standard should be revised and with work already underway the aim is to publish in 2019.

For further information, contact GS1 Global Office Healthcare team - E: healthcare@gs1.org