Discussion paper on medicines identification requirements on primary level packaging using GS1 standards

Purpose

The purpose of this paper is to facilitate the discussions about the development of the requirements for identification of medicines on primary level packaging using GS1 standards. In particular this document focuses on providing recommendations to align with the globally harmonised framework for traceability of pharmaceuticals while enabling timely, less complex and more cost-effective implementation.

Scope

The scope of this document is medicines, not medical devices.
"Primary level packaging", in the context of this document, refers to the application where medicines in primary level of packaging (e.g. blisters, ampules, vials, etc.) are contained within marked secondary level of packaging according to the illustration below (*see GS1 General Specification for the GS1 definition of primary level of packaging)*.

Figure 1: Different packaging levels

About GS1 Healthcare[1]

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. GS1 Healthcare members include 112 leading Healthcare organisations worldwide.

GS1 traceability standards in Healthcare

Within the GS1 system are a complete set of standards for implementing traceability to enable fully actionable visibility of pharmaceuticals and medical devices from point-of-production to point-of-sale, point of dispense or point-of-care. Implementation of these standards ensure maximum interoperability between traceability systems across the Healthcare supply chain and across borders.

GS1 standards are ISO-compliant[2] and likewise, ISO standards are a mainstay of the references within GS1 documents.

To ensure the safety of the pharmaceutical supply chain, traceability is a key objective of regulators around the world. More and more regulators require the use of unique identifiers to be encoded into data carriers on the secondary level of packaging and linked to relevant information in a database. Increasingly, regulators are recommending or requiring the use of GS1 standards to implement these traceability requirements.

For example, GS1 standards are followed for drug coding and identification referenced for use in compliance with regulations from Argentina, Egypt, Europe, Japan, Jordan, Saudi Arabia, South Korea, Turkey, the U.K., the U.S.A., and for export products in India. Adopting requirements for a harmonised approach across countries, using global standards, enables these regulators to efficiently address the issues surrounding falsified medicines and to allow cross-border traceability.

State of play: Focus on serialisation of medicines on secondary level packaging

In many countries today – around 70 -, the regulatory requirements for traceability of pharmaceuticals are implemented using GS1 standards. In practice, the GS1 GTIN is encoded in a GS1 DataMatrix, applied on the secondary level packaging, with an expiration date, a batch/lot number and a serial number (as additional Application

1 www.gs1.org/healthcare

2 https://www.gs1.org/docs/GS1-and-ISO-06BD.pdf see further CEN ISO TS 16791, which addresses Requirements for international machine-readable coding of medicinal product package identifiers

Identifiers or “AIs” within the same barcode). This provides the basis for globally unambiguous identification of pharmaceuticals and builds a global and secure framework for a full traceability system across packaging levels.

Figure 2: Example of GS1 DataMatrix

The overall objective is to improve patient safety based on globally traceable medicines and effective recalls. It is also to enhance the supply chain efficiency by reducing the complexity of production and cost of traceability globally as the great majority of countries are already using GS1 standards for pharmaceutical traceability.

At present nowhere around the globe where serialisation on primary packaging level has been considered as a requirement has it been implemented. If a regulator decides to move forward with such a requirement, it will be the first and only country worldwide with such a requirement for pharmaceuticals. As the pharmaceutical industry becomes more global, managing the labelling and packaging used in so many countries globally and having to adapt their processes to meet individual country requirements, becomes more and more challenging and will significantly impact potential successful implementation (e.g. cost, timeframe).
In addition, the benefits relating to patient safety at the primary level of packaging can be achieved without serialisation.

Global standards enable identification of medicines on primary packaging level

GS1 recognises that identification of primary level of packages such as vials, pre-filled syringes or solid forms in blister cavity is an important prerequisite for successful point of care verification and registration in electronic health records.
A few stakeholders (e.g. AMGROS in Denmark) already require their suppliers to identify primary level of packages with barcodes. Hospital implementation can be observed in several countries such as Belgium, Netherlands, Portugal, Brazil, USA, Spain, Switzerland, Argentina, Singapore.

GS1 standards support the identification of medicines at the primary level of packaging, each being identified with its own GTIN, and optionally with variable information such as lot/batch number and expiry date, but not with serial number.

The ISO/IEC 16791:2019 paragraph 4.7 also states that "*serial numbers are allocated to secondary or tertiary level packaging and shall not be found on the primary package (unit of use, i.e. blistered solid forms).*" In cases where a medicinal product is marketed in its primary level of packaging, then the primary level of packaging is identified as secondary packaging with a serial number.

Conclusion

It is widely recognised that global traceability is necessary to combat counterfeiting across borders, and increase national and international supply chain security. The use of global supply chain data standards, namely the GS1 standards, is recommended by inter-governmental organisations (e.g. USAID) as well as by key trade associations across the world. The GS1 standards are used and implemented by the healthcare sector in at least 70 countries worldwide.

- GS1 Healthcare recommends that the regulators continue to use GS1 standards to ensure harmonisation and alignment with other healthcare regulators across the world.

- GS1 Healthcare recommends that regulators do not require serialisation at the primary level of packaging at this moment, and instead start with the implementation of serialisation on secondary level of packaging as well as the underlying systems necessary to take advantage of this. Primary level of packaging serialisation should be a subsequent step with a realistic time frame based upon open interaction with the global pharmaceutical industry stakeholders.

Reference documents

- GS1 General Specifications:
https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
- GS1 position paper on the identification of the primary package level of drugs:
https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/single_unit_position_paper_final300617.pdf
- GS1 Regulatory Roadmap on the traceability of Medicinal products:
https://www.gs1.org/docs/healthcare/Public-Policy/GS1_Healthcare-ROAD-MAP_FINAL.pdf