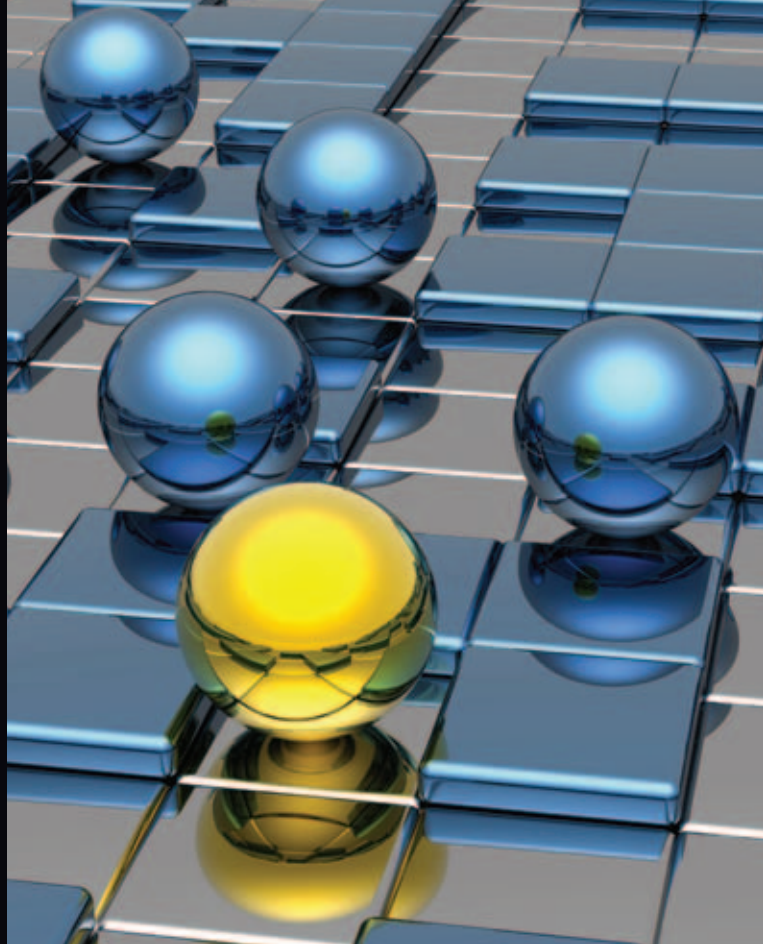


ON THE RIGHT TRACK

Safety and security of pharmaceuticals are at the forefront of industry concerns. As a result, numerous costly and incompatible solutions have been proposed to industry and government stakeholders. **Ulrike Kreysa** and **Jan Denecker**, GS1, explain why the GS1 System of Standards is well suited for drug traceability.



The complexities of the increasingly global healthcare supply chain are vast. A supply chain that delivers healthcare products crosses geographic and political borders, with products changing ownership a number of times. Significant inconsistencies in the amount of legislation, regulation and resources exist from country to country and these inconsistencies further complicate an already complex distribution system.

Healthcare products are supplied through multi-echelon global supply chains that lack transparency. Products are not always shipped directly from the manufacturer to the customer, but are instead sold through primary and secondary distributors.

Authentication and traceability

Counterfeit pharmaceutical products are a risk to public health. It is almost impossible for patients and dispensing healthcare professionals to spot the fakes. The consequences of counterfeit drugs include: treatment failure, drug resistance and even death. The lack of transparency in the healthcare supply chain makes it vulnerable to infiltration by counterfeiters. Illegal opportunists take advantage of this lack of transparency in an attempt to profit from the sale of substandard and/or counterfeit therapies, creating a situation where providers can unknowingly use impotent or harmful products, potentially causing patients to suffer ill effects.

The World Health Organization (WHO) reports that 10% of all pharmaceuticals worldwide are counterfeit; in parts of Africa and Asia this figure exceeds 50%. For example, in Cambodia, 60% of 133 drug vendors sold anti-malaria medications lacking the active ingredient. Out of the million people who die each year from malaria, the WHO estimates that 200,000 perished because of counterfeit medication.

Author profiles



Ulrike Kreysa has responsibility for Healthcare at the GS1 Global Office in Brussels, Belgium. Before joining GS1 in October 2004, Kreysa worked at GHX (Global Healthcare Exchange) Europe, an international e-commerce platform in healthcare, where she held the position of managing director for Benelux and France.



Jan Denecker is marketing manager GDSN & Healthcare for GS1 Global Office in Brussels. Prior to joining GS1 in January 2007, he worked for Agfa Healthcare as global marketing manager digital radiography. His responsibilities included creating and implementing global marketing strategies.

Counterfeiting is not a problem that is confined to developing countries; it is an increasing reality throughout the world. In Europe and North America, 1% of pharmaceuticals are now counterfeit, according to the WHO, and this is rising. This has been confirmed by the increase in pharmaceuticals seized by European customs and by the US FDA, which reports 'an increase in counterfeiting activities and a more sophisticated ability to introduce counterfeits'. Direct sales through mail order or the internet are also heavily affected. Pharmaceuticals bought via websites are counterfeit in over 50% of cases.

The introduction of a unique identification for each pack of pharmaceuticals, where appropriate, will enable traceability and authentication systems with available technology. This would significantly improve the safety of pharmaceuticals and patients, and make it much more difficult for counterfeiters to intrude into the healthcare supply chain; or at least, make it uneconomic for them to do so.



In one instance, this unique identification allows the dispensing healthcare professional to cross-check a pack of drugs online, in a database or through its electronic pedigree. When the identification numbers are cross-checked, and there is no confirmed dispensing record, the healthcare professional can dispense the pack of drugs. Counterfeiters would need a legitimate identification number that is registered in the database or an electronic pedigree to enable authentication. In the worst case, two packs of drugs with the same serial number would be present in the supply chain, in which case stakeholders would be alerted about this intrusion when the second pack is being cross-checked.

This authentication and tracing should be combined with other preventative measures, such as: introducing tamper resistant packaging (bottles with external seals or tamper evident screw caps, boxes with seals or perforated panels) and the certification of websites for internet sales.

Enabling traceability systems

Traceability is generally defined as ‘the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration’. The GS1 Global Traceability Standard is a process standard that defines the traceability business process and the minimum data management requirements for all traceability systems independently from the technology. A traceability system typically consists of the following building blocks:

Unique identification

- Global product identification number based on GS1 Identification Keys (globally unique and non-significant numbers identifying products and services, and providing access to information held in computer files).
- Lot/batch number and serial number (unique number at the unit level).

Data capture

- Data to be carried on any type of data carrier, a GS1 bar code (linear or 2D) or an EPCglobal radio frequency identification (RFID) tag, on the specific product or packaging.
- GS1 DataMatrix bar codes (2D) enable the coding of more fixed and variable information, within a significantly smaller area compared with linear bar codes.
- EPCglobal tags can also hold all the necessary information and does not require line of sight to be read.
- Links management.

GS1: NEUTRAL PLATFORM FOR ALL SUPPLY CHAIN STAKEHOLDERS

GS1 is a neutral, not-for-profit standards organisation. It is a user-driven organisation dedicated to the development of global supply chain standards and to the facilitation of adopting and implementing of such standards. GS1 is driven by more than a million companies, which execute more than six billion transactions a day with the GS1 System of Standards. GS1 has local member organisations in 108 countries, with offices in Brussels, Belgium, Princeton, US, and London, UK. For more information, visit www.gs1.org.

- Managing identification from the point-of-manufacture to the point-of-sale/point-of-care.

Data communication

- Associates the physical flow of products with the information flow.
- Different information sharing models, including:
 - One up, one down: point-to-point information sharing for daily operations.
 - Chain of custody or chain of ownership: point-to-point information sharing of cumulated product history information; typically an electronic document communicating the custody history of that particular product. This information-sharing model is the basis for a number of anti-counterfeiting regulations in the US including California, Florida and Nevada. For example, the Pedigree Legislation in California prescribes that a ‘pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution’, which will come into force as of 1 January 2011.
 - Real time (one source): repositories or a central database for data search. There is no point-to-point information sharing and all data is on request based on traceable item identifier.

The above will make it much more difficult for counterfeiters to intrude into the healthcare supply chain and will improve the process of recalling products and reporting adverse events.

Global and open standards

Healthcare is by nature a global sector, with supply chains that often cross borders. A global standardised system for traceability, from product manufacture to patient treatment, is imperative to comply with the increasing legal requirements for product traceability worldwide. In cases of cross-border trading, a global identification number can be used to identify that product in any country without any restrictions or errors.

Local needs are incorporated into global standards, but local standards will jeopardise the realisation of the related benefits. Local standards hinder interoperability and compatibility, which significantly reduces the economic benefits. Additional R&D and manufacturing resources have to be devoted to meeting heterogeneous local standards.

Open, technology-independent standards, such as those of GS1, permit full interoperability and compatibility. End users are not locked into proprietary solutions and R&D resources can be freed up for other added value developments once standards have been adopted. **WPF**