

Traceability and Serialisation – Effective Implementation

Ulrike Kreysa and Jan Denecker at GS1 argue that the key to fighting counterfeiting lies in a global standards-based approach to the problem

The complexities of the increasingly global healthcare supply chain are vast. Healthcare products are supplied through complex, multi-echelon global chains that currently lack transparency. Supply chains that deliver healthcare products cross in and out of geographic and political borders, with products changing ownership a number of times. Significant inconsistencies in the degree of legislation, regulation and resources exist from country to country, and these inconsistencies further complicate an already complex distribution system.

Combating Counterfeiting Through Traceability Systems

Counterfeit pharmaceutical products are, in the first place, a risk to public health, with consequences including treatment failure, drug resistance and sometimes death. It is almost impossible for patients and dispensing healthcare professionals to identify the fakes. Furthermore, counterfeit pharmaceutical products are not confined to developing countries, but are an growing global threat, and are becoming an increasing reality in developed countries in Europe and North America. Both European Customs and the US Food and Drug Administration (FDA) report an increase in counterfeiting activities and a more sophisticated ability to introduce fakes into legitimate drug distribution channels.

Illegal opportunists take advantage of patient desperation and a supply chain that lacks transparency in an attempt to profit from the sale of substandard and counterfeit therapies, creating a situation whereby providers can unknowingly use impotent or harmful products, potentially causing patients to suffer ill effects.

The introduction of a unique identification for each and every pack of pharmaceuticals, where appropriate, will enable traceability systems with readily available technology, and will provide an indication of authenticity. This would significantly improve patient safety and the integrity and security of the supply chain. It would make it much more difficult for counterfeiters to intrude into the healthcare supply chain or, at least, make it uneconomical.

This unique identification allows the dispensing healthcare professional to verify each pack of drugs online in a database or through its electronic pedigree. When the identification numbers are verified, and there is no confirmed dispensing record or error, 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 case where two packs of drugs with the same identification number are present in the supply chain, the stakeholders would be alerted about this intrusion when the second pack is being verified.

These traceability systems 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 Global Traceability Standard for Healthcare (GTSH) provides a foundational framework, which

describes the traceability process and defines the minimum requirements for all stakeholders, independent of technologies, organisation size or operational sophistication. The GTSH will enable maximum interoperability between traceability systems across the healthcare supply chain and across borders. A traceability system typically consists of the following building blocks:

- Unique identification
- Data capture
- Links management
- Data communication

A Unified Approach

Product identification should be based on globally unique identification keys. These keys allow the identification of products anywhere in the world and provide access to information held on these products in computer databases. More importantly, they ensure compatibility and interoperability amongst traceability systems. The global trade item number (GTIN) is assigned by the manufacturer to any item (product or service) that may be priced, ordered or invoiced at any point in any supply chain. GTINs have been used for more than 30 years as the standard identification key in the retail and consumer packaged goods (CPG) sectors worldwide: products with a GTIN are scanned more than six billion times per day. Also, pharmaceutical products are identified with GTINs in more than 70 countries worldwide. Some countries still require national identification numbers, adding cost and risk for international suppliers, but also affecting interoperability and compatibility across borders.

Serialisation puts a unique mark at various packaging levels. In particular, the introduction of a serialised unique

identification at the unit-of-sales level, where appropriate (risk-based), will enable traceability and authentication systems, such as chain of custody, chain of ownership, product identifier authentication or recall, with readily available technology. Mass serialisation is expected to become a reality over the next five years in the pharmaceutical industry. Government mandates are the driver for serialisation, for example in California and Turkey. More recently, serialisation has received even more attention because of the US FDA and the European Commission. Both have conducted public consultations in the last 18 months on serialisation as an anti-counterfeiting measure for drugs. Many pharmaceutical manufacturers are already considering how to implement these important changes and have serialisation projects underway, or are planning them.

Automatically Capturing Data

The product identifier (fixed/static – GTIN) as well as the production identifier (variable/dynamic – serial number) need to be carried in the data carrier, either a barcode (linear or two-dimensional) or a radio frequency identification (RFID) tag. Global standards are critical to ensure an effective and efficient implementation of such systems throughout the healthcare supply chain and across borders. Different data carriers can be useful to address the needs of different applications, but the healthcare sector, as a whole, needs to agree on a standard set of data carriers that will be used and can be read by anyone anywhere. Non-standard data carriers unnecessarily complicate the process.

The GS1-128 linear barcode can hold a large amount of data, which is necessary to fulfil traceability requirements. The GS1 DataMatrix 2D barcode enables, in an efficient way (high production rates and reliability), coding of more fixed and variable



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information, within a significantly smaller area than a linear barcode. EPCglobal RFID tags can also hold all the necessary information and do not require line of sight to be read, while a barcode needs to be read with a barcode scanner aimed at the barcode.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organization considers, in the short term, the 2D barcode as the most realistic possibility to enable traceability of pharmaceutical products. The European Federation of Pharmaceutical Industries and Associations (EFPIA) advocates the need for standardisation, and proposes GS1 DataMatrix.

Data Communication: ePedigree or Point-of-Dispensing Verification?

These unique codes are uploaded to an event repository database that can be accessed by various parties, including dispensing pharmacists, law enforcement officials and even consumers, after the product is shipped and placed on the market. However,

Traceability in Healthcare

Driving development and implementation of global standards, GS1 Healthcare is a global, voluntary user community, bringing together healthcare supply chain stakeholders including: manufacturers, wholesalers, distributors, hospitals, pharmacies, regulatory bodies, trade associations and GS1 member organisations. Its mission 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. One of its work groups is 'Traceability in Healthcare', which has already published the Global Traceability Standard for Healthcare (GTSH) and related implementation guidelines. The team is now developing a suite of global standards that enable traceability in healthcare (including process standard(s) and technical standards) by mid-2010. GS1 is a neutral, not-for-profit organisation with 108 Member Organisations, dedicated to the design and implementation of global standards and solutions to improve efficiency and visibility in supply chains

different information sharing models exist and are being proposed to supply chain stakeholders or will be mandated. Traceability standards need to meet the requirements of the various models.

One Up, One Down

This is point-to-point information sharing for day-to-day operations.

Chain of Custody or Chain of Ownership

This refers to point-to-point information sharing of accumulated product history information; typically an electronic document communicating the custody

or ownership 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 requires 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 1st January 2015.

Real Time (One Source)

This scenario involves repositories or a central database for data search, no point-to-point information sharing, all data on request, and is based on a traceable item identifier. EFPIA proposes such a system intended to be an end-to-end product verification process at the point-of-dispense. EFPIA is currently testing this model in Sweden through 180 dispensing points in the Stockholm area that will verify 110,000 packs in a four-month trial.

These systems involve costs for all parties involved: an appropriate information technology infrastructure will have to be constructed that will allow trusted parties to query through a central data portal. Data will be routed to the distributed database where information on the unit in question is kept, requiring definition of governance structures between key stakeholders.

About the authors



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