

Ensuring Traceability of Medicines in Serbia

ABSTRACT

Pharmaceutical supply chains across the world are often very complex and non-transparent. Such complexity, as well as the occurrence of falsified medicines in the market, seriously threatens the security of patients.

Serbian stakeholders joined forces and initiated a traceability pilot project aimed at creating a medicines traceability system from production to patient. In addition to ensuring traceability and reinforcing the fight against the occurrence of falsified medicines, the pilot also wanted to prove the importance of automating the work processes to meet European regulations.



by **Milorad Komljen** and **Bogdan Pavlović**

Project objectives

The project goal was to demonstrate that it is possible to provide visibility across the healthcare supply chain, from manufacturer to patient, using GS1 Standards. A key element of the project was also to implement the GS1 DataMatrix carrier and item serialisation. Standards used included Automatic Identification and Data Capture (AIDC) technologies and Business-to-Business electronic messaging (eCom). Such a traceability system was set to demonstrate the possibility of tracking medicines at any chosen point across the distribution chain and provide key data about the product (e.g. the batch or lot number and expiration date), connecting the medicine to the patient.

In addition, the project was intended to demonstrate that a documented recall of specific batches or lots of medicines from the market could be achieved in a relatively short time.

Lastly, the project participants were motivated to expand the scope to demonstrate that the use of GS1 Standards could increase the security of the supply chain and strengthen the fight against the growing threat of falsified products penetrating the market.

Participants and sponsors

The system tracked two domestic medicines that are reimbursed by the Government Healthcare Fund and included 11 companies representing the whole healthcare supply chain up to the retail pharmacy, of which:

Domestic Medicine Manufacturers

Galenika a.d.

Hemofarm Stada a.d.

Medicine Wholesalers

Farmalogist a.d.

Phoenix Pharma a.d.

Velefarm a.d.

Pharmacies

Apoteka Beograd with its 54 Pharmacies and about 150 dispensing points.

Solution Providers

Metadata for designing of a specific central data base.

Panteon Group® for the message exchange.



Apoteka Beograd



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The Ministry of Health of Serbia and the Medicines and Medical Devices Agency of Serbia supported the project and approved the use of GS1 DataMatrix to be applied to the medicines secondary packaging.

588,163 packs of medicines from 32 batches were marked with GS1 DataMatrix, amongst which 524,066 carried serial numbers. 8,528 individual packs of medicines were issued to patients.

GS1 Serbia provided education and understanding of the regulations, standards and guidelines and provided complete support and guidance to all project stakeholders whilst also managing the central data base. The GS1 Healthcare Team of GS1 Serbia also acted as the project Coordinator.

Application of GS1 Standards

As the Serbian Drugs Law of 1993 already mandates the use of GTINs to identify products, the use of a GS1 DataMatrix data carrier to encode the GTIN was seen as a continuation of the standardisation process.

GS1 Standards applied in the project included:

- GS1 DataMatrix placed on the medicines secondary packaging holding the GTIN, Batch or Lot Number, Expiration Date and Serial Number
- GS1 Serialised Shipping Container Code (SSCC) also known as a Logistics Label
- Global Location Numbers (GLN) for the unique identification of the trading partners and their operational premises (e.g. warehouse, pharmacy)
- GS1 eCom Despatch Advice (DESADV; XML version 2.5)
- A database modeled on the GS1 Global Data Synchronisation Network (GDSN) standard, holding the master data of each medicine (GTIN) and trading partners (GLN)

The database included all the transactions related to the medicines, which enabled visibility of medicines along the supply chain. Data and reports were only available to the project participants. According to regulatory requirements, patient data was available only to pharmacy institutions.

The process

The manufacturers selected the prescription products to be included in the project and got trained to the use and application of GS1 Standards, ie. how to apply the GS1 DataMatrix carrier to the secondary packaging (Figure 1), how to implement the logistics label (SSCC) and how to generate and exchange electronic (eCom) messages.

Accordingly, the wholesalers developed the ability to improve the warehousing processes by monitoring the products GTIN, Batch or Lot Number and Expiration Date.



Figure 1: Marked products with GS1 Standards

In parallel to the movement of the medicines across the supply chain downstream, from manufacturer to wholesaler to pharmacy, a DESADV message was sent. A copy of each message, together with all the information about the sender, dispatched goods and receiving parties were registered in the GS1 Serbia database. This process enabled to centralise the information on each medicine, its Lot Number and quantity transacted in the supply chain (Figure 2).

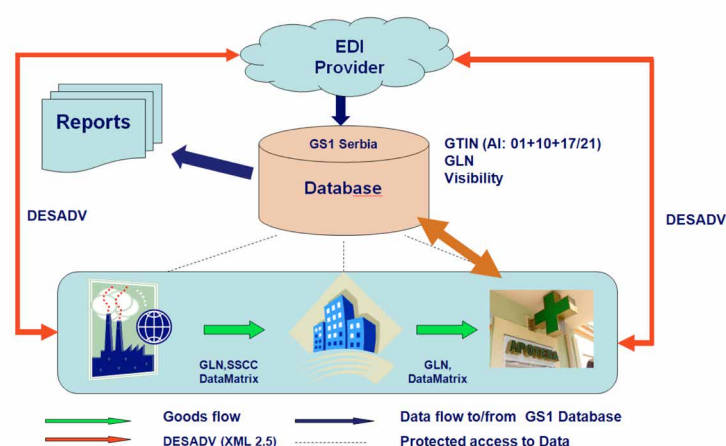


Figure 2: Goods and information flow

During the project the pharmacies needed to ensure they could accept and store the medicines in line with GS1 Standards. Every pharmacy was thus equipped with an image scanner at the dispensing point terminal, which could read DataMatrix carriers (see Figure 3).

In addition, every prescription of medicine carried a GS1 DataMatrix encoded with the patient's name, address and the national product code of the prescribed medicine used for reimbursement purposes. So, when a patient came to the pharmacy, the pharmacist would scan the GS1 DataMatrix on the prescription and, at the point of dispense, scan the GS1 DataMatrix on the medicine's packaging.

This process allowed to link the patient's information to the medicine dispensed. In order to secure patients information, their data was kept in the pharmacy's database while the identification number of each transaction, prescription and the

GTIN number, Batch or Lot Number, Expiration Date and Serial Number on the medicine were held in GS1 Serbia's Data Base. The visibility obtained by linking the data about the medicine dispensed to the receiving patient provided the possibility of recalling medicines directly from the patient.

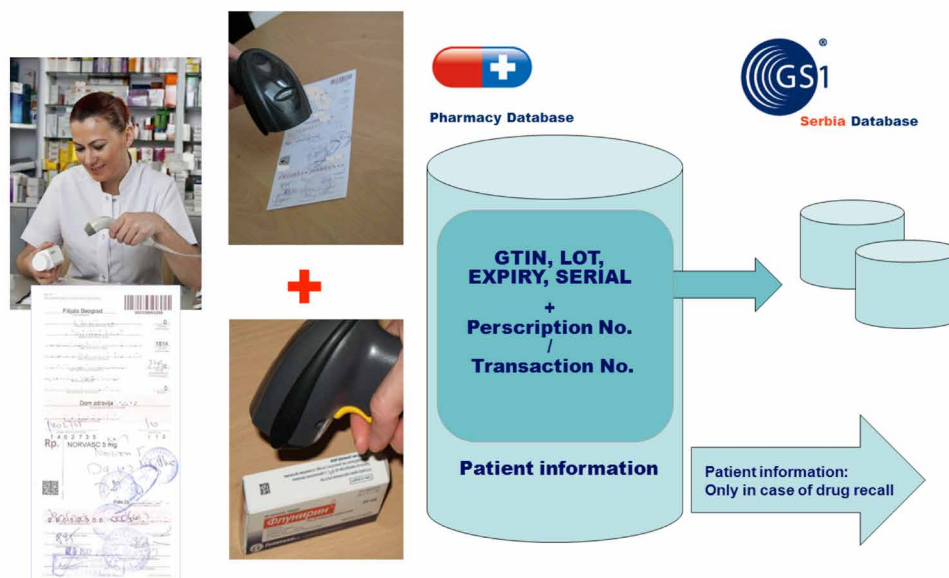


Figure 3: Pharmacist reading a DataMatrix carrier at the point of dispensing

A first test was undertaken to **prove the authenticity of the medicines**. 118 scans of Serial Numbers were conducted on inventory held at the wholesalers and pharmacy locations (Figure 4), as well as at the dispensing point in pharmacies. The manufacturers verified the Serial Numbers and confirmed that no duplicates had been found at the points of dispensing.



Figure 4: Serial numbers being checked

Two additional drug recall tests were undertaken on specific batches. In less than an hour, the packs from these batches were located - whether at the manufacturer, wholesaler, pharmacy or patient.

Findings

The operational part of the project lasted one year and the direct costs amounted to less than €10,000. The project was based on already existing IT equipment purchased by manufacturers for printing and scanning GS1 DataMatrix carriers. Pharmacies were already equipped with image scanners to read GS1 DataMatrix carriers on prescriptions. The changes to Pharmacy software was financed by GS1 Serbia, while the funds tied to eCom providers' solutions were very limited.

It was demonstrated during this project that the efficiency and accuracy of data, as well as the efficiency of all the logistical processes can be improved whilst minimising operational errors and manual activities.

The implementation of GS1 DataMatrix placed on the medicines' packaging holding the GTIN, Batch or Lot Number, Expiration Date and Serial Number proved to be fundamental to:

- Enable medicine traceability
- Strengthen the fight against falsified products
- Increase the visibility of medicines across the supply chain
- Improve the efficiency of the medicine recall process
- Increase the protection of patients from falsified, expired or recalled medicines

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About the authors

Milorad Komljen, BSc. econ, is the ICT Executive Manager at the Galenika company. He has gained 35 years of experience in informatics while working in different companies from Economics Institute Belgrade to Galenika where he was actively involved in different IT projects.

Bogdan Pavlović, BSc IT, is the Head of IT Development in Hemofarm. He has been with Hemofarm since 2002, starting as an Application Developer. Currently as Head of IT Development, he has worked on a number of projects which included several cycles of alignment with logistic standards. He is proud to have been aligning Hemofarm logistics with GS1 Standards.

About the co-authors

Miroslav Ilic is CEO of GS1 Serbia and has 34 years of working experience. Miroslav has been engaged in pharmaceutical industry in IT sector and management for the past 25 years. He was previously employed by the oldest pharmaceutical company in the Balkans, starting in IT and becoming the general manager for the company. He was the President of the Medicine Wholesalers Group within the Serbian Chamber of Commerce.

Branislava Mitic is the Team Leader for GS1 Identification at GS1 Serbia and has been in the Association for the past 19 years. In addition to leading the team engaged with identification standards labelling and coding, she is also engaged in Traceability initiatives in various sectors and supports Healthcare at GS1. She is the President of the Serbian Institute for Standardisation Board - KSI 1/SC 31 for Automatic Identification and Data Capture, and the member of the mentioned Institute Board KSI / TC 215 - Health informatics.

About the participants

Hemofarm A.D. is one of the leading generic pharmaceutical manufacturers in Serbia and the region. Founded in 1960, the primary activity of Hemofarm is the production of high-quality, safe, and effective generic pharmaceutical products. In 2006 the company became part of the STADA Group. It has about 2,500 employees and operates in the markets of more than 30 countries.

Galenika A.D. was founded in 1945 and is the oldest Serbian manufacturer. Its assortment includes over 250 products in different forms, which covers almost all groups of drugs, dietary supplements, medical devices, dental products and equipment for general use. It has 2,500 employees. Beside domestic production, it also operates in Serbia as well as in the European, Asian and African markets.

Phoenix Pharma Co. was established in Belgrade in 1991 under the name Pharmanova. Starting as wholesaler, incorporating pharmacies, it quickly started to produce its own products. In 2009 it became a member of The Phoenix Group and now operates as part of this famous wholesaler under a new name, PHOENIX Pharma Ltd.

Farmalogist Co., a domestic wholesaler, was founded in 2002. Thanks to ongoing investment in the modernisation of business centres, business process development and integration of all aspects of sales including online ordering, this company was ranked amongst the leading wholesalers in the domestic market.

Velefarm A.D., is a long-standing wholesaler in the country founded in 1979. For more than 30 years it has expanded its network of business centres outside the country, with the modern concept of operations and high-shelf warehouses built on the latest international standards.

Apoteka Beograd was formed immediately after the Second World War as a system of state pharmacies in Belgrade. The company has a network of 123 pharmacies in the territory of Belgrade's 17 municipalities. With 1,200 employees, Pharmacy "Belgrade" is a leader in size and number of employees and a renowned medical institution in the Balkans and South-Eastern Europe in general.

Panteon Group® offers services in the field of inter-organisational e-business, primarily between companies (business to business - B2B) and between businesses and public institutions (Business to Government - B2G). It offers to customers all the necessary services and complete solutions for the restructuring of classical business processes with e-business services.

MetaData, founded in 1991, is engaged in research and development, design, construction, implementation and maintenance of management information systems, as well as with study of information systems development (BSP study), business process re-engineering, computer network projects, and project management.

Implementing a medicine traceability system along the supply chain, from manufacturer to the patient, can improve the security of the supply chain. Linking the physical product flow with the information flow assists in identify when falsified product enter the legitimate supply chain and, if necessary, can assist in the quick location and therefore removal of recalled products from the market.