SmartLog: a Swiss drug traceability pilot

Article by **Laurent Médioni** and **Christian Hay**

ABSTRACT

SmartLog, a Swiss drug traceability pilot supported by Refdata, allowed all participating organisations to gain a better understanding of the benefits of an extensive use of GS1 Standards for their daily operations. The pilot also highlighted the need for good practices in the delivery process, especially between suppliers and hospitals. During 3 months, almost 39,000 retail packs have been serialised and traced in more than 7,000 events. Cross checks by Swissmedic on about 3.000 data sets demonstrated the consistency of collected data.

Environment

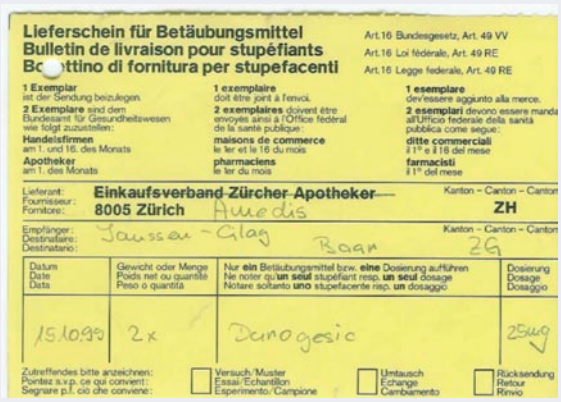
Pharma market observers in Switzerland considered 2 years ago trends and projects based on product serialisation, RFID and optical data carrier, pedigree and authentication. They noticed that these subjects were totally unknown in the Swiss domestic market. Representatives of wholesalers and regulators had preliminary talks about the benefit they could gather by running a pilot on the field with controlled drugs as narcotics. Two assets facilitate such a project: firstly trade of narcotics is monitored by law with a very efficient system for nearly 15 years; secondly Swiss healthcare disposes since 2001 of a foundation (Refdata) which objective is to facilitate processes by use of GS1 standards for product and party identification.

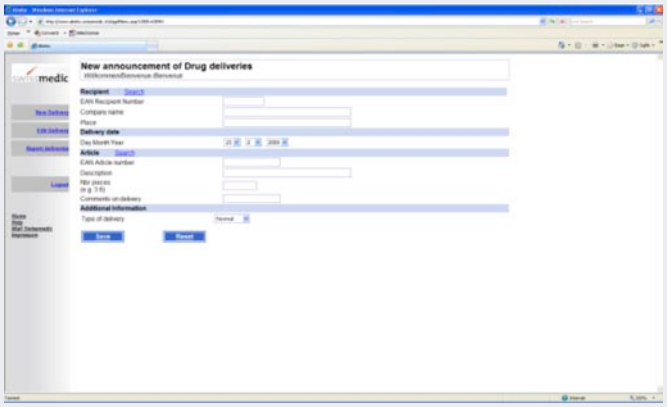
The discussion has been brought to the Refdata board, which decided to support the pilot which was then named "Smartlog". Refdata's board defined the scope of the pilot, delegated the operations to a team which had to deliver reports at the end of the pilot. A major role has been played by both e-mediat Ltd and GS1 Switzerland. E-mediat Ltd is a subsidiary of Galenica, a major player in the Swiss Healthcare, providing services as data management to the Healthcare industry. E-mediat runs since 2001 on behalf of Refdata the reference databases with GS1 identification keys for pharmaceuticals and for Healthcare parties. The databases are used for narcotic control, statistics, logistics and health invoicing; their use for eHealth and other areas is encouraged by Refdata. GS1 Switzerland provided its support by involving its user community as a validation platform for various aspects of the pilot. Smartlog appears to be an additional "proof of concept" for the domestic market, illustrating that similar choices are made in surrounding countries for the next years.

Narcotic control in Switzerland

Narcotic control has been reengineered in Switzerland in the early 1990. The purpose was to replace paper work by electronic data management, which allows increased efficiency both in human resources and in sparing public spending. After an in-depth study, the Swiss narcotic control office launched regulatory changes to mandate the use of GS1 keys to run narcotic control. GS1 keys were chosen as they were not specific to narcotic control, and thus reduce costs of database maintenance. Pharmaceuticals are identified in Switzerland with a GS1-GTIN since 1984; the Swiss pharma branch association (which was leading GS1 use on the marketplace at that time, and replaced since 2001 by the Refdata foundation) was planning to introduce GS1 identification for Healthcare actors countrywide – a project which suited narcotic control office's needs. Narcotic substances have been listed and allocated a GS1 identification key by the narcotic control office. 1994 all the conditions to deploy electronic data collection and processing were given.

Broadly, narcotic for medical use are controlled and involve 50 suppliers, over 1,300 retail pharmacies, 800 hospitals and 35,000 medical and veterinary doctors. The number of deliveries to be declared to the authority is about 350,000 per annum.





The role of the federal narcotic control office consists (among else) in collecting the declarations and providing appropriate information to the local authorities so that they can proceed in on-site controls where and when necessary. The power of the narcotic control system is to deliver within 30 days a country-wide picture of all transactions involving narcotics for medical use, and therefore concentrate on observations revealing peaks and other suspicious movements.

By disposing of that IT infrastructure (which can be accessed through the web: http://www.abeko.swissmedic.ch/) and by building on GS1 identification keys used for several other purposes on the marketplace, narcotic control is managed in the most cost-efficient possible way, by providing accuracy and full coverage to the federal and local authorities. It is further estimated that the user community saves considerable workforces because of the integrated processes with non-specific identification keys.

Refdata foundation

Refdata foundation (www.refdata.ch) has been launched in 2001 to group efforts and to maintain directions taken by a previous organisation. Its objective consists in securing identification of pharmaceuticals and healthcare providers across the country, with GS1 keys. Nearly all the Swiss healthcare industry is represented in Refdata's board: Associations of Pharmaceutical, Medical Devices manufacturers and wholesalers; for the care givers, the associations of medical doctors, pharmacists, droguists and hospitals; for the insurance side, the association of illness insurers and the pool of federal insurances (accident, disability, etc.). Swissmedic and the Federal Office for Public Health participate as observers.

Refdata has contracted with e-mediat Ltd for the operative activities, consisting in maintaining and developing the reference databases with GS1 identification keys for the Swiss market.

Project participants

Lead of the pilot is delegated by Refdata to a pluridisciplinary team grouping representatives of wholesale, manufacturers, pharmacists and GS1 Switzerland. E-mediat, a service provider which is managing databases for the healthcare market in Switzerland, has been designated to manage the project and develop the necessary IT infrastructure. Pilot participants were invited to monitor the project from its conception to its delivery in a few joint meetings.

Technical concept

By tracking and tracing individual drug packs, the project corresponds to the US-Pedigree model; full traceability is provided by documenting each "event" during the journey of each pack, from the manufacturer's premises (or its representative), to the dispensing to the patient.

The project was planned for a limited time frame: 3 months. As a consequence it was not foreseen that each project participant integrates the new processes into its operational IT environment; a separate "in vitro" framework has been developed by e-mediat Ltd, which allowed some simplifications (i.e. only one "event" database; central serial number allocation).

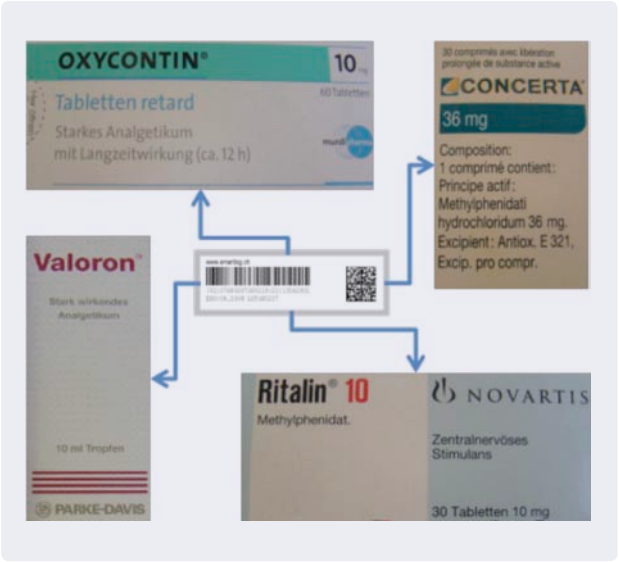
The set of operations was therefore built on a web-application with a safe level of protection and access. Each project participant accessed the web-application with its own data and had visibility to the previous and the next step

in the supply chain. Only Swissmedic benefit of full overview through the supply chain, so that comparison with the usual monitoring system became possible.

At the end of the project, participants are informed about aggregated data, whilst Swissmedic receives all details to assess the results towards the usual monitoring system.

Project participants and selected project products

Four Pharma Manufacturer (Janssen-Cilag, Mundipharma, Novartis Pharma [pre-wholesaler: Voigt], Pfizer [pre-wholesaler: Alloga]) joined the pilot by selecting one pack size of one of their controlled products. All the wholesalers participated with a small number of retail pharmacies. The project did not address hospitals: the supply chain to hospitals in Switzerland is very simple because they are usually supplied directly from manufacturers or their representatives.



Before being sent on the market, the selected retail packs were stickled with a linear barcode and a Datamatrix. The two data carriers included a GS1 data structure, the linear GS1-128 including only the GTIN and the serial number of that retail pack, whilst the Datamatrix included GTIN, lot, expiry date and serial number. With the double bar-coding, project participants wanted to secure that any retailer could participate to the pilot without needing to purchase a new scanner.

The pilot was limited to 3 months: compliance in maintaining separate, additional processes on a relatively large scale was a challenge; it was not necessary for the pilot to request longer efforts from the participants. 38,825 retail packs have been serialised and traced in 7,221 events. Because the small number of participating pharmacies, only 281 retail packs made their journey within project participants. Manufacturer (pre-wholesalers) delivered 23,504 retail packs to project participants, mostly wholesalers. Cross checks made by Swissmedic on about 3,000 data sets, based on the narcotic control processes in place, and demonstrated consistency of the collected data within Smartlog. The reduced number of discrepancies (~1%) concerned recipient identification in

Smartlog's records and was due to the non-integration of the processes and to human errors in selecting the recipient of a delivery.

Project outcome

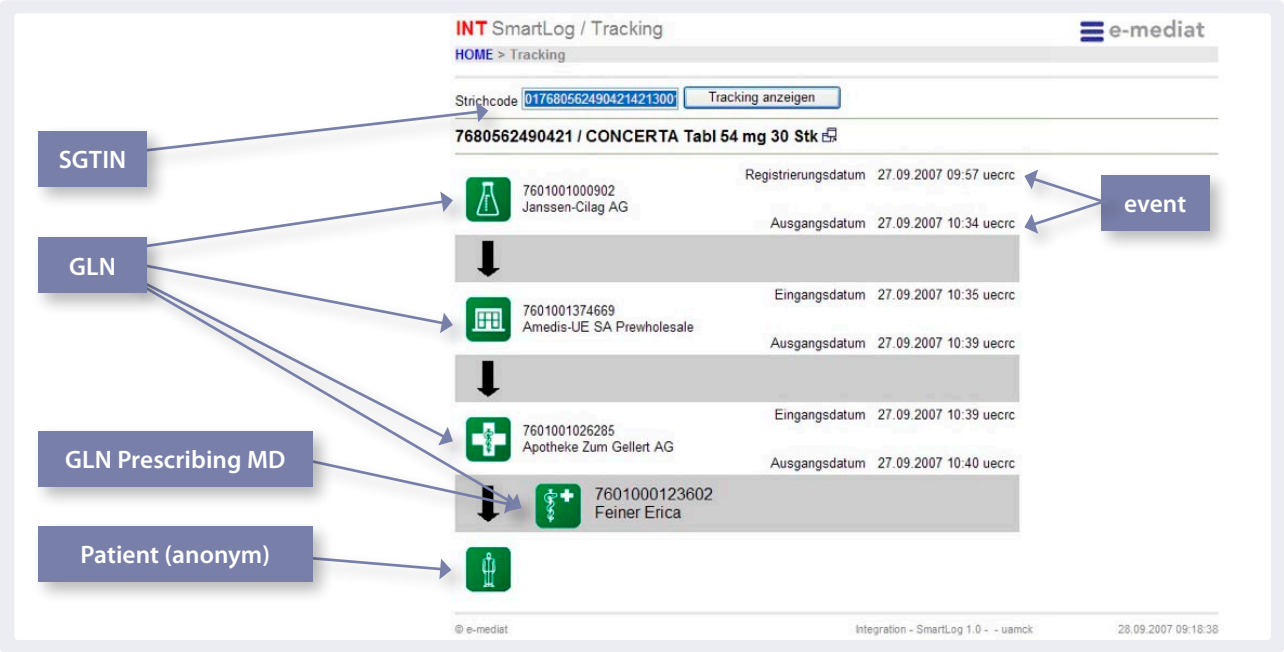
Participant feed-back has been very positive in general. Without surprise, wholesalers declared that optical marking is not appropriate to track and trace at the speed they have to work in preparing deliveries. Retail pharmacies expressed their interest in disposing of a better instrument for their stock management, including the management of recalls.

Smartlog raised questions about ownership, access to and sharing sales data. During the pilot, participants had only access to their direct supply chain data (one step before, one step after). This met requirements on data ownership. As an instrument to fight against counterfeiting, individual product tracing needs the development of intelligent tools to automatically discover unwished entrants in the supply chain as well integrity disruptions. The intelligent tools will alert concerned parties with appropriate information each time suspicion of counterfeiting is captured.

Because of its simplified organisation Smartlog did not include the "intelligent tools", which in return were recognised by project participants as a key to meet the objective of fighting counterfeiting, whilst respecting ownership of sales data.

Smartlog's outcome is published in two reports: a technical report, explaining the project from its origins to its achievement, and a strategic report presenting learnings and statements as a message to the community.

Example of product flow for Swissmedic



Conclusions and vision

From a series of articles in the specialised press across the country to the adoption of the final reports, through the running of the pilot, numerous actors in the Swiss healthcare have developed a better understanding of the benefits of an extensive use of GS1 standards for their daily operations. The reports, which are publicly available (www.gs1health.net/smartlog), list statements and lessons which help stakeholders in preparing future activities. This includes hospitals, even if these were not part of the pilot (in Switzerland hospitals are currently mainly supplied by the manufacturers or their local representative; the supply chain is therefore the most direct possible and excludes practically any counterfeiter to supply its pharmaceuticals to hospitals).

For GS1 Switzerland's user community, Smartlog helped understand the need to develop good practices in the delivery processes, especially between suppliers and hospitals. A working group has been set up immediately after Smartlog to address this subject.

We expect the federal authorities to dispose of a good information base in the case of any sudden incident involving the trade of counterfeited drugs, through the usual supply chain.

AUTHORS

Laurent Médioni is currently canton's pharmacist in Fribourg. He was previously head of the Swiss narcotic control office and led the reengineering of narcotic control in the early 1990. He started his career as a hospital pharmacist in a regional hospital before joining his first position as canton's pharmacist in Neuchâtel. Beside narcotic control, canton's pharmacists are in charge of surveying retail and hospital pharmacies and to maintain plans for public health, as in the case of pandemics.

Christian Hay works currently for GS1 Switzerland and GS1 Global Office. Educated as a lawyer, he worked for the pharmaceutical branch since mid of 1980s in various positions. He was involved since the early stages in GS1 standard deployment in the Swiss healthcare.