

# smartLOG

*Technical Report*

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## II. Journal of modifications

Name of file	Version	Date	Remark / author
SmartLog_Technical_Report_v1	1	3.7.2008	Initial Draft CH
SmartLog_Technical_Report_v2	2	8.8.2008	Updates with LM and AL contents (§ 2.2, 4.4, 6.1 and chapter 5)
SmartLog_Technical_Report_v2.1	2.1	6.10.2008	Updates with NF remarks, add conclusions
SmartLog_Technical_Report_v4	4	22.10.2008	Updates with Swissmedic comments
SmartLog_Technical_Report_v4.1	4.1	28.10.2008	Update with Galexis comments
SmartLog_Technical_Report_v5.0	5.0	4.12.2008	English wording cleaned by J. Kite

## III. List of References

Terminology refers to the GS1 General Specifications, version 8, issue 2 (May 2008)

## IV. Abbreviations

GS1	GS1 is a neutral, not-for-profit organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. The GS1 global Healthcare User Group is a voluntary and open group formed by leading global pharmaceutical and medical devices companies, wholesalers, hospitals and trade associations from around the world. Its primary objective is to enhance patient safety worldwide through accurate and standardised product identification.
Refdata	Refdata is a Swiss foundation which has taken up in 2003 the responsibility to identify uniquely, with the GS1 System, registered drugs and partners in the Swiss Healthcare. Refdata is a member of GS1 Switzerland.
Swissmedic	Swissmedic is the Swiss Federal Agency for Therapeutic Products. Swissmedic is a member of GS1 Switzerland.
e-mediat Ltd	e-mediat is a company of the Galenica Group, offering services to the Swiss Healthcare industry. e-mediat is a member of GS1 Switzerland. e-mediat is managing the GS1 identifications for registered drugs and partners in the Swiss Healthcare on a contractual base with Refdata.
GS1 Switzerland	GS1 Switzerland is the local Member Organisation of GS1.
IFPMA	International Federation of Pharmaceutical Manufacturer Associations
EFPIA	European Federation of Pharmaceutical Manufacturer Associations

## V. Terminology

GTIN            Global Trade Item Number

SGTIN	Serial Global Trade Item Number (a GTIN followed by a unique serial number)
GLN	Global Location Number (in Switzerland all the actors in the Healthcare are identified with a GLN; see: <a href="http://www.medwin.ch">www.medwin.ch</a> )
SSCC	Serial Shipping Container Code

## 1 Introduction and purpose

### 1.1 Introduction

In early 2007 the Board of Refdata decided to undertake a field study to better understand current trends and technical possibilities related to item level traceability. Item level traceability requires significant effort that has not been quantified to date.

The members of the project's leadership team were:

- Mr Walter Hölzle, Chairman, Refdata Board
- Mr Nicolas Florin, CEO, GS1 Switzerland
- Mr René Jenny, representing the wholesalers
- Mr Dominique Jordan, representing the retail pharmacists
- Mr Christoph Bangerter (until end of April 2008), project director
- Mr Ueli Schaefer (since Mai 2008), project director

Support of Authorities was crucial to undertaking and the success of the project, as packaging had to carry an additional data carrier.

The SmartLog pilot has therefore been conceived with Swissmedic, and the choice of a selection of narcotics in defined pack sizes has been made.

Involvement of wholesalers has been particularly requested and was a prerequisite for the success of the project.

PharmaSuisse, the association of the Swiss pharmacists, helped to recruit retail pharmacies for participation in the pilot. Involvement of hospitals would have been welcomed, but the choice of drugs and pack sizes has been a limitation factor. Less as 5 % of the chosen items reach hospitals, according marketing information.

### 1.2 Purpose

The purpose of this report is to summarise the key findings of the project in regards to supply chain processes related to item level serialization of pharmaceutical products.

A separate report covers strategic aspects, including governance of data.

## 2 Background

### 2.1 Historical aspects

Drug identification with EAN-13 was introduced in Switzerland in 1984. At that time the purpose was to enhance point of sale (POS) processes in the consumer goods sector. EAN-13 allows the automatic reading of item identity via optical symbology, generally at the point of sale. Although, since the mid-1990s, additional market needs have included traceability and stock management.

Early 2000, the EU has released a regulation requiring traceability for food products (Regulation 178/2002); this regulation impacted the Swiss food producers as their largest market is EU country based customers. The Regulation 178/2002 also included animal drugs, which are part of the food supply chain („from the farm to the fork“).

To meet the requirements of this regulation, GS1 users from all industries have required changes to the GS1 System. This led to the adoption of GS1-128 symbology and data structure, made with „Application Identifiers“ (ISO/IEC 15418). However, there has been limited implementation (only 2 electronic standard messages) by the Swiss pharmaceutical industry.

## 2.2 Narcotic control in Switzerland

In Switzerland, Narcotic drugs for medical use are controlled by Swissmedic using a computerised system. This system enables the tracking of these products from the manufacturer / importer to the dispensing point in the pharmacy. The objective of the system is to dissuade malicious people from abuses with narcotic drugs, and if so to detect abuses. The system complies with the Swiss Law on narcotics and other related regulations.

Suppliers must notify Swissmedic of every delivery of narcotic; Swissmedic, the Swiss Agency for therapeutic product, records about 550'000 deliveries every year. Each notification contains information on a single delivery and includes the name of the supplier (identified by its GLN), the name of the recipient (identified by its GLN), delivered product (identified by its GTIN), delivery date and quantity of packages.

The Data is managed cost effectively and efficiently by the computerised system for the benefit of all users. Cantonal authorities can access the data held by Swissmedic and are responsible to undertake local inspections and controls by suppliers and their customers. These authorities make sure that notified deliveries by suppliers correspond to reality and that narcotics are not misused or diverted.

The system has proven its effectiveness. Abuses can be easily detected by competent authorities, which is particularly important if the abuse happens on a large scale. During recent years, few cases have been detected within the narcotic drugs by distribution channel.

## 2.3 Counterfeiting as new risk

International Federation of Pharmaceutical Manufacturer Associations (IFPMA) began its consideration of drug counterfeiting in the middle of 1990. Collaboration with the World Health Organisation (WHO) was initiated. Initially the subject did not reach large audience.

Since the beginning of the new century, drug counterfeiting has increasingly been recognised as a growing public health risk and a number of initiatives have taken place:

- Council of Europe organises workshops, sets up an expert group and publishes a report on the subject
- WHO launches International Medical Products Anti-Counterfeiting Taskforce (IMPACT) with several stakeholders
- States in the US discuss and publish regulations for drug authentication (pedigree), i.e. California, Florida, etc.
- In Europe, European Federation of Pharmaceutical Manufacturer Associations (EFPIA) launches a working group to discuss and implement a common vision for item traceability across the region, to avoid development and implementation of different solutions by member states that would build barriers to free movement of goods. Consensus on a common solution has been reached and a large scale pilot is planned for early 2009.
- Italy, where drugs have been identified at item level with a „Bollino“ for many years, is considering migration to a new, internationally compatible, solution.

- European Commission launches a consultation about possible regulatory solutions to address marketing of counterfeited drugs, and to avoid that member states adopt non-compatible solutions for the same problem.

These initiatives come from the increased presence of counterfeited drugs in European market. European Commission has mentioned examples in its report for the consultation, that demonstrates the growing risk in counterfeiting in pharmaceutical markets that are the most open (e.g. the United Kingdom or Netherlands). The consultation make proposals that are simpler than that of EFPIA.

## 2.4 The European concept

There are various overt and covert ways to fight counterfeiting: for example the inclusion of security elements such as holograms, special ink marking, that make the counterfeiters job harder. An additional way is to identify objects and collect and hold traceability data at item level which enables verification of an items authenticity. This is the consensual approach across Europe.

Identification at item level means that each item is serialised and therefore unique. Whilst sequential serialisation can be easily copied, the pharmaceutical industry together with GS1 has developed the concept of pseudo-randomised serialisation. This means that the serial numbers are not sequential, but generated by an algorithm defined by the manufacturer. Numbering capacities have been calculated so that the combination GS1 Global Trade Item Number (GTIN) and its attributed serial number can be used by all healthcare sectors (vaccines, biologics, implants, instruments, etc.). GTINs can be allocated either in a central way (France, Switzerland) or in a de-central way (normal GS1 rules, as in the UK, Ireland, etc).

Serialised GTIN (SGTIN) can be carried on a 2-dimensional carrier (e.g. GS1 DataMatrix) together with, if required, lot number and expiry date. The "barcode" will be generated at the end of the manufacturing process and stored in a dedicated database.

At the end of the supply chain, e.g. at the retail pharmacy, a final check can be made to verify authenticity of the SGTIN: firstly at the receipt stage and secondly at the dispensing time. If a drug pack is declared as unknown, already scanned at another place or subject to a recall, the pharmacy is informed during the validation process and the appropriate action can be taken (e.g. quarantine of the product), potentially avoiding patient harm.

A similar process is planned in the US. But here the single retail pack will be checked and documented (i.e. Pedigree) at each step of the supply chain; whilst at current RFID seems to be the preferred marking technology for an automated process in the US (GS1 EPC), the Europeans prefer an optical data carrier (e.g. GS1 DataMatrix).

## 3 Organisation of Smartlog project

### 3.1 Selection of products

The project leadership team defined the scope of the Smartlog project as a small selection of controlled narcotic drugs for medical purposes, thus allowing for direct comparison between the project results and Swissmedic data; Swissmedic agreed to this concept. In addition, it was further agreed that only retail pack size was selected (no hospital packaging).

The selected products are:

- Concerta 36 mg, 30 comprimés (Janssen-Cilag)

- Valoron gouttes 50mg / 0.5ml, 20ml (Pfizer)
- Oxycontin 10mg, 60 comprimés (Mundipharma)
- Ritaline 10mg, 30 comprimés (Novartis Pharma)

### 3.2 Selection of project participants

Once the brand owners of the chosen products agreed to participate in the project, pre-wholesalers, wholesalers and retail pharmacists were approached. The following agreed:

- Pre-wholesaler: Alloga (for Pfizer); Voigt (for Novartis Pharma);
- Wholesaler: Galexis (all 3 distribution centres); Amedis (Swiss-German distribution centre); Voigt (all distribution centres).
- Retail pharmacies: Pharmacie Dr. Bruhin, Lachen; Pharmacie Hemmemann, Bern; Pharmacie Hörning, Bern; Bärenapotheke, Zürich; Pharmacie Dr. Schmid, Oberdiessbach. The Pharmacie Rose Rouge Anne Dupraz, Renens, joined the project in a second stage.

### 3.3 Concept for serialisation

As GTINs are centrally allocated in Switzerland, involving the Refdata foundation and e-mediast as enabler, as well as Swissmedic for the market authorisation number, it was appropriate that the serial number allocation should be done in the same, centralised way.

In full scale implementation the serialisation process will be decentralised to each brand owner / manufacturer.

Furthermore the project leadership team considered that the serialisation process was not a focus area for Smartlog and therefore a centralised and sequential serialisation process would best serve the project objectives.

### 3.4 Product marking

Product marking is managed at manufacturer or pre-wholesale level. A label, including a linear barcode (GS1 128 with SGTIN) and a 2D code (GS1 DataMatrix with GTIN, lot number, expiry date and serial number), is applied to each retail pack. The linear barcode is a "summary" of the 2D code, so that project participants who are not equipped with a camera-based scanner can read the linear barcode.

Special authorisation has been provided by Swissmedic for the additional labelling.



The manufacturer / pre-wholesaler logs into Smartlog's web-based application with appropriate security settings, and they key in the product description, lot number and expiry date and request a quantity of labels.

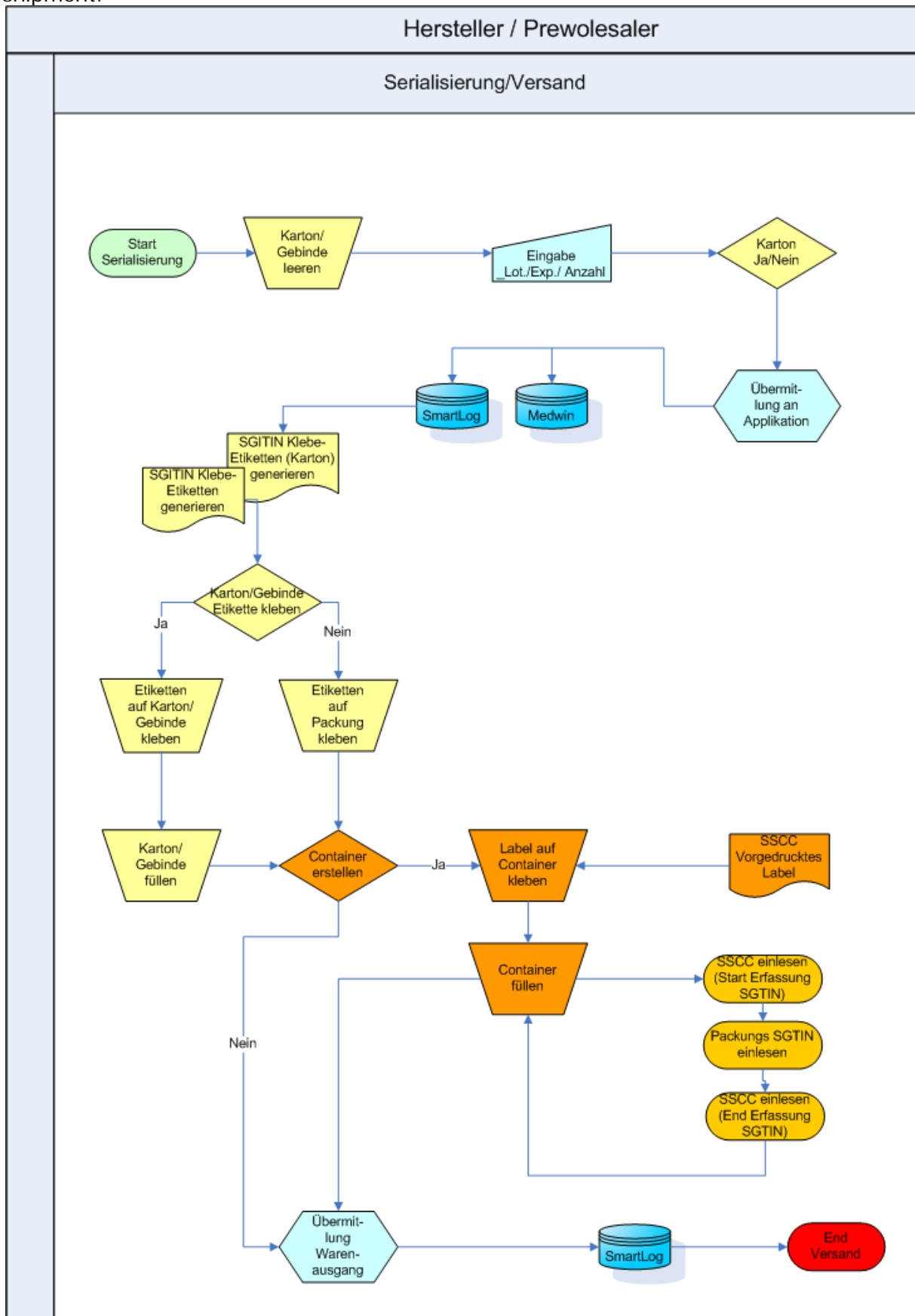
Two possibilities were provided to the producer / pre-wholesaler:

- To use only the pre-defined quantity of labels, corresponding to a full carton and stick them onto each item but without identifying the carton with the provided GS1 SSCC, or



- To use the provided GS1 SSCC label and apply and scan a label to each pack included in the carton and associate each item to the carton . This provided greater flexibility because the content of the carton did not need to be declared when requesting the labels.

The process is described in the following chart, from label request through serialisation to shipment.



### 3.5 Information flow

The following screen shot illustrates the information flow. Please note, that the information flow of the Smartlog pilot has been managed on a web-based application programmed exclusively for this purpose; no interfaces to operational ERP systems of the participants were implemented. This had affect on the information flow, only on data capture process.

Each actor is identified with its GLN (Global Location Number). Safely logged in, the actor populates information to the database. Information consists in documenting the unique pack ("Strichcode" = SGTIN) and event (first registration, delivery, incoming, outgoing, etc.); for outgoing packs, the information has to include the GLN of the targeted recipient. The final task is linking the delivery to the patient (anonymous) with the GLN of the prescribing doctor.

The screenshot displays the 'INT SmartLog / Tracking' interface. At the top, there is a navigation bar with 'HOME > Tracking' and the 'e-mediat' logo. Below this, a search bar contains the 'Strichcode' 017680562490421421300 and a 'Tracking anzeigen' button. The main content area shows the product details: '7680562490421 / CONCERTA Tabl 54 mg 30 Stk'. A vertical timeline of events is shown, with arrows indicating the flow between actors. The events are: 1. Registration (Registrierungsdatum: 27.09.2007 09:57 uecrc) by Janssen-Cilag AG (GLN: 7601001000902). 2. Outgoing delivery (Ausgangsdatum: 27.09.2007 10:34 uecrc) to Amedis-UE SA Prewholesale (GLN: 7601001374669). 3. Incoming delivery (Eingangsdatum: 27.09.2007 10:35 uecrc) from Amedis-UE SA Prewholesale (GLN: 7601001374669). 4. Outgoing delivery (Ausgangsdatum: 27.09.2007 10:39 uecrc) to Apotheke Zum Gellert AG (GLN: 7601001026285). 5. Incoming delivery (Eingangsdatum: 27.09.2007 10:39 uecrc) from Apotheke Zum Gellert AG (GLN: 7601001026285). 6. Outgoing delivery (Ausgangsdatum: 27.09.2007 10:40 uecrc) to Feiner Erica (GLN: 7601000123602). The footer contains '© e-mediat', 'Integration - SmartLog 1.0 - - uamck', and the timestamp '28.09.2007 09:18:38'.

The screen shot above shows a full tracking record for an individual pack as Swissmedic could see it. Project participants had access to a similar page but that showed only their products and the stage immediately before (upstream) / after (downstream) of their position in the supply chain.

## 4 Key features of the project

### 4.1 Introduction

The project took place over 3 months, January 15, 2008 to April 15, 2008.

At the initial stage, all the products in the supply chain (manufacturer / pre-wholesaler and wholesaler) were labelled.

All the project information was collected and managed by the participants separate to their operational IT systems.

The granularity of the traceability data at item level has allowed a cross-verification with Swissmedic, who collects information on all transactions with narcotics (in quantities). Swissmedic made verifications on the period between 1<sup>st</sup> February and 31 March and demonstrated that project data was consistent with the regular, and process integrated, declarations of transactions to the control authority.

## 4.2 Definitions

We define as *project product* one of the 4 selected narcotics, in the defined pack size (corresponding to a single GTIN).

We define a *project participant* as an actor who collected data for the selected narcotics for the purpose of the project.

We define an *event* as being an encounter of incoming / outgoing products, regardless of the quantity, i.e. a delivery of 150 GTIN x = an event, or a receipt of 2 GTIN y.

## 4.3 Project statistics

The system has recorded a total of 7'221 events during the project. 281 events were recorded between project participants (3,9%). The small proportion of events between project participants came from the small number of retail pharmacies that were involved; retail pharmacies and dispensing doctors were generating the largest amount of events.

The system recorded 38'825 project products as having been delivered by manufacturer / pre-wholesale to their customers. 23'504 project products were delivered by manufacturers / pre-wholesale to project participants (60.5%). The other 39.5% were delivered to customers who were not participating to the project.

Grouping function was used as follows: the importers / pre-wholesalers preferred to use the SGTIN to identify the carton and all the serialised retail packs included (1'360 uses). Although the SSCC corresponds closer to the practice, users did not utilise this possibility.

A very small number of project products passed through the whole supply chain during the project. Individual checks confirmed that the sequences of data were accomplished by all project participants.

## 4.4 Control of project data by Swissmedic

Control consisted of comparison of Swissmedic's data on selected products with data collected within Smartlog at each level of the supply chain. Swissmedic delegated a pharmacist to undertake the comparison.

Comparison was made on a representative sample of data. About 15'000 data sets were recorded during Smartlog; 3'000 (20%) of them were checked.

Overall the data was consistent. Differences were noticed at the beginning and at the end of Smartlog. This can be explained as follows:

- all project participants did not start or end at exactly the same time.
- During the full month of February, data quality was excellent, with a discrepancy rate below 1% (18 differences for 2'000 data sets). All deliveries were announced to Swissmedic as well as recorded in Smartlog. Errors concerned recipient identification in Smartlog's records. No product identification or delivered quantity errors were noticed.
- Occasionally delivery dates were not exactly the same between Swissmedic's records and Smartlog's records. This may have been caused by the non-integrated IT system for Smartlog.

## 5 Project participant feedback

Project participants were interviewed by phone about their experience during the pilot.

## 5.1 Manufacturer / pre-wholesaler

Manufacturers (Mundipharma, Janssen-Cilag) and pre-wholesalers (Alloga for Pfizer and Voigt for Novartis) expressed a strong interest in the principle of serialised products for traceability reasons.

Two important remarks were made:

- Container function and labelling; the possibility to label cartons to capture all the included serialised retail packs is considered as crucial in the receiving and delivery process.
- Clear and un-ambiguous identification of the recipient has to be provided; this should be integrated into the operational IT system in order to avoid additional workload.

## 5.2 Wholesaler

Process simplification, especially for narcotics (controlled products) would strongly be appreciated.

Scanning and selecting of recipients turned out to be very time consuming during the project. Therefore the scanning process regarding individual tracking must be integrated into the normal picking and scanning process of the wholesaler. However, this will become more and more difficult, as automatic picking will increase in future.

Linking to the recipient has to be secured automatically by the IT.

Non compliance should be tolerated for returned goods: the retailer does not always scan this kind of outgoing good, and when the wholesalers records this as incoming good the system reports a non compliant situation.

## 5.3 Retail pharmacies

Participating retailers expressed strong interest in the project. Both project scope and implementation were appreciated.

Any roll out of item level traceability has to be integrated into the pharmacy IT. Additional manual processes should be avoided due to the additional time constraints and the limited human resources.

The key success elements are data quality (recognising product), label quality (readability) and partner database (ease to find prescribing doctor).

# 6 Efficiency of project's processes

## 6.1 Efficiency of towards regulatory narcotic control

Data comparison was useful for both Swissmedic and the Smartlog project group. For Swissmedic it confirmed that delivery notification of narcotics by suppliers (manufacturer, importers, wholesalers), in line with regulation, is of good quality. One can further state that if errors were found in Swissmedic's data comparison, these do not come from IT limitations.

From the point of view of Smartlog's project group, the data comparison demonstrated that project participants are compliant with the defined project processes.

The data analysis illustrated that IT tools facilitated control activities, e.g. possible narcotic diversion: because the items are identified, the authorities can undertake cost effective, targeted research to identify where the chain of custody had been interrupted. Increased, cost effective control is very attractive in regards narcotics, blood derivatives or expensive drugs.

## **6.2 Efficiency regarding good delivery (chain of custody)**

The project documented the custody chain. This means that the supplier announced the “outgoing” shipment event to the targeted recipient and the recipient announced the “incoming” delivery event from which supplier.

The matching of the two events established the chain of custody.

We noticed only a few issues in this context: some project participants did not capture the right partner as supplier or recipient; this was due to the fact that some participants dispose of several GLNs, that correspond to different sectors / locations / functions in the same facility (for example: wholesaler “A” has one GLN for the delivery place for narcotics, whilst the supplier captured that GLN for accounting department). By selecting the GLN for the delivery recipient, the wrong GLN was chosen in some cases, this was notified by the system to the recipient at delivery receipt (and should have been notified to the supplier at the same time).

Another issue occurred when a partner returned a good (for any reason) to its supplier (wholesaler or manufacturer /pre-wholesaler), this “outgoing” delivery had to be captured. But not all the participants followed this process. In such cases, the system notified the receiver about the chain of custody disruption.

## **6.3 Efficiency regarding counterfeiting**

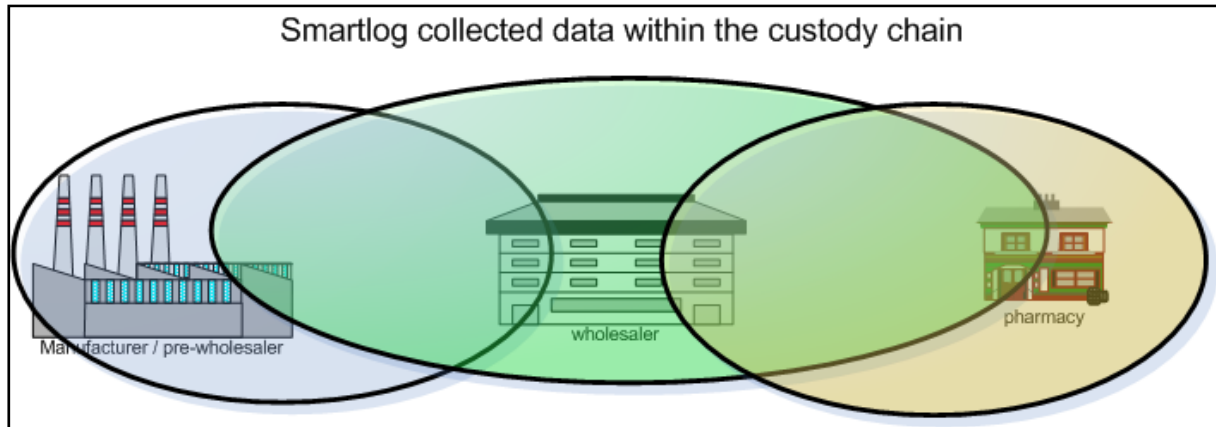
Due to the choice of (controlled) products, the number of issues in this respect was extremely small. But the project also had a strong focus on combating counterfeiting. Therefore the project participants could only describe the warning system theoretically rather than test it in reality.

First, we stated that the market authorisation holder was the partner that has to be informed about any malfunction, particularly in the case of products entering the supply chain coming from the outside the chain of custody. The warning system should consist of a secured email, notifying which product (GTIN, lot # and serial #) has entered the supply chain in which location (GLN), supposed to come from which supplier (GLN).

## **6.4 Governance of collected data**

Supply chain data was critical topic for the Smartlog project. All participants were concerned about who would be able to access the data. Manufacturers would have been very interested to gain visibility of their own products up to the dispensing point. Logistic providers were very concerned about such development as today they can sell their data to manufacturers or specialised market information companies.

Smartlog’s purpose is to make the supply chain more secure and not to gather marketing information. It was therefore decided that participants would only have access to their own data related to the flow of product between themselves and partners immediately before (upstream) and after (downstream) them.



Swissmedic enjoyed, due to the regulatory environment for narcotic products, full and detailed access to all collected data. Governance had to address the above mentioned warning system so that efficiency could cope with good governance.

## **7 Conclusion**

The Smartlog project showed that SGTIN, to ensure traceability throughout the supply chain, would be very welcome by market partners and authorities. Reluctance is mainly due to the potential additional handling needed to secure a consistent process. An acceptance of operational implementation would also be linked to unambiguous governance about ownership of supply chain data. It's also clear that implementation starts at manufacturer level. The marking of the products with SGTIN needs to be integrated into the manufacturing process. Relabeling, at any point in the supply chain, would not provide the security required and would not be economically viable.

In order to further rationalise the supply chain, manufacturers should also implement the principles of GS1 128 for logistic unit marking (e.g. full cases and pallets). This would allow importers, pre-wholesaler and wholesalers to read only one carrier as long as the full case remains intact.