

smartLOG

Strategic Evaluation Report

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II. Journal of modifications

| Name of file | Version | Date | Remark / author |
|---|---------|------------|-------------------------------------|
| SmartLog_Strategic_Evaluation_report_v1 | 1 | 12.12.2008 | Initial Draft CH |
| SmartLog_Strategic_Evaluation_report_v2 | 2 | 22.12.2008 | Modifications N. Florin introduced. |

III. List of References

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

IV. Abbreviations

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| 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: (www.medwin.ch)) |
| SSCC | Serial Shipping Container Code |

1 Introduction and purpose

1.1 Introduction

The Board of Refdata has decided early 2007 to launch a field study for a better understanding of trends and technical possibilities for item level traceability.

A project lead has been appointed, with the following composition:

- Mr Walter Hölzle, Chairman of 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), as project director
- Mr Ueli Schaefer (since Mai 2008), as project director

Detailed traceability, at the level of the single item, requires an effort which has not been measured up to now. Support of Authorities was crucial in this 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

Beside a technical report, the present report addresses strategic learnings and statements which have been made possible on the base of the outcomes of the Smartlog project.

2 Background

Healthcare in developed countries is experiencing a regular increase in costs and a permanent research for solutions containing these costs or even reducing them.

In parallel, more effective health care is provided with more specific products, which price and/or volume become so much attractive that counterfeiters develop strategies to succeed in introducing fake products

in the official supply chain. It is disputed to correlate the number of counterfeited products with the openness of a market, but fact is that the European national markets start to become concerned about the observed evolution.

Suppliers of pharmaceutical products and medical devices are highly interested in market data; the reasons are not only for marketing purposes, but also because of their market responsibility regarding vigilance and traceability. Market data are collected and investigated for a long time; this has become a strategic and commercial issue for the other parties in the supply chain as wholesalers, retail pharmacists and others. Full transparency in the healthcare supply chain does therefore not exist outside the existing information channels.

For further background, including historical aspects as well as the current projects and tentative in Europe and other part of the world, we refer to the technical report.

3 Fighting against counterfeiting

3.1 In General

The number of tools to fight against counterfeiters is extremely wide. In general the users community recognises that solutions as holograms, pack sealing, etc. do make counterfeiter's work harder but do not secure product's authenticity.

More sophisticated solutions have been developed in the last years, including dot recognition on packages (similar to pack's biometry), Radio Frequency Identification tags, etc, all contributing to secure product's authenticity. As soon as counterfeiters discover a new authentication tool, they invest to bypass this new barrier.

Without excluding all efforts to authenticate products, the idea has grown to use process and information exchange tools for authentication purpose. Process tools consist in collecting information along the supply chain, to make it safer –it is then named a “custody chain”. Instead of delivering a kind of a passport to any item as a drug pack or a medical device, the concept is based on item identification and the linking of product's journey along the supply chain. This solution has been named in the US “ePedigree”. At the time it had been conceived, the user community intended to adopt RFID to replace optical marking (barcode), which allows data capture in conditions and speed optical data capture cannot offer. Especially at level of wholesaler outbound execution speed is crucial. But due to the immature technology the implementation has been postponed.

An intermediate solution has been developed, which consists just to authenticate product at their delivery point. This is possible with optical marking and existing standard solutions.

Smartlog has to be understood as a kind of an “ePedigree” project, with optical marking.

3.2 Smartlog’s processes

Starting with product identification at item level, the concept of Smartlog requires each partner in the supply chain to capture serialised identity of each item both at the reception and at the delivery processes.

Each capture is named an “event” which includes, beside item identification, reference of the place of data capture and the identity of the previous, respectively the next step in the supply chain. Custody is achieved when a single delivery corresponds to its later receipt.

All Smartlog processes have been based on GS1 identification keys, such as SGTIN for item identification and GLN for supply chain partner identification. The existing identification keys have been used by leveraging the Swiss datapool with all GTINs (Swissmedic registered drugs) and GLNs on the healthcare marketplace.

At the very beginning of the project, participants recognised that data capture for a large number of packages (i.e. between manufacturer and wholesaler) is nearly impossible and therefore requested a solution to group serialised pack numbers in their carton, the which being serialised accordingly.

4 Discussion of Smartlog’s outcome

4.1 Data capture processes

Smartlog has been conceived as a non-integrated process; therefore staff members of project participants had to work according their usual procedures and additionally to handle individual packages separately in a special IT environment (Smartlog was 100% web based, and required a dedicated working station and a scanner).

Whilst the supply chain partners handling small volumes –retail pharmacists- expressed their interest in the easier capture of value added information on the packaging, the ones moving larger volumes of packages demonstrated that manual processes are not compatible with current business practices, event for narcotic drugs.

During Smartlog, manufacturer had to stick manually special labels on a predefined place on the packs. This burdening step would be obsolete in a productive environment as the serialisation process would be secured at the end of the packaging line; any other solution would require special

processes according GMP and be extremely expensive. This would be the only step which could be enhanced in any productive environment.

First statement: Smartlog could not be run in a productive environment with the optical data capture process at each step of the supply chain. This is mainly true at outbound level of the wholesaler.

Second statement: RFID is not a realistic short term option due to technical hurdles at all levels of the supply chain including hospitals.

Third statement: A SmartLog supply chain is only possible if the process is fully integrated in the current ERP and other SCM software solutions.

4.2 Data collection

Smartlog has been built around a central database, where the events have been collected and it has been possible to verify coherence between the events.

Project participants had restricted access to data limited to the supply chain step immediately before and/or after their own supply chain position.

The restrictions in data access built a kind of governance, which secured no interference with current practices in market data collection and trade. The project defined that each supply chain partner is understood as owning its own data (which include the step immediately before/after in the supply chain).

Fourth statement: market data cannot be shared within supply chain partners unless special agreement.

4.3 Efficiency

Being positioned as a tool to fight against counterfeiting, supply chain custody requires a technical solution which allows disruptions in the custody chain to be reported automatically to the appropriate supply chain partner (at least the brand owner).

This has not been tested during Smartlog as the chosen products (narcotics) are already closely controlled along the supply chain. This situation does not mean that project partners did not bring their attention to this essential strategic question.

Verification of coincidence between events has to be addressed by developing security routines for that purpose. Security routines verify that an event targeting to partner "A" has a correspondence with another event in the sphere of "A", indicating provenance from the sender. When this is not the case, or when a new product enters unexpectedly in the supply chain, that event and the item(s) concerned have to be automatically reported to the brand owner and eventually to other supply chain partners.

The situation above would have been easily implemented in Smartlog's central database. In networked databases, an appropriate security routine would also be necessary, which project participants recognise.

Fifth statement: efficiency in a "ePedigree" environment requires security routines which allow unexpected events to be reported to the appropriate party.

5 Learning's and strategic vision

All the major project participants have insisted during the evaluation process that Smartlog reveals very positive learning's, but at the same time cannot be implemented as-is.

For **manufacturers**, serialisation has to be made by editing pseudo-randomised numbers which have to be unique and at the same time not reproducible by counterfeiters. Projects of this dimension and complexity are currently undertaken by major pharmaceutical companies and cannot integrate any exception for the Swiss market. It is questionable if manufacturer would be willing to pool their serialised information in one single database; here also a separate and specifically Swiss process is uncertain.

Learning one: regarding serialisation process, the Swiss market has to align to global implementations. The principles for the allocation of serialised GTINs are described in the GS1 General Specification

Wholesalers and **pre-wholesalers** reported on the lack of feasibility by capturing item identification manually, as well as in selecting manually recipient of deliveries. Without automatic processes wholesalers and pre-wholesalers cannot implement item traceability. Both expressed their interest in the new data carrier, which includes value added information as SGTIN, lot and expiry date; this availability of information may be helpful for items returned by customers such as retail pharmacies or hospitals, for traceability purposes. The better marking of cartons (including the value added information above) is also considered as an asset. A major issue is to capture the single item during the outbound process. Volume and speed are such that a 100% item capturing with optical data carrier is just not possible.

Learning two: handling of large volume of serialised items is not possible with the current technical possibilities. Better marking of packages (Datamatrix) and carton (GS1-128) helps enhance accuracy in traceability.

Retail pharmacies have expressed their interest in the better labelling of packages, so that they can improve their stock management and handle recalls in a safer and faster way. Datamatrix has been welcomed and did not raise any negative comment. Item serialisation has not been commented.

Learning three: retailers on the Swiss market appear to be interested in a better labelling, including automatic capture of value added information as lot numbers and expiry date.

6 Authentication model

As well as EFPIA, the European Union is defining a model to secure the medicinal product supply chain, which combines lot traceability for the large volumes and item serialisation for authentication at manufacturing and at dispensing points.

Smartlog has demonstrated that the European model offers the best possible solution on the marketplace. Lot traceability enhancement, as the Commission has proposed early 2008, secures processes within free circulation of goods. It allows detecting unwished situations at an early stage as well as in a reactive way.

7 Governance

Governance addresses in the present context the management of networked and shared sales data.

Refdata foundation is best placed to adopt governance rules within all the supply chain partners in Switzerland. Governance defines ownership of the data, cost sharing for necessary new infrastructures and transparent rules for market players, which include in particular the agreed security routines to detect and announce unwished situations.

Governance has not to be confused with any regulation of competition; in the environment of fighting against counterfeiters, governance confirms ownership of data, the processes necessary to achieve fighting against counterfeited products which includes which kind of information has to be made available / communicated to which party.

Governance confirms also the necessity to adopt and respect standardised data structures and messaging so that data for items entering or leaving the Swiss market can be accessed and processed regardless of the country of origin or destination.

8 Conclusion

Smartlog has raised a large and wide interest on the Swiss market place. It is understood that Switzerland cannot be an isolated place where a diverging process could be deployed. At the same time it is recognised that Switzerland could be ready for a faster implementation, for certain product segments which are facing the highest risk in counterfeiting.

Technology and standard choice secures international interoperability (example: France adopting GS1 Datamatrix as from January 2009), as well as new processes involving the patient/consumer (verification of product authenticity by reading Datamatrix with mobile phones).

It is Refdata's value that makes this possible, and there is no doubt Smartlog has played its role in communicating about the possibilities the healthcare market is facing.

22.12.2008