The „SmartLog“ Project
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London, 31 October 2007
Overview of this presentation

- Sponsors/organisation of the project
- Objectives/Scope
- Technical Concept
- Timeframe
- Expected results
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• Pilot sponsored by Refdata Foundation representing Swiss Organisations of
  • Manufacturers (pharma, med-tech) and wholesalers (Interpharma, VIPS, ASSGP, GRIP, FASMED, pharmalog)
  • Care givers organisations (MDs, pharmacies, drugstores, hospitals)
  • Insurers, GS1
  • Swiss federal authorities (BAG, Swissmedic)
Project Participants

- **Project lead**: e-mediat on mandate of Refdata Foundation
- **Manufacturers**:
  - Janssen-Cilag, Mundipharma, Pfizer
  - Novartis (?)
- **Pre-wholesalers**:
  - Alloga, Voigt
- **Wholesalers (100%)**:
  - Amedis, Galexis, Voigt
- **Selected pharmacies (6 pharmacies, plus voluntary participants)**
- **GS1 Switzerland**
Financial aspects

- all participating organisations support their own cost in the project (infrastructure / CHF / HR)
- the budget of the project (cash out) is limited to 55'000.- CHF, mainly for external programming of the pilot application
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Objectives of the Pilot

- Track & trace
- Combat counterfeiting
- Learn
- Evaluate acceptance problems
- Establish a basis for a later industrial roll-out
- Learn about ownership of supply chain data
Objectives of the Pilot / details

- **Track & trace** selected controlled narcotic substances
  - from manufacturer -> each level of the supply chain (retail market) –> patient dispensing (anonymous)
- Use of GS1 standards
  - considering international trends
- Investigating an „early warning system“ for **counterfeit products**
- Learn about requirements for the **integration** of new processes into existing infrastructures and processes
- Identification of implementation and **acceptance** problems
- Establish a basis for a later industrial roll-out
- Learn about **ownership of supply chain data** and problems in relation with access to data (only Swissmedic has full access to data; project participants access data about the product they are handling, inclusive the next step upstream and downstream)
Out of Scope of the Pilot Study

- completeness of tracking for the labelled products
- process integration at involved partners
- non-pharma products
- hospital supply chain
- limited implementation of “container functions” (linking SGTIN of included packages to case)
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Willkommen bei Smartlog!

Wer sind wir?

Smartlog ist ein Kooperationsprojekt der Stiftung Refdata, Swissmedic, GS1 Schweiz und e-mediag AG.

Projektziel

Testung eines einfachen Frühwarnsystems zur Identifikation von gefälschten Produkten. Im Rahmen des laufenden Pilotprojektes werden Einzelpackungen von ausgesuchten Betäubungsmitteln mittels Barcode speziell ausgezeichnet und können dadurch über einen Webservice vom Produzenten bis zur Abgabe an einen anonymisierten Patienten verfolgt werden.

Detaile...

Möchten Sie mehr über die vorliegende Medikamentenpackung erfahren? Dann geben Sie den Strichcode manuell oder mit einem Lesegerät ein.

Strichcode: [eingabefelder] anzeigen
Technical Settings

- Cross organisational online platform, additional and parallel to existing local client-server systems
- Modern scanner technology in combination with ASP technology
- GS1 standards for labelling issues
- Monitoring flow of goods (not flow of funds)
- Centrally managed data pool for all parties, with the design option of later migration to decentralised data management
Retail packs are labelled with sticker containing in parallel

1D Code:
- Product-ID (GTIN),
- Serial number

2D Code:
- Product-ID (GTIN),
- Batch number,
- Expiry Date,
- Serial number
Indentification of labelled products

- Labelling by manufacturer / pre wholesaler
  - According GDP
  - Special Swissmedic agreement to consider labelling outside manufacturing rules for the purpose of the pilot (limited number of product, limited time frame)
Why:

- Controlled Narcotic Substances:
  - existing workflow,
  - clear legal basis regarding deliveries towards federal authorities,
  - little critical business intelligence to be gained from pilot
  - Validation of pilot outcome with data collected and managed by Swissmedic within the usual narcotic declaration processes
Example of data capture for manufacturer
Example of product flow for Swissmedic

INT SmartLog / Tracking

HOME > Tracking

Strichcode: 017680562490421421300

7680562490421 / CONCERTA Tabl 54 mg 30 Stk

76010010003902
Jansen-Cilag AG

Registriermgsdatum: 27.09.2007 09:57

Ausgangsdatum: 27.09.2007 10:34

7601001374669
Amedis-UE SA Prawholesale

Eingangsdatum: 27.09.2007 10:35

Ausgangsdatum: 27.09.2007 10:39

7601001028285
Apotheke Zum Gellert AG

Eingangsdatum: 27.09.2007 10:39

Ausgangsdatum: 27.09.2007 10:40

7601000123602
Feiner Enca
Example of product flow for Swissmedic

INT SmartLog / Tracking

HOME > Tracking

Strichcode: 017680562490421421300

SGTIN

7680562490421 / CONCERTA Tabl 54 mg 30 Stk

GLN

event

Prescribing MD

Patient (anonym)
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Timeframe

- Project definition
- Enrolment of project participants
  - Pharmaceutical companies, Pre wholesalers,
  - Wholesalers (all)
  - Pharmacies (~6)
- Programming and documentation of the Webservices
- Communication about pilot
- Training of the participants
- Pilot Start

- First Half year 2007
- Autumn 2007

- December 2007, on going

- January 2008, for 3 months

Problem of the renewal of the supply chain (when do new marked product cross the whole supply chain ?)
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Expected results of pilot:

- proof of concept for track & trace, anti-counterfeit functions
- Cross check by Swissmedic with official data collection for narcotic trade

**Minimal requirements/definition** of interfaces between various systems with respect to future integration with existing infrastructures and processes

- **Structure of decentralised data centre organisation**, allowing for maximum system interoperability without compromising data confidentiality
- **Security of access** to and necessary level of encryption of shared databases
- **Identification of future implementation and roll out problems**
Questions?

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