

- Sponsors/organisation of the project
- Objectives Scope
- **Technical Concept**
- Timeframe
- Expected results

Deutsch

Willkommen bei Smartlog!

Wer sind wir?

Smartlog ist ein Kooperationsprojekt der **Stiftung Refdata**, **Swissmedic**, **GS1 Schweiz** und **e-mediat 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.

```

            graph LR
            A[Produzent] --> B[Grosshandel]
            B --> C["Einzelhandel  
(Apotheke, SD Arzt)"]
            C --> D["Patient (anonym)"]
            
```

Details...

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

Strichcode

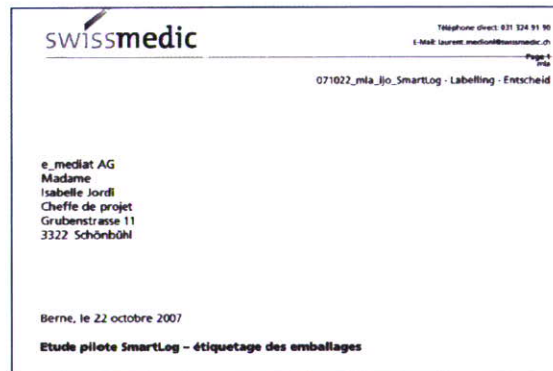
- cross organisational online platform, additional and parallel to existing local client-server systems
- modern scanner technology in combination with ASP technology
- GS1 standards for labelling issues
- Monitoring flow of goods (not flow of funds)
- Centrally managed data pool for all parties, with 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



- 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)



15

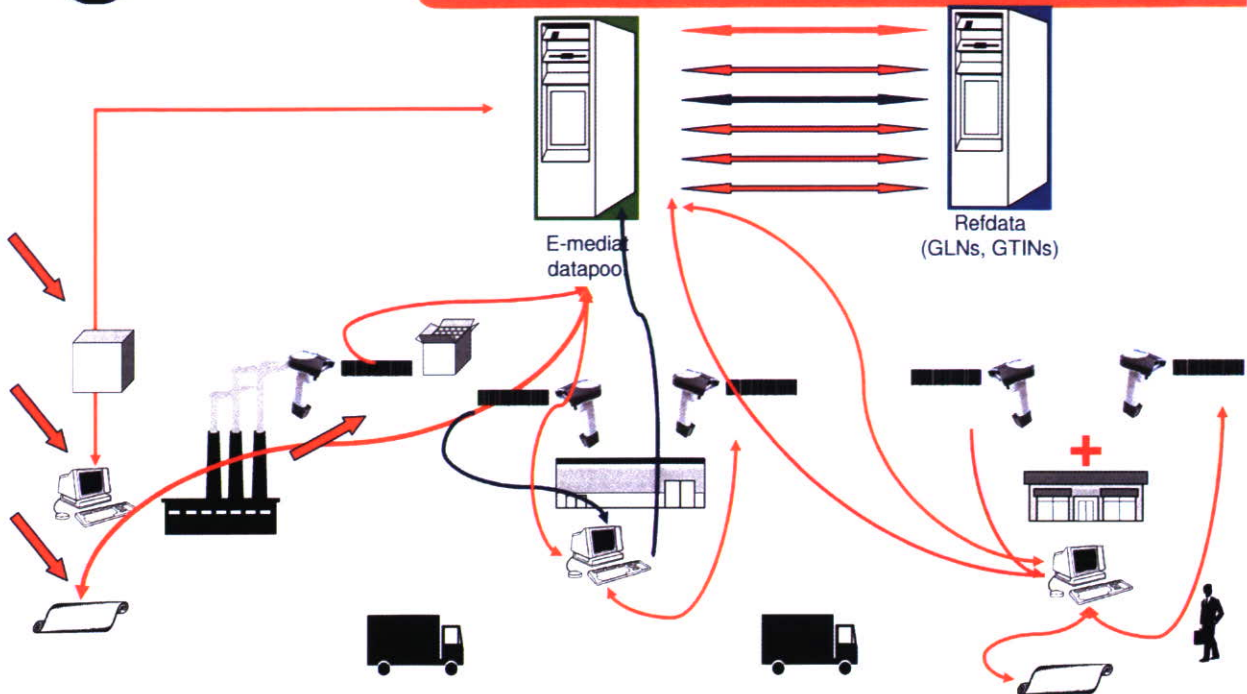
©2007 GS1

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

16

©2007 GS1



INT SmartLog / Willkommen Janssen-Cilag AG **e-mediat**

HOME

Sie sind angemeldet als: Marek Cichocki (uamck) Deutsch

<p>Tracking</p> <p>Janssen-Cilag AG</p> <p>Registrieren</p> <p>Ersatzetikette drucken</p> <p>Versand erfassen</p> <p>Wareneingang erfassen</p> <p>Abgabe erfassen</p> <p>Retoure erfassen</p> <p>Administration</p>	<p>Tracking der Einzelpackung oder Versandeinheit anzeigen</p> <p>Einzelpackung und Versandeinheit registrieren</p> <p>Ersatzetikette für Einzelpackung oder Versandeinheit drucken</p> <p>Versand Einzelpackung oder Versandeinheit erfassen</p> <p>Wareneingang Einzelpackung oder Versandeinheit erfassen</p> <p>Abgabe der Einzelpackung erfassen</p> <p>Retoure Einzelpackung oder Versandeinheit erfassen</p> <p>Parameter verwalten</p>
---	--

© e-mediat Integration - SmartLog 1.0 - Janssen-Cilag AG - uamck 28.09.2007 09:17:36

INT SmartLog / Tracking e-mediat
 HOME > Tracking

Stichcode

7680562490421 / CONCERTA Tabl 54 mg 30 Stk

	7601001000902 Janssen-Cilag AG	Registrierungsdatum 27.09.2007 09:57 uecr
↓		Ausgangsdatum 27.09.2007 10:34 uecr
	7601001374669 Amedis-UE SA Prewholesale	Eingangsdatum 27.09.2007 10:35 uecr
↓		Ausgangsdatum 27.09.2007 10:39 uecr
	7601001026285 Apotheke Zum Gellert AG	Eingangsdatum 27.09.2007 10:39 uecr
↓	7601000123602 Feiner Erica	Ausgangsdatum 27.09.2007 10:40 uecr

© e-mediat Integration - SmartLog 1.0 - - uamck 28.09.2007 09:18:38



INT SmartLog / Tracking e-mediat
 HOME > Tracking

Stichcode

7680562490421 / CONCERTA Tabl 54 mg 30 Stk

	7601001000902 Janssen-Cilag AG	Registrierungsdatum 27.09.2007 09:57 uecr	SGTIN	event
↓		Ausgangsdatum 27.09.2007 10:34 uecr	GLN	
	7601001374669 Amedis-UE SA Prewholesale	Eingangsdatum 27.09.2007 10:35 uecr	GLN	
↓		Ausgangsdatum 27.09.2007 10:39 uecr	GLN	
	7601001026285 Apotheke Zum Gellert AG	Eingangsdatum 27.09.2007 10:39 uecr	GLN	
↓	7601000123602 Feiner Erica	Ausgangsdatum 27.09.2007 10:40 uecr	GLN	Prescribing MD
			GLN	Patient (anonym)

© e-mediat Integration - SmartLog 1.0 - - uamck 28.09.2007 09:18:38



- Sponsors/organisation of the project
- Objectives/Scope
- Technical Concept
- **Timeframe**
- Expected results



- 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 ?)



- Sponsors/organisation of the project
- Objectives/Scope
- Technical Concept
- Timeframe
- Expected results

- 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 ?



Christian Hay
GS1 Switzerland
Delegate Healthcare
D +41 (0)76 369 10 54
F +41 (0)21 825 32 19
E christian.hay@gs1.ch
W www.gs1health.net
W www.gs1.org/healthcare



Building Radio frequency IDentification solutions for the Global Environment

BRIDGE Project
Pharma Traceability
GS1 Healthcare conference, 31 October 2007





Bridge Objectives

- To research and develop a set of technologies facilitating the deployment of RFID and EPCglobal network applications in Europe
- To perform trials and pilots leading to best practice guidelines for implementing RFID in seven different sectors
- To deliver demonstration tools, a comprehensive education package as well as economic and policy studies on the technology and its applications



© 2007



BRIDGE Partners

GS1	Labs/ Universities	End users	Solution Providers
Global Office (Coordinator) China France Germany Poland Spain UK	Cambridge ETH Zürich Fudan TUG Graz UPC Barcelona	Bénédicte Carrefour El Corte Inglés ⁽¹⁾ gardeur Kaufhof Nestlé UK Northland ⁽²⁾ Sony	AIDA Centre AT4 wireless BT CAEN Confidex Domino JJ Associates Melior SAP UPM Rafalatac Verisign UK
7	5	7	11

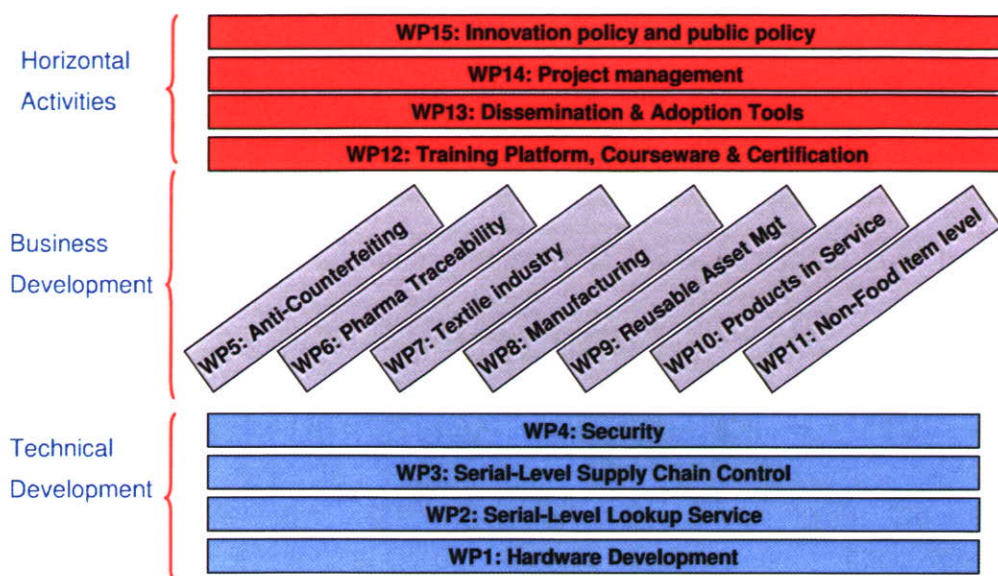
(1) Leaving partner
(2) New partner



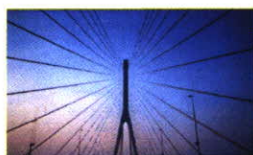
© 2007



Building Radio frequency IDentification solutions for the Global Environment



© 2007



BRIDGE: A few facts

- A 3 years project
- Started on July 1st 2006
- 15 work packages
- Total estimated cost: €13 millions
- Total EU Funding: €7,5 millions



© 2007



Building Radio frequency IDentification solutions for the Global Environment

BRIDGE

WP6 – Pharma Traceability Pilot



WP6: Pharma Traceability Pilot - objectives

- Implement a complete supply chain traceability system for Pharma products
- To enable the development of related supply chain applications e.g. *Product authentication, Recall, Inventory management, Financial reconciliation*
- Demonstrate a business case regardless of:
 - Pharma product packaging level and product type
 - Serialised data tag (RFID and/or Data Matrix code)



© 2007



What are the problems?

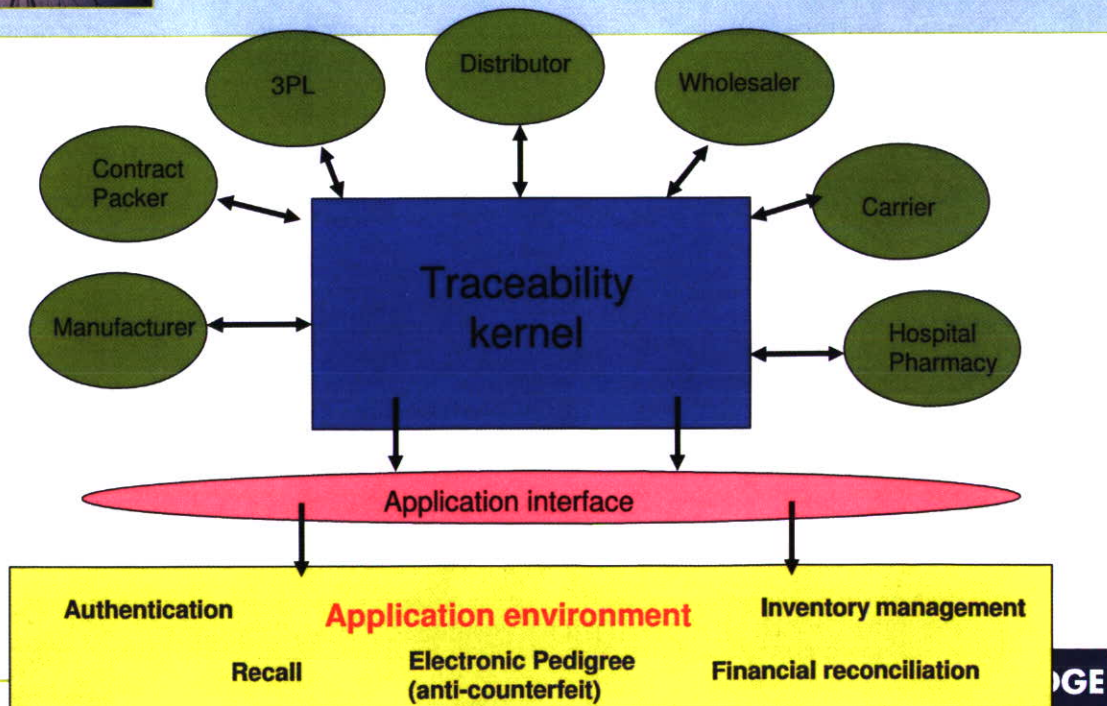
- Medication errors
 - Mis-identification of medicines
 - Harm and death to patients
- The threat of counterfeit medicines – for branded and generic products
 - European wide and Globally
 - Multiple industry, regulatory bodies & media recognise the problem
- Supply chain inefficiency
 - Lack of automation
 - too much administrative overhead



© 2007



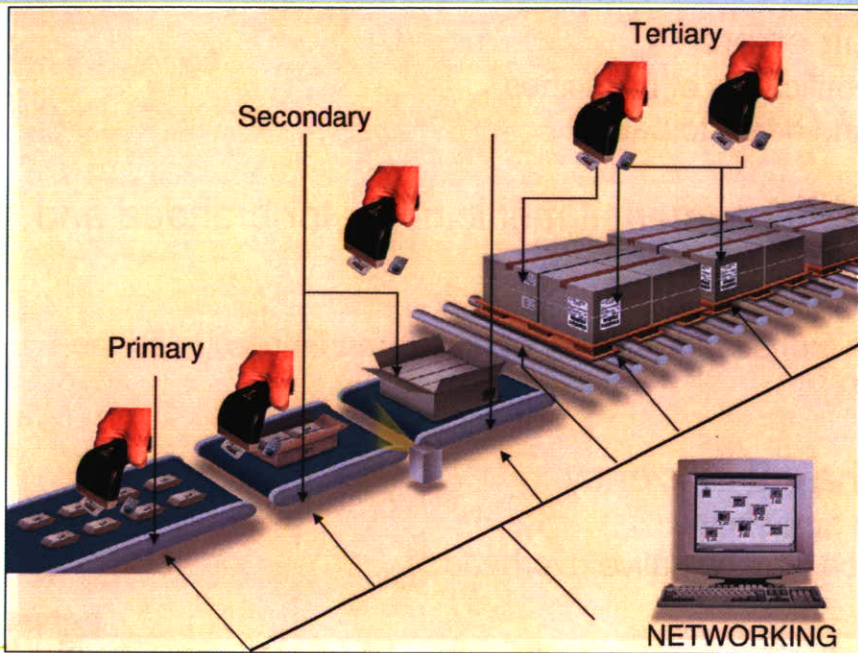
Pharma Traceability Pilot e-Traceability enabling multiple applications



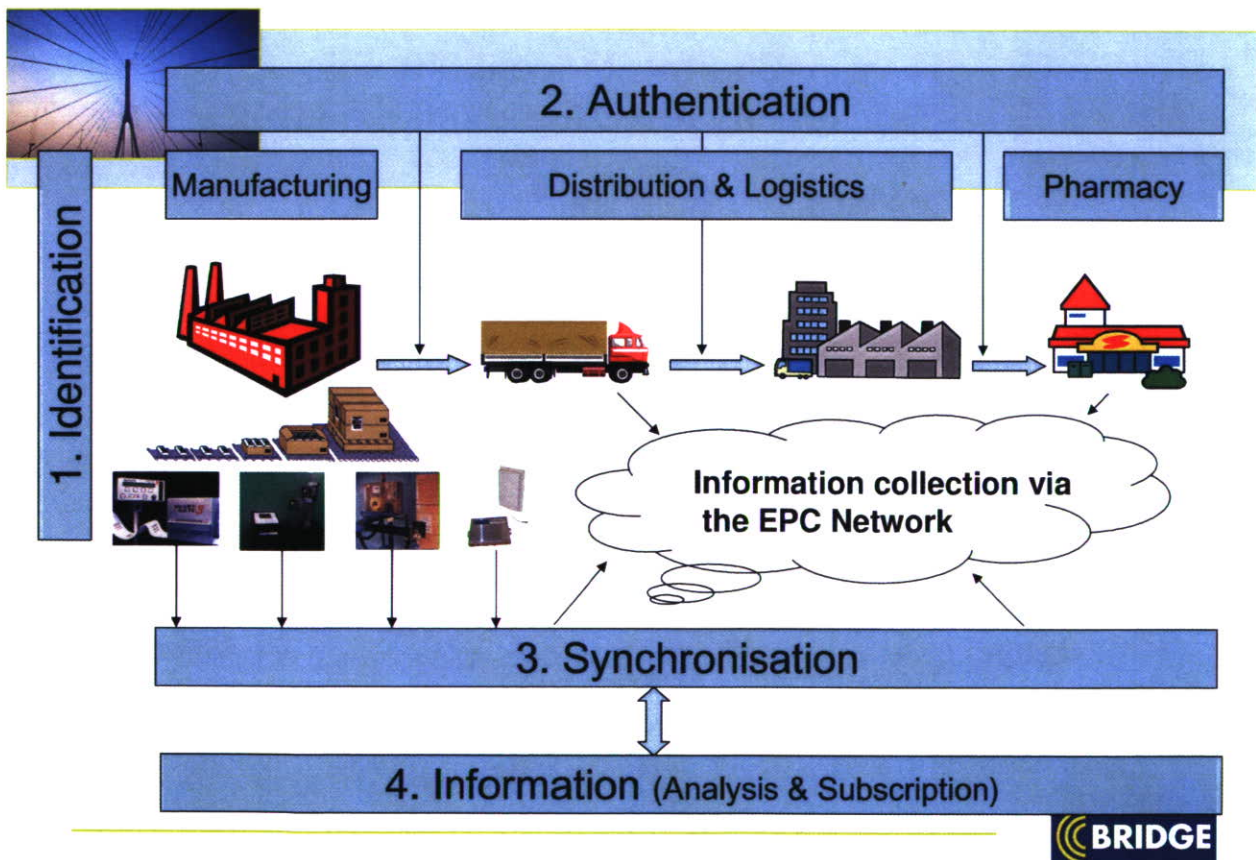
© 2007



Print and/or Tag and validate at each level of packaging – patient pack, case & pallet – at the point of production



© 2007



© 2007



WP Partners

Leader:

- JJ Associates

BRIDGE Partners:

- Domino Integrated Solutions
- GS1 UK
- Melior Solutions
- Verisign



© 2007



Our User Community

- Manufacturers
 - Actavis (UK)
 - Athlone Laboratories (Ireland)
 - Sandoz (UK)
- Contract packer
 - Tjoapack (The Netherlands)
- Pre-wholesaler
 - CPG (UK)
- Distributor/Storage
 - Kent Pharmaceuticals (UK)
- Transport & Logistics
 - Healthcare Logistics (integrated)
 - and others
- Wholesaler
 - UniChem (UK)
- Hospital
 - Barts and The London NHS Trust (UK)



Tjoapack

UniChem



© 2007



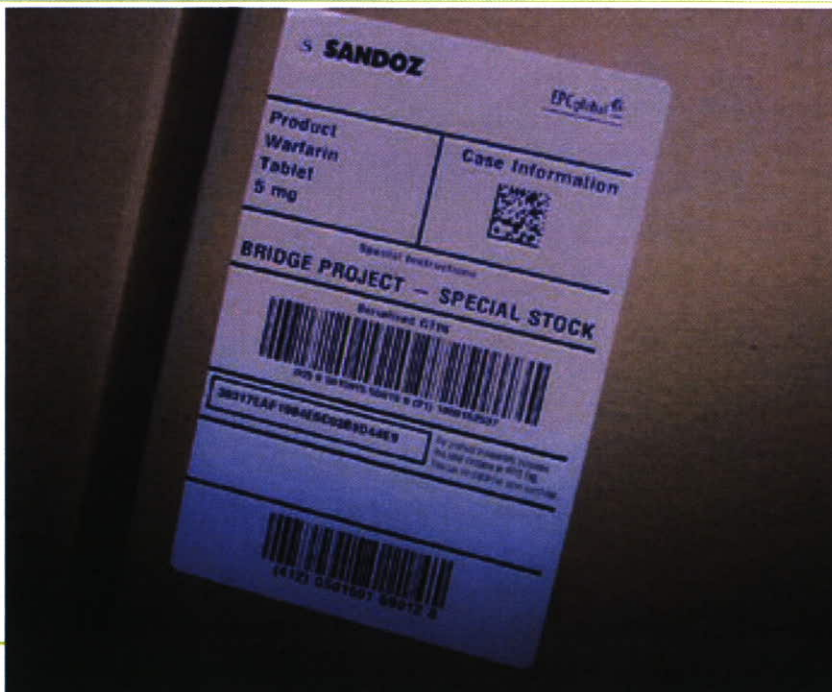
Pilot Products

Product	Form	Pack
Aqueous Cream 500mg	Tubs	1
Warfarin 1/3/5mg	Tabs	28
Clindamycin 150mg	Caps	24
*Dihydrocodeine 30mg	Tabs	28
Prednisilone E/C 5mg	Tabs	28
*Co-Codamol 8/500mg	Tabs	30
Flucloxacillin 250 / 500mg	Caps	28
Penicillin V 250mg	Tabs	28
Amoxicillin 125 / 250mg	Susp/Sugar Free	100ml
Amoxicillin 250 / 500mg	Caps	21
Penicillin 125 / 250 mg	Susp/Sugar Free	100ml
Flucloxacillin 125 / 250mg	Susp	100ml

* controlled substances



© 2007



© 2007



© 2007



© 2007



Problem Analysis

- Improving patient safety is the No. 1 priority for all players
- Medication error is one of the most significant hazards
- Counterfeit threat exacerbates the risk
- Supply chain inefficiency creates significant overheads
- End to end traceability supported by Bar Code and RFID technologies offers significant benefits



© 2007



Requirements Analysis

- Track and trace is the critical element
- Mass serialisation needed to trace to item level
- Industry supported carriers e.g. Data Matrix, as well as RFID at higher levels of packaging
- Product code, serial number, expiry date and batch number data elements
- Use of GS1 standard keys adds to completeness of traceability system
- EPC Network offers information access and visibility for all parties
- Requirement is broader than just pedigree – financial reconciliation, inventory management, product recall, authentication are all key, all enabled by the traceability application



© 2007



Business Case Report

- How can one value people's lives in a financial model?
- Mass serialisation and the granularity it provides strengthens the Business Case
- Financial benefits of cost reduction, efficiency gains, opportunities for additional revenue and cash generation
- Level of benefits depends upon supply chain role and extent of integration with internal and supply chain systems



© 2007



Pilot Preparation

- Hardware solution outline - EPCglobal Network, coding and tagging by laser and inline inkjet printing, Class 1 Gen 2 UHF tags, Data Matrix codes, various inline data verification equipment,
- Software solution - web based software: manufacturer, distributor, wholesaler, pharmacy modules
- GPS tracking system for additional pallet level security
- User pilot process defined, installation and user training
- Performance and evaluation processes
- Promotion and publicity plans



© 2007



Plan for the next 6-12 Months

- Pilot operation and management
 - Completion of Pilot Implementation report
- Pilot evaluation
 - Pilot Evaluation Report
- Increasing focus on information & experiences dissemination



© 2007



For More information

Website: www.bridge-project.eu

- A Newsletter (bi-monthly edition), registration on the website
- Public deliverables available from the web site
- Any question: Henri Barthel
henri.barthel@gs1.org
Tel + 32 2 788 7823



© 2007

TURKISH DRUG & MEDICAL EQUIPMENT

NATIONAL DATA BANK PROJECT

Presentation Plan

1. Goal
2. Current Situation
3. Recommended Model
4. Issued Performances
5. Developed System
6. Current Datas