EU Traceability Pilot in Pharmaceutical Supply Chain

Henri Barthel, GS1 Global Office
Washington DC, 18 June 2009
The BRIDGE Project

• A 3 years project
• Started on July 1st 2006
• 31 Partners
• 15 work packages
• Total budget: €13 millions
• European Union funding: € 7,5 millions
### BRIDGE Partners

<table>
<thead>
<tr>
<th>GS1</th>
<th>Labs/Universities</th>
<th>End users</th>
<th>Solution Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Office (Coordinator)</td>
<td>Cambridge</td>
<td>Bénédicta</td>
<td>AIDA Centre</td>
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<td>ETH Zürich</td>
<td>Carrefour</td>
<td>AT4 wireless</td>
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<td>Fudan</td>
<td>Covap</td>
<td>BT</td>
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<td>TUG Graz</td>
<td>gardeur</td>
<td>CAEN</td>
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<td>UPC Barcelona</td>
<td>Kaufhof</td>
<td>Confidex</td>
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<td>Nestlé UK</td>
<td>Domino</td>
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<td>Northland</td>
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<td>UPM Raflatac</td>
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<td></td>
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<td>Verisign UK</td>
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</tbody>
</table>

- **China**
- **France**
- **Germany**
- **Poland**
- **Spain**
- **UK**

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Building Radio frequency IDentification solutions for the Global Environment

Horizontal Activities

- WP12: Training Platform, Courseware & Certification
- WP13: Dissemination & Adoption Tools
- WP14: Project management
- WP15: Innovation policy and public policy

Business Applications

- WP1: Hardware Development
- WP2: Serial-Level Lookup Service
- WP3: Serial-Level Supply Chain Control
- WP4: Security
- WP5: Anti-Counterfeiting
- WP6: Pharma Traceability
- WP7: Textile industry
- WP8: Manufacturing
- WP9: Reusable Asset Mgt
- WP10: Products in Service
- WP11: Non-Food item level

Technical Development

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Pharma traceability objectives

- Implement a complete supply chain traceability system for pharma products in a **real life operational environment**
- **Multi-application support capability e.g.**
  - Electronic pedigree
  - Product authentication
  - Recall
  - Inventory management
  - Financial reconciliation
- **Compliant with open standards (GS1)**
- Easy to use, robust system
Pharma traceability scope

Traceability kernel

Application interface

Authentication
- Recall
- Electronic Pedigree (anti-counterfeit)

Application environment

Inventory management
- Financial reconciliation

CPG Logistics
- Kent Pharma
- Distributor
- Transporter
- Wholesaler

Tjoapack
- 3PL
- Contract Packer

Manufacturer

Actavis Athlone Labs. Sandoz

UniChem
- Hospital Pharmacy

Barts and The London NHS Trust

Manufacturer

Hospital

Pharmacy

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Pharma Traceability Pilot participants: solution and technology suppliers

- Provision and deployment of the inline equipment and printing solution
- Provision of standards and RFID consultancy
- Project management, business consulting & marketing
- Technical design and software development
- EPCIS database provision

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Pharma Traceability Pilot participants: *End Users*

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

• Nine supply chain end users involved
• 19 product lines selected
  – one years pharmacy stock ordered and manufactured
  – Different packs and forms, includes 2 controlled drugs
• Production line encoding/printing equipment specified, acquired, configured and installed at Contract Packer and one Manufacturer
• Application software specified, developed and implemented
<table>
<thead>
<tr>
<th>Product</th>
<th>Form</th>
<th>Pack</th>
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<tbody>
<tr>
<td>Aqueous Cream 500mg</td>
<td>Tubs</td>
<td>1</td>
</tr>
<tr>
<td>Warfarin 1/3/5mg</td>
<td>Tabs</td>
<td>28</td>
</tr>
<tr>
<td>Clindamycin 150mg</td>
<td>Caps</td>
<td>24</td>
</tr>
<tr>
<td>*Dihydrocodeine 30mg</td>
<td>Tabs</td>
<td>28</td>
</tr>
<tr>
<td>Prednisilone E/C 5mg</td>
<td>Tabs</td>
<td>28</td>
</tr>
<tr>
<td>*Co-Codamol 8/500mg</td>
<td>Tabs</td>
<td>30</td>
</tr>
<tr>
<td>Flucloxacillin 250 / 500mg</td>
<td>Caps</td>
<td>28</td>
</tr>
<tr>
<td>Penicillin V 250mg</td>
<td>abs</td>
<td>28</td>
</tr>
<tr>
<td>Amoxicillin 125 / 250mg</td>
<td>Susp/Sugar Free</td>
<td>100ml</td>
</tr>
<tr>
<td>Amoxicillin 250 / 500mg</td>
<td>Caps</td>
<td>21</td>
</tr>
<tr>
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</table>

* controlled substances
Lessons learned

• Inline production equipment installation is a complex, precise and resource intensive operation
• Data Matrix / RFID operates effectively in hybrid environment & generally provided good quality reads
• Integration of traceability data into back office systems is key
  – For inventory management, exploiting batch & expiry date data
  – For financial reconciliation – order/goods received/invoice
  – For product recall
  – For traceability purposes – product locations, sales made, consumption
Conclusions

- Business Case varies according to supply chain role & function
  - Clear patient safety benefits: all parties buy-in to that
  - Electronic chain of custody as counterfeit combatant
  - Recall systems, increased efficiency, inventory management, financial reconciliation are all integration dependent
- Supply chain wide traceability totally feasible with
  - Good planning & resourcing
  - User commitment (senior level) and prioritisation
  - Easy to use, intuitive, robust user systems and processes
  - Clear policy on integration with in-house systems
  - Good user training – for all operatives involved
  - Full trading partner collaboration & communication
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Thank you for your attention!