EDQM Track & Trace project

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A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)

Mission: to contribute to a basic human right: access to good quality medicines and healthcare
EDQM contribution - European Regulatory Network

- European Authorities

- European Union
  - European Union
  - Council
  - Parliament
  - Commission
  - DG Health and Consumers
  - Brussels

- Edward Medicines Agency
  - EMA London
  - European Directorate
  - for the Quality
    of Medicines & HealthCare
  - Ph. Eur.

- Certifications
  - EDQM
  - Strasbourg

- OMCL Network
  - Organ Transplantation
  - Blood Transfusion
  - Pharmaceuticals
    Pharmaceutical care
  - Cosmetics/food packaging

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Anti-Counterfeiting Strategies

Multiple actors / multifocal threat

Multi-level (“holistic”) strategy

• Custom level (importation)
• Legal instruments (pharmaceutical crime)
• Pharmaceutical level
  • Inspection
  • Testing – evidence for enforcement
  • Packaging (traceability of serialised items)
Mass serialisation: current situation

- EU Pharma package under discussion
- Existing or on-going development of Track & Trace national systems at item level in Belgium, Italy, Greece, Spain, Germany, Ireland + Turkey Serbia
  - Batch level in France
  - EFPIA pilot study in Sweden
Main features of systems existing or under development

- From manufacturer to Point of Dispensing = “end-to-end” (exc. pilots in DE and ES)
- No coverage of Internet sales
- Developed bottom-up from community pharmacies or top-down from manufacturers
- No interoperability / different standards & data carriers (no GS1 standards in BE GR IT)
- Expansion country by country
EU Pharma package

- EC proposed amended Dir 2001/83/EC on prevention of the entry into the legal supply chain of falsified medicinal products
  - safety features make possible to ascertain identification, authenticity and traceability of medicinal products
  - shall allow wholesale distributors or pharmacists to identify individual packs
Current situation: End-to-end solutions

- Manufacture
  - Generation of item code

- Distribution

- Retail pharmacy
  - Verification at dispensing point
Proposed EDQM Track & Trace Solution

Governance: EDQM as an intergovernmental organisation guaranteeing sustainable confidentiality of data
EDQM Project: Track & Trace Service

• Mass serialisation with UMI = Unique Medicine Identifier per item
• UMI unique, unbreakable and interoperable with other existing systems (e.g.: by using GS1 standard)
• Data carrier:
  – Human-readable number
  – Barcode (state-of-the-art = Datamatrix)
  – Need for flexibility to accommodate other suitable technologies (e.g.: RFID in the future)
• Query to EDQM Track & Trace Service to verify existence of UMI to a directory of EPCIS repositories (Electronic Product Code Information System GS1 standardised)
Directory vs. Repository

1 - Manufacturers uploading their UMIs

UMI Queries: Pharmacies, patients, customs etc.

2 – Manufacturers with own UMI repositories

Track & Trace Service for Medicines

Directory Service (Rules Engine)
**Real time (one source)**

- No point-to-point information sharing
- All data on request based on traceable item identifier

Repositories for data search

Information flow

- Manufacturer
- Distributor
- Provider

Physical flow

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Scope of the Project (1 of 3)

- Any Pharmaceutical products on a voluntary basis
- Any registered business stakeholders within distribution
- Patients
- Authorities
All 36 member states of the European Pharmacopoeia and beyond if interested (observers?)
Scope of the Project (3 of 3)

Manufacturers/Innovators

Logistic service provider (i.e. wholesaler)

Pharmacies (Physical/Online)

Hospitals

Patients

Bundle

Secondary packaging (e.g.: folding box, bottle)

Possible additional scope

Dosage form (e.g.: tablets)

Primary packaging (e.g.: Blisters)

Current scope

Secondary packaging (e.g.: folding box, bottle)

Bundle

Dosage form (e.g.: tablets)

Primary packaging (e.g.: Blisters)
General Overview on Project

Phase 1
Concept development

Alignment with stakeholders and user and business requirements

Dec 09-March 2010

Phase 2
Live demo

Apr 2010 – 2Q11

Phase 3
Service development

From Q3 2011
Unique Medicine Identifier: no new or proprietary standards

- UMI will use GS1 GTIN or ‘NTIN’
- Use of the AI (application identifiers)
  - Product code
  - Serial number
  - Expiry date
  - Batch number
- Use of GLN or DUNS for business actors
UMI using national code (no GTIN or NTIN)

- Allows the integration of national product codes
  - EDQM specific application identifier?
  - 3-digit country code following the GS1 standards for country codes
  - national code (e.g. in Germany 7 digit PZN)
  - variable length but maximum 20 digits

![Diagram of UMI with national code]

Example UMI with national code: (01)03700011234562(21)01234XY78901234567AB(17)100201(10)00345E(90)03412345678
“Core” – Product codes registration interface

- Product code registration interface:
  - Integration of product code data imported from national organisations (e.g. IFA in Germany)
  - GTIN linked with PZN (non-GTIN DE code) in IFA DB
  - Integration of product codes sent by the manufacturers before sending the UMIs
National schemes vs. pan-European scheme

- Multiplicity of coding format:
  - will require higher investment costs from manufacturers (inline packaging)
  - Cost passed on to other parties (patients / health insurance)

- Governance
  - Procedures for alerting authorities without delay in case of detection / suspicion of counterfeiting
    - Trusted third party (not a service provider) establishing/managing them
  - Repositories architecture
    - Network of decentralised repositories vs. centralised repository
Alignment with GS1 standard EPCIS

• EPCIS = Electronic Product Code Information Service
  – communication standard to ensure interoperability among the actors
  – EPCIS specifies standard data sharing interface

• Types of required communication messages
  – EPCIS communication messages contain events
  – Events typically generated by an EPCIS capturing application
Companies *not willing* to send UMI to EDQM T&T service or to receive UMI generated by EDQM T&T service.

Companies *willing* to send UMI to EDQM T&T service or to receive UMI generated by EDQM T&T service.

* Contract manufacturers
  * Special group

**Track & Trace service for medicines**

**Directory Service (Rules Engine)**

**Capture Service**

**Query Service**

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Summary and Outlook

- Users and business requirement phase completed mid March 2010
- Phase 2 (live demo development) start Q2 2010
- Along Phase 2 EDQM will
  - keep interacting with relevant stakeholders, partners for live demo (ERP, WMS, POS, associations of stakeholders)
  - Validating exhaustively country by country technical options taken (business cases)
- Live demo used a proof of concept to rally support of stakeholders for phase 3 (system development) and 4 (phased implementation and deployment)
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