EDQM Track & Trace project

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GS1 HealthCare Conference

24 June 2010, Geneva

European Directorate for the Quality of Medicines & HealthCare (EDQM)

A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)
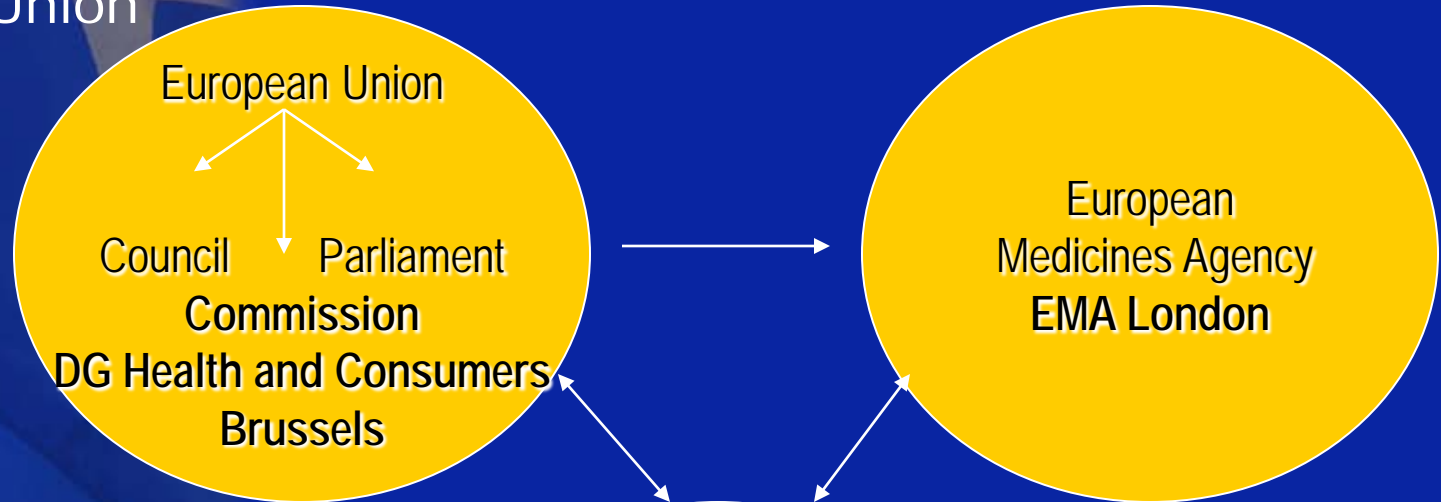
Mission: to contribute to a basic human right : access to good quality medicines and healthcare
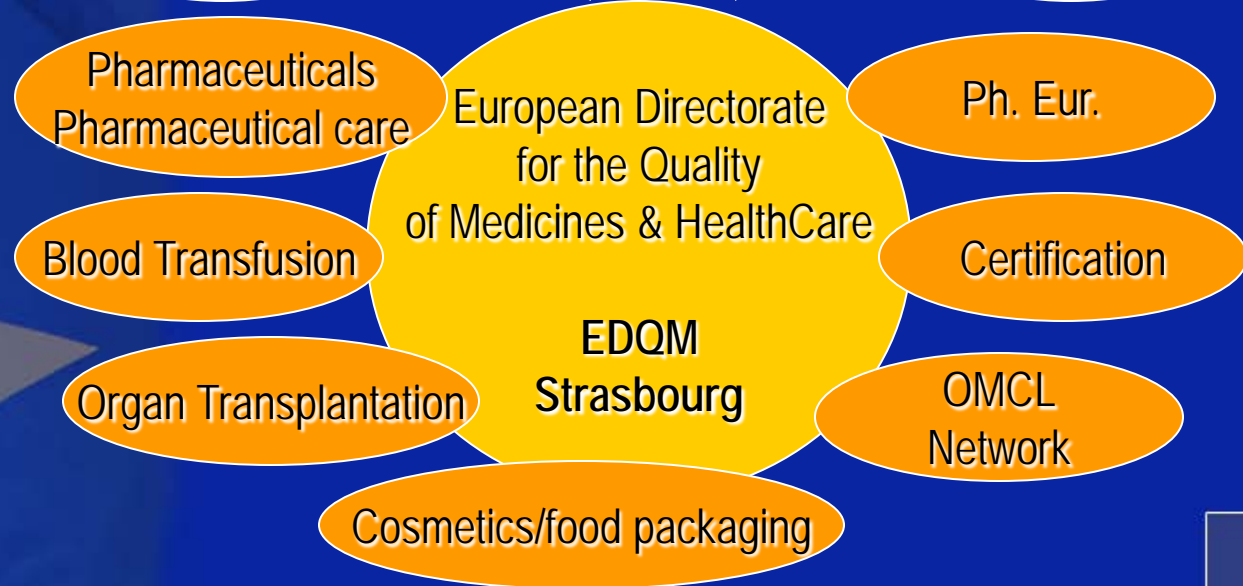
EDQM contribution - European Regulatory Network

• European Authorities

• European Union

European Union

Council — Parliament
Commission
DG Health and Consumers
Brussels

European
Medicines Agency
EMA London

Pharmaceuticals
Pharmaceutical care

European Directorate
for the Quality
of Medicines & HealthCare

Ph. Eur.

Blood Transfusion

Certification

Organ Transplantation

EDQM
Strasbourg

OMCL
Network

Cosmetics/food packaging

• Council
of Europe

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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)

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The Beatles

4381439

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
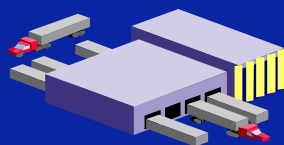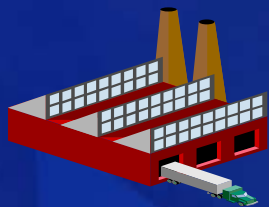
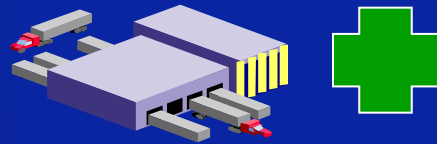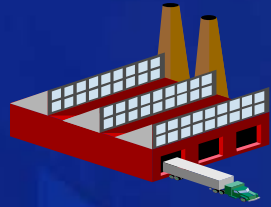**Manufacture** → **Distribution** → **Retail pharmacy**

Generation of item code

Verification at dispensing point

Proposed EDQM Track & Trace Solution

Manufacture

- Distribution
- Pharmacies
- Internet/mail-order pharmacies

Patients

Generation of UMI

Tracing & Verification of UMI

Verification of UMI

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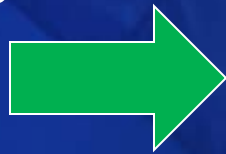
EDQM Project: Track & Trace Service

- 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)
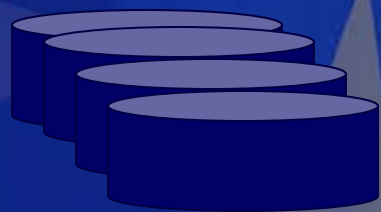
Directory vs. Repository

**Track & Trace
Service for Medicines**

**Directory Service
(Rules Engine)**

Capture Service

Query Service

edqm

European Directorate for the
Quality of Medicines & HealthCare

1 - Manufacturers uploading their UMIs

UMI Queries: Pharmacies, patients, customs etc.

2 – Manufacturers with own UMI repositories

edQm

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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
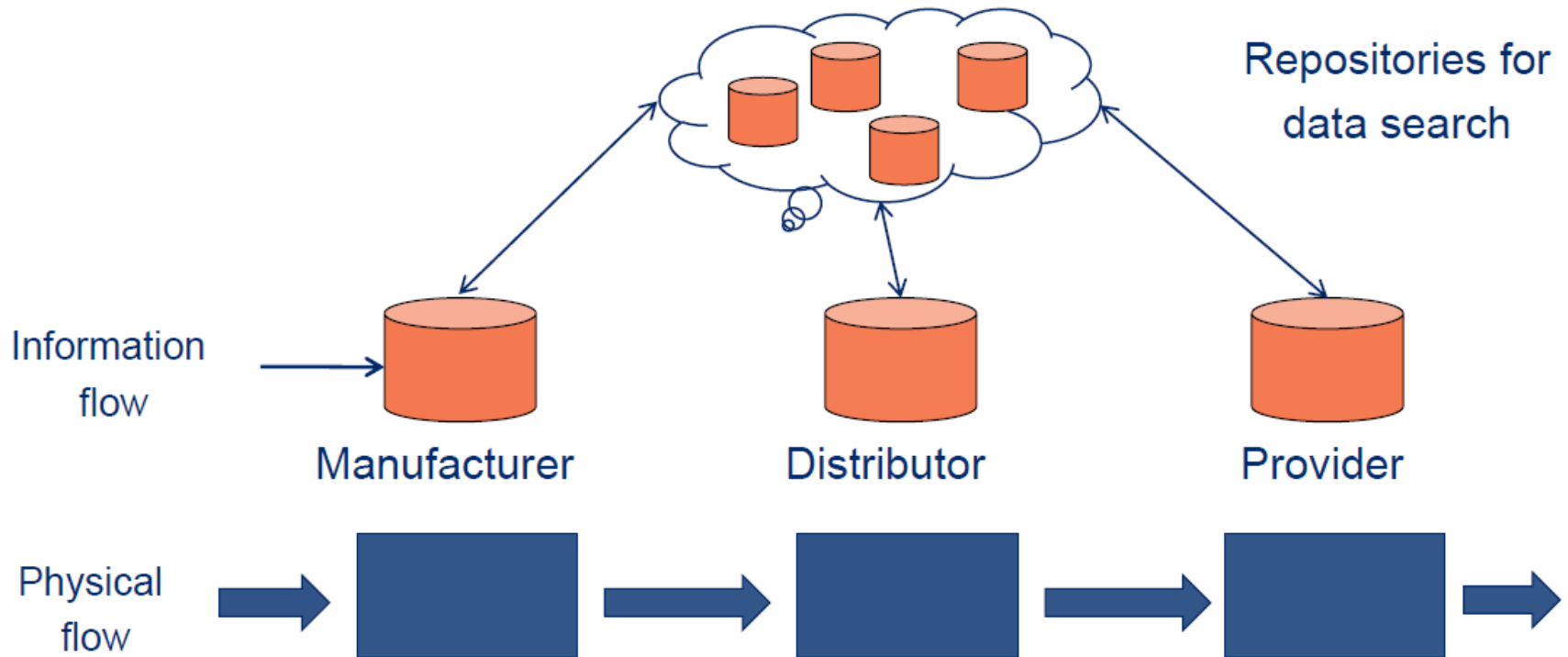
Scope of the Project (1 of 3)

- Any Pharmaceutical products on a voluntary basis
- Any registered business stakeholders within distribution
- Patients
- Authorities

Europe

Observers countries non-members of the Council of Europe

Algeria
Argentina
Australia
Belarus
Brazil
Canada
China
Israel
Kazakhstan
Madagascar
Malaysia
Morocco
Senegal
Syria
Tunisia
USA

Member states
Observer states

All 36 member states of the European Pharmacopoeia and beyond if interested (observers?)

Scope of the Project (3 of 3)

General Overview on Project

Phase 1
Concept development

Phase 2
Live demo

Phase 3
Service development

Alignment with stakeholders and user and business requirements

Dec 09-March 2010	Apr 2010 – 2Q11	From Q3 2011

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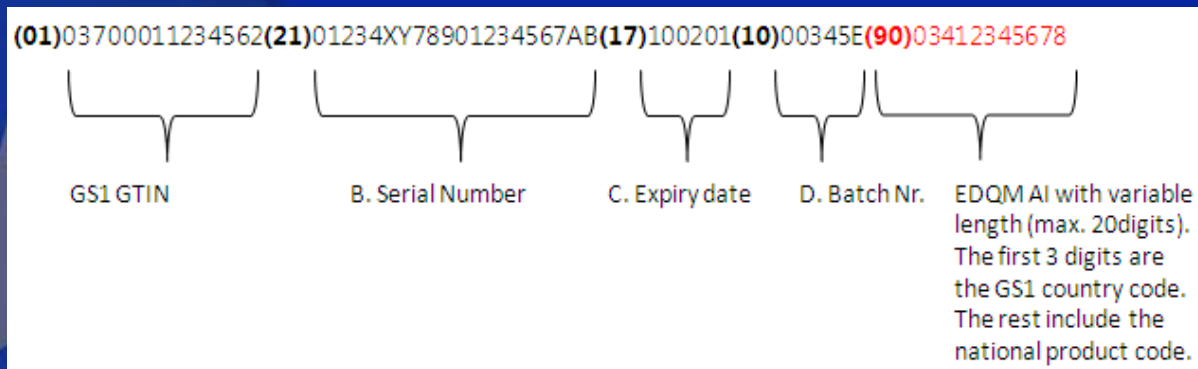# Unique Medicine Identifier:
no new or proprietary standards

- UMI will use GS1 GTIN or 'NTIN'
- Use of the AI (application identifiers)
  - Product code
  - Serial number
  - Expiry date
  - Batch number

(01)03700011234562**(21)**01234XY78901234567AB**(17)**100201**(10)**00345E

A. GS1 GTIN
Or
National GTIN

B. Serial Number

C. Expiry date

D. Batch Nr.
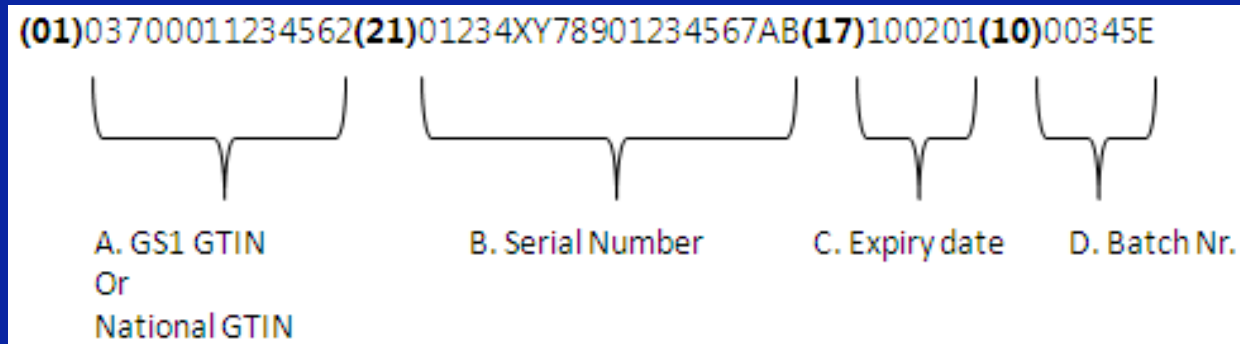
- Use of GLN or DUNS for business actors
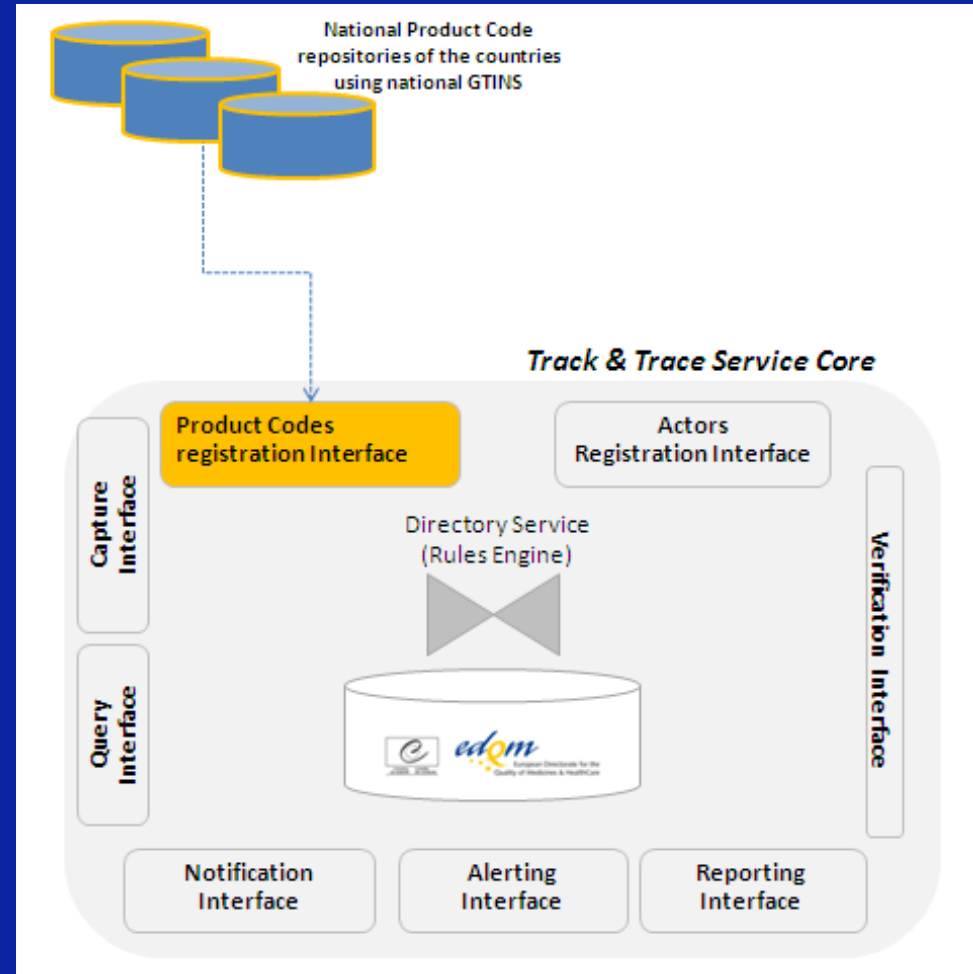
UMI using national code (no GTIN or NTIN)

- 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

(01)0370011234562**(21)**01234XY78901234567AB**(17)**100201**(10)**00345E**(90)**03412345678

GS1 GTIN   B. Serial Number   C. Expiry date   D. Batch Nr.   EDQM AI with variable length (max. 20digits). The first 3 digits are the GS1 country code. The rest include the national product code.

example UMI with national code

"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 Product Code repositories of the countries using national GTINS

Track & Trace Service Core

Capture Interface

Query Interface

Product Codes registration Interface

Actors Registration Interface

Directory Service (Rules Engine)

Verification Interface

Notification Interface

Alerting Interface

Reporting Interface

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

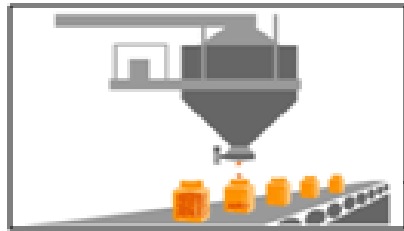# Alignment with GS1 standard EPCIS

- 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
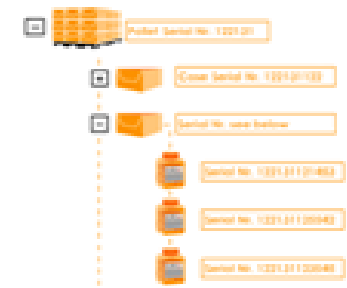 - Events typically generated by an EPCIS capturing application
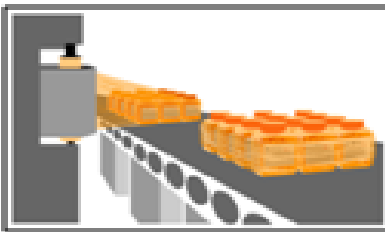
Companies **not willing** to send UMIs to EDQM T&T service *or to receive UMIs generated by EDQM T&T service*
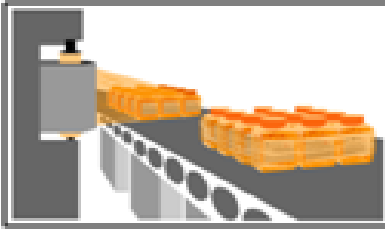
Companies **willing** to send UMIs to EDQM T&T service *or to receive UMIs generated by EDQM T&T service*

* **Contract manufacturers**
* **Special group**

Track & Trace service for medicines

Capture Service

Directory Service
(Rules Engine)

Query Service

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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