EDQM activities around counterfeiting and traceability

GS1 Healthcare Conference

Lisbon, 23-25 October 2012

The eTACT project

1. Introduction

  ⇨ What is the background to the project?

  ⇨ EDQM proposal

  ⇨ Focus on some demo functionalities

  ⇨ Progress of the project – workshops and beyond
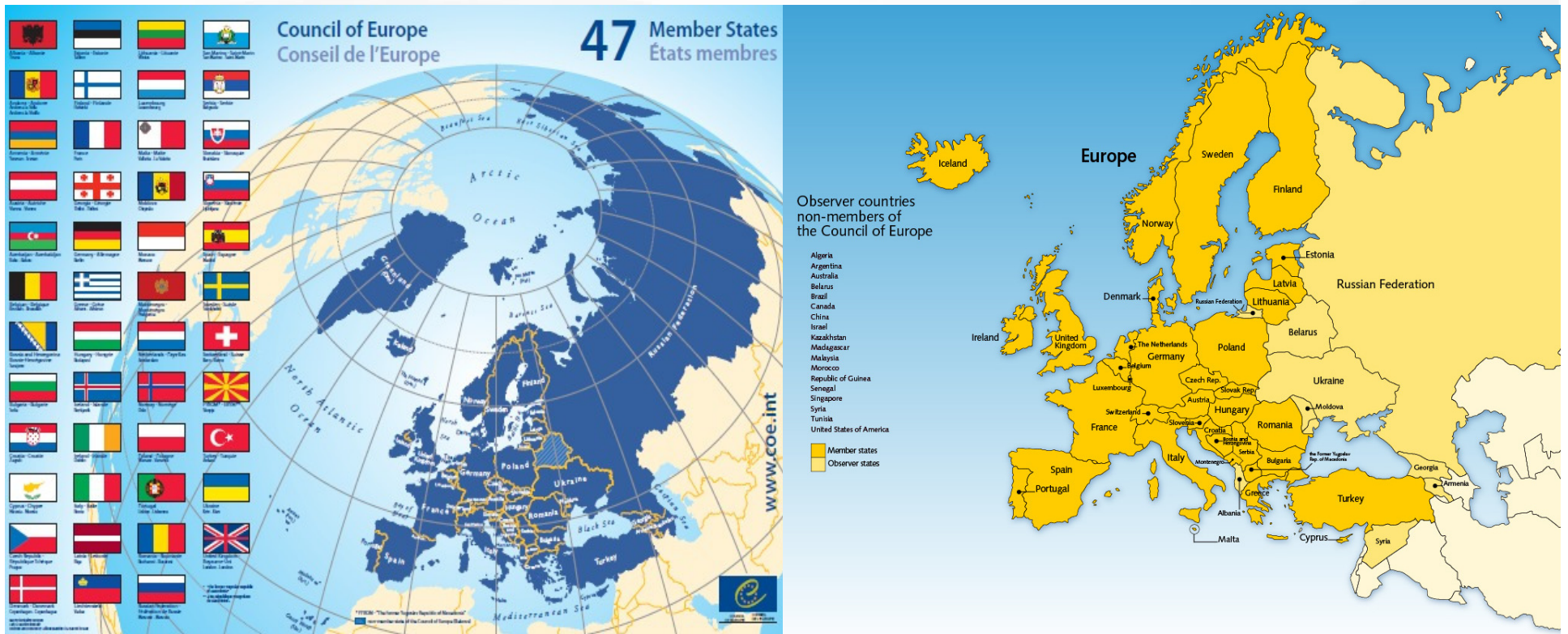
  ⇨ Benefits

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

European Pharmacopoeia

- Official standards for the quality control of medicines in Europe

- Legal and scientific basis

- Principles of elaboration keep pace with
  - regulatory needs of Public Health authorities
  - technological/scientific advances and industrial constraints

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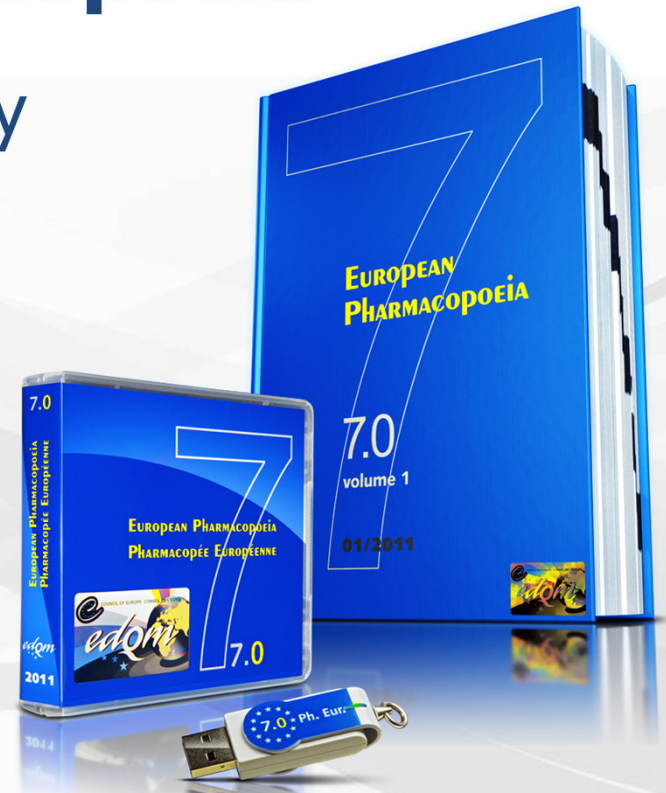
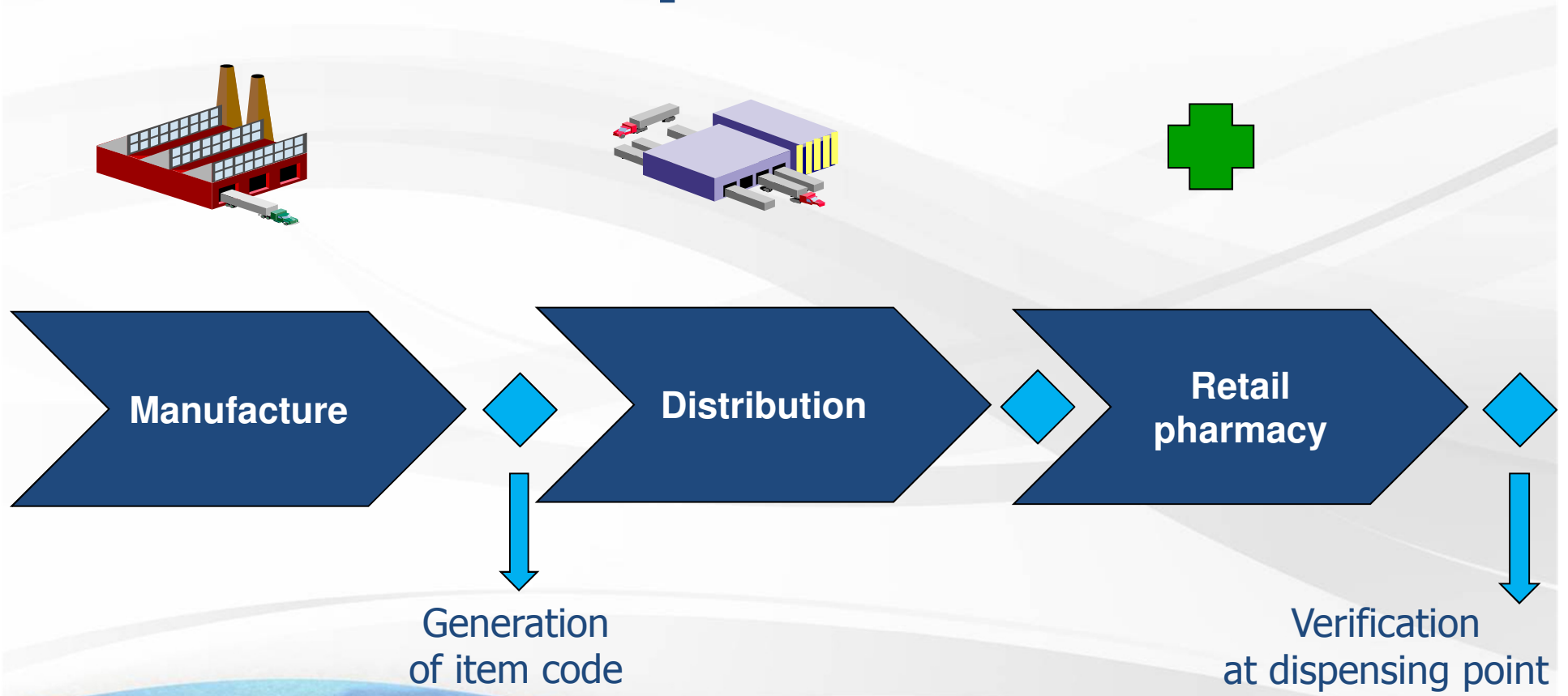# CoE/EDQM anti-counterfeiting strategy

The opportunities: mass serialisation

Public	Business
Bollino (IT)	GS1
CIP-13 (FR)	Aegate (BE, GR)
eTACT (CoE/EDQM)	EFPIA (SE 2010 -> ESM)
FMD (EU)	Securpharm (DE)

Current situation:
Point-of-Dispense verification

Manufacture ◆ **Distribution** ◆ **Retail pharmacy** ◆

Generation
of item code

Verification
at dispensing point
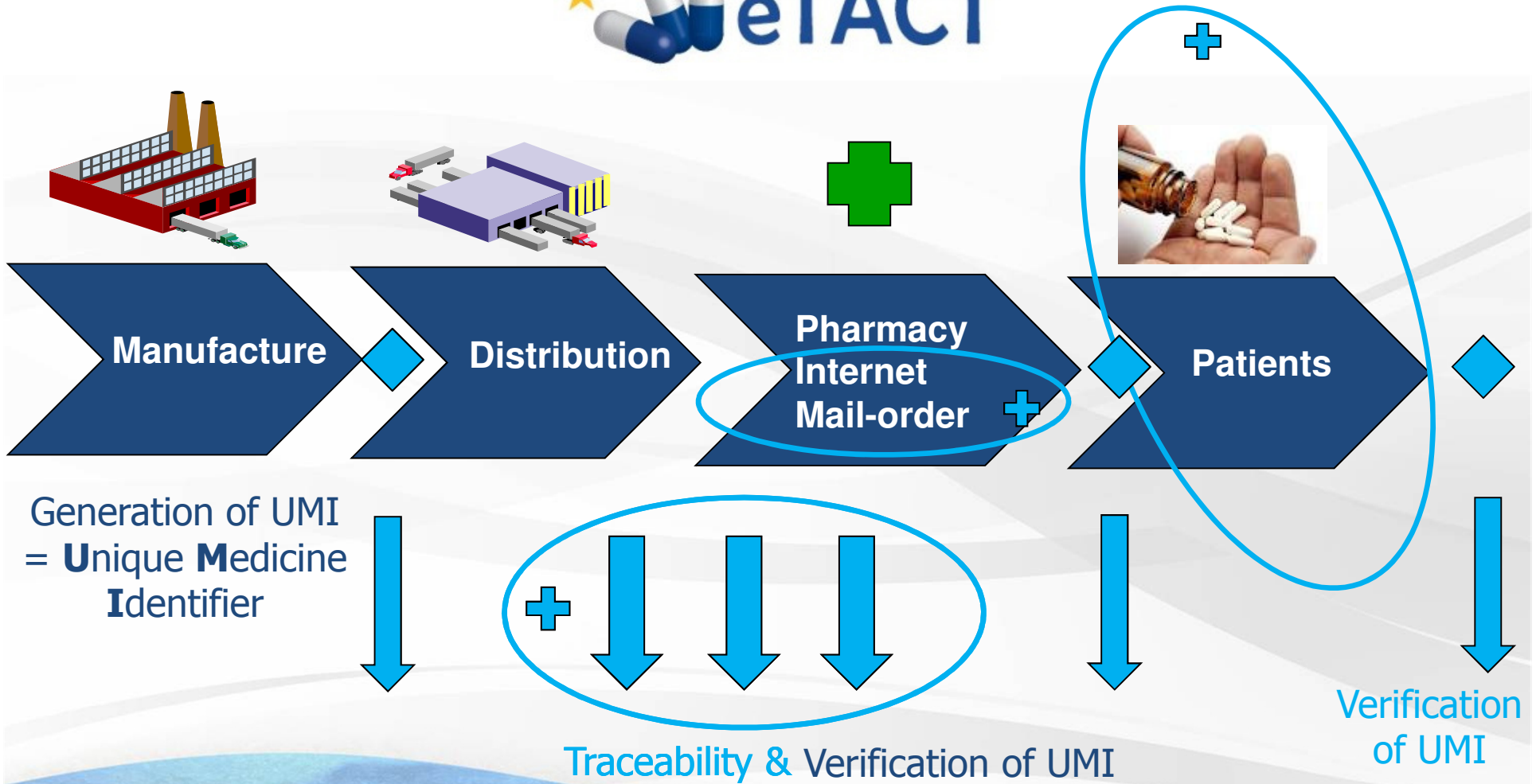
Falsified Medicines Directive (FMD)

- Directive 2011/62
  - Safety features
    - ⇨ Identifier that is readable by wholesale distributors and pharmacists
    - ⇨ Tamper-proof device (outside scope of eTACT)
  - Public consultation Nov 2011-Apr 2012
  - Impact study ⇨ Delegated Acts 2014

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eTACT

Manufacture → **Distribution** → **Pharmacy Internet Mail-order** → **Patients** →

Generation of UMI = **U**nique **M**edicine **I**dentifier

Traceability & Verification of UMI

Verification of UMI

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Public governance

⇨ EDQM / Authorities

⇨ Business stakeholders

⇨ Confidentiality of data

More information at the eTACT workshop 14-15 Nov Sofia
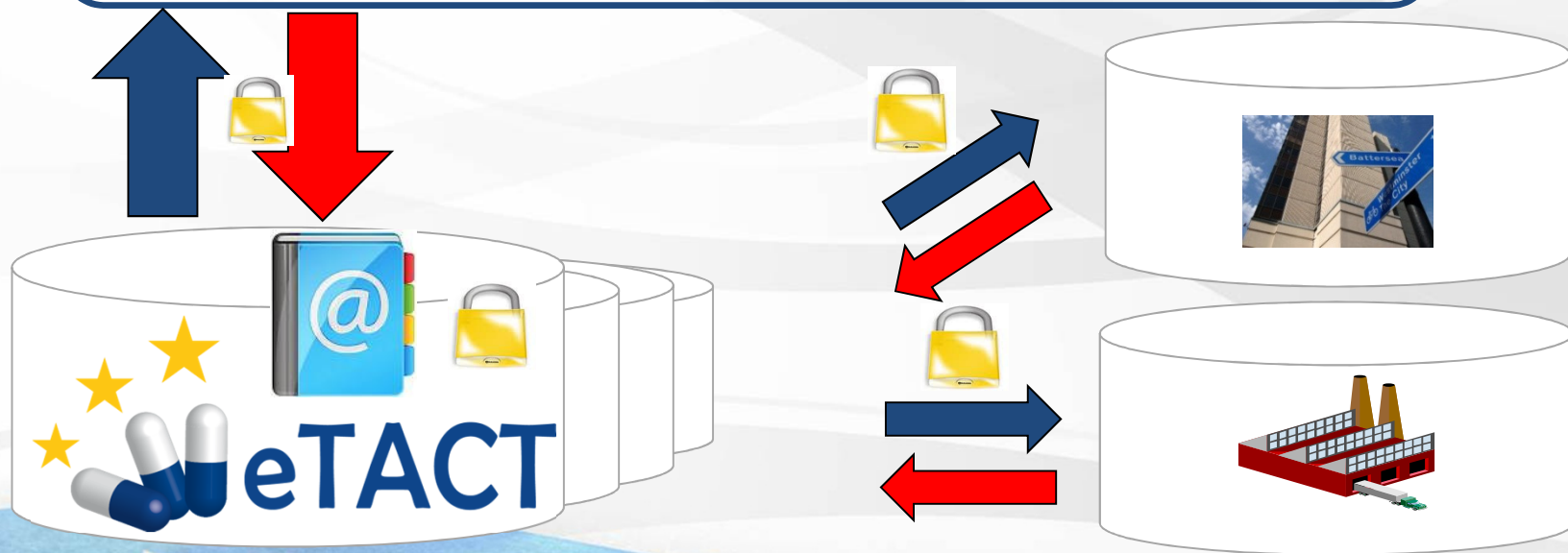
Unique Medicine Identifier (UMI)

GTIN (01):7680303330054

SERIAL (21)0402748246

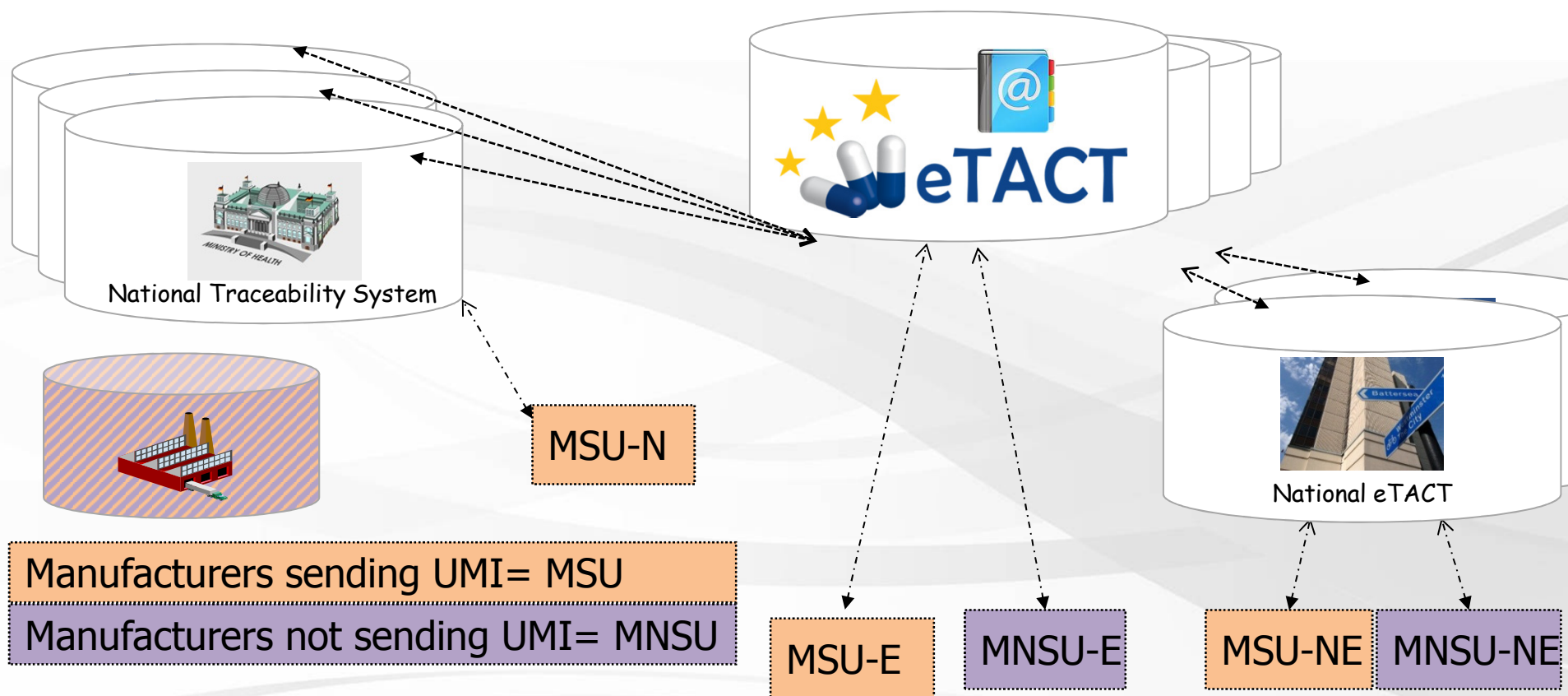BATCH (10): 144GC1214

EXPIRY (17): 111130

NHRN(90): 049-75241456

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Architecture

Queries from authenticated stakeholders and patients

eTACT

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Manufacturers landscape & interactions

National Traceability System

National eTACT

MSU-N

Manufacturers sending UMI= MSU

Manufacturers not sending UMI= MNSU

MSU-E

MNSU-E

MSU-NE

MNSU-NE

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Scope

- Any pharmaceutical products
- Actors:
  ⇨ Any registered business stakeholders
  ⇨ Authorities
  ⇨ Patients
- 36 member states of the European Pharmacopoeia and beyond
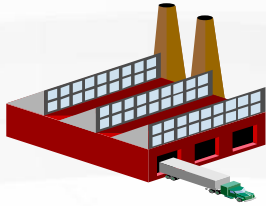- Secondary packaging
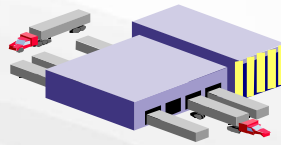
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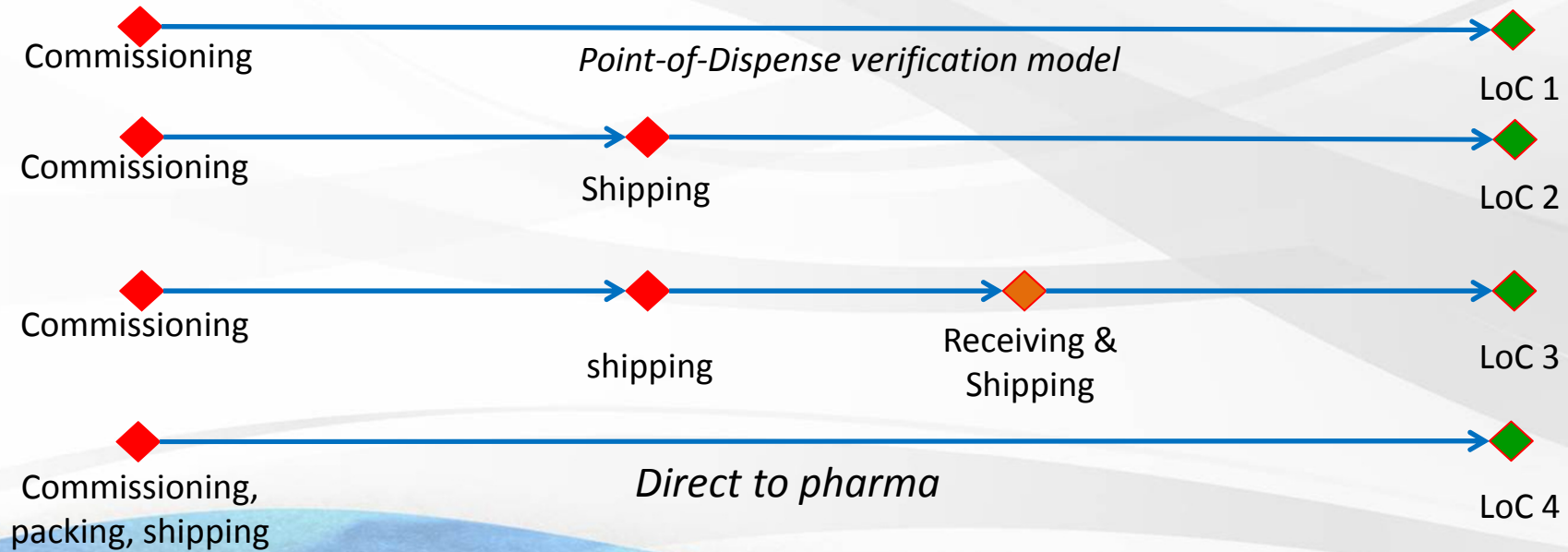
Level of Confidence (LoC)

Manufacturer B   Distributor A   Pharma A
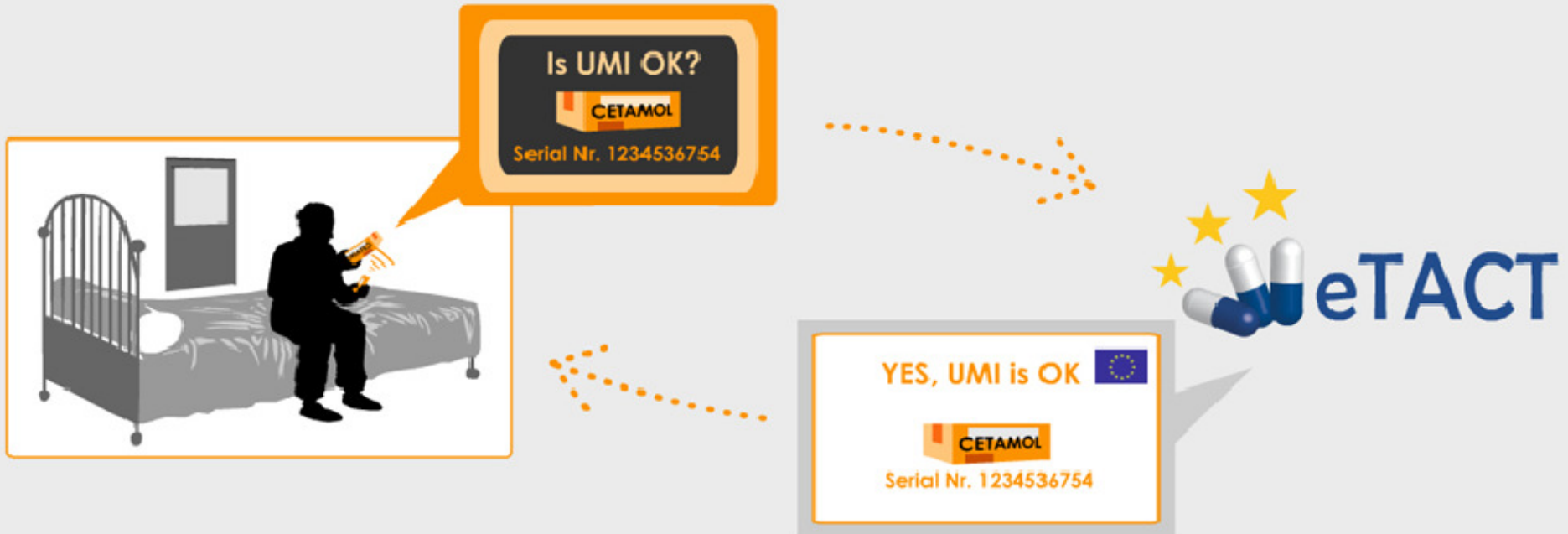
Commissioning   *Point-of-Dispense verification model*   LoC 1

Commissioning   Shipping   LoC 2

Commissioning   shipping   Receiving & Shipping   LoC 3

Commissioning, packing, shipping   *Direct to pharma*   LoC 4

VERIFYING UMIs BY MOBILE PHONE

Is UMI OK?
CETAMOL
Serial Nr. 1234536754

YES, UMI is OK
CETAMOL
Serial Nr. 1234536754

eTACT
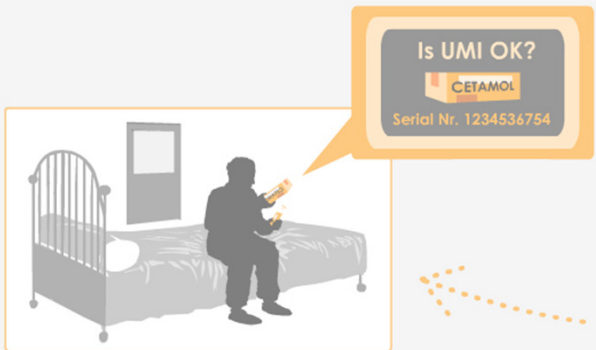
In case the UMI exists in the repository:

Verified UMI
Status: "UMI Known in the eTACT service"
Product Name
Product Brand Owner
Product Expiry Date
Product Batch
Disclaimer

In case the UMI does not exist in the repository or the UMI exists but was not dispensed:

Verified UMI:
Status: "UMI unknown in the eTACT service"
or "UMI registered but not dispensed"
Disclaimer

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or the UMI exists but was

Verified UMI:
Status: "UMI unknown in the eTAC
or "UMI registered but not dispen
Disclaimer

VERIFICATION RESULTS

Product name:	Simvastatin Lab B
Product brand owner:	Lab B
Status:	Counterfeit (on 11/10/06 15:57:13)

DETAILS

| Product code: | 7680303330016 |
| Serial number: | 8877212564 |

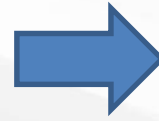## DISCLAIMER

Provided by EDQM without warranty

Hospital pharmacy
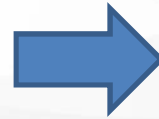
Hospital pharmacy

eTACT

Business rule management system

Separate logical decisions from the application

RULES   RULESENGINE   APPLICATION

Dispensing: if UMI status= « decommissioned » then « This box cannot be dispensed… »

This box cannot be dispensed…

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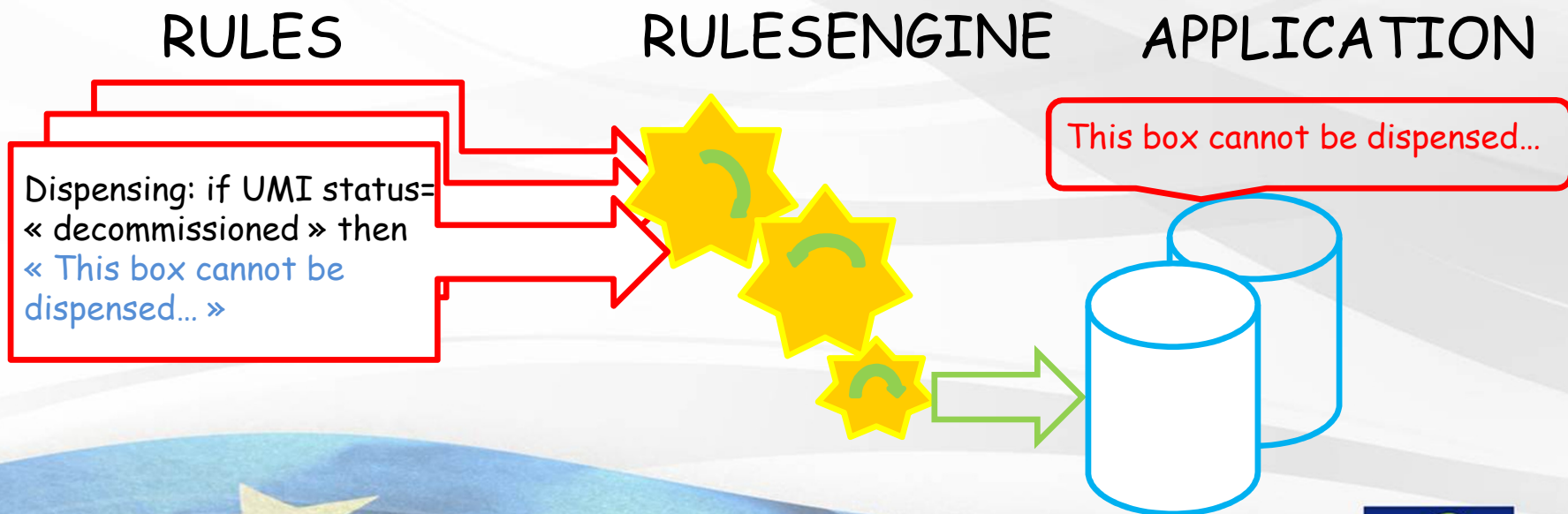
Participants from authorities and supply chain stakeholders / 53 requests for functionalities

Demo system 24.5%

Production system 39.6%

To be discussed 34.0%

No action 1.9%
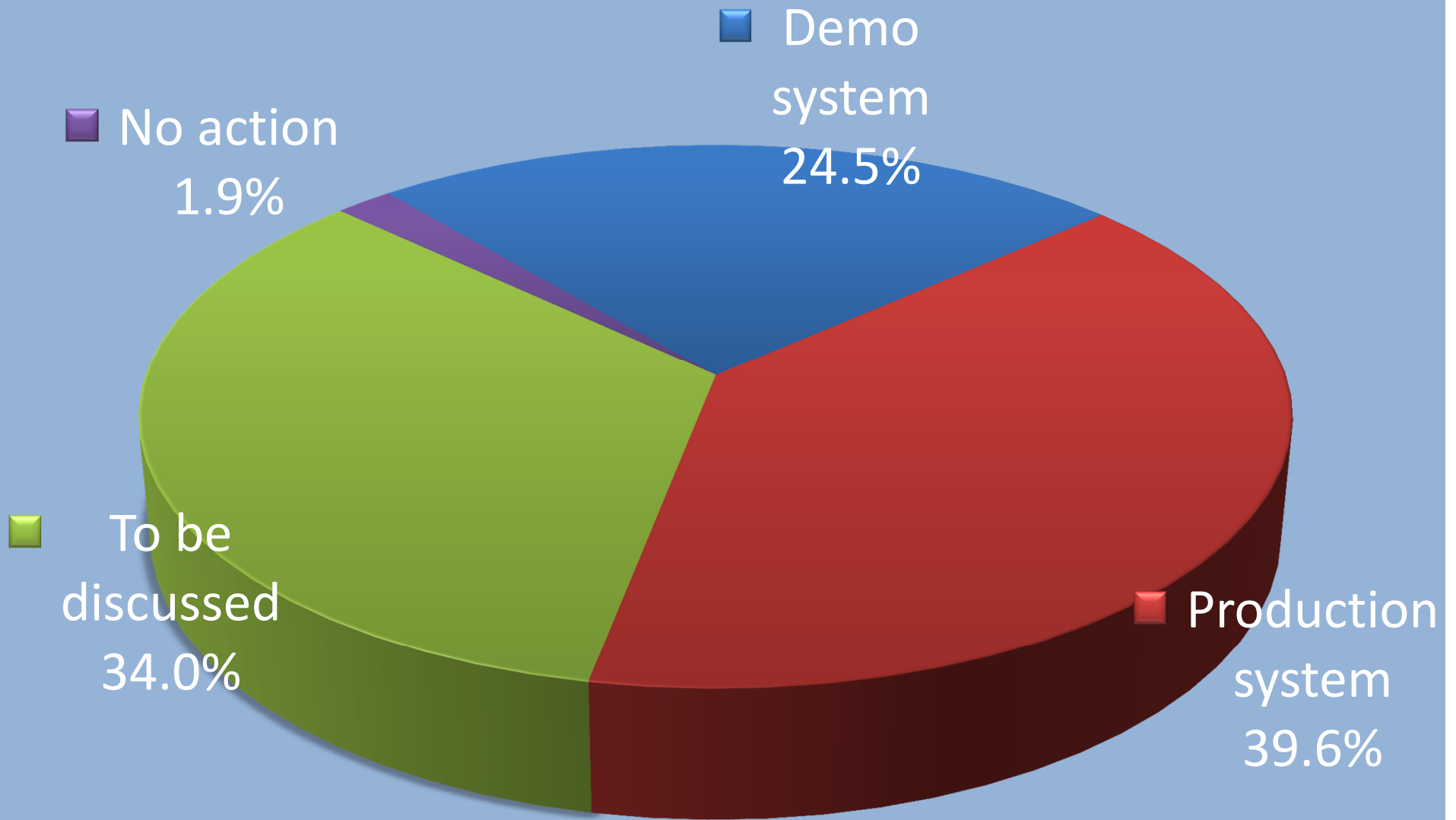
Functionalities by category (%)
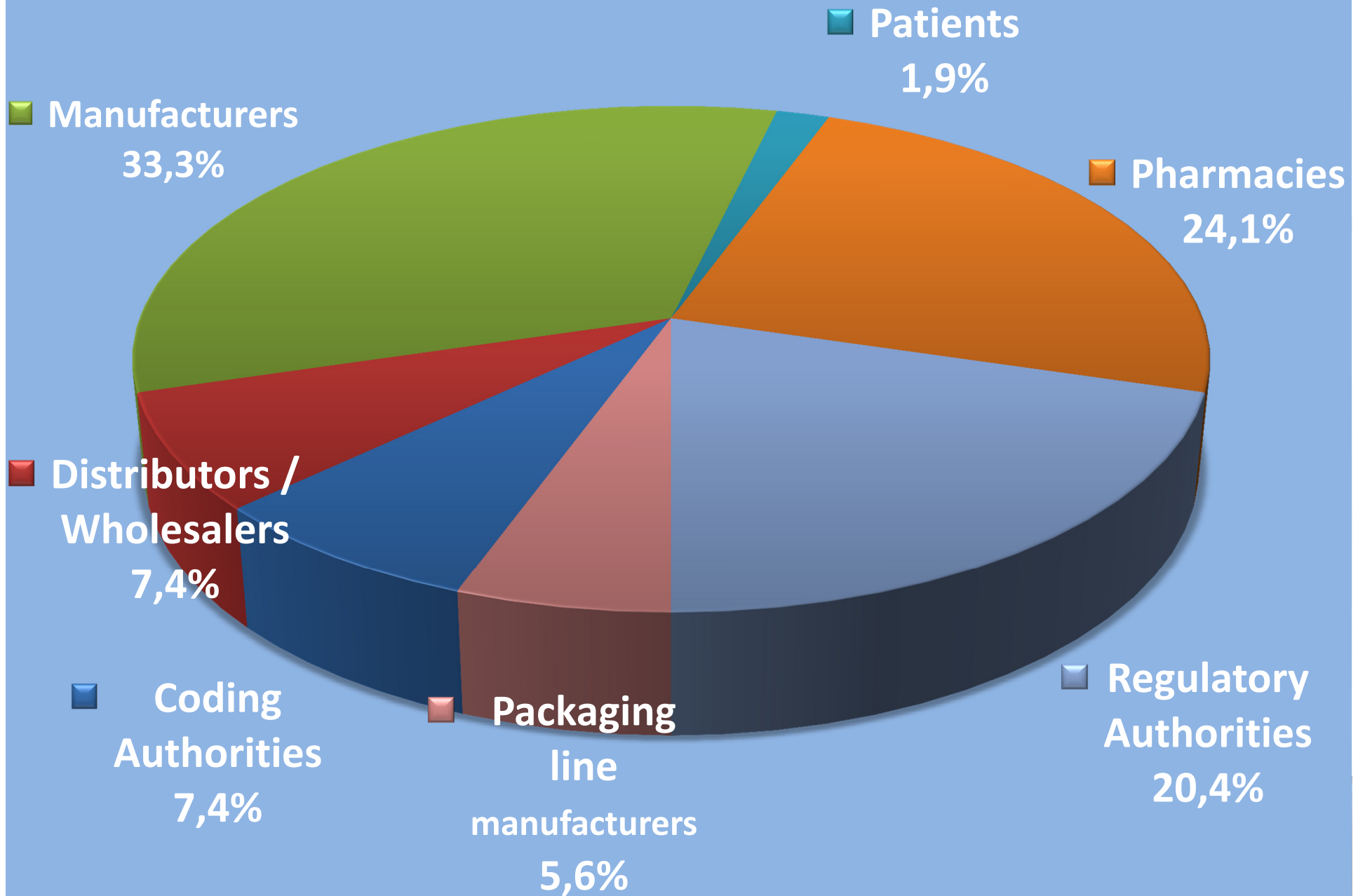
- Patients 1,9%
- Pharmacies 24,1%
- Manufacturers 33,3%
- Distributors / Wholesalers 7,4%
- Coding Authorities 7,4%
- Packaging line manufacturers 5,6%
- Regulatory Authorities 20,4%

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General overview of eTACT

Phase 1:
Concept
development

2a: System
development

2b:
Workshops

Phase 3:
Service
development

Phase 2: Live demo
2010 – 2012

2009-2010
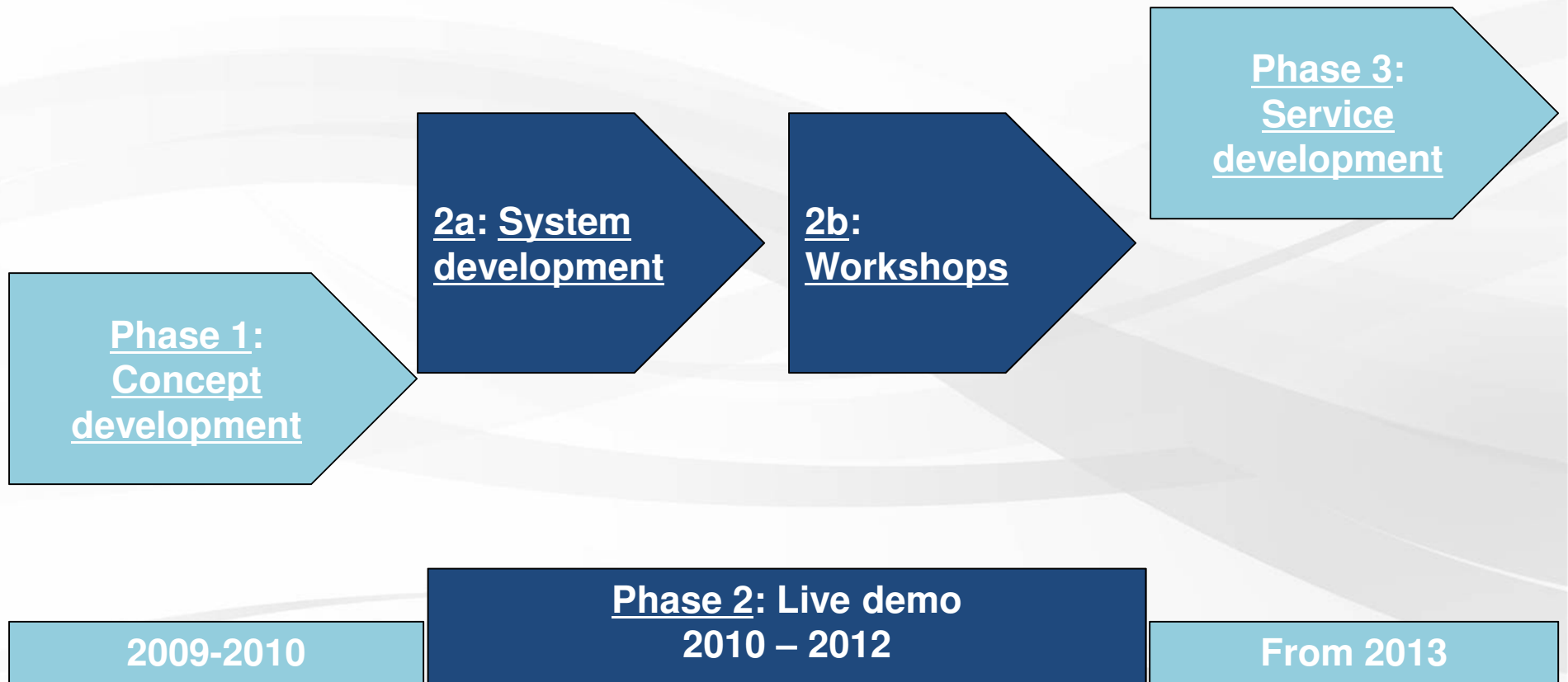
From 2013

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Benefits...

- Creates a harmonised approach
  - ⇨ Inter-operable and flexible

- Protects confidentiality of data
  - ⇨ Public governance

- Allows patients to verify their medicines

...to protect Public Health