

Council of Europe

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



**EDQM anti-counterfeiting
Traceability service for
medicines**

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Global GS1 Healthcare Conference – 4-6 Oct. 2011, Amsterdam, NL



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The Council of Europe

- Founded in 1949
- Development of European common and democratic principles
- 47 member countries
- Headquarters in Strasbourg
- Core values :
 - protection of human rights
 - pluralist democracy & the rule of law



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

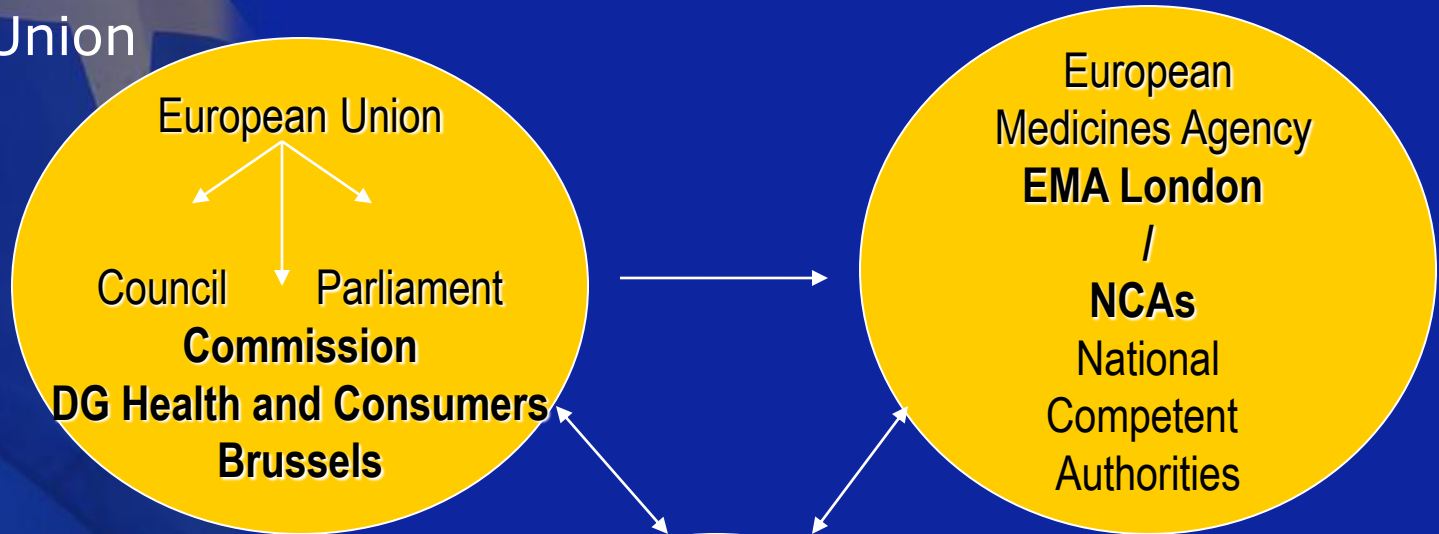
- A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)
- Mission: to contribute to a basic human right : access to good quality medicines and healthcare



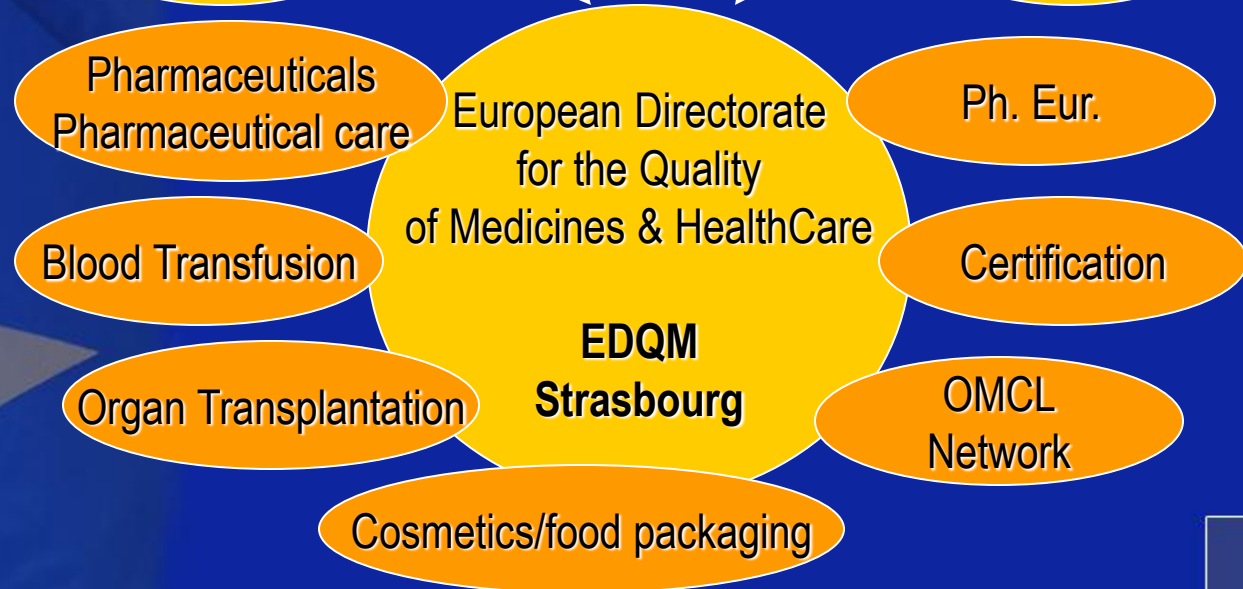
EDQM contribution -European Regulatory Network

• European Authorities

• European Union



• Council of Europe



EDQM anti-counterfeiting strategy

Multiple actors / multifocal threat

Multi-level (“holistic”) strategy

- Custom level (importation)
- Legal instruments (pharmaceutical crime)
- Pharmaceutical level
 - Inspection
 - Testing (detection / provide enforcement officers with evidence)
 - Surveillance of pharmacovigilance reports from users
 - Packaging (traceability of serialised items)





INTRODUCTION

The Council of Europe drafted a convention which constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health (**MEDICRIME Convention**).

The Council of Europe has long been concerned about the absence of harmonised international legislation, non-deterrent sanctions that were not proportionate to the harm caused to patients, and the involvement of criminal organisations which operate across borders.

NEWS

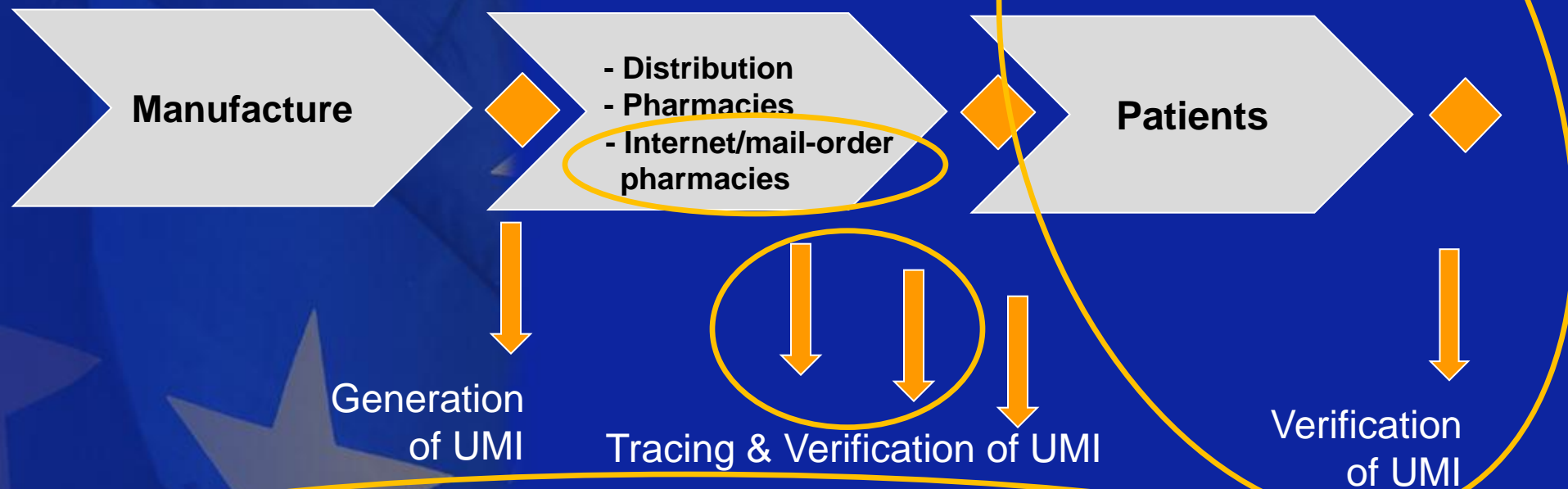
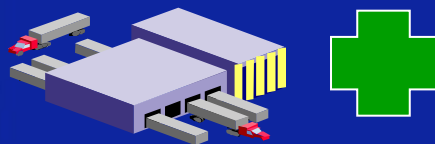
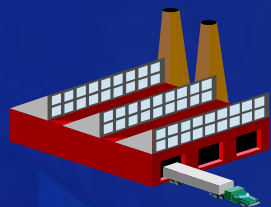
■ International High-Level Conference:

The Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (Medicrime Convention) - Countering the spread of counterfeit medical products - Moscow, 26-28 October 2011: [More Information](#)

■ **The MEDICRIME Convention** was adopted by the Committee of Ministers of the Council of Europe on 8 December 2010: [Press Release](#)



Proposed EDQM Traceability service



Governance: EDQM as a intergovernmental organisation guaranteeing sustainable confidentiality of data



EU Pharma package

- Amended Dir 2001/83/EC (adopted – EP 16/02/2011, EU Council 27/05/11) on prevention of the entry into the legal supply chain of falsified medicinal products

Safety features making possible

- for wholesale distributors and pharmacists
- to verify authenticity and identify individual packs



EDQM Traceability Service

NOW



1D barcode coding for product number only

NEXT



(01)03700011234562(21)01234XY78901234567AB(17)100201(10)00345E(90)03412345678



GS1 GTIN
(product number)



B. Serial Number



C. Expiry date



D. Batch Nr.

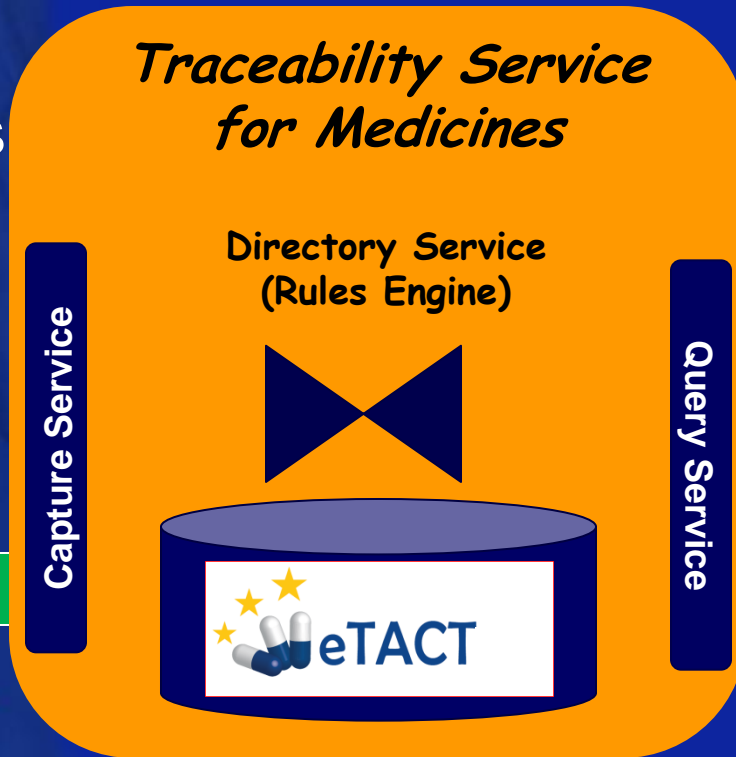
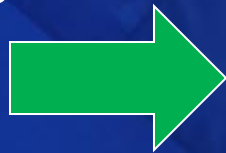
EDQM AI with variable length (max. 20 digits). The first 3 digits are the GS1 country code. The rest include the national product code.

UMI



Directory vs. Repository

1 - Manufacturers uploading their UMIs



UMI Queries:
pharmacies,
patients,
customs, etc.

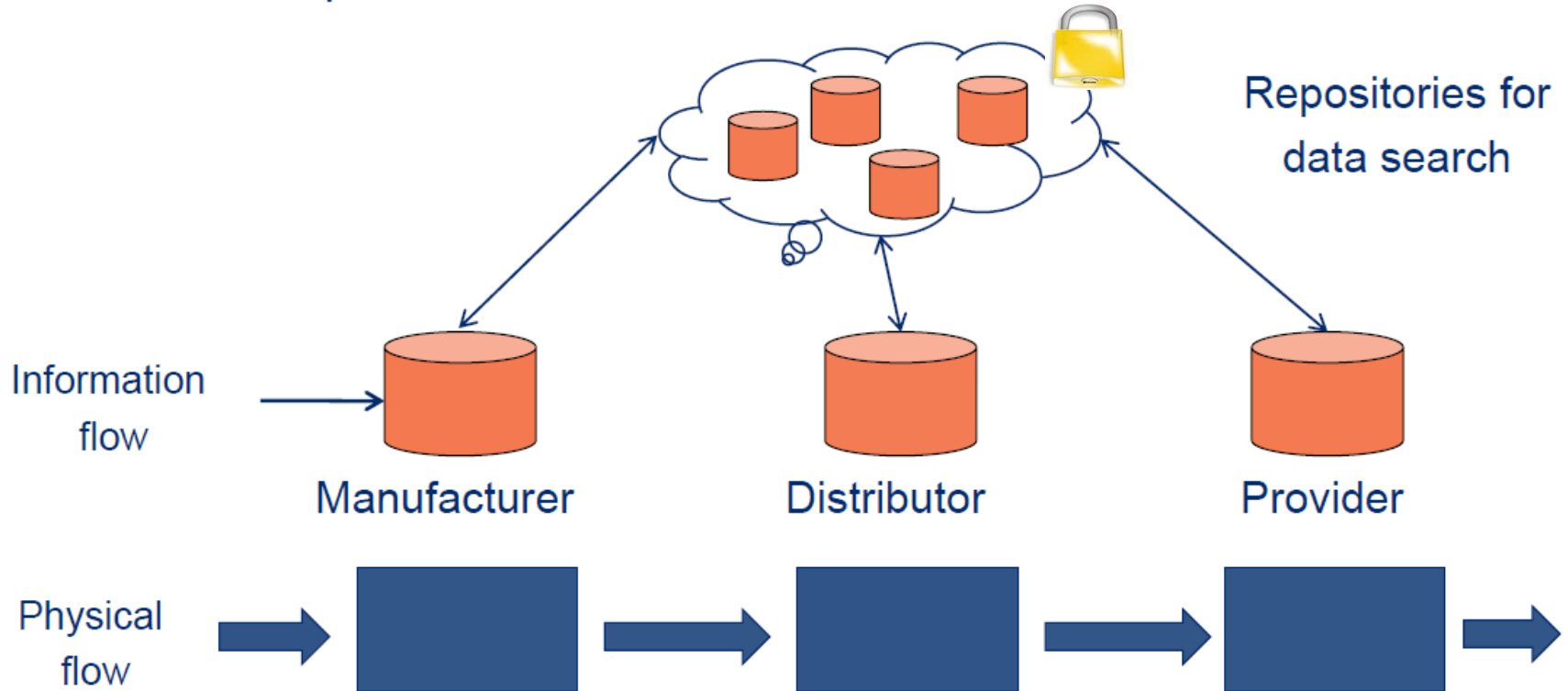
2 – Manufacturers with own UMI repositories



GS1 Healthcare Information sharing model 3

Real time (one source)

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



Scope of the EDQM project

- Any Pharmaceutical products on a voluntary basis
- Any registered business stakeholders within distribution / patients / authorities
- Any of the 36 member states of the European Pharmacopoeia and beyond if interested
- Secondary packaging (e.g.: folding box, bottle)



General overview on EDQM project

Phase 1:
Concept
development

2a: System
development

2b:
Workshops

Phase 3:
Service
development

26-27 Jan 2012:
EDQM workshop

Phase 2: Live demo
Apr 2010 – 2012

Dec 09-March 2010

From 2012



Aim of the workshops

- Showing functionalities of the demo system by simulating the lifecycle of pharmaceutical packs in the supply chain
- Audience: pharmaceutical authorities and business operators from the supply chain
- Objectives:
 - collecting comments to fine tune the concept
 - Discussing with stakeholders on the suitability of:
 - technical approach
 - project governance
 - implementation strategy

What will be shown in the eTACT live demo

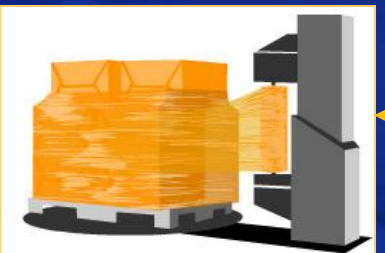
- Simulation of the supply chain
 - A real ERP for manufacturers
 - A real Point of Sales (PoS) system for the retail pharmacies
 - A set of applications simulating other actors and patients
- Business intelligence tools providing advanced reporting and analytics capabilities (business space)

What will be shown in the eTACT live demo (2)

- Core eTACT system able to collect information about the entire lifecycle of serialized pallets, cases, and individual items as they are commissioned, moved through the supply chain, dispensed, and finally decommissioned



D



E



F



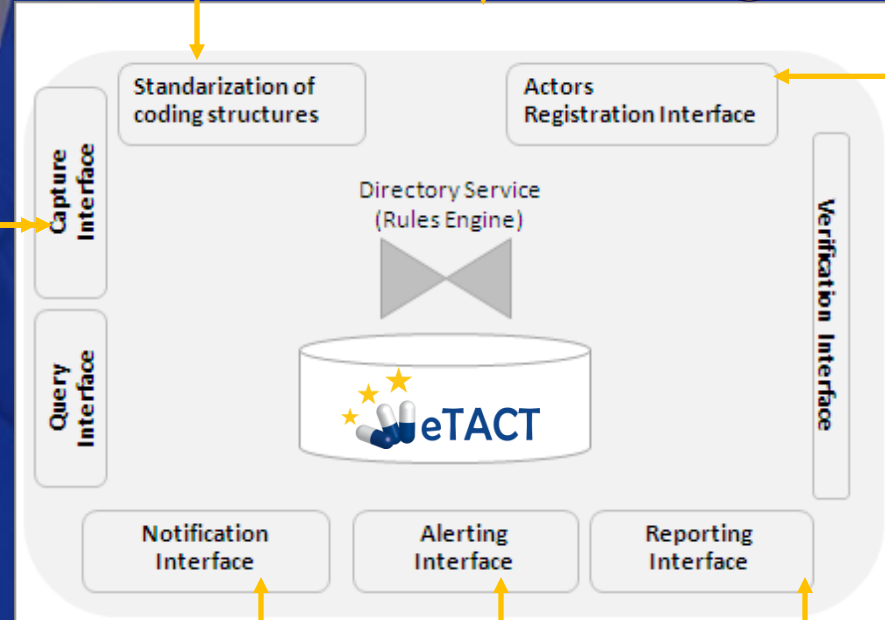
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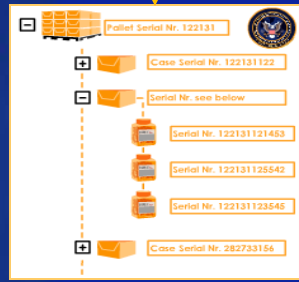
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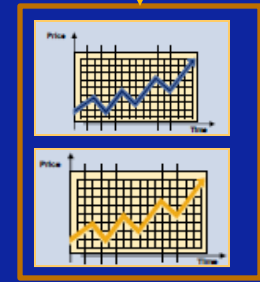
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I

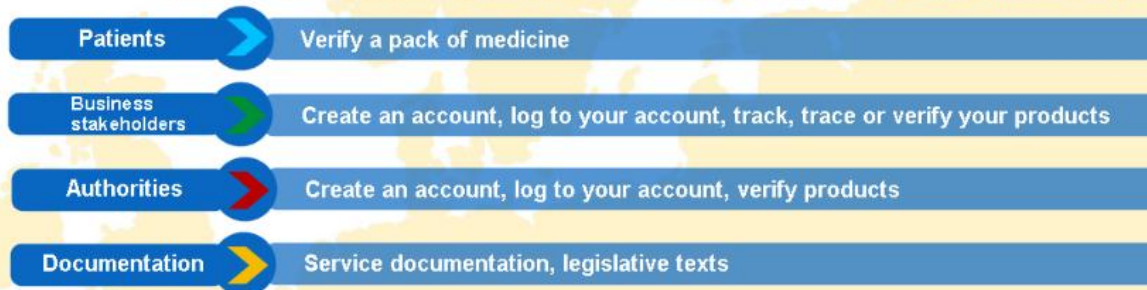
A bit of flavour from the eTACT system



eTACT

eTACT is the name for the service provided by EDQM for verifying whether packs of medicines distributed in the supply chain are genuine. The services allows as well authorities and business stakeholders increasing the transparency of the supply chain using tracking and tracing tools they can use on a voluntary basis.

Together with the Council of Europe MEDICRIME Convention which is the first instrument to criminalise counterfeiting of medical products and similarly dangerous crimes, while providing a framework for proportionate sanctions, victim protection and international cooperation, and a number of other projects including a "fingerprint" database for active pharmaceutical ingredients and multisectorial training for government officials, the eTACT project is part of a holistic strategy to combat counterfeited medical products in order to protect Public Health.



The EDQM (European Directorate for the Quality of Medicines & HealthCare) is a leading organization that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognized as a scientific benchmark world-wide. The European Pharmacopoeia is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues. Please visit WWW.EDQM.EU for more information. The EDQM is part of the Council of Europe, a political organization set up in 1949 to promote democracy and human rights continent-wide. The Council of Europe also develops common responses to social, cultural and legal challenges in its 47 member states. Please visit WWW.COE.INT for more information.



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The eTACT service is maintained and operated by the EDQM. Access to the general public is granted for verification of dispensed medicines. The content of the service run as a directory is provided by the brand owners, item owners or competent authorities. For this reason, the EDQM accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this directory.





eTACT

Business Stakeholders

Learn
how to use
this service



Register
now!

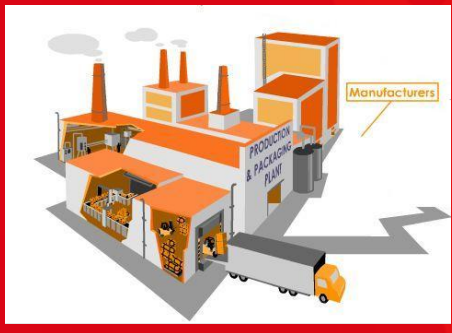
Logon

Password

Login

Directory of
products
tracked by
the EDQM





Manufacturer
product

Actor
registration

Product
registration



Example of actors interfacing



Internet
Pharmacy



Receive & Verify



Dispense



Decommission



Internet Pharmacy





Dispense

Select Order






Scan UMIs

Dispense

UMIs ready for dispense: 1

	Compliant:	1
	Compliant - Near to Expire:	0

UMIs not ready for dispense: 0

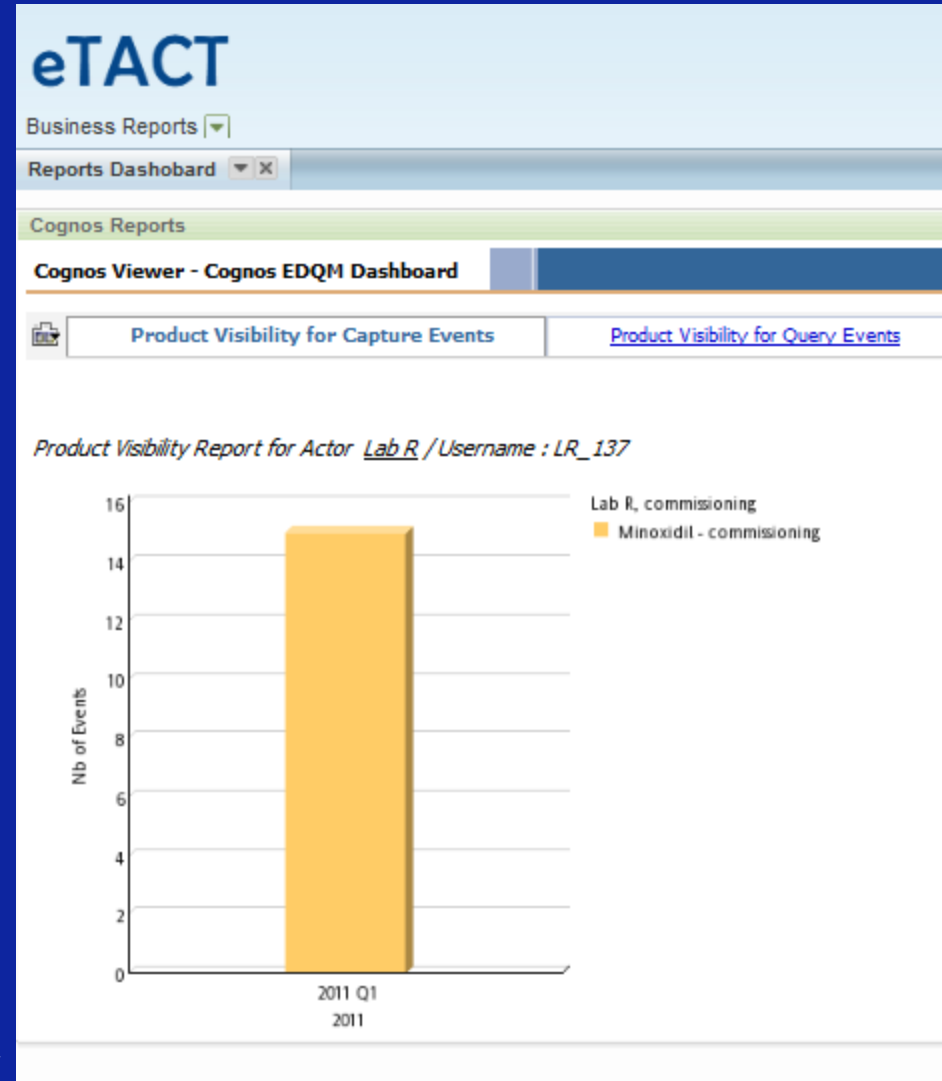
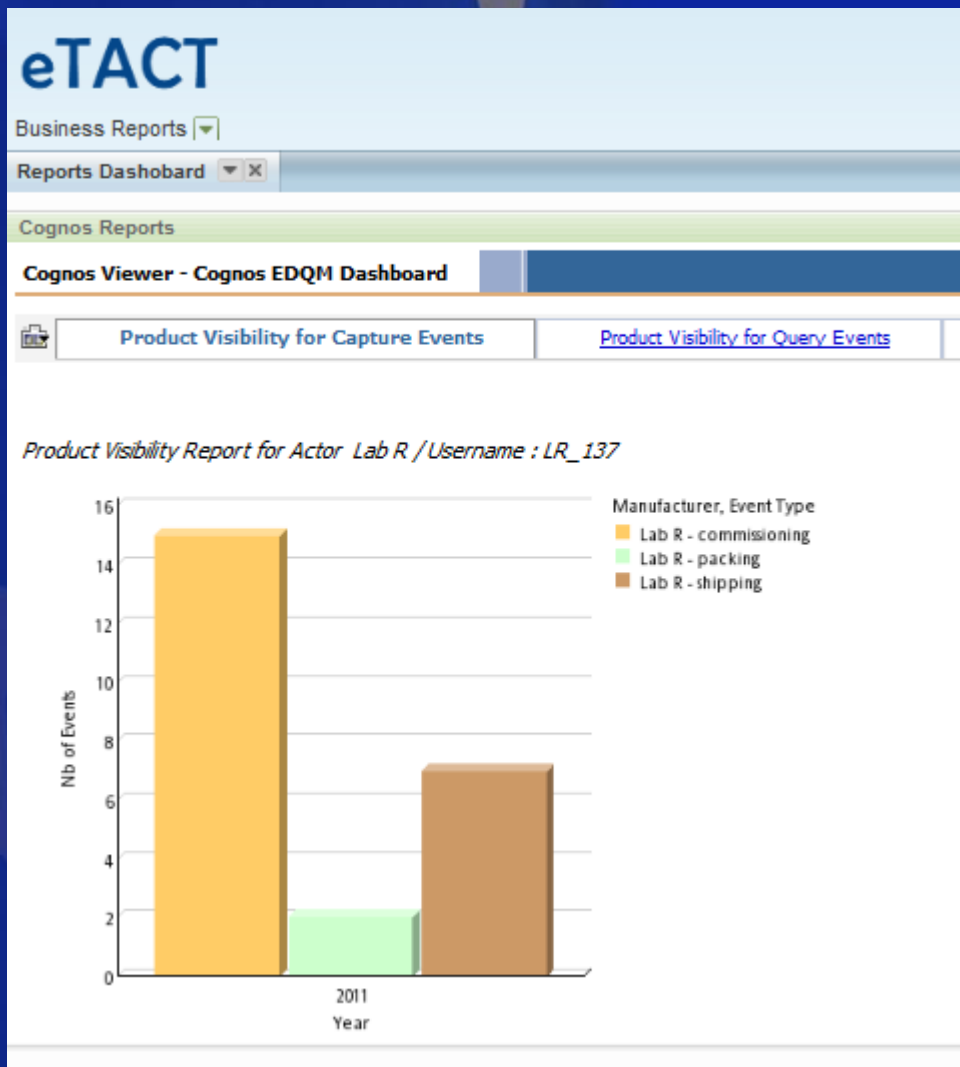
	Expired:	0
	Not Ready:	0
	Counterfeit:	0
	Suspicious:	0
	Status unavailable:	0

Dispense

Back

>> Home

Business intelligence tools



Business intelligence tools (2)

Welcome LR_137 | Help | Logout

Manage Business Spaces

LR_137 Log Off  Launch  About

[Packaging](#)

[Service Usage - Commissioning](#)

[Service Usage - Decommissioning](#)

Service Usage - Commissioning Events

Year	Capture Source Location	GLN	Event Time	UMI EPC	Product
2011	Lab R	7601001394148	Feb 20, 2011 5:57:08 PM	urn:epc:id:umi:7680209000037.0D620Y34K7XM77YYM491 urn:epc:id:umi:7680209000037.0ECSWDK0AY152DTMGK8C urn:epc:id:umi:7680209000037.0ETT30215C5M1WR17RNG urn:epc:id:umi:7680209000037.0EX70W9VGH5F3G603N7R urn:epc:id:umi:7680209000037.0FSK8NFM7KT2E5GN3EA urn:epc:id:umi:7680209000037.0GHV3HSE9FGG3NP6SNRX urn:epc:id:umi:7680209000037.0GRWN801GWPKPPPE9DPH urn:epc:id:umi:7680209000037.0HHGTG7F8GCM0ENX046X urn:epc:id:umi:7680209000037.0HPDRX55PGS6FCDF1EP9 urn:epc:id:umi:7680209000037.0HRPYNMA24A4K28V46AG urn:epc:id:umi:7680209000037.0KVFP8KRA14TG91RK65S urn:epc:id:umi:7680209000037.0MS8YE4TFM9H2KGV78GT urn:epc:id:umi:7680209000037.0NEHR3STPY11H00WKEXA urn:epc:id:umi:7680209000037.0RREHR7E51REVDSABK1X urn:epc:id:umi:7680209000037.0T49MP6PFBN230SCV12W	Minoxidil

eTACT

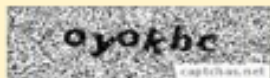
Patients

Verification interface

Input mode selection

UMI only Composed input

UMI:



Check

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**Looking forward to seeing
stakeholders in Strasbourg
for eTACT workshops!**



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