



The EDQM anti-counterfeiting Traceability service for medicines

GS1 Healthcare conference

1-3 April 2014, Seoul

François-Xavier Lery©2014 EDQM, Council of Europe. All rights reserved.

edqm
European Directorate
for the Quality
& HealthCare
Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

The eTACT project

- ⇒ What is the background to the project?
- ⇒ The eTACT project
- ⇒ Patient access
- ⇒ Summary

CoE/EDQM anti-counterfeiting strategy

Multisectorial training

Medicrime

Inspection Testing



Medicrime: signatures and ratifications

Signatures

■ Arménie	20/09/2012
■ Autriche	28/10/2011
■ Belgique	24/07/2012
■ Chypre	28/10/2011
■ Danemark	12/01/2012
■ Finlande	28/10/2011
■ France	28/10/2011
■ Allemagne	28/10/2011
■ Hongrie	26/09/2013
■ Islande	28/10/2011
■ Italie	28/10/2011
■ Liechtenstein	01/11/2011
■ Luxembourg	22/12/2011
■ Moldova	20/09/2012
■ Portugal	28/10/2011
■ Russie	28/10/2011
■ Espagne	08/10/2012
■ Suisse	28/10/2011
■ Turquie	29/06/2012
■ Ukraine	28/10/2011
■ Guinée	10/12/2012
■ Israël	28/10/2011
■ Maroc	13/12/2012

Ratifications

■ Hongrie	09/01/2014
■ Espagne	05/08/2013
■ Ukraine	20/08/2012

	Signatures des États membres du Conseil de l'Europe
	Signatures des États non-membres du Conseil de l'Europe
	Ratifications de la Convention Médicrime



2014@EDQM, Council of Europe. All rights reserved.

The eTACT project

⇒ What is the background to the project?

⇒ The eTACT project

⇒ Patient access

⇒ Summary

Expected benefits...

- A harmonised approach for Europe
 - ⇒ Inter-operable and flexible by using standards (ISO, GS1 (Datamatrix, EPCIS), EU GMP Annex 11, GAMP...)
- Protects confidentiality of data
 - ⇒ Public governance
- Allows patients to verify their medicines

...to protect Public Health

Regulatory background

- EU Falsified Medicines Directive (FMD) 2011/62
 - Safety features
 - ⇒ Identifier that is readable by wholesale distributors and pharmacists
 - ⇒ Tamper-proof device (outside scope of eTACT)
- National European countries: Italy Bollino, Belgium/Greece Aegate, French NTIN CIP, Turkey ITS, Serbia GS1 traceability project

Business environment

- ESM project
- securpharm
- Common wish to avoid multiple/not interoperable systems
- Need to control costs and/or get RoI

Regulatory & business: EU Impact study ⇒ Delegated Act 2014/15

- Unique identifier harmonised
 - Manufacturer product code
 - Serial number
 - National reimbursement number, if present
 - Batch number
 - Expiry date
- 2D barcode (data matrix)



EU Impact study (cont'd)

- Systematic verification of the safety features at the dispensing point
- Risk-based verification by wholesale distributors when:
 - product not obtained from manufacturing authorisation holder or marketing authorisation holder
 - return from another wholesale distributor or from a pharmacy

EU Impact study (cont'd)

- Establishment and management by stakeholders
 - Stakeholders have to guarantee protection of commercial, confidential and personal data
- Supervision by relevant authorities
 - full access to the repository system
 - competent authorities can supervise its functioning

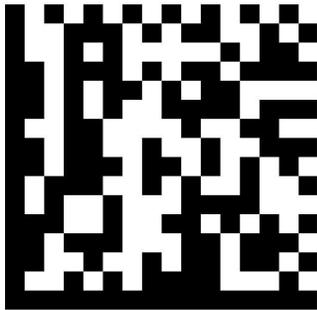
Challenges for interoperability

- Within EU:
 - Italian Bollino system 100% publicly governed / reimbursement
 - Authorities supervision at national level / pan-European level

Challenges for interoperability (2)

- Beyond EU
 - Public gouvernance + full T&T in Turkey and Ukraine
 - Competent authoities to decide on governance
- Beyond Europe: which interoperability standard?

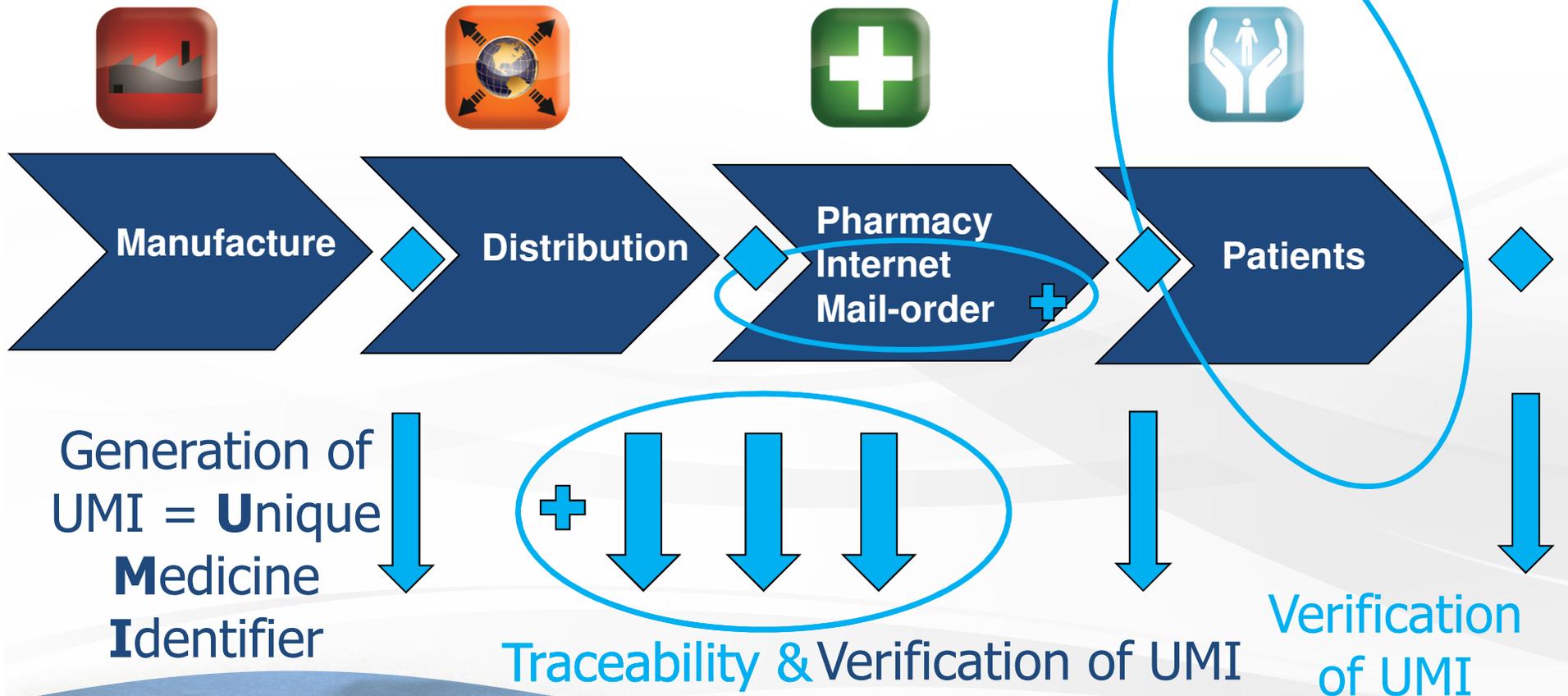
eTACT Unique Medicine Identifier (UMI)



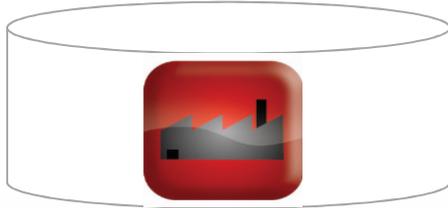
GTIN (01) : 07680303330054
SERIAL (21) : 0402748246
Batch (10) : 144GC1214
EXPIRY (17) : 111120
NHRN (710) : 049-75241456



EDQM Traceability service - eTACT



Flexible system architecture

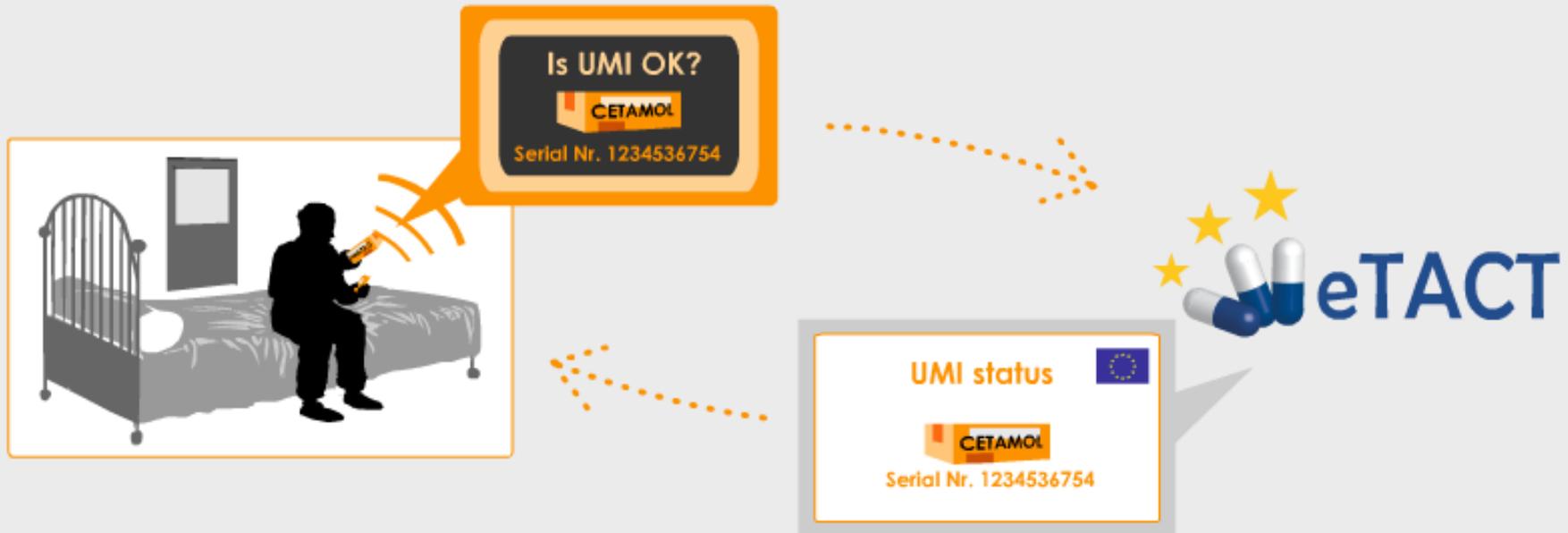


- Likelihood of decentralised system in Europe with national databases and pan-European hub/proxy/gateway
 - Data capture
 - Queries from authenticated stakeholders
 - Queries from patients
 - Links with reimbursement/pharmacovigilance?

The eTACT project

- ⇒ What is the background to the project?
- ⇒ The eTACT project
- ⇒ Patient access
- ⇒ Summary

VERIFYING UMIs VIA MOBILE PHONE



In case the UMI has been dispensed and is valid:

Message: "Medication compliant"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Dispensed"
Disclaimer

In case the UMI has not been dispensed or has been flagged as under investigation/suspicious/counterfeit/recalled/expired...:

Message: "Please contact your pharmacist"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Not yet dispensed/Counterfeit/....."
Disclaimer

In case the UMI does not exist

Message: "Please contact your pharmacist"
Status: "UMI not covered by the eTACT service"
Disclaimer

VERIFYING UMIs VIA MOBILE PHONE



In case the UMI has been dispensed and is valid:

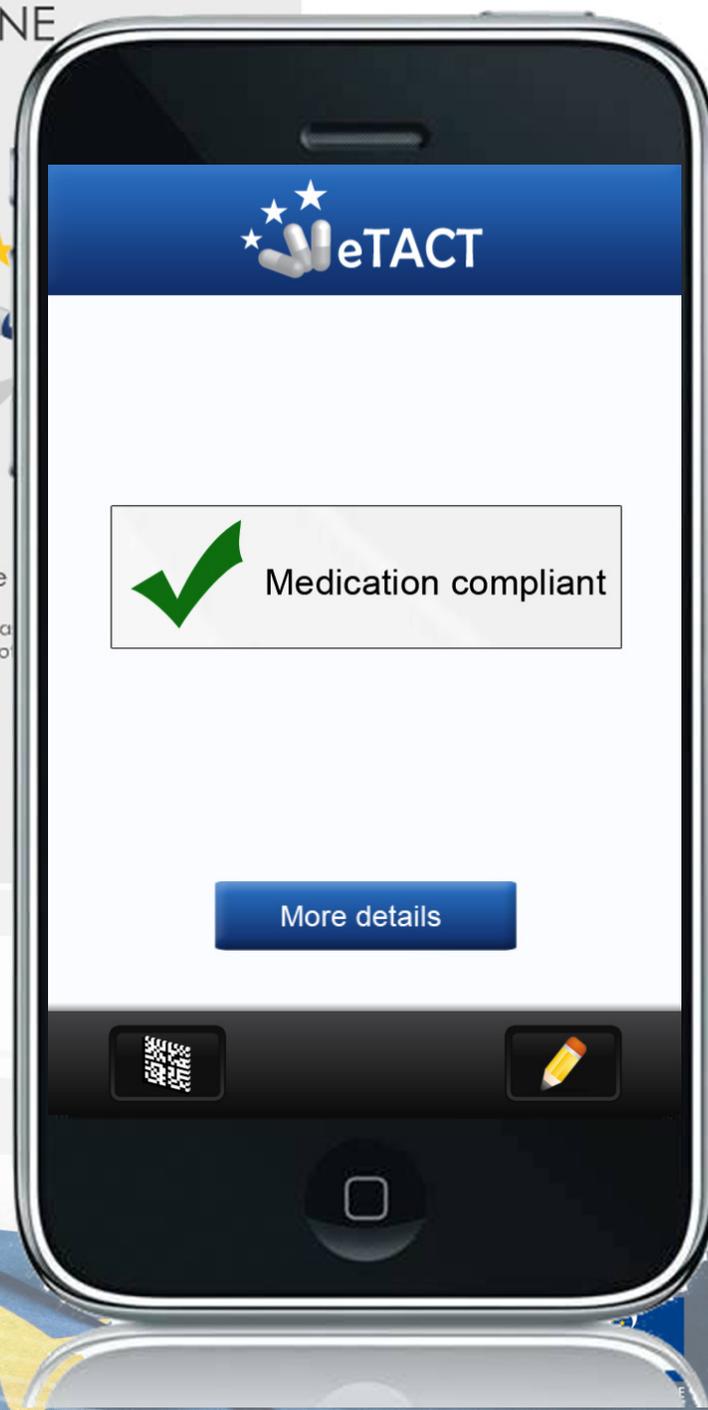
Message: "Medication compliant"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Dispensed"
Disclaimer

In case the UMI has not been dispensed or has been flagged as under investigation/suspicious/counterfeit/recalled/expired...:

Message: "Please contact your pharmacist"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Not yet dispensed/Counterfeit/...."
Disclaimer

In case the

Message: "Plea
Status: "UMI no
service"
Disclaimer



VERIFYING UMIs VIA MOBILE PHONE



In case the UMI has been dispensed and is valid:

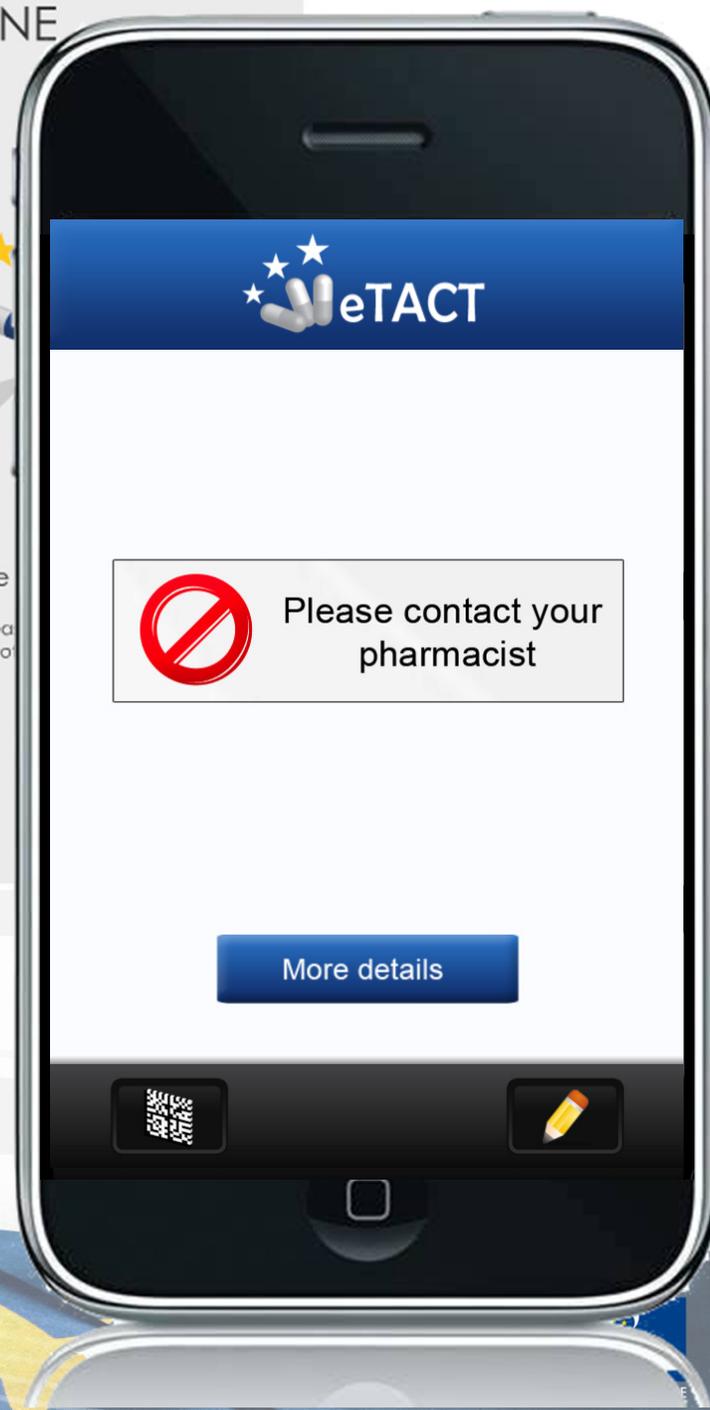
Message: "Medication compliant"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Dispensed"
Disclaimer

In case the UMI has not been dispensed or has been flagged as under investigation/suspicious/counterfeit/recalled/expired...:

Message: "Please contact your pharmacist"
Product Name
Product Brand Owner
Product Code
Serial Number
Status: "Not yet dispensed/Counterfeit/...."
Disclaimer

In case the

Message: "Plea
Status: "UMI no
service"
Disclaimer



The eTACT project

- ⇒ What is the background to the project?
- ⇒ The eTACT project
- ⇒ Patient access
- ⇒ Summary

Expected benefits...

- A harmonised approach for Europe
 - ⇒ Inter-operable and flexible by using standards (ISO, GS1 (Datamatrix, EPCIS), EU GMP Annex 11, GAMP...)
- Protects confidentiality of data
 - ⇒ Public governance
- Allows patients to verify their medicines

...to protect Public Health

Thanks for your attention



François-Xavier Lery©2014 EDQM, Council of Europe. All rights reserved.

