The European Union's Directive on falsified medicines

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Agenda

Background

Detailed rules for a unique identifer

Next steps

Background: the new European Union (EU) Directive 2011/62/EC - main contents

Obligatory safety features	*Actors in the supply chain*	*Quality of active substances*	*‚Online pharmacies‘*

Background: new rules on 'safety features'

- The rules for ‚safety features' for medicines are going to be harmonised at EU level
- Legislator has mandated the Commission to work out all technical aspects in a 'delegated act'
- This delegated act is scheduled for adoptoin in 2014

Background: Content of the safety features

a. **Unique identifier on the packaging:**
   - Authenticity feature identifying individual packs ('serialisation number')
   - „Repositories system“: database where the serialisation numbers are stored
   - Verification

b. **Anti-tampering device**

Background: Scope of the safety features

- ***All prescription medicines*** *(with possibility of exception on the basis of risk)*
- ***Over-the-counter medicines excluded*** *(with possibility of inclusion on the basis of risk)*
- ***Inclusion / exclusion by way of Commission legal***

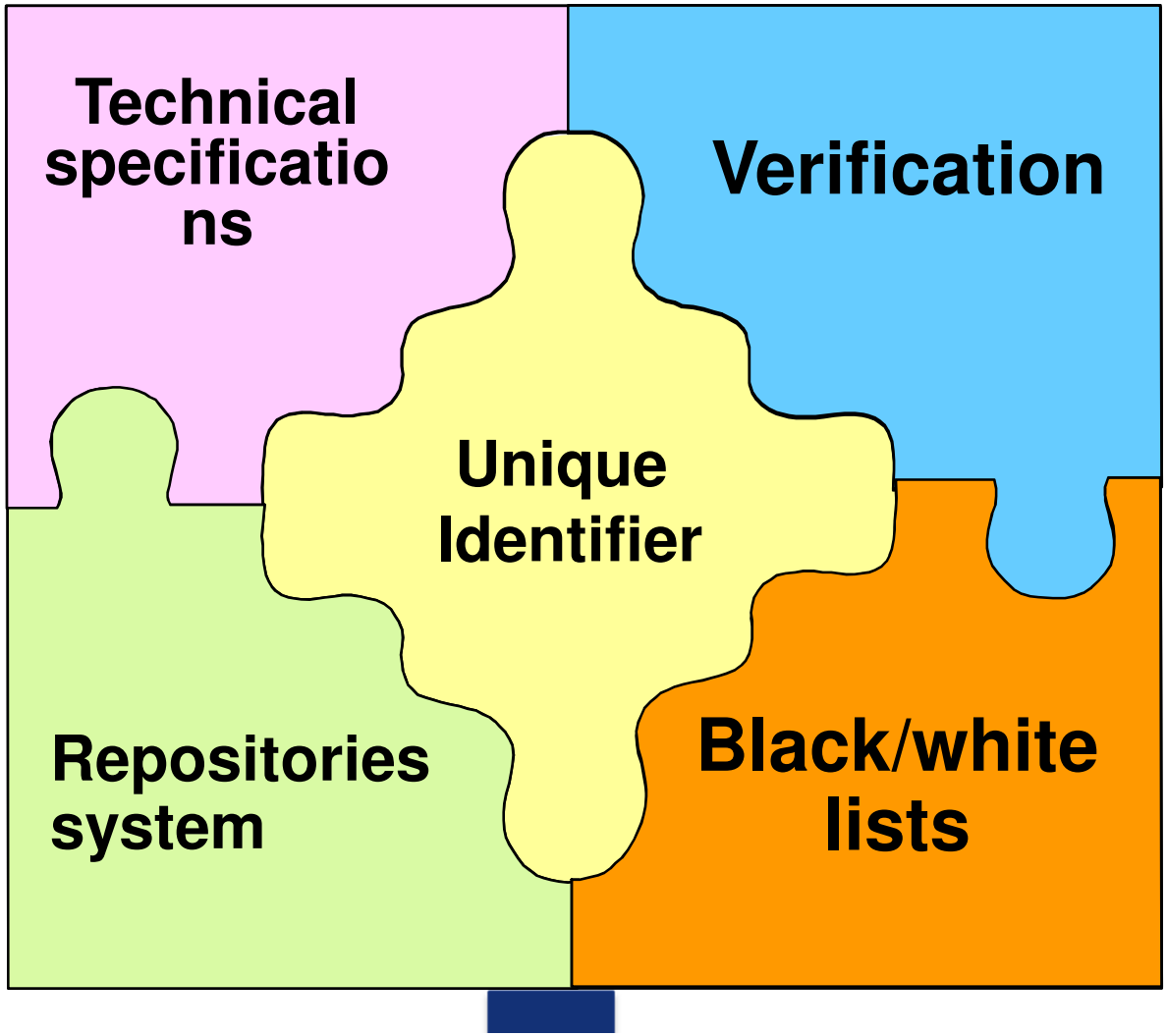
Background: concept paper on the unique identifier

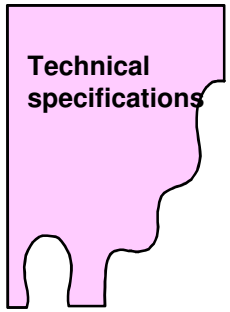
Public consultation on the detailed rules for a unique identifier ended on 27 April 2012

About 90 contributions (published on Commission website)

- *analysis on-going.*
- *consultation of Member State experts*
- *impact assessment ongoing*

Detailed rules for a unique identifier





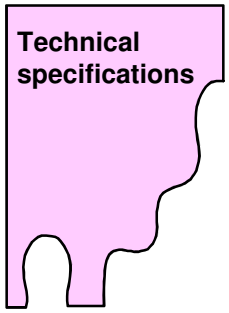
Detailed rules for a unique identifier

Policy option No 1/1:

Leaving the choice of the technical specification to the individual manufacturer

Policy option No 1/2 :

Harmonisation through regulation

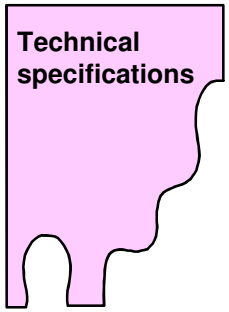


Stakeholders' input
Policy option No 1/2:
Harmonisation through regulation

Benefits:

- Ensure **interoperability across EU MS** of the repository system between different manufacturers and MS
- **Uniform application** of the system across the EU
- Allow **common standard readers and software**
- **Minimal costs for companies which already have a system of serialization in place**
- Crucial for WD and pharmacies to receive products with **harmonised machine readable data**

→ Unanimously in favour of this option



Stakeholders' recommendation

- Use established harmonised and internationally recognised standards for identification of products e.g use of ISO standards which are overarching standards such as GS1

Benefits:

1) It facilitates the uniqueness of the medicine codes on a global scale
2) It is suggested to reach a balance among interoperability between countries and national requirements

Technical specifications

Regulation of the composition of the unique identifier

Manufacturer product code (+prefix code)	Random number= serial number

or

Manufacturer product code (+ prefix of the country)	Serial number of the pack	National reimbursement number	Expiry date	Batch number

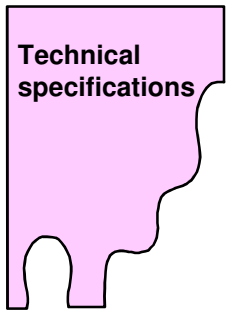
\+ + +

Technical specifications

Stakeholders' input
Additional product information:
batch number and expiry date

Benefits:

- **Facilitates** requirement for distributors to **record the batch number** (Art. 80(e) of Directive 2011/62/EU) (savings of 13.2 million euros of labour costs per year)
- Provides **traceability** of medicines in the supply chain
- Improves **recall processes**
- Improve **stock management of the supply chain according to expiry dates**
- Enhance **patient safety** (beneficial for pharmacovigilance purpose)
- Help healthcare providers to **prevent medical errors**

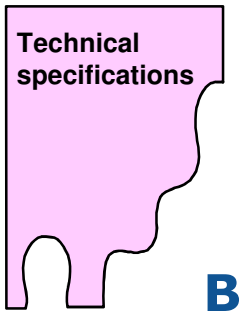


Stakeholders' input
Additional product information: batch number and expiry date

Disadvantages:

- Requires the **use of a 2D Barcode** which is not readable by all pharmacies so far (info could be retrieved through the repository system when the medicines are scanned)

- **Additional costs** for **generic companies** that use pre-print cartons

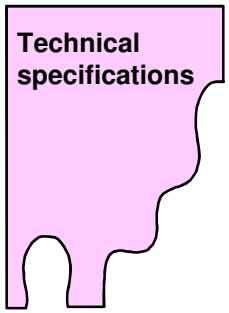


Stakeholders 'input
Additional product information:
National Reimbursement Number

Benefits:

- National numbers **required in some countries in a machine readable format**
- Prevent the packaging from being cluttered by 2 sets of coding
- **Facilitate reimbursement** and logistic processes
- This option potentially allows the inclusion of more than one national number in the same code → additional **benefit for multi-country packs**

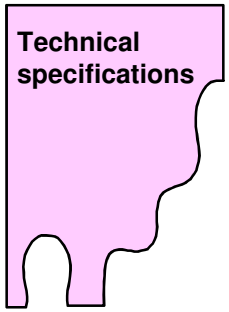
→ A cost–effective option



Regulation of the technical characteristics of the carrier

Options

- Linear Barcode
- 2D- Barcode
- Radio- Frequency identification device (RFID)



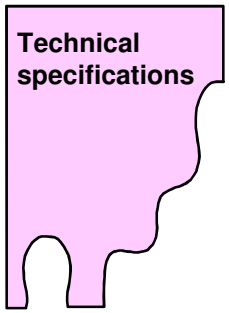
Stakeholders 'input
Linear Barcode

Benefits:

- Currently widespread (including in healthcare systems)
- Pharmacies can read them
- Sufficient to be in line with the scope of the Directive

Disadvantages:

- Not suited to hold more than 1 or 2 data elements
- Size pack problem
- More difficult to print
- More prone to damage
- Have lower read rates than the 2D-Barcode



Stakeholders 'input
2D - Barcode

Benefits:

- **Start to be widely spread** in the industry and in other sectors
- Can carry a **large quantity of data on a relatively small area/label**
- **No excessive requirements** on printing and scanning technology
- **Readable in all the directions** on different supports and with other technology (e.g. smartphone)

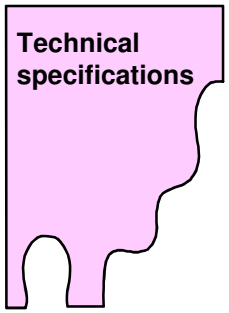
→ More reliable and affordable

Technical specifications

Stakeholders 'input
2D - Barcode

Disadvantages:

- Not possible to pre-print of the UI on cartons. Require additional change of manufacturing lines (input from generic companies)
- New reading devices needed for certain wholesale distributors, hospital pharmacies, pharmacies and retail points
- → impact on the logistic chain and in the packaging lines



Stakeholders 'input
RFID

Benefits:

- Allows to "read" the tag when it is out of the line of sight, but within the range used by the antenna
- Can carry a lot of information within fixed information

Disadvantages:

- **High costs** (5 times higher compared to 2D Barcode, € 0.10 to 0.15 per tag, reading device: € 3000)
- Not suitable for routine use
- Concern over a possible interference with product quality
- Not appropriate given the current state of RFID technology

Next steps

2013

- **Impact assessment**
- **Next meeting of the expert group**
- **Meeting with stakeholders**

2014

- **Adoption of the delegated act**

Thank you!