The European Union’s Directive on falsified medicines

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Agenda

Background

*Detailed rules for a unique identifier*

Next steps

- 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 adoption 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

- Technical specifications
- Verification
- Unique Identifier
- Repositories system
- Black/white lists
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
**Regulation of the composition of the unique identifier**

<table>
<thead>
<tr>
<th>Manufacturer product code (+prefix code)</th>
<th>Random number= serial number</th>
</tr>
</thead>
</table>

**or**

<table>
<thead>
<tr>
<th>Manufacturer product code (+ prefix of the country)</th>
<th>Serial number of the pack</th>
<th>National reimbursement number</th>
<th>Expiry date</th>
<th>Batch number</th>
</tr>
</thead>
</table>

**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**
- Improves **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
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
**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
**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!