FMD edusammud ja väljakutsed

Ravimiameti infopäev
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Mart Levo
REKS Eesti

Mart.Levo@reks.ee
EU-FMD Timeline

Publication has set the tight 3-year implementation clock ticking for EU-FMD compliance: **every pharma company supplying prescription drugs into the European Market will need to be fully EU-FMD compliant by early 2019**

2011 - Publication of Directive in EU Official Journal
2012 - Transposition into National Law
2013 - Adoption / Publication of Safety Features DA
2014 - Compliance for MS without pre-existing measures
2015 - Transposition into National Law
2016 - Publication of Directive in EU Official Journal
2017 - Compliance for MS w. pre-existing measures
2018 - Adoption / Publication of Safety Features DA
2019
2020
2025
Unique Identifier

- Data-Matrix code, developed to ISO-standards
- Key data elements:
  - Product code (GTIN/NTIN)
  - Batch number
  - Expiry date
  - Randomised unique serial number
  - National health number (where necessary)

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 180500
S/N: 12345AZRQF1234567890

2D DM as data carrier of choice: Compact, Robust, Cost-effective
Examples for Anti-Tampering Devices (ATD)

Thanks to Dieter Mößner, Carl Edelmann GmbH
Europe-wide scope of EU-FMD “Safety Features”

Safety Features consist of 2 elements:

**Unique Identifier**
- **Tamper Evidence**

**All Prescription Medicines (Rx) are in scope....**
...apart from those on the Whitelist

Currently white-listed:
- Radionuclides
- Medicinal gases
- IV solutions in ATC therapeutic subgroup B05B ‘blood substitutes and perfusion solutions’
- Contrast media
- Homeopathic medicinal products

**Over the Counter Medicines (OTC) are out of scope...**
...apart from those on the Blacklist

Currently black-listed:
- 2 strengths of Omeprazol

Rx Must carry the safety features

OTC Must Not carry the safety features
## Key elements of the EU-FMD

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1) Unique Identifier</strong></td>
<td>Fully harmonised across the EU: <strong>2D barcode containing 4 mandatory elements</strong> – 1) product code, 2) serialisation number, 3) batch number and 4) expiry date and – optionally – as a 5th element the national reimbursement number (if requested by Member States)</td>
</tr>
<tr>
<td><strong>2) Tamper-Evidence</strong></td>
<td>Medicinal Products must be tamper-evidenced (EN standard EN 16679:2014 recommended)</td>
</tr>
<tr>
<td><strong>3) Repackagers</strong></td>
<td>Parallel distributors to <strong>replace safety features with equivalent features</strong> = UI de/re-commission</td>
</tr>
<tr>
<td><strong>4) Scope</strong></td>
<td><strong>All prescription</strong> medicines (unless white-listed), <strong>no OTC</strong> medicines (unless blacklisted)</td>
</tr>
<tr>
<td><strong>5) Process</strong></td>
<td><strong>Systematical end-to-end verification</strong> (“<em>before being dispensed to patients e.g. at pharmacy level</em>”) supplemented by <strong>risk-based verifications by wholesale distributors</strong>: “<strong>Medicines at higher risk of falsification (returns or medicines not being distributed directly by manufacturers or marketing authorisation holders or wholesalers distributing on their behalf)</strong>”</td>
</tr>
<tr>
<td><strong>6) Timing</strong></td>
<td>Compliance across all 28 MS (+ 3 EEA) on Publication of DA + 3 years (or + 9 years for BE, GR, IT)</td>
</tr>
<tr>
<td><strong>7) Establishment and Operation of the Repository Systems</strong></td>
<td>The repository containing the unique identifiers should be set up and managed by stakeholders (<strong>stakeholder model</strong>) with access and a supervisory role granted to National competent authorities</td>
</tr>
<tr>
<td><strong>8) Funding</strong></td>
<td><strong>Manufacturers bear the cost</strong> of the repository systems</td>
</tr>
</tbody>
</table>
Repositories Systems to carry out the Systematical Point of Dispense Verification

National System

National System

National System

National System

National System

National System

National Blueprint System

National Blueprint System

National Blueprint System

Parallel Distributor

Pharmaceutical Manufacturer

Pharmacy

Wholesaler
Approach based on the concept: Systematical “Point of dispense verification”
Executive Summary
Country Readiness April 2017

- Early Adopter
- Main Stream
- Late Follower
- No Information
- Non EU Countries
• Edusammud
  • REKS moodustamine peale 1,5 a läbirääkimisi
  • Haiglaapteekrite kaasamine
  • BSP valiku protsess
  • LOI Arvato Systems

• Väljakutsed
  • Arvato Systems läbirääkimised
  • Projekti ellu viimine
  • Erinevate lepingute sõlmimine (EMVO, Apteek, Hulgimüük, MAH)
  • Rahastuse tagamine
Mida peaks MAH tegema?

- Uute 2D elementidega pakendite registreerimine
- Emvo-medicines OBP portaaliga liitumine
- Uute pakendite sisestamine süsteemi
- Laenuleping REKS ramp-up faasi finantseerimiseks
- Leping MAH-REKS NMVS süsteemi kasutamiseks
- Teenustasu planeerimine
- MAH optimeerimine
- SOP loomine - kuidas käsitletakse süsteemis tekkinud alarme
- Back-up plaan juhuks kui ...
EMVO on-boarding portal for OBP

- [ ] https://www.emvo-medicines.eu/eu-hub-on-boarding/obp-portal/
  - Request to participate tab

- [ ] On-boarding Information Package
  - On-boarding Guideline/Manual
  - On-boarding PowerPoint Presentation
  - Sample of the Non-Disclosure Agreement (NDA)
  - Sample of the Participation Agreement (PA)
Mida peaks Eesti MAH tegema?

- Uute 2D elementidega pakendite registreerimine
- Tootmise võimekus 2D koodi pakendile printida
- Emvo-medicines OBP portaaliga liitumine
- Uute pakendite sisestamine süsteemi
- Leping MAH-REKS NMVS süsteemi kasutamiseks
- Teenustasu planeerimine
- SOP loomine - kuidas käsitletakse süsteemis tekkinud alarme
- Back-up plaan juhuks kui ...
How charging works (examples, not real figures)

- KDH Pharmaceuticals
  - €81,000
  - 231 Products

- ABC Pharmaceuticals
  - €60,000
  - 6 Products

- Tiny Pharmaceuticals
  - €9,000
  - 1 Product

- Other companies and products with various costs and product counts.
The key elements of the EU-FMD

- **Serialization** by manufacturer
- **Risk based** verification by Wholesalers
- **Verification** and **check-out** at point of dispense

**Safety features:**
- UI = Code (‘unique identifier’)
  +
- ATD = Anti-Tampering Device

- Manufacturers shall **bear the cost** of the repositories system
- EMVO / NMVOs set up and operated by supply chain stakeholders
- Oversight by competent authorities

Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890
Suur tänu!

Mart Levo
Mart.Levo@reks.ee
Implementation of the unique identifier (UI) (2D barcode)

New marketing authorisation applications

For any new MAA submitted from April 2016 the revised QRD template shall be used.

Ongoing marketing authorisation applications

Applications with a CHMP opinion from April 2016 onwards: shall comply with the revised QRD template.

Existing marketing authorisations

Use upcoming regulatory procedure affecting Product Information Annexes to implement the revised QRD template in order to place the safety features on the packaging. CHMP opinion or EMA notification shall occur no later than 9 February 2019.

If no regulatory procedure affecting the Annexes occurs within this timeframe, then MAHs are requested to submit a Notification pursuant to article 61(3) of Directive 2001/83/EC (no later than the 9 February 2019).
In most cases, the implementation of the ATD is not expected to impact the product information.

- Regulatory procedure needed only in the case of medicinal products where the ATD is placed on the immediate packaging because there is no outer packaging and the ATD affects the container and its closure system(s).

- Required to include information on the ATD and how the ATD affects the container and its closure system(s) (sections 3.2.P.2.4 and/or 3.2.P.7 of the Notice to Applicants Volume 2B).

- Required to submit information on the ATD and how the ATD affects the container and its closure system(s) at the latest with the replies to the Day 180 list of outstanding issues.

- Required to submit the appropriate variations to include the information on the ATD and how the ATD affects the container and its closure system(s). CHMP opinion or EMA notification shall occur no later than the 9 February 2019.

If the addition of the ATD has an impact on the readability of the packaging information, MAHs are requested to submit mock-ups (process clearly defined [here](#)).
<table>
<thead>
<tr>
<th>Requirement (routine operation)</th>
<th>Pharma - Brand Owner and Generics</th>
<th>Pharma - CMO</th>
<th>Parallel Distributors</th>
<th>Wholesaler/Distributor</th>
<th>Pharmacist</th>
<th>National Competent Authorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Pay for EMVS (“Bearing the costs for the system”)</td>
<td>Yes</td>
<td></td>
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</tr>
<tr>
<td>2) Apply Unique Identifier</td>
<td>Yes</td>
<td></td>
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</tr>
<tr>
<td>3) Apply Anti-Tampering Device</td>
<td>Yes</td>
<td></td>
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</tr>
<tr>
<td>4) Connect to European Hub: Upload UIs</td>
<td>Yes</td>
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</tr>
</tbody>
</table>
Glossary

- BP - Blueprint System
- DR - Delegated Regulation
- EMVO - European Medicines Verification Organisation
- EMVS - European Medicines Verification System
- FMD - Falsified Medicines Directive
- MOU - Memorandum of Understanding
- NBPS - National Blueprint System
- NMVO - National Medicines Verification Organisation
- NMVS - National Medicines Verification System