Introduction to FMD
Implementing the EU Falsified Medicines Directive in the UK

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Falsified medicines – a real problem

The Pharmaceutical Journal, 5th June 2014
Why we need a Directive

• Falsified products still being found in legitimate medicines supply chain – major risk to patient safety
• Failure to address falsification could put trust in our entire industry at risk
• Up to half of medicines purchased online believed to be falsified – action taken to improve security of legitimate internet pharmacies
• Stronger controls now over raw materials and products manufactured under contract outside EU
FMD overview and timeline
Falsified Medicines – what’s the solution?

“Safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering.”

Directive 2011/62/EU, Para 11

- All packs of almost all prescription medicines will have to have two safety features:
  - Visual tamper-evident seals or packaging
  - Unique identifiers (serial numbers) in a 2D barcode
- Authenticity is checked in two ways:
  - Visual inspection of the tamper-evident features
  - Scanning and checking unique identifiers against databases (“repositories”) at EU and national levels
“Medicinal products subject to prescription shall bear safety features on their packaging”

FMD Delegated Regulation 2016/161, Article 2
FMD concept for verification

Manufacturers
(brands or generics)

European Hub

Parallel traders

Pharmacies

Wholesalers

Data uploads
Data exchange
Verification
Authentication
Falsified Medicines Directive (FMD) timeline

- **2011**: Directive 2011/62/EU adopted
- **2013**: First elements of Directive come into force (APIs and excipients)
- **2015**: EMVO and European Hub established
- **2016**: Delegated Regulation 2016/161 published
- **2017**: Set up NMVOs/pick BSPs
- **2018**: FMD pilots
- **2019**: Full requirements of Directive start (scanning)
- **2024**: End of non-2D packs (could be earlier)
- **2018**: FMD onboarding
- **2019**: Brexit?
FMD Delegated Regulation – key questions answered
FMD – key questions answered

Who is involved?

You are

“Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying it to the public.”

Delegated Regulation 2016/161, Article 25(1)
FMD – key questions answered

What is included?

Everything

“This Regulation applies to: medicinal products subject to prescription ... unless included in the list set out in Annex 1; medicinal products not subject to prescription included in the list set out in Annex 2”

Delegated Regulation 2016/161, Article 2(1)
FMD – key questions answered

When does it start?

Very soon

“This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. It shall apply from Saturday 9th February 2019.”

Delegated Regulation 2016/161, Article 50
FMD – key questions answered

Will I have to pay for it?

In part

“The costs of the repositories system shall be borne by the manufacturers of medicinal products bearing the safety features.”

“The repositories system shall not include the physical scanning equipment used for reading the unique identifier.”

Draft Delegated Regulation, Articles 31(5) and 32(4)

PSNC is assessing the costs (implementation and ongoing) to discuss with DHSC
FMD – key questions answered

Can we opt out?

No?

“This Regulation shall be binding in its entirety and directly applicable in all Member States.”

Delegated Regulation 2016/161, Article 50
FMD Delegated Regulation – what do you have to do?
FMD – requirements for manufacturers

• Delegated Regulation requires manufacturers to:
  • Put safety features (tamper-evident and unique identifier) on almost all prescription medicines
  • Encode unique identifier in 2D barcode meeting certain standards
  • Print 2D barcodes and certain details on all relevant packs
  • Upload unique identifiers into repositories system (consisting of European hub and national repositories)
  • Set up and pay for the repositories system via non-profit legal entities
  • Report any suspected incidents of tampering or falsification
  • Decommission certain products
  • Notify repositories of any recalled, withdrawn or stolen products
FMD – requirements for wholesalers

- Delegated Regulation requires wholesalers to:
  - Verify authenticity of any returns and products not bought directly from manufacturers or their contracted distributors
  - Decommission identifiers of products being exported, withdrawn, destroyed or taken as samples
  - Decommission products being supplied to public by other routes (i.e. not via pharmacy, dispensing doctors or hospitals)
  - Not distribute or supply decommissioned products (other than those they are required to decommission for others)
  - Notify authorities of any suspected incidents of tampering or falsification

[Note: also applies to pharmacies who hold wholesale licences]
FMD – requirements for pharmacies

• Delegated Regulation requires pharmacies to:
  • Verify the authenticity of products (checking tamper-evident and unique identifiers) and then decommission identifiers “at the time of supplying it to the public”
  • Only be able to revert decommissioned products (undispense) within 10 days of the original dispensing
  • Decommission products that cannot be returned to wholesalers or manufacturers or which are taken as samples
  • Not to supply decommissioned products (other than those they decommission themselves as part of dispensing)
  • If technical problems prevent authentication, to record unique identifiers and then verify and decommission when possible
  • Notify authorities of any suspected incidents of tampering or falsification
The journey of a patient pack
Potential benefits from FMD (beyond identification of falsified medicines)
FMD – potential benefits

Patient safety benefits
• Accuracy and date checking made easier
• Impact on indemnity costs?

Pharmacy stock benefits
• Accurate pack-level data for all products

Patient information benefits
• Able to generate patient-specific information
FMD implementation – key players
European Stakeholder Model and EMVO

- Research-led manufacturers
- Generics manufacturers
- Parallel distributors
- Wholesalers
- Pharmacies

NMVO

NMVO

NMVO

NMVO

NMVO

NMVO

UKFMD

Working Group for Community Pharmacy
SecurMed UK – the UK’s NMVO

Research-led manufacturers
Generics manufacturers
Parallel distributors
Wholesalers
Pharmacies

ABPI
BGMA
BAEPD
HDA
NPA/CCA

National Medicines Verification System

Manufacturers
Wholesalers
Pharmacies
Hospitals
GP surgeries
UK FMD Working Group for Community Pharmacy

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<th>Pharmacy contractor associations</th>
<th>Pharmacy negotiating bodies</th>
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<td>NPA</td>
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<td>AIM</td>
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- Representing contractors’ interests to DH/MHRA
- Process mapping and options development
- Establishing **FMD Source** as trusted FMD resource
- Bringing suppliers and IT providers together
FMD Implementation Advisory Board

- Established by DHSC/MHRA to advise Health Ministers
- Brings together all those involved with implementing FMD
- Many working groups established
- Leading to Impact Assessment and formal consultation
Implementing FMD – what happens next?
FMD timeline for the UK

- **2011**: Directive 2011/62/EU adopted
- **2014**: UK bodies participating in ESM discussions
- **2016**: EMVO and European Hub established
- **2016**: Delegated Regulation 2016/161 published

- **2016**: SecurMed UK established
- **2017**: UK BSP decision
- **2018**: FMD pilots start in UK
- **2018**: DH/MHRA consultation
- **2018**: IT system upgrades
- **2018**: FMD stock starts to appear
- **2019**: All parties connected to NMVS
- **2019**: Brexit?

- **2011**: DH/MHRA consultation
- **2016**: FMD stock starts to appear
- **2016**: EU referendum
- **2017**: FMD pilots start in UK
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What about Brexit?

• The UK’s decision to leave the European Union adds an extra layer of confusion and complexity

• In theory, the Delegated Regulation will be incorporated into UK legislation under EU (Withdrawal) Bill

• UK progress on implementation has been heavily delayed

• Lack of clarity about what happens afterwards and whether UK would “inside” FMD and connected to EMVS

• Clear patient safety risks if UK is outside FMD

• Expect a UK solution will be developed if we can’t access the European system
FMD “flexibilities”

Medicines supply chains vary across Europe. The Delegated Regulation gives Member States some “flexibilities” for this.

Current MHRA/DHSC consultation:

• **Coding** Use of national remuneration numbers and inclusion of additional patient information in UIs

• **Decommissioning** Allowing wholesalers to undertake decommissioning for “Article 23” groups who supply medicines on irregular or infrequent basis

• **Supervision** Oversight of National Medicines Verification Organisation

• **Enforcement** Penalties where the regulations are breached
FMD – key issues for pharmacies

• Authentication “at the time of supply”
• 10-day rule for reversing decommissioning
• Updating internal IT systems and processes
• Visibility of pharmacy data under FMD
• Variable models of dispensing
• Dealing with FMD incidents
### Summary FMD readiness checklist for pharmacies

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<tr>
<th>What needs doing</th>
<th>Why?</th>
<th>Who is involved?</th>
<th>Done?</th>
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<tbody>
<tr>
<td><strong>Software upgrades for pharmacy systems</strong></td>
<td>FMD compliance and interface with EMVS/NMVS</td>
<td>Software suppliers</td>
<td>Work started</td>
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<tr>
<td><strong>New scanners</strong></td>
<td>2D-capability and spares needed</td>
<td>Hardware suppliers</td>
<td>Still to do</td>
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<td><strong>Possible internet connection upgrades</strong></td>
<td>Suitable bandwidth to manage data traffic</td>
<td>Telecoms suppliers</td>
<td>Still to do</td>
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<tr>
<td><strong>Updated operating procedures</strong></td>
<td>Staff readiness for FMD and compliance with professional standards</td>
<td>Pharmacists and pharmacy teams</td>
<td>Still to do</td>
</tr>
<tr>
<td><strong>Managing FMD incidents</strong></td>
<td>Readiness for negative scans and how to respond</td>
<td>Pharmacists and pharmacy teams</td>
<td>Still to do</td>
</tr>
<tr>
<td><strong>FMD information for patients and customers</strong></td>
<td>Reassurance on quality and standards</td>
<td>Pharmacists and pharmacy teams</td>
<td>Still to do</td>
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Implementing FMD – what needs to happen?

- National Medicines Verification System to be set up
- Pilot verification systems in pharmacies, wholesalers, hospitals
- Integrate FMD verification software with existing systems
- Upgrade hardware (scanners) and IT connections
- Develop processes for authentication in day-to-day practice
- Develop procedures to deal with offline and “fail to authenticate”
- Establish governance, inspection and enforcement rules
- Explain to all in supply chain why, what and when of FMD
- Explain to public and media why, what and when
- Go live (2019) then iterate/develop
- ... and lots, lots more
What do contractors need to do now?

• Read the guidance available at https://fmdsource.co.uk/
• Explore the system options – list of suppliers on FMD Source
  ➢ Integrated with PMR
  ➢ Standalone
• Decide how you want to implement FMD – will you take a staged approach?
• Select your supplier and decide what hardware you need (additional terminals, power supplies, wireless scanners...)
• Think about the optimal way to implement FMD in your pharmacy and then revise your SOPs
“Full fat” implementation
Implementing FMD – time for action is now

The clock is already ticking!
Questions and discussion

https://fmdsource.co.uk/