GS1 Ireland Healthcare User Group (HUG) Information Day

What does FMD mean for community pharmacy?

Dan Burns, Boots Ireland

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The Falsified Medicines Directive – What does it mean for Community Pharmacy?

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FMD overview and timeline
Falsified Medicines – what’s the problem?

“There is an alarming increase of medicinal products detected in the Union which are falsified in relation to their identity, history or source. These products usually contain sub-standard or falsified ingredients, or no ingredients, or ingredients (including active substances) in the wrong dosage thus posing an important threat to public health.”

Directive 2011/62/EU, Para 2

- Involving nearly 2500 cases, EU Customs seized **27.4 million** doses of falsified medicines at EU borders in 2011 - an almost seven-fold increase from 2007

Source: EC Annual Report on Customs Actions to enforce IPRs
When does Falsified Medicines Directive (FMD) start?

Article 50

**Entry into force** 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 **9 February 2019**. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Time is ticking = 684 days which is 482 working days
Falsified Medicines – what’s the solution?

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

Directive 2011/62/EU, Para 11

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

**Unique identifier**

Randomised serial number captured in 2D Data-Matrix Code

<table>
<thead>
<tr>
<th>Product #</th>
<th>09876543210982</th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch</td>
<td>A1C2E3G4I5</td>
</tr>
<tr>
<td>Expiry</td>
<td>140531</td>
</tr>
<tr>
<td>S/N</td>
<td>12345AZRQF1234567890</td>
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Falsified Medicines – what’s the solution?

“Time of supply to patient” - Decommission
FMD – what’s been happening and where are we now?
Progress to date

Irish Pharmacy Union (IPU) as representatives of community pharmacy...

• have been working closely with the other four constituents in establishing the IMVO
• have been involved in the blueprint provider selection and the agreed constitution for the IMVO.
• will be a founding member of the IMVO and therefore will contribute to the running and governance costs of this organisation
• will have a director sitting on the IMVO board
• have set up a Community Pharmacy Working Group who will look at the practical implications of this legislation.
Implications for community pharmacy
FMD – requirements for pharmacies

- DR requires **pharmacies** to:
  - Change I.T. systems and hardware to enable scanning for verification and decommissioning of medicines
  - 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 at same location
  - 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
Implementing FMD in a pharmacy – what needs to happen?

- The Irish repository established (IVMS)
- Interface built between repository and pharmacies
- Pilot verification systems in pharmacies
- Integrate FMD verification software with existing systems, or build standalone verification system
- Upgrade hardware (scanners)
- IT networks upgrade if required – data connection/speed are important
- Develop processes for verification/decommissioning in day-to-day practice
- Develop new SOPs and training of staff on this new legislative requirement
- Develop procedures to deal with offline and “fail to verify”
- Develop procedures for verification errors or alerts that require notification
## FMD – Cost impacts for pharmacy

<table>
<thead>
<tr>
<th>Expected cost impact – pharmacy</th>
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<tbody>
<tr>
<td>Scanning packs in pharmacy (including IT and scanners)</td>
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<tr>
<td>Transaction and latency costs</td>
</tr>
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<td>Costs to participate in national organisation (IMVO)</td>
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<td>Costs of adjusting internal processes and documentation</td>
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<tr>
<td>Costs from reversing decommissioning, including stock write-offs under 10-day rule</td>
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<tr>
<td>Costs of dealing with “failure to authenticate” incidents</td>
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<td>Costs of training on new legislation and new procedures</td>
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Points of discussion for Community Pharmacy Working Group

• Value and costs of implementing FMD in pharmacy
• How FMD impacts our current pharmacy procedures – and how to minimise disruption to workflow and patient facing time
• Evaluation of where in process would be most appropriate to undertake the verification and decommissioning scans
• Solutions for integrating new systems (i.e. standalone vs integrated IT solutions)
• Flexibilities – link pack to patient in PMR?
• Unknown requirements around compliance reporting
• Pilot and testing (Timescale unknown with regards to Manufacturers producing FMD compliant packaging)
• At what point to decommission stock if there is an owing of an item
• Home delivery, daily dosage systems, care homes - point of decommission
• Management of split packs already decommissioned
Benefits of FMD
FMD – Potential Benefits for Community Pharmacy

- Reduced risk of falsified medicines reaching patients
- Better recalls, down to patient level
- Potential to improve accuracy at point of dispensing
- Date checking made easier
- Authentication of medicines – Patient confidence in community pharmacy
- Potential to move to original pack dispensing and PILs included in all packs
Questions

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