Key requirements of the EU Falsified Medicines Directive

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• 25+ year experience in chemical and pharmaceutical industry
• Product security, master data management, global supply chain systems, pack coding / GTIN
• Project lead for AstraZeneca’s global serialisation system
• Expert on EFPIA’s coding & serialisation / ESM – EMVS project team
• Member of the recently set up ISPE GAMP Serialization and T&T SIG
• 3C Integrity Ltd., consulting company specialising in serialisation, traceability and product security
• 2-Day Serialisation Readiness Workshops
1. Serialisation – Background and Context
2. EU-FMD – Key Requirements
3. Serialisation Readiness
Serialisation
Background and Context
Strategies to fight counterfeiting and other threats

AC Technology

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Coding Requirements affecting Rx “3CPharm” Products

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Widespread Agreement on:

**Code Carrier:** 2D Data Matrix  
**Coding Standards:** GS1  
**Data Model:** EPCIS
EU-FMD Key Requirements
Example: EU Falsified Medicines Directive

- Directive published 1 July 2011
- Entered into force 1 January 2013
- Contains measures to increase security of the medicinal supply chain in Europe
  1. Strengthen Good Manufacturing and Good Distribution Practices including the sourcing of active ingredients
  2. Improve supervision of actors in the distribution chain (e.g. wholesalers, parallel distributors...)
  3. Ensure product integrity and authentication of medicines (safety features and product serialisation)
EU FMD

What does the Directive mandate?

• Safety features that enable relevant persons to
  ✓ “Verify...authenticity”
  ✓ “Identify individual packs”
  ✓ “Randomised number”
  ✓ “Provide evidence of tampering”
• Risk-based approach: Rx included, OTCs excluded, but some exceptions (risk assessment)
• Obligations on Repackagers
  “equivalent” features, liability
• Govts can use the system for reimbursement and/or pharmacovigilance purposes
• MAHs will pay for the “repositories systems”

What will be determined by Delegated Act?

• Characteristics & technical specifications of the “unique identifier”
• “Extent and modalities of verification of the safety features” to “ensure the verification of authenticity of each dispensed pack”
• Criteria for the risk assessments / Black and White List
• Establishment (including accessibility) of the “repositories”
EU-FMD Timeline

- Publication of Directive in EU Official Journal
- Transposition into National Law
- Publication of Safety Features DA (anticipated)
- Compliance for Member States without pre-existing measures
- Compliance for MS w. pre-existing measures

Timeline:
- 2011
- 2012
- 2013
- 2014
- 2015
- 2016
- 2017
- 2018
- 2019
- 2020
## What do we know about the DA?

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2. May include a national product code  
3. Include UI information as human-readable  
4. UI barcode will take the place of all other visible barcodes on the packs | 1. Familiar from other coding requirements including EFPIA’s Sweden Pharmacy pilot in 2009/2010  
2. There is little practical experience with 5-element codes in pharma  
3. Incompatible with SecurPharm coding  
4. Potentially massive pack artwork change |
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| Application of UI                                                   | 1. manufacturing authorisation holder (“manufacturer”) is responsible (i.e. would mean CMOs)  
2. parallel importers can continue to use the original UI            | 1. Different to approach taken by the ESM (responsibility to upload UI should be with Brand Owners / Marketing Authorisation Holders)  
2. Headache for ESM and the ‘code ownership’ approach to data validation. |
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### “Extent and modalities of verification of the safety features” to “ensure the verification of authenticity of each dispensed pack”

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<td>1. mandatory point-of-dispense check in ‘pharmacies’ 2. risk-based check undertaken by wholesalers (estimated 3% of cases) 3. obligation on wholesalers to check out UIs that are exported from the EU</td>
<td>1. As expected – ideal outcome for all stakeholders 2. Ditto 3. Headache for wholesalers; step towards T&amp;T; may drive implicit requirement for aggregation</td>
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<td>3. Nod towards future verification by patients even though this is currently not intended or supported by the ESM system</td>
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<td>Criteria for the risk assessments / Black and White List</td>
<td>Currently under consultation through Member States who are asked to comment on the proposed criteria:</td>
<td>Clear need to keep approach simple to ensure consistency across member states, brands and types of manufacturers.</td>
</tr>
<tr>
<td></td>
<td>1. <em>The reimbursement price and the sales volume of the medicinal product</em>;</td>
<td>• Strict approach to those prescription medicines that could be eligible for the white list; excluding a) priced higher than a low limit (e.g. EUR 5.00)</td>
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<td>2. <em>The number and frequency of previous incidents of falsified medicines reported in the Union and in third countries</em>;</td>
<td>b) “Lifestyle drugs”</td>
</tr>
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<td>3. <em>The specific characteristic of the product</em>;</td>
<td>c) life-saving or life-sustaining medicines</td>
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<td>4. <em>The seriousness of the conditions intended to be treated</em>;</td>
<td>• Over-the-Counter medicines will be blacklisted in cases where there is at least one documented counterfeit case within the EU or a ‘collaborating third country’</td>
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<td>5. <em>Other potential risks to public health.</em></td>
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What does this mean for MAHs?

The exact outcome of the Delegated Act (2014/2015) is not yet clear, but there are clear indications of the direction of travel:

Participation in a systems-based, Europe-wide Medicines Verification process is a given

- MAH should start now to get ready
- The general direction is clear even if the exact route is not yet known
- Delaying is not an option
EUFMD „Hope for the Best, Plan for the Worst“

“The DA on the Safety Features will become applicable 3 years from its publication in the Official Journal (Article 2(2) of Directive 2011/62/EU). (6 years in those MS having an authentication system in place on 1 July 2011)

The Commission aims at adopting the Delegated Act by the end of 2014.

Publication in the OJ will follow in the first half of 2015, due to Parliament, Council and WTO scrutiny rights.

If this timing is respected, the Delegated act will become applicable sometimes in the first half of 2018” (1)

“The Commission does not consider possible to derogate from the implementation period of 3 years ...

Stakeholders should prepare for the 3 year implementation period without any transitional measures.”

Proposed 2-year cut-over to flush out slow-moving stock in pharmacies and supply chain

NOT transition period to give manufactures additional time
Serialisation Readiness
Serialisation is really easy...

Just put numbers on pack, collect them and put them in a database so they can be sent out to the authorities or supply chain partners, right?

So why are many companies struggling with their programmes, taking years and spending millions and taking a permanent productivity hit?
The Pace of Adoption
The Serialised Pack is Central

**At-Line Coding**
- Printing Technology
- Mechanical Handling
- Presentation of the Pack
- Inspection
- Grading

**Carton and Artwork**
- Pack Design
- Substrate
- Surface / Varnish
- Preprinted Information

**Tamper-Evidence**
- Labels?
- Interaction with the variable Data

**The Right Code**
- Bluebox Requirements
- GTIN/NTIN/NHRN
- Systems and Dataflow

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The Technology Stack

Level 4
Business Logistics

Enterprise level

Location

Level 3
Manufacturing Operations Management

Level 2
Production Control (supervisory)

Level 1
Production Control (manipulating)

Collaboration Layer

Site Manager

HMI

Packing Line

Line Manager

Station Manager

Printer

Camera

RFID reader

Scanner

Packaging

Distribution

Number management

Master data

Query I/F

Capture I/F

Authentication services

Compliance module

WMS
Technology does not exist in isolation.

Diagram:

- **Level 1**: Device
  - Printer
  - Camera
  - RFID
  - Scanner

- **Level 2**: Line Control
  - HMI
  - Packing Line

- **Level 3**: Site Manager
  - Number Mgt.
  - Repository
  - Capture I/F
  - Authentication
  - Compliance module
  - WMS

- **Level 4**: Enterprise level

- **Validation, GxP, GAMP**
- **Master Data Mgt., GTINs etc.**
- **Packs, TE and Artwork**
- **BAU Transition**
- **Communication**
- **CMOs**
- **Wider SC Impact**
- **Artwork Mgt Processes**
- **Wider Strategy**
- **Incident Management**
You need a Coding Specialist!
Engaging your Senior Stakeholder
# Project Organisation

<table>
<thead>
<tr>
<th>Functions:</th>
<th>Operations</th>
<th>Engineering</th>
<th>IT</th>
<th>Supply Chain / Logistics</th>
<th>Regulatory</th>
<th>Planning</th>
<th>Artwork</th>
<th>Quality</th>
<th>Validation</th>
<th>Product Security</th>
<th>Marketing / Commercial</th>
<th>External Sourcing</th>
<th>Procurement</th>
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<tr>
<td>Teams:</td>
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<td>Steering / Oversight Team</td>
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<td>Global Core Team</td>
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<td>Site-based Implementation Team</td>
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<td>Subteams (artwork, regulatory, master data &amp; coding etc.)</td>
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<td>Example Pack Changes</td>
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You need the right team
EUFMD „Hope for the Best, Plan for the Worst“

Publication of “Delegated Act“ for safety features


Go - Member States without pre-existing measures

Go - MS with pre-existing measures

2-year Cutover

Analysis, URS, Vendor Sel. etc.

Implement on Pilot Line

Implementation on additional lines

Operate Pilot line in BAU

Confirm capability on all lines

Make compliant product

Go

Project Preparation

Go
Your Business Plan?

Priority # 1:
Stay in business - do not lose 80% of our sales.
Start! – Now!

CLICK HERE
Conclusions

Expectation is that all prescription products will be tracked & traced by the 2020s, worldwide.

In key markets, participation in a systems-based verification will be required even earlier.

Shift from Compliance focus to look at wider Opportunities and the key capabilities required:

- Item-level coding is going to be a critical core capability – without it you will not be able to manufacture and sell your products.
- Chose an approach based on flexible, adaptable technology that will allow you to comply not just with the current but also future requirements.
- Don’t let the focus on Compliance blind you to the ultimate goal = Safer Medicines.
Don’t miss the train....
Thank you very much for your attention!

christophk@3cintegrity.com