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Falsified Medicines Directive

Impact for Wholesalers

Wholesale Distribution Information Day, 28th September 2012

Lorraine Nolan
Healthcare Products
Distribution Manager

Contents

1. Falsified medicines legislation
2. Main changes & requirements
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4. IMB approach to implementation

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Legislation

Directive 2011/62/EU of European Parliament & of the Council

amending Directive 2001/83 on the Community code for medicinal products for human use, as regards the prevention of entry into the legal supply chain of falsified medicinal products

Published 1st July 2011

Entry into force 2nd January 2013

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Main Changes

1. Active Substance (API)
2. Safety Features
3. Supply Chain & GDP
4. Internet Sales

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Definition: Falsified Medicinal Product

Any medicinal product with a false representation of:

a) its identity, including its packaging and labelling, name, composition in respect of any of its components and strength;

b) its source, including the manufacturer, country of manufacturing, country of origin, MAH or

c) its history, including the records and documents relating to the distribution channels used.

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Active Substance Requirements

- ✓ Mandatory audits by finished product manufacturers
- ✓ Registration requirements for manufacturers, importers & distributors
- ✓ Provisions for import into EU
  - Third country listed by Commission or
  - Written confirmation for each lot by 3rd country authorities

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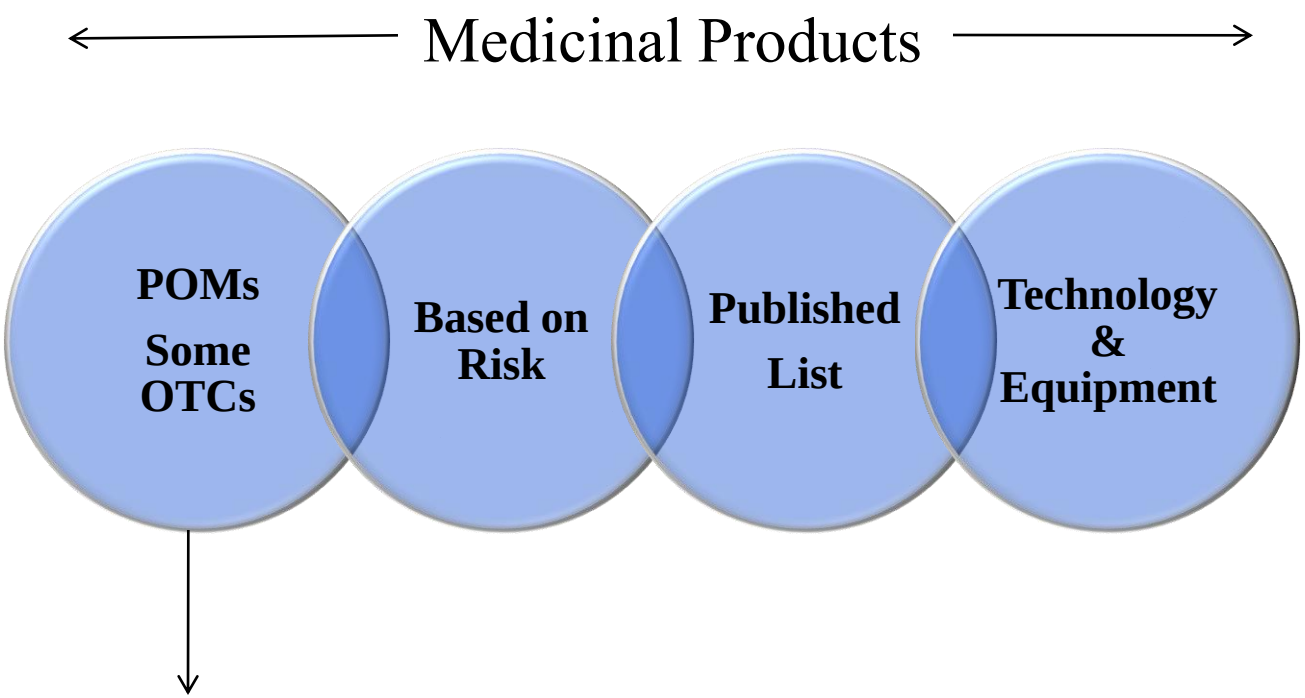
Safety Feature Requirements



"White List"- Safety Features
"Black List"- Others

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Safety Feature Requirements

Manufacturer

- QP to Verify Application
- Specific requirements for parallel importers

Wholesaler

- Verify Authenticity
- Identify individual packs
- Verify tamper-evidence device intact

Technology & Processes

Delegated Act

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Safety Feature Requirements

- ✓ Commission "Concept Paper" on the "*Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, & its Verification*"

- ✓ Public consultation: Nov 2011 to Apr 2012
  http://ec.europa.eu/health/human-use/falsified_medicines/developments/2012-06_pc_safety-features.htm#

- Characteristics and technical specifications
- Modalities for the verification & identification
- Information repository systems
- Risk procedures for product selection

- ✓ Impact Assessment & Legislative Proposal to follow

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Safety Features Requirements

Safety Features: GDP Requirements

Safety Features	Practical Considerations
1.Safety Feature Verification	•**Recording of batch numbers linked to safety feature requirements** •Keep informed on EU Developments •IMB information day on safety features proposed for 2013 •Implementation strategy should be developed as the content of the "Delegated Act" progresses -Processes -Technologies/Equipment -Budget & cost -Implementation -Validation -Training
2. Record of Batch Numbers Note 1 & 2: From 2017	

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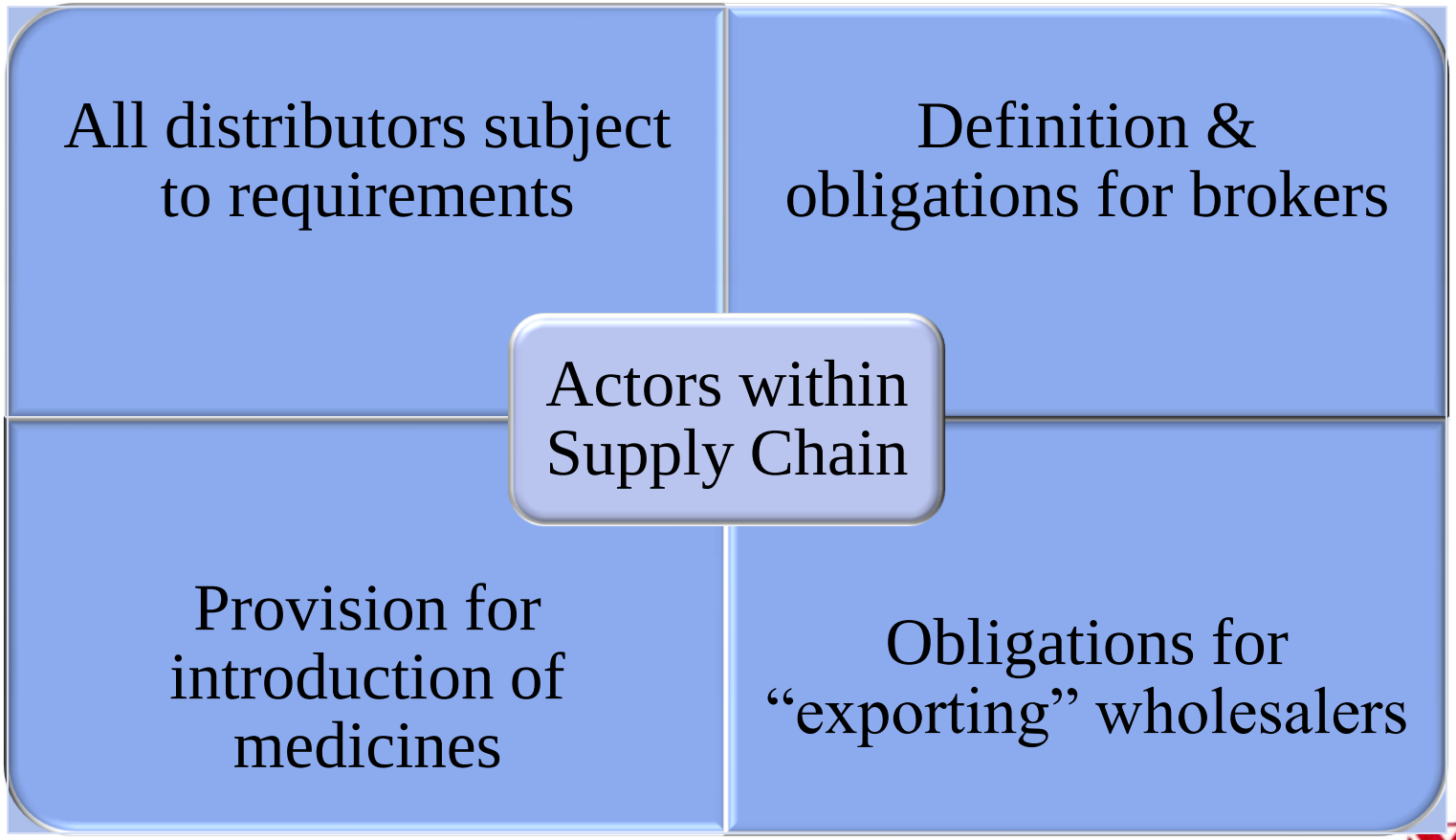
Supply Chain Requirements



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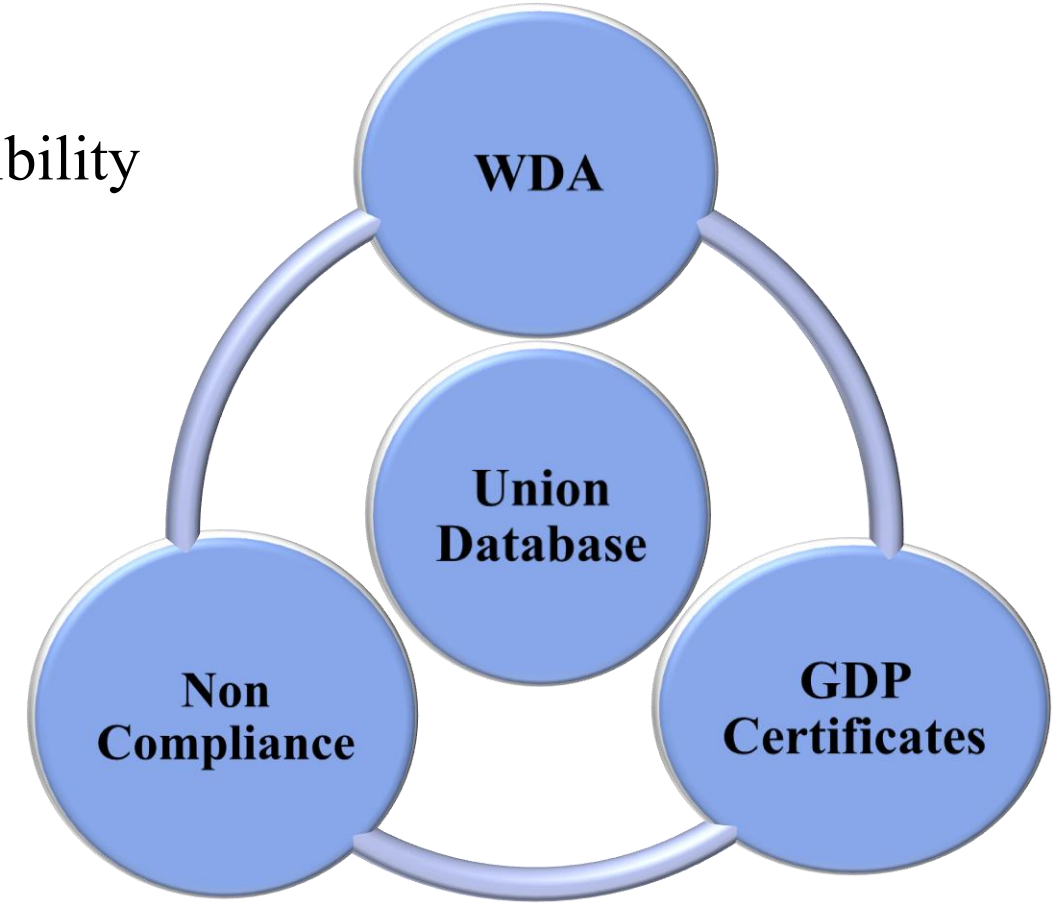
Supply Chain Requirements

Increased Visibility



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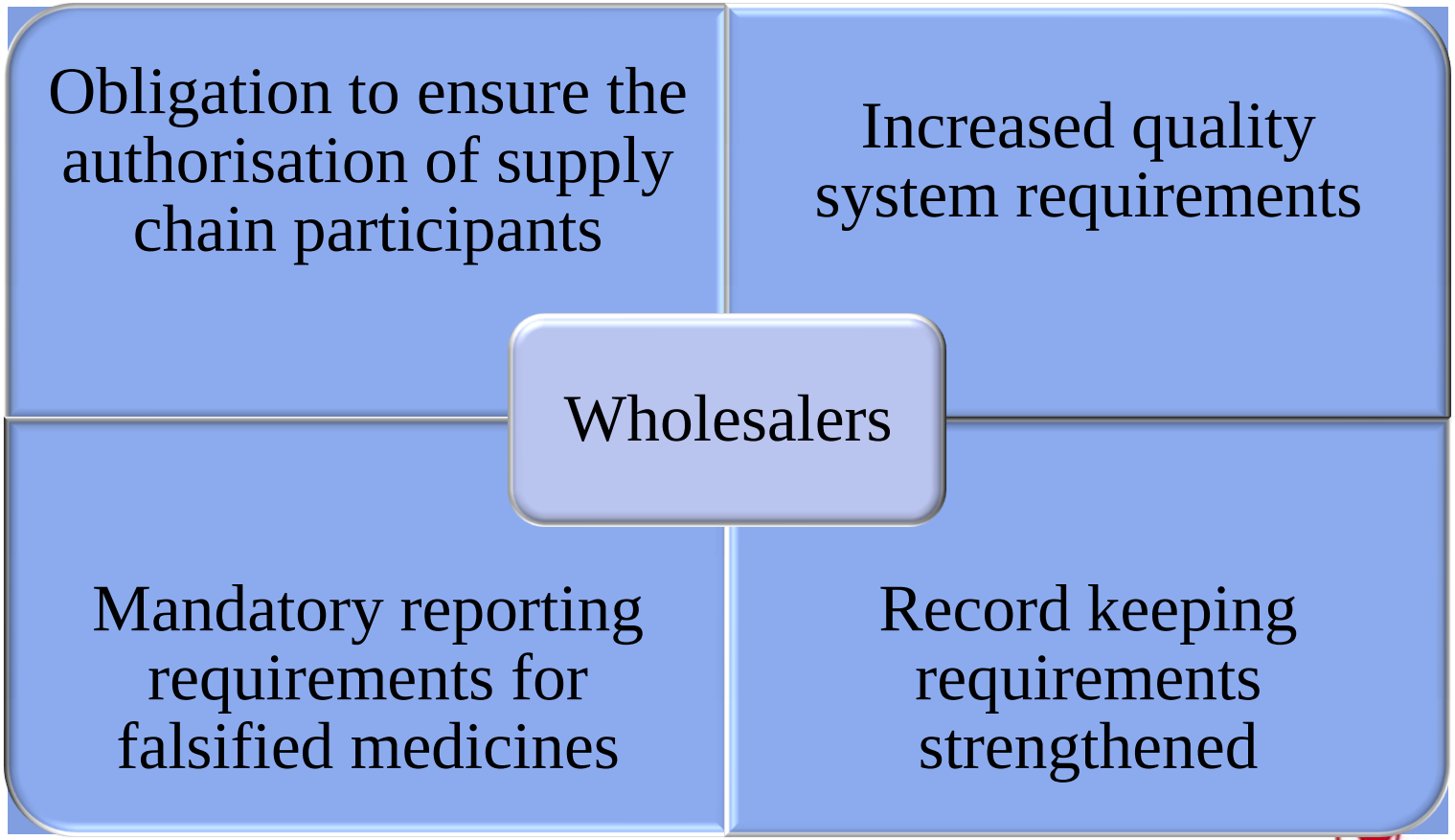
Wholesaling & GDP Requirements



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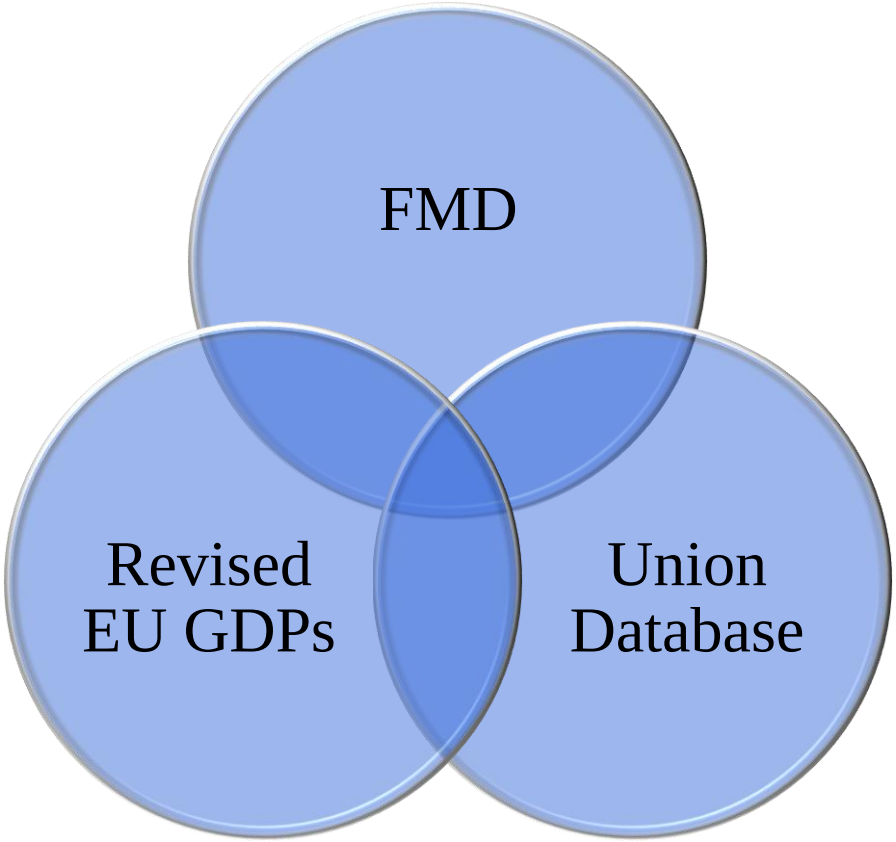
Wholesaling & GDP Requirements

Implementation Strategy



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Wholesaling & GDP Requirements

Increased Obligations

✓ **Quality Systems**

- Mandatory
- Use of QRM Principles

✓ **Supplier Qualification**

- Verification of compliance with GDP
- Carrying out & receiving audits

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Wholesaling & GDP Requirements

Quality System	Practical Considerations
1.Quality Systems Legal Requirement	•Define procedure for QRM approach •Review QMS, processes & systems •Identify key risk areas •Start by focusing on one area •Develop implementation plan to include all identified risk areas
2. Use of QRM Note 1 & 2: From Jan 2013	

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Wholesaling & GDP Requirements

Supplier Qualification	Practical Considerations
1.Verification of Compliance with GDP	•Review existing suppliers/ GAP Analysis •Review associated documentation/agreements •Explore methods for assessing GDP compliance •Based on risk assessment define criteria for auditing suppliers •Introduce alternative assessment approaches for non-audited suppliers •Proceduralise approach •Document the qualification exercise
2. Conduct & Receive Audits Note 1 & 2: From Jan 2013	

Wholesaling & GDP Requirements

Broker Qualification	Practical Considerations
1.Verify Authority to act	•Identify existing brokers utilised & inform of new requirements
2. Conduct Audits Note 1 & 2: From Jan 2013	•Define & audit programme to include: -Frequency & Content -Reporting methodology & Follow up •Use of contract support •Proceduralise approach •Document qualification exercise •Onus on customers to ensure broker is registered

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Internet Sales Requirements

- ✓ **Not legitimate in Ireland for POMs**
  - National provisions shall apply including those relating to supply of "general sale" products

- ✓ **FMD Requirements**
  - Notifications for Internet pharmacies & other "general sale" product suppliers;
  - Notification to include address, website, products offered;
  - Requirement to display new EU logo and link to authority's website;
  - Member States to list authorised internet "pharmacies"

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IMB Implementation

Timeline: September 2011 – January 2013

Project Groups: Six groups reviewing impacted areas
Cross Departmental representation
Policy & procedure updates

National Legislation: Regular interaction with Department of Health on transposition &amending national legislation

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Key Messages

- ✓ Significant number of changes for wholesalers under FMD: Focus on transparency; traceability; security; accountability
- ✓ Revision of EU GDPs supports FMD implementation & necessary to give full effect
- ✓ Implementation timelines from 2013 to 2017
- ✓ Development of implementation plan will enable compliance with regulatory obligations

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Follow Up

Questions

For further information:

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