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Falsified Medicines Directive

Irish Medicines Board Information Day 2012

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Chris Cullen
Senior Inspector
Compliance

Content

1. The Backdrop
2. Falsified Medicines Directive (FMD)
3. Safety features
4. Supply Chain Actors - Important Practical Considerations
5. Active Substances
6. Internet Sales

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The Backdrop

Falsified medicines: there are indications for new trends in the EU…

- From illegal to legal **supply chain**
- From **lifestyle to life-saving** drugs
- Misuse of **freezones/ customs warehouses**
- Counterfeit/ low-quality **active pharmaceutical ingredients (API)**

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The Backdrop..... Falsified Medicines 2007

CLOPIDOGREL (Plavix)	Prevention of **heart attacks** & strokes	Thousands of patients received product; Insufficient protection may lead to heart/brain strokes
OLANZAPINE (Zyprexa)	Treatment of **psychiatric disorders** including schizophrena	Thousands of patients received product; Risk of manic episodes due to underdosing
Bicalutamide (Casodex)	Treatment of **prostate cancer**	Impaired treatment

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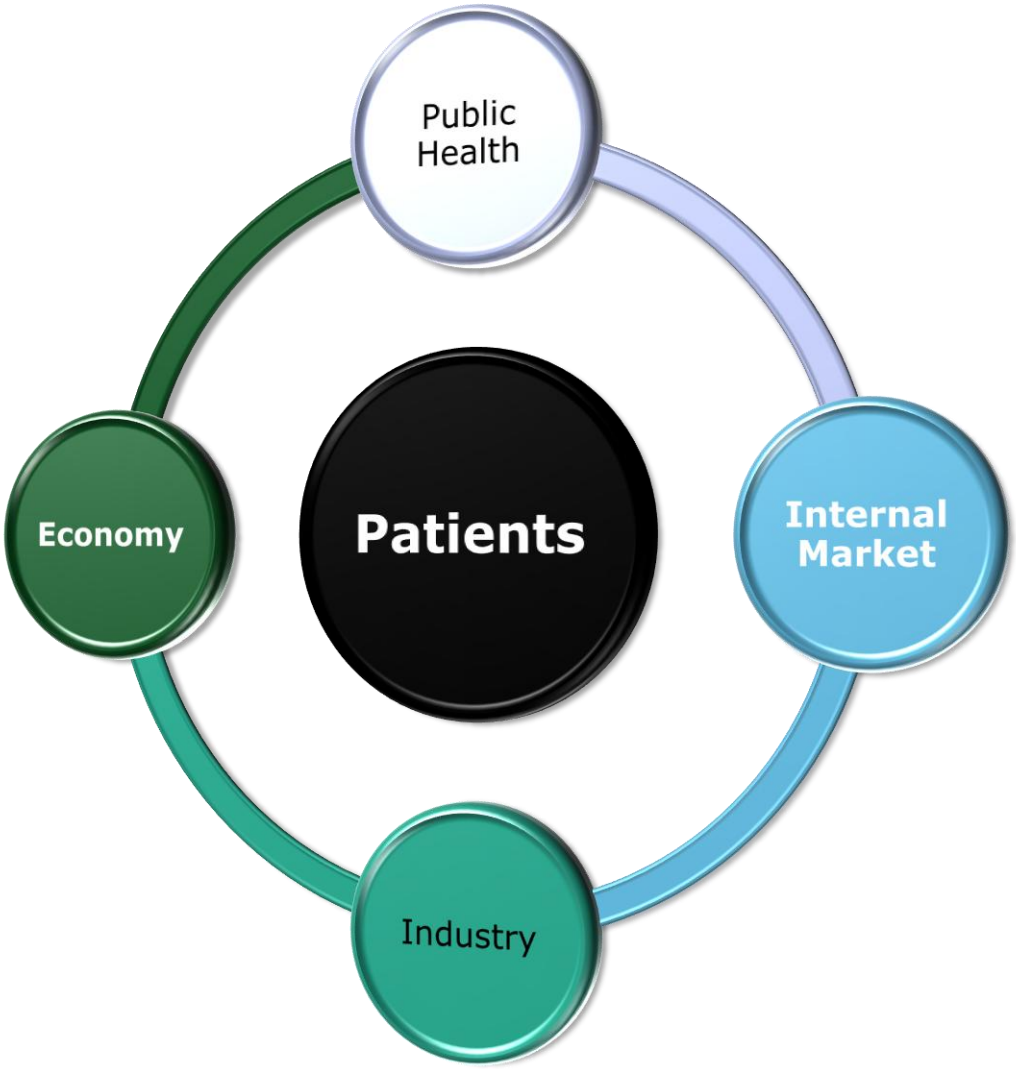
New Risk Profile Has Consequences for ...



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Falsified Medicines Directive

- Amends Directive 2001/83/EC
- Focus:
  - The prevention of the entry into the legal supply chain
  - Human medicinal products falsified in relation to their identity, history or source

➢ Directive 2011/62/EU

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Directive 2011/62

- Applies to Human Medicines only
- Investigational medicinal products are excluded.
- Supplementary legislation to be written
- Most provisions come into effect 2nd Jan 2013
- Longer period for those articles dependant on Delegated Acts and Implementing Measures

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4 Pillars – Legal Changes

Product labelling

- **Safety features**
  - Unique identifiers
  - Tamper evident seals

Supply chain actors

- API Manufacturers importers & distributors
- Brokers

Active Substances

- Registration
- GMP

Internet sales

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Safety Features

To verify

1) that the pack is authentic and identified
2) that the outer packaging has not been tampered with

What it applies to:

- Obligatory for POM unless specified on list
- Will not apply to non POM unless specified on list

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Safety Features – Delegated Act

Commission tasked with develop requirements for unique identifier:

- characteristic & specifications
- modalities for verification
- provision for repositories systems
- the 2 lists of products to which it applies

Concept Paper on delegated act. The response to the publice consultation is at http://ec.europa.eu/health/human-use/quality/res_del_act_en.htm

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Safety Feature– Delegated Act

Policy options

1) Individual manufacturers free to choose appropriate technology
2) Commission to specify details of the unique identifier and its carrier
3) Inclusion of batch no. and expiry date
4) Inclusion of national reimbursement no.

Product code	UI no./pack	Reimbursement No	Expiry date	Batch No.
5 013457	898149	31798	12/2012	0957010

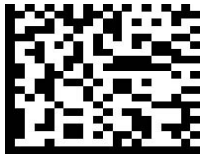
Safety Feature– Delegated Act

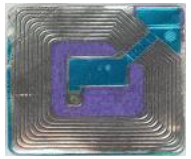
Policy options (contd.)

3) Characteristics of the carrier

Options included in concept paper:

Linear barcode 

2D-barcode 

Radio-frequency identification 

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Safety Feature– Delegated Act

Policy options (contd.)

4) Repository systems

Options include:

- To let relevant actors set up the appropriate infrastructure
- System to which all actors are connected, which is governed by an EU body
- National databases with interconnections to allow intra-Union trade

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Safety Feature– Delegated Act

Policy options (contd.)

4) Repository systems – other issues

- 4.1 Commercially sensitive information
- 4.2 Protection of personal data
- 4.3 Repackaging of medicines

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Safety Feature– Delegated Act

Consultation commenced in November 2011

Concluded 27th April 2012

Important Dates: January 2nd 2013

July 2nd 2013

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Conclusion

- Effective implementation of systems of unique identification of medicines and medical devices will optimise patient care by improving market surveillance activities and also provide for a reduction in medication errors and medical errors

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Drug Product Manufacturers

- Obligations of Manufacturing Authorization Holders
- Audit Manufacturers and API Distributors
- Must ensure appropriate GMP application for excipients.
- Report suspected falsification to competent authorities
- Verify registration status of manufacturers , importers or distributors.

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Active Substances Manufacturing

- The quality of Active Substances is assured:

  When manufactured by registered manufacturers within the EU.

  Accompanied by a written confirmation of equivalent GMP.

  The exporting country is named on a list by the European Commission

  Manufacturing sites holding a valid current EU GMP Certificate.

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API Manufacturers/Importers

- GMP directly applicable
- Registration required for API manufacturers / importers
- IMB will inspect all API Manufacturers
- Importation controls on non EU APIs
- Currently 22 of 25 API Irish Manufacturers in IMB Voluntary Inspection Programme
- Importers - some are known but a number are currently unknown to IMB

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API Importers

- Where an API has entered the EU at the first EU border it must clear customs for a particular site which is the first importer i.e. the shipping company is not necessarily the importer.
- The manufacturer which finally uses the active should also have access to the written statement

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API Importers

- API importer responsibilities will be similar to API distributor responsibilities.
- Definitions to be included in the GDP Guide for active substances which will be developed.

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API Distributors

- Registration Process is being developed.
- Envisaged a common registration process will be used where feasible.
- Distributors who hold current medicinal product wholesale authorizations will be registered.
- Inspections will be risk based and take into account existing GMP/GDP status i.e. Holders of Authorizations/GMP Certificates.
- Distributors - some are known but a number are currently unknown to IMB

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Registration and Importation Controls

- All manufacturers, importers and distributors will be registered
- It is envisaged these will include:
  - API Manufacturers
  - Drug Product Manufacturers
  - Importers who resell
  - Importers who export APIs
- Registration process is being developed.
- Importation boundary is the EU border. Free movement within EU.

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Internet sales

- <u>The issue:</u>
- Many counterfeit products supplied over the internet – no regulation of this activity
- Internet pharmacies & other suppliers to notify to Member State of address, website, products offered,
- Must display new EU logo
- Link to authority's website

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Acknowledgements

- Anne Hayes Inspection Manager
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Thank you

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