EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of Falsified Medicines Directive

Meeting with Patients and Consumers Organisations
30 November 2011

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An agency of the European Union

Agenda

Background

Overview of Falsified Medicines Legislation

Role of EMA in implementation

What is a Falsified Medicine

According to EU legislation it is a medicine with a false representation of:

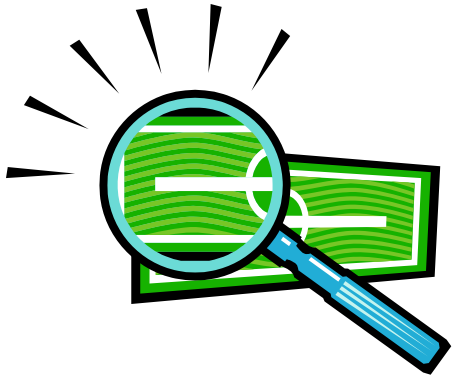
- Identity e.g. name or composition
- Source e.g. country of origin, marketing authorisation holder
- History e.g. distribution records

Does not include unintentional quality defects

What is the extent of the problem?

No accurate data is available

A WHO report in 2006 stated the following:



- 10% of medicines globally may be “Falsified”
- Associated with weak regulatory systems

  In the developed world WHO’s estimate was 1%

  WHO estimated that 50% of falsified medicines come from internet purchases where the physical location of the internet pharmacy is concealed

Falsified medicines have been found in the legitimate EU distribution chain.

- In most cases these have been genuine medicines intended for export markets (i.e. Diverted to the EU market for economic gain)

EU Falsified Medicines Legislation: 4 Pillars

1.	2.	3.	4.
Safety Features	Good Distribution Practices	Active Substances	Internet Sales

Implementation timelines

Entry into force 2 January 2013

- Provisions for import of active substances: 1 July 2013
- Safety features: 3 years after relevant delegated act
- Internet Common Logo: 1 year after relevant delegated act

Safety Features

Objective: To secure integrity and authenticity of products

Development subject to further legislation

Products to which safety features are applicable yet to be identified

In principle to apply to all prescription medicines

Distribution of Medicinal Products

Objective:

Strengthened Good Distribution Practice (GDP) provisions

- e.g. Obligation for wholesalers to notify authorities when in receipt of or offered products identified or suspected of being falsified

Introduction of brokers into scope of pharmaceutical legislation

- Registration with relevant National Competent Authority
- Some GDP obligations
- Possibility for inspection

Union database for Wholesale Distribution Authorisation Holders (and GDP Certificates)

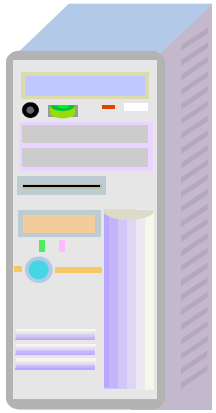
Brokers

EudraGMP

Manufacturing Authorisations

GMP Certificates

GMP non-compliance (not public)



Search capabilities
Alert on event capabilities

Future modules:

- **Inspection planning in third countries**
- **"Faulty Manufacture" (Quality Defects)**
- **Wholesale Distribution Authorisations / GDP certificates**
- **EU Active substance manufacturer, importer, distributor registrations**

Active Substances

Objective: strengthen obligations and supervision

Registration of EU manufactures, importers and distributors of Active substances to be included in EU database

Manufacturing authorisation holder legally obliged to audit (or have audited on its behalf) manufacturers and distributors of Active Substances used.

Applicant for marketing authorisation is required to submit a written statement confirming that the Active substance used is manufactured in accordance with Good Manufacturing Practice (GMP)

Conditions for Import of Active Substances into EU

*Only to secure supplies of medicines
Importing Member State must inform European Commission if this option is used

List of Third Country Authorities

Further legislation under development (delegated act of European Commission)

Listing is upon request and follows assessment to ensure an equivalent level of public health protection

- Review of Documentation
- On-site review of regulatory system including observed inspections*

*(not required where MRA applies)

- Ongoing verification

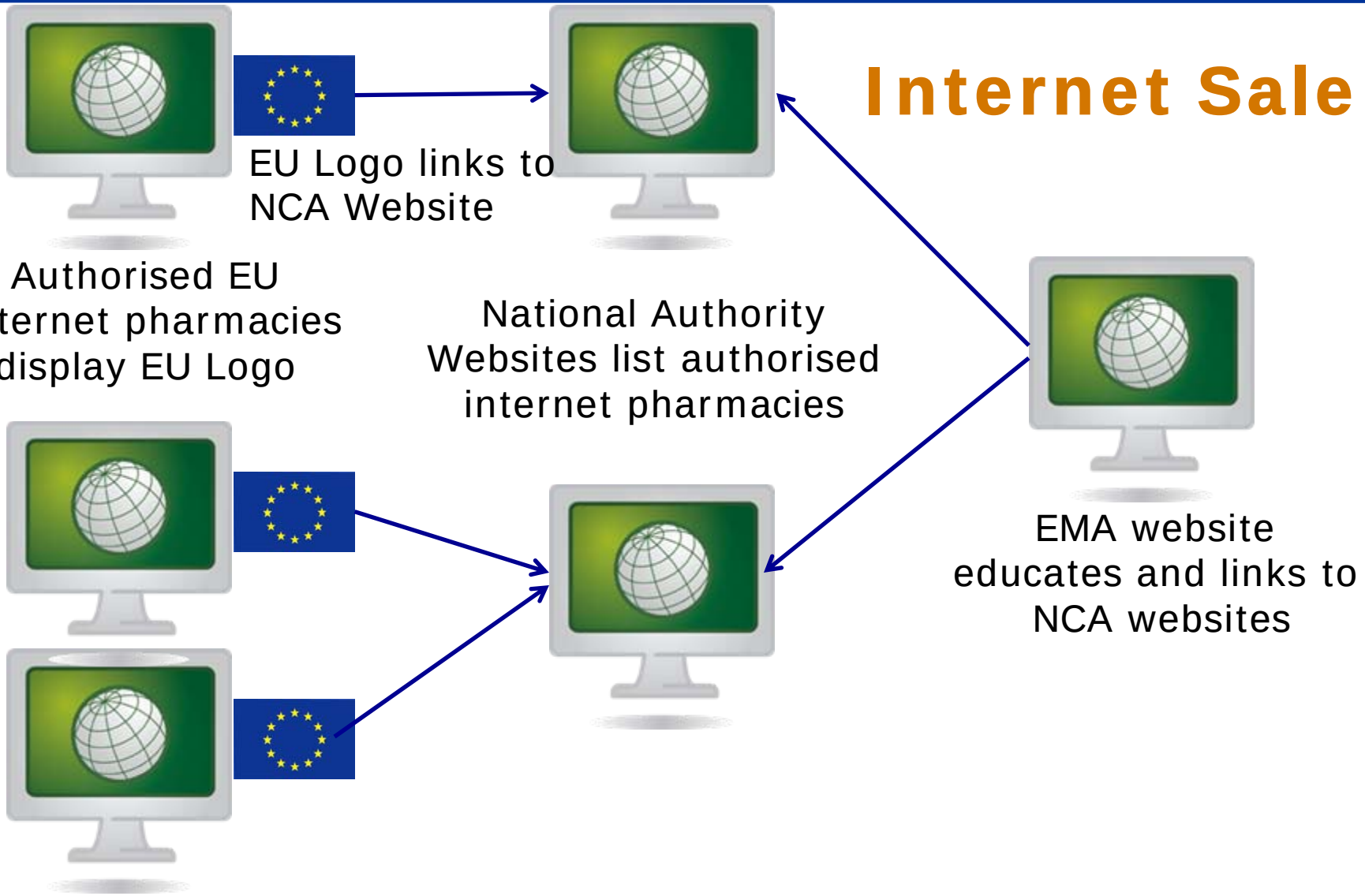
Particular account taken of:

- GMP Rules
- Inspection and enforcement
- Communication of non-compliance

Internet Pharmacies

Objective: Protection of public health with regard to retail purchase of medicines through the internet

Internet Sale



Other significant new measures

Provisions for **introduction** of medicines (i.e. physically imported but not placed on EU market)

- Further legislation may be developed (Delegated Act)

New possibilities for inspections

- Distributors of Active Substances
- Manufacturers or importers of excipients
  - Subject to further guidance on risk assessment of excipients

Public Awareness

Information campaigns raising public awareness

- Risks associated with internet purchase of medicines
- Member states to organise meetings with patient and consumer organisations to communicate prevention and enforcement actions

Public announcements when defective or falsified medicines posing a serious risk to public health reach patients

Penalties

Member States to impose penalties that take into account the threat to public health from Falsified Medicines

- Including the unlawful operation of an internet pharmacy

Penalties should be effective, proportionate and dissuasive.

Role of EMA (1)

EMA had no role in developing the legislation but will have a major role in implementation

Develop the Union Database (EudraGMP)

Assist European Commission to develop further implementing acts

- Requirements for Listing of Third Country Authorities

Develop guidance on behalf of the Commission

- Good Distribution Practice for active substances
- Risk assessment for excipients

Role of EMA (2)

Develop numerous detailed aspects with Member States to facilitate harmonised practical implementation

Establish a website explaining the EU logo for on line pharmacies and link to National authorities websites

Collaborate in public awareness campaigns with respect to internet pharmacies

Thanks for listening