Design for safety: the industry approach

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There isn't "the" industry approach but many good examples

- Highly regulated area
- New requirements on their way – Falsified Medicines Directive
- Delay in European initiative – Commission assessment report regarding readability
- Industry initiatives on e-product information and coding
- Examples for safe design and "Single-Dose-Packages"

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Conflict of interest

Manufacturer or Service Provider	Nature of Relationship
Research-based pharmaceutical Industry association	employee

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Questions „Design for safety: the industry approach "

1. Are the details of packages for medicinal products

☐ primarily results of a design decision by pharmaceutical companies or

☐ regulated by an EU-Directive and specified by guidelines and templates

2. Are the future "safety features" on packages

☐ 2D-Matrix Codes to be scanned and to provide information about the identity of the product or

☐ intended to allow the identification of each tablet

3. Are single dose containers

☐ requiring more packaging material and more space or

☐ technically not feasible

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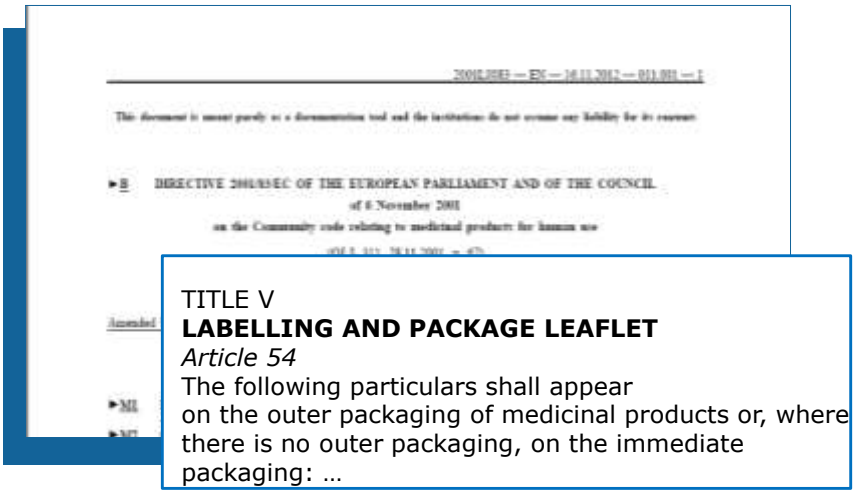
Highly regulated area – Basis: EU Directive 2001/83/EC



DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 November 2001

TITLE V
LABELLING AND PACKAGE LEAFLET
Article 54
The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: …

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Highly regulated area

Examples for the regulation of information on medicinal products (guidelines /templates)
Name of the medicinal product
▪ Guideline on the acceptability of names for human medicinal products processed through the centralized procedure
Packaging of medicinal products
▪ Quality Review of Documents, QRD-template ▪ Guideline on the packaging information of medicinal products for human use authorized by the Union
Summary of Product Characteristics (SmPC): information intended for the prescriber
▪ SmPC guideline with detailed explanations on EMA website

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Highly regulated area

Examples for the regulation of information on med. products

Package information Leaflet (PL): information intended for the patient, about the product and included in the package

- Readability guideline, includes requirement for a user test; Quality Review of Documents, QRD-template

European Public Assessment Report (EPAR):

- Summary of the scientific assessment by the CHMP, technical document
- European Medicines Agency Template (www.ema.europa.eu)

EPAR summary for the public:

- Short summary by the EMA (EMA Homepage, alphabetic list under "find medicine")
- It explains how the CHMP assessed the medicine (benefit, risk) and its recommendations on the conditions of use

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New requirements on their way – Implementing Falsified Medicines Directive

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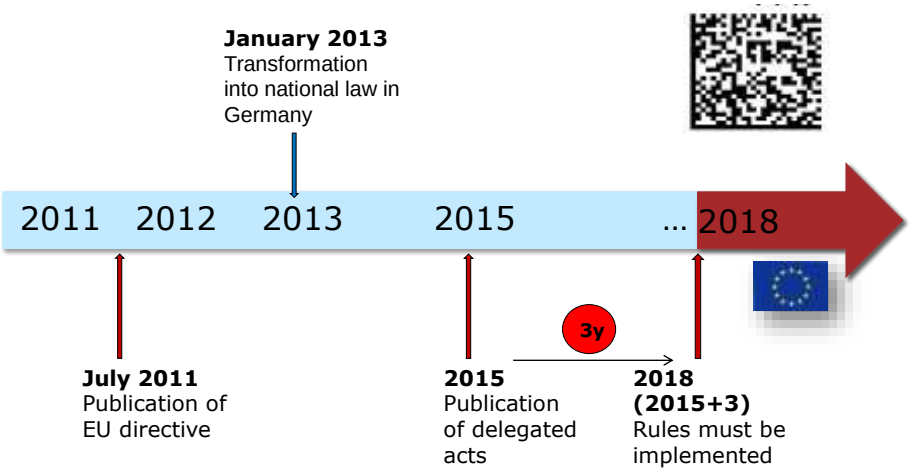
Implementation of the Falsified Medicines Directive (serialisation/2D-Matrix Code)



Delay in European initiative – Commission assessment report regarding readability

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Industry initiatives on e-product information and coding

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Available Digital Information

„Think out of the box"-Product information 2.0

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Legal question

Article 58

The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory

unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.

Electronic product information for medicines in the European Union

- Research-Based Pharmaceutical Industry fully supports providing comprehensive, accurate and up-to-date information on medicinal products both for patients and healthcare professionals.
- Such information must be easily accessible. It needs to be adjustable to the need of the individual patient to provide the necessary level of detail for the most effective and safe use of the medicine.
- In order to provide really up-to-date information a switch from package leaflets accompanying the medicinal product to dissemination of product information via electronic means should be aimed for in the future.

Electronic product information for medicines in the European Union

Internet is widely used as source for medical information

Many people look for medical information on the internet.

An increasing number of all age groups takes benefit of the steadily growing number of electronic health information and applications.

Yet, the quality of these sources of information greatly varies.

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Electronic product information for medicines in the European Union

- Research-Based Pharmaceutical Industry sees the necessity to start the process of introducing new methodologies for providing **product information in more user-friendly structures and styles**.
- Research-Based Pharm. Industry believes that **electronic dissemination** of regulatory authority approved product information will lead to further improvement.
- A **single trusted source of authorised product information** could support the **empowerment of patients** by providing the best available knowledge about a medicine. This approach fits also into both the EU Commission's Digital Agenda (i.e. eHealth and Ageing) and the EU cross-border healthcare Directive.

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Electronic product information for medicines in the European Union

An **electronic database containing health authority approved package leaflets and summary of product characteristics (SmPCs)** allows **up-to-date and targeted information** on medicinal products.

Currently there is a **time lag of up to two years** between regulatory agreement of new information and the provision of products with updated leaflets in the supply chain.

Furthermore the compilation under one address will create **one trusted source** with authority approved product information.

Electronic product information for medicines in the European Union

- The use of electronic presentation and dissemination methods for the **officially approved medicinal product information** can also play an important role in **better meeting the individual needs of the customer** (patient, user, carer or HCP).
- Such a novel approach would open the possibility to provide **tailor-made format** (personalized to the individual user), which is readily accessible through one **single point of entry** and **fully searchable**. Access can be made spontaneously, compatible with life-style (i.e. even at midnight) and provided at the right time (whenever needed or wanted).
- Electronically available systems could also better meet the need of **visually impaired people** (e.g. audio versions) or of people with specific requirements of information representation (e.g. video, charts).

One source of information for medicinal products

- The technology required for any electronic solution, including the 'database' underlying such an electronic Product Information tool cannot and **should not be developed by one single stakeholder**.

- **Bar- and Matrix Codes** with url-links to electronic versions of package leaflets are becoming increasingly popular and QR codes are meanwhile accepted by regulatory agencies (cf. CMDh position paper on the use of QR codes to provide information about the medicinal products).

→ To harmonise this information an **electronic database or portal as single source** of information should be developed.

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securPharm

The German initiative against falsified medicines

(Version as of March, 16, 2015)

All product types affected by counterfeits

Originals
(Avastin® Feb-2012)

Generics
(Omeprazol® Mar-2013)

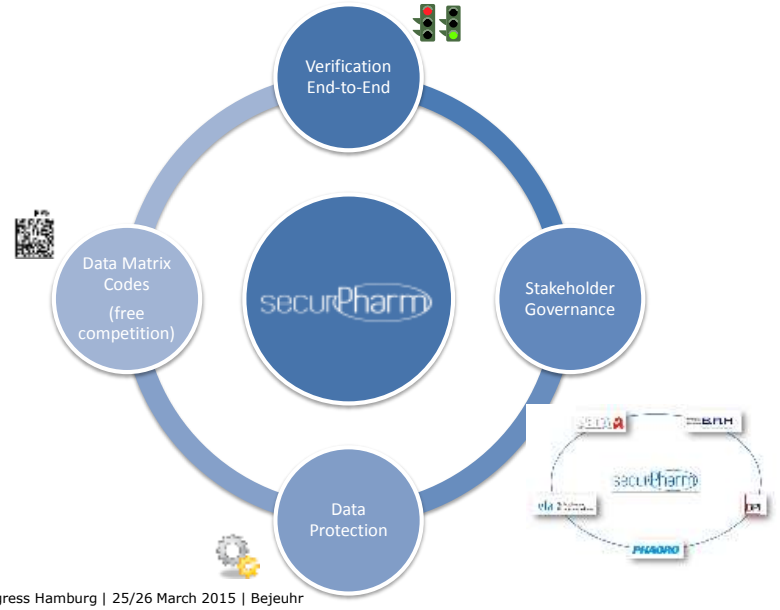
OTC
(Aspirin® May-2013)

Imports
(Pegasys® Nov-2013)

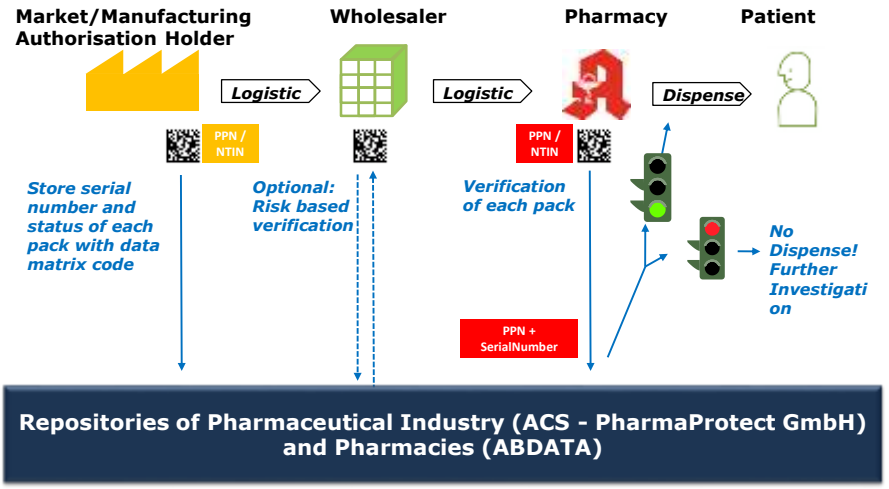
Countermeasure

EU published directive 2011/60/EU:
the Falsified Medicines Directive (FMD)

Core Principals of securPharm



End-to-End Verification



Coding information with Data Matrix Code to identify the pack

	readable	digital
PZN-7	✓	✓
Lot	✓	
Expiry date	✓	

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	readable	digital
PZN-8	✓	✓
Ser.No.		✓
Lot	✓	✓
Expiry date	✓	✓

PPN

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Examples for safe design and "Single-Dose-Packages"

eahp-Position Paper

REQUEST FOR THE PRODUCTION OF SINGLE DOSE-PACKED DRUGS, JUNE 2007 / REVISED IN JUNE 2010

Request summary

To improve patient safety in drug therapy and to ensure the highest quality in medical treatment in European hospitals, the General Assembly of the ***European Association of Hospital Pharmacists, EAHP****, demands:*

- the production of single dose-packed drugs from the pharmaceutical industry,
- the mandatory inclusion of a barcode on each single dose.

Examples from ADKA Congress 2013
Poster by B. Zeiter and J. Roer; Uni Mainz

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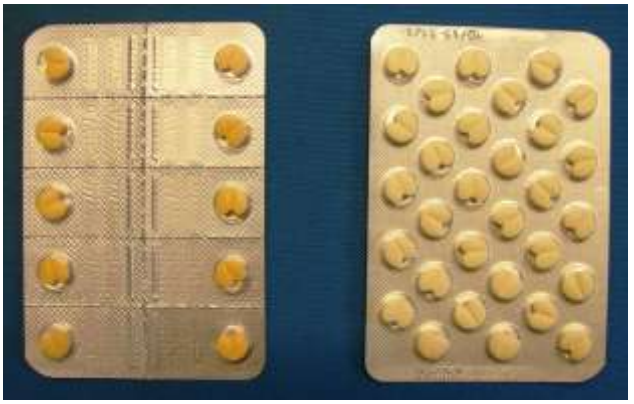
Example demonstrating increase in size and material needed



In this example the size triples from usual blister to single-dose blister

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Current situation: Single-dose blisters are technically feasible and already on the market

- Main characteristics:
  - Spreading information on the blister without variable data (lot/expiry data) easier
  - Information for each dose requires different layout
  - Very complex: combination of codes and readable information for each unit
- Some companies have specific hospital programmes.
- More material and complex production creates additional costs.
- In a discussion with hospital pharmacists in Germany it turned out that they concentrate on the cost aspect.
- Single-dose blister prices cannot compete with generic medicines prices.

Further potential pilot products

Medicinal products where single-dose blister could be applied and could be useful:

- **cardiovascular medicines** (ACE inhibitors, beta-blockers, statins, AT1-antagonists etc.), **oral antidiabetics** and **NSARs**
- **high price products**, which could be scanned directly at the bedside to include the information into the documentation: **immunosuppressives, oral cytostatic medicines or oral anticoagulants**
- and under **therapeutic safety aspects** medicinal products **with unusual dose intervals like bisphosphonates or MTX**

Conclusion: Please think out of the box

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