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2. securPharm European Conference on the Falsified Medicines Directive

22.7.2015
for German pharmaceutical industry, wholesalers und pharmacies

23.7.2015
for international stakeholders

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Welcome

to the

2. securPharm Infoday

Frankfurt, 23rd, July 2015

ABDA Bundesvereinigung Deutscher Apothekerverbände

Bundesverband der Arzneimittel-Hersteller e.V. B.A.H beraten • analysieren • handeln

BPI Bundesverband der Pharmazeutischen Industrie e.V.

PHAGRO

vfa. Die forschenden Pharma-Unternehmen

5 Questions to set the mood

1. Do we need the Falsisfied Medicines Directive (FMD) at all?
2. Who is responsible for its sucessful implementation?
3. How much time do we have/need until then?
4. What are the biggest challenges?
5. How to start your own project?

Counterfeits in the legal supply chain 2009 - 2015
Strong increase and all product categories affected

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year	product	categorie	destination	source
2009	Combivir (HIV)	Rx-Original	Germany	Afrika
2011	Botox	Import	Germany	Polen
2012	Avastin	Rx-Original	USA	Egypt (?)
2013	Sutent	Rx-Import	Germany +? Europe	
	Pegasys	Rx-Import	Germany +? Europe	
	ASS	OTC	France/Spain	China (?)
	Omeprazol	**Generic**	**Germany**	**Germany**
2014	Alli (Orlistat)	OTC	USA	(?)
	Herceptin,, Alimpta, Humatrope, Sutent, Gardasil, Avastin …..	Rx-Import	Germany +?	Europe
2015	Humira, Viread, Neulasta	Rx-Import	Germany +?	Europe
	Viagra	Rx-Original	Germany +?	?
	Petnidan	Rx-Original	Germany	Turkey
	…..			

Enacting of the FMD
+
Start securPharm

Since 2014: new „counterfeit-business-model“ in Europe:

Theft of high priced drugs and recirculation to market, also partly manipulated (=counterfeit).

2014 : 40 products affected with totally 390 transactions!

Who is responsible for successful implementation?

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- **Success and responsibility**

  Note issued by EU-commission as of 31. January 2014

  …*the **repository** containing the unique identifiers **will be set up and managed by stakeholders**. National competent authorities will be able to access and supervise the database.*

- **securPharm is a stakeholdermodel!**

  manufacturers, wholesalers and pharmacist jointly set up, manage and run the verification system.
  Major burden: manufacturers

Roadmap for FMD implementation

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March 2011
Foundation securPharm e.V.

January 2013
Start securPharm-real life t esting

6/2013
End of pilot-phase

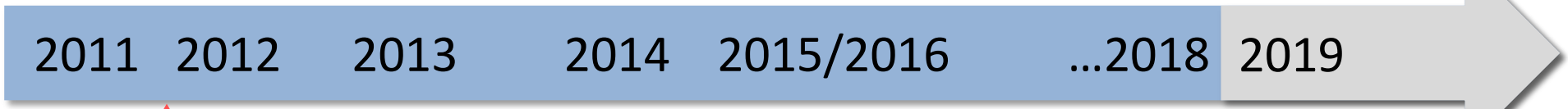
Q4 2015
Start data upload via EU-Hub

End of 2017
Switch to serialized packs completed

Q4/Q1 2018/19
End of "bringing to market" for Rx-packs without safety features

12 M

1 year training period for serialization datá management



July2011
Enacting of EU-FMD

+

Start
Delegated act process

54 month

Q3 2015 „scheduled"
Issuing of delegated acts

Q4/Q1 2015/16
Enforcement delegated acts
= completion of law setting process

36 month

Q4/Q1 2018/19 (2015+3)
Provisions of the FMD must be implemented in all EU member states..

"No dispense without verification!"

Global challenge: Coding & serialization

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United States

Data Matrix ECC 200 + Tamper evidence
Congress Bill signed in December 2013 which pre-empt previous california Law
Jan 2015: traceability at batch level within all the supply chain
Dec 2017 (4 years after enactment): Serialization of Packs & homogeneous cases
Dec 2023 (10 years after enactment): Traceability at unit level (pack) required with control system to be defined by stakeholders after pilots studies

Europe

Data Matrix ECC 200 + Tamper evidence
End 2018 (at the latest tbc in Delegated Acts) Serialization only + Verification at point of dispense for all countries except Belgium, Italy and Greece (end 2023)

Ukraine

Data Matrix ECC 200
2017 (tbc): Serialization for all Medicines (tbc)

China

Linear barcode
Since 2011: Serialization & Aggregation (at case level only) with no verification at dispensing point
for EDL products only
End 2015: all products

Turkey

Data Matrix ECC 200
Since Jan 2012: Serialization & Aggregation + Verification at all levels of the supply chain (including point of dispense) for all prescription medicines

Jordan

Jan 2017: Non Serialized Data Matrix ECC 200
Jan 2018: Serialization only with State/MoH (JFDA) Database

South Korea

Data Matrix ECC 200
Serialization only for all registered Medicines
Jan 2015: 30% products
Dec 2015: 100% of products
2017 (tbc): Aggregation

Brazil

Data Matrix ECC 200
Dec 2015 (2 years after enactment): Serialization & Aggregation for 1 pilot (1 product/3 lots)
Dec 2016 (3 years after enactment) for all medicines)

India (N/A)

Data Matrix ECC 200 +Tamper evidence when serialized
Non serialized datamatrix for Governments tenders
Since 2012: Serialization & Aggregation for exported drugs to countries with no serialization regulation

Argentina

Data Matrix ECC 200 +Tamper evidence
Since 2011: Serialization & Aggregation (required by wholesalers) with no verification at point of dispense for high risk products up to all prescription medicine

Nigeria

Local Serialization + possible verification by patient Mobile Authentication System (serialized scratch label) for Antimalarials (Jan 2013) & Antibiotics (March 2013)

Saudi Arabia

March 2015: Non Serialized Data Matrix ECC 200
Mar 2017: Serialized Datamatrix (Aggregation + reporting tbc later on)

Already enforced **2015** **2016** **2017** **2018**

Serialization Status Update
23 December 2014

Coding & serialization - the underestimated challenge

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- Application of an unique identifier (+ tamper evidence feature) to all Rx-products.

PPN

2D-Datamatrixcode

- product number (PZN)
- seral number
- batch-No
- expiry date

- Zero-defect verification of all serialized Rx-packs. This requires timely, sound and complete data-upload into the national verification systems for all marketed packs. No dispense without verification!

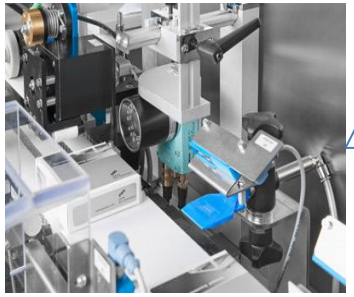
Network of challenges

Protect patients from
counterfeits in the legal
supply chain

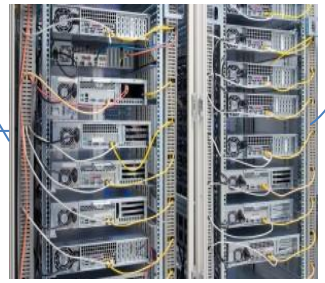
Setting up and „living“
of a stakeholderteam

Maintain marketability of
serialized products

and avoid supply
bottlenecks



upgrade of nearly all production
lines worldwide
for coding and serialization and
tamper evidence



setting up of
100& - Zero fault
verification infrastructure

Dos and Donts
for a successful FMD-implementation

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Dos

✓ **Set up and „live“ your national stakeholderorganisation**
- rules for cooperation
- financing and cost sharing

✓**Get in touch with your national competent authorities**
- practical conditions for „access and supervision„

✓**Shape your national verification system**
- common or segregated databases?
- blueprint or national solution?
- local or multicountry solution?
- suitable partners for muliticountry-solutions?

✓**Select your systemprovider**
- EMVO approved blueprint providers: Aegate, Arvato and Solidsoft

✓**GO: Start practical testing under real life conditions as soon as possible**

Donts

✓**Don´t loose time!**