

Science For A Better Life

# The German securPharm Initiative

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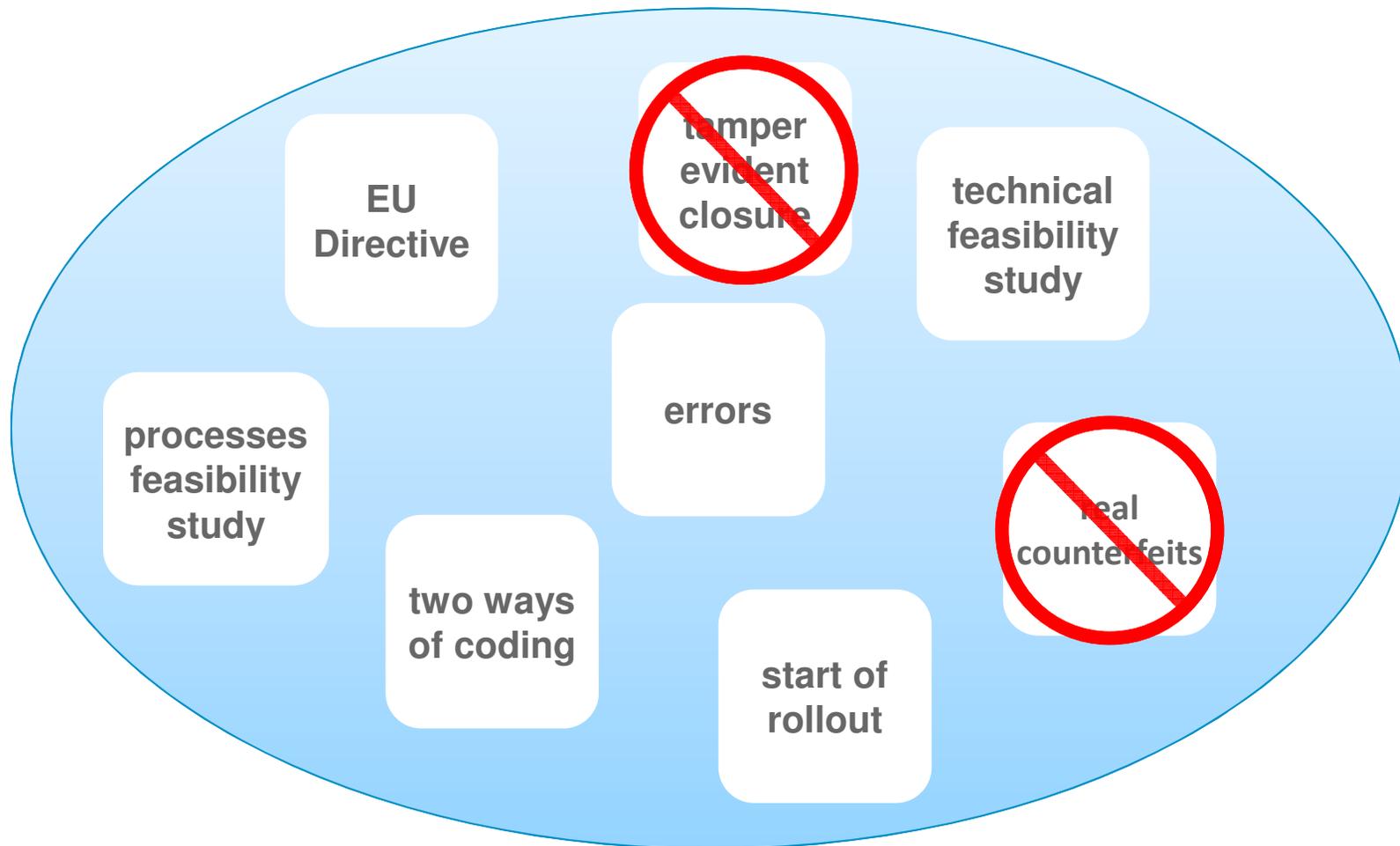


# securPharm - Stakeholders





# securPharm - Goals





# The occasion: EU-directive 2011/62/EU

L 174/74

EN

Official Journal of the European Union

1.7.2011

## DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, and point (c) of Article 168(4), thereof,

Having regard to the proposal from the European Commission,

medicinal products from other illegal medicinal products, as well as from products infringing intellectual property rights. Furthermore, medicinal products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms 'active substance' and 'excipient' should also be defined.

+ 3 years delegated acts = 2014 + 3 years to fulfill the obligations = 2017



# Objective of the EU-directive

## Main objective

- Increase protection of patients against counterfeited drugs

## Approach

- Making counterfeits unprofitable

## Additional benefits

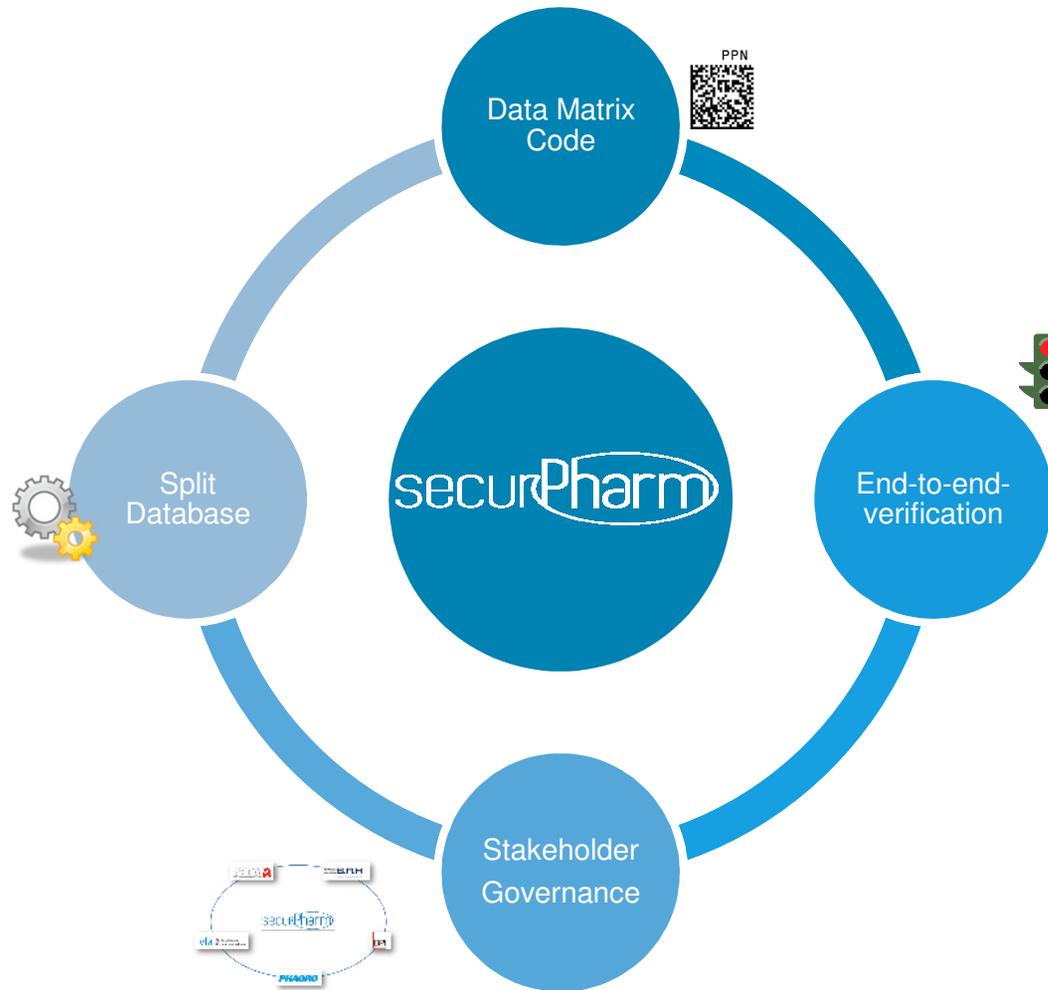
- Precise callbacks
- Optimized goods management with machine-readable product data
- Optional: Reimbursement



- Product number
- Batch number
- Expiry date
- Serial number

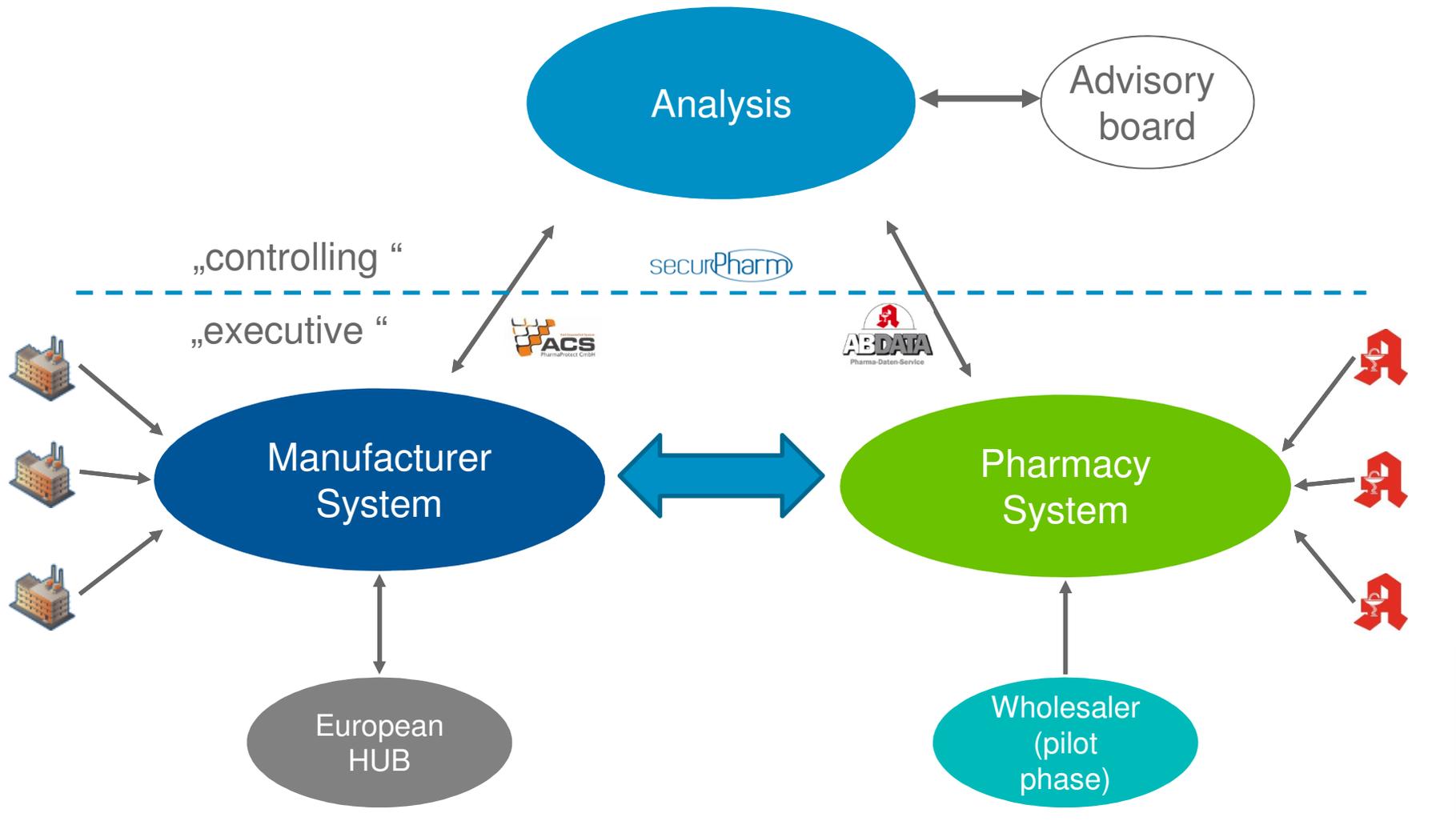


# securPharm - Concept



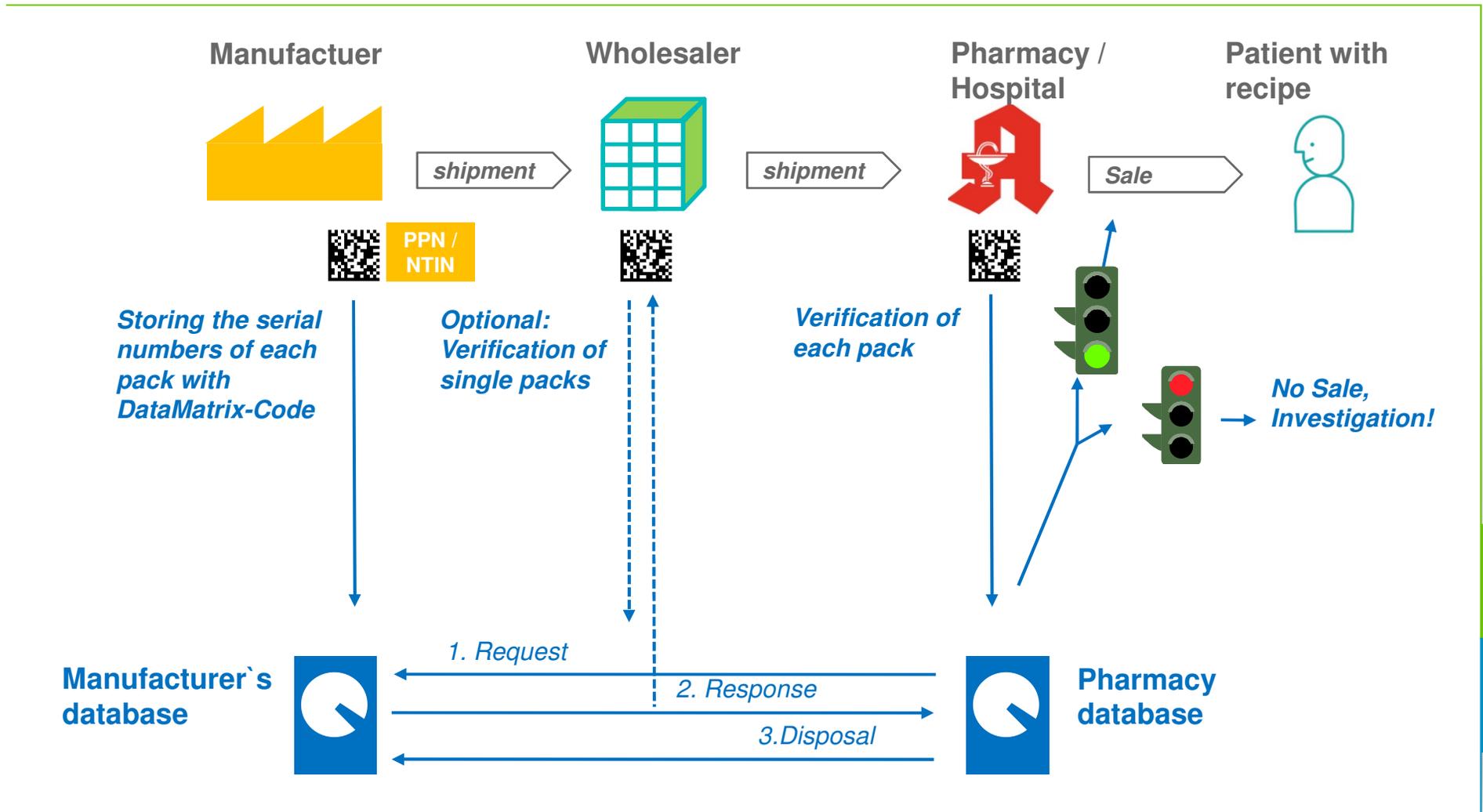


# Data Ownership





# securPharm - End-to-end-principle





# Coding with Data Matrix Code

Today	In plain text	Machine-readable
<b>PZN-7</b>	✓	✓
<b>Batch</b>	✓	
<b>Expiry-date</b>	✓	

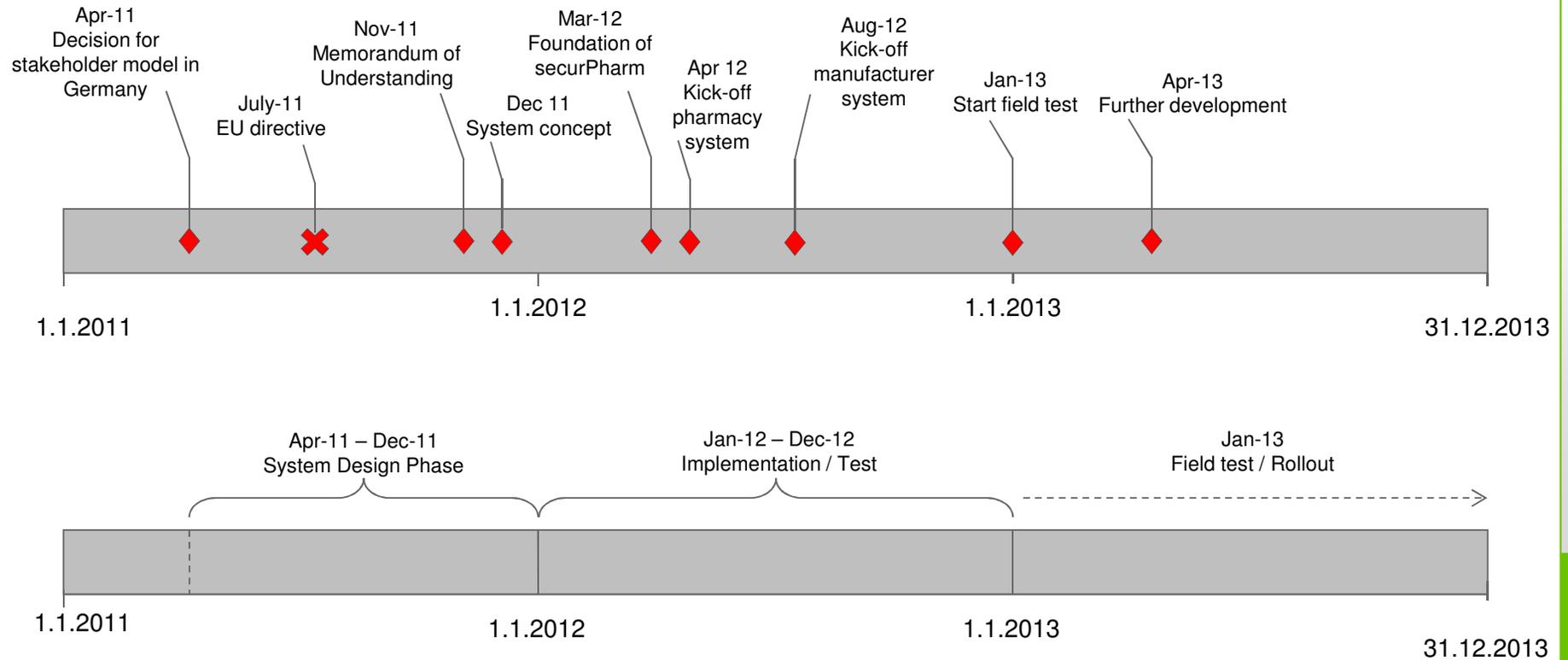


Future	In plain text	Machine-readable
<b>PZN-8</b>	✓	✓
<b>Ser.Nr.</b>		✓
<b>Batch</b>	✓	✓
<b>Expiry-date</b>	✓	✓





# Timeline



The field test is the start of the rollout!



# Status March 2013

- 24 manufacturers are participating with 86 products (different PZNs)
- more than 3 million packs already serialized

Manufacturer



- no directed distribution
- every wholesaler supplies coded products
- wholesaler checks code (optional)

Wholesaler



- approx. 200 pharmacies are currently registered with 8 software products
- full integration into day-to-day business

Pharmacies



Heterogenic technology

Heterogenic responsibility

Real products



# Status March 2013



registered pharmacies (source: Google)

- Stakeholder system is up and running since 2013-01-02
- Datamatrix Code is the appropriate data carrier
- approx. 25.000 successful verification scans
- average system response time securPharm system: 100 ms
- system availability: 99,9 % (some downtimes due to updates)



# securPharm Partner - Status Q1/2013

AAA-Pharma GmbH	<b>Abbott</b> A Promise for Life	abbvie
APOGEPHA	AstraZeneca	Bayer
Biotest	Boehringer Ingelheim	<b>DESITIN</b> SUCCESS IN CNS
EURIM PHARM	GLENWOOD	janssen   PHARMACEUTICAL COMPANY of Johnson & Johnson
kohlpharma	<b>MEDA</b>	<b>MERCK</b>
<b>MSD</b>	<b>NOVARTIS</b>	<b>Pfizer</b>
POHL BOSKAMP	<b>ROTTAPHARM</b>   <b>MADAUS</b>	<b>SANOFI</b>
<b>S</b> Mit der Natur. Für die Menschen. <small>10370908</small> Dr. Wilmar Schwabe GmbH & Co. KG	<b>WORWAG</b> PHARMA	<b>ABDATA</b> Pharma-Daten-Service Kompetent beraten
<b>ACS</b> PharmProtect GmbH	<b>PHOENIX</b> group	<b>ADG</b> Pharmacy Software A COMPANY OF PHOENIX GROUP
<b>ASYS</b> Apotheken Systeme	<b>awinta</b>	<b>cida</b>
<b>PHARMATECHNIK</b> Die neue Welt der Apotheke	<b>arvato</b> SYSTEMS	



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Thank you!



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