



How implementation can work an introduction into the securPharm project

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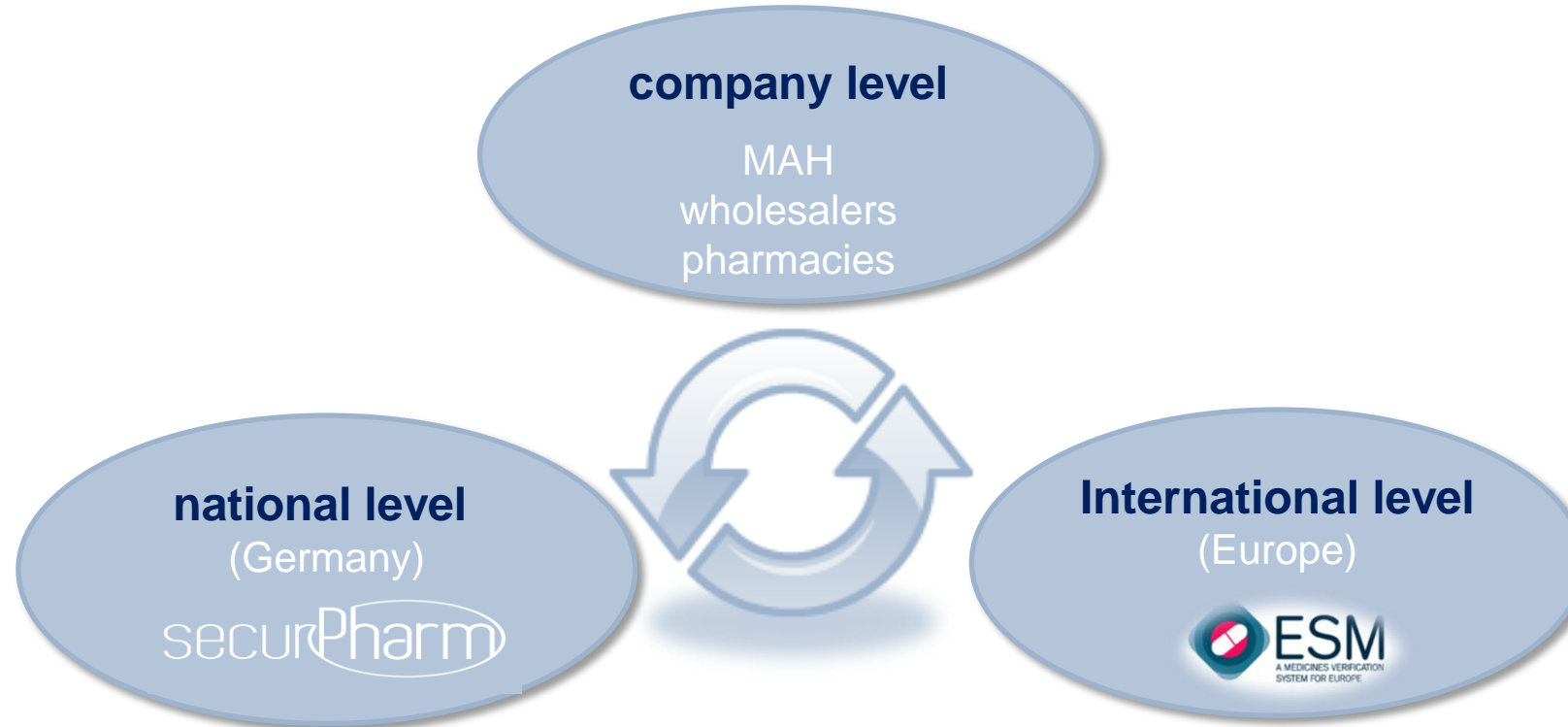
Increasing problem



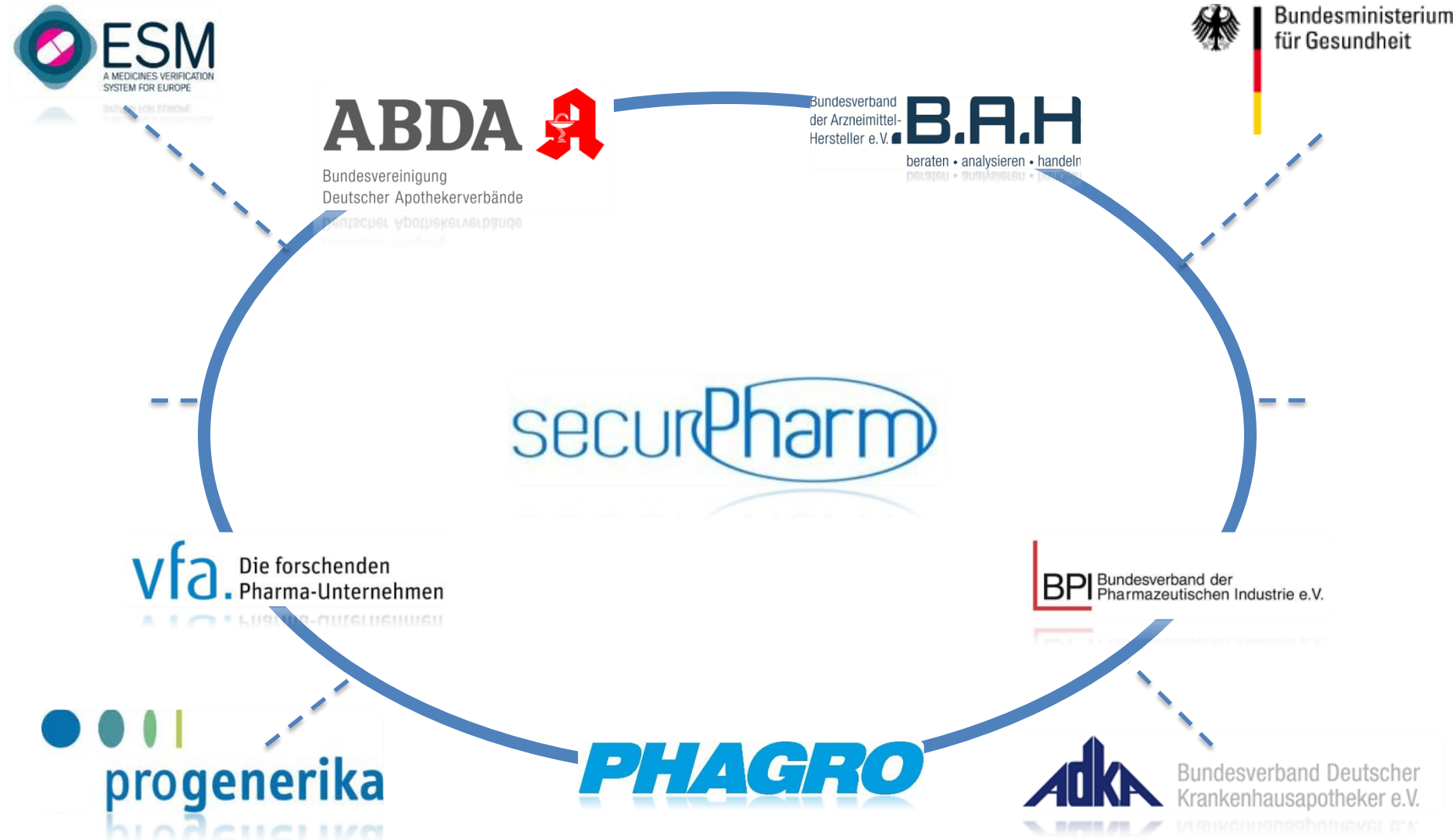
Countermeasure



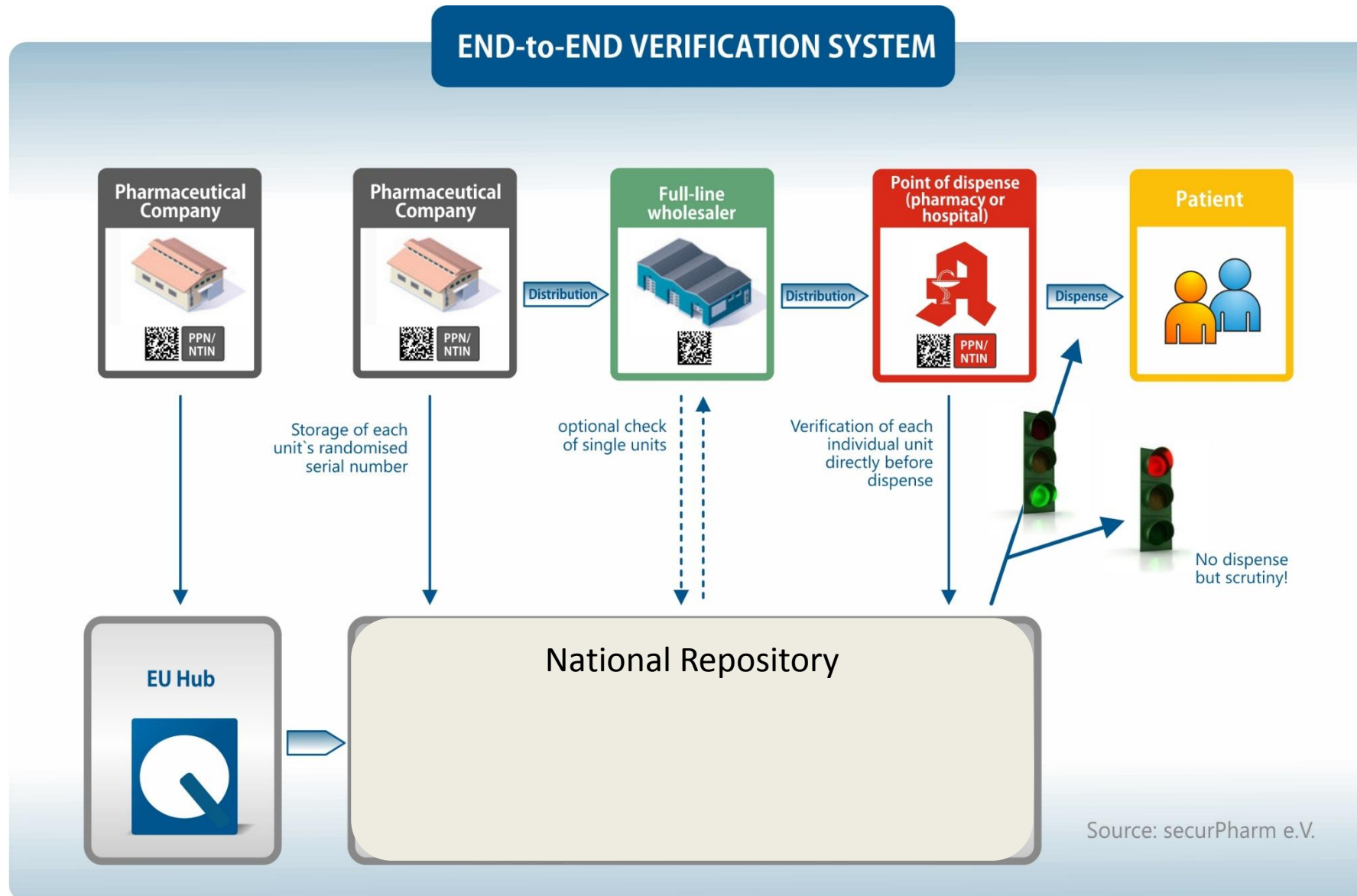
EU published directive 2011/60/EU:
the Falsified Medicines Directive (FMD)



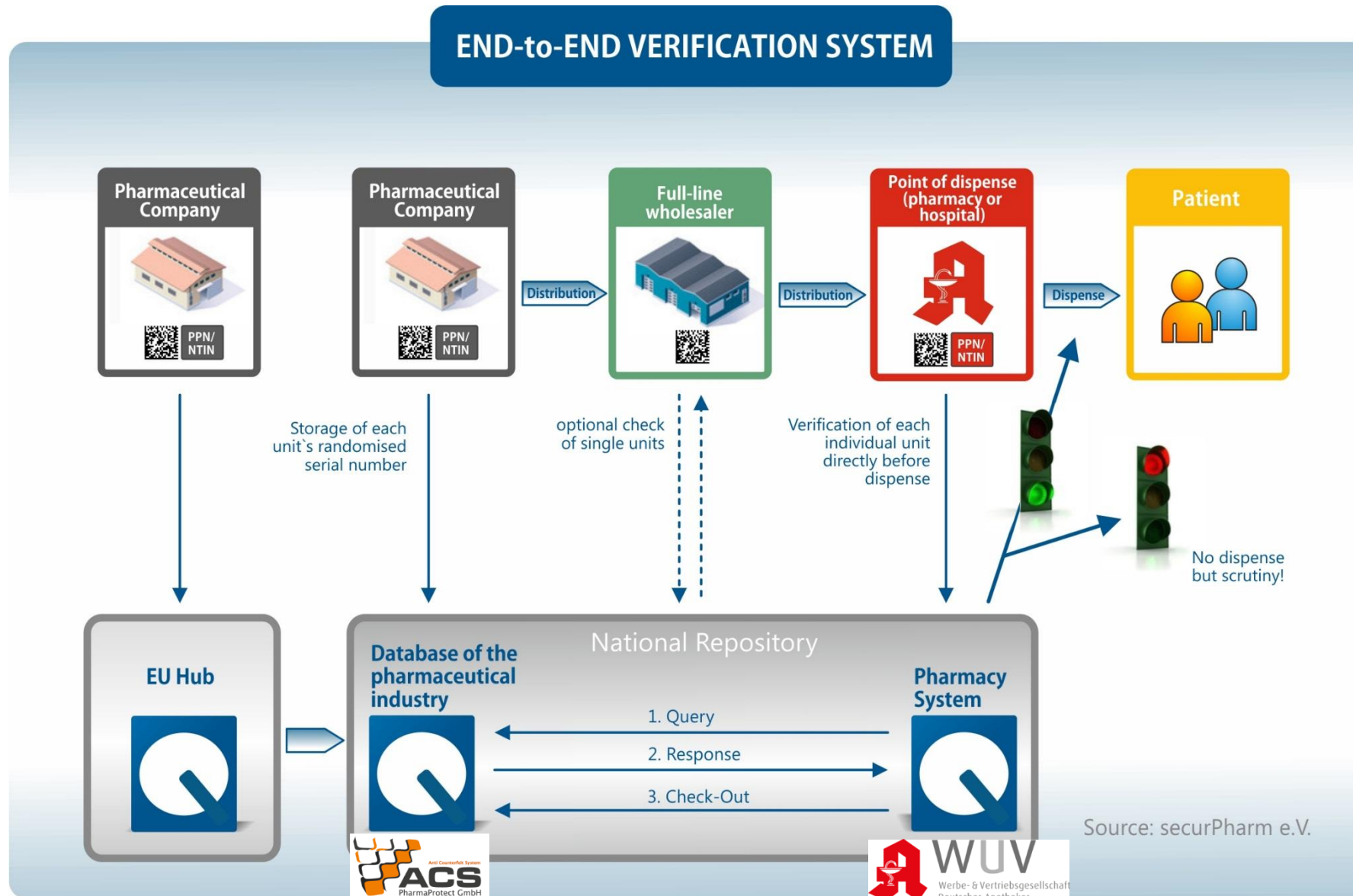
securPharm is the German Stakeholder Model – a building block for the security network of the European Stakeholder Model (ESM)



Data protection by design: separate data bases



Data protection by design: separate data bases



governance
(top-level board)



management
(legal entity)



operations
(technical provider)



arvato
SYSTEMS



* 2015-04-20



securPharm:
it works under real life conditions

Identifier of Both Schemes Based on Existing National Product Code (PZN)



both based on same ISO standards

IFA-coding scheme



- **PPN (contains PZN)**
- serial number
- batch
- expiry date

GS1-coding-scheme



- **NTIN (contains PZN)**
- serial number
- batch
- expiry date

Parallel use of PPN and NTIN well-proven since 2013

today
in your conference binder

next monday
on the website



Design Principles (Approved by COM)



setup & management by stakeholders

- open to use by all distribution chain partners
- cooperation with rel. nat'l competent authorities (access & supervision)



national verification system

- end-to-end design
- risk based approach



data protection by design

- no patient data at all
- separated databases at MAH- and pharmacy-level



composition, format and carrier of the unique identifier

- 2D data matrix code
- 4(5) elements

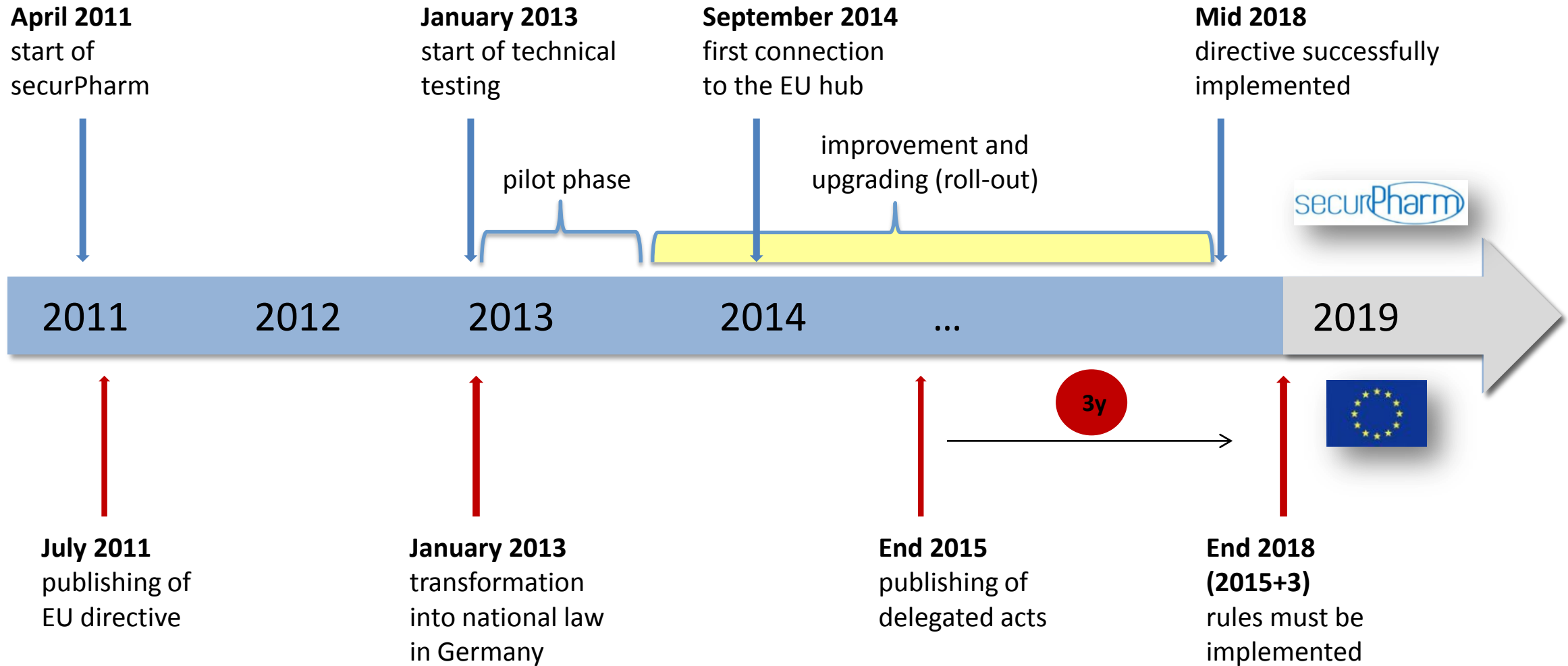


free competition of coding schemes

- IFA-Code: PPN
- GS1-Code: NTIN



Roadmap securPharm Implementing the Falsified Medicines Directive



Analysis of exceptions

