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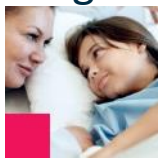

Verification of Medicinal Products in Europe

Andreas M. WALTER

EMVO Director General a.i.

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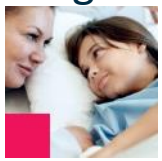

- Introduction of the Falsified Medicines Directive
- Introduction of the European Stakeholder Model
- The National Blueprint approach
- European roll-out

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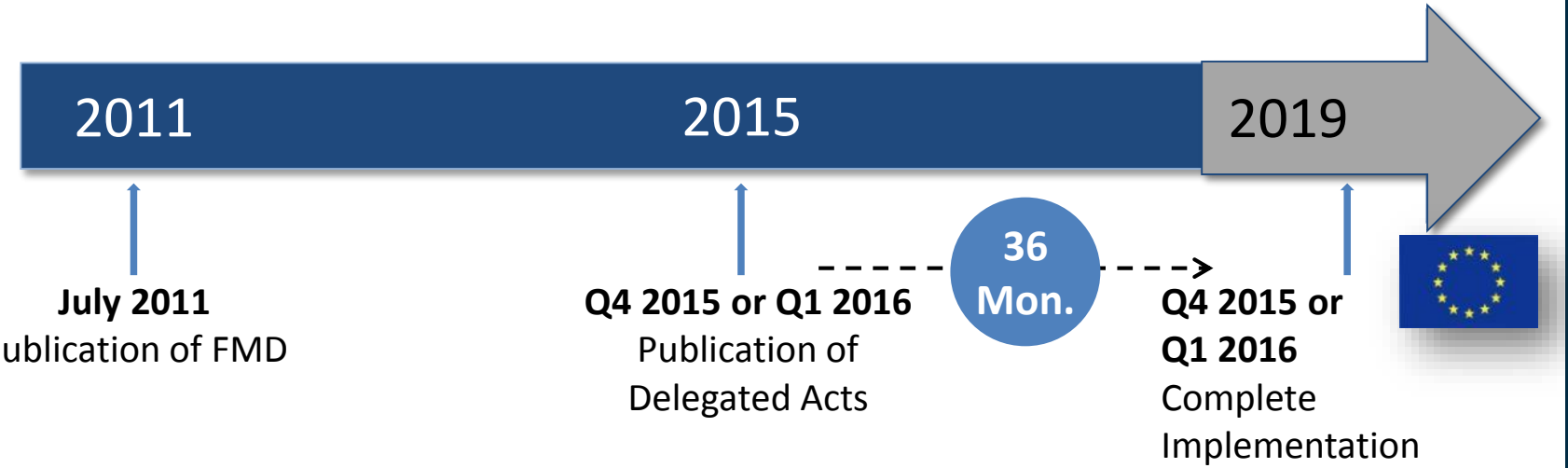
Implementation of Falsified Medicines Directive (FMD) required until 2018

- Objective Protection of patients from counterfeited medicines in the legal distribution chain
- Content Pan-European system to verify the authenticity of medicinal products



Non-compliance puts sales at risk

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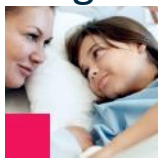

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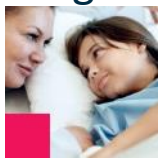
EMVO stakeholders have a common vision of medicines verification



- Protect patients
- Secure the legal supply chain
- Be proactive as market partners
- Set up a stakeholder-governed model that is
  - Functioning
  - Harmonised
  - Cost-effective
  - Inter-operable

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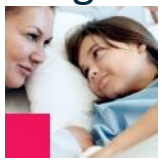
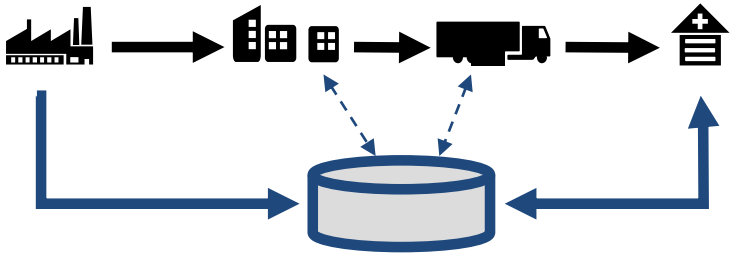
Delegated Regulation will mandate rules for medicines verification



Serialization by manufacturer

+

Verification at point of dispense



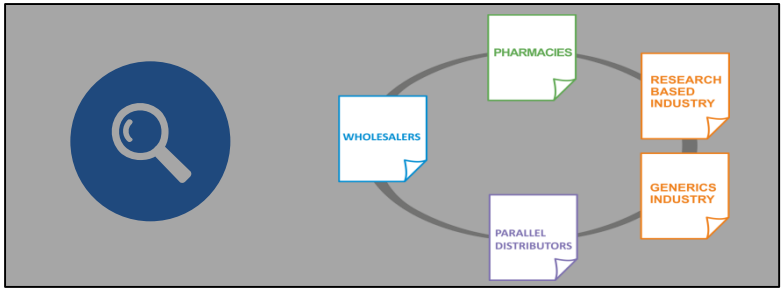
Code ('safety feature')

+

Tamper evidence

Product #:	09876543210982
Batch:	A1C2E3G4I5
Expiry:	140531
S/N:	12345AZRQF1234567890

System set up and governed by stakeholders under supervision of authorities



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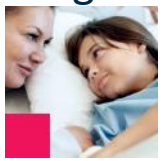
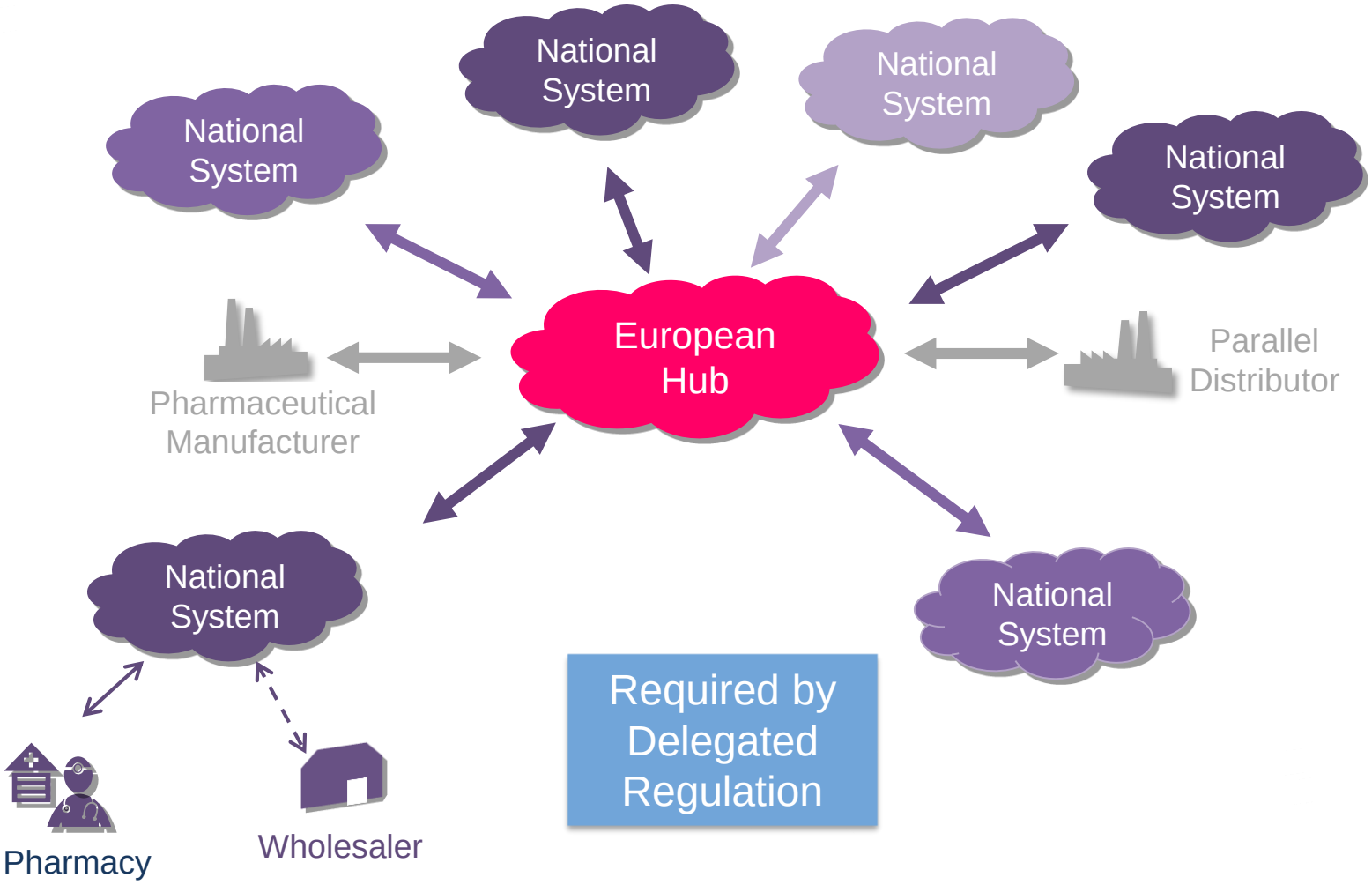
Pan-European Structure





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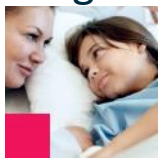

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- **The National Blueprint approach**
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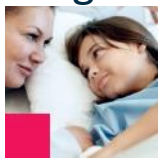
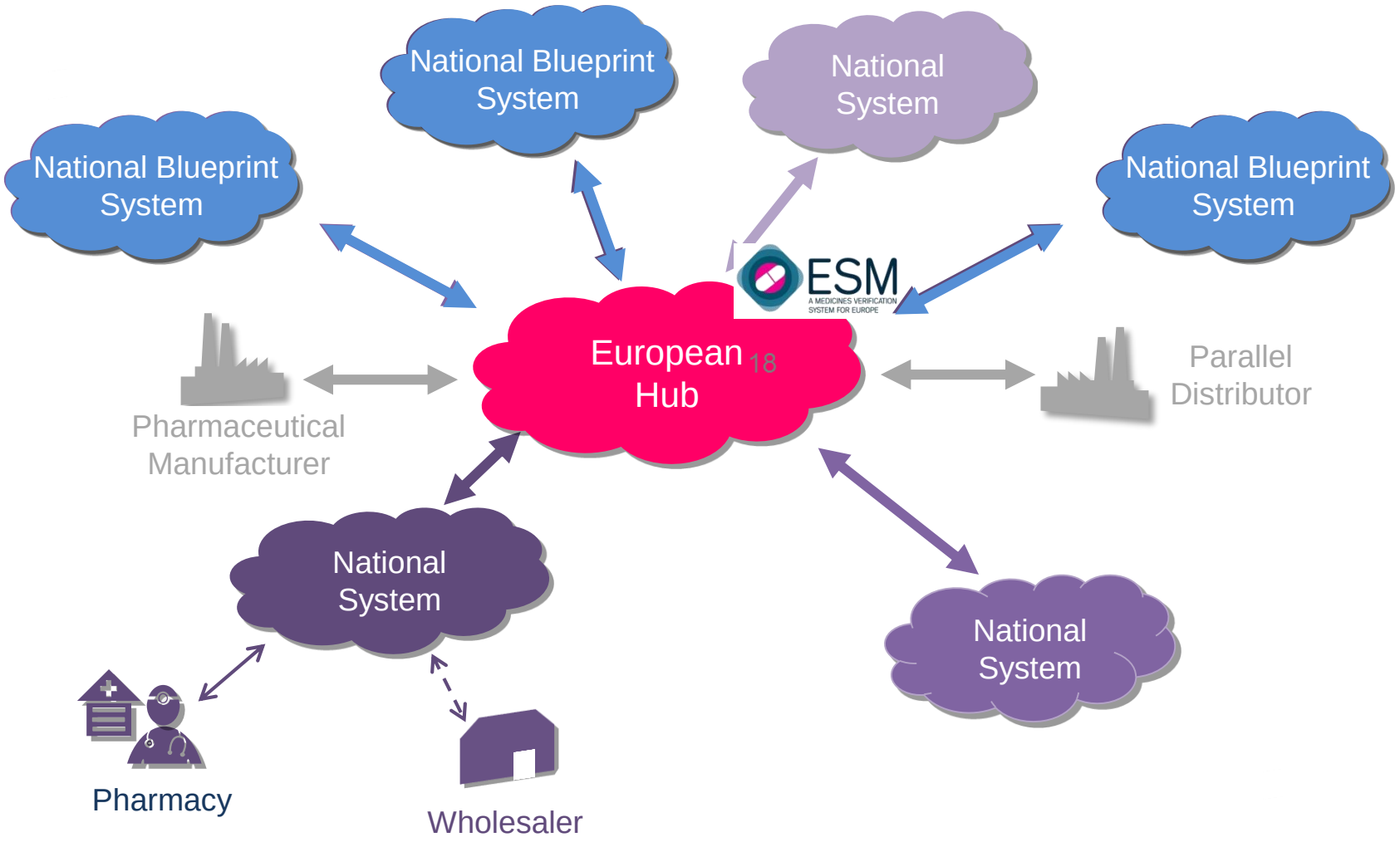
Pan-European architecture: The „National Blueprint System“ approach





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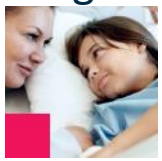
A Blueprint system is a lot more than standardised software



Main elements

- Implementation of national systems based on a common standard, i.e. compliance with URS
- Support for national stakeholders by EMVO during deployment process (to be paid for by national stakeholders)
- Management by EMVO on behalf of the respective national stakeholders (paid by them)
- Technical operation by a limited number of IT providers

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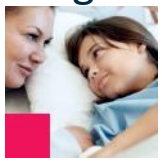

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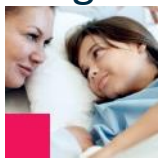
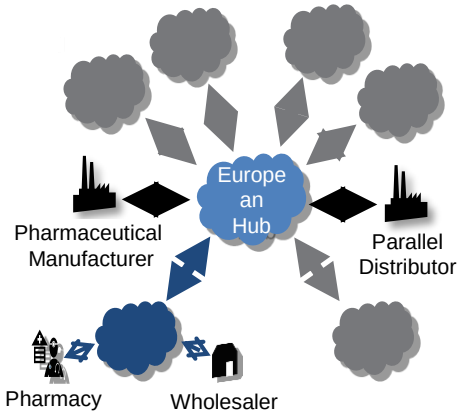
Full operation phase: Who will have to pay ?



Installations for pack coding	Installations for pack verification	Repository system (Hub & national
		
Marketing Authorisation Holders	**Pharmacists, wholesalers, …**	**Marketing Authorisation Holders**

MAHs selling products in a Member State pay for respective national system and a share of the European Hub

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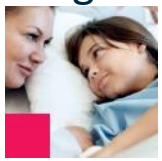
What are the actions/tasks at national level?



- Agreement between stakeholders
  - Principles for cooperation (MoU blueprint)
  - Establish stakeholder implementation project
  - Foundation of National Medicines Verification Organization (NMVO)
  - Definition of technical requirements
  - Select IT provider (if blueprint out of the EMVO selection)
  - Provide funding
- Cooperation with competent authority
- System implementation

⇒ System complete in 2018 !

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Questions?