European Medicines Verification System (EMVS)

Status March 2015

European Federation of Pharmaceutical Industries and Associations

www.efpia.eu

Introduction

- Grant Courtney
  - Previously a member of the EFPIA Serialisaiton & Coding Steering Team
  - Member of GS1 Healthcare Leadership Team
  - 20 Years experience in healthcare

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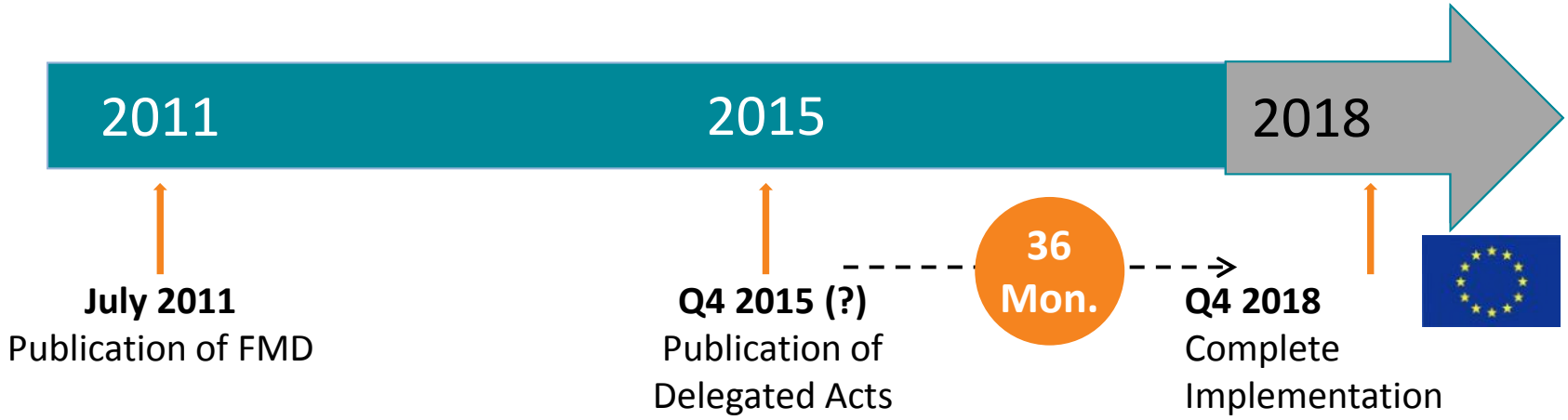
Implementation of the Falsified Medicines Directive (FMD) required until 2018

- 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

Delegated Acts will mandate rules for medicines verification

Serialization by manufacturer

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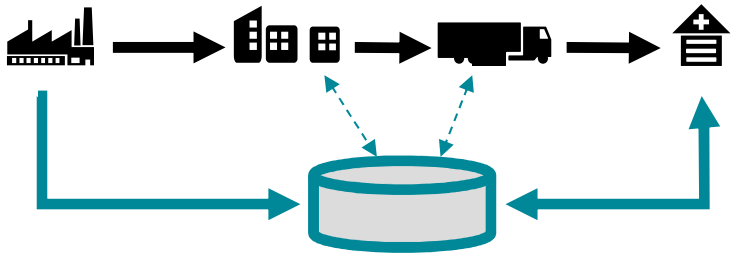
Verification at point of dispense



Code ('safety feature')

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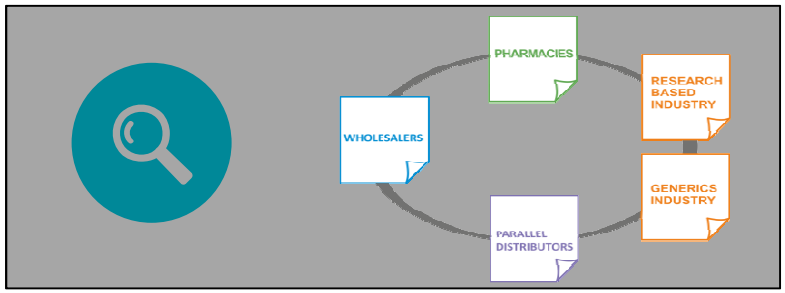
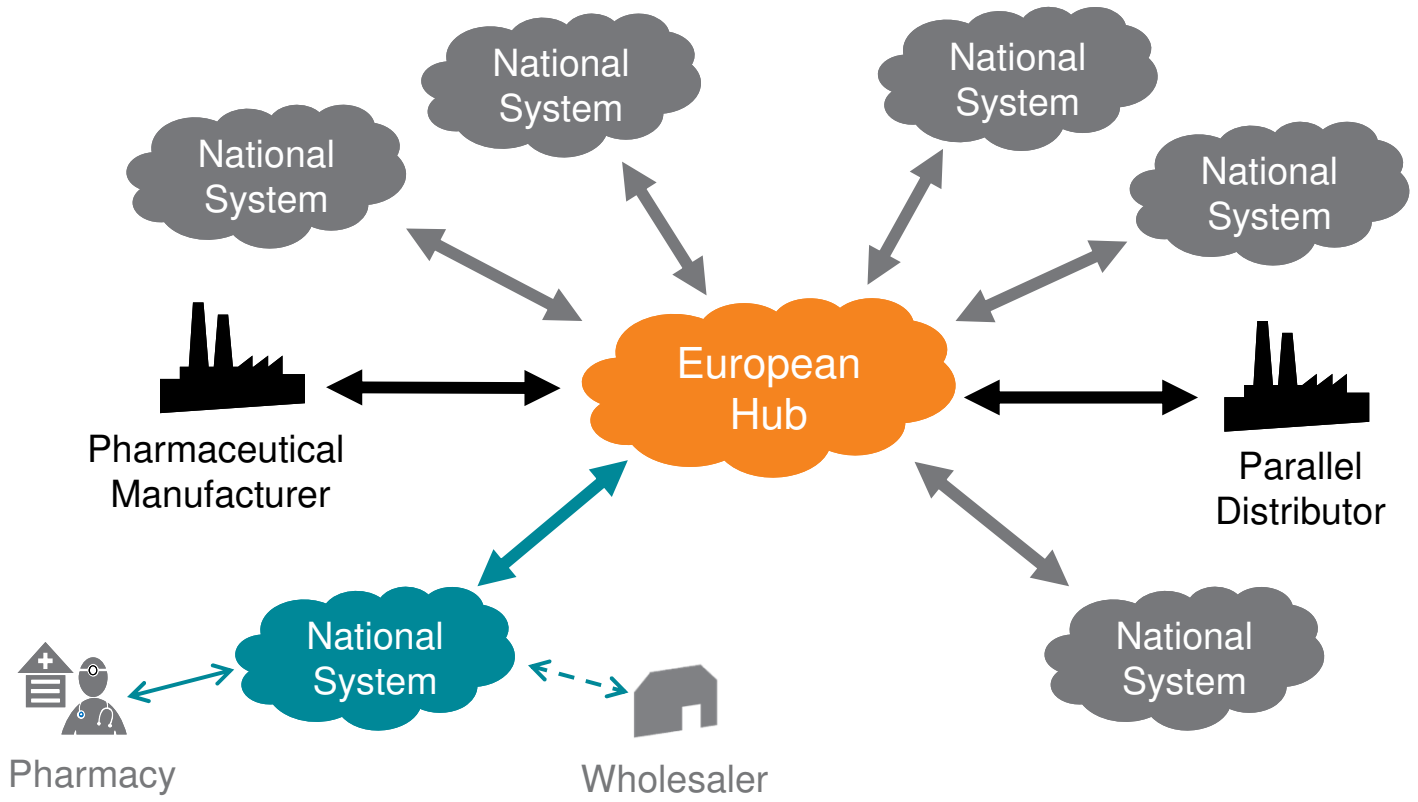
Tamper evidence

GTIN (01)	09876543210982
Batch (10)	A1C2E3G4I5
Expiry	31 May 2014
SN (21)	12345AZRQF1234567890

System set up and governed by stakeholders under supervision of authorities



Pan-European System: National Systems connected by the European Hub



European Stakeholder Model: Status

FMD	• Publication of Delegated Acts announced for Q4 2015
Stakeholders	• EMVO founded on 13 February 2015
System	• European Hub: Final test in April 2015 • Negotiations with Blueprint providers started
Member states	• First “Advisory Group” meeting to inform national stakeholders on progress of negotiations with Blueprint providers in February 2015, next end of May.
Other	• Progress audit agreement with EDQM

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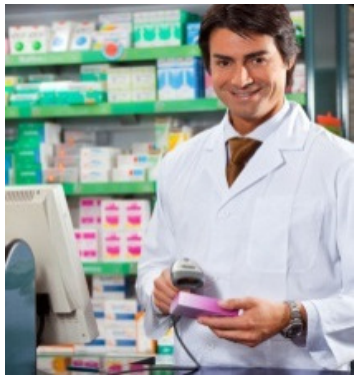
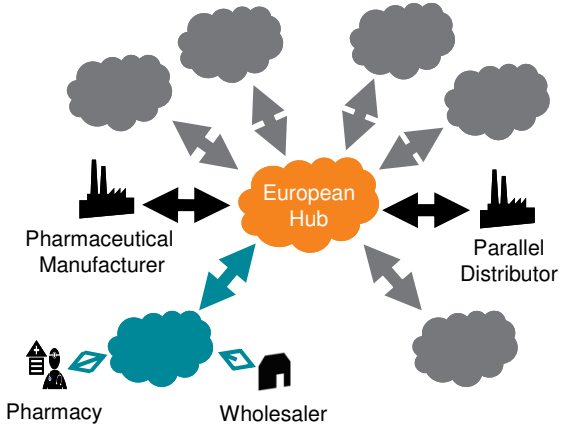
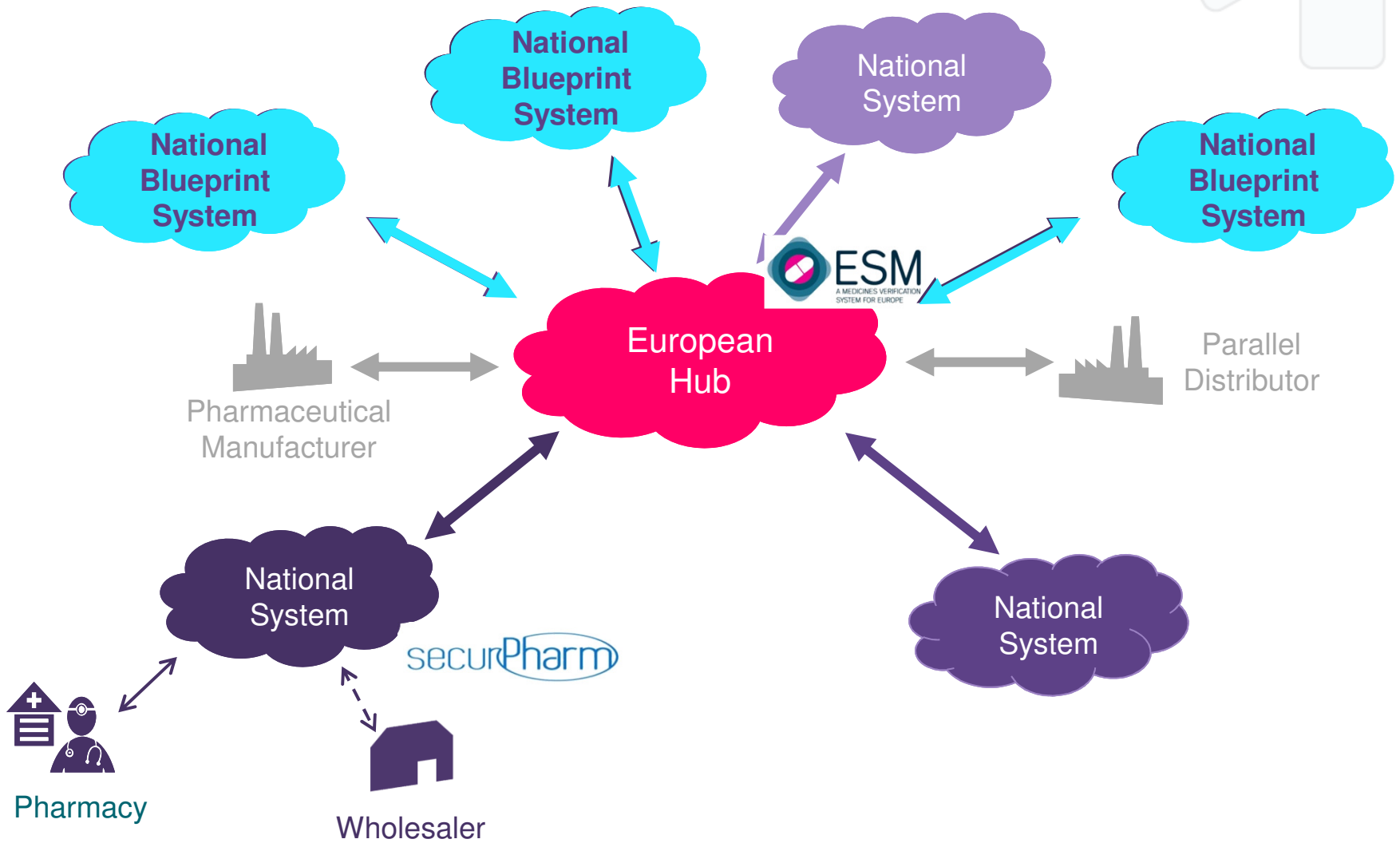
Full operation phase: Who will have to pay ?

Installations for pack coding	Installations for pack verification	Repository system (Hub & national systems)
		
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

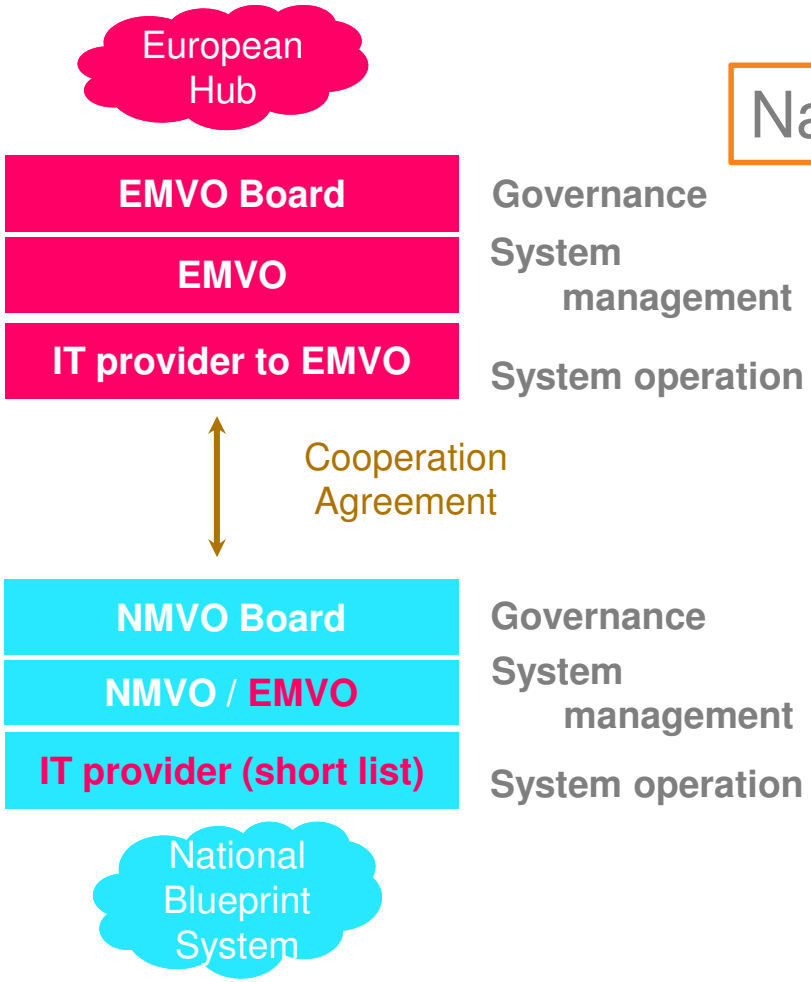
Pan-European architecture: The „National Blueprint System“ approach



The Blueprint approach provides substantial benefit

- Complexity reduction for NMVOs:
  - Allows national stakeholders to build national system without starting from scratch
    - Based on a “standard” national verification system providing all necessary functionality
  - Strong support by EMVO during deployment & operation (system management)
- Cost reduction for payers through economy of scale
  - Fewer, but bigger (aggregate) systems are less costly than many (individual) smaller systems
- Benchmark for Total Cost of Ownership

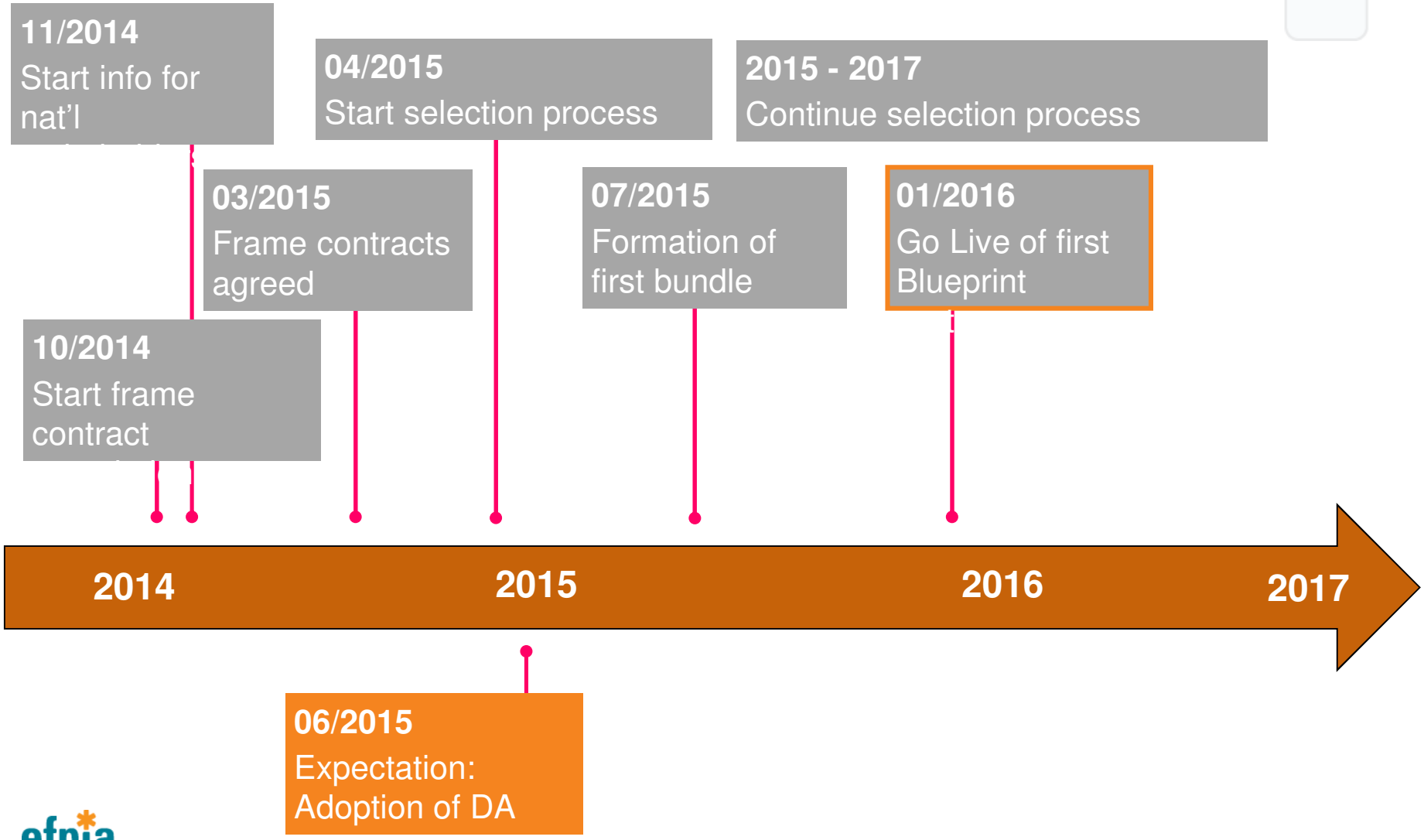
The National Blueprint System: Governance & management



National Blueprint System

- **Governance** by national stakeholders
- **Management** by EMVO on behalf of the respective national stakeholders
- **Operation** by IT provider as preselected by EMVO

Timeline (as of 01/2015)



Ramp up phase

What are the actions/tasks at national level?

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

⇒ System complete in 2018 !

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EMVO Interim Organisation (Responsibilities until Q2-Q3 2015)