EMVO

European Medicines Verification Organisation

Verification of Medicinal Products in Europe

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European Medicines Verification System

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AGENDA

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

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EU Falsified Medicines Directive

- Manufacturers must apply safety features (unique identifier + tamper evidence) to allow verification of authenticity and identification of individual Rx packs and provide evidence of tampering
- Repository systems must be established to house the information on the safety features. Costs shall be borne by the Manufacturing Authorisation holders (MAH)

- Risk-based approach – “white list” for prescription medicines, “black list” for OTC
- Parallel distributors must replace safety features with equivalents and are liable for errors

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Possibility for national extension of scope

- Member States can require the placing of:
  - The unique identifier on any medicinal product subject to prescription or to reimbursement
  - The anti-tampering device on any medicinal product

- Member states may use the information contained in the repository systems for the purposes of:
  - Reimbursement
  - Pharmacovigilance
  - Pharmacoepidemiology

- Some Members States are already considering to extend the scope of the safety features

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Fundamental principles for medicines verification in the EU

SAFETY FEATURES	• Unique identifier with randomised serial number • Check of pack's authenticity at point of dispense
SYSTEM DESIGN	• Flexible to implement national solutions within an EU technical framework (according to User Requirement Specifications) • Interoperable between different national systems through European Hub
DATA	• Transactional data belongs to stakeholder that generated it, e.g. pharmacists for dispensing data • No access to data of other stakeholders except for verification purposes
GOVERNANCE	• Systems governed by non-profit organisations, established and managed by relevant stakeholders • Systems supervised by EU and/or national authorities • Quality supervision by EDQM (tbd)

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Stakeholders take Action to Protect Patients from Falsified Medicines

VISION

- Protect legal medicines supply chain throughout EU
- Comply with the FMD in a pan-European effective and cost-efficient way

STATUS

- Design for Pan-European system and governance in place:
  SecurPharm connected to the European Hub
- Start up implementation in place

PLAN

- Work with EU and national stakeholder associations towards effective rollout and collaborate with EU and national authorities

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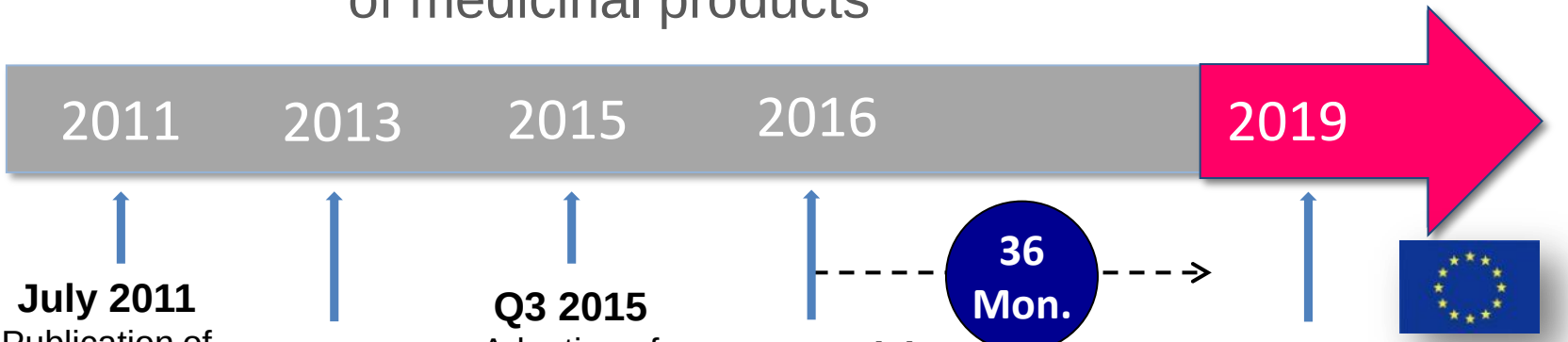
Implementation of the Safety Features part of FMD required in all MS 3 years after publication DAs

Objective Protection of patients from falsified 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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ESM 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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EMVO members are allocated to a constituency

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

PHARMACIES

RESEARCH BASED INDUSTRY

efpia
European Federation of Pharmaceutical Industries and Associations

WHOLESALERS

GIRP
the vital link in healthcare

GENERICS INDUSTRY

EGA

PARALLEL DISTRIBUTORS

E A E P C
European Association of Euro-Pharmaceutical Companies

Membership open to other stakeholder associations

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Effective Management of the Verification System

GENERAL PRINCIPLE

System management and governance by not-for-profit organisation under supervision of relevant competent authority

EU LEVEL

European Medicines Verification Organisation (EMVO, founded February 13, 2015)

NATIONAL LEVEL

National Medicines Verification Organisations (NMVOs), e.g. securPharm

EU level and national level organisations cooperate on the basis of service level agreements

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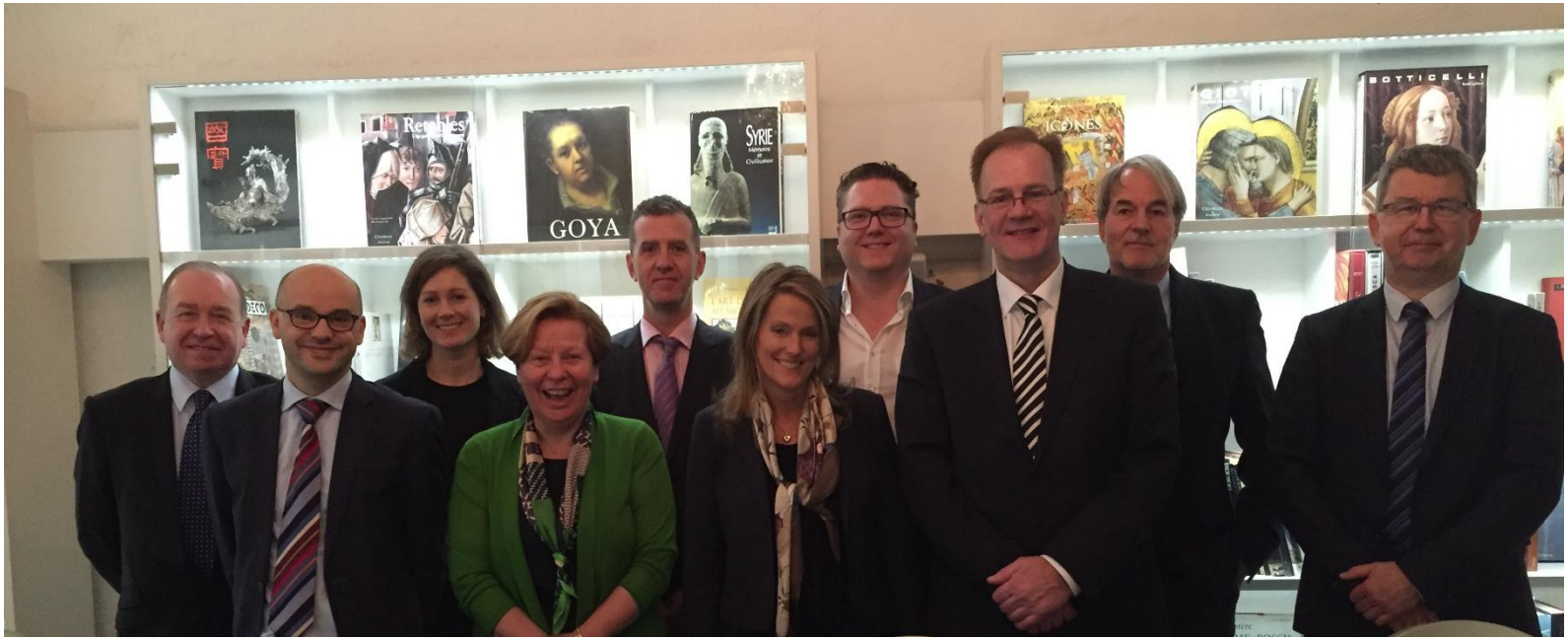
Official EMVO establishment on 13th February 2015 in Luxembourg



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What the ESM partners have achieved

- Ten Core Principles to protect patients from falsified medicines
- Elaboration and formal endorsement of Memorandum of Understanding (and its technical annexes also know as the “foundation documents”) providing the foundation for the pan-European system
- Statutes for European Medicines Verification Organisation (EMVO) – up and running
- Ongoing dialogue with additional stakeholders
- Ongoing dialogue with European and national authorities

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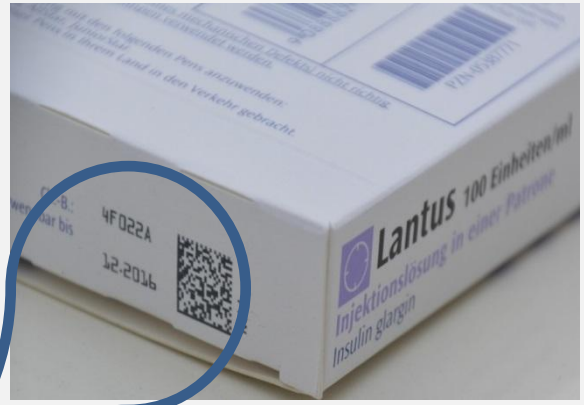
Common basic concept: Unique Identifier

- **Data-Matrix code, developed to ISO-standards**
- **Key data elements:**
  - Product code (GTIN/NTIN or PPN)
  - Randomised unique serial number
  - Expiry date
  - Batch number
  - National health number (where necessary)



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

Expected to be required by Delegated Acts

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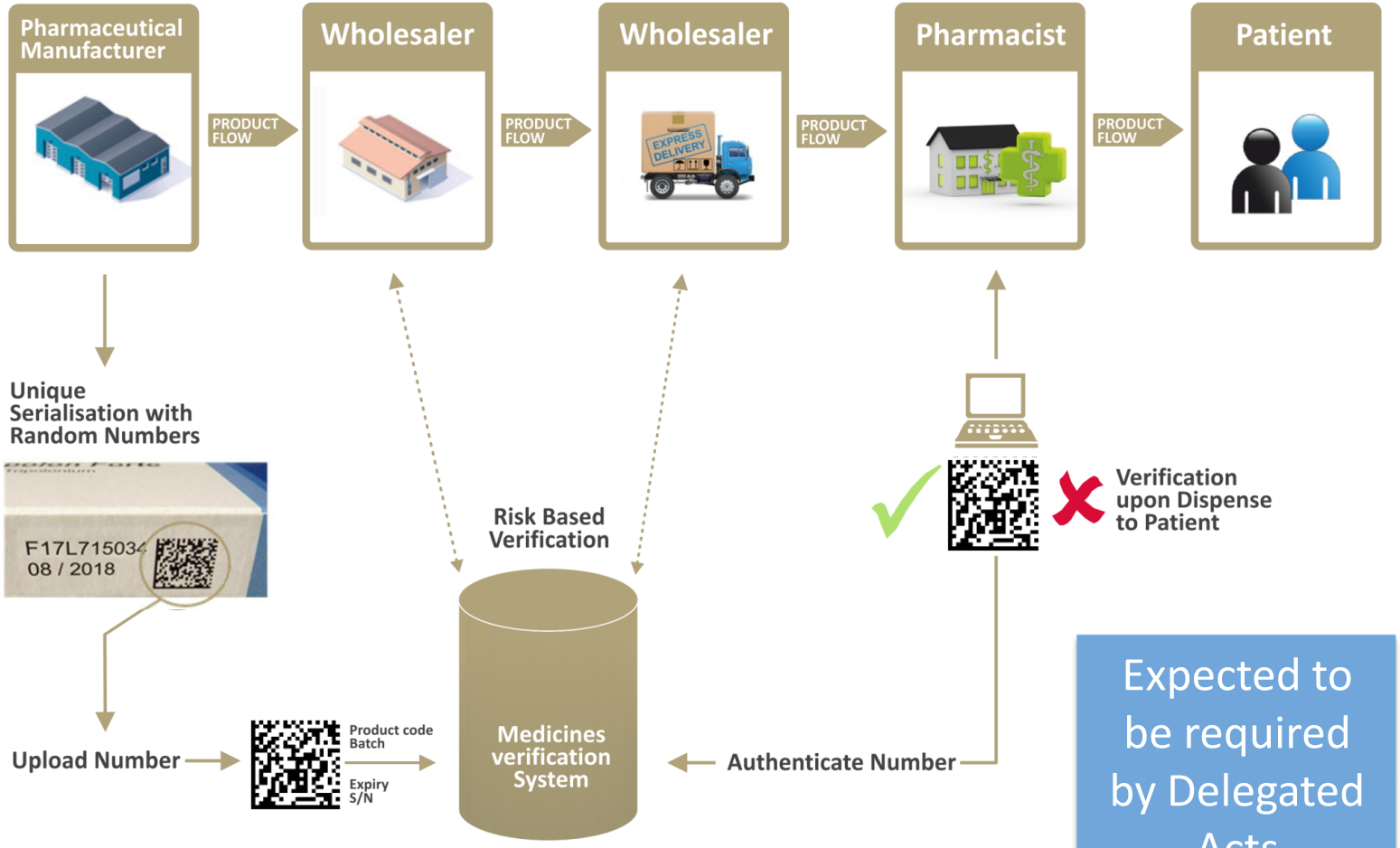
Common basic concept: “Point of dispense verification”



Expected to be required by Delegated Acts

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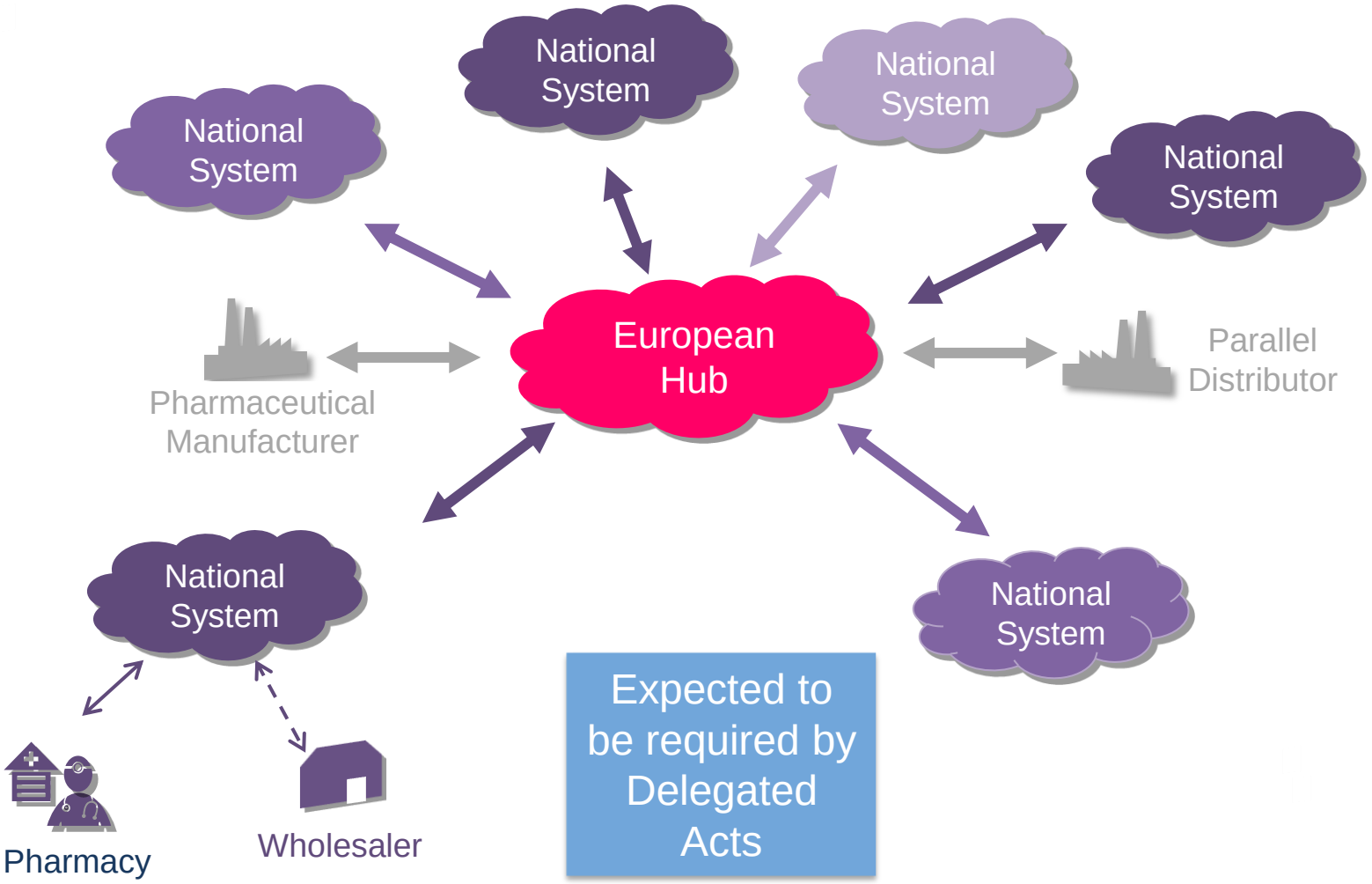
Pan-European Structure



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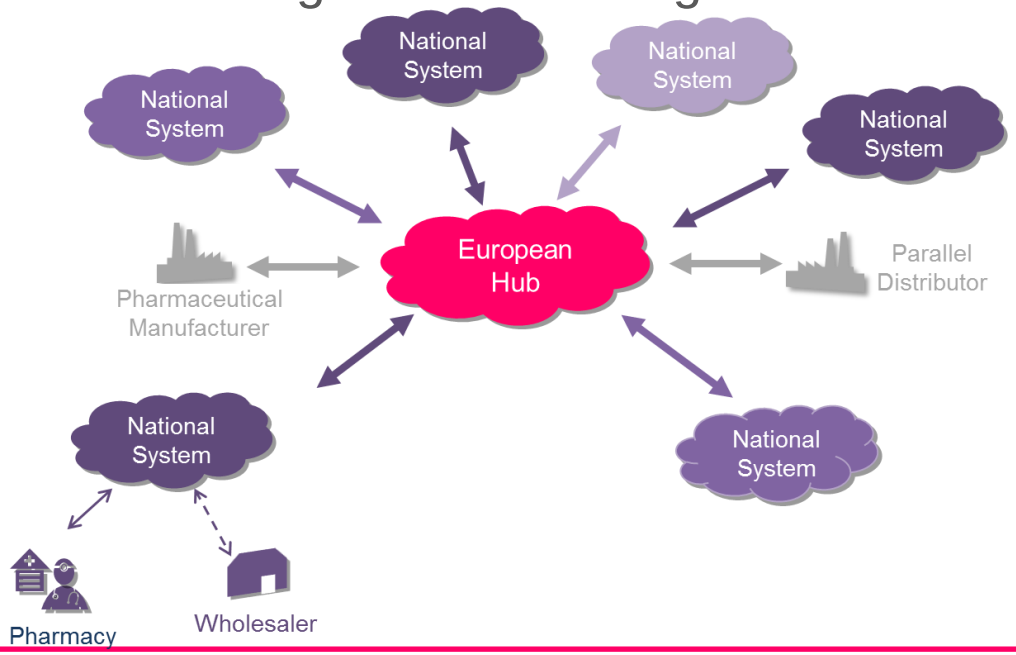
The European Hub is reality and its value undisputed

European Hub

- Secures cross-border trade
- Ensures interoperability between national systems
- Supports establishment of standard interfaces
- Provides cost savings for connecting manufacturers



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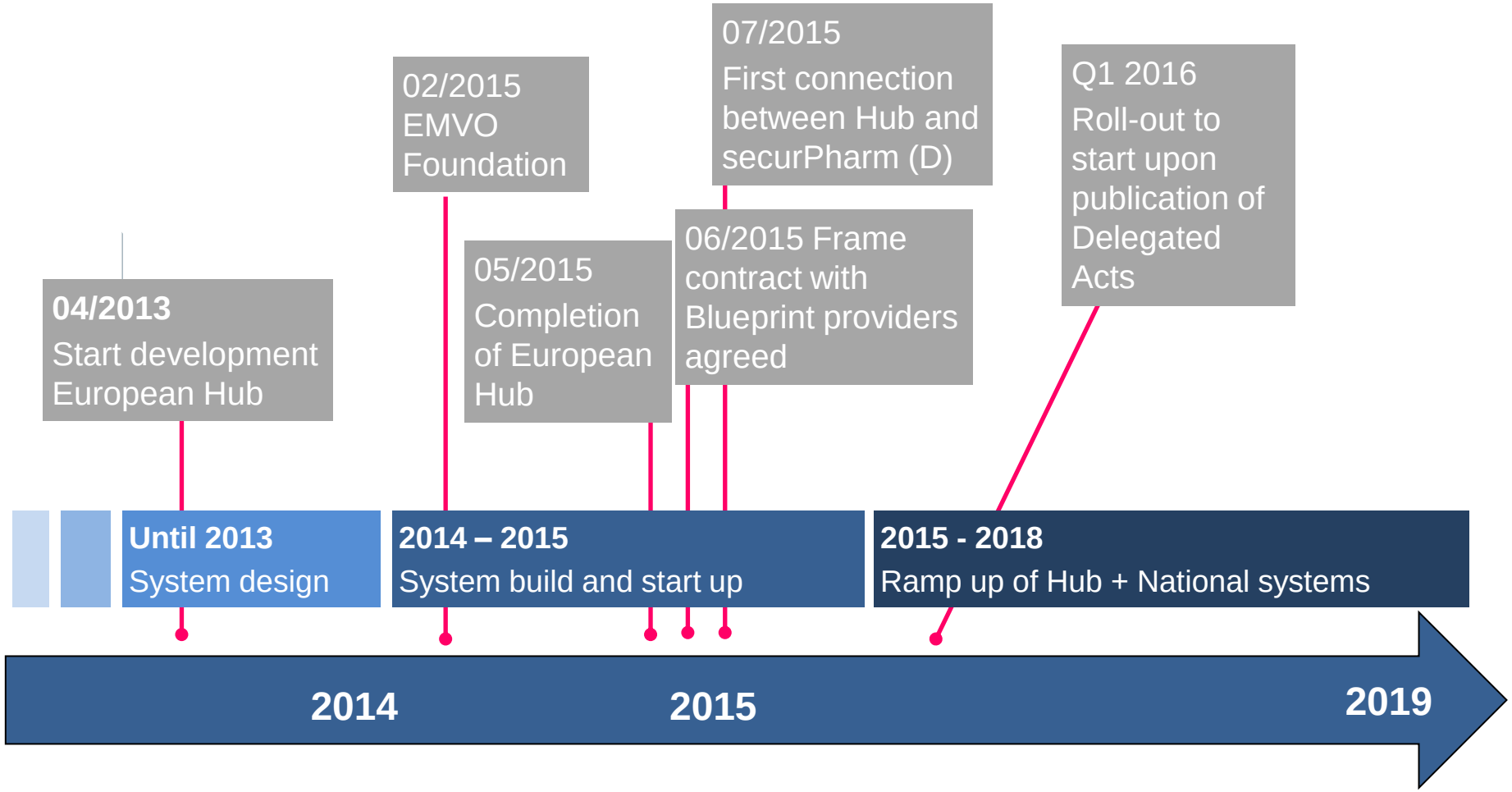
The EU Hub is operational and connected to the first national system



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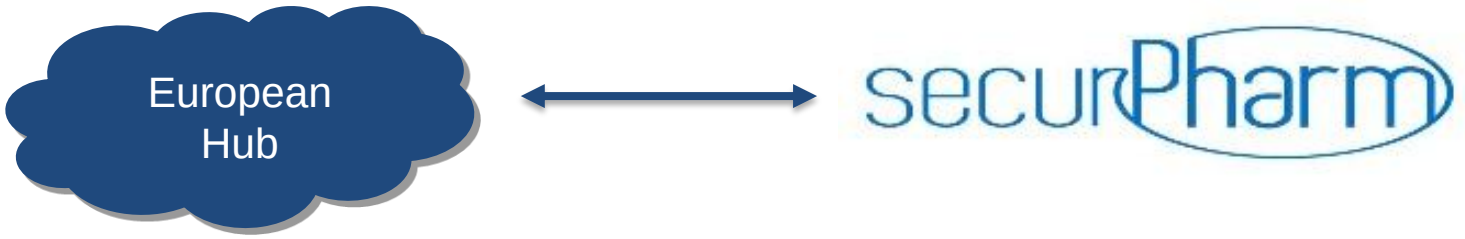
First Hub connection with a Member State

July 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1		2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

link up established



Pharmaceutical manufacturers are now able to upload their serialised data onto the system

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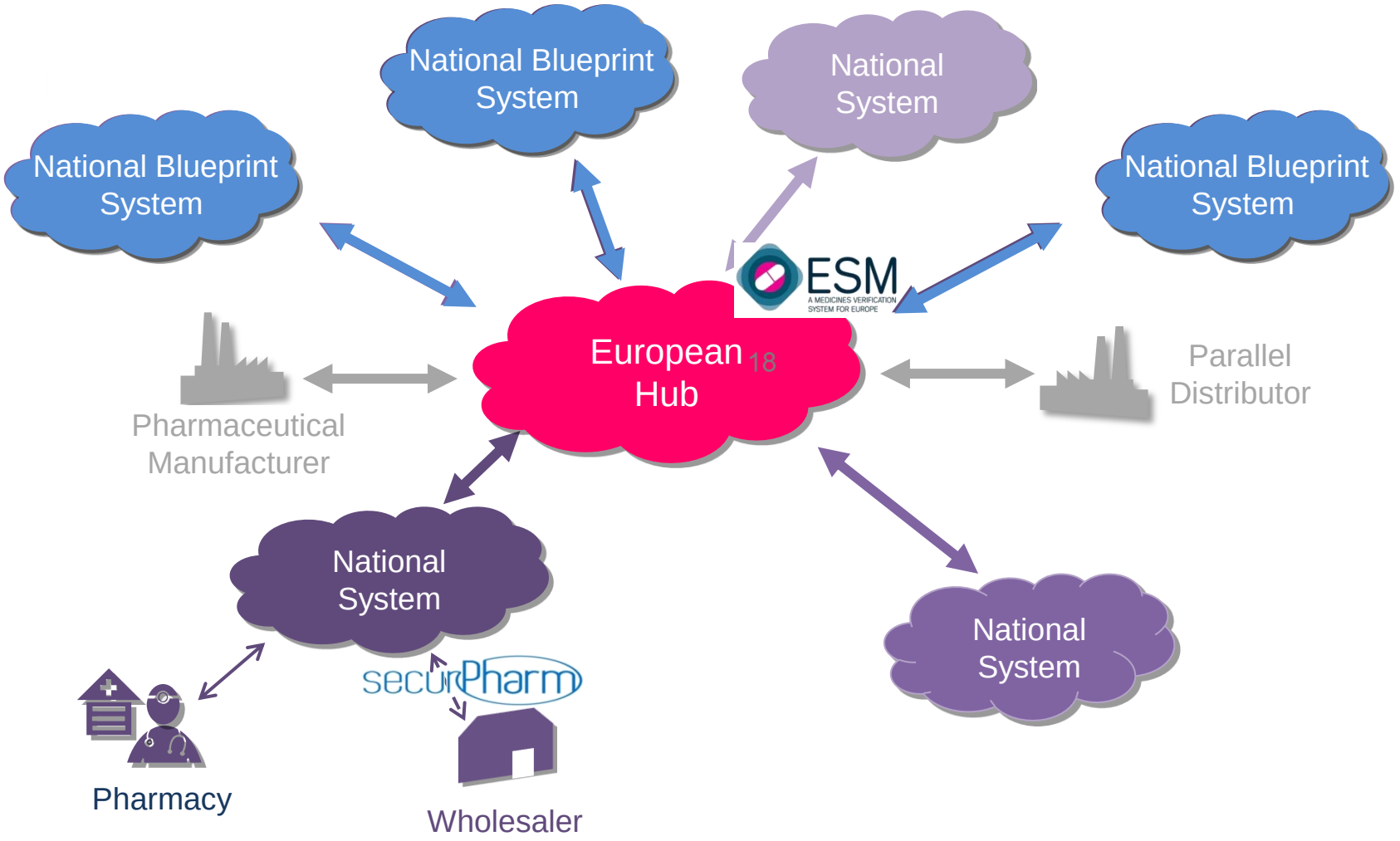
Pan-European architecture: The „National Blueprint System“ approach



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The National Blueprint approach provides substantial benefit

National Blueprint System

- 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
  - Several countries buying from the same supplier
  - Coordinated operation
- Benchmark for Total Cost of Ownership

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The National Blueprint System: Governance & Management

EMVO Board — Governance

EMVO — System management

IT provider to EMVO — System operation

Cooperation Agreement

NMVO Board — Governance

NMVO / EMVO — System management

IT provider (short list) — System operation

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Remit:

- Establish, manage and operate European Hub
- Ensure interoperability of connected systems
- Conclude agreements with NMVOs
- Set standards for the EMVS
- Manage 'national Blueprint' systems at request of national stakeholders

National Blueprint System

Remit:

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

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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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The Blueprint approach provides substantial benefits

Expected Benefits

- **De-facto standard for implementation of national systems**
- **Complexity reduction for NMVOs**
  - During deployment (support by EMVO)
  - During operation (management by EMVO)
- **Cost reduction for MAHs through economy of scale**
  - During deployment (procurement of ‘many’ national systems from one single IT provider - 3 IT providers to chose from)
  - During operation (management of ‘many’ systems by EMVO)
  - High savings potential
- **Benchmark for Total Cost of Ownership**
- **National adaptation for specificities possible**
- **National choice of IT provider within the framework**

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Negotiations on IT service for Blueprint finalised

Contract structure

Frame agreement
EMVO – Service provider

To ensure that all markets will be served

Template national Blueprint agreement
(incl. annexes)
NMVO – Service provider

Conditions at which services will be delivered

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Framework Contract

- Frame contract between the EMVO and the service provider
- general terms and conditions under which the supplier is prepared to enter into National Blueprint Agreement with NMVOs
- prices for development and operation of the National Blueprint System in compliance with specifications to be provided by supplier
- additional functionalities can be agreed upon between an NMVO and supplier
- interested NMVOs negotiate with supplier on the basis of model contract

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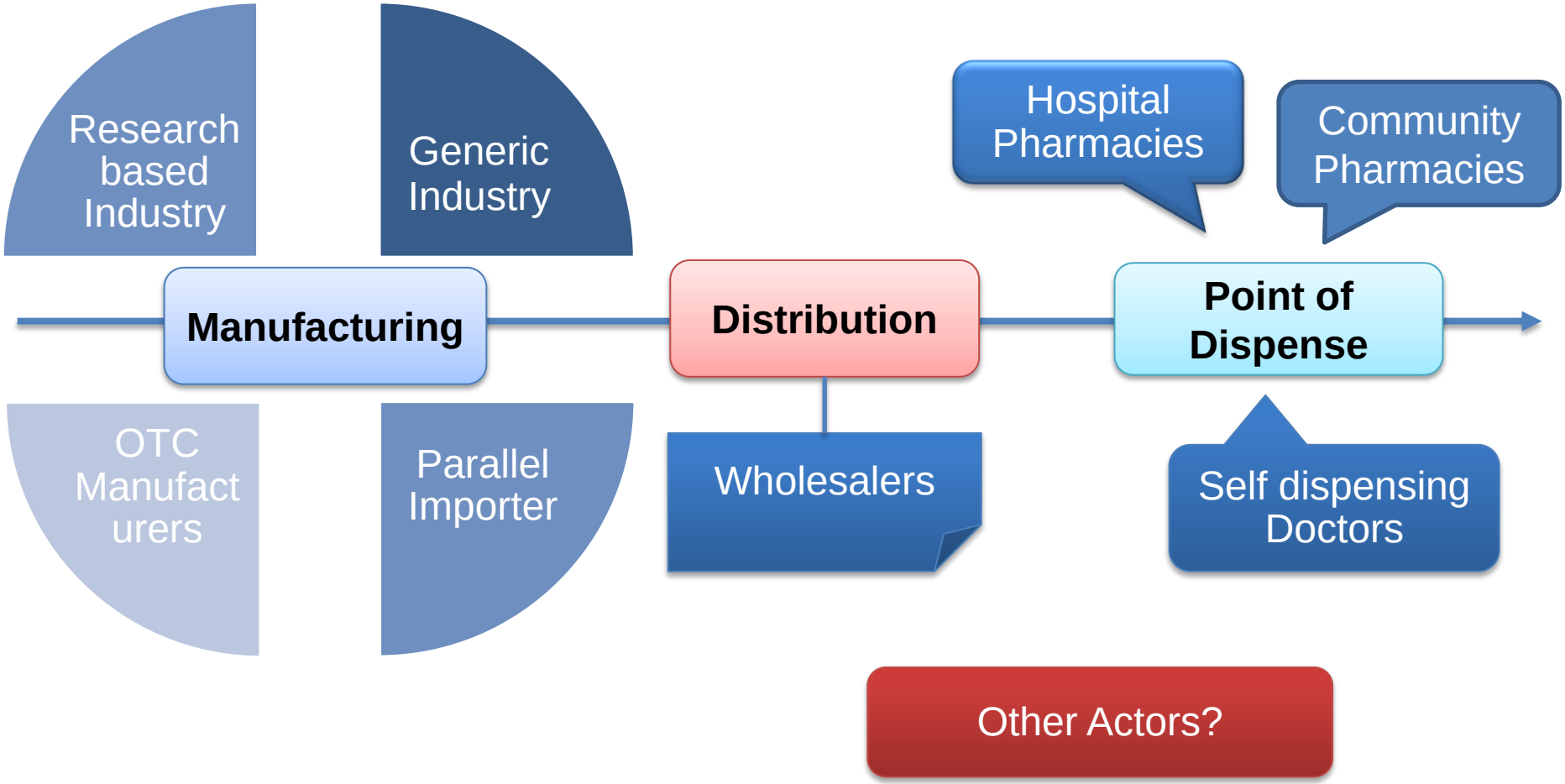
Identifying national supply chain actors



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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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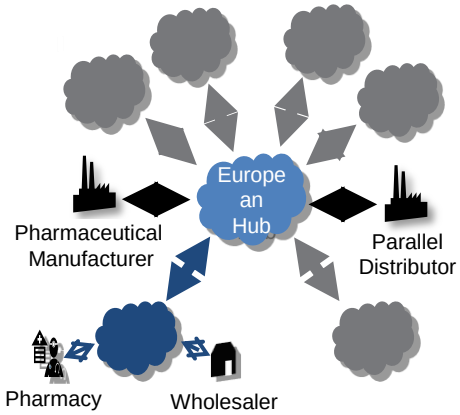
Full operation phase: Who will have to pay ?

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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Cost allocation model: Conclusion on a flat fee model

- Practicality
  - Easy way of calculating: equal division amongst MAHs and PD
- Fairness
  - Takes into account market activity: companies with multiple MAHs pay more
- Transparency
  - Simple accountancy / audit

- Predictability
  - Calculations based on number of active participants in the market the year before the fee adjustment
- Balanced
  - A company can be more active in country A, compared to country B and will therefore pay more in country A
- Upfront payment
  - In order to prevent free-riders, easy calculation gives opportunity to pay upfront

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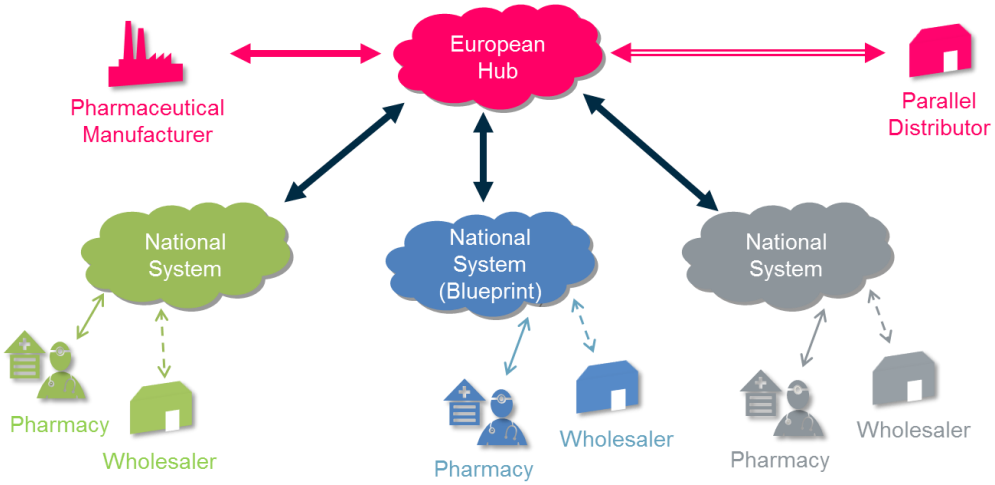
Conditions for a cost-effective Pan-European system

- Leverage functionality of the European Hub
- Not more than one national system per Member State
- Not too many different service providers to supply the Member States
- Staged approach for system implementation to avoid many ‘last minute implementations‘ in parallel
- Collective administration and management of several national systems by one organisation



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EMVO offers support for national stakeholders: “Implementation Package“

Administrative

- Template for a Memorandum of Understanding (MoU)
- Template for statutes of an NMVO
- Proposed cost allocation scheme between MAHs

Technical

- Support for project set-up
  - Project organisation and project plan
- User requirement specification for national system
- Support for selection of system provider (Blueprint)
  - List of Blueprint providers
  - Frame contracts with Blueprint providers

Package available !!

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NMVO: project organisation

General Manager

- Represent NMVO
- Develop / control policies
- Manage human resources
- Manage budget
- Provide communications
- Report to Board (stakeholders)

Quality Assurance

- Establish / maintain NMVO QM system
- Supervise QM of IT provider
- Represent NMVO in external audits

Operations

- Manage system performance
- Manage technical relationship with IT provider
- Define system enhancements
- Analyse exceptional events (technical, functional)

Administration (incl. F&A)

- Plan / control budget
- Manage accounts

Commercial / Partner Management

Establish and maintain relationships and contracts with MAHs, NMVOs, IT provider

NB: Not all positions need to be filled by FTEs, depending on NVMO organisation

- Tasks coloured in blue may be outsourced to European Medicines Verification Organisation (EMVO)

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What's next?
First steps at national level

Build on **existing knowledge and experience**

Develop **principles for cooperation** (MoU, NMVO statutes)

Determine scope of **functionality**

Blueprint **provider selection**

Develop **milestone plan**

- Governance organisation
- Implementation of technical system

Plan for **budgets**

EMVO will provide support for national implementation

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Questions?