

European Stakeholder Model (ESM) Verification of Medicinal Products in Europe

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1 INTRODUCTION

2 COMMON CORE CONCEPTS & PRINCIPLES

3 MEDICINES VERIFICATION IN THE EU

- System design and architecture

- Stakeholder governance

4 TRANSPOSITION THROUGHOUT EUROPE – IT WORKS:

- securPharm – An already operating national verification system

- EU Hub & Blueprint – Securing interoperability, harmonisation and cost effectiveness

5 NEXT STEPS FOR TIMELY IMPLEMENTATION ACROSS THE EU

ESM STAKEHOLDERS TAKE ACTION TO PROTECT PATIENTS FROM FALSIFIED MEDICINES

VISION

- Protect legal medicines distribution chain throughout EU
- Comply with FMD in an effective and cost-efficient way

STATUS

- Design for Pan-European system and governance in place: National systems connected by European Hub
- Start up implementation in place

PLAN

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

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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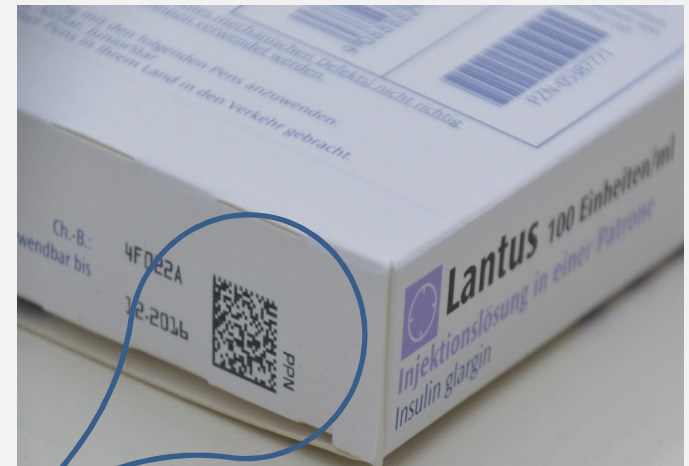
EU Hub & Blueprint – Securing interoperability,
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5 NEXT STEPS FOR TIMELY IMPLEMENTATION ACROSS THE EU

FUNDAMENTAL PRINCIPLES FOR MEDICINES VERIFICATION IN THE EU

SAFETY FEATURES	<ul style="list-style-type: none">• Unique identifier with randomised serial number + tamper evident packaging• Check of pack's authenticity at point of dispense
SYSTEM DESIGN	<ul style="list-style-type: none">• Coding system harmonised across Europe based on ISO-standards allowing integration of existing national codes• Flexible to implement national solutions within an EU technical framework• Interoperable between different national systems through European Hub
DATA	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Systems governed by independent non-profit organisations, established and managed by relevant stakeholders• Systems supervised by EU and/or national authorities• Data accessible for competent authorities for reimbursement, pharmacovigilance & pharmaco-epidemiology purposes

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

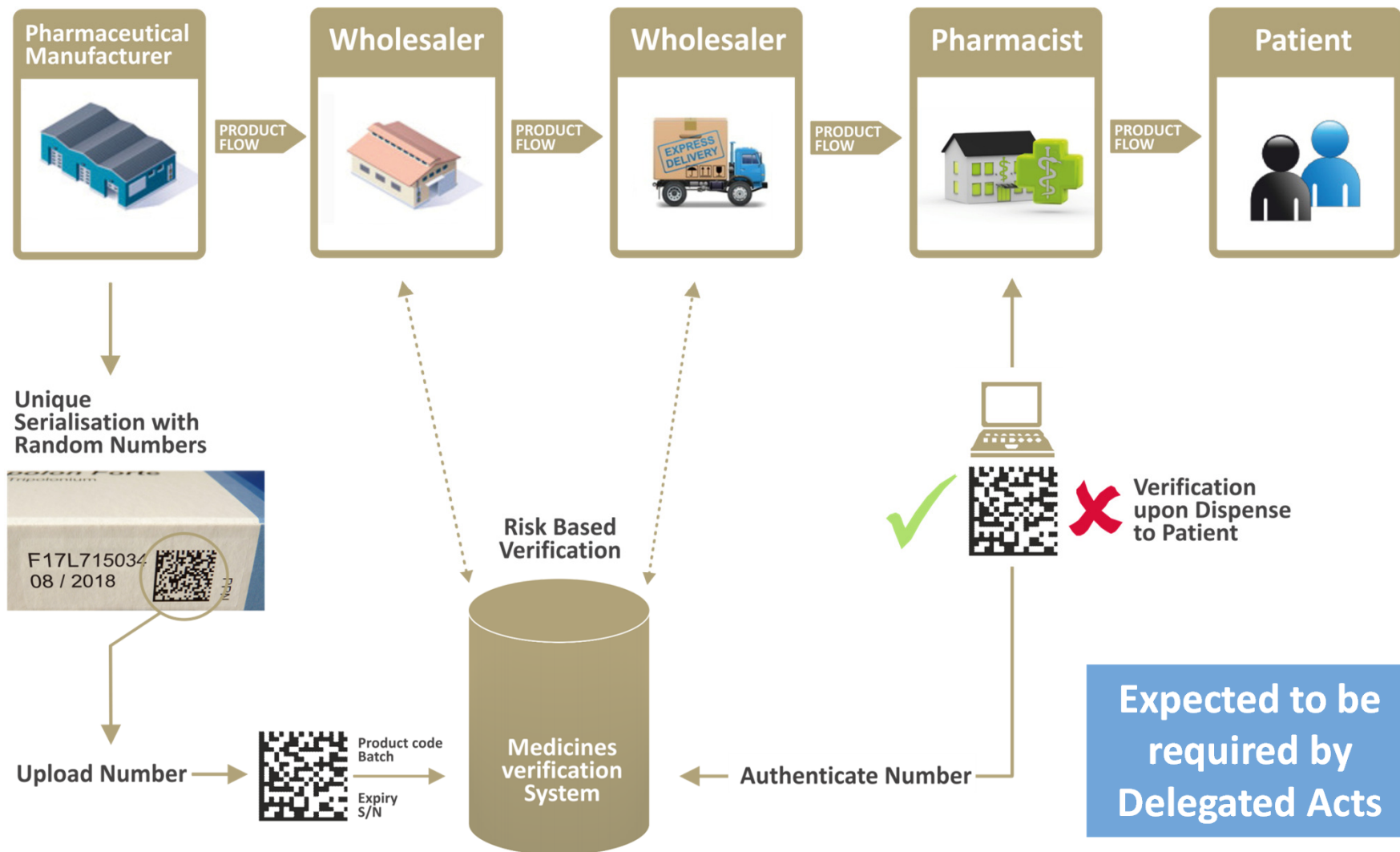


Product #: 09876543210982
Batch: A1C2E3G4I5
Expiry: 140531
S/N: 12345AZRQF1234567890



**Expected to be required by
Delegated Acts**

COMMON BASIC CONCEPT: “POINT OF DISPENSE VERIFICATION”



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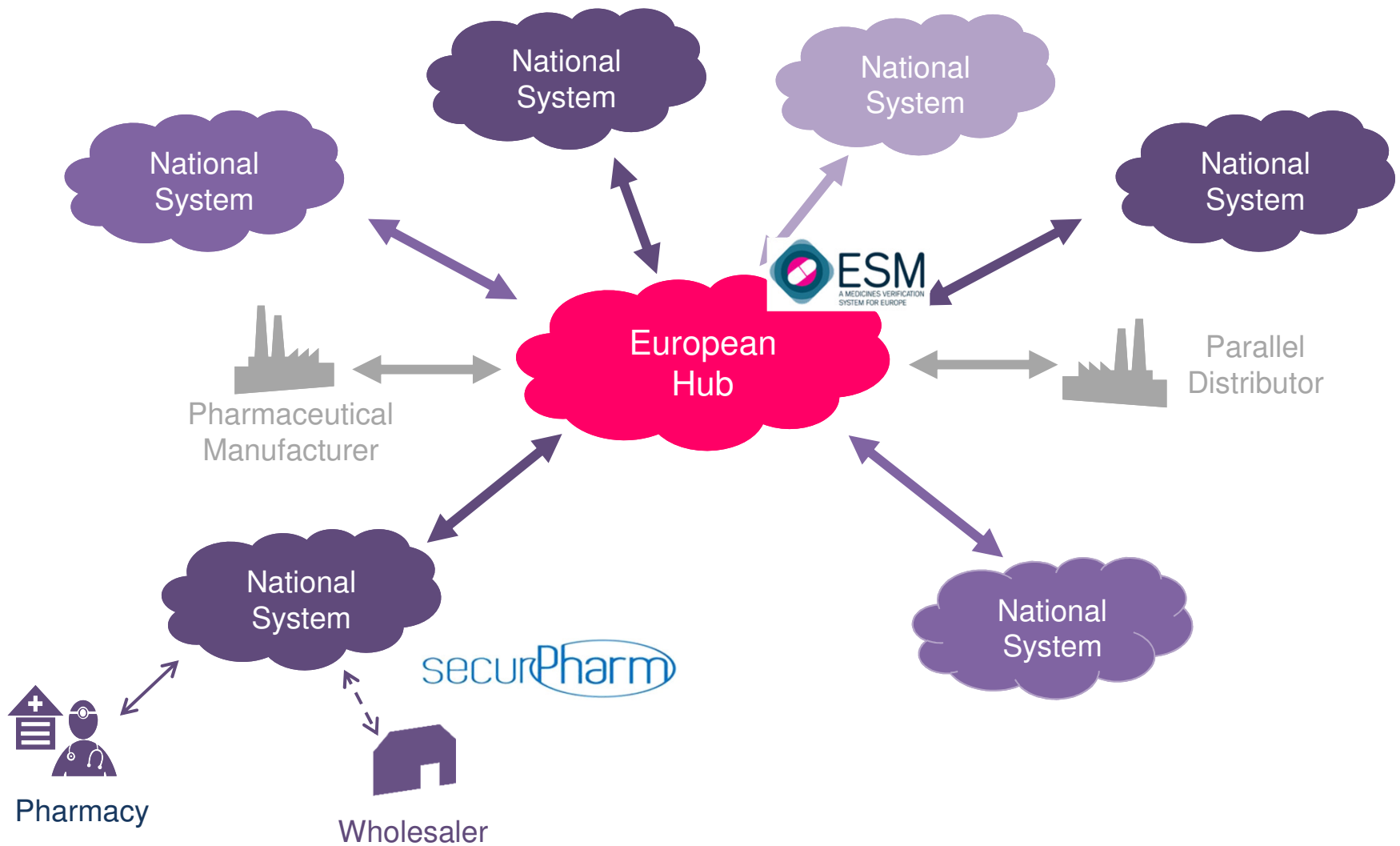
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PAN-EUROPEAN ARCHITECTURE: DESIGN FOR INTEROPERABILITY AND EFFICIENCY



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GOVERNANCE STRUCTURE ALLOWS FOR EFFECTIVE MANAGEMENT OF 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, to be founded)

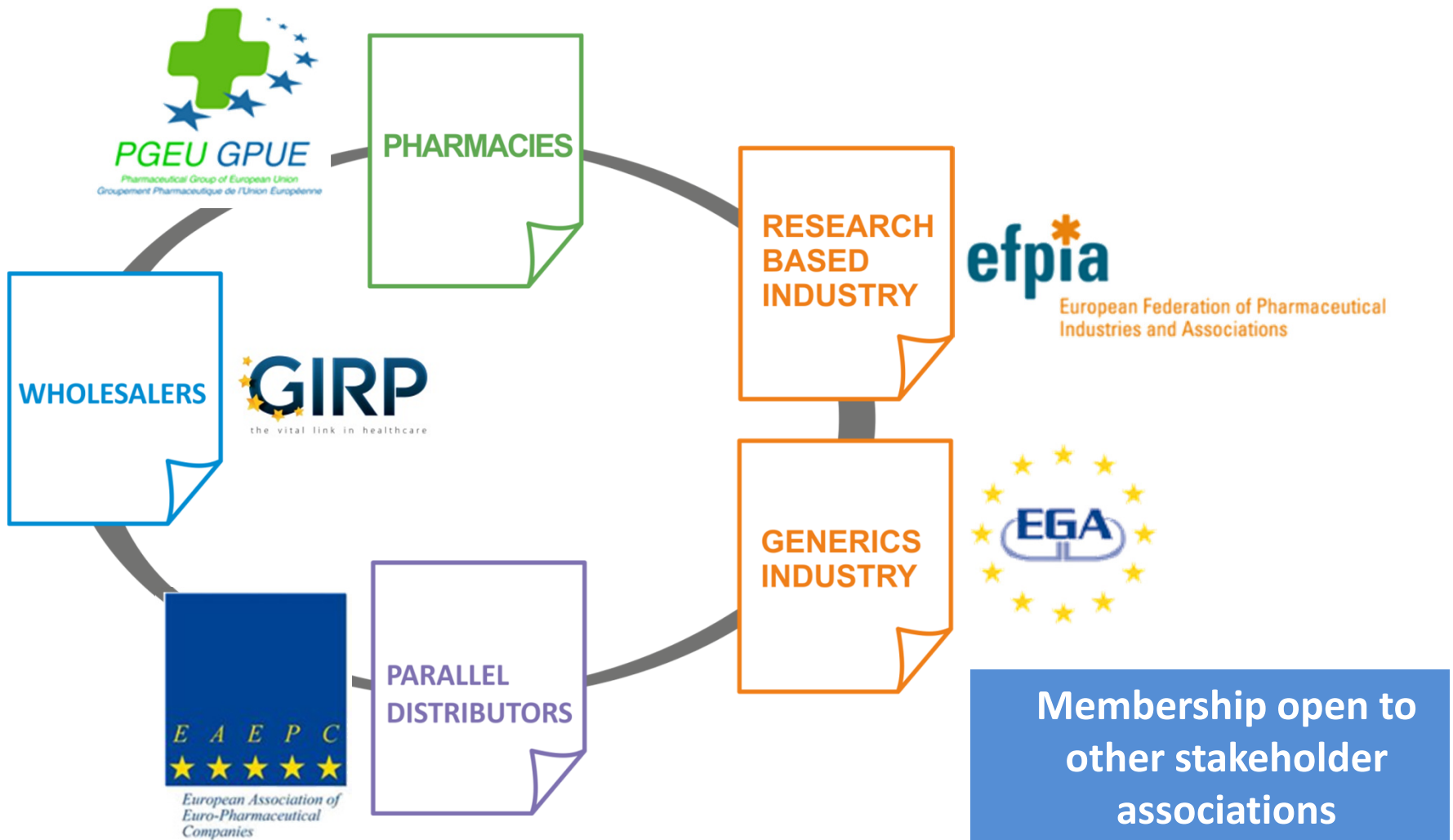


NATIONAL LEVEL

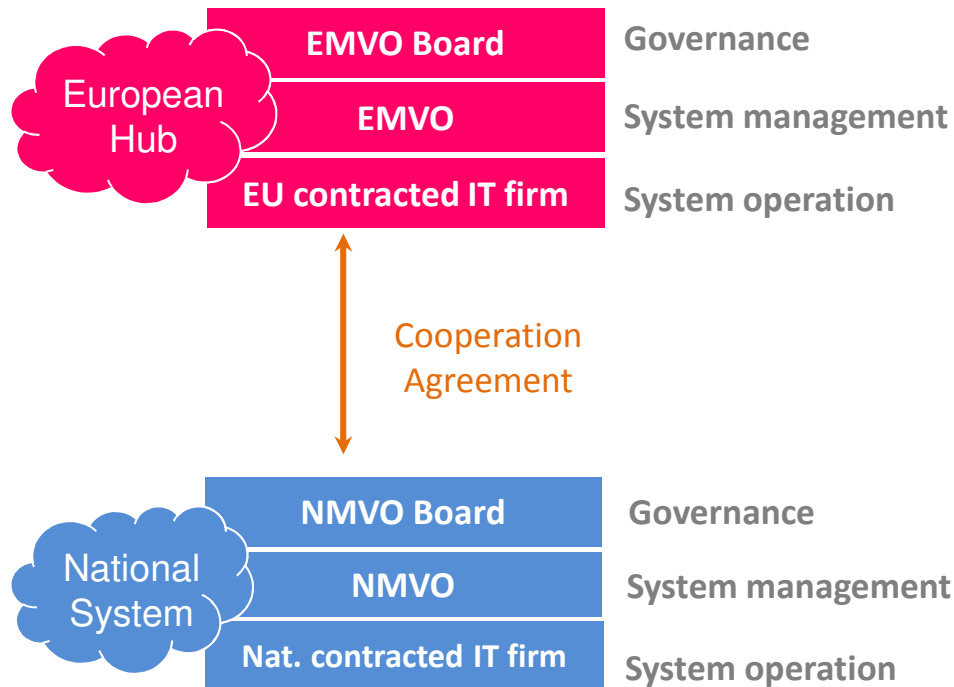
National Medicines Verification
Organisations (NMVO), e.g.
in Germany: securPharm e.V.

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

EMVO-MEMBERS ARE ALLOCATED TO A CONSTITUENCY



A CLOSER LOOK AT RESPONSIBILITIES AROUND GOVERNANCE AND SYSTEM MANAGEMENT



EMVO

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

NMVO

Remit

- Establish and manage national system
- Ensure interoperability with European Hub
- Conclude agreement with EMVO
- Analyse exceptional events at national level

Expected to be required by Delegated Acts in combination with supervision by competent authorities

SUPERVISION

- Observer Status in EMVO/NMVOs

DATA ACCESS

- For reimbursement, pharmacovigilance & pharmaco-epidemiology purposes (FMD Article 54a.4+5)
- Systems security determines access configuration (i.e. standardised interfaces)
- Regular standard reports by the EU / national system administrators

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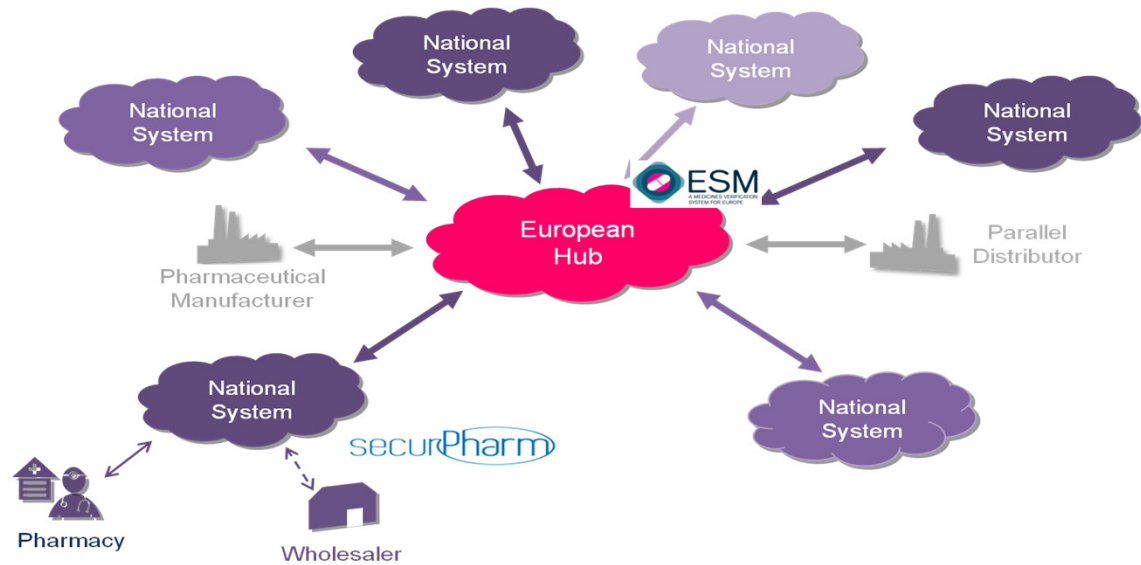
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4 **EU HUB & BLUEPRINT – SECURING INTEROPERABILITY,
HARMONISATION AND COST EFFECTIVENESS**

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THE EUROPEAN HUB IS REALITY AND ITS VALUE UNDISPUTED

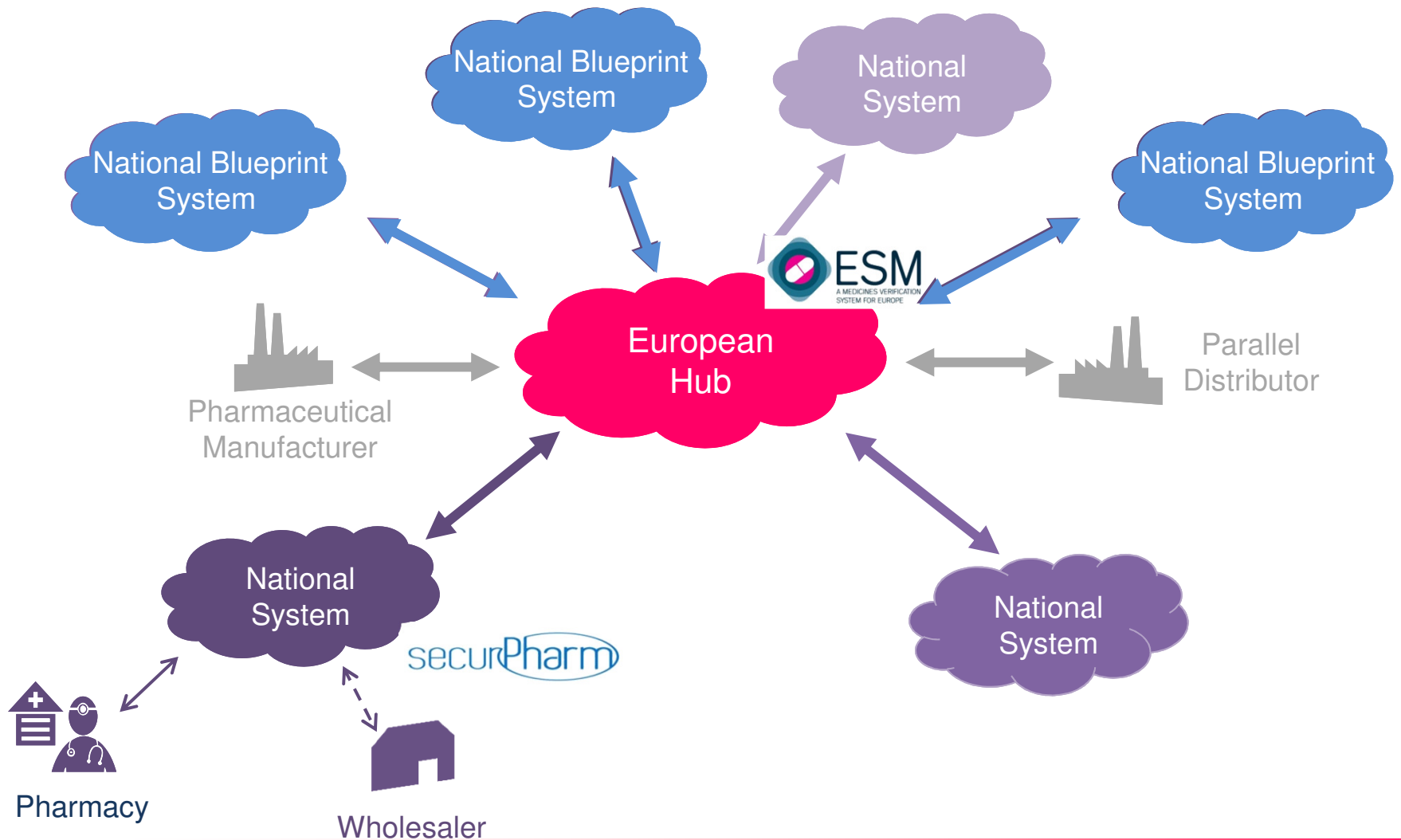


European Hub

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



Pan-European architecture: The National Blueprint System approach

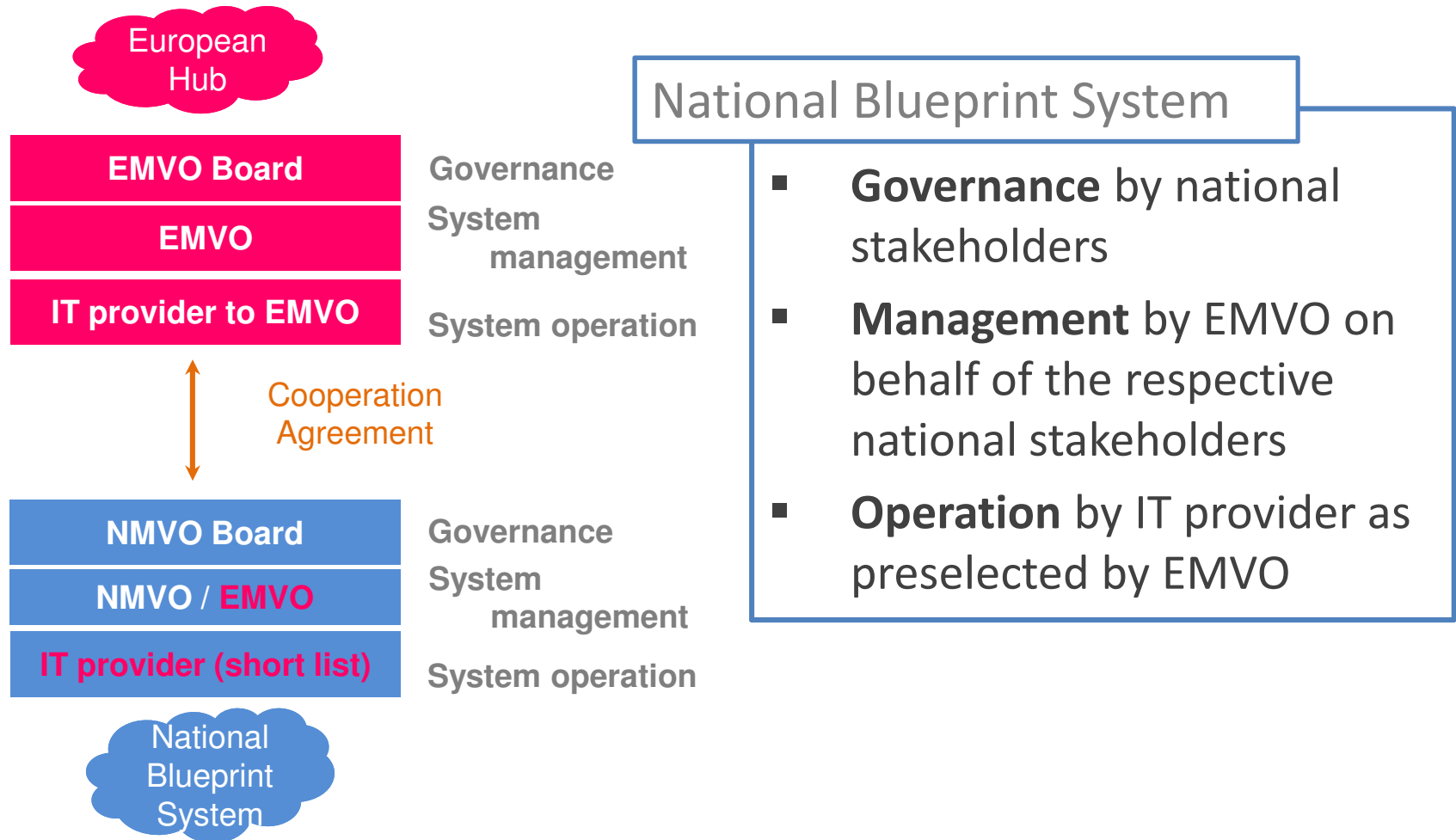


THE BLUEPRINT APPROACH PROVIDES SUBSTANTIAL BENEFITS

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
 - 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



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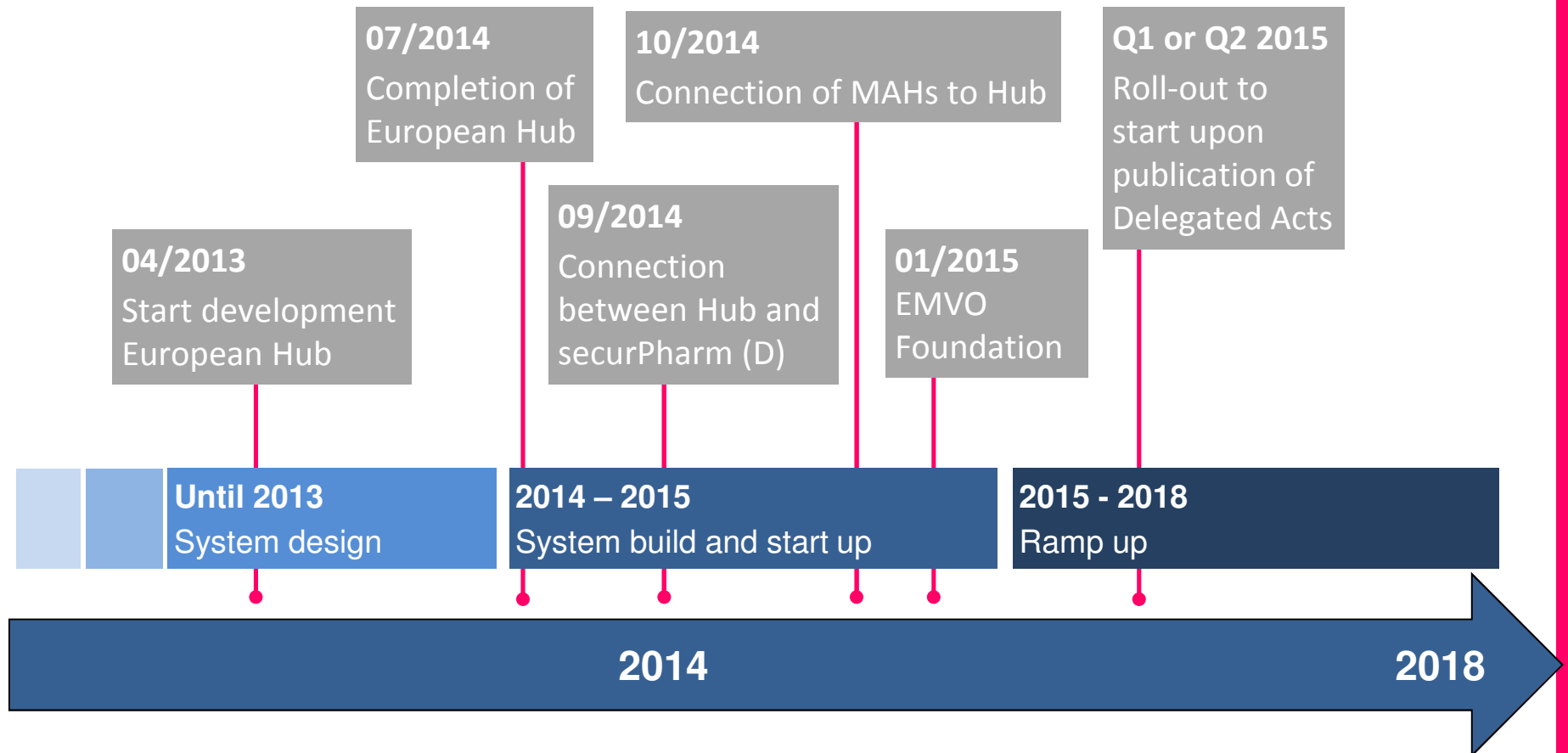
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THE EUROPEAN HUB IS OPERATIONAL AND CONNECTED TO THE FIRST NATIONAL SYSTEM



WE ENCOURAGE STAKEHOLDERS ANT NATIONAL LEVEL TO ENGAGE **NOW**

Build on **existing knowledge and experience**



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

Determine scope of **functionality**



Evaluate options to realise technical system (e.g. Blueprint)

Develop **milestone plan**

- Governance organisation
- Implementation of technical system



Plan for **budgets**



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
 - High level budget estimate
- User requirement specification for national system
- Support for selection of system provider (Blueprint)
 - List of Blueprint providers
 - Frame contracts with Blueprint providers
- Proposal for EMVO to act as system manager for NMVO

Package available by Jan 2015

HOW WE BELIEVE COMPETENT AUTHORITIES CAN SUPPORT IMPLEMENTATION

Invite national stakeholders to **open dialogue**

Articulate authority's **expectations**

Provide clear positions as a **reliable basis for planning**

THE STAKEHOLDER MODEL IS READY FOR ROLL-OUT ACROSS EUROPE

Governance structure and technical design are in line with expected content of Delegated Acts

Common principles are the basis for cooperation

“Early birds” are ready to share hands-on experience

Start-up implementation is operational

Thank You!