The Global Language of Business

Michael P. Rose

Johnson & Johnson

The Global Language of Business

The European stakeholder model with end-to-end authentication of medicines to prevent counterfeiting

Michael P. Rose, Vice President Supply Chain Visibility, Johnson & Johnson

19 April 2016

European Stakeholder Model Implementing the European Medicines Verification Organization and System

April 2016

Mike Rose
Johnson & Johnson Supply Chain

Chairman, EFPIA Supply Chain Workgroup

European Federation of Pharmaceutical Industries and Associations
www.efpia.eu

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Content

Medicines verification in the EU: Overview

European Stakeholder Model → EMVO

Progress to date

EU Falsified Medicines Directive

Product Safety Features

Authenticity

Pack Identity

Tamper evidence

Feb 9, 2019

Good distribution

Wholesalers & Brokers

GDP

2013-Q1

Active substances

GMPs for excipients

Jan 2, 2013

Registration API activities

July 2, 2013

Internet Sales

Community logo

2015

Implementation of serialization, verification system and tamper evident features

- Objective: Protection of patients from counterfeited medicines in the legal distribution chain
- Content: Pan-European system to verify the authenticity of medicinal products
- Cost: Paid by Marketing Authorization Holders

Delegated Regulation mandates medicines verification

Serialization by manufacturer

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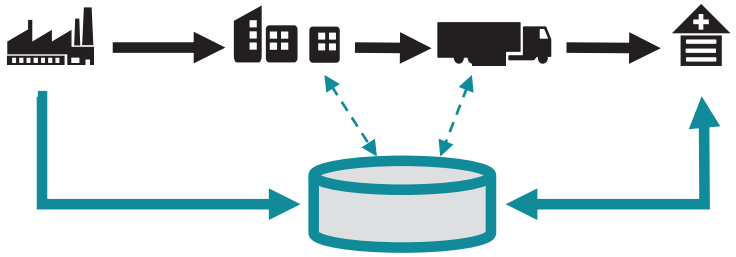
Verification at point of dispense



Code

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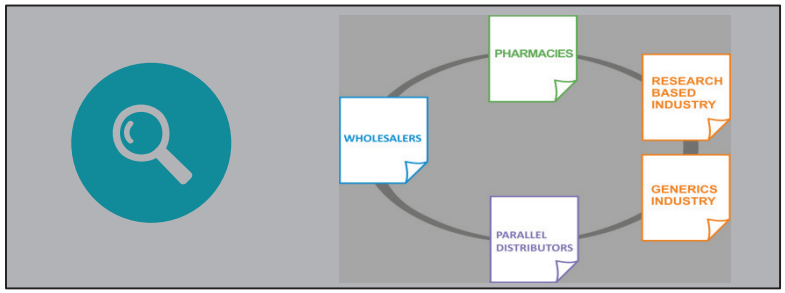
Tamper evidence

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

System set up and governed by stakeholders under supervision of competent authorities



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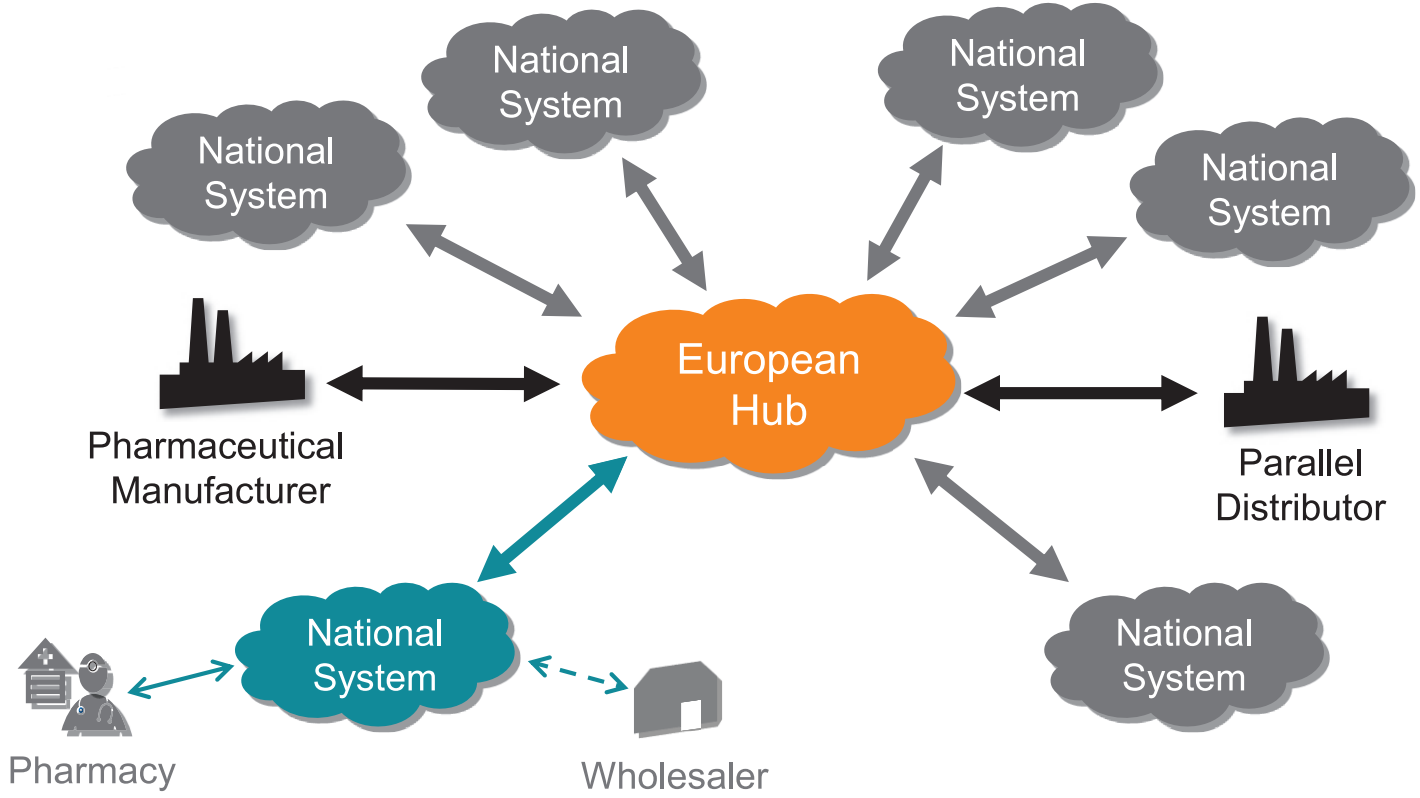
Pan-European System

National verification Systems (NMVS) connected by the European Hub



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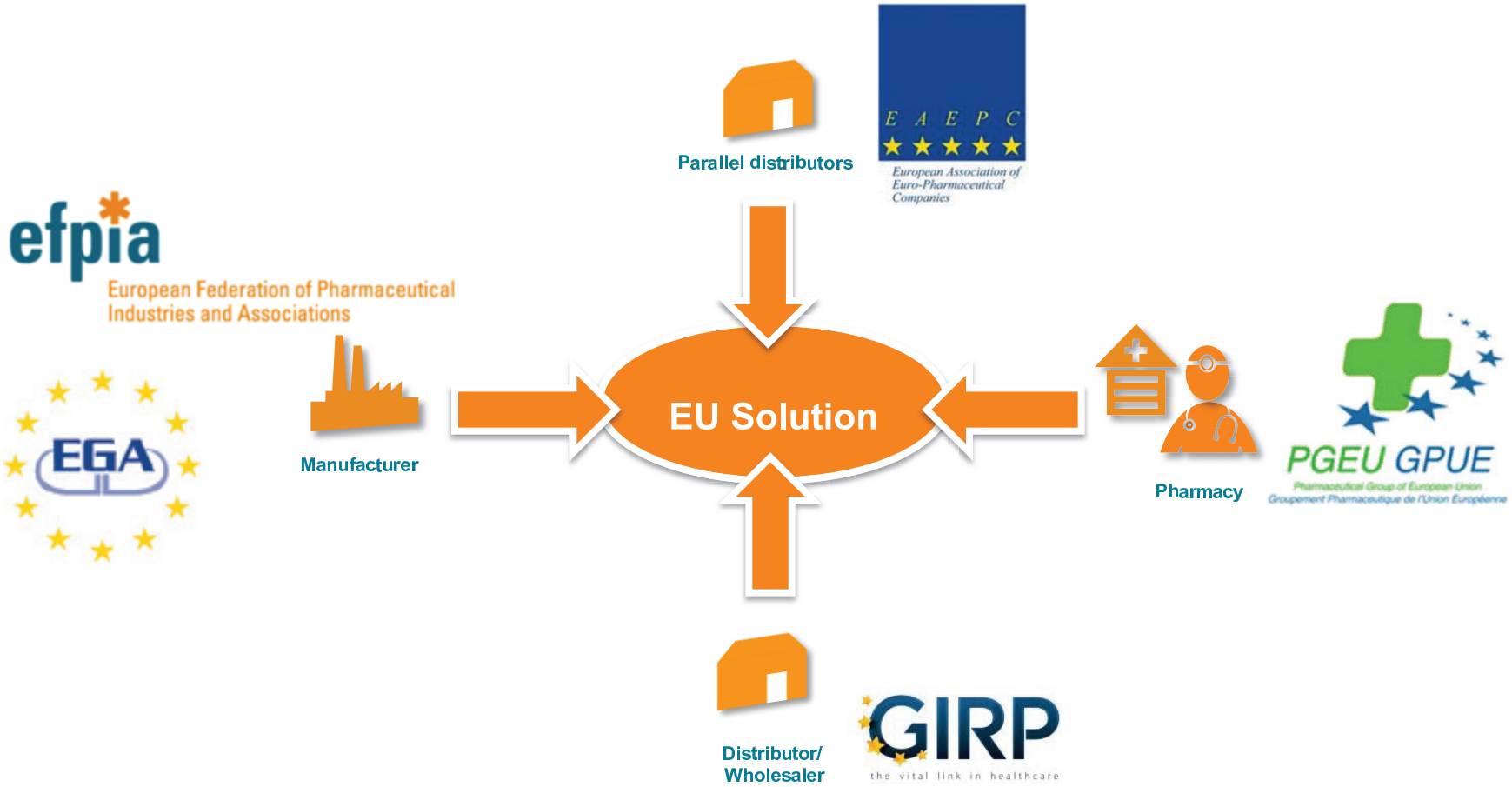
Progress to date

Multiple stakeholders are involved



Stakeholders work together to deliver a solution across Europe which delivers the patient safety objectives

European Stakeholder Model

Aligned to a Common vision to protect patients

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European Federation of Pharmaceutical Industries and Associations

- Protect patients
- Secure the legitimate supply chain
- Be proactive as market partners
- Formed a stakeholder-governed model that is
  - ✓ Functioning
  - ✓ Harmonised
  - ✓ Cost-effective
  - ✓ Inter-operable
- Established the European Medicines Verification Organization (EMVO)
- Andreas Walter, EMVO, General Manager
  andreas.walter@emvo-medicines.eu

European Medicines Verification Organization (EMVO)

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

EU LEVEL

- Governance model includes EU industry associations with supervision by EC
- Oversees
  - ✓ EU Hub
  - ✓ Blueprint template
  - ✓ Service providers
  - ✓ Service agreements

NATIONAL LEVEL

- National Medicines Verification Organisations (NMVO), e.g. in Germany: securPharm e.V.
- Governed by national stakeholders with supervision by competent authorities

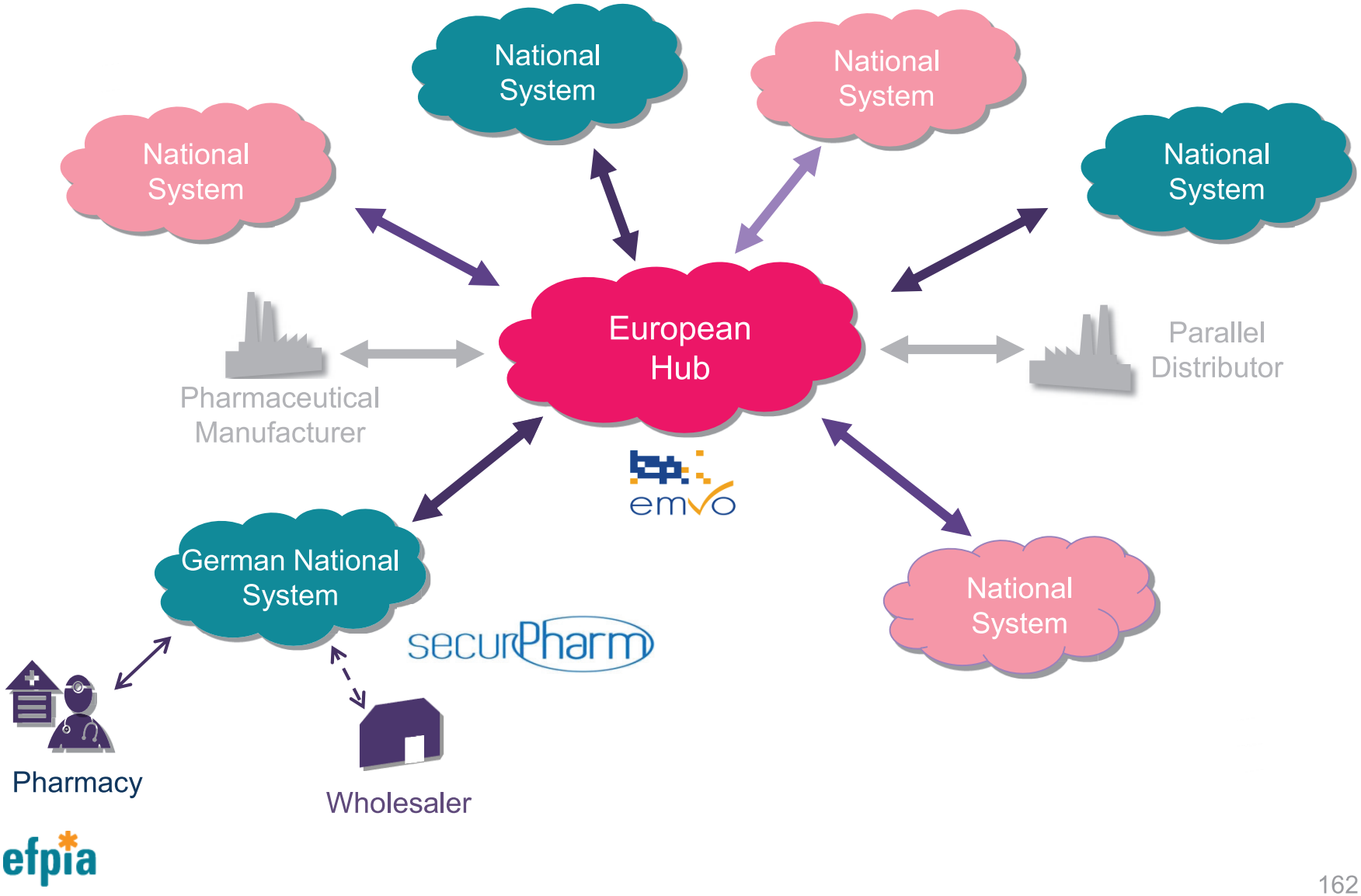
EMVO and National Organisations (NMVOs) cooperate on the basis of service level agreements

Governance Structure
Allows for Effective Management of Verification System

Basic Principles

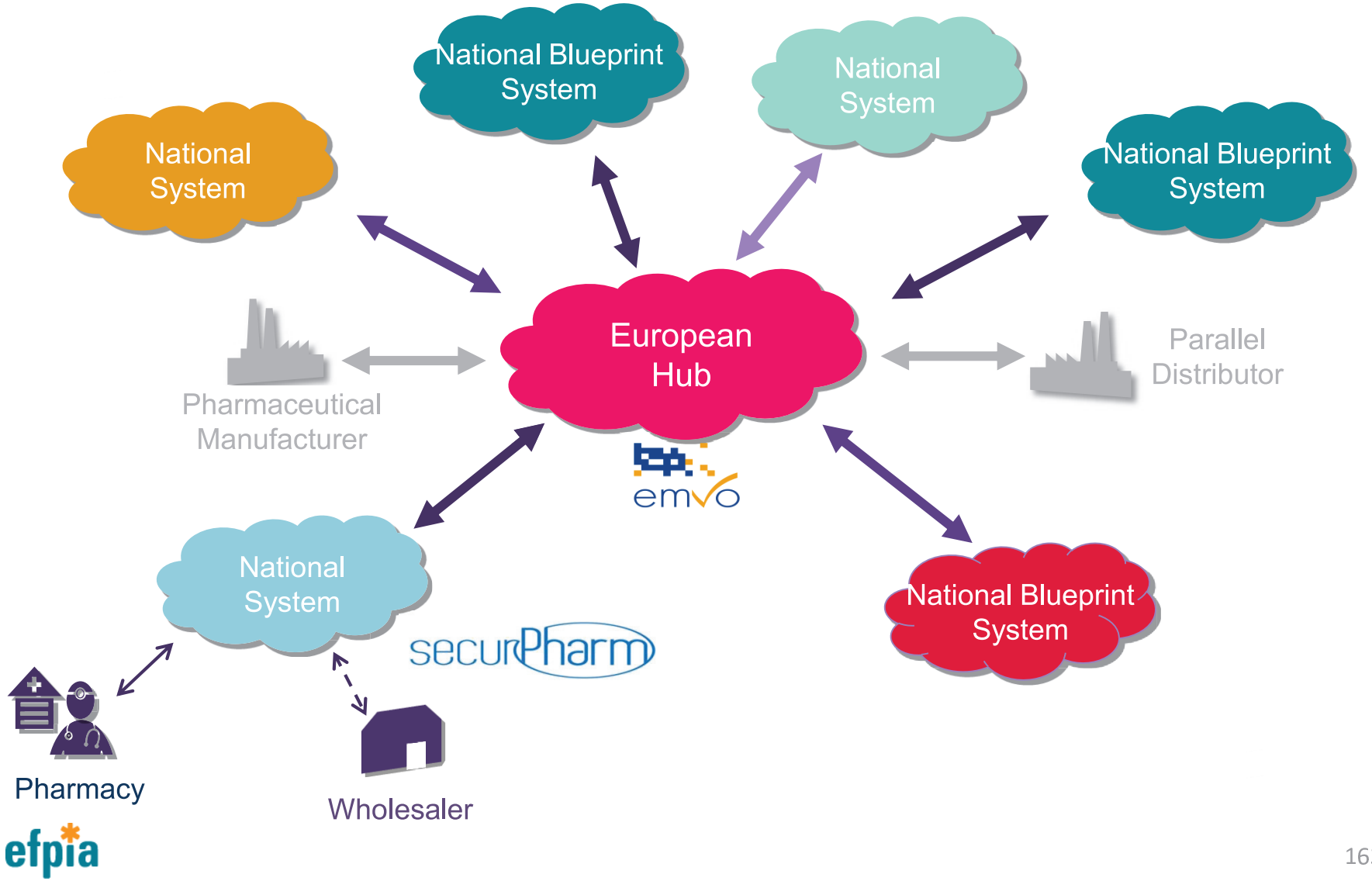
- Basic concept: “Point-of-Dispense Verification”
- All verification activities are performed in national systems of the EU member states
- Interoperability between the different national systems through European Hub
- Data are owned by party that generates it
- Data of other parties cannot be accessed except:
  - ✓ For verification purposes
  - ✓ If specifically agreed between partners
- Supervision by relevant competent authorities
  - ✓ For reimbursement / pharmacovigilance purposes

Pan European Architecture
Designed for interoperability and efficiency



The National Blueprint System Approach

Interoperable, cost efficient, reduced complexity



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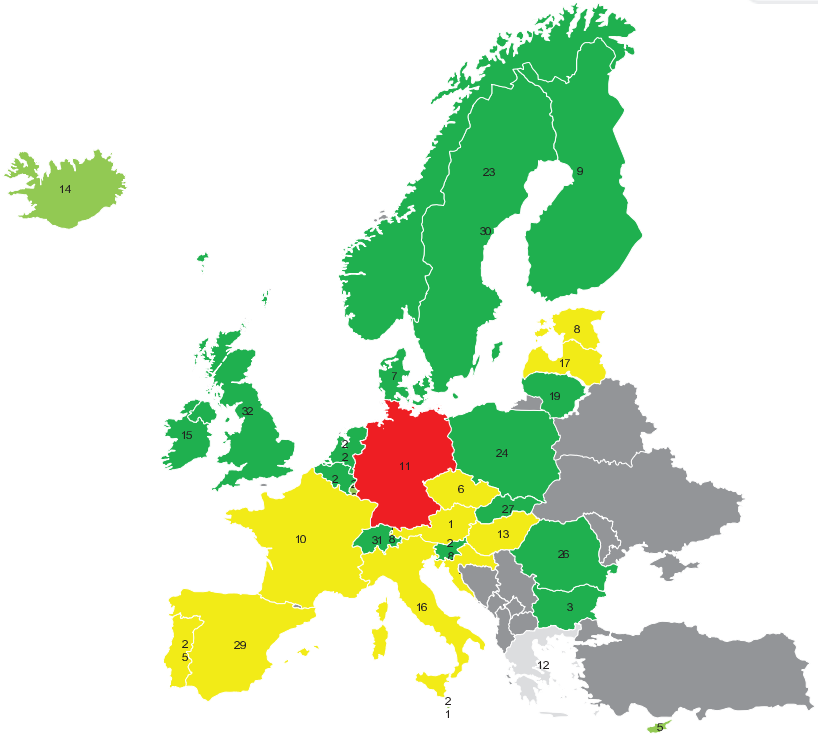
EU Hub Progress to Date

- EU Hub built and operational
- Companies testing data uploads to EU Hub
- EU Hub connected to German securPharm system
- Companies preparing to load data to EU Hub intended for the German securPharm system

NMVO/NMVS Current Status

- NMVS Blueprint Template solution providers selected and frame contracts negotiated
- Majority of countries prefer adopting the Blueprint Template
- Working with national associations to form NMVOs and prepare to deploy national systems



Next steps

- NMVOs forming now
- NMVOs selecting template vendor in 2016
- Deploying 32 NMVS's in advance of February 9, 2019 deadline

EFPIA Brussels Office

Leopold Plaza Building
Rue du Trône 108
B-1050 Brussels - Belgium
Tel: +32 (0)2 626 25 55

www.efpia.eu