ESM
A MEDICINES VERIFICATION SYSTEM FOR EUROPE

Ensuring patients have access to safe medicines

A European Medicines Verification System

Fighting counterfeit medicines to ensure patient safety in Europe

Speaker: Grant Courtney

Event: Global GS1 Healthcare Conference

Date: October 2013

Who am I

Grant Courtney

- Part of EFPIA team working on the ESM
- Member of the GS1 Healthcare Leadership Team
- 18 years in product security for GlaxoSmithKline

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About EFPIA

efpia

European **F**ederation of **P**harmaceutical **I**ndustries and **A**ssociations

represents the **research-based** pharmaceutical industry operating in Europe

brings together 31 national pharmaceutical associations and 38 leading companies

ESM Stakeholders

- EFPIA is on of the 4 stakeholders developing the ESM solution
- The ESM solution is being developed by the stakeholders who will use it day-to-day
- Talks ongoing with AESGP, EAHP, EGA and HOPE

AESGP	Association of the European Self-Medication Industry
EAHP	European Association of Hospital Pharmacists
EGA	European Generic Medicines Association
GIRP	European Association of Pharmaceutical Full-line Wholesalers
HOPE	European Hospital and Healthcare Federation
PGEU	European Association Representing Community Pharmacists

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Introduction

Context & Background

- The threat of falsified medicines penetrating the European supply chain is substantial and growing
- The EU Falsified Medicines Directive (FMD) is an important step in protecting patients from counterfeit medicines, adoption on July 1, 2011
- ESM are developing a system that will meet the requirements of the FMD

What is the ESM?

- A cost-effective solution for medicines verification
  - Run on a non-profit basis
- A pan-European system called the EMVS (European Medicines Verification System) enabling medicines to be verified at point of dispensing
  - Developed by the stakeholders who will use it on a day-to-day
- Immediate verification of the pack
  - Ensures safe access to medicines
  - Is interoperable solution

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A medicines verification model for Europe

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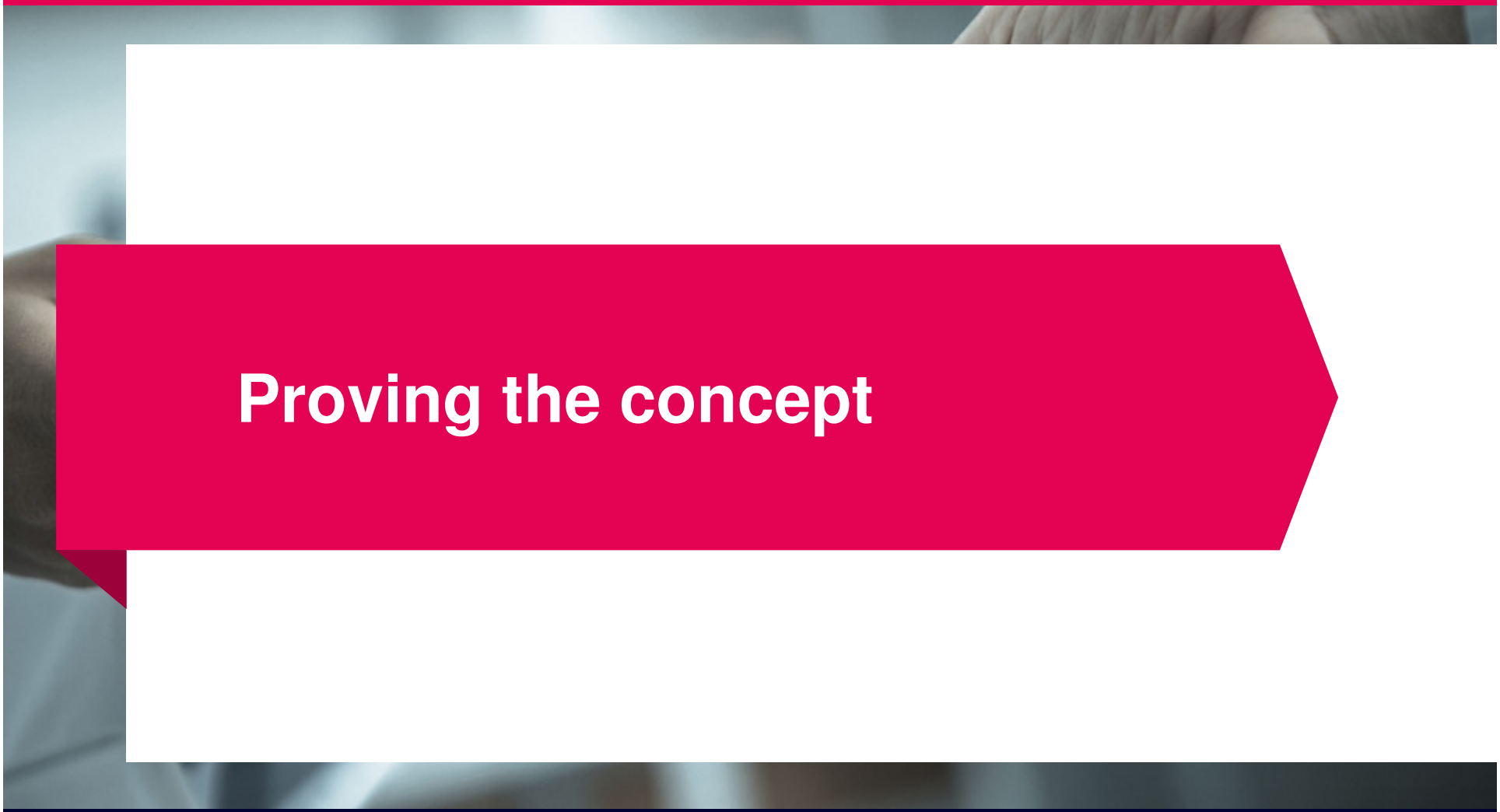
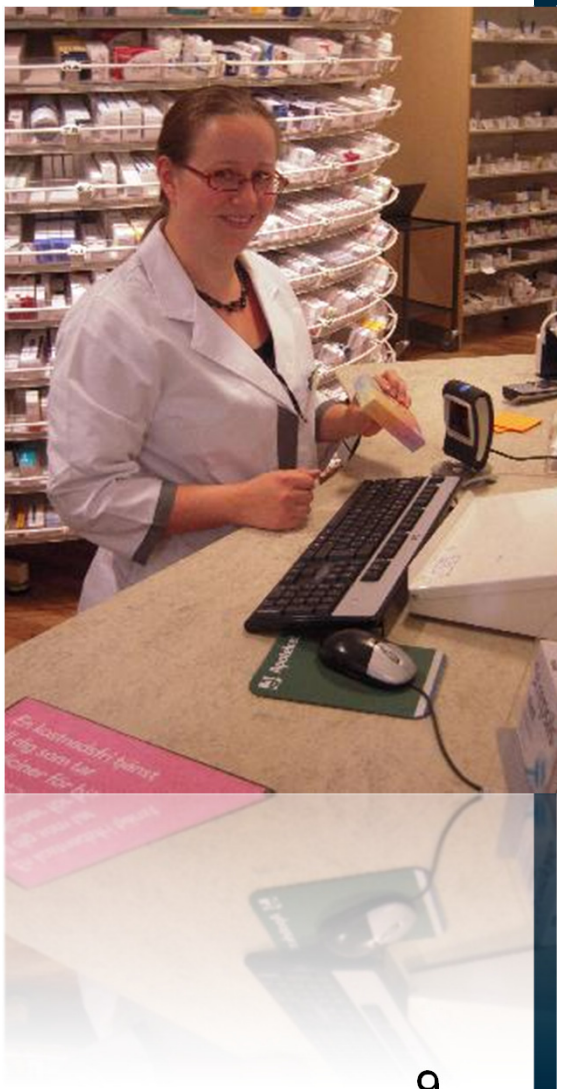


Proving the concept

Testing and evolution

- Swedish pilot project (Sep 09 - Feb 10)
- 25 pharmacies in greater Stockholm.180 dispensing points
  - 25 products. 110,000 packs. 14 manufacturers
- Key findings
  - Allows pharmacists to **work at normal pace**
  - Is customised to **existing workflows**
  - Is **integrated** into existing pharmacy software
  - Pharmacists and wholesalers are keen to get expiry date and batch number in machine-readable form

Sweden exceeded expectations and proved the concept in practice



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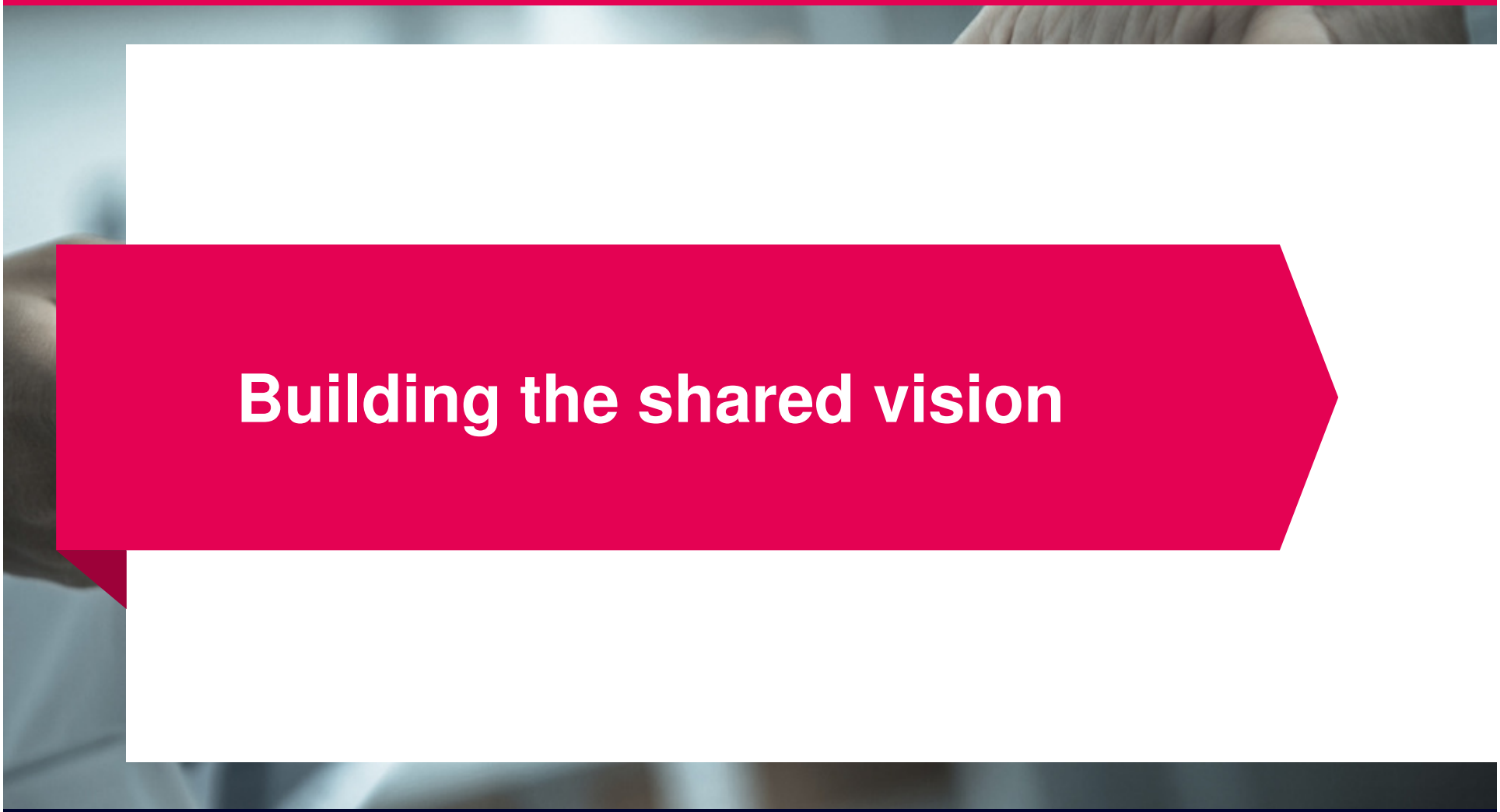


Building the shared vision

ESM view on implementation of the FMD

Safety Features	• Combine tamper-evident packaging and a unique randomised serial number • Verify product authenticity by checking each pack against a central database at the point of dispensing
System Design	• Harmonised standard coding system across the EU that allows national codes to be incorporated as necessary • **Sufficient flexibility to implement national or multi-country solutions within an overall EU technical framework**
Data	• Manufacturers do not seek, and will not have access to, individual patient / prescribing profile information • **Transactional data belongs to stakeholder that created it e.g. pharmacists for dispensing data**
Governance	• Systems should be established and managed by the stakeholders that will use them day-to-day • **Systems governed by independent non-profit organisations jointly managed by relevant stakeholders**

2D barcodes

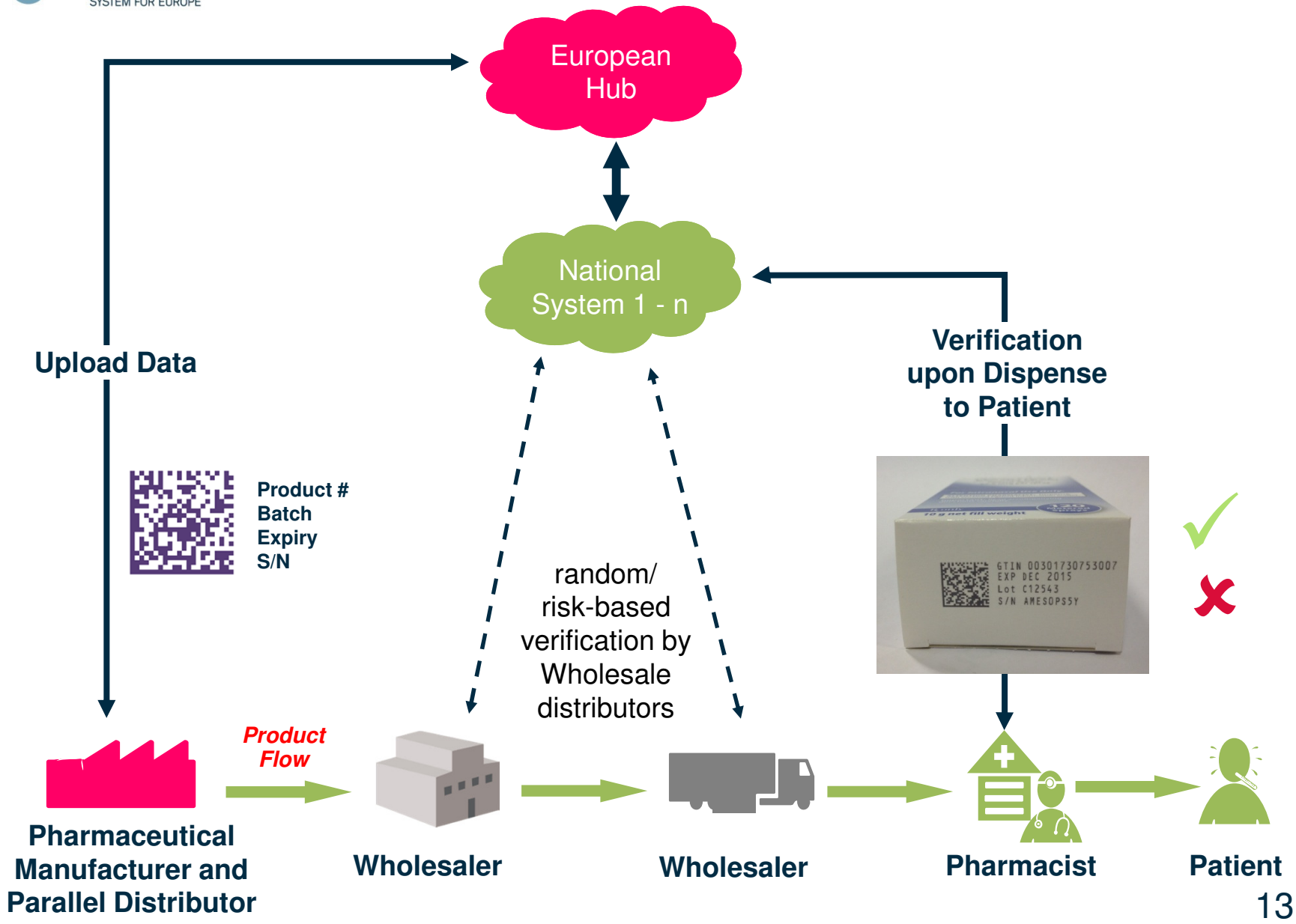
- The ESM uses a 2D barcode, developed to internationally recognised standards

- Four key data elements:
  - 14 digit Manufacturer Product Code
  - Randomised Unique Serial Number
  - Expiry Date
  - Batch Number (up to 20 alpha-numeric characters)

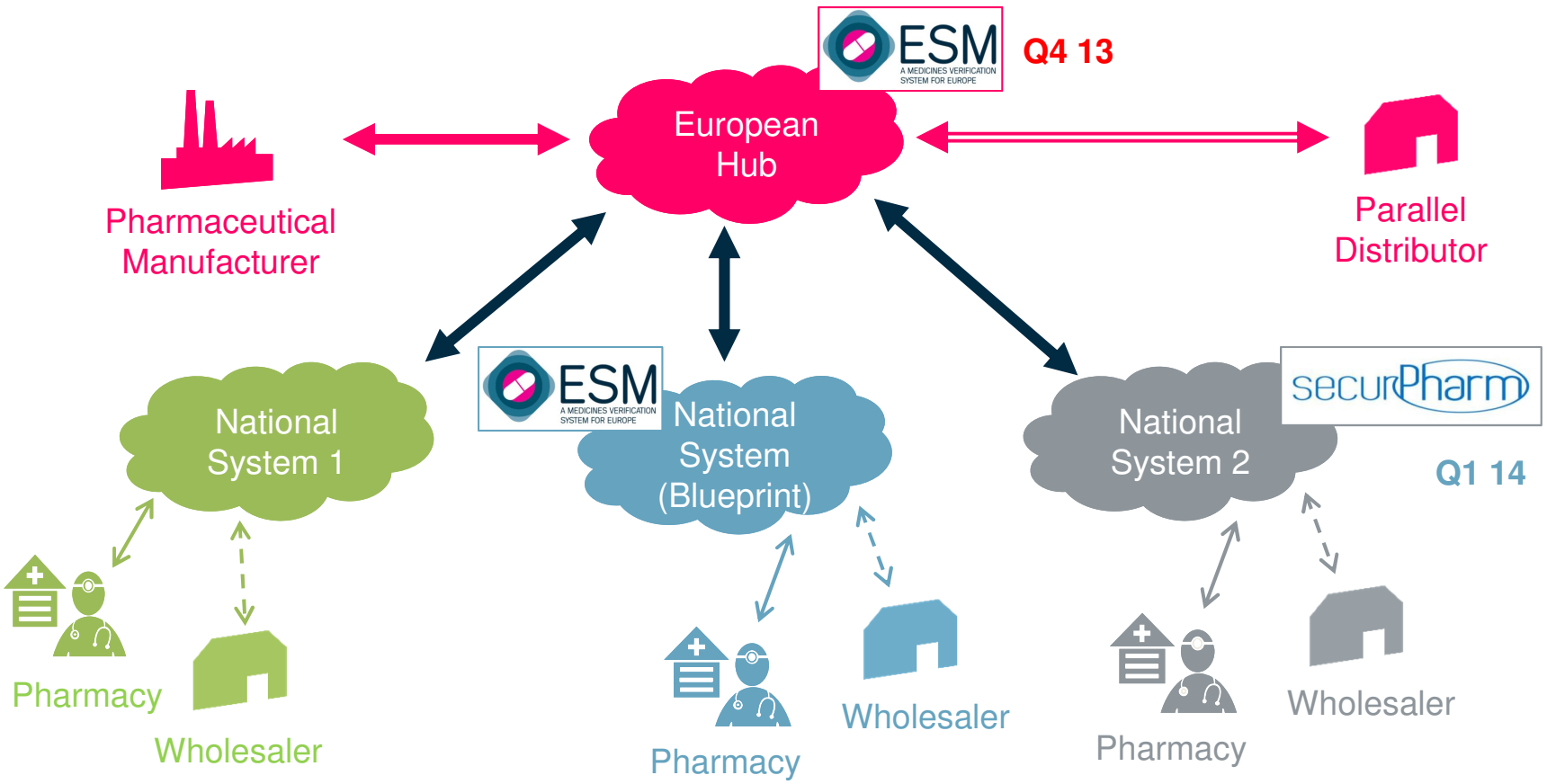
- Example:

Product #: (01)09876543210982
Batch: (10)A1C2E3G4I5
Expiry: (17)140531
S/N: (21)12345AZRQF1234567890

Model and process



Infrastructure overview



System design for interoperability and efficiency

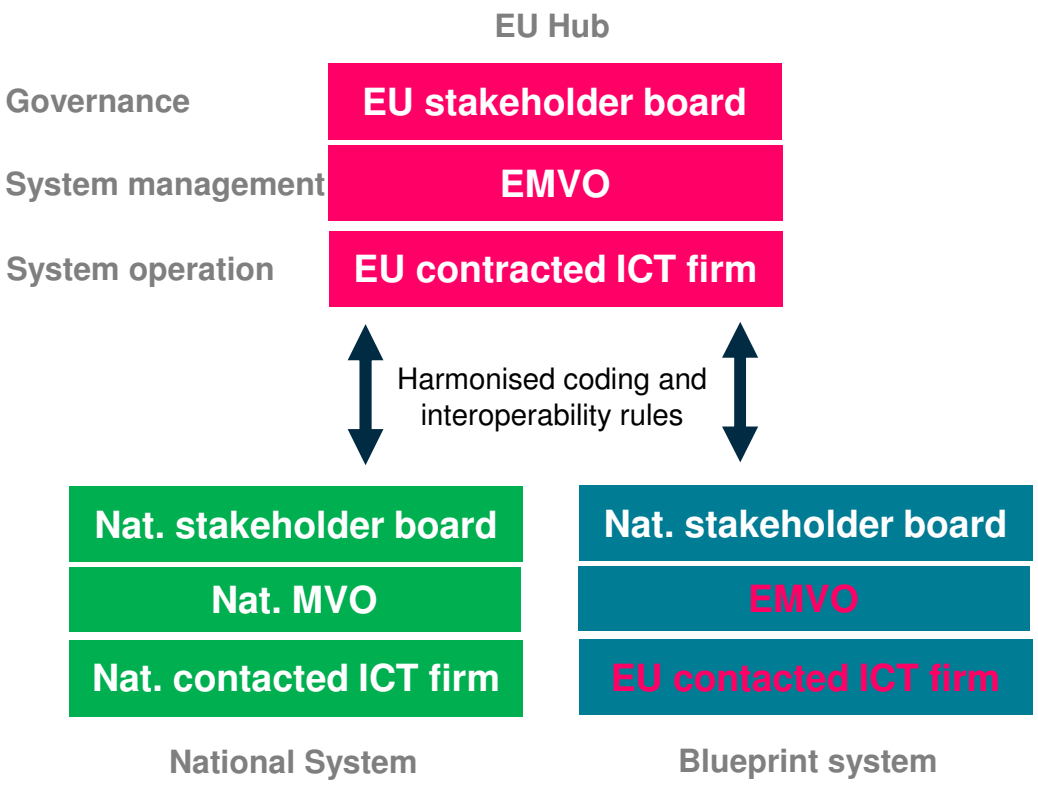
Operation and governance

- The ESM will be operated by a not-for-profit independent organisation called the European Medicines Verification Organisation (EMVO)

- Governance of the EMVO will include representatives from the stakeholder organisations in an EU Stakeholder Board

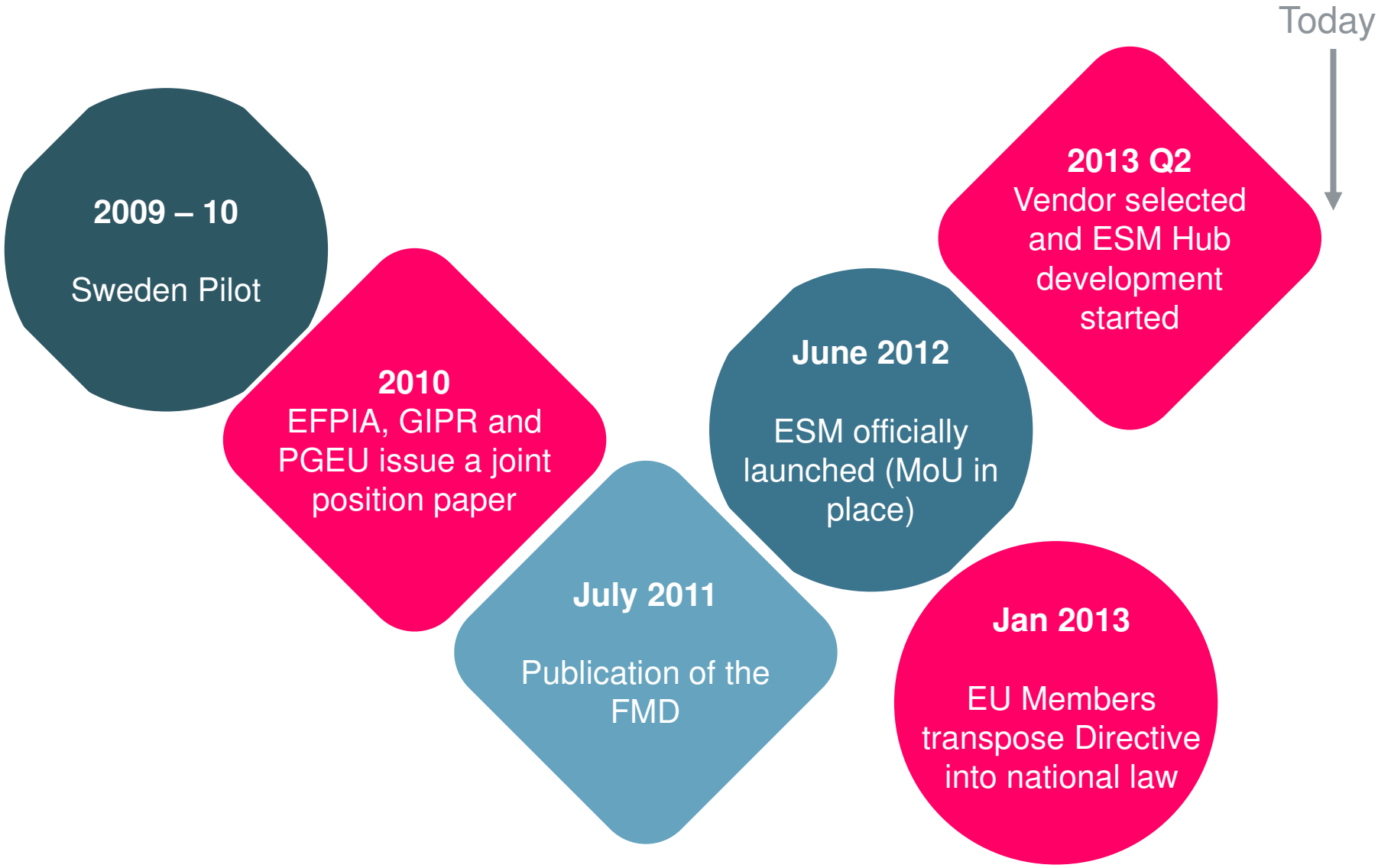
- EMVO will
  - Develop and control EMVS policies and processes
  - Communicate with authorities and the broader public
  - Establish relationships (and contracts) with national stakeholder organisations (NMVO)
  - Oversee development of European Hub and Blueprint Template
  - Provide reports to stakeholders
  - Manages the operation of the Hub and national Blueprint System(s)

EMVO – stakeholder-led governance structure



- EMVO will govern EU hub, set standards for the system, and conclude legally binding agreements with national system governance bodies
- National systems will have to create their own stakeholder-based, legal entities (Medicines Verification Organisations, MVO) that would contract with the EMVO
- Blueprint system to be governed nationally, but managed and operated on EU level

Key milestone to date



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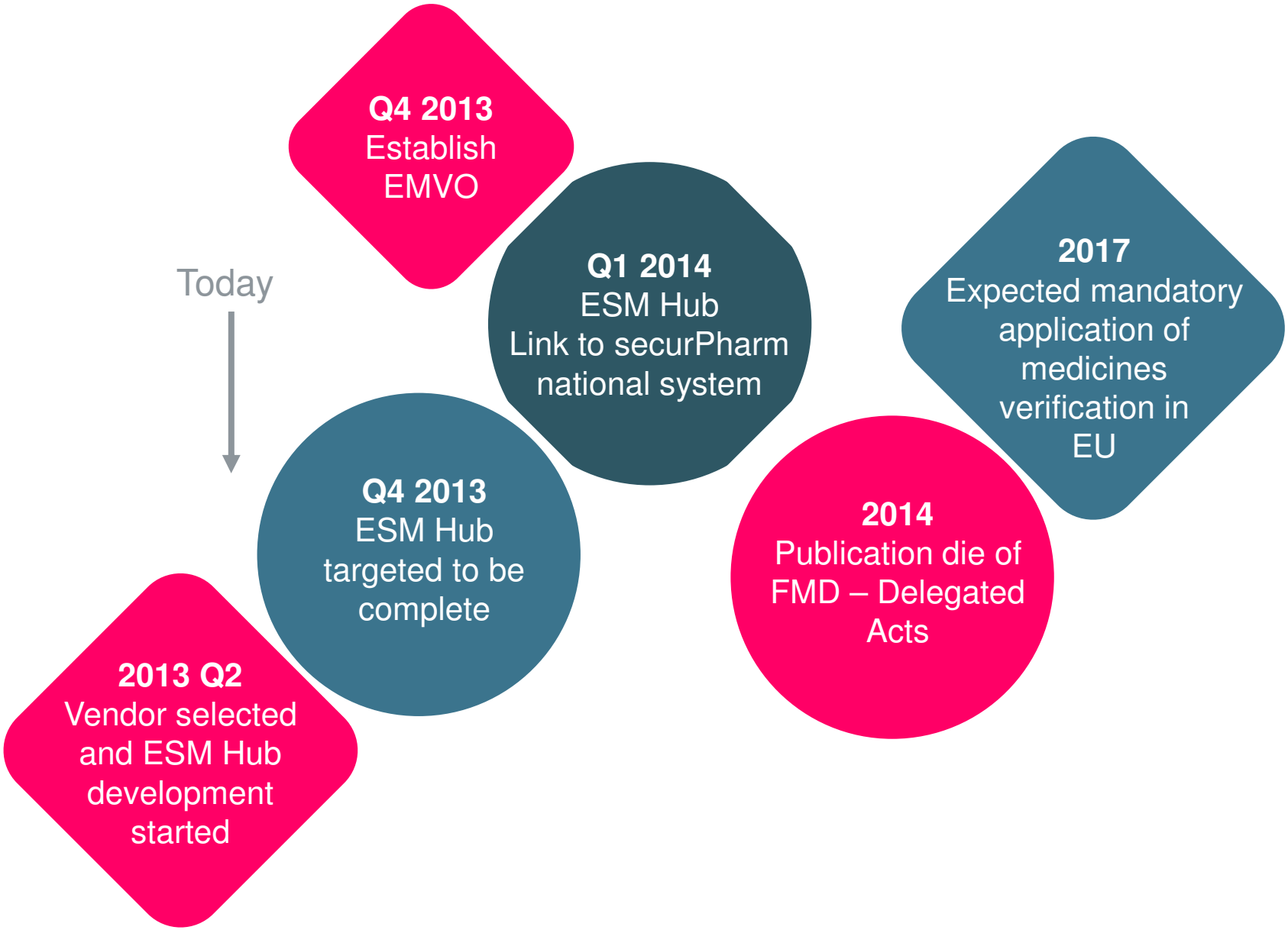
Next steps

Next major milestones



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Thank you

http://www.esm-system.eu/home.html

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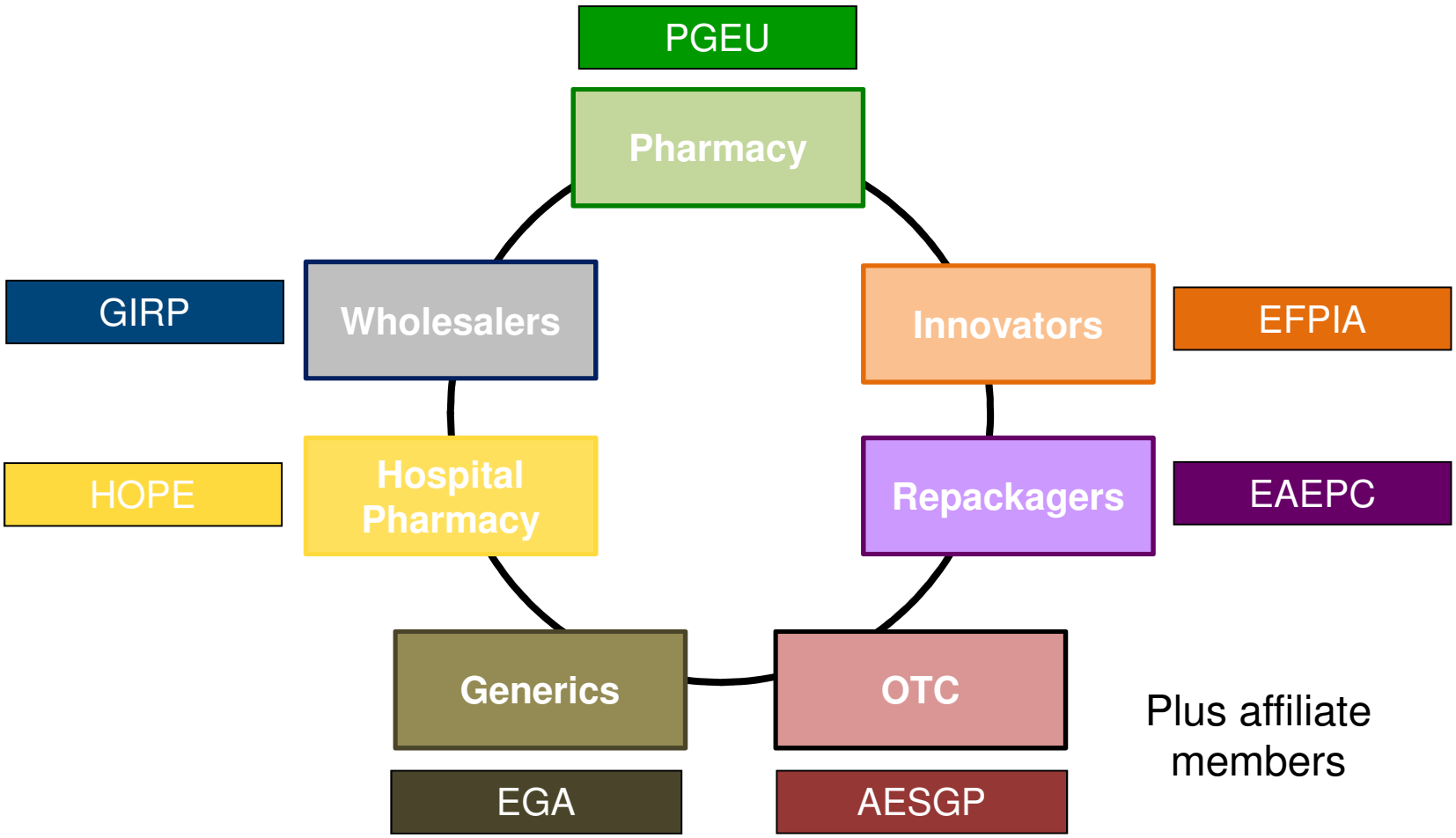
Back up slides

Will not be presented but may be distributed

EMVO – Membership

Members Are Allocated to a Constituency



Plus affiliate members

Memorandum of Understanding (MoU) provides the foundation

European level:

- Negotiated between EAEPC, EFPIA, GIRP and PGEU
  - Have elaborated and formally endorsed a MoU providing the foundation for the pan-European system
  - Talk ongoing with other constituents

- Contents
  - General goals and expectations
  - The 10 Core Principles
  - System Architecture
  - Entry & Exit Points
  - Data Access
  - Governance
  - Technical Annexes

Principles of sharing the cost of the verification system

Overall policy framework	• ESM is not-for-profit • Costs to be shared in a fair and equitable manner
Scope	• Repositories system only
Cost allocation	• To be based on value and volume components • Value based on total sales in specific market
Consistency	• Clear rules to avoid excessive variations
European Hub cost	• To be shared between connected national systems on the basis of the pack data transferred
Invoicing	• Market by market • Include share of European Hub