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

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Event: Global GS1 Healthcare Conference

Date: April 2014

Who am I

Grant Courtney

- Have worked as part of EFPIA team which established the ESM
- Member of the GS1 Healthcare Leadership Team
- 19 years in product security for GlaxoSmithKline

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Introduction

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
EAEPC European Association of Euro-Pharmaceutical Companies
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

ESM Stakeholders have a common vision

- 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
  - Supervisable by competent authorities

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EU Falsified Medicines Directive

new legal framework

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

The Directive – Safety Features

What Does the Directive Mandate?

- Safety features that enable relevant persons to
  - "verify…authenticity"
  - "identify individual packs"
  - Tamper evidence
- Rx and Vx included, all OTCs excluded. some exceptions based on a risk assessment
- Governments can use the system for reimbursement and/or pharmacovigilance purposes
- MAHs will pay for the 'repositories systems'

What Will Be Decided by Implementing Measures?

- Characteristics & technical specifications of the 'unique identifier'
- Criteria for the risk assessments & process for notification of products included
- "Extent and modalities of verification of the safety features" to "ensure the verification of authenticity of each dispensed pack"
- Establishment (including accessibility) of the 'repositories'

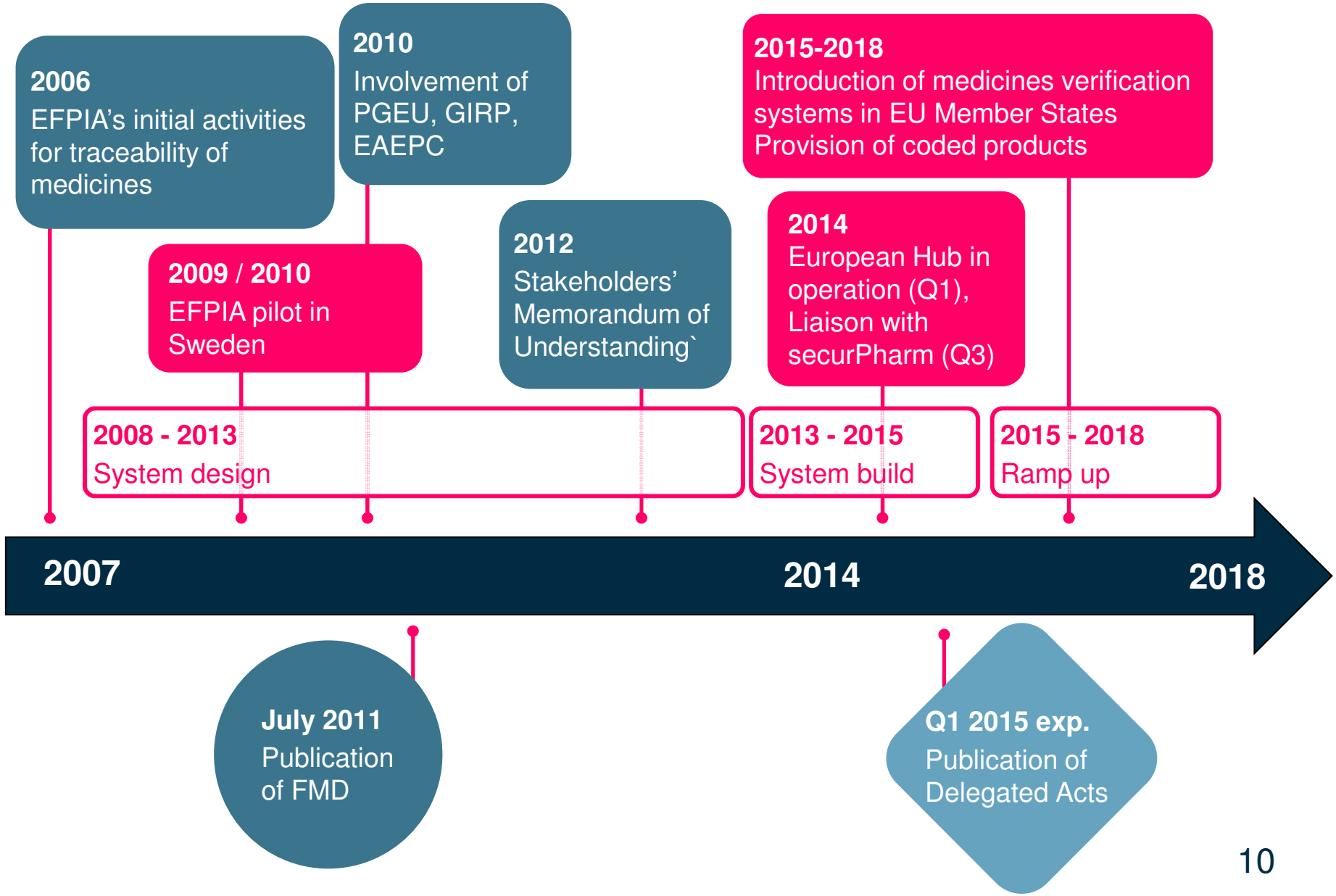
Result of COM's impact assessment

Conclusions (I)

- In summary, the Commission will propose:
  - Harmonisation of the composition of the number and the data carrier
  - Systematic verification of the safety features at the dispensing point and risk-based verification by wholesale distributors
  - Establishment and management by stakeholders with supervision by the relevant competent authorities

Source EC presentation at 13th EGA regulatory and scientific affair conference, 24 Jan 2014

The EMVS: Result of a long evolution



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EMVS Design and architecture

The joint stakeholder proposal

EMVS Basic Principles

- 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
- 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 (article 54a.4+5)

ESM
A medicines verification model for Europe
Using the
EMVS (European Medicines Verification System)

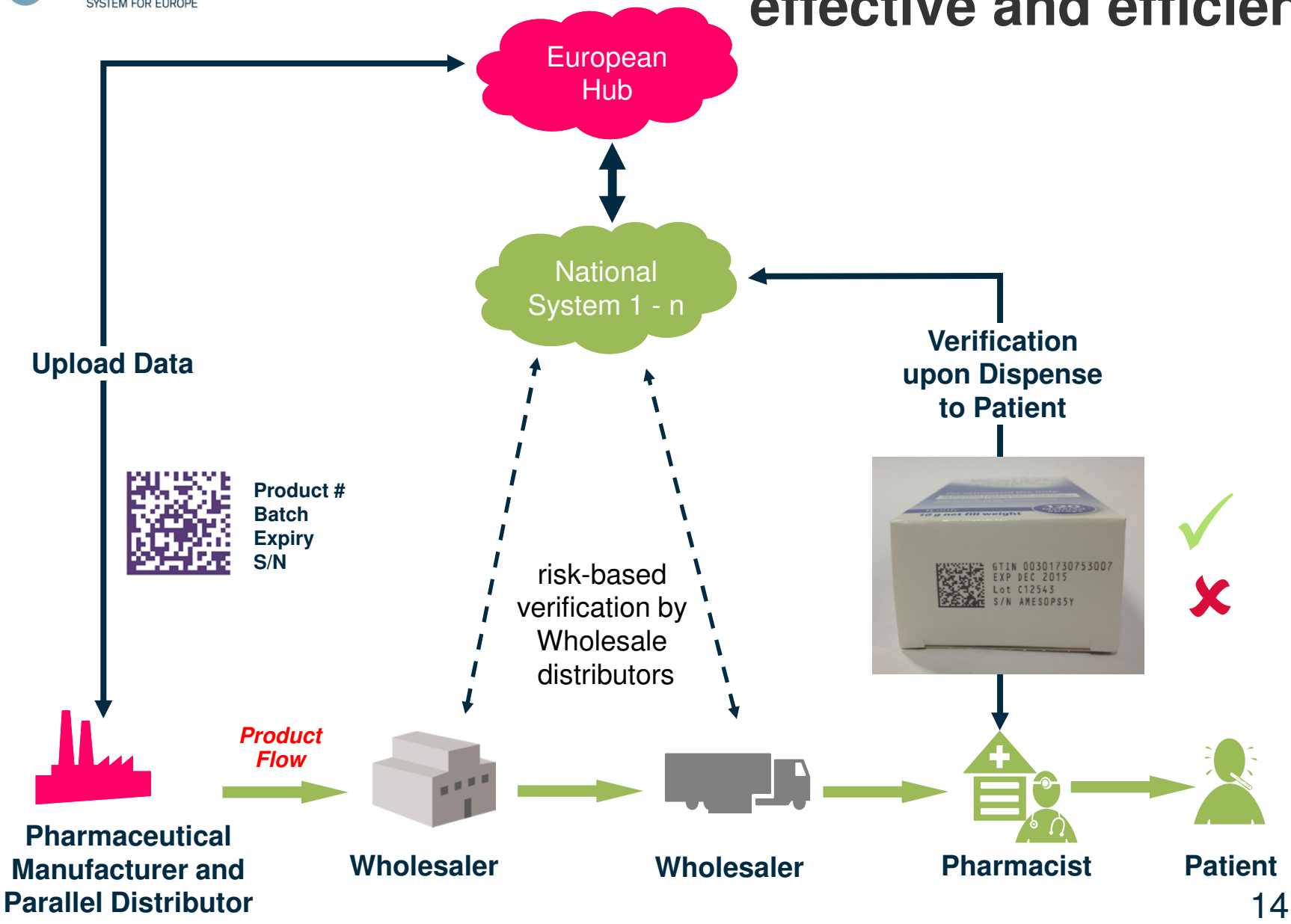
Each pack has its own unique identity

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

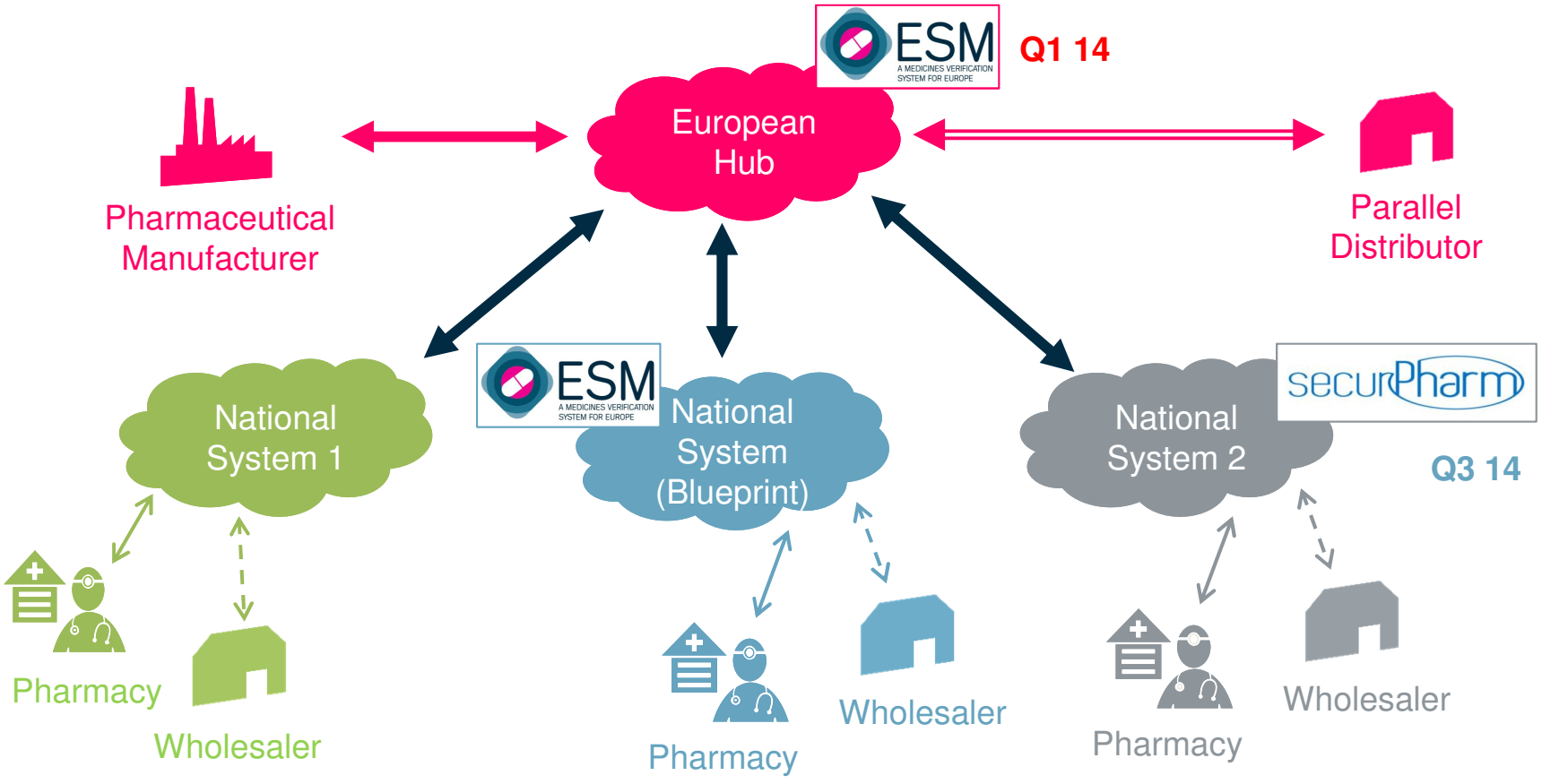
- Four key data elements:
  - 14 digit Manufacturer Product Code
  - Randomised Unique Serial Number
  - Expiry Date
  - Batch Number (up to 20 alpha-numeric characters)

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

“Point of Dispense Verification” is effective and efficient



Pan-European Architecture: The Hub connects National Systems



Parallel Distributor: mandatory verification + data upload

Manufacturer: data upload + voluntary verification

Periodic cross-region update

Pharmacy: mandatory verification

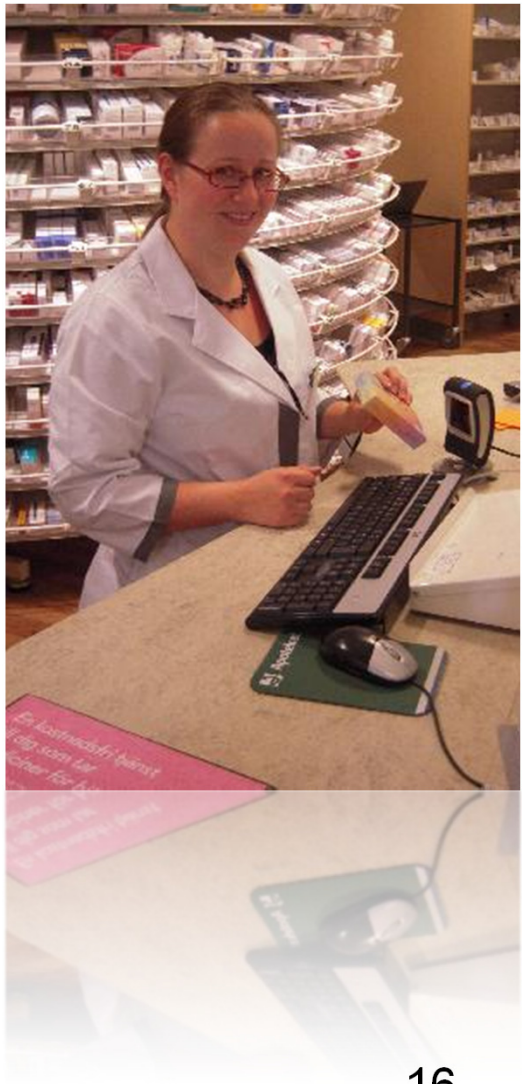
Wholesaler: voluntary verification

System design for interoperability and efficiency

The system has been demonstrated to be feasible

- 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



The benefit of Hub and Blueprint systems

European Hub

European Hub

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

National Blueprint system (nBPS) - optional

National System (Blueprint)

- Allows national stakeholders to join the EMVS without the need of building a separate own national system
  - Based on a “standard” national verification system providing all necessary functionality
- Fewer, but bigger (aggregate) systems are less costly than many (individual) smaller systems
- Particularly attractive for Member States with no system/ infrastructure in place

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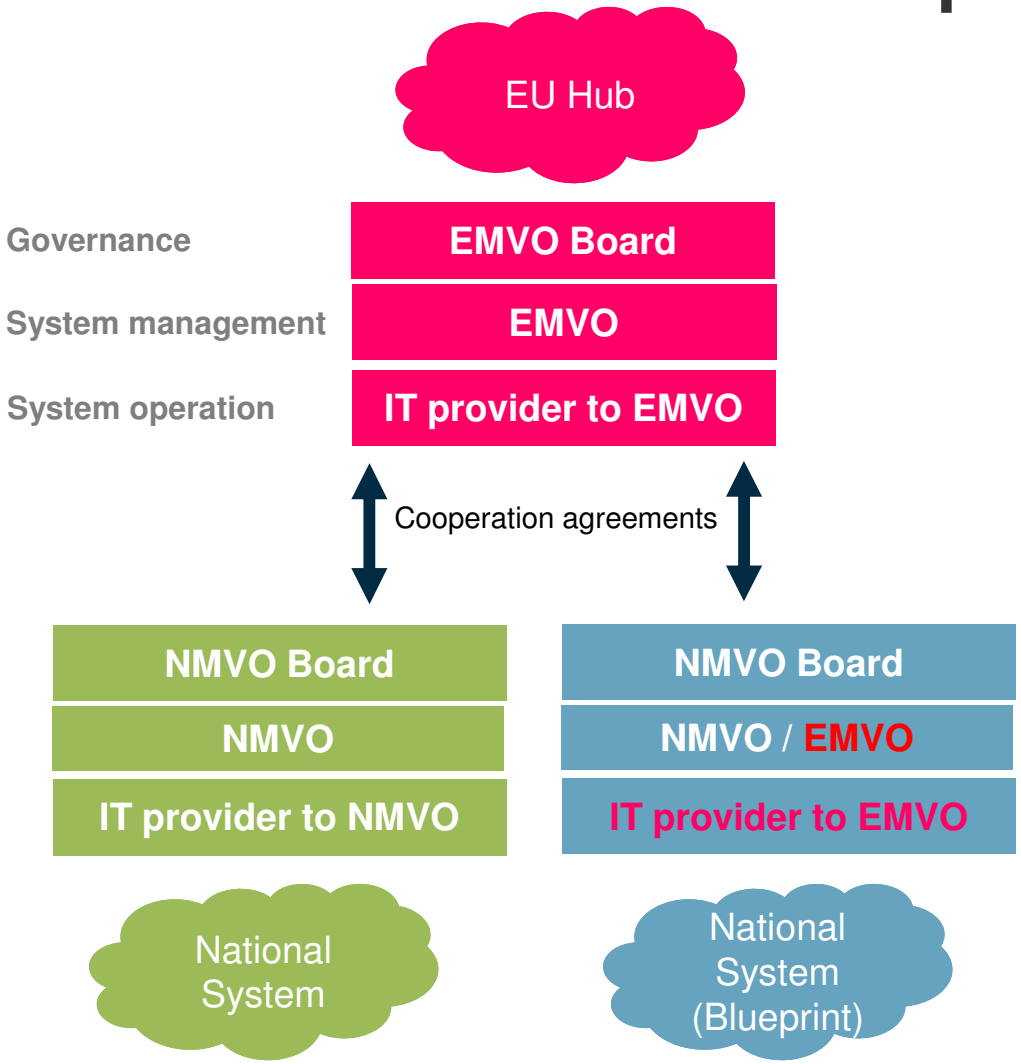
Stakeholder governance at the European & national levels

Who should be member of the governance organisation ?

- Each relevant market partner constituency should be represented:
  - Pharmacists
  - Wholesalers
  - Marketing Authorisation Holders (branded & generic products)
  - Parallel traders

- supervision by competent authorities

Governance is required at European and National level



European Medicines Verification Organisation (EMVO) will

- ❑ Govern EU Hub
- ❑ Set standards for the system
- ❑ Conclude agreements with NMVOs

National stakeholders govern national systems through National Medicines Verification Organisation (NMVO)

Blueprint system to be governed nationally, but managed by EMVO

supervision by competent authorities

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Cost-effectiveness

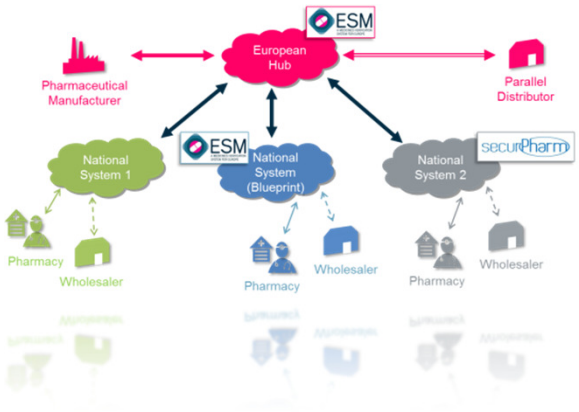
Designed with cost in mind

The Directive asks for cost effectiveness

ESM item	How this drives cost effectiveness
Point of dispense authentication (and risk based checking in the supply chain)	• Less complex than a full track and trace model to build and operate
2D DataMatrix	• International recognised standards reduces manufacturing complexity and drives harmonisation in the supply chain
Use of a Hub	• Dramatically reduces the number of point to point interfaces required and so reduces cost
National Blueprint system	• Templated national system which reduces development and implementation costs
Stakeholder governed	• The system operated on a not-for-profit basis

Overall costs are incurred by different elements

Repository system (Hub & national systems)

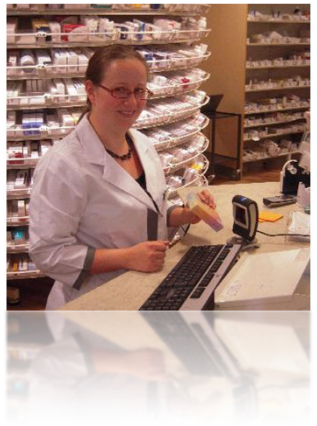


Manufacturers

Installation for pack coding

Manufacturers

Installations for pack verification



Pharmacies / wholesalers, respectively

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Status and next steps

Perspectives for EU roll out

Phased Implementation

- First steps towards the implementation of the EMVS' first phase have been initiated in 2012

- Timeline
  - 04/2013: Start development European Hub
  - 03/2014: Completion of European Hub
  - 07/2014: Connection between Hub and securPharm (D)
  - 07/2014: Connection of MAHs to Hub

- Roll-out to start upon publication of Delegated Acts (Early 2015)
  - Start date for development of Blueprint system not yet decided

Timely implementation requires concrete planning **now**

- Clarify **governance** options (private, public, private-public)
  - Delegated Act: stakeholder-governed model under supervision/ oversight by authorities…
- Develop **principles for cooperation**
- 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**

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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

Ten core principles as agreed by the current ESM members

- Combine tamper-evident packaging and unique serial number
- Continuity of protection by integration of parallel traders
- Ensure a single coding and identification system across EU
- Ensure interoperability of the national product verification systems
- Verify every serialised pack at pharmacy level
- Maximise potential benefits of mass serialisation by integration of batch number and expiry date in the coding system
- Transactional data remain in the sole ownership of the originator
- Use safety features that are simple, robust and cost-effective
- Key stakeholders work together in the interests of patient safety
- Involve other stakeholders (e.g. supervision by relevant competent authorities)

Manufacturers decide on Tamper-Evidence technology

- Diverse solutions for tamper-evident closure of original manufacturer's package exist
  - Glued cartons with/without perforation
  - Security seals
  - Wrap with foil
  - Bottles with tamper-evident screw caps
- Cost-effectiveness and technical feasibility need to be considered
- Selection should be left at each manufacturer's discretion

Cost for the EMVS covers all relevant items

Set-up cost	• Core system development (incl. interfaces) • Testing and Quality Assurance • User Training • Project Management
Technical running cost	• Licences • Information technology infrastructure • System & application maintenance • Help-desk
Administrative cost	• Accounting • User administration • Management of system provider • Analysis of exceptional events / reporting • Public relations