EFPIA & The EU's Falsified Medicines Directive

Working Together for Patient Safety

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Introductions

Who is EFPIA?

- The Voice of the innovation-based pharmaceutical industry in Europe
  - The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the pharmaceutical industry operating in Europe.
    - Direct membership of 31 national associations and 38 leading pharmaceutical companies including their affiliates
  - EFPIA is to promote **pharmaceutical research & development and** the best conditions in Europe for companies to bring to patients **new medicines that improve human health and the quality of life around the world.**

Introductions

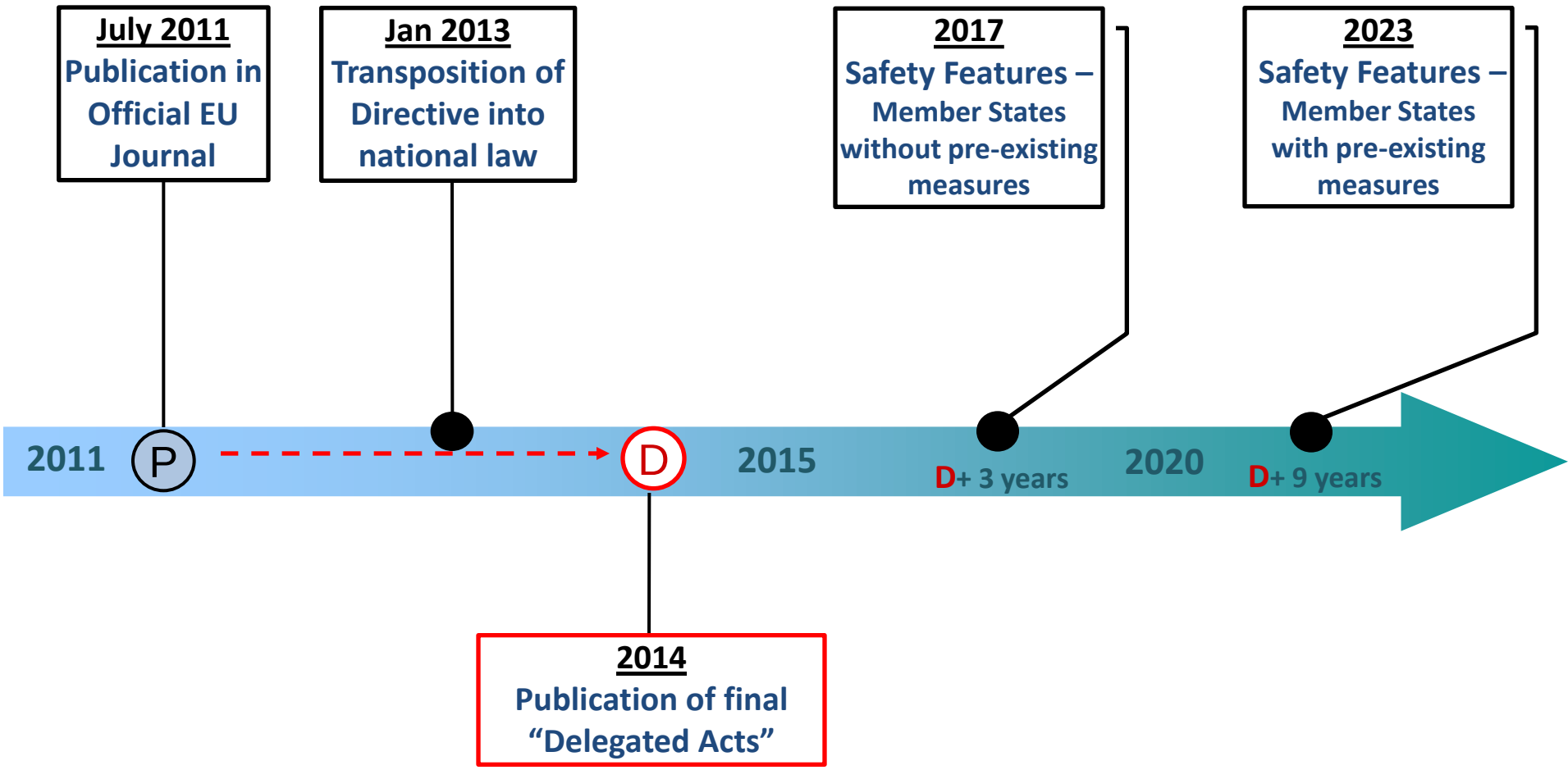
Who am I?

- Director of Public Affairs in Pfizer's Brussels office
- 10+ years of experience in the pharmaceutical industry across many commercial functions
- Member of key EFPIA work groups related to the Falsified Medicines Directive

Overview

- The Directive, Safety Features, & Verification
- The EFPIA POD, Stakeholder-Owned System
- The Way Forward

Directive Milestones & Timelines



The Directive – Safety Features

What Does the Directive Mandate?

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

What Will Be Decided by Delegated Acts?

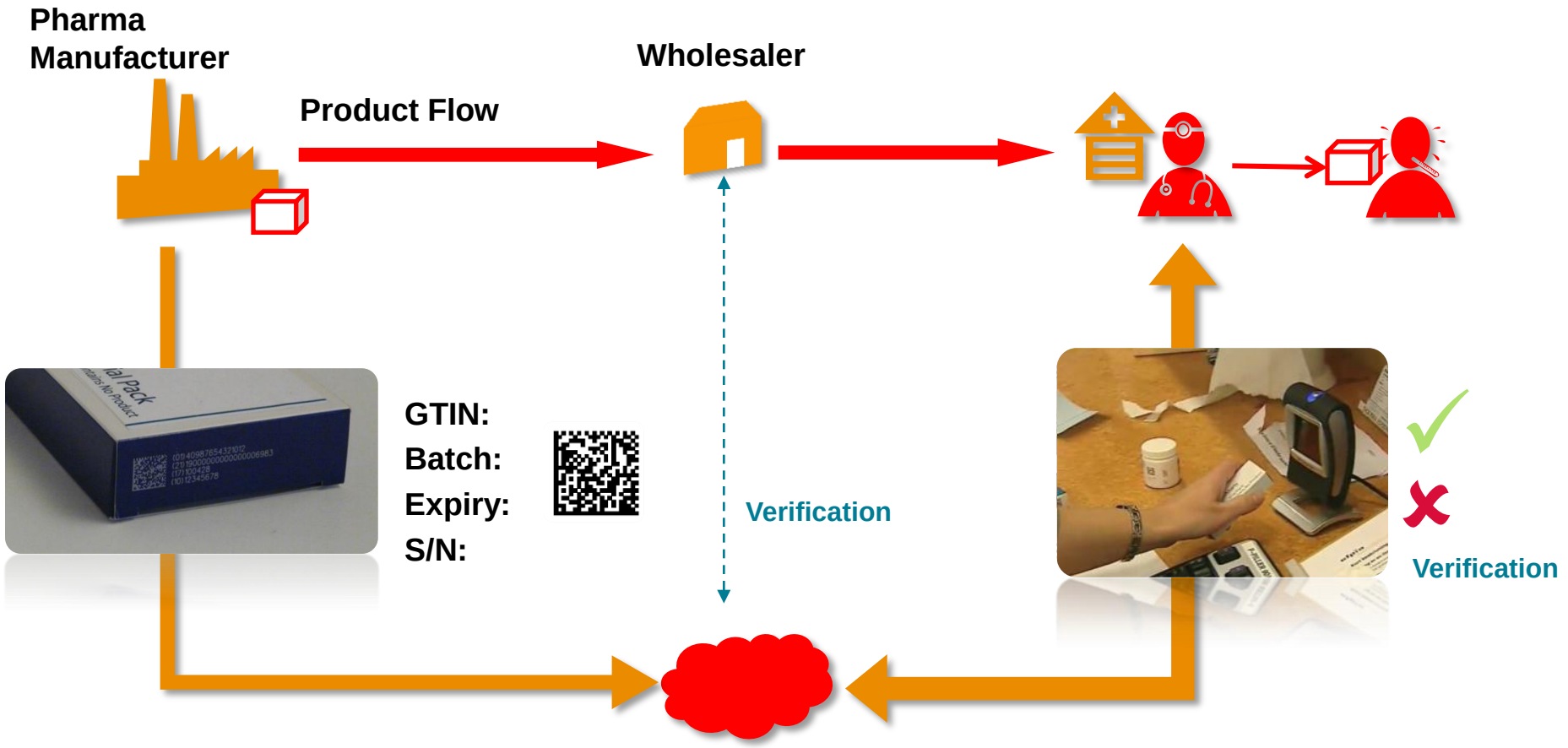
- Characteristics & technical specifications of the "unique identifier"
- Criteria for the risk assessments & process for notification of products included
- "Extent and modalities of verification of the safety features" to "ensure the verification of authenticity of each dispensed pack"
- Establishment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

EFPIA's Objectives

- Improving patient safety
  - **Reduce the risk of counterfeit** products being dispensed
  - **Detect expired products** automatically
  - Perform **product recalls** more effectively and efficiently
  - **Deliver the right product** to the patient

The Point-of-Dispense Model

Secure All Entry & Exit Points



Testing the Concept

- A pilot project in cooperation with pharmacists
- Objective was to demonstrate the EFPIA proposal as
  - an **aligned approach** with the Falsified Medicines Directive
  - a **practical and effective solution** for relevant stakeholders (manufacturers, pharmacists, wholesalers)
    - That can be fully integrated into their existing operations
  - a model that works based on **common standards** & mature technology
    - High performance and a secure system
  - A **credible alternative to proprietary national systems**, aligned with government requirements

Swedish Pilot 2009-10

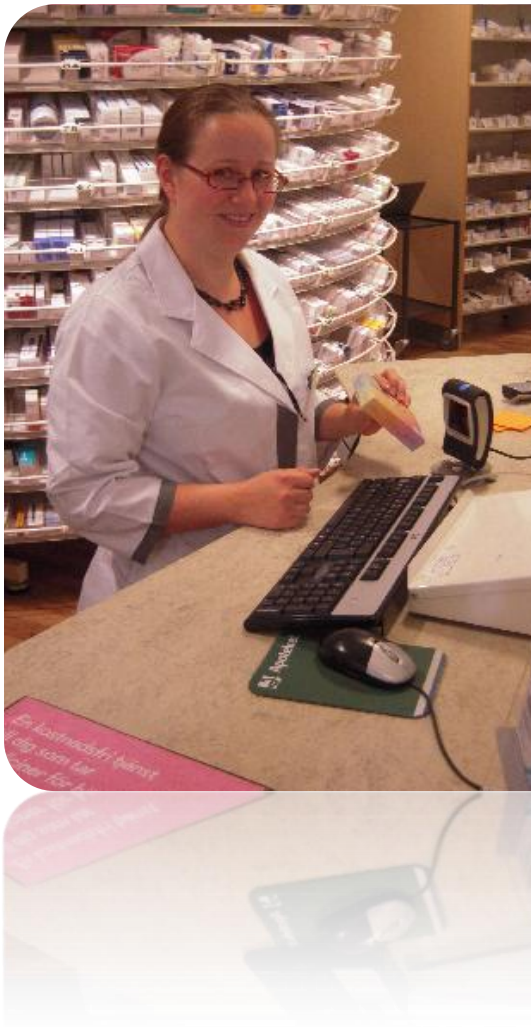
- Key figures
  - 25 pharmacies in the greater Stockholm area (owned by Apoteket AB) with a total of 180 dispensing points
  - 25 products (SKUs) with total of 110.000 packs
  - 14 manufacturers
  - 4 months duration of operational phase

- Operational phase
  - Started with 3 pharmacies on 17 September
  - Remaining 22 pharmacies joined on 24 Sept

- Wholesalers labelled and distribute packs
  - Kronans Droghandel
  - Tamro

Key Conclusions

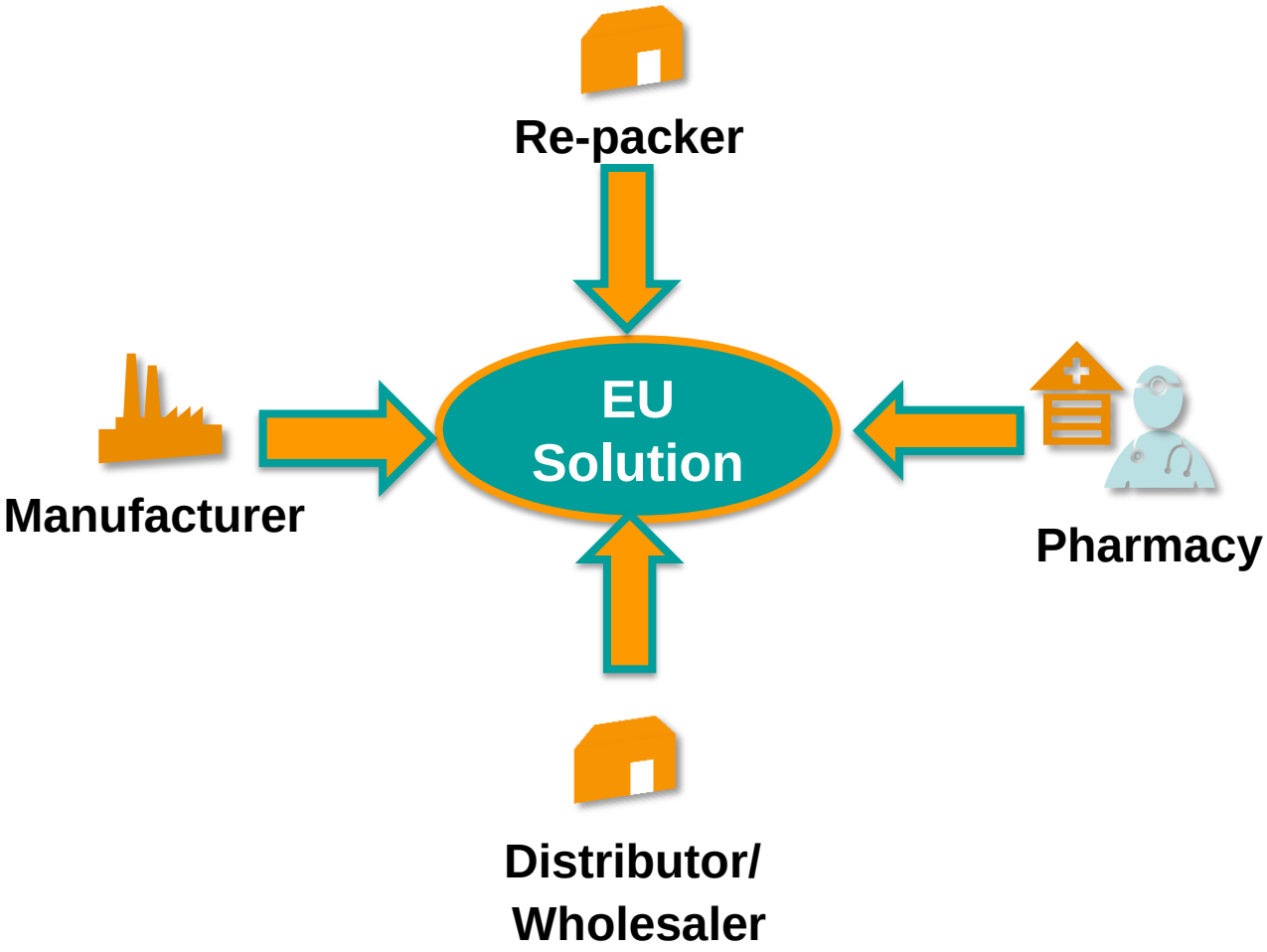
- **Works in practice** and allows for effective identification of fake packs
- System availability and performance **allowed pharmacists to work at normal pace** and without significant additional effort
- System was **easy to use** when fully integrated into pharmacy workflow and existing IT system
- System **should be customised to existing pharmacy workflow**, processes, local conditions and regulatory requirement.
- The presence of **more than one code on the pack causes confusion for the user and will jeopardise user acceptance**
- Pharmacists are **highly interested to get expiry date and batch number in machine readable form** through the 2D data matrix



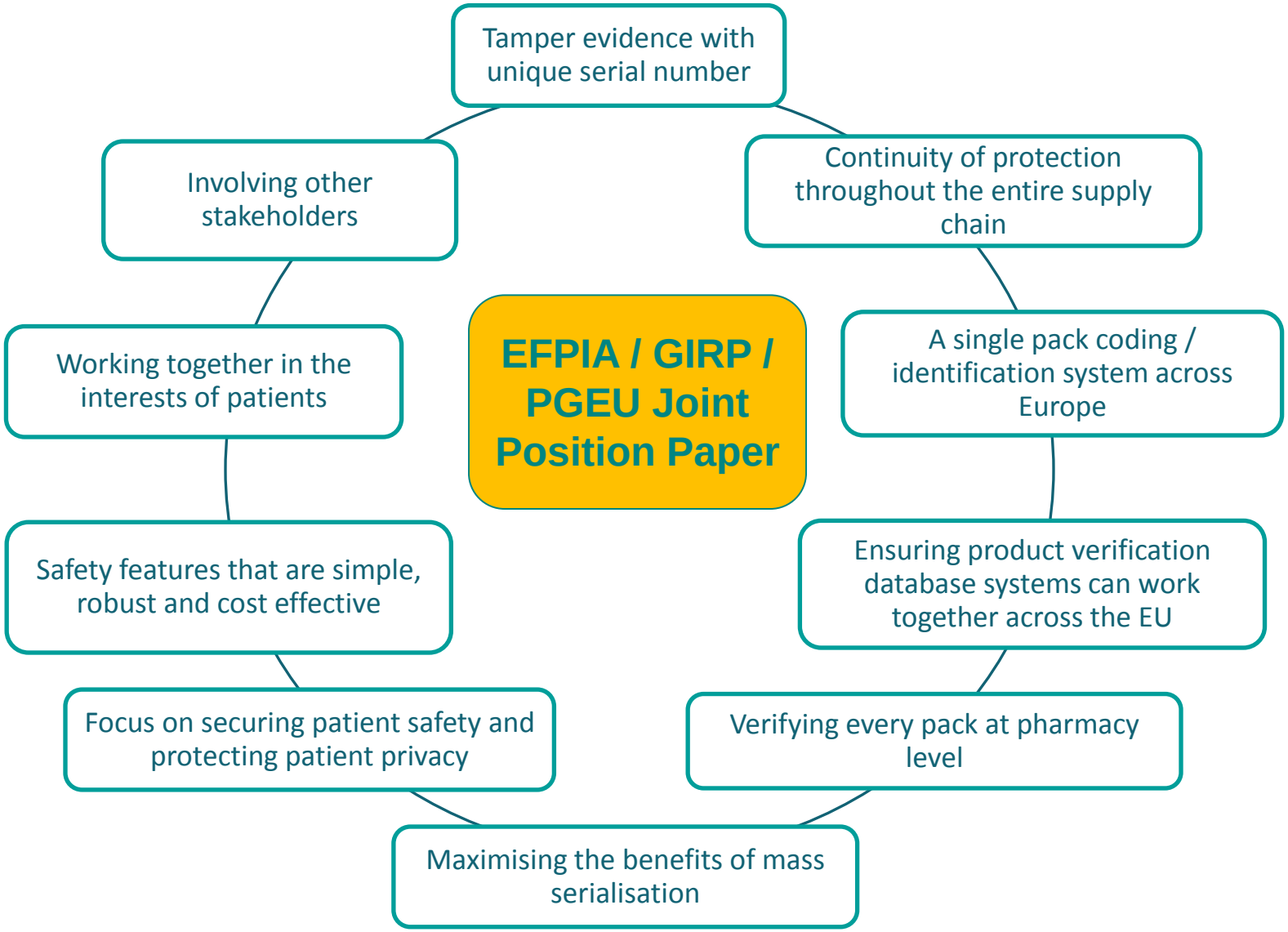
Looking Ahead - Key Success Factors

Issues		Requirement
• Cross border movement and multi-market packs.	→	• Systems will have to be interoperable to maintain patient safety
• Difficulty of multiple codes and ensuring uniqueness	→	• Single unique code to scan for all purposes e.g. verification, reimbursement, etc
• Many stakeholders are involved in getting the product to the patient	→	• Stakeholders are going to have to work together and define the governance to design, deliver and run solutions
• Access to data	→	• System must be highly secure, with strict control • Additional access requirements for some scenarios – ie negative verifications, recalls

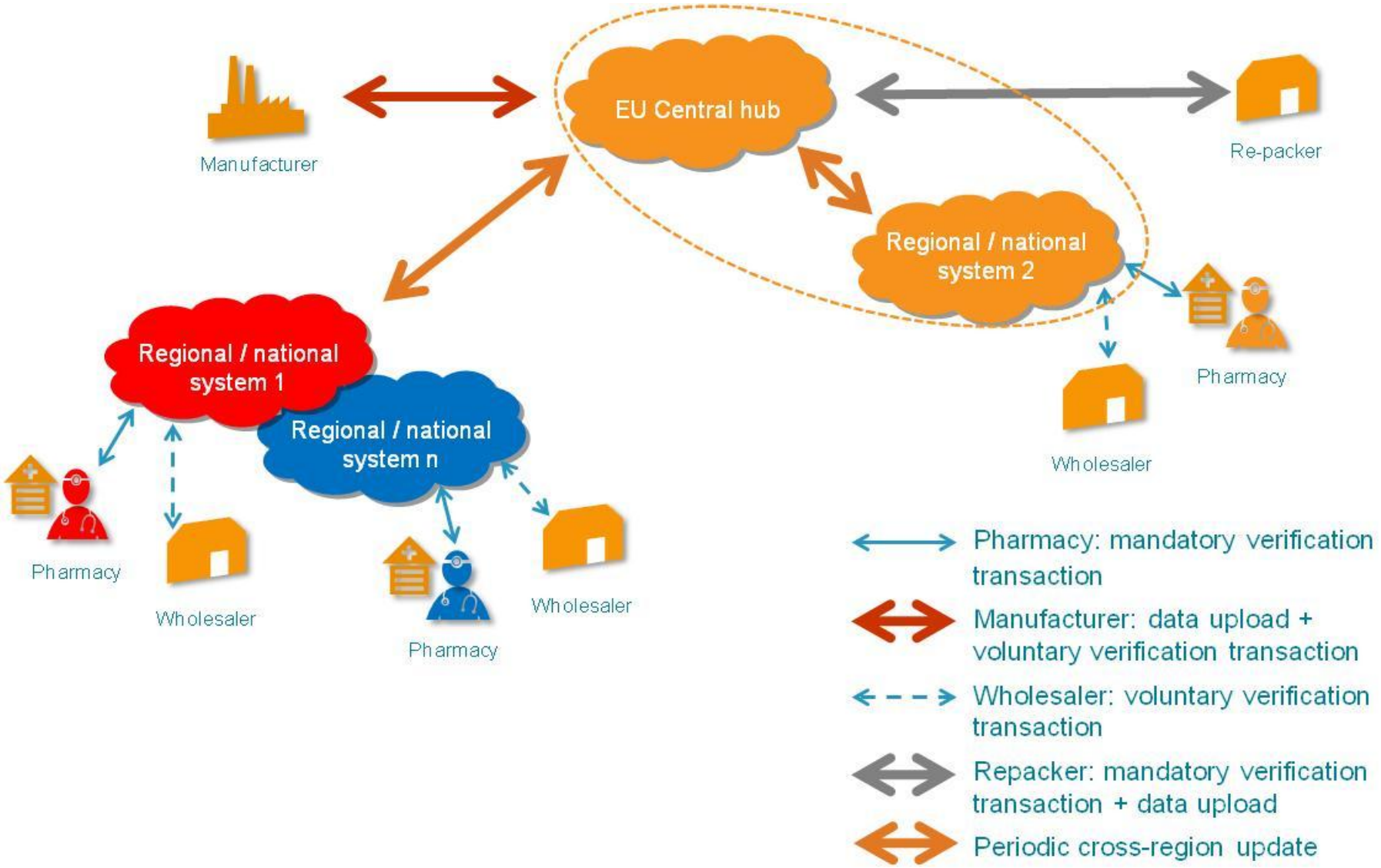
Stakeholders Working Together Across Europe



Stakeholders Working Together



Pan-European Model



Key Benefits of the Pan-EU Model

- Use of Datamatrix code **reduces required space** on pack & provides higher robustness compared to linear barcode
- "Point of dispense verification" is **far less complex** than Track & Trace and provides needed improvements in patients safety
- Including batch number and expiry date in the code allows **for logistic and Patient Safety advantages**
- Based on **common principles** and can accommodate **regional needs**
- Stakeholder governance is critical to **ensure a responsive, cost-effective system that works for patient safety**
- European hub provides a **single point of data entry** for manufacturers, facilitates multi-country pack s, and accounts for parallel traded packs

Status & Next Steps

Continue Progress Towards Implementation

- Approach endorsed by the EFPIA Board
- Continue building the partnership with PGEU & GIRP
  - Joint work streams already in place on stakeholder involvement / governance, system development, and communications
- Seek support of other key stakeholders
- Work with national level stakeholders to develop and implement national level systems

Thanks

http://www.efpia.org

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