efpia

European Federation of Pharmaceutical Industries and Associations

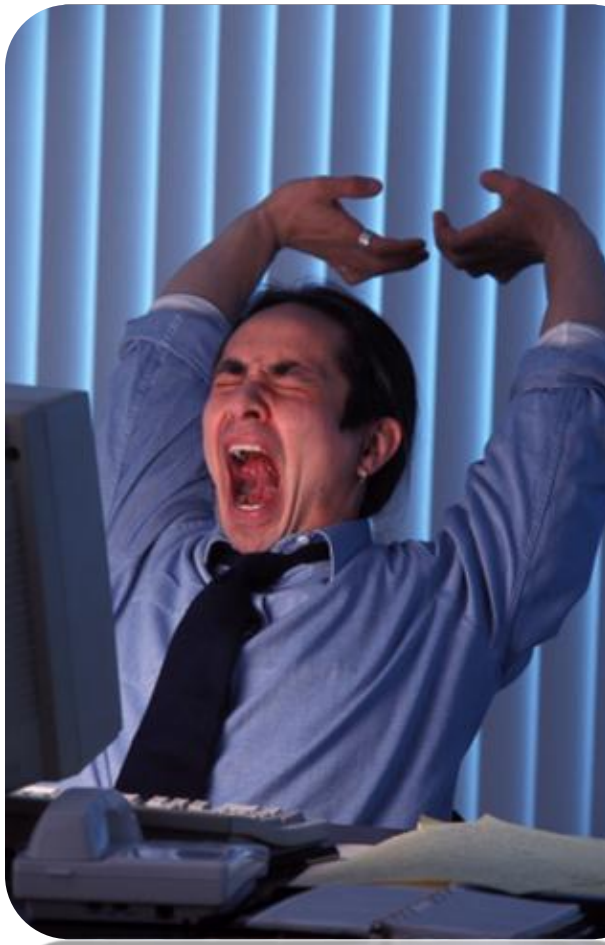
On the Way to a Pan-European serialisation & product verification model

Speaker: Grant Courtney

Event: GS1 Global Healthcare Conference

20th - 22nd March 2012

The boring bit !



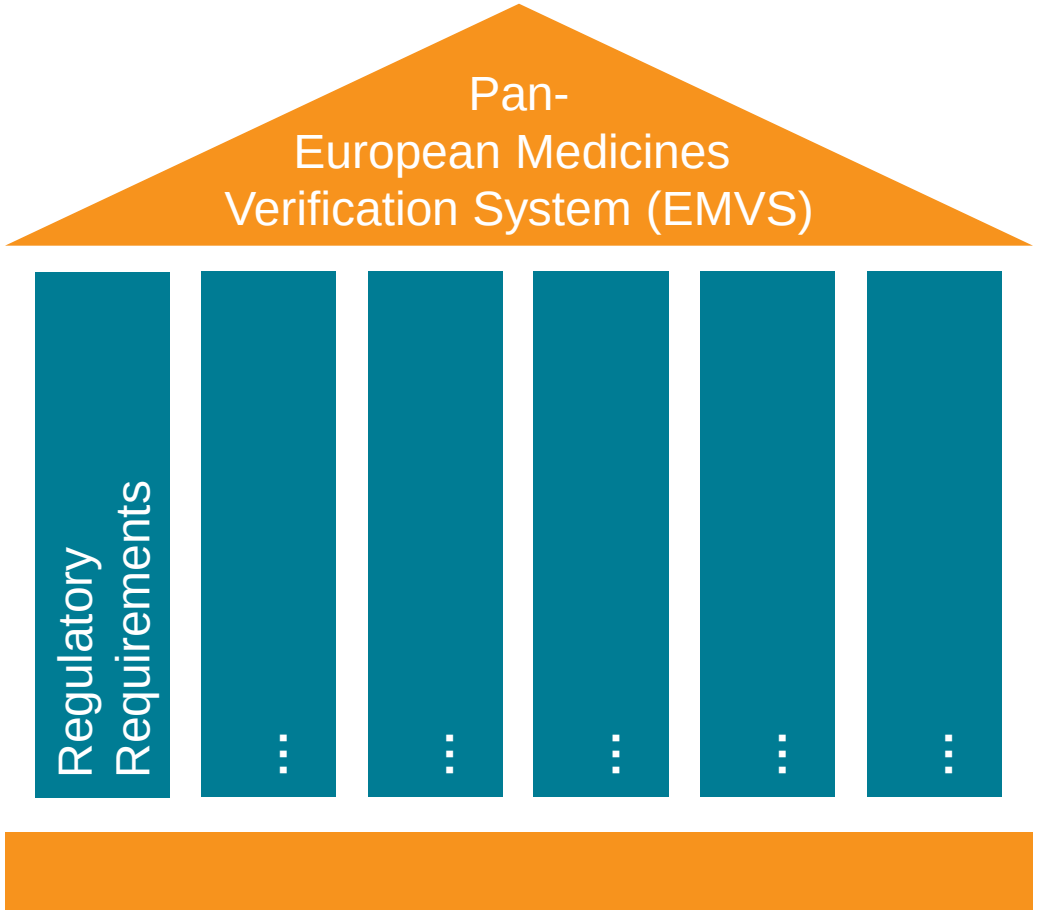
About EFPIA


European Federation of Pharmaceutical Industries and Associations
represents the **research-based** pharmaceutical industry operating in Europe
brings together 31 national pharmaceutical associations and 38 leading companies

Who am I ?

- 16 years supply chain and product security for GlaxoSmithKline
- Member of the GS1 Healthcare Leadership Team and Co-Chair of the Public Policy Team
- Sit on various **efpia** groups addressing product coding

Design of pillars for EMVS is well underway



New EU Directive to combat falsified medicines launched

Safety Features

- Safety features to allow **verification of authenticity** and identification **of individual packs**, and provide **evidence of tampering**
- Risk-based approach – “white list” for prescription medicines, “black list” for OTC
- Parallel importers must replace safety features with equivalents & are held liable for damages

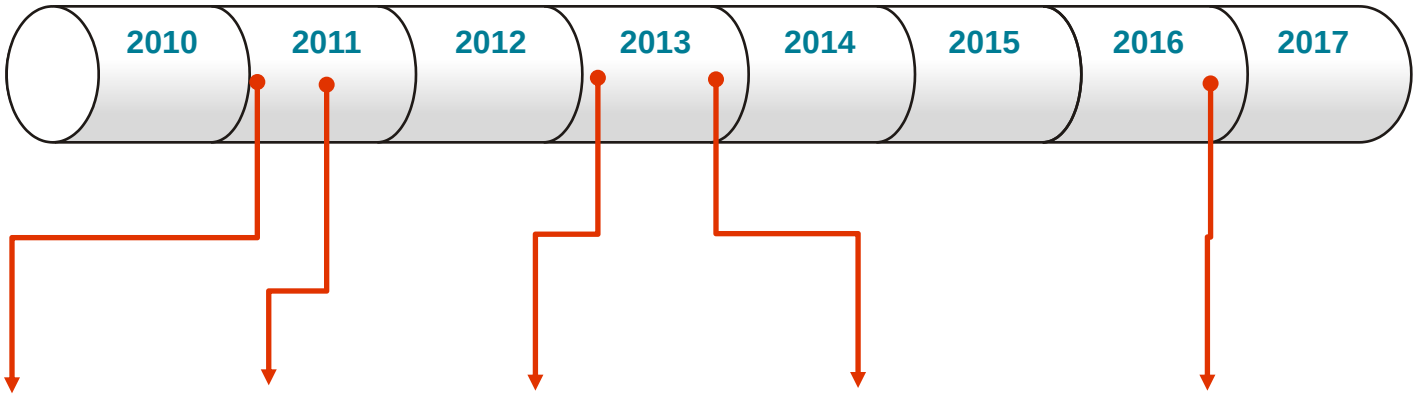
Repositories System

- System to contain information on the safety features
- Member states may use safety features for other purposes e.g. reimbursement
- **Costs shall be borne by the manufacturing authorisation holders**

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

Serialisation Status in Europe



16 Feb
European Vote

July 2011
Publication in Official EU Journal

Jan 2013(?)
Transposition of Directive into national law

Q3-4 2013 (?)
European Commission "Delegated Acts"

Q4 2016 (?)
Implementation in Member States without pre-existing measures

Some countries could deploy earlier than 2016

But does it work . . . ?

- Stakeholder proposal for a Pan-European serialisation & product verification model
- Operating the proposed model in Sweden
- Current activities

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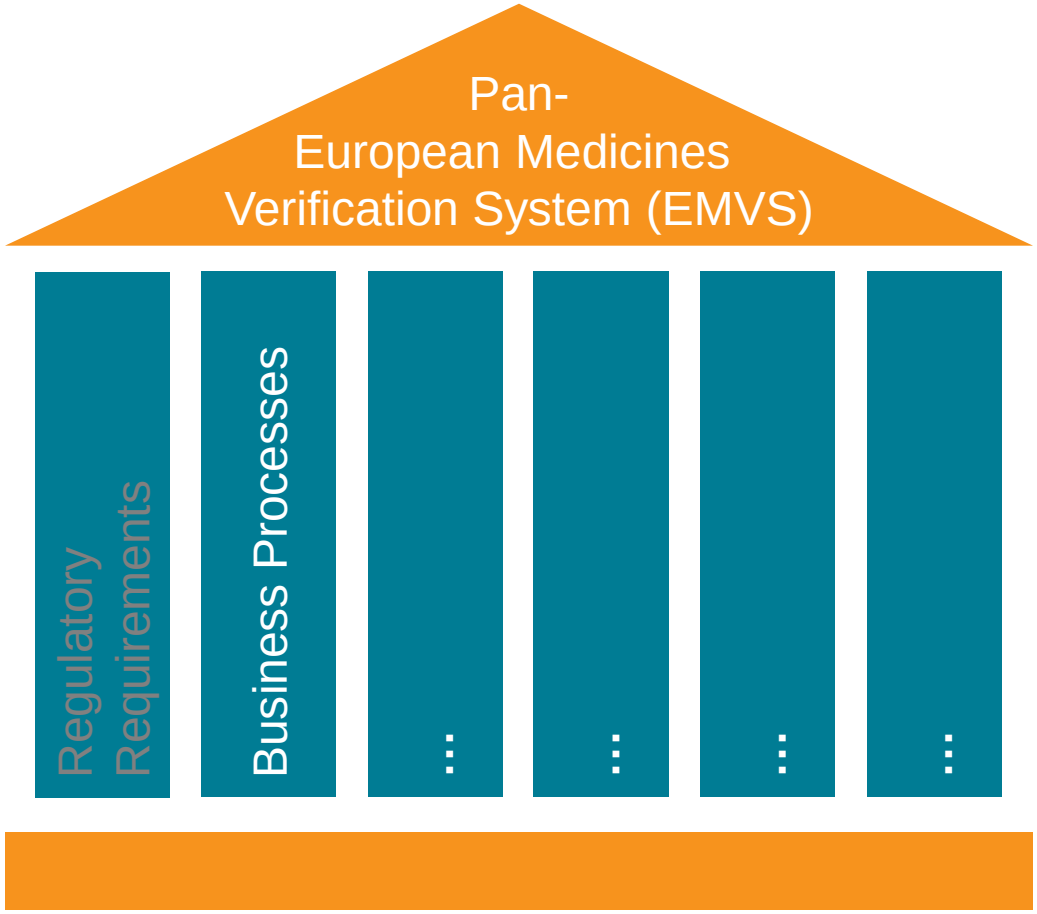


EFPIA proposes a 2D DataMatrix for pack verification

DataMatrix coding proposal using GS1 standards

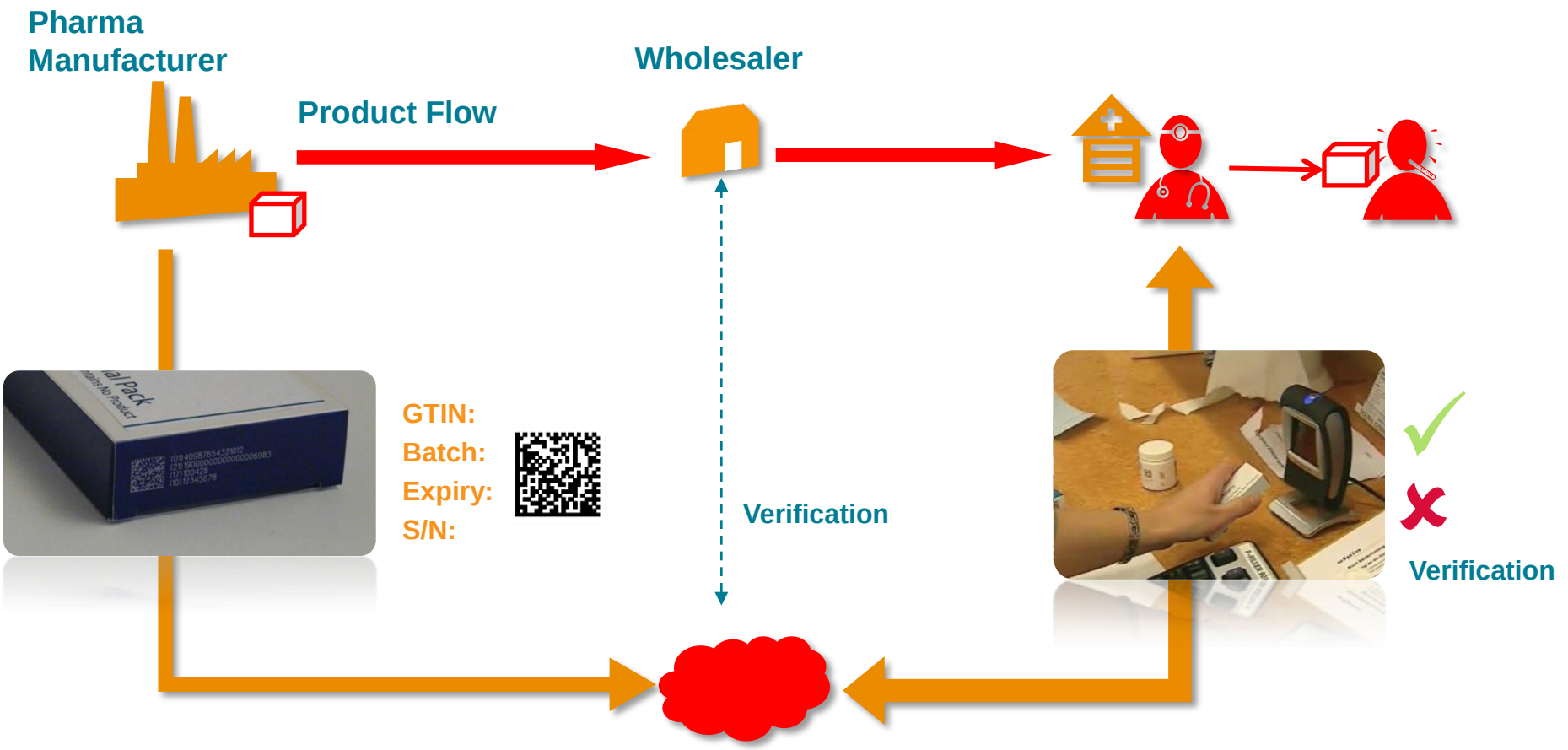
(EAN 128 syntax with Application Identifiers; Data matrix ECC200)

Manufacturer Product Code (GTIN or NTIN)
Unique Serial Number (randomized)
Expiry Date
Batch Number

Example:

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

We advocate securing all entry and exit points of a country's supply chain through a point of dispense authentication model



But does it work . . . ?

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Pilot project overview

- Objective - to demonstrate the EFPIA proposal as:
  - an **aligned approach** with the EC's pharmaceutical package
  - a **practical and effective solution** for relevant
  - a model that works based on **common standards** & mature technology
  - A **credible alternative to proprietary national systems**, aligned with government requirements

- 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
  - Operational phase from Sep 2009 – Feb 2010

Key conclusions of the Pilot

- **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. It is therefore recommended to run a pilot phase for each deployment (region) so that defects can be eliminated before roll-out
- The presence of **more than one code on the pack causes confusion for the user and will jeopardise user acceptance**
- Necessary **data segregation and security** can be technically ensured
- Pharmacists are highly **interested to get expiry date and batch number in machine readable form** through the 2D data matrix

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What's next . . . ?

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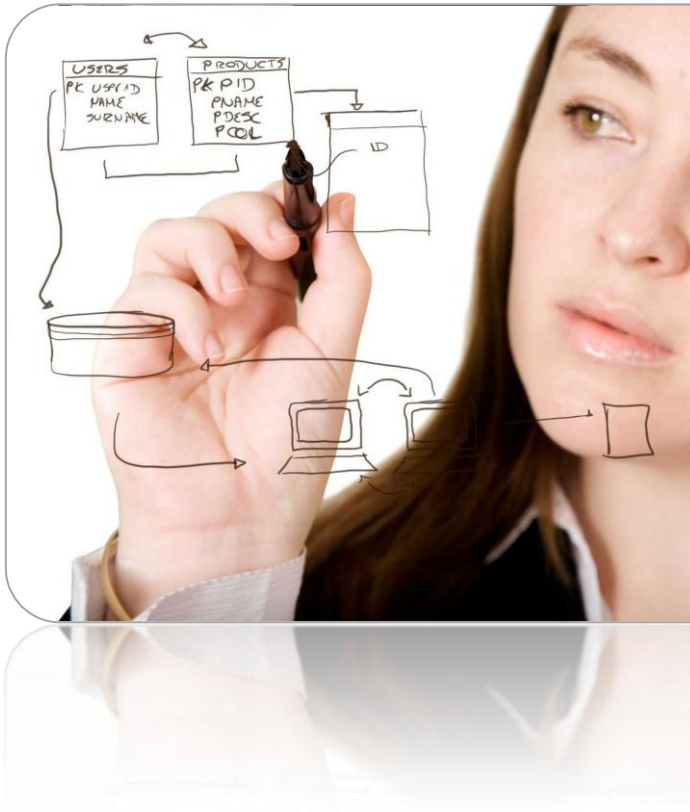
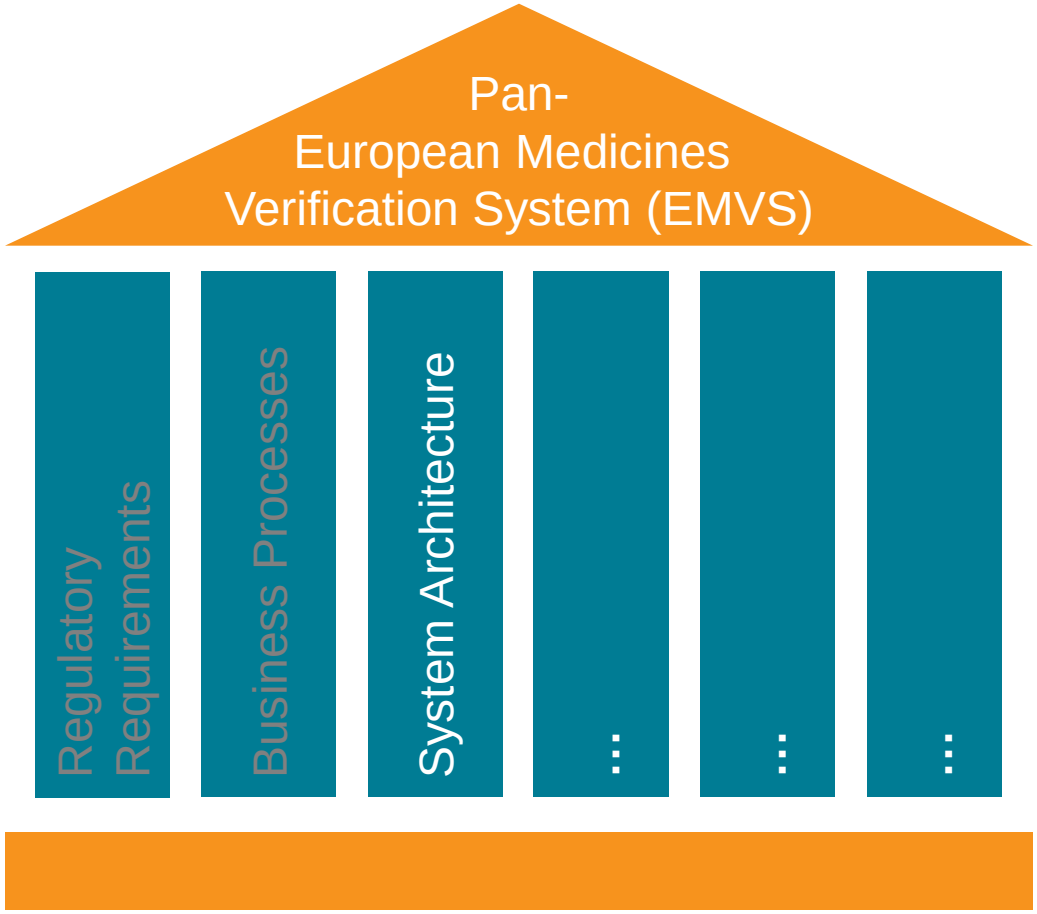
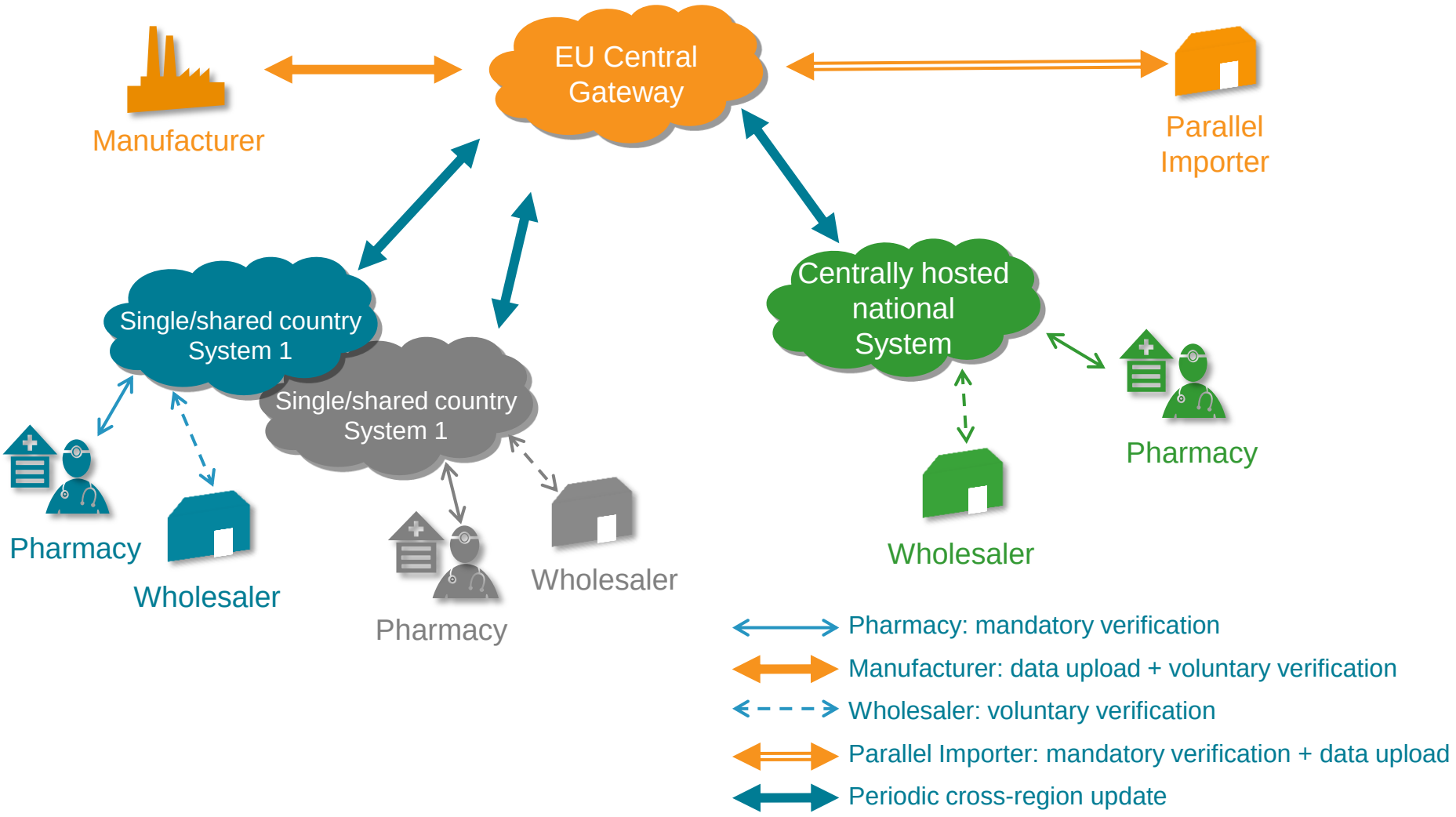


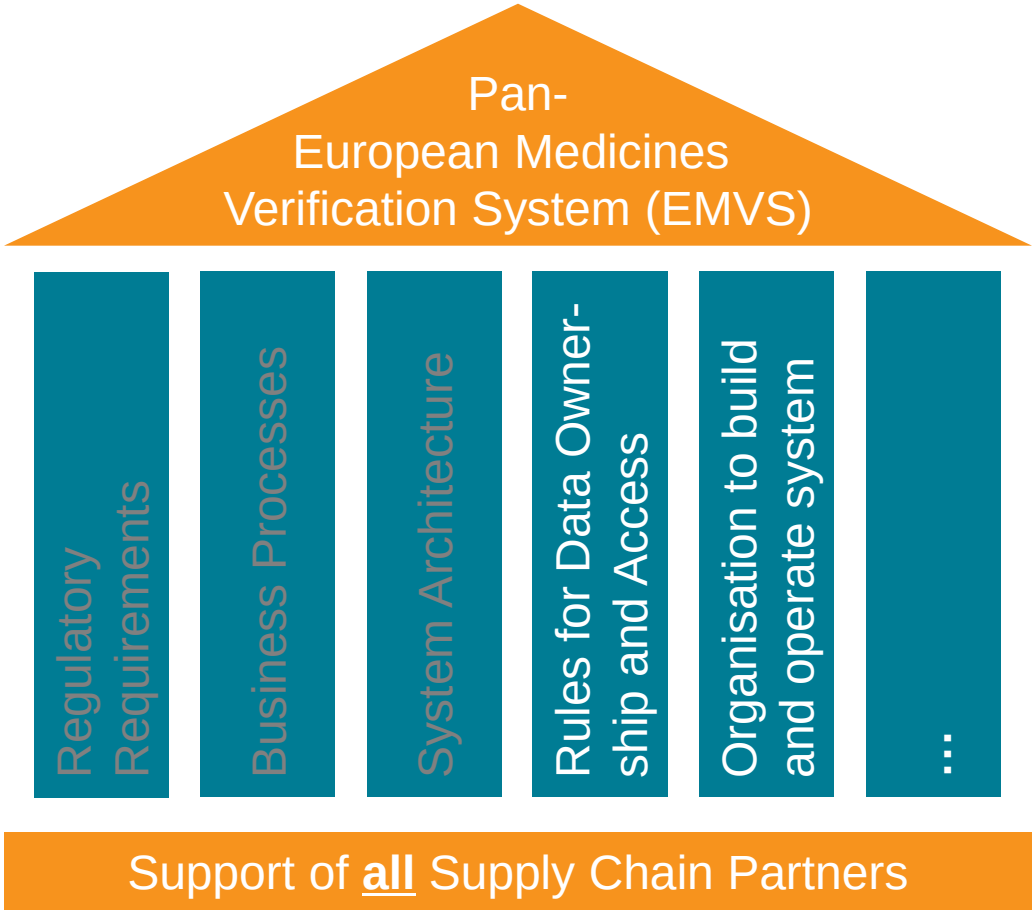
Design of pillars for EMVS is well underway



Proposed Framework for a European medicines verification system



Stakeholder support is key to success



Joint view on implementation of Directive EAEPC, EFPIA, PGEU and GIRP

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

Major supply chain partners working together

- EAEPC, EFPIA, GIRP, and PGEU have:
  - agreed upon a **joint position paper** "Ten Core Principles to Protect Patients from Falsified Medicines"
  - elaborated a Memorandum of Understanding towards **foundation of European stakeholder organisation**
  - Plan to launch a Request for Proposals for implementation of **European Medicines Verification System (EMVS)**

- Talks ongoing with AESGP, EGA, and HOPE

TEN CORE PRINCIPLES TO PROTECT PATIENTS FROM FALSIFIED MEDICINES
EFPIA/PGEU/GIRP Joint Position Paper
March 2011

The Directive on falsified medicines introduces mandatory, harmonised pan-European safety features for medicines at risk of falsification. With counterfeit medicines a clear and growing threat, EFPIA, PGEU and GIRP fully support this move. New technologies can offer significant protection against breaches in the legitimate supply chain. However, this also demands greater clarity on how best to use these features to provide robust protection.

EFPIA, PGEU and GIRP believe any framework for implementing the Directive, in particular the delegated acts and all preparatory work, should reflect the following key principles:

1. *Combining tamper-evident packaging with a unique serial number:*

- EFPIA, PGEU and GIRP support the requirement in the falsified medicines directive that the safety features should consist of a unique serial number placed on each pack together with packaging that would reveal if a pack has been opened or tampered with.
- Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispensing is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system.
- EFPIA and PGEU consider that safety features should be applied to all prescription medicines to ensure the same level of security. Therefore if a risk-based approach for prescription medicines is pursued, exemptions should be based on specific categories, narrowly (e.g. ATC 4 level), rather than individual

AESGP	Association of the European Self-Medication Industry
EAEPC	European Association of Euro Pharmaceutical Companies
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

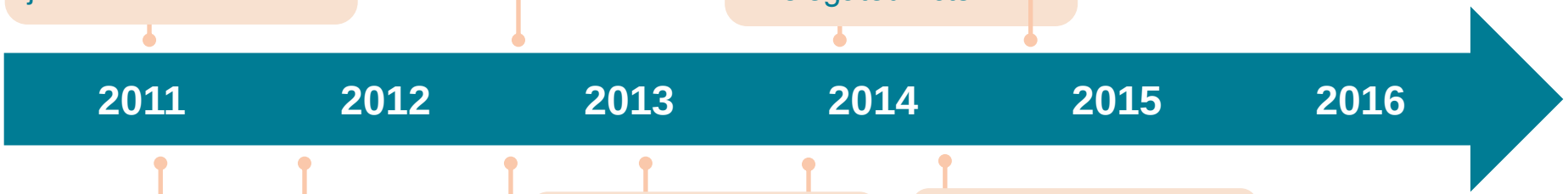
Schedule towards pan-European medicines verification is tight

July 1, 2011
Publication of directive in official journal of EU

January 2, 2013
EU member states to convert directive to national law

2014 – 2016
Introduction of medicines verification systems in EU member states
Provision of coded products

2014 (est.)
Publication of addt'l provisions in "Delegated Acts"



Q4 2011
MoU between EFPIA, PGEU, GIRP signed

Q1 2012
System design document released

Q4 2012
MoU with additional stakeholders signed

Q1 2013
System development Phase 1 completed

Q4 2013
EMVO stakeholder organisation established

Q4 2014
EU Central Gateway in full operation

EMVO European Medicines Verification Organisation

Summary

- Point-of-Dispense Verification **model successfully operated** in Sweden in 2009/2010
- **Proposed framework** for a pan-European medicines verification system **in place**
- Involvement of supply chain stakeholders is key for success
- EFPIA and its partners EAEPC, GIRP and PGEU are working to meet the requirements of the EU Falsified Medicines Directive
  - Contribution to public consultation on Delegated Act for safety features
  - Push forward foundation of European Stakeholder Organisation (“MoU” and Foundation Documents)
  - Prepare Request for Proposal for EMVS

So how is GS1 supporting EFPIA

- Contributed to a shared vision for GTIN across Europe
  - Worked to define the **vision** and support roll out
  - Development of the new AI for National Health Reimbursement Number (NHRN)
  - Working with individual countries to agree how to migrate towards GTIN
- Helping to shape legislation
  - Ensuring that **the views** of stakeholders are well represented as **part of public consolation**
- General **education** and support


EFPIA - GS1 Healthcare shared vision for product identification

EFPIA & GS1: a shared vision for product identification in the context of the EU Directive on Falsified Medicines

European Federation of Pharmaceutical Industries and Associations

PURPOSE

The purpose of this paper is to explain GS1 and EFPIA shared vision for product identification and marking of pharmaceutical products in Europe and some of the key reasons behind the vision. It is not intended to define the specific route which a country should take to achieve the desired end state; it does, however, lay out potential options. Which of these are adopted will need to be agreed on a case by case basis between all impacted stakeholders.

Vision in summary

The common vision is to place a GTIN (Global Trade Item Number) on pharmaceutical products in Europe, and beyond, and use this to look up attributes of that product such as any national number(s) where required. This is a long term vision, not an end state that can be achieved in the short or medium term and will require a period of transition in countries which require national numbers on packaging today.

BACKGROUND

The EU Falsified Medicines Directive (FMD)

The Falsified Medicines Directive (Directive 2011/62/EU) was published in the EU Official Journal on 1 July 2011. The 1 July 2011 date is therefore the kick-off date for transposition timelines (Member States to transpose the Directive into their national legislation by 1 January 2013). In summary:

- All prescription-only medicines will have to bear safety features (i.e. a unique serial number placed on each pack together with tamper evident packaging). Certain products or product categories of prescription-only medicines might be exempted according to a risk assessment; OTCs are excluded in principle from the scope of the Directive unless there is a risk of falsification.
- The Commission will decide the specifications of the serial number allowing identification/ authentication of individual packs and will set out the provisions for establishment, management and accessibility of databases in the so-called 'Delegated Acts' (implementing rules).
- The Delegated Acts should be released with the next 24 to 36 months and companies will have then 3 years to comply with the technical requirements as of the date of publication of the Delegated Acts in the EU Official Journal.

EFPIA's view on coding in the context of the Falsified Medicines Directive

EFPIA is supportive of the use of GS1 standards for the identification of products using a 2D GS1 DataMatrix as data carrier of choice, encoded with a product code, serial number, batch number and expiry date. This information should be encoded using the relevant GS1's application identifiers. In this respect, EFPIA's vision is aligned with the objectives of GS1 and its members.

The choice of GS1 standards have been driven by a broad number of factors including but not limited to:

- Patient safety - globally unique codes and certainty of product identification
- Interoperability – ability for the proposal to work across markets, stakeholders and sectors
- Complexity reduction – one solution which can be leveraged for all levels of packaging while allowing to chose the appropriate symbology
- Technical suitability – factors such as robustness of data carrier, ability to print on line, etc
- Cost effectiveness of solutions – appropriate for needs of users
- Flexible and future compatibility – part of an ongoing standard which will not be superseded
- Proven solution - used in the retail sector worldwide

EFPIA-GS1 Healthcare shared vision for product identification – January 2012

Supporting industry to stand ready to comply with the requirements of the EU Falsified Medicines Directive

Thank you

Grant Courtney

www.efpia.org