e-verification of Pharmaceuticals
- what will it mean for the pharmaceutical industry?

Information session 2016-10-28
The implementation project team
Solidsoft Reply Ltd
Introduction

- Formal implementation project established March 2015
- Steering group and two working groups; technical and governance
- Participants from LIF, FGL, LH, SvAF and LDF in all groups
- Two major milestones reached in June 2016:
  - The mandatory governance organisation, e-VIS was formed
  - The system provider, Solidsoft Reply, was selected
- Sweden is well placed to meet the legal requirements:
  - Experience from the Swedish Pilot 2009-2010
  - Advanced infrastructure and collaborative climate
Implementation of Falsified Medicines Directive (FMD) required Feb 2019

- **Objective**: Protection of patients from counterfeited medicines in the legal distribution chain

- **Content**: Pan-European system to verify the authenticity of medicinal products

Non-compliance puts sales at risk
The Delegated *Regulation* mandates rules for medicines verification

Serialization by manufacturer
Risk based verification by Wholesalers
Verification and check-out at point of dispense

Safety features:
Code (‘unique identifier’) + Tamper evidence

System set up and governed by manufacturers and marketing auth. holders in consultation with other stakeholders. Oversight by competent authorities

Product #: 09876543210982
S/N: 12345AZRQF1234567890
Batch: A1C2E3G4I5
Expiry: 140531
e-VIS (e-verifikation i Sverige)

- Association

- Statutes
  - Membership by constituency
  - Two categories; Full membership and associated membership
  - Full membership is required for voting/veto and a seat on the Board
  - Veto rights for the industry regarding key decisions about the National system they are mandated to set up, run and pay for
e-VIS

• We have 5 constituencies participating in the project
• Only 4 are members of e-VIS (all have Full Membership)
• The Pharmacy Association has chosen to remain outside e-VIS due to principal reasons
• e-VIS Board will make all the formal decisions, but…
• A ”consultation group” (includes the Pharmacy Association) will discuss all information and intended decisions
Government contacts
Competent authority – Medical Products Agency

- Have been kept informed over the past few years
- Formal consultation with MPA in June
  - A few adjustments to e-VIS statutes to allow for their participation should they decide so
- Legal review of the Delegated Regulation and possible need for further adjustments of the Swedish law is ongoing with both MPA and Ministry
  - Verification/decommissioning for hospitals needs to be clarified – the ambition is to avoid this burden/cost on health care personnel if at all possible – Key for setting up the system
  - Decommissioning of Vaccines is a big concern – there are some 4000+ places where vaccines are given....
EMVS and the European Hub

An Overview for Manufacturers and Parallel Distributors

Charles Young
EMVS Overview
European Medicines Verification System

Distribution of product and pack data to markets
Verification at the point of dispense
Additional Verification in the supply chain

Product and pack data upload from MAHs and PDs
Repacking
Multi-market packs
Notifications, alerts and reports
Verification, and decommissioning by pharmacies and wholesalers
Supply to public (dispense) by pharmacies
EMVS Components

- **Manufacturer System**: Owner = Manufacturer
- **Pharmacy System**: Owner = Pharmacy
- **Pharmacy Interface**: Owner = Pharmacy
- **Wholesaler System**: Owner = Wholesaler
- **Wholesaler Interface**: Owner = Wholesaler
- **European Hub**: Owner = EMVO
- **National System**: Owner = NMVO
- **National Blueprint System**: Owner = NMVO
- **Parallel Distributer System**: Owner = Parallel Distributer
- **Web Access**: Owner = EMVO

The diagram illustrates the components and interfaces within the EMVS system, showing how different systems are connected and owned by various entities.
Data Flow (Normal Operation)
European Hub Capabilities
For Pharmacies and Wholesalers/Distributors
European System Scope

Precisely meets the EMVS and Delegated Regulation requirements

EMVO implements on-boarding portal for Manufacturers and Wholesalers

Operations Management Support

Root Certificate Signing Authority
Meets EMVO’s Requirements

<table>
<thead>
<tr>
<th>Use Cases</th>
<th>Primary Stakeholder(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Master Data Upload</td>
<td>Manufacturing Authorisation Holder (MAH)</td>
</tr>
<tr>
<td>• Product Pack Data Upload</td>
<td></td>
</tr>
<tr>
<td>• Recall Batch</td>
<td></td>
</tr>
<tr>
<td>• Withdraw Product</td>
<td></td>
</tr>
<tr>
<td>• Request Report</td>
<td></td>
</tr>
<tr>
<td>• Verify Single / Bulk of Pack(s)</td>
<td>Pharmacist, Wholesaler, MAH</td>
</tr>
<tr>
<td>• Dispense Pack</td>
<td>Pharmacist (Wholesaler)</td>
</tr>
<tr>
<td>• Re-Introduce Dispensed Pack</td>
<td></td>
</tr>
<tr>
<td>• Decommission Single / Bulk of Pack(s)</td>
<td>Pharmacist, Wholesaler, MAH</td>
</tr>
<tr>
<td>• Undo Decommission Single / Bulk of Pack(s)</td>
<td></td>
</tr>
<tr>
<td>• Export Bulk of Packs from EU</td>
<td>Wholesaler</td>
</tr>
<tr>
<td>• Undo Export Bulk of Packs from EU</td>
<td>MAH</td>
</tr>
</tbody>
</table>
Each Manufacturer / PD provides many Products

Each Product is produced in many Batches

Each Batch contains many Serialised Items

Each Serialised Item has many Events recorded

Each Product is licenced to be sold in one or multiple Markets
# Pack Identifiers

## Product Code Scheme:
Product Code Coding scheme (GTIN or PPN)

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Code:</strong></td>
<td>The product code</td>
</tr>
<tr>
<td><strong>Serial Number:</strong></td>
<td>Serial number of the pack.</td>
</tr>
<tr>
<td><strong>Batch Number:</strong></td>
<td>The batch (or lot) number for the set of product packs being created or updated</td>
</tr>
<tr>
<td><strong>Expiry Date:</strong></td>
<td>The batch expiry date.</td>
</tr>
</tbody>
</table>

## Multi-Market Support
- NTINs
- Reimbursement - NHRNs

## Human-Readable Representation
- Anti-Tamper Device

 chase solidsoft
# Product, Batch and Pack Data

<table>
<thead>
<tr>
<th><strong>Product Master Data</strong></th>
<th><strong>Product per Market Data</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>Member state ISO ID</td>
</tr>
<tr>
<td>Coding scheme</td>
<td>National code</td>
</tr>
<tr>
<td>Name</td>
<td>Article 57 code/PCID (TBC)</td>
</tr>
<tr>
<td>Common name</td>
<td>MAH ID</td>
</tr>
<tr>
<td>Pharmaceutical form</td>
<td>MAH Name</td>
</tr>
<tr>
<td>Strength</td>
<td>MAH Address</td>
</tr>
<tr>
<td>Pack type</td>
<td>Serialisation Flag</td>
</tr>
<tr>
<td>Pack size (Dose Count)</td>
<td>List of Wholesalers with ID,</td>
</tr>
<tr>
<td>Product Code Status</td>
<td>name and address who have</td>
</tr>
<tr>
<td>Product Code Version</td>
<td>a written contract with the</td>
</tr>
<tr>
<td></td>
<td>MAH above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Batch Data</strong></th>
<th><strong>Pack Data</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Batch number</td>
<td>Serial Number</td>
</tr>
<tr>
<td>Expiry date</td>
<td>Serial Number Status</td>
</tr>
<tr>
<td>Manufacturer ID</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Name</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Address</td>
<td></td>
</tr>
<tr>
<td>Batch Number Status</td>
<td></td>
</tr>
</tbody>
</table>
European Hub Features

Fully managed service operation
Cloud Hosted
Full operated and monitored
Maintained
Full Disaster Recovery
Self-service On-Boarding
Technical Help Desk
SDK including:
Full Technical Documentation
Working code sample (including store & forward)
Class Libraries & other code artefacts
Integration Strategy

Software Development Kit
Documentation and Guidance
Code Examples (Java, C#)
Working example of store & forward
Tools and libraries

Development Portal
Development hub
Will evolve to capture ‘lessons learned’, best practice, etc.
Sign NDA for access

Helpdesk
Technical support
Implementation Approach

Set-up
Create System Environments
Agree Scenario Processes / publish guidelines / Training
Identify Pilot Participants (invite only)
Work with ISV’s to enable integration
Engage with MAHs / Parallel Distributers

Pilot
Register participants
Start On-boarding participants
Prove Use Cases / Scenarios
Review / Amend Processes

Ramp-up
Open system to all stakeholders
On-boarding Process – To Be

1) Participation Request
   - Initial Contact
   - Portal registration
   - Non-Disclosure Agreement

2) Legitimacy Check
   - Level 1 checks
   - Person checks
   - (more detailed checks if necessary)

3) Contractual/Commercial On-boarding
   - Registration fee payment
   - Connection Request
   - Participation Agreement

4) Technical On-boarding
   - System Connection
   - System Testing
   - System Operation

Managed and administered by the EMVO’s Commercial and Partnership Management Team

Managed by EMVO and supported by IMS

Managed by EMVO and supported by IMS

Carried out by EMVO and supported by IMS

Managed by the EMVO’s Operations Team & Solidsoft Reply
## Contractual On Boarding

<table>
<thead>
<tr>
<th>1. Non-Disclosure Agreement</th>
<th>2. Participation Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Covers <strong>provision of Confidential Information</strong> by EMVO, e.g. on</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Contractual framework for participation in the On Boarding project, e.g.</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>- Purpose: <strong>Assessment of participation</strong> in the EMVS project</td>
<td></td>
</tr>
<tr>
<td>- Purpose: <strong>Execution of Technical On Boarding</strong></td>
<td></td>
</tr>
</tbody>
</table>
Environments

- **ITE** (Integrated Test Environment)
  - Sandbox for interface / connectivity testing

- **IQE** (Integrated Quality Environment)
  - Self certification

- **Prod** (Production Environment)
Coffee break
Codes and coding schemes

- 2D Data Matrix is to be used
Labelling of packages

- Medical Products Agency

https://lakemedelsverket.se/english/All-news/NYHETER-2016/Requirements-regarding-safety-features-for-packages-for-medicinal-products/

- CMDh and EMA

- Marketing authorization holders for the concerned Swedish medicinal products shall follow the guidelines published by CMDh and EMA with the purpose to update the labelling and the QRD-template.
NTIN to GTIN

- Currently NTIN, which is not always unique, is used instead of GTIN for pharmaceuticals in the Nordic countries. In other markets, many pharmaceutical companies already use GTIN.

- Since the format of NTIN and GTIN is the same, it is technically possible to replace the current NTIN with a GTIN.

- To change all NTINs into GTINs will take a long time. The implementation of GTIN could therefore, if necessary, be phased.

- The Vnr will continue to be printed on all packages.

- Articles with a Vnr only used in one Nordic country can be changed at any time, as long as the systems using the NTINs can handle more than one GTIN.

- For articles with common Nordic Vnrs the change must be synchronized in the Nordic countries.
Why change to GTIN?

- e-verification will need unique NTIN/GTIN.

- To be able to distinguish the different packages a unique identity on the package level will be needed (GTIN/unique NTIN).

- There is no connection between the different packages and the serial number. The serial number is not enough to identify the different packages.

- Thus - the combination of the serial number and the GTIN/unique NTIN will identify a pack.
Difference 2D and QR

GS1 DataMatrix

QR-kod
QR-code

- Bestämmelser från CMDh

- Bestämmelser från EMA
Useful links


# High Level Project Plan

## Timeline

- **28 Months**
- **8 Months**
- **11 Months**
- **9 Months**

## Milestones

<table>
<thead>
<tr>
<th>Year</th>
<th>Quarter</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Jan</td>
<td>Selection / Contracts</td>
</tr>
<tr>
<td></td>
<td>Apr</td>
<td>System Setup</td>
</tr>
<tr>
<td></td>
<td>Jul</td>
<td>Pilot</td>
</tr>
<tr>
<td>2017</td>
<td>Oct</td>
<td>Ramp-Up</td>
</tr>
<tr>
<td></td>
<td>Jan</td>
<td>FOC</td>
</tr>
</tbody>
</table>

**Note:** Milestones include:
- Supplier System Rollout
- Manufacturers / PO Onboarding
- Pharmacy / Wholesalers Onboarding
- Pilot Preparation / Support
- Proof

**Tools:**
- Reply
- solidsoft
What is the “Pilot”? A limited, well controlled implementation of the total system
What is endpoint and what happens then?
Ramp up to full implementation

All MAH

Swedish MAH (equiv)

MAH

EU Hub

EMVO

SMVS

e-VIS

All Pharmacies

Ph

All Whole-salers

ws
Prerequisites to start the Pilot

• A number of Pharmacies and Distributors are ready:
  • IT systems adapted and connected to Swedish system
  • Personnel trained

• Serialised packs available in a sufficient number
  • MAH with high volume products on the Swedish market have serialised these and uploaded to the EU Hub

• SOPs/instructions for events affecting more than one actor have been developed to a final draft
  • In particular exceptions occurring when verifying or decommissioning packs
Processes/Guidelines/SOP:s
Use cases, status and exceptions

- **Master Data Upload**
  - **Product Pack Data Upload**
  - **Recall Batch**
  - **Request Report**
  - **Verify Pack.**

- **Dispense Pack**
  - **Dispensed**
  - **Re-Introduce Dispensed Pack**
  - **Decommissioned Pack**

- **Pharmacy**
  - Available
  - Repacked (PD)

- **Wholesaler, PD**
  - Available
  - Recalled
  - No status change

- **Manuf., PD, Wholesaler, Ph.**
  - Available
  - Export Pack from EU

- **Exception**

Use cases & exceptions to be described in instructions/Standard Operating Procedures.
Use case example, "Dispense Pack"

**Normal case**
- Dispensed
- Swedish BluePrint system

**Exception**
- Pack already dispensed
- Product exported
- Product on recall
- Etc.

**Technical system reaction**
- Inform system administrators (Exception Level 3 to 4)
- Inform also relevant stakeholder (Exception Level 5)

**No status change**
- Inform Pharmacy, (Exception Level 2 to 5)
- Inform Pharmacy only (Exc. Level 2)

**Procedural measures**
- To be described in instructions/Standard Operating Procedures

**Dispensed Pharmacy X**
- Swedish BluePrint system

**Dispense Pack Pharmacy X**
Actions needed

• Prepare for serialisation of packs:
  • Unique product codes, serial numbers, encoding and printing
  • IT system adaption
  • Artwork changes and regulatory submissions

• On-boarding to the EU Hub
  • Contractual process – define who is the on-boarding partner
  • Technical process - decide focal point for uploading

• Start to serialise some high volume product for the Swedish market to support the pilot
  • Provide input to the governance; processes, SOP:s, training etc

• Plan for the full implementation to be ready well ahead of Feb 2019
Implementation timelines – no time to loose!

- Connect appr 2500 manufacturers to the EU Hub
- Establish National Systems for 32 countries
- Connect many thousand Pharmacies and Wholesalers
- Serialise all pharmaceutical packages in scope (10.5 bn)

- July 2011: Publication of FMD
- 9 Feb 2016: Publication of Delegated Acts
- 9 Feb 2019: Mandatory verification of all packages in scope
- 36 Mon.:
Access to information

- EMVO HUB on-boarding webinars
  - [https://youtu.be/jrObT4r0CRw](https://youtu.be/jrObT4r0CRw)
  - Contact via helpdesk@emvo-medicines.eu
  - Connection request forms from connection@emvo-medicines.eu

- Implementation project Q&A version 1 available now [http://www.lif.se/grundfakta/e-verifikation/](http://www.lif.se/grundfakta/e-verifikation/)

- Solidsoft Reply: Charles Young, c.young@reply.eu
  +44 (0)1256 375700

- e-VIS web page planned to be available early 2017
Questions?
Thank You