The FMD at Spire Healthcare
GS1 Healthcare Conference
10 April 2019
## Introduction

<table>
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<tr>
<th>Tanya Hunt</th>
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<td>Spire Healthcare – Programme Manager</td>
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<tr>
<th>Judie Finesilver   MR PharmS</th>
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<tr>
<td>Central and North West London NHS Foundation Trust – Consultant Pharmacist</td>
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Falsified Medicines Directive

Introduction
What is the FMD?

- EU Falsified Medicines Directive FMD


- It aims at improving patient safety by mandating the Marketing Authorisation Holders and manufacturers to put a system in place that is preventing falsified medicines from entering the legal supply chain, the European Medicines Verification System.

- The European Medicines Verification System (EMVS) should guarantee medicines authenticity by an end-to-end verification.

- Placed on statute books so embedded in British law.

- Three years to plan for its introduction.

- EU Go live date: Saturday 9th February 2019.
What is the FMD?

- Unique identification of every box of a batch of medicine.
- Prescription Only medicines.
- Tamper evident seals.
How does it work?
How does it work?

**System Landscape 1**

- Pharmaceutical Manufacturer
- European HUB
- Parallel Distributor

**European Medicines Verification System EMVO**

- National System 1
- National System n
- National Blueprint System 1
- National Blueprint System n
How does it work?

Responsibilities of the Supply Chain Partners

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

SAFETY FEATURES:

- Code (unique identifier) + Tamper evidence

System set up and governance by MAH together with other stakeholders

Oversight by competent authorities

MAH Market Authorisation Holders
NMVS National Medicines Verification System
FMD at Spire Healthcare
Background for Spire Project

- 39 hospitals, eight clinics and one oncology centre across the UK
- Each hospitals has it’s own in-house pharmacy
- Pharmacy teams manage their own stock levels and do their own ordering
- Stock management done in centralised ERP System : SAP ECC 6 (UNIX platform)
- Formulary team made up of five senior pharmacists
Path and Process – Decisions & Design

- Visit to typical Pharmacy - Understand Process: May 1, 2018
- Pharmacy process workshop: Jun 2, 2018
- MD only decision: Aug 1, 2018
- Project Start: Sep 1, 2018
- NMVS Baseline Acceptance: Jan 18, 2019
- Group 1 Go-live: Feb 4, 2019
- Group 2 Go-live: Feb 12, 2019
- Group 3 Go-live: Feb 13, 2019

- Initiation: Mar 1, 2018
- Engage GS1: Apr 1, 2018

2018
- Mar
- May
- Jul
- Sep
- Nov
- 2019
- Mar

Investigate off-the-shelf solutions: Jun 25, 2018 - Jul 13, 2018
FMD only or integrate with MM: Jul 1, 2018 - Aug 17, 2018
Build: Aug 20, 2018 - Nov 30, 2018
Test: Dec 1, 2018 - Dec 21, 2018
Hardware roll out: Jan 1, 2019 - Jan 31, 2019
Training: Feb 8, 2019 - Feb 22, 2019

Looking after you.
FMD at Spire Healthcare

- To implement or not to implement? Brexit uncertainty
  - **Decision**: Yes to implement
    - Patient Safety is our number one priority
    - UK version of FMD ‘likely’ to be in place post Brexit
  - FMD compliance only or Full integration with Material Management.
    - **Decision**: MVP – FMD compliance only

- What should Spire do to implement FMD requirements? Off the shelf solution or In-house development?
  - **Decision**: In-House solution
## FMD at Spire Healthcare

### Off-the-shelf solution

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<th>Against</th>
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<td>Connection with NMVS</td>
<td>High Capital investment</td>
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<tr>
<td>Ready to use</td>
<td>No integration with Material Management system</td>
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<td>External support</td>
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### In-house solution

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<td>Cost effective</td>
<td>Would need to engage with NMVS provider</td>
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<tr>
<td>Experience with developing scanning solutions</td>
<td>Internal support required</td>
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<td>Centralised access to FMD data</td>
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<td>Easier to integrate with other systems</td>
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Decided on an in-house developed solution.

Add Decommissioning step into Ordering and Receipting process.

Basic BluTooth hand held scanner with data hosted in SAP, using PI to achieve connectivity to NMVS.

GS1 barcode data and NMVS return message stored in SAP hosted database for future reporting.

Would not integrate into Material Management module in SAP, mainly due to time constraints. Solution designed to allow for this in a future rollout.
Path and Process – Build and Delivery

- **Initiation**: Mar 1, 2018
- **Engage GS1**: Apr 1, 2018
- **Visit to typical Pharmacy - understand Process**: May 1, 2018
- **Pharmacy process workshop**: Jun 2, 2018
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2018

- **Investigate off-the-shelf solutions**: Jun 25, 2018 - Jul 13, 2018
- **FMD only or Integrate with MM**: Jul 1, 2018 - Aug 17, 2018
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- **Test**: Dec 1, 2018 - Dec 21, 2018
- **Hardware roll out**: Jan 1, 2019 - Jan 31, 2019
- **Communication to Pharm teams**: 1/29/2019 - 3/8/2019
- **Training**: Feb 8, 2019 - Feb 22, 2019

Looking after you.
Build Process

- Complicated by the fact we were both software supplier and end user (Pharmacy).

- As software supplier:
  - Complete Access Request Form
  - Sign End User Licence Agreement
  - Pass NMVS Baseline Acceptance Test

- As Pharmacy:
  - Create GLN for each location (was assumed but not required)
  - Register each site
  - Create/download certificate for each site
Build Process – Decommission Screen
Build Process – Reporting Screen

- Report Screen used to see all items scanned.
- Also used to reverse decommissioning in the case where items are being returned to the supplier.
Issues and challenges

- Building a solution that required interfacing to an external system that was still in development.

- NMVS – 3 point verification for authenticating users:
  - Username/Password/Certificate
  - Certificates are difficult to manage from a centralised solution, SAP and UNIX are not able to do this effectively.
  - Certificate Management Tool - (Apache) to ensure certificates were presented correctly during authentication. Will need to be managed going forward, certificate renewal process is complex.

- Data set not well defined, no examples, and it changed frequently. This complicated the build process.

- Registration process with SecurMed for each location was complex. Bulk registration had to be done by financial entity and still resulted in multiple spreadsheets of data.
Rollout

- Scanners pre-configured and distributed directly to pharmacies.
- IT Engineers installed set-up scanners.
- Effective communications plan. Regular communications to Hospital Directors, Matrons and Pharmacy managers.
- FMD process well documented. Process change documents and User Guides distributed to Pharmacy teams ahead of go-live.
- Remote training, multiple sessions over multiple days.
- Phased rollout. Group 1 – small group of Formulary Team hospitals with remaining hospitals divided into two groups.
- FMD scanning results available centrally making it easy to monitor the volume of scanning per site.
- Formulary team – First line support.
Between 4 Feb 2019 and 31 March 2019, a total of 14,394 POM were scanned.
Summary

Did we succeed?

In summary - Yes!

- Fully functioning FMD solution in all hospitals.
- Central access to FMD data.
- Easy to use reporting capability.

In-house solution was correct choice for Spire Healthcare.

What we did well:

- Made best use of internal skills and resources.
- Relied on advice from the professionals.
- Clear and frequent communications to stakeholders.