

The FMD at Spire Healthcare GS1 Healthcare Conference

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Introduction

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Falsified Medicines Directive

Introduction

What is the FMD?

- EU Falsified Medicines Directive FMD
- European Legislation. In order to counter the threat of falsified medicines entering the legal supply chain, the European Parliament and Council have released a Directive on Falsified Medicines (2011/62/EU) (amending Directive 2001/83/EC).
- 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.

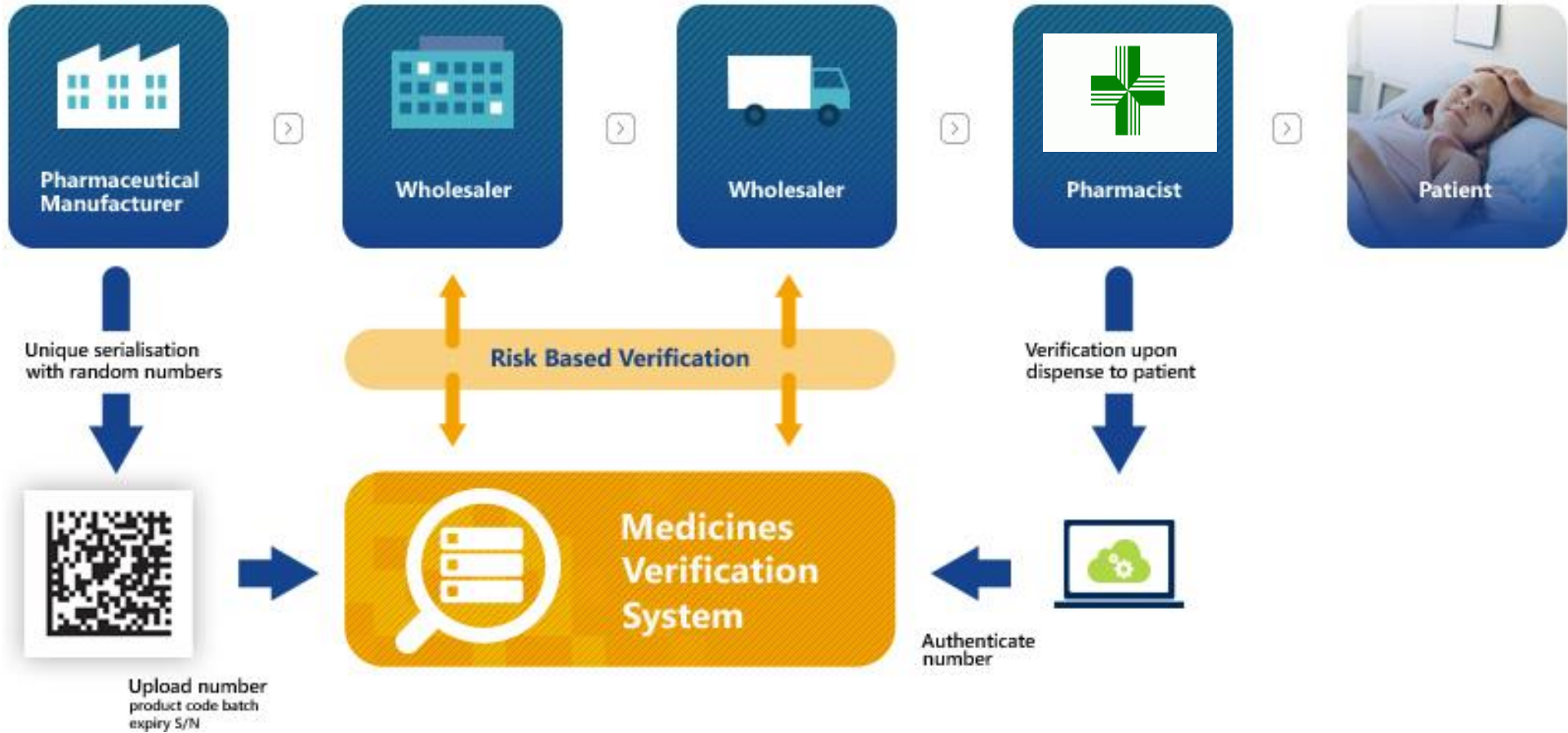
What is the FMD?

- Unique identification of every box of a batch of medicine.
- Prescription Only medicines.
- Tamper evident seals.



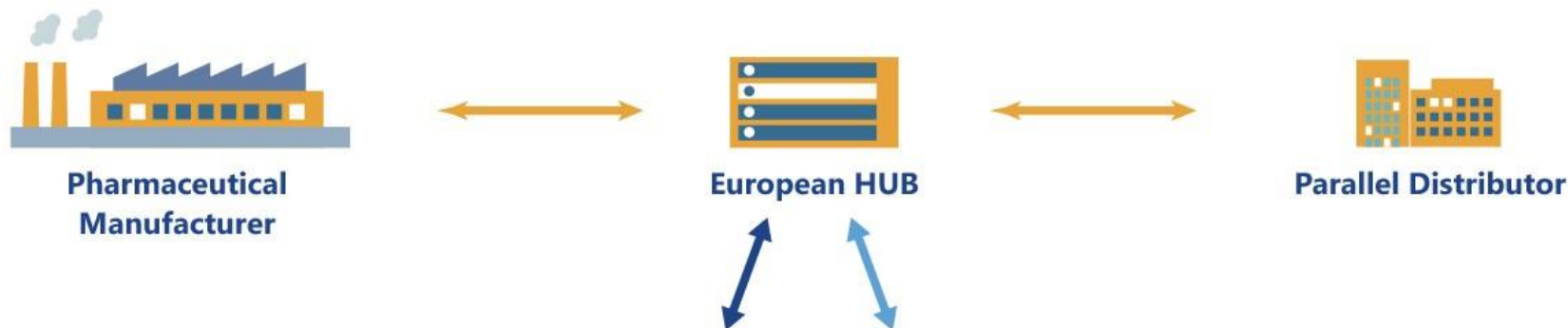
How does it work?

PRODUCT FLOW



How does it work?

System Landscape 1



European Medicines Verification System EMVO



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:

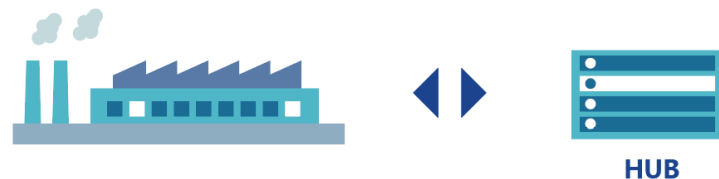
Code (unique identifier) + Tamper evidence

Product #: 09876543210982
S/N: 12345AZRQF1234567890
Batch: A1C2E3G4I5
Expiry: 135032



System set up and governance by MAH together with other stakeholders

Oversight by competent authorities



MAH Market Authorisation Holders
NMVS National Medicines Verification System

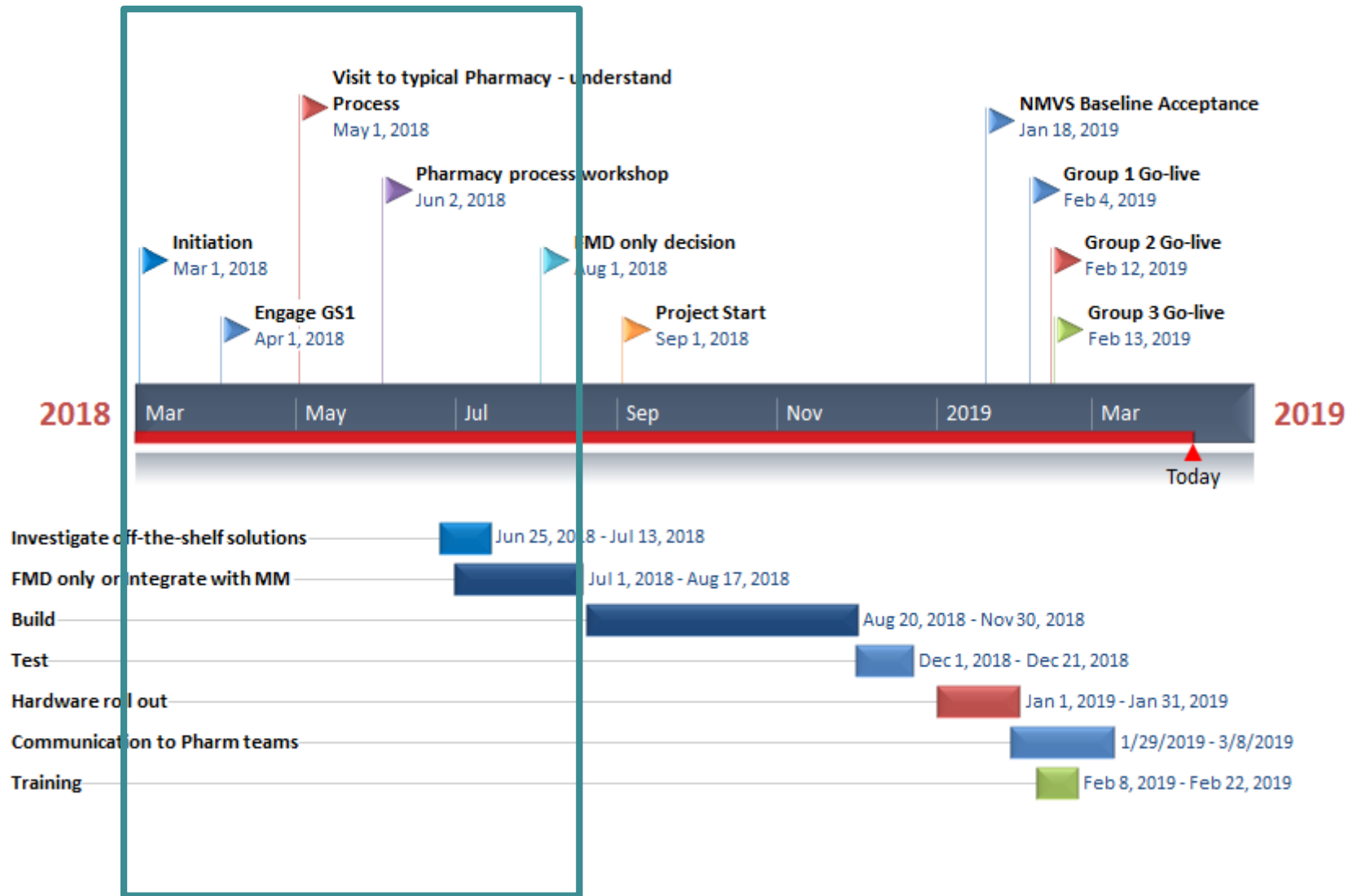
FMD at Spire Healthcare

Background for Spire Project

- 39 hospitals, eight clinics and one oncology centre across the UK
- Each hospital has its 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



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

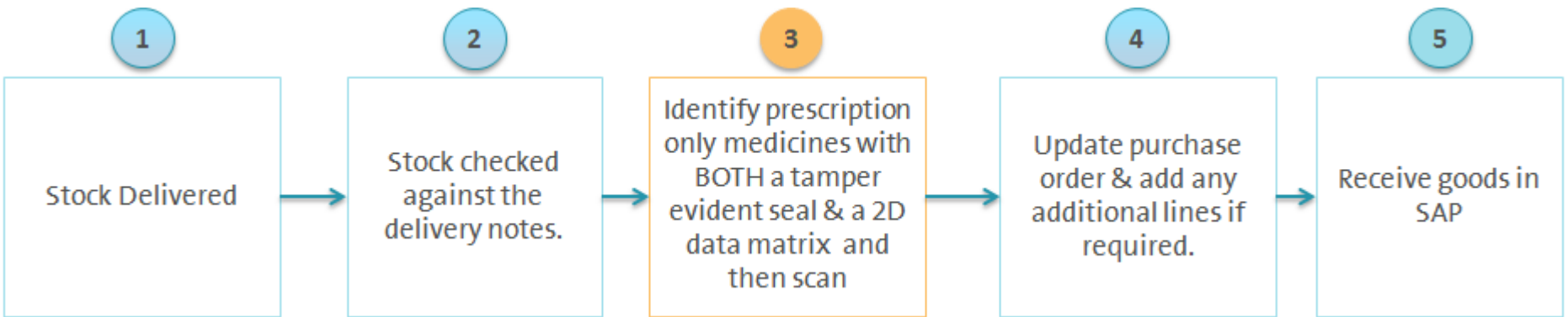
For	Against
Connection with NMVS	High Capital investment
Ready to use	No integration with Material Management system
External support	

■ In-house solution

For	Against
Cost effective	Would need to engage with NMVS provider
Experience with developing scanning solutions	Internal support required
Centralised access to FMD data	
Easier to integrate with other systems	

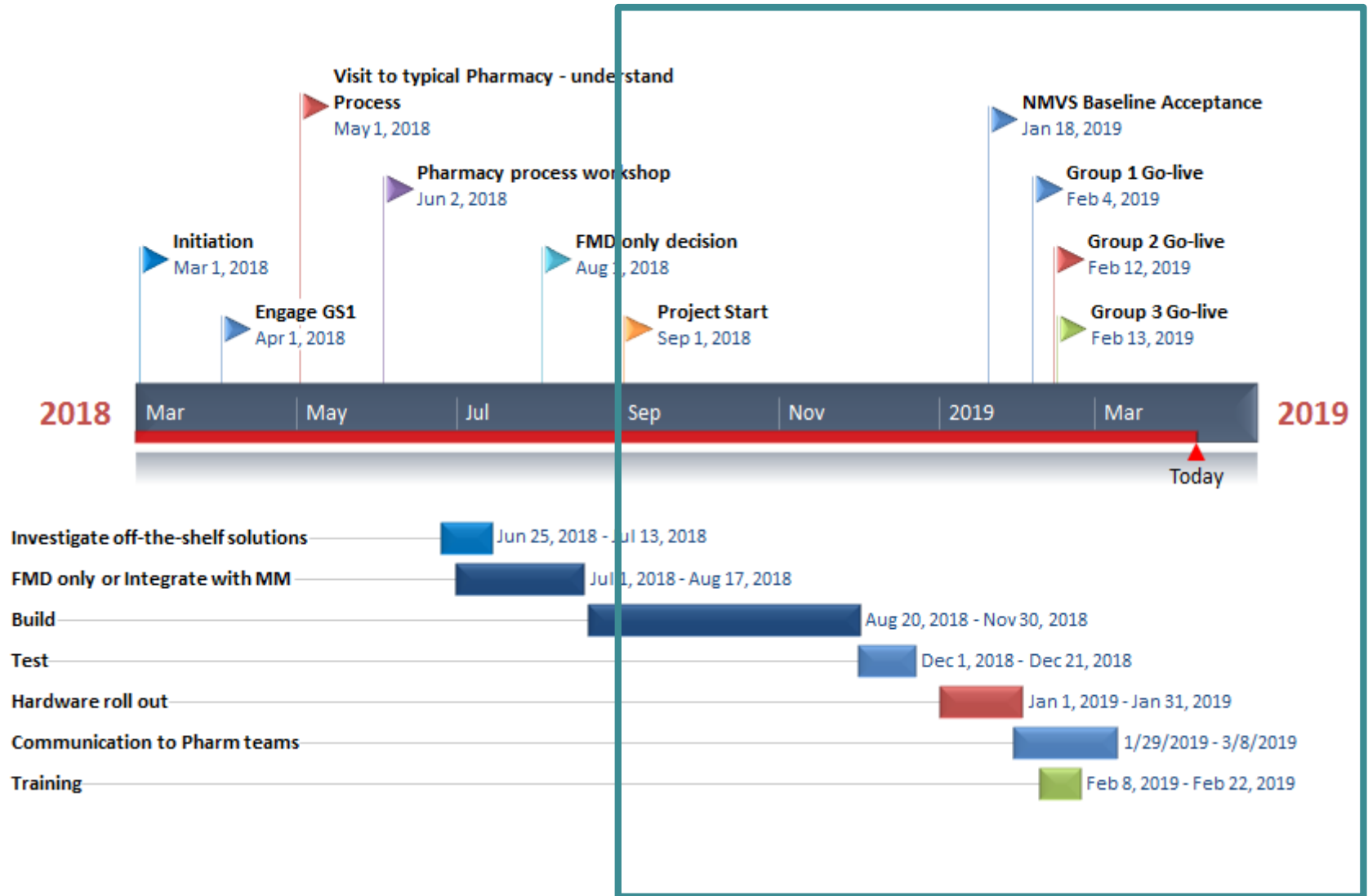
Design decisions

- 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





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

EU Falsified Medicines Directive (FMD) - Decommission

Spire Hospital Code:

Scan GS1 Bar Code:

National Medical Verification System Response and Spire Action

[Click here to enter manually](#)

Bar Code Data:

GTIN Code	<input type="text"/>
Serial Number:	<input type="text"/>
Batch Number:	<input type="text"/>
Expiry Date (DD.MM.YY):	<input type="text"/>

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.

EU Falsified Medicines Directive (FMD) Decommissioning Rept.



Hospital	Entered Date & Time	GTIN Code	Batch Number	Serial Number	Batch Exp. Date	NMVS Status	NMVS Reason	Spire Return Code Desc.	Spire Action	NMVS Response Date	Spire User
HWD	18.02.2019 09:42:53	05017007050841	103712	10086347611549	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:03	05017007050841	103712	10046214809527	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:10	05017007050841	103712	10077221066677	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:15	05017007050841	103712	10065683603744	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:19	05017007050841	103712	10076927282937	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:23	05017007050841	103712	10003139633234	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE
HWD	18.02.2019 09:43:27	05017007050841	103712	10067802299208	31.07.2021	INACTIVE	SUPPLIED	Successfully processed	Pack can be dispensed	18.02.2019	FUHRHE

Issues and challenges

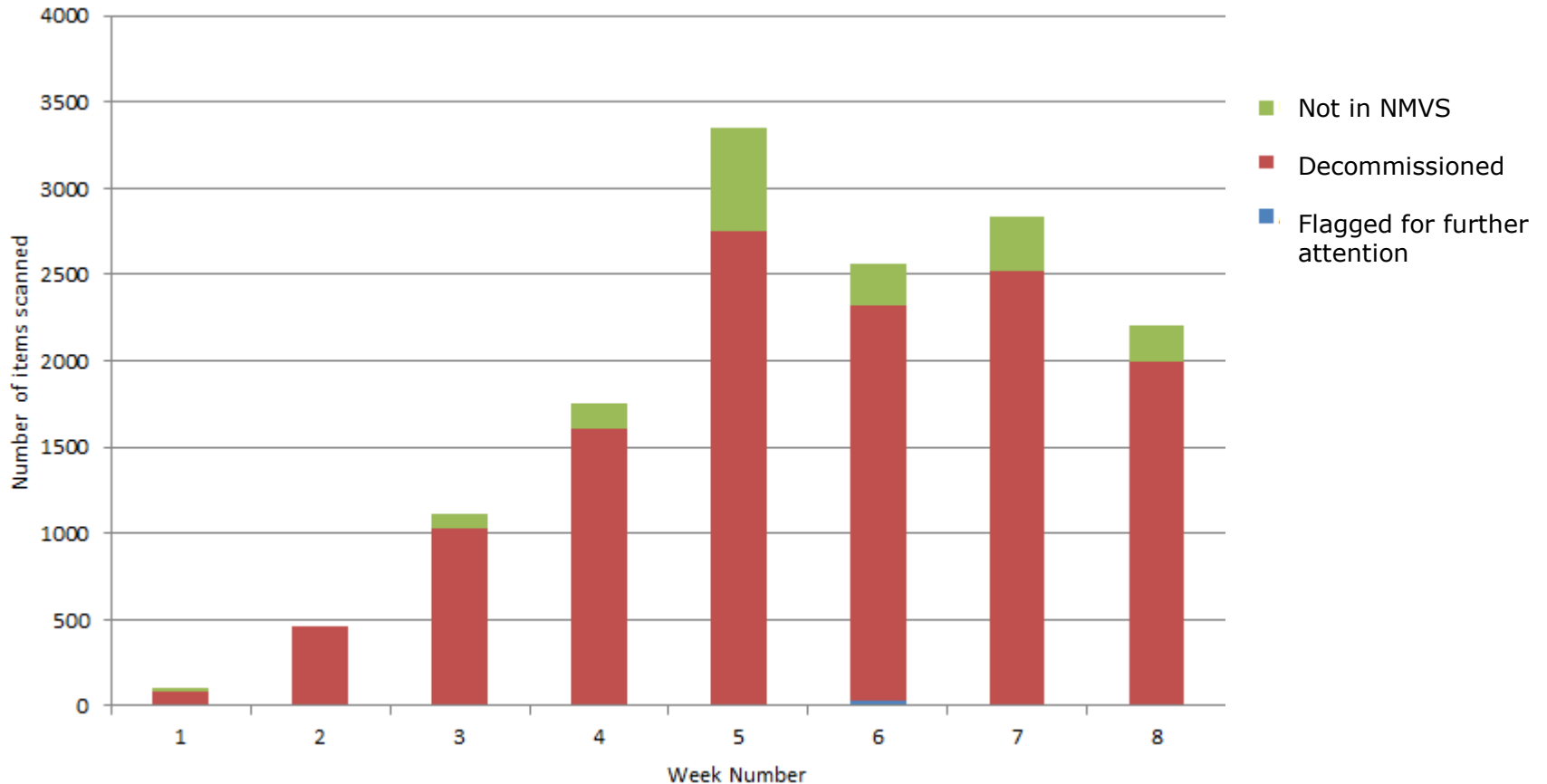
- Building a solution that required interfacing to an external system that was still in development.
- NMVS – 3 point verification for authenticating users:
 - Username/Password/Certificate
 - Certificates are difficult to manage from a centralised solution, SAP and UNIX are not able to do this effectively.
 - 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.

Outcomes – Scanned volumes by week

■ 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.

