Patient Safety and the Implementation of the Falsified Medicines Directive in the Hospital Environment

Practical solutions and benefits

European Alliance for
Access to Safe Medicines

www.eaasm.eu

Contents

Glossary of Terms

ASOP EU	Alliance for Safe Online Pharmacy in the EU
EAHP	European Hospital Pharmacy Association
EAASM	European Alliance for Access to Safe Medicines
EFPIA	European Federation of Pharmaceutical Industry Associations
EMVO	European Medicines Verification Organisation
EUIPO	European Intellectual Property Office
FDA	Federal Drug Administration
FiMVO	Finnish National Medicines Verification Organisation
FMD	Falsified Medicines Directive
NABP	National Association of Boards of Pharmacy
NMVO	National Medicines Verification System
OECD	Organisation for Economic Co-operation and Development
TLD	Top Level Domain Name
URL	Uniform Resource Locator
SOP	Standard Operating Procedure

Benefits found in hospitals following implementation of the FMD using automation

1. **Automated solutions result in a reduced manual scanning burden of up to 63%**

2. **No extra staff required to run a robotic system and frees time for resources to be directed towards improving pharmaceutical services**

3. **Robotics allows:**
   - Guaranteed inventory management
   - Reduced inventory resulting in cost savings
   - Improved ordering for bulk lines
   - A vital part of the medication process secured
   - Automatic decommissioning for a significant part of the internal supply chain
   - Visibility of recycled/returned products allows for analysis and subsequent improvements

4. **Utilisation of technology has across-the-board ramifications and opportunities for IT**

5. **Redesigned workflows optimise "goods in" and "goods out"**

6. **Very positive development of relationships with commercial provider to support development of NHS**

7. **Adaptations ongoing to accommodate both FMD and local operational**

Foreword

MEP Manuel Pizarro
European Parliament
S&D group

It is an alarming fact that the COVID pandemic has highlighted the issue of falsified medicines as a plethora of COVID-19 web scams have been observed preying on the fear and anxiety of the public. Of course we should remind ourselves that, whilst the FMD protects the legitimate supply chain, we need to be aware that patients and consumers can be duped into buying medicines from websites selling medicines illegally. So I encourage you all to play your part, as indeed I will do, to raise public awareness around this disturbing criminal-led abuse. We must also encourage public-facing campaigns as research indicates there is a woeful lack of awareness amongst the public of these websites which are operating illegally.

With the launch of vaccines, this will inevitably give rise to fraudulent cyberspace activity. One simple and strong message for all peoples around the world is that there will never, ever be a vaccine sold via a website. If one is found using this method of sale, it can only be a falsified vaccine.

The fact that the Commission is now looking closely to develop a new fit-for-purpose Digital Services Act to replace the 20-year-old e-Commerce Act is to be welcomed. Activities by the EUIPO/Observatory where they have created a number of expert groups which includes “Collaboration with Intermediaries” will bolster the evidence on which the Commission can act.

Turning back to the legitimate supply chain, it is a well-known fact that the Falsified Medicine Directive has put the EU at the vanguard of securing a supply chain for patient safety. The inclusion of a unique identifier on each prescription pack has been a hugely complicated task. And whilst the introduction of the FMD has proved difficult within the hospital environment, we heard today that once implemented, benefits beyond simply authenticating the medicine are achieved, with an acceleration of modernity within the existing pharmacy department footprint. Greater connectivity to other aspects of hospital systems was found; this impacts positively on patient safety, whilst also resulting in more accurate product recall and more efficient inventory levels with ensuing cost reductions.

I therefore commend the good work of all those parties involved in implementing the FMD in hospitals, which will add another layer of patient safety.

Mike Isles
Executive Director,
European Alliance for
Access to Safe Medicines

European Alliance for
Access to Safe Medicines

This meeting on the implementation of the Falsified Medicines Directive (FMD), is the second that the EAASM has organised. Both had the aim to provide practical solutions to help hospitals deliver this important step. As before, we heard from the organisations that form the backbones of the IT infrastructure, without which the authenticity of packs could not be verified. The overview by the European Medicines Verification System, shows good progress in terms of a downward trend of false product alerts. However, it was also somewhat surprising to note that 22 countries were now beyond the allowed stabilisation period and so moving into uncharted waters with the EU Commission in terms of future actions required to deliver a fully functional FMD.

It was most encouraging to note that the appraisal of the Finnish system was very positive with an alert rate of 0.8% which was often the result of scanning issues and not detection of a falsified medicine. The overview by the European Association of Hospital Pharmacists (EAHP) clearly showed that challenges still existed and ranged from non-compatible infrastructure to limitations from software providers to integrate the systems. On the positive side, also echoed by a report commissioned by the European Federation of Pharmaceutical Industry Associations (EFPIA), additional improvements were anticipated in stock management and traceability of medicines. In fact, one analysis showed that at one hospital, it resulted in cost savings to the value of 4.4 million euros per annum due to better management of inventory and ordering patterns. Most importantly the report stated that an FMD implementation exercise provided a platform for better inventory and procurement, an ability to recall accurately and efficiently, and benefits with dealing with local shortages and repacking identification.

Focusing on the actual practical steps for a successful implementation, two experienced hospital pharmacists took the opportunity to describe this process. Whilst it was a complex and time-consuming exercise, it was regarded as an essential step forward. This had equipped the hospital to meet the new digital environment. It had also opened up diagnostic gains via artificial intelligence, enhanced inventory planning and medication traceability pathways, all of which contributed greatly to patient safety.

The EAASM sincerely hopes that this report will be read by the hospital pharmacy community and that it elicits discussion so that the lessons learned can be put to good purpose by any hospital embarking on implementing the FMD.

Expert views on the Falsified Medicines Directive

Maija Gohlke-Kokkonen, General Manager, Finnish National Medication Verification Organisation

"It is good to report that the percentage of "alerts" starting from February 2019 has been low at 0.08% and is decreasing. However, these alerts are not due to falsified medicines but to scanning, data management and non-EU serialised packs' issues. Transactions having stabilised at just below 15,000 per month are now also on the increase. Hospitals have reported aggregation and 2D printing quality as areas for improvement. A joint effort will be required as we all engage in providing a secure supply chain for the COVID-19 vaccines in the verification system."

Grant Courtney, Consultant for the Be4ward expert supply transformers consultancy

"The report commissioned by the European Federation of Pharmaceutical Industries and Associations (EFPIA) clearly illustrates the benefits of implementing the FMD in hospitals. This is because serialised prescription packs act as a data anchor within the hospital and so enables greater visibility, both from a logistics perspective but more importantly, allows for greater traceability and thus enhances patient safety. In one hospital, significant cost savings to the value of 4.4 million euros per annum had been achieved due to better management of inventory and ordering patterns. These barcodes are also opening up the opportunity to digitally web-enabled products, allowing the provision of live data and services directly to the healthcare provider."

Julia Asplin, Pharmacy Logistics Lead and Purchasing Team Manager, The Lister Hospital, Stevenage, UK

"A proven robotics system was chosen to spearhead the implementation. This gave us the opportunity to reconfigure and thus optimise workflows which resulted in greater teamwork, cohesion and efficiency gains in many areas. There were 10 phases which took one year to complete but it was so worth it, as using an automated solution reduced the manual scanning burden by up to 63%. The results were, guaranteed inventory management with subsequent cost savings. In addition, to be able to secure further the medication process from a patient safety point of view, is so important. Combine this with an opportunity to re-vitalise a continuous improvement culture and you have a recipe for success."

Valerie Pelletier, Hospital Pharmacist, Supply Chain Manager, Rouen University Hospital, France

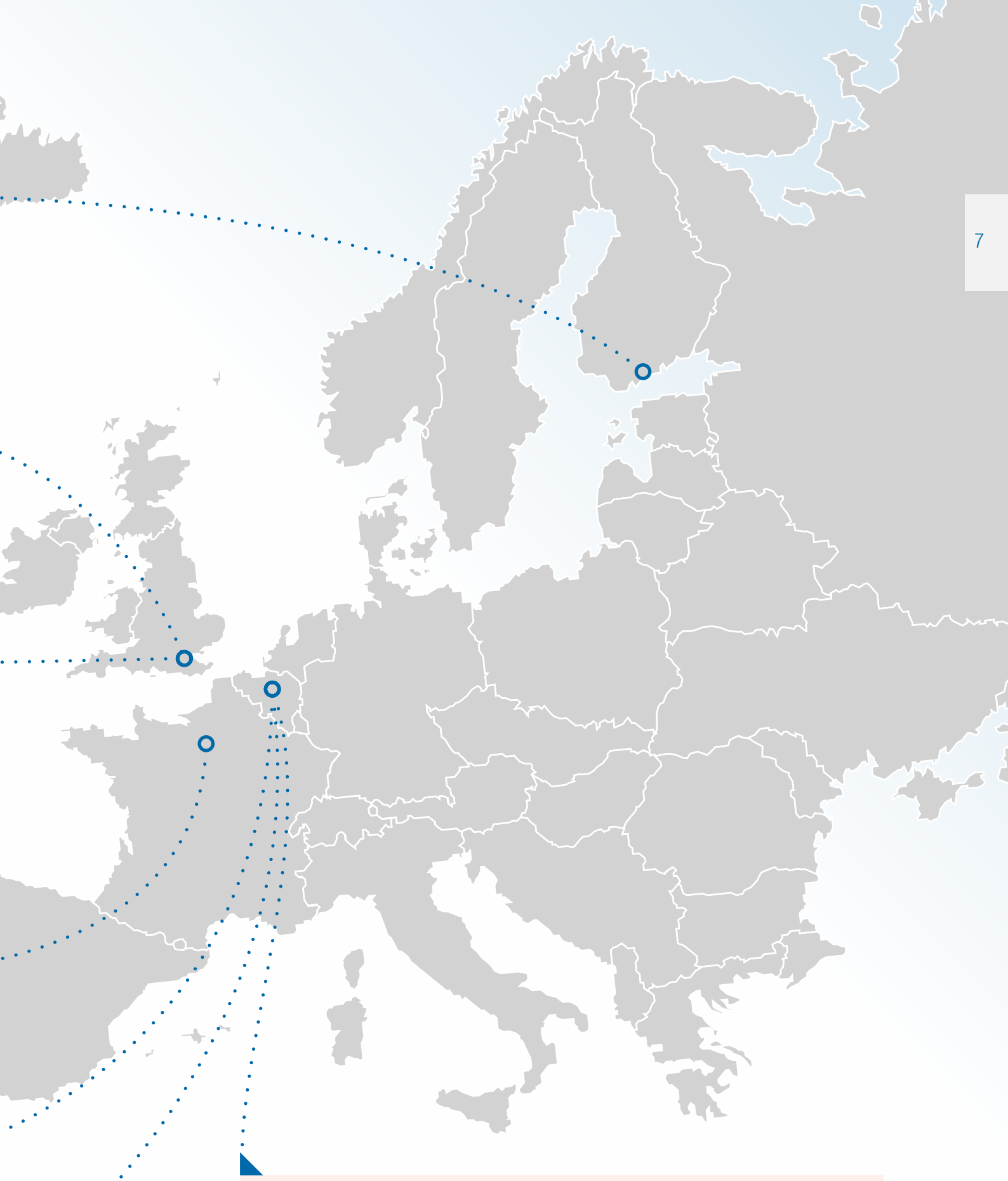
"The use of an automated dispensing system means that decommissioning is done automatically, and with no extra staff needed. This has greatly enhanced our operational efficiency. However, we still face challenges such as dispensing issues due to a lack of serialisation on a percentage of packs and medicines wrapped in plastic film combined with a need to unpack each carton so that scanning can take place. Despite this, it is vital that all hospitals in France undergo automation which has so many associated benefits."

Agnès Mathieu-Mendes, Deputy Head of Unit B4 Medical products: quality, safety, innovation, DG Health and Food Safety, European Commission

"Of particular note is the significant drop in the alert rate and all the hard work by all those parties involved is not to be under-estimated. We are not over the finish line yet but undoubtedly the progress to date via the various FMD phases has made the supply chains safer and of a better quality. In addition, the online Common Logo and the safety features have greatly enhanced the security of the supply chain and thus greatly enhanced patient safety which was the primary objective of the FMD."

Fanny Trenteseaux, Project & Partner Manager, Legal Partner Engagement of the European Medicines Verification Organisation (EMVO)

"I am able to summarise the key take home messages are as follows: the number of "Alerts" (this is where on decommissioning of a pack, the system does not authenticate the unique serialised data matrix on the prescription pack) still varied greatly between countries, with four countries having alert rates of greater than 1%. However, the positive news was that the overall trend was downwards as more and more technical issues were resolved."



András Süle, President of the European Association of Hospital Pharmacies (EAHP)

"The role of hospital pharmacists is key to patient safety and this includes the aspect of ensuring a safe supply chain. However, there are ongoing current practical issues and barriers. These range from infrastructure incompatibilities to software provider inadequacies. Our challenges include the difficulties of integrating the FMD into existing hospital systems. Another pressing issue is the burden brought on by manual scanning. In addition, challenges such as medicine shortages, IT problems, readability of data, storage of packs and alert rates are adding to the problem. However, we at the EAHP are supporting our members by having regular discussions with EMVO combined with regular exchanges of intelligence and data collection via surveys of its members."

The impact of COVID-19 on supply chains

It is vital that healthcare professionals understand the full background to the rising problem of falsified medicines. The FMD was put in place to safeguard what is often termed the "legitimate" supply chain where the medicine is manufactured by the pharmaceutical company, which is then delivered to a pre-wholesaler and the on to a wholesaler or distributor and then on to the pharmacist (or indeed posted to the patient if the necessary legal documents – e.g. proof of prescription are supplied). If the medicine is parallel imported to another Member State, the pack has to be decommissioned and a new serialised barcode added to the pack.

In March 2020 Europol supported a pan-European operation targeting the illicit online and offline trafficking of misused and falsified medicines.

This operation resulted in 12 organised criminal groups being disrupted with 165 suspects arrested in Belgium, Cyprus, Finland, France, Greece, Hungary, Italy, Portugal, Slovakia, Spain, Ukraine, and the United Kingdom. Incredibly, nearly €1.5 million of assets were recovered with nearly 36 million units of medicines seized (such as pseudoephedrine, anti-cancer drugs, antihistamines, anxiolytics, erectile dysfunction medicines, hormone and metabolic regulators, narcotics, painkillers, antioestrogens, antivirals, hypnotics and doping substances) to the value €7.9 million. In addition, a worrying trend was observed where oncological medicines were being stolen from hospitals.[1]

The impact of the pandemic cannot be underestimated in terms of the increased use of the Internet to conduct the purchase of items online. Buying medicines online has not escaped a scourge of fraudulent activity preying on the lack of knowledge, fear and anxiety of a vulnerable population.

Certainly, Customs' organisations have seen very big increases year on year as people, in general, seek to buy more and more products online. COVID-19 has accelerated this phenomenon. This makes for a very difficult situation: how can borders adequately control the movements of millions of small packages? One estimate has suggested that over 130 million people are buying medicines online within Europe.

This number was extrapolated from a survey carried out in 2014.[2] Today one would expect this figure to be much higher, catalysed by the pandemic.

Criminal activities require websites and Internet domain names to run phishing, spam and malware campaigns. During March 2020, at least 100,000 new domain names were registered containing terms like "covid," "corona," and "virus". Other domains have been registered and used to spam out advertisements for COVID-themed scams. New domain names fitting these criteria are being registered at the rate of around 1,000 per day.[3]

What are the most popular fake pharmaceuticals sold?

A recent report by the OECD[4], to which ASOP EU & EAASM were asked to contribute, clearly demonstrates that countries such as China and India are playing a key role in this illegal activity.

Examples of falsified/counterfeit pharmaceutical products recorded in the database of customs seizures developed for the OECD/EUIPO (2019) study are various and striking. Over the 2014-2016 period, customs authorities worldwide recorded seizures of medicines for the treatment of malaria, HIV/AIDS and cancer. These pose a very serious threat to consumer health.

However, a quick review of the data suggests that substandard and falsified antibiotics, lifestyle drugs and painkillers were the most targeted by counterfeiters.

A recent study by the National Association of Boards of Pharmacy (NABP)[5] entitled Rogue RX Activity Report, highlighted the following:

- ★ Dozens of illegal online pharmacies peddling Rx-only medicines marked as COVID-19 treatments
- ★ 100s of newly created domain names, not yet active but may be used in the future
- ★ Over 90% of the COVID-related domain names identified were registered anonymously, which makes it difficult for law enforcement agencies to investigate these sources
- ★ Government agencies, regulators, members of Congress and state attorneys are cracking down on this activity whilst reaching out to the private sector for support
- ★ Many Internet intermediaries are actively shutting down fraudulent face mask, vaccine and test kit sellers
- ★ However, illegal Internet pharmacies continue, largely unabated

The Rogue Rx Activity report highlighted the following selection of prescription-only medicines that have gained much media attention:

- ★ Chloroquine, azithromycin, and lopinavir/ritonavir. Chloroquine (Aralen®) and hydroxychloroquine (Plaquenil®) are antimalarial drugs that have received emergency use authorisation from Food and Drug Administration (FDA) for the treatment of certain hospitalised COVID-19 patients
- ★ Azithromycin is being used in combination with chloroquine and hydroxychloroquine
- ★ Lopinavir and ritonavir (sold together under the brand name Kaletra®) are antiretrovirals that are being tested as a possible COVID-19 treatment
- ★ NABP has also identified websites peddling diltiazem, furosemide, and mefloquine – all of which are being studied as possible coronavirus treatments

Of course, all these treatments are unproven, and dangerous if taken without proper oversight.

Raising public awareness is essential

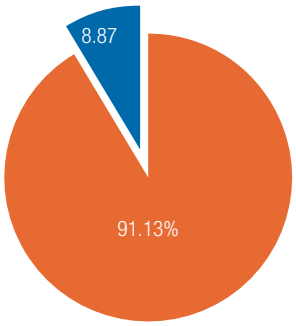
A long term public awareness campaign, carried out by ASOP EU and the EAASM over a number of years[6], revealed vital information about the number and behaviour of would-be purchasers of medicines online. The campaign ran in 5 European countries (France, Germany, Italy, Spain and UK) and was generated by Google Adwords using keywords such as “pharmacy online”, “buy medicines”, etc. During the campaign no less than 35,000 first page results were recorded per day (this is when the advertisement to the educational website appears on the first page of the Google search results) with 1,200 people per day clicking on the link to the campaign. On each educational page, the viewer had an option to complete a 10 question survey. Over 2,300 surveys were completed.

What kind of medicines do you want to buy/have you bought?

One key question was which medicines are they looking to buy and the answers revealed that all types of medicines were searched for.

Condition/Medicine for	Respondents
Female contraception, Hair loss, Arthritis, Blood pressure Cancer, Diabetes, Hepatitis, HIV, Cholesterol Lowering, Psychiatric	>6%
Antibiotic therapy	7%
Pain relief	18%
Erectile dysfunction	12%
Other	29%

Another key question revealed a woeful lack of understanding about the risks of buying online but once told of the fact that 96% of websites selling medicines were operating illegally, 91% of people were actually willing to change their behaviour.



Not willing to change their

Willing to change their behaviour and find an authentic website selling medicines or visit their local pharmacy

The NABP Top Level Domain name program .Pharmacy

.pharmacy

Educating consumers about the dangers of such potentially harmful purchases is part of the reason NABP started the .Pharmacy Top Level Domain (TLD) Program.[7] Pharmacy websites enable consumers to identify safe online pharmacies simply by looking for ".pharmacy" in a website address/URL.

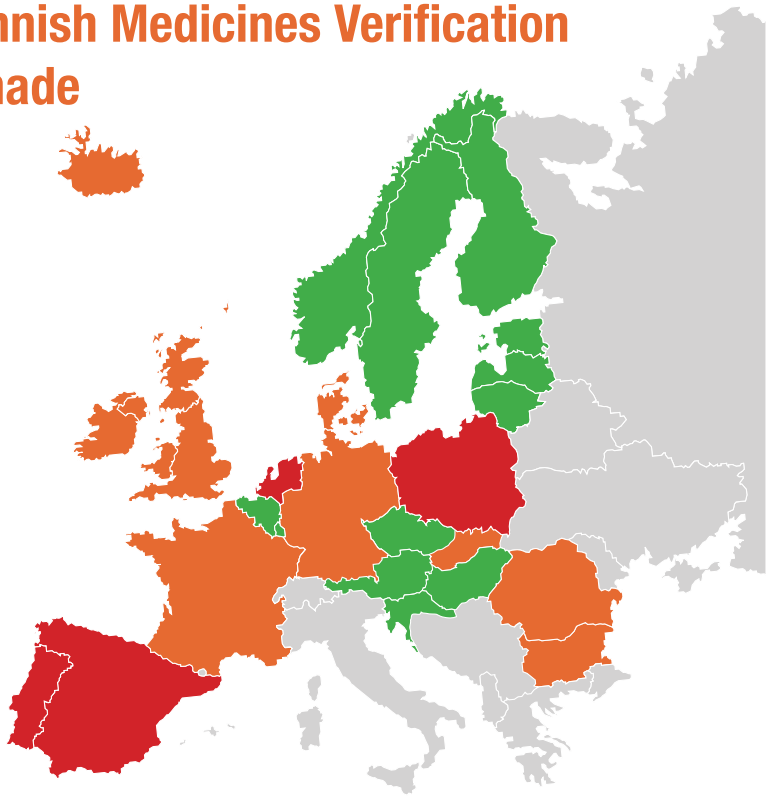
In addition, one of the .Pharmacy TLD programme standards requires pharmacies using the domain to obtain a valid prescription from the patient. Being able to separate legitimate online pharmacies from rogue internet drug outlets is an essential part of protecting public health. Consumers no longer need to look for safety seals, which can be faked, since the fraud-proof mark of safety is in a .pharmacy website's URL. To see the list of trustworthy .pharmacy websites, visit the Buying Safely section of www.buysaferx.pharmacy.

The practical steps that can be taken to help protect the hospital patient

- ★ All healthcare professionals (especially doctors, pharmacists, nurses and auxiliary staff) should be trained on falsified medicines and the purpose of the FMD

- ★ On entering a hospital, all patients should not only have their history of medication explored but be asked specific questions around buying medicines from the Internet which could give rise to contra-indications that would otherwise be unknown

Status of the European and Finnish Medicines Verification Systems - variable progress made



Alert rate

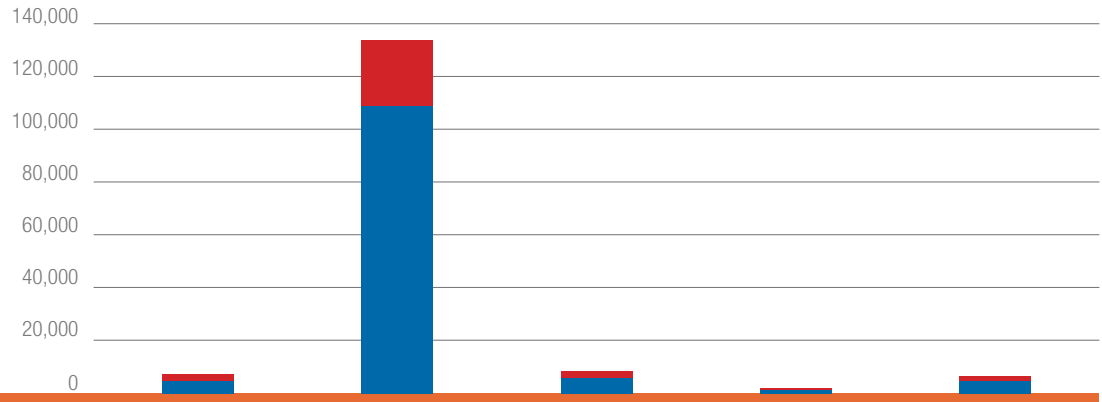
- < 0.1%
- > 0.1% and <1%
- > 1%

Note: the objective for the EMVS countries is to reach an alert rate of less than 0.05%

30th September 2020
Patient safety and the implementation of the falsified medicines directive in the hospital

The key take-home messages can be summarised as follows: the number of "Alerts" (this is where, on decommissioning, the system does not authenticate the unique serialised data matrix on the prescription pack) still varied greatly between countries, with four countries having alert rates of greater than 1%. The positive news that the overall trend was downwards as more and more technical issues were resolved.

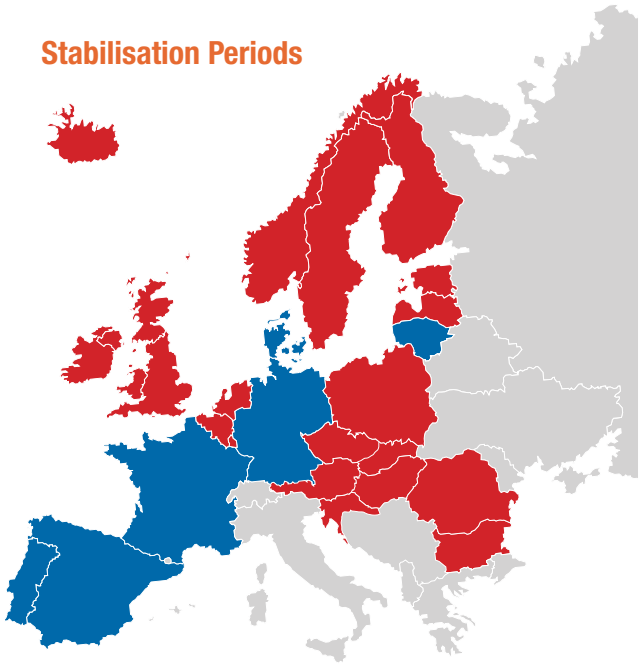
End-users not connected



	Wholesalers	Pharmacies	Healthcare Institutions	Dispensing Doctors	Other Decommissioning Channels
Not connected	2,026	23,430	2,172	734	5,531
Connected	5,277	109,053	6,557	1,564	986
Percentage remaining	27.74%	17.69%	24.86%	31.94%	84.87%

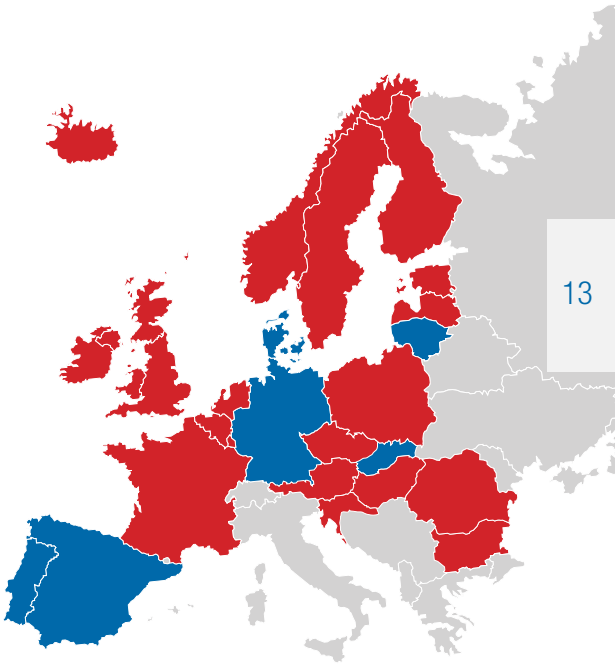
Those manufacturers who had signed Participant Agreements and those who were connected to the hubs were steadily rising. The estimated number of product codes to cover all prescription packs across Europe was believed to have been achieved, notwithstanding the fact that this number will be in constant flux.

Stabilisation Periods



Stabilisation period on-going
7 countries

Not in stabilisation period
22 countries



No fines yet applicable
6 countries

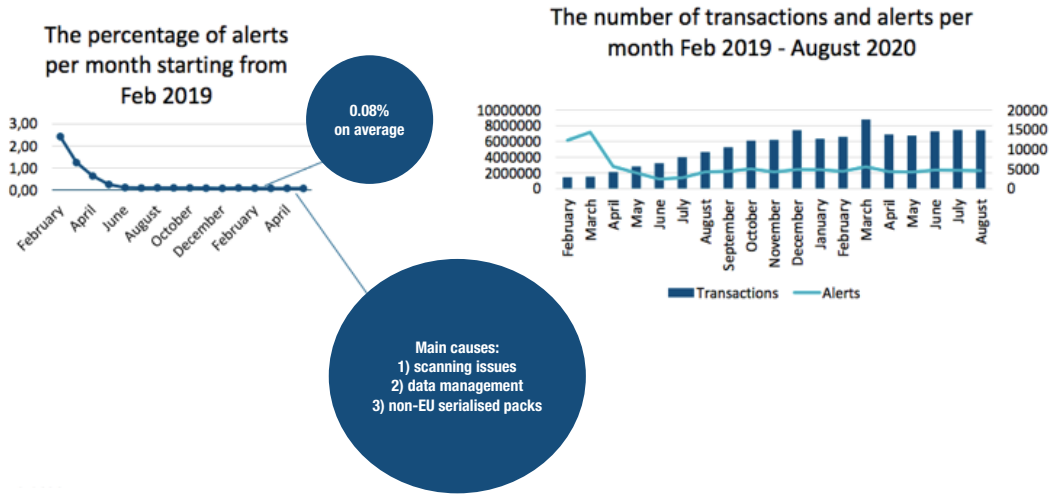
Fines under applicable law
23 countries

30th September 2020
Patient safety and the implementation of the falsified medicines directive in the hospital environment

Of further concern was that 22 countries were now beyond their "Stabilisation" periods and so theoretically open to national fines.

FiMVO
Suomen Lääkevarmennus

Alert summary



A positive picture in Finland revealed that the percentage of alerts starting from February 2019 was very low at 0.08%.

However, these alerts are not due to falsified medicines but because of scanning, data management and non-EU serialised packs' issues. Transactions, however, had stabilised at just below 15,000 per month. A final room-for-improvement slide focused on the area of aggregation, quality issues (e.g. packs with poor 2D quality backgrounds) combined with a precautionary warning around the need for forward planning pending the arrival of a COVID-19 vaccine.

The challenges and benefits of implementing the FMD

The report entitled "Benefits beyond the EU FMD - The Hospital Setting"[8] revealed that the installation of robotics and conveyor systems which automate the verification and decommissioning of products brings a halo of benefits. Product identification, barcodes and interoperable data models were identified as being increasingly important as the use of technology advances.

The use of barcodes in healthcare has increased dramatically over the past 5-10 years and hospitals across Europe and worldwide are implementing programmes which deliver:

- ★ Improved patient safety
- ★ Enhanced clinical effectiveness
- ★ Operational efficiencies
- ★ Improved product recalls

The focus within hospitals is now starting to shift beyond simple compliance to the legislation and on to leveraging the EU FMD infrastructure to deliver additional benefits.

Standardisation is proving key to intra-operability across systems

The EU FMD has brought about the standardisation of medicinal product identification, common 2D barcodes which include the product code, batch/lot and expiry information on all prescription product packs and product master data availability. Without such rigorous standards, data and enforcement, hospitals were previously faced with disparate sorts of information in barcodes that effectively made them unusable in practical terms. The EU FMD enables hospitals to leverage further benefits opportunities which were difficult to realise without this level of harmonisation and barcoding prevalence, including:

- ★ **Packs more easily transformed and repacked into kits and unit packs**
- ★ **Reduced errors during data capture and pack handling**
- ★ **2D barcode provides opportunity to web enable digital content for multiple usage**
- ★ **Traceability using scanning can improve product recall**
- ★ **Closer integration with existing processes which require the capture of product code, batch/lot and expiry**
- ★ **More use of automation equipment and robotics**
- ★ **Access to digital data and services leveraging the barcode**
- ★ **Increased interoperability through product identification and data**

Benefit mapping to maximise FMD implementation potential

The benefits of implementing the FMD in hospitals can be summarised by a "benefit map" shown opposite. Detailed analysis of achieving these benefits is contained in the report and is recommended reading.

9.0 The hospital supply chain - benefit types & areas

Benefit mapping

There are several models used to describe the activities of a hospital, all of which are portrayed from different perspectives (patient journey, system models, etc). As this report is focussed on the benefits derived from the EU FMD pack product flow, it uses a materials management type model but breaks this down into four areas of focus. The first three represent specific areas of the supply chain operation whereas the fourth, digital, has applications across the entire materials flow.

1) Logistics
Management of the flow of products through the hospital supply chain including both the physical products and associated data flows.

2) Manufacture and transform
Either the manufacture of medicinal products within the hospital or the operations which transform the packs into different physical/ packaging states e.g. from a pack of 12 tablets into individual unit dose packs.

3) Clinical
The processes involved with providing the product to the patient.

4) Digital
This encompasses the use of digital information and services provided via portable electronic devices and IT systems, this is also referred to as eHealth or telehealth.

Figure 6: Benefit Model

The level of medical errors which occur in hospitals is well documented, with experts estimating around 100,000 deaths a year. The financial costs are also significant for a hospital, resulting from factors including corrective treatment, litigation costs and additional hospital stays, the UK alone reports 2 billion euros per year are spent on avoidable hospital stays. There are also broader economic factors to consider such as loss of the ability of the patient to work and contribute to society. In developed countries, medication errors occur in around 10% to 20% of all patient administrations.

Medication errors can lead to an adverse drug event (ADE), of which there are estimated to be around 25 million worldwide. These ADE's can have serious impacts on patients, leading to physical and mental harm, long-term disabilities and even fatalities. The personal impacts are significant not only for the patient and their families but also for the healthcare workers involved; sadly this human aspect is often overlooked but a real factor in the impact errors have.

Grant Courtney, author of the report, emphasised the following:
"The ability to identify and trace a medicine is therefore essential"

Cost savings

Other areas of operations are also shown to benefit with increased efficiencies and reduced waste. A major hospital that had implemented automated inventory management system reported a much greater level of control and visibility of the supply chain.

"So far, this hospital has saved €4.4 million on reduction of waste through over-ordering. Other hospitals are also delivering savings with one having saved €360K related to stock management and another with a €915K opportunity to increase chargeback revenue vs the previous year."

Practical hurdles and challenges of implementing the FMD in a French and UK hospital

Julia Asplin, Pharmacy Logistics Lead and Purchasing Team manager Lister Hospital Stevenage, UK

NHS
East and North Hertfordshire
NHS Trust

Business case / Funding / Resources

Before embarking on implementing the FMD, it is crucial to undertake a full appraisal of the options available. This entails research of technology packages, quantification of hardware and scanner options. This enables a full understanding of what is required and the costs associated which contribute to the overall plan and which can then be presented to the regional health authority in your country.

Operational overview

It is important as part of the planning process to assess the advantages of reconfiguring the workflow (capacity for the flow of packs and area required for an automated system. This will of course vary depending on product opted for). The capability of the different robotic systems will determine the different synergies that can be realised from automation.

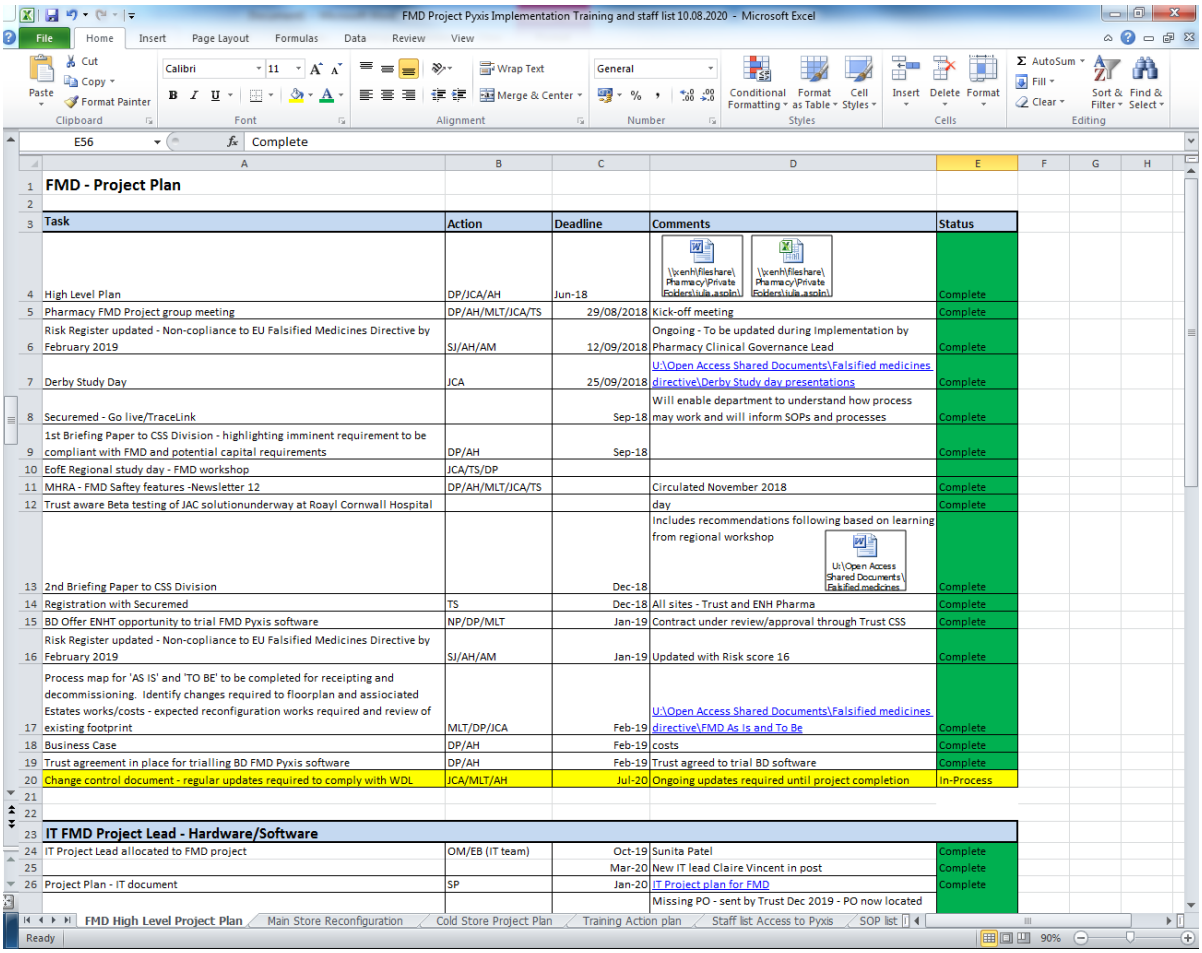
Any new workflow with its governance rules requires a robust change management process. This requires strong leadership and a willingness to delegate and gain the maximum buy-in from staff with commensurate training. This is also a significant opportunity to introduce cultural change whereby a commitment of openness and honesty is established – in this way learnings can be seen as essential to instil an environment that respects continual improvement with subsequent efficiencies.

Having confidence in the ongoing IT support pre, per and post implementation is essential, therefore thorough testing of the system is required.

Anticipation of managing incidents following the ‘go-live’ needs careful planning. For instance, the correction processes for managing ‘red’ alerts or the interpretation of NMVS response codes requires robust SOPS.

All of the above needs to be planned out and captured on a single document. In the Lister Hospital case, an excel spreadsheet was used with the headings Task, Action, Deadline and comments (in which more granular plans can be placed).

FMD Project Plan



FMD Project Pyxis Implementation Training and staff list 10.08.2020 - Microsoft Excel

E56: Complete

FMD - Project Plan

Task	Action	Deadline	Comments	Status
High Level Plan	DP/JCA/AH	Jun-18	\\xenh\fileshare\Pharmacy\Private Folders\ula.asoln\ \\xenh\fileshare\Pharmacy\Private Folders\ula.asoln\	Complete
Pharmacy FMD Project group meeting	DP/AH/MLT/JCA/TS	29/08/2018	Kick-off meeting	Complete
Risk Register updated - Non-copliance to EU Falsified Medicines Directive by February 2019	SJ/AH/AM	12/09/2018	Ongoing - To be updated during Implementation by Pharmacy Clinical Governance Lead	Complete
Derby Study Day	JCA	25/09/2018	U:\Open Access Shared Documents\Falsified medicines directive\Derby Study day presentations	Complete
Securemed - Go live/TraceLink		Sep-18	Will enable department to understand how process may work and will inform SOPs and processes	Complete
1st Briefing Paper to CSS Division - highlighting imminent requirement to be compliant with FMD and potential capital requirements	DP/AH	Sep-18		Complete
EofE Regional study day - FMD workshop	JCA/TS/DP			
MHRA - FMD Saftey features -Newsletter 12	DP/AH/MLT/JCA/TS		Circulated November 2018	Complete
Trust aware Beta testing of JAC solutionunderway at Roayl Cornwall Hospital			day	Complete
2nd Briefing Paper to CSS Division		Dec-18	Includes recommendations following based on learning from regional workshop Ui\Open Access Shared Documents\Falsified medicines	Complete
Registration with Securemed	TS	Dec-18	All sites - Trust and ENH Pharma	Complete
BD Offer ENHT opportunity to trial FMD Pyxis software	NP/DP/MLT	Jan-19	Contract under review/approval through Trust CSS	Complete
Risk Register updated - Non-copliance to EU Falsified Medicines Directive by February 2019	SJ/AH/AM	Jan-19	Updated with Risk score 16	Complete
Process map for 'AS IS' and 'TO BE' to be completed for receipting and decommissioning. Identify changes required to floorplan and assiociated Estates works/costs - expected reconfiguration works required and review of existing footprint	MLT/DP/JCA	Feb-19	U:\Open Access Shared Documents\Falsified medicines directive\FMD As Is and To Be	Complete
Business Case	DP/AH	Feb-19	costs	Complete
Trust agreement in place for trialling BD FMD Pyxis software	DP/AH	Feb-19	Trust agreed to trial BD software	Complete
Change control document - regular updates required to comply with WDL	JCA/MLT/AH	Jul-20	Ongoing updates required until project completion	In-Process
IT FMD Project Lead - Hardware/Software				
IT Project Lead allocated to FMD project	OM/EB (IT team)	Oct-19	Sunita Patel	Complete
		Mar-20	New IT lead Claire Vincent in post	Complete
Project Plan - IT document	SP	Jan-20	IT Project plan for FMD	Complete
			Missing PO - sent by Trust Dec 2019 - PO now located	

Sheet tabs: FMD High Level Project Plan | Main Store Reconfiguration | Cold Store Project Plan | Training Action plan | Staff list Access to Pyxis | SOP list

Ready 90%

Key dates

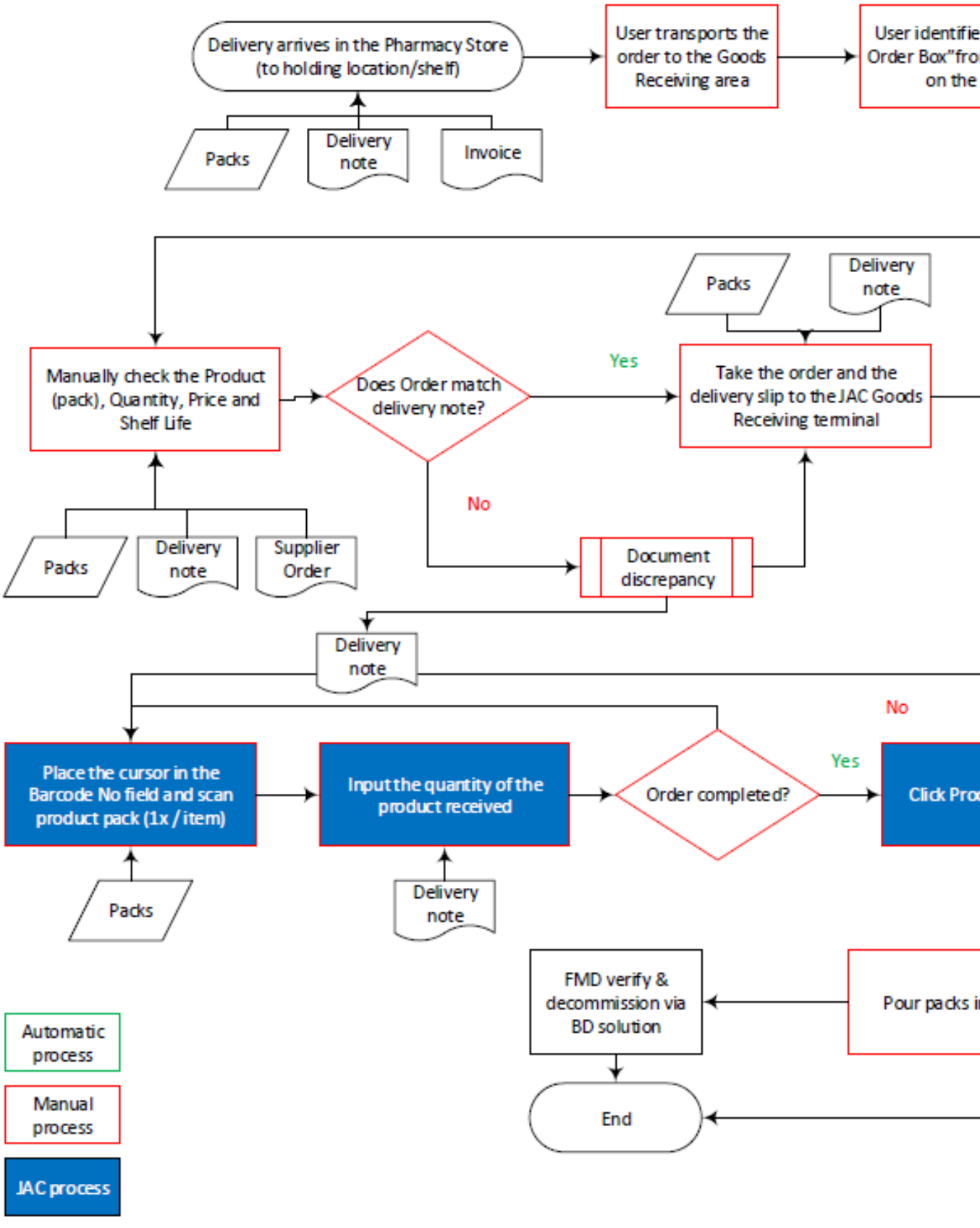
Project start date June 2018
Project approved for implementation October 2019

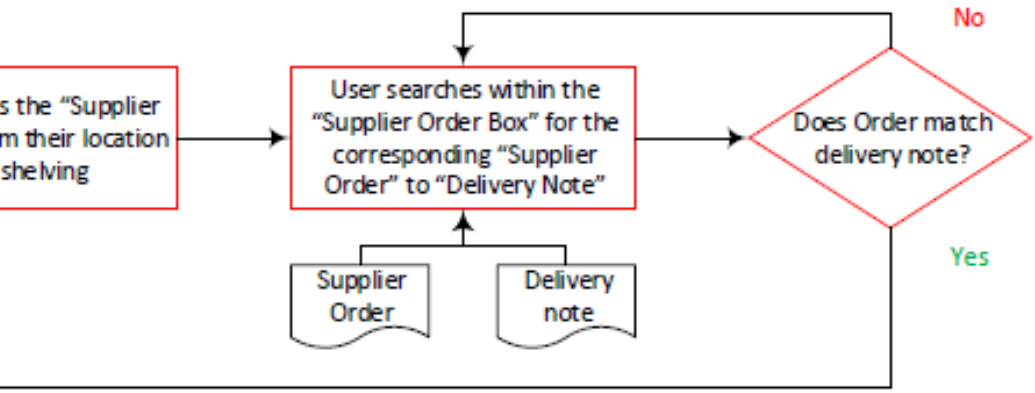
Once the FMD project had been approved with the funding of 33,000 euros, secured procurement to complete the project could be made.

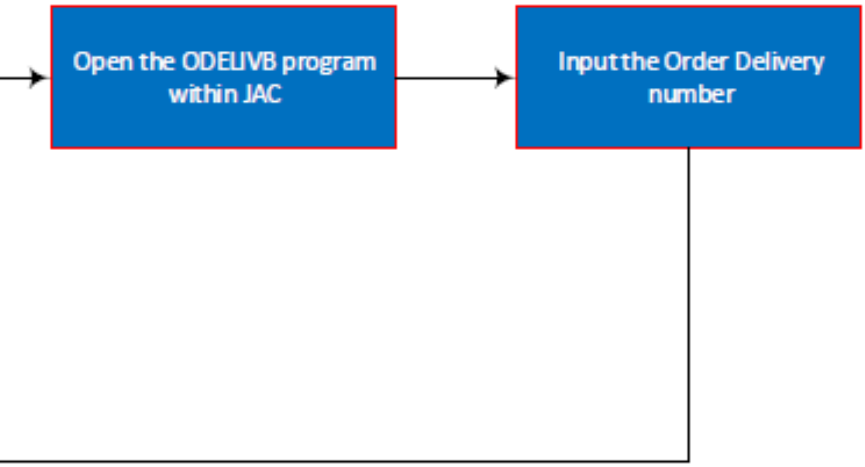
- ★ Software purchase initiated (go live was dependent on coordination with ongoing projects)
- ★ Equipment purchased and received December 2019
- ★ Phase 1 started August 2019 with Phase 10 completed August 2020

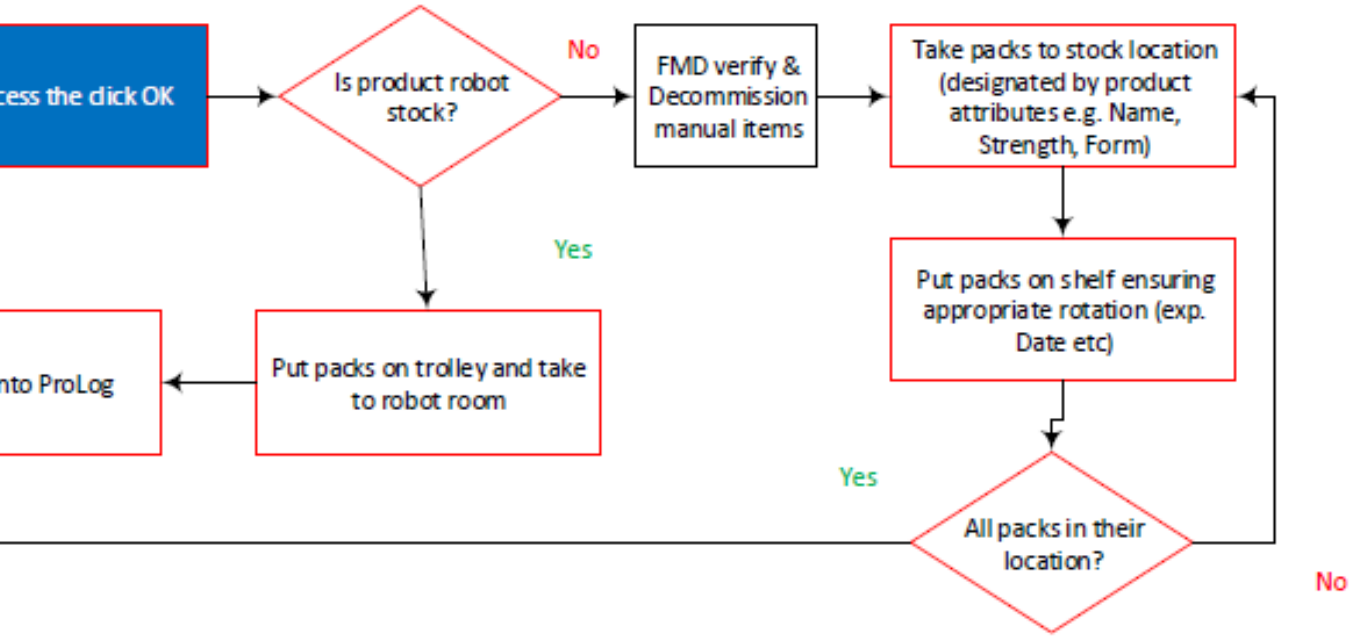
East & North Hertfordshire NHS Trust

Lister Hospital Goods In (Pharmacy Store)




s the "Supplier
m their location
shelving
User searches within the "Supplier Order Box" for the corresponding "Supplier Order" to "Delivery Note"
Supplier Order
Delivery note
Does Order match delivery note?
No
Yes


Open the ODELIVB program within JAC
Input the Order Delivery number


cess the click OK
Is product robot stock?
No
FMD verify & Decommission manual items
Take packs to stock location (designated by product attributes e.g. Name, Strength, Form)
Yes
Put packs on shelf ensuring appropriate rotation (exp. Date etc)
nto ProLog
Put packs on trolley and take to robot room
Yes
All packs in their location?
No

Key elements / Checklist

1. **Estates enabling works - Additional sockets for PCs + equipment (Ordered November 2019 – installed May 2020), FMD Workbench (Ordered November 2019 – installed May 2020)**
2. **IT support elements**
    a. New Network Points required (Ordered October 2019 – installed February 2020)
    b. Installation of new PCs required in two locations
    c. Installation of scanners – Windows 10 not fully supported
    d. Roll out of EPMA affecting availability of IT resource to support FMD project
    e. Communication between software provider and local IT department
3. **Process and workflow review**
    a. Interpreting directive - appropriate point to Verify + Decommission
    b. WDA Customer base – impact/risk assessment
    c. Managing additional scan burden
    d. Staff Training

To underline the success of the implementation of the FMD, it is important to note that during this period various projects were running in parallel, namely a new pharmacy cold store installation and a pharmacy manufacturing unit refurbishment, which included an “Arrest” kit preparation area moved to the main store area whilst at the same time the aseptic compounding services were outsourced.

Due to the fact that there was no budget for the pharmacy re-configuration, the pharmacy team worked together to dismantle and reconstruct the storage system in the main store.

At the planning stage when the new workflows were being analysed, it became clear very quickly that the FMD work station required room for two PCs and a desk work area. The “Goods in” area was opened out so that the footprint was complete open plan.

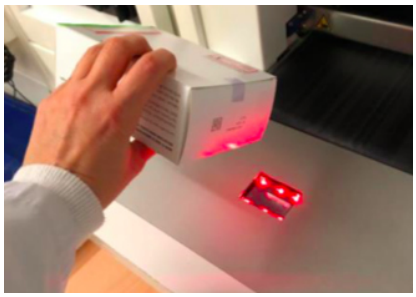
Valerie Pelletier, hospital pharmacist, Supply Chain Manager, Rouen University Hospital

The ROUEN University Hospital is large and comprises 2,429 beds divided in to five locations. The central pharmacy manages the procurement and distribution of all the medicines, medical devices and PPE. Specifically with medicines, this means that on average 100,000 boxes at any one time are being stored.

The storage systems are split into two areas: one for manual storage on shelves and a second using an automated robotic dispensing system.

The staff manually scan each pack and the robot then automatically places it within the storage area having recorded the expiration date and the batch number. This scanning is the process whereby the pack is checked for its authenticity and is decommissioned. The anti-tampering device is checked visually at the time of scanning. It should be noted that some systems have an automatic feed and so the packs are simply loaded onto a conveyor belt and automatic scanning takes place relieving the manual burden. However manual scanning can be very quick and efficient, and this is achieved for the medicines stored on the shelves using a hand-held device. This requires additional staff time.

Combining the two storage references, a total of 1,538 packs are stored in the robot and 1,184 stored externally (but within a digital software system that is totally connected).



Currently, 81% of the prescription packs received from suppliers are FMD compliant (i.e. have a 2D barcode and a tamper-evident seal).

It is problematic that not all medicines have been uniquely serialised with a 2D barcode. In fact, a recent analysis revealed that 22.2% of packs had no unique identifier. This is because some manufacturers have not yet serialised the packs. In some cases, this is due to long dated stock with very slow usage.

Challenges to be overcome

1. Packs wrapped in plastic film gives rise to time-wasting as it is not possible to scan through this material
2. In a carton following the scanning process, it sometimes fails to read all the boxes resulting in one pack not being decommissioned
3. For the manual decommissioning exercise, the practicalities are very difficult. One pallet of 286 cartons contains 675 boxes of medicine. The unpacking of each carton is time-consuming and a careful process needs to be adhered to if mistakes in double scanning or failure to scan happens
4. Computer network issues
5. Issues relating to reading/scanning the barcode
6. One incidence of a cyber attack occurred
7. Decommission failures (on average running at 3.6%)

Recommendations for the France hospital community

1. Medication errors can be significantly reduced following the automation of pack traceability. The investment is worth it on patient safety grounds with multiple benefits which includes fiscal savings. All France hospitals should be planning to provide a justification for investing in automation.
2. Improved quality of printing of 2D barcodes on packs to ensure consistent scanning capabilities
3. Aggregated codes on pallets would impact very positively on the decommissioning process
4. Manufacturers should now complete the serialisation of all prescription packs in line with the FMD (which is a mandatory requirement under national laws)
5. Further support needed to support error messages following scanning

Benefits found in hospitals following automation

1. **Automated solutions result in a reduced manual scanning burden of up to 63%**

2. **No extra staff required to run a robotic system and frees time for resources to be directed towards improving pharmaceutical services**

3. **Robotics allows:**
   - Guaranteed inventory management
   - Reduced inventory resulting in cost savings
   - Improved ordering for bulk lines
   - A vital part of the medication process secured
   - Automatic decommissioning for a significant part of the internal supply chain
   - Visibility of recycled/returned products allows for analysis and subsequent improvements

4. **Utilisation of technology has across-the-board ramifications and opportunities for IT**

5. **Redesigned workflows optimise "goods in" and "goods out"**

6. **Very positive development of relationships with commercial provider to support development of NHS**

7. **Adaptations ongoing to accommodate both FMD and local operational**

EAASM Call to Action

We call upon all stakeholders to build on the implementation of the FMD by:

- ★ Encouraging all national and regional medical authorities to become even more involved to help ensure that any hospitals who need to support the implementation of the FMD do so;
- ★ Implementing a continuous improvement culture that involves inclusive collaboration with all staff and parties involved to capitalise on the many opportunities to use the data collected for positive patient care;
- ★ Procedural and system improvements by embracing technology such as Artificial Intelligence IT infrastructure to introduce automated dispensing solutions to save time and to alleviate the manual actions that lead to mental burden;
- ★ Introducing Smart applications to help connected services (ambulance, satellite hospitals) and robotics to aid the verification process and enhance the security of the medication use process;
- ★ Encouraging hospitals when onboarding patients to carry out a thorough discussion on the patients' medication history, to include questions around whether medicines have been bought on the Internet and thus introduce education to safeguard against patients taking themselves outside of their national health systems

---

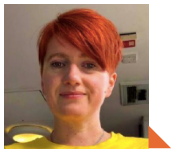
If you would like to contact any of the speakers to enable you to help make choices about how to progress your implementation of the FMD please find their details below:

Andreas WALTER
General Manager of the European Medicines Verification Organisation
andreas.walter@emvo-medicines.eu

Maija GOHLKE-KOKKONEN
General Manager of the Finnish Medicines Verification Organisation
maija.gohlke-kokkonen@laakevarmennus.fi

András SÜLE
Director of Finance at the European Association of Hospital Pharmacists
andras.sule@eahp.eu

Grant COURTNEY
Principle Consultant for Be4ward, expert supply chain transformation consultancy
grant.courtney@be4ward.com



Julia ASPLIN
Pharmacy Logistics Lead and Purchasing Team Manager, The Lister Hospital, Stevenage, UK
j.asplin@nhs.net

Valerie PELLETIER
Hospital Pharmacist, Supply Chain Manager, Rouen University Hospital, France
valerie.pelletier@chu-rouen.fr

Agnès MATHIEU-MENDES
Deputy Head of the Unit on the quality, safety and innovation of medicinal products, DG SANTE, European Commission
agnes.mathieu-mendes@ec.europa.eu

References

1. EUROPOL Newsroom - €7.9 MILLION OF ILLEGAL PRODUCTS SEIZED IN A HIT AGAINST MEDICINE TRAFFICKERS (not in capital letter please), 06 March 2020 https://www.europol.europa.eu/newsroom/news/€79-million-of-illegal-products-seized-in-hit-against-medicine-traffickers#:~:text=€7.9 million of illegal products seized in a hit against medicine
2. Happy Curious study 2014
3. The Internet is drowning in COVID-19-related malware and phishing scams." Ars Technica, 16 March 2020, at: https://arstechnica.com/information-technology/2020/03/the-internet-is-drowning-in-covid-19-related-malware-and-phishing-scams/and "Coronavirus Used in Malicious Campaigns." Trend Micro, 20 March 2020, at:https://www.trendmicro.com/vinfo/us/security/news/cybercrime-and-digital-threats/coronavirus-used-in-spam-malware-file-names-and-malicious-domains
4. Trends in Trade in Counterfeit and Pirated Goods https://euipo.europa.eu/ohimportal/en/web/observatory/trends-in-trade-in-counterfeit-and-pirated-goods
5. https://nabp.pharmacy/wp-content/uploads/2020/05/Rogue-Rx-Activity-Report-May-2020.pdf
6. ASOP EU and EAASM – data on file 2018
7. .Pharmacy Verified Websites https://nabp.pharmacy/programs/dotpharmacy/
8. Grant Courtney - Benefits beyond the EU Falsified Medicines Directive – in the hospital setting Be4ward September 2020 Release 1.1 https://www.be4ward.com/expert-publishing/
9. Medicine Shortages: From Assumption to Evidence to Action - A Proposal for Using the FMD Data Repositories for Shortages Monitoring François Bouvy and Mihai Rotaru* Frontiers In Medicine POLICY AND PRACTICE REVIEWS published: 03 February 2021 doi: 10.3389/fmed.2021.579822

Acknowledgements

This report has been made possible by an unrestricted educational grant from Becton Dickinson SA.

www.eaasm.eu

All correspondence regarding this publication should be sent to:
EAASM
1386 London Road
Leigh-on-Sea
Essex SS9 2UJ
UK

Contact Directly: Mike Isles mike.isles@eaasm.eu +44 (0) 7540 462867
Laura Cigolot laura.cigolot@eaasm.eu