



# **The Falsified Medicines Directive – implementing practical solutions in the hospital arena**

**A report of the EU Parliament meeting that brought together experts to support knowledge sharing and best practices around processes and authentication**

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### Glossary of Terms

<b>ASOP EU</b>	The Alliance for Safe Online Pharmacy in the EU	<b>IQE</b>	Integrated Quality Environment
<b>ATD</b>	Anti-tampering Device	<b>MA</b>	Marketing Authorisation
<b>DG Sante</b>	European Commission – Directorate General for Health and Food Safety	<b>MAH</b>	Marketing Authorisation Holder
<b>EAASM</b>	European Alliance for Access to Safe Medicines	<b>MAS</b>	Medicine's Authentication System
<b>EEA</b>	European Economic Area	<b>NABP</b>	National Association of Boards of Pharmacy
<b>EMA</b>	European Medicines Agency	<b>NCA</b>	National Competent Authorities
<b>EMVO</b>	European Medicines Verification Organisation	<b>NMVO</b>	National Medicines Verification Organisation
<b>EMVS</b>	European Medicines Verification System	<b>NMVS</b>	National Medicines Verification System
<b>ESA</b>	Electronic Shipment Advice	<b>OBP</b>	Onboarding Partner
<b>FMD</b>	Falsified Medicines Directive	<b>PRD</b>	Productive Environment
<b>FTE</b>	Full Time Equivalent	<b>UI</b>	Unique Identifier
<b>GDP</b>	Good Distribution Practice	<b>UNI.HA</b>	La coopérative des acheteurs hospitaliers
		<b>WG IV</b>	Working Group IV Implementation of the FMD in Hospitals
		<b>WMS</b>	Warehouse Management System

## Forewords

by MEP José Inácio Faria and Mike Isles, EAASM



**MEP José Inácio Faria**  
European Parliament,  
EPP group



We must not underestimate the complexity of the implementation of the safety features enshrined in the Falsified Medicines Directive.<sup>1</sup> I congratulate all stakeholders involved in implementing such a comprehensive initiative that makes patients safe and health systems trustworthy. Already they have overcome big challenges and no doubt there will be more to come as this last stage of the FMD beds down.

This is the time when each prescription pack within each Member State starts to bear a unique serial number, included in a 2D data matrix barcode, which can be verified against a database. Large

volumes of packs will have to be dealt with by several stakeholders at the operational level until the final destination – the patient.

In the spirit of wanting to support the introduction of the FMD safety features and to share best practices, this meeting has brought together a group of experts with practical hands-on experience and are clearly demonstrating the implementation of the FMD's safety features within the hospital arena.

I would encourage you to review the results and to disseminate this throughout your hospital networks.



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



The European Alliance for Access to Safe Medicines has been deeply involved in the FMD since 2005 making representations to the EU Parliament and confirming through research and collaboration categorically that falsified medicines cause great harm to the EU citizen.

However, we must also pay regard to the many EU citizens who buy medicines, often unwittingly from the Internet. A recent estimation puts the figure at 130 million people, most likely without the need for a prescription. The EAASM therefore advocates strongly that the public are informed about the dangers from falsified medicines and encourages all Member States and DG SANTE to fulfil Article 85d<sup>2</sup> of the Directive which legally obliges this. We also advocate that in addition to the Common Logo (another security measure within the FMD) being present on each

web page of a registered pharmacy, that pharmacies also consider taking up the Internet top level domain name *.pharmacy* which is governed well by the National Association of Boards of Pharmacy<sup>3</sup>. It is important therefore that hospitals when onboarding patients carry out a thorough discussion on the patients' medication history to include questions around whether medicines have been bought on the Internet and introduce education to safeguard against patients taking themselves outside of their national health systems.

We hope that this report can be used to encourage the sharing of best practice and thus support the hospital environment as they go about implementing what can be regarded as the most important advance in protecting the patient from falsified medicines ever."

# Expert views on the Falsified Medicines Directive

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

"Falsified medicines affect every region of the world and causes significant harm to patients with a subsequent loss of confidence in medicines. In 2017, nearly 7 million euros of falsified medicines were seized at the EU Border. And between 2013-17 four hundred falsification incidents were reported. The successful implementation of the Falsified Medicines Directive with its unique identifier and tamper

evidence seal on each prescription pack is therefore a vital security initiative to improve patient safety within Europe."



## Andreas M. Walter, General Manager European Medicines Verification Organisation, Brussels

"The European Medicines Verification System (EMVS) is now working in all 28 Member States as well as the EEA countries of Iceland, Lichtenstein and Norway. We must remember that this is the biggest serialisation/verification programme

in the world. Yes, there are teething problems but that is to be expected. We now need a period of stabilisation to ensure a controlled application of the National Medicines Verification Systems (NMVS) with a flexible and smooth approach to handling

alerts in close cooperation with the National Competent Authorities (NCA). I am confident and pleased with the tremendous collaboration that has taken place between our EMVO's stakeholders, the authorities and the NMVOs."



## András Süle, Director of Finance, European Association of Hospital Pharmacists, Brussels

"We are pleased to report that all hospital pharmacies in the 29 participating countries are largely ready. There are nevertheless challenges remaining to address the complexities, such as inter-hospital movement of packs and emergency dispensing situations and

integration of the FMD processes into everyday practices. And more urgent engagement by certain national competent authorities and enhanced information on alert handling procedures. In particular we need more engagement by hospital managers, as there is a

clear need to further invest in human resources and in software to ensure decommissioning is as efficient as possible with the clear potential for enhancing stock management, medication traceability and patient level costing solutions to create enhanced in-hospital efficiencies."

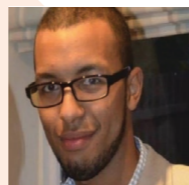


## Aaron Cox, Hospital Pharmacy team, NHS Wales Informatics Service, UK

"Whilst the build process has been long, the All-Wales Hospital Pharmacy System is now successfully communicating with the UK National Medicines Verification System. We are overcoming the challenges for sure. Going forward,

we need to leverage existing IT solutions, smooth the workflows as they vary from hospital to hospital and continue to share go-live experiences. A good example of this was to develop an app to facilitate the FMD process for smaller and

decentralised pharmacies as well as the ambulance service. I am a firm believer in technology to overcome inefficient manual aspects which will undoubtedly provide subsequent revealing data and time saving benefits."



## Patric Mazaud, University Hospital Lille, France

"France is slowly implementing the final stage of the FMD with an amount of difficulties. However, the good news is that some hospitals have a plan in place to implement it and numerous IT solutions are now available. But a clear barrier to implementation is that there is not sufficient support from the French government. This is causing major

financial and technical obstacles, such as no budget allocation and so only a few software solutions being installed. On the other hand, major investment is necessary by the pharma supply chain around digital aggregation. For this, the support of new partners for encryption, security of data recommended by the WG IV<sup>4</sup>, has been achieved in France

but it could be the same for the whole European area. I am confident though if we work even more closely by capitalising on the strong support by the Hospital Managers Federation and pharmacy representatives combined with enhanced support from the Marketing Authorisation Holders and wholesalers, we can overcome these challenges."



## Ana Herranz Alonso, Hospital General Universitario Gregorio Marañón, Madrid, Spain

"The new FMD IT architecture and implementation should provide opportunities to create an agile framework for interconnectivity with existing IT support systems to

allow more efficient warehousing and checking systems with greater visibility and connectivity of patient records, safer compounding, dispensing and administration. All

this will lead to greater security of the medication use process and provide real value to patients."



## Maija Gohlke-Kokkonen, General Manager, Finnish Medicines Verification Organisation

"It is important to note that there have been 3 cases of falsified medicines in to the Finnish supply chain and all were in the hospital pharmacy setting. We have 70 million prescription packs yearly to verify, spread between over 800 privately owned pharmacies and 23 hospital pharmacies with the

support of 6 IT suppliers. Yes, we face challenges of planning, volume, complexity, slow decommissioning and staffing. However, productive solutions will be developed, such as more use of personal digital assistants (already in use by a lot of hospital pharmacies), automatization and warehouse robots. I am

confident that we will see many halo benefits, with increased patient safety, streamlining procedures and utilising the unique identifier to enhance stock management and uninterrupted medicinal treatment processes."

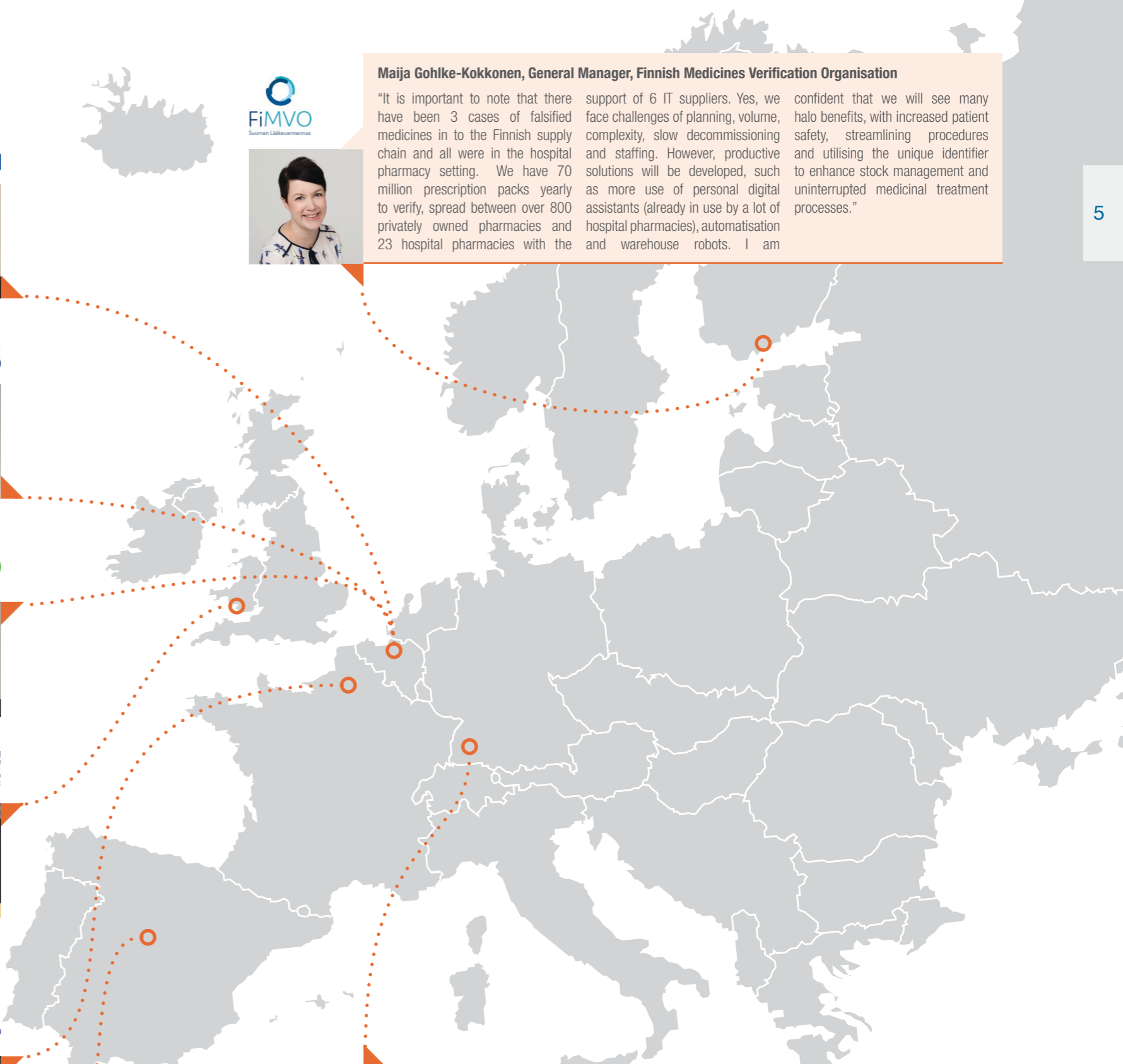


## Martin Hug, University Medical Center Freiburg, Germany

"It is of paramount importance that hospitals work out the additional amount of IT and human resource required. In Germany, the relationship between number of hospital pharmacies and hospitals is roughly 1:5 so almost every pharmacy will decommission for more than one hospital. Based on two years data of our 2,400 bed hospital, we estimate consumption of 1,000 packs per bed per year

or 2.7 packs per day. While this appears high, our pharmacy also dispenses medication for roughly 100 outpatient clinics. Our analysis<sup>5</sup> revealed that an extra resource of 1 to 2 extra staff will be required in a hospital of our size. There will be positive patient benefits notably; protection from falsified medicines, the potential to track and trace on pack level with lot number and shelf life monitoring. On the less

positive side are the complexities of IT connectivity, costs for technical infrastructure and the need for additional staff resources. However, we could demonstrate that utilisation of the electronic shipment advice (ESA) as a container to transmit multiple codes in accordance with section 6.6 of the Q&A document of the EU Commission will ease the process but requires the willingness of the MAHs to provide these codes."



## The Falsified Medicines Directive and the impact on the legitimate supply chain

The manufacture and distribution of fake medicines is an enormous and growing public health risk with an untold cost to lives. Vast profits are made by organised criminal gangs who will use the proceeds to support other criminal activities.

The prevalence of falsified medicines has risen internationally in recent years. A recent report by EUROPOL following a crackdown by law enforcement, customs and health regulatory authorities from 16 countries in Europe has led to 435 arrests and yielded items seized worth in the region of €168 million, including 13 million units and 1.8 tonnes of medicines. 24 organised crime groups were disrupted, and criminal assets worth €3.2 million were recovered. The illicit trade not only covered opioid medicines, but also pharmaceutical products used for the treatment of major illnesses such as cancer and heart conditions, as well as performance and image enhancing drugs.<sup>6</sup>

Evidence shows that consumers and patients are becoming increasingly reliant on, and trusting of, the Internet, which also provides the channel to buy illegally distributed falsified medicines, in the majority of cases by an unaware and unwitting public.

According to the Alliance for Safe Online Pharmacy in the EU (ASOP EU), there are up to 35,000 illegally operating websites that target consumers and patients across Europe. Falsified medicines may have too much, too little or a different active ingredient, may contain poisons, paint thinners and other potential harmful or deadly ingredients. They can also be made in unsanitary or non-sterile environments with unsafe conditions.

Following adoption by the European Council and the European Parliament, the Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011, and applies since 2 January 2013, amending Directive 2001/83/EC.

The Directive introduces harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled. These measures include:

- ★ Obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of prescription medicines
- ★ A common, EU-wide logo to identify legal online pharmacies and a legal obligation by Member States and DG Sante to publicise this
- ★ Tougher rules on import of active pharmaceutical ingredients
- ★ Strengthened GDP and record-keeping requirements for distributors

On 9 February 2019, almost 8 years after its adoption, the final elements of the Directive came into force to introduce an end-to-end verification system; a medicines authentication system which includes mandatory safety features and a repository that stores information on each individual pack.

Hospitals must verify the safety features on prescription medicines (UI and ATD) and decommission the unique identifier before supply to each patient. Considering that hospitals receive large volumes of medicinal products which are administered to the patient at ward level, decommissioning may take place at any time the medicine is in the physical possession of the healthcare institution, as long as no sale takes place between delivery and supply.



The FMD has ramifications for many stakeholders, including market authorisation holders (MAHs), wholesale distributors, parallel distributors and pharmacy dispensers, who are asked to scan medicines at different points in the supply chain to introduce them into the repository, verify their authenticity and decommission them from the database at the time of dispensing.

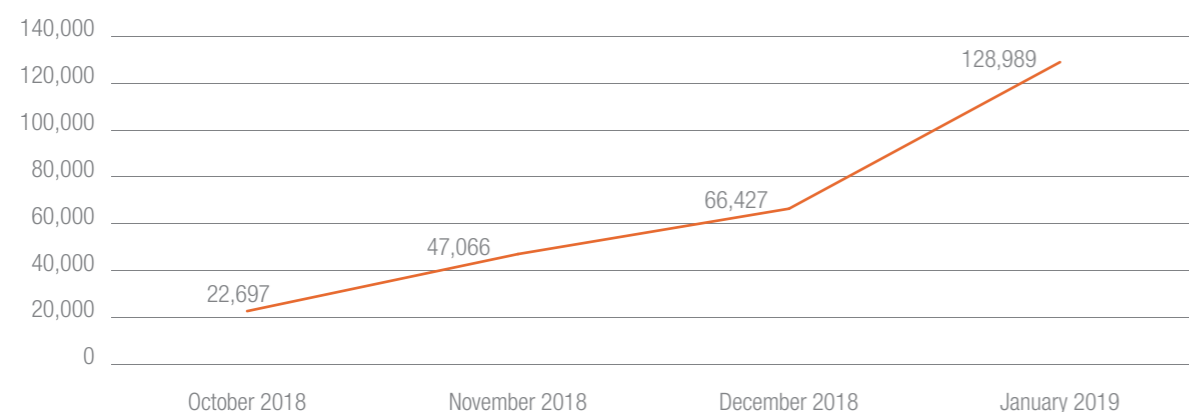
Community pharmacists, hospital pharmacies and healthcare institutions play a critical role and are key to protect patient safety.

“In other words, every pharmacy or hospital in the EU will be required to have a system that will make the detection of falsified medicines easier and more efficient. While some more work will need to be done after the launch of the system to make sure that the new system functions properly across the EU, I am positive that we are providing another safety net for citizens to protect them from the dangers of unauthorised, ineffective or dangerous medicines”, said EU Commissioner for Health and Food Safety Vytenis Andriukaitis. “Since the beginning of my mandate, I have been encouraging national ministers to monitor the implementation of this new system and help all stakeholders prepare for the new rules that prevent falsified medicines ending up in the hands of patients. In the coming weeks and months, the new system will be monitored to make sure that it functions properly”, he added<sup>7</sup>.

## Status of the implementation of the FMD in Europe

There has been much talk about the challenges of implementing a robust process-driven verification system of prescription packs within the hospital settings in Europe. The current status of implementation was summarised by Andreas M. Walter, General Manager at EMVO. He showed a graph that illustrates significant positive trends for the uploading of Master Data with a rapid rise of data inputted from October 2018 of 22,697 to 128,989 in January 2019.

### Uploaded product master data in the system collected on 4 February 2019



He also highlighted the good progress for the onboarding process which are being monitored by various key performance indicators, namely: OBP's on the portal, signed participation agreements, legitimacy check passed, OBPs connected to the hub (PRD & IQE) and OBPs connected to the hub (PRD) who have uploaded data.

There are significant differences amongst Member States regarding the status of implementation within the hospital arena and there is a need for a stabilisation period while maintaining patient safety to ensure a controlled application of the NMVS and an uninterrupted supply of medicines.

***“The European Medicines Verification System (EMVS) is now working with all 28 Member States as well as the EEA countries of Iceland, Lichtenstein and Norway. We must remember that this is the biggest serialisation/verification programme in the world. Yes, there are teething problems but that is to be expected. We now need a period of stabilisation to ensure a controlled application of the National Medicines Verification Systems (NMVS) with a flexible and smooth approach to handling alerts in close cooperation with the National Competent Authorities (NCA). I am confident and pleased with the tremendous collaboration that has taken place between our EMVO's stakeholders, the authorities and the NMVOs.”***

In Finland, the first verification took place in September 2018 and the system is up and running with 99% of end users connected. Maija Gohlke-Kokkonen, General Manager of the Finnish Medicines Verification Organisation, summarised the positive situation as follows:

***“It is important to note that there have been three cases of falsified medicines into the Finnish supply chain and all were in the hospital pharmacy setting. We have 70 million prescription packs yearly to***

***verify spread between over 800 privately owned pharmacies and 23 hospital pharmacies with the support of 6 IT suppliers. Yes, we face challenges of planning, volume, complexity, slow decommissioning and staffing. However, productive solutions will be developed, such as more use of personal digital assistants (already in use by a lot of hospital pharmacies), automatisisation and warehouse robots. I am confident that we will see many halo benefits, with increased patient safety, streamlining procedures and utilising the unique identifier to enhance stock management and uninterrupted medicinal treatment processes.”***

In France, Patric Mazaud, Procurement and Purchasing Manager of the Institute of Pharmacy, Pole Public Health Pharmacy of the Central Counsel of the National Order of Pharmacists in Paris (France), stated that a large majority of hospitals were not ready. However, there is strong support from the Hospital Managers Federation and pharmacy representatives as well as from the French Health Ministry.

In Spain, Ana Herranz Alonso, Assistant Manager of the pharmacy department at Gregorio Marañón Hospital in Madrid, reported that the public hospitals are in the process of updating their technologies with verification usually done at reception of the medicines. She also explained that compounding, automation and warehousing are common practices. An issue they have faced is that of aggregation because every company packs their products differently. Another issue is that compounding and/or administration errors can occur and that with the FMD there is an opportunity for standard product codes and primary labels to be attached to vials to enable better monitoring with subsequent patient safety benefits. This would make it possible to provide greater security to the Medication Use Process in the pharmacy department and to scan medicines at each step of the process.

Aaron Cox, Hospital Pharmacy team, NHS Wales Informatics Service in the UK, emphasised the following

***“Whilst the build process has been long, the All-Wales Hospital Pharmacy System is now successfully communicating with the UK National Medicines Verification System. We are overcoming the challenges for sure. Going forward, we need to leverage existing IT solutions, smooth the workflows as they vary from hospital to hospital and continue to share go-live experiences. A good example of this was to develop an App to facilitate the FMD process for smaller and decentralised pharmacies as well as the ambulance service. I am a firm believer in technology to overcome inefficient manual aspects which will undoubtedly provide subsequent revealing data and time saving benefits”.***

The European Commission is an observer trying to facilitate the discussion between stakeholders as the level of awareness is still not sufficient and so there is a need for more outreach to those involved. To this end, DG SANTE together with the Head of Medicines Agency and European Medicines Agency (EMA) sent a letter<sup>8</sup> in October 2018 to approximately 2,000 marketing authorisation holders to remind obligations of all stakeholders and increase awareness. The Commission has also set up a sub group of Member States competent authorities to investigate possibilities of having a system of data files with suppliers instead of aggregation where they can ensure decommissioning under certain safety checks.

After the current period of stabilisation, the system will be fully operational and will provide benefits. Meanwhile, important challenges need to be addressed, such as procurement of new IT systems, volume of packs, complexity of distribution pathways within the hospital, slow decommissioning, staffing resource issues and planning procedures for in-bound stock.

## Main barriers to the implementation of the FMD

### Human resources

A significant challenge that was recognised at the Parliament meeting was that of the added human resource required. Martin Hug, delegate of the German Society of Hospital Pharmacists had analysed the added workload involved in the authentication of prescription packs that flowed through the hospital. The calculation was based on actual measurements that were taken during two consecutive years. The current estimate for the hours a regular FTE in a German Hospital is working adds up to approximately 1,500 hours per year (this assumes a 38.5 hour per week minus holidays, sick leave and training). However, in order to achieve full compliance, a backup resource was needed and so this analysis recommended a resource of approximately 1 - 2 FTEs. He went on to state that in Germany, the exact number of boxes that needs to be processed per hospital is difficult to ascertain as the relation between number of hospital pharmacies and hospitals respectively is roughly 1:5. This means that every single pharmacy will verify and decommission packs for more than just one hospital.

However, the data presented are more or less representative for the 77 maximum care facilities in Germany.

Martin Hug also provided a methodology to estimate the resource needed in smaller hospitals based on an analysis at the University Medical Center Freiburg<sup>5</sup>.

2.6 million prescription packs per year are dispensed by the hospital pharmacy which covers the needs of 2,400 beds. This results in roughly 1,000 packs per bed per year which equates to 2.7 packs per day. This appears at first sight to be an over estimate but it has to be borne in mind the pharmacy also dispenses medicines to almost 100 outpatient clinics that are not accounted for in that equation (because they don't have any beds). In addition, 10-20% of the packs that are shipped onto the wards will be returned. This work also analysed the time taken to decommission a pack which was found to be 2.1 seconds (median value). However some hospitals may choose to verify the pack on first receipt at Goods in and then decommission at point of dispensing. This would then increase the scanning time to 4.2 seconds. The table overleaf reflects the analysed data with additional projections to enable different human resource calculations to be made.

**Table 1 Additional Human Resource required to decommission prescription packs in the hospital pharmacy**

Based on work carried out at the University Medical Center Freiburg, Germany

Number of packs dispensed by the hospital pharmacy in one year	Time in seconds taken to verify and/or decommission a pack*	Additional month's work	Human resource required as a Full Time Equivalent (FTE)**
2.6 million	2.1-4.2	24 - 48	2 - 4
1 million	2.1-4.2	9 - 18	0.75 - 1.5
0.5 million	2.1-4.2	4.5 - 9	0.375 - 0.75
0.25 million	2.1-4.2	2.25 - 4.5	0.18 - 0.375

\* This analysis included the time taken to verify and decommission a pack in Goods in, IV antibiotics, a normal dispensed pack, an emergency distributed pack and dispensing of narcotics.

\*\* It is worth noting that the people scanning in hospitals are more likely to be pharmacy technicians and stores people, with senior technicians and pharmacists available to make clinical decisions.

It should be noted that taking the average number of packs per hospital (this will of course vary greatly) as approximately 250,000 then this will require an extra 2.25 to 4.5 extra month's work. This is a situation that needs to be further analysed to ensure that a broader picture across Europe is captured. But clearly extra resource is required and the introduction of robotics and enhanced IT will undoubtedly increase efficiencies and reduce decommission time. This is in contrast to the COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT C(2015) 6601 final SWD(2015) 188 final.<sup>9</sup> Here the report maintains "...The costs incurred by hospital pharmacies are expected to be higher than the costs for community pharmacies. Hospital pharmacies currently do not have to scan medicines so they are not equipped with the necessary scanners and software. Total costs needed to buy the necessary equipment are estimated at €2 to 4 million, with costs per hospital pharmacy up to €750 (see Annex 7, page 86). These investment costs are relatively low and will not impact significantly on the total budgets of hospitals." Based on the minimum time of 2.1 seconds to scan a pack in the University Medical Center Freiburg then for an average hospital taking in 250,000 packs per year results in an additional workload of 2.25 months work. If the operatives were being paid 25 euros per hour then 750 euros only pays for 30 hours, barely one week's work.

### IT Connectivity

Another challenge to the implementation of the FMD was outlined by András Süle of the European Association of Hospital Pharmacists who stated that existing IT infrastructure (if indeed it was already in place) was not compatible with the requirements of the FMD and procurement of new scanners was necessary. In addition, it was reported also by Aaron Cox of the UK that the software providers took time to deliver what was required and was not always able to provide all of the solutions in time for a pilot project which led in certain situations to delays in the preparation of the systems. Patric Mazaud observed that software that allows hospitals to connect to the NMVO in many places was still not installed. However recently an agreement has been signed with a major software operation which allows connectivity to the French NMVO.

### Lack of funding and engagement at European, National and Regional level

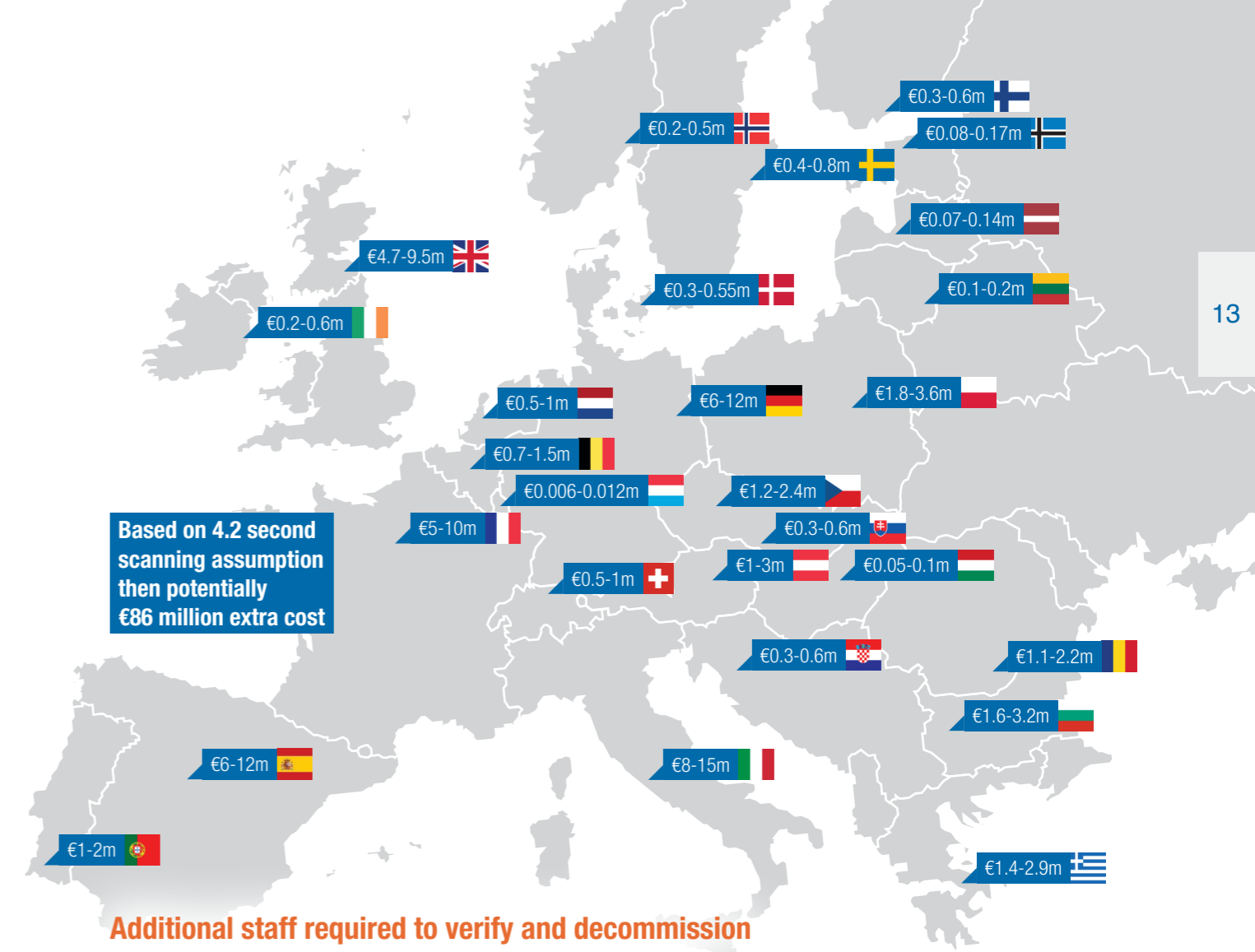
It was established that Member States are facing financial and budget restrictions which are required to fund the planning, preparation and procurement of the IT solutions, in addition to the extra work within a hospital that the FMD will bring.

In France, Patric Mazaud, Procurement and Purchasing Manager of the Institute of Pharmacy, Pole Public Health Pharmacy of the Central Counsel of the National Order of Pharmacists, identified this as being a major barrier.

**“...But a clear barrier to implementation is that there is not sufficient support from the French government. This is causing major financial and technical obstacles, such as no budget allocation and so only a few software solutions being installed. On the other hand, major investment is necessary by the pharma supply chain around digital aggregation. For this, the support of new partners for encryption, security of data recommended by the WG IV, has been achieved in France but it could be the same for the whole European area.”**

András Süle, Director of Finance at the European Association of Hospital Pharmacists, summarised his view as follows:

**“...In particular we need more engagement by hospital managers as there is a clear need to further invest in human resources and in software to ensure decommissioning is as efficient as possible with the clear potential for enhancing stock management, medication traceability and patient level costing solutions to create enhanced in-hospital efficiencies.”**



### Additional staff required to verify and decommission a prescription pack in the hospital environment

Country	FTEs required at 2.1 sec per scan	FTEs required at 4.2 sec per scan
Austria	21	42
Belgium	15	30
Bulgaria	32	64
Croatia	6	12
Czech Republic	24	48
Denmark	6	12
Estonia	2	4
Finland	6	12
France	101	202
Germany	125	250
Greece	29	58
Hungary	10	20
Ireland	5	10
Italy	153	306
Latvia	1	2
Lithuania	2	4
Luxembourg	0.12	0.24
Netherlands	10	20
Norway	5	10
Poland	36	72
Portugal	20	40
Romania	22	44
Slovakia	6	12
Spain	119	238
Sweden	8	16
Switzerland	10	20
UK	95	190



## Integration of scanning and verification in to daily work processes

A major practical issue raised during the debate was the integration of new scanning and verification and decommissioning processes into the everyday workloads of those pharmacists and technicians involved. This required a significant revision of work processes and where robotics were present there was a re-programming need.

Patric Mazaud stated that performing the decommissioning exercise at the point of arrival of the total delivery of packs in to the hospital was currently the preferred time with 75% of hospitals adopting this practice. However, other hospitals were scanning at point of stocking which required an integrated stocking process which was supported by informatics (WMS). Or performing the decommissioning at point of delivery which required an integration of the dispensing process again supported by informatics. There was the need for every pharmacy staff member to be trained and the information technician to be available throughout the planning and implementation as well as an ongoing responsibility. In respect of enhancing the ease of decommissioning hospital deliveries the issue of aggregated packs was raised. Martin Hug suggested a potential solution by using “...**the electronic shipment advice (ESA) as a container to transmit multiple codes in accordance with section 6.6 of the Q&A document of the EU Commission will ease the process but requires the willingness of the MAHs to provide these codes.**” Patric Mazaud suggested a solution that had been put forward by the UNI.HA. whereby the support of new partners for encryption, security of data recommended by the WG IV, which has been achieved in France but it could be the same for the whole European area.

## Opportunities for the future

Despite the significant work undertaken and given the complexities associated with setting up the medicines verification systems across the EU, it is anticipated that a number of opportunities will be forthcoming. Some of these were identified at the meeting:

- ★ Strengthened support from national bodies to ensure alignment and financial support where possible across national health systems
- ★ Communication between stakeholders (from hospital to hospital and allied services; ambulance services etc.) to standardise the processes to ensure that the technology platforms are compatible and fully integrated into existing workflows
- ★ Solid relationship with third-party automation providers and their understanding and cooperation to work out the final optimal approach
- ★ Definition and better handling of false alerts
- ★ A clear and understandable language within the system read outs
- ★ Automated stock management systems to allow for automatic inbound scanning, storage, fetching and outbound scanning, including potential decommissioning of medicinal products
- ★ Automation via robotics and dispensing systems has the potential to avoid manual reading mistakes, decrease patient's waiting times, redeploy staff time, enhance stock control accuracy
- ★ Unique aggregated identifiers for hospitals



# How a medicine's authentication system (MAS) can support the implementation of the FMD

## Austrian study

A study was performed at the Innsbruck University Hospital. This University supplies nearly all regional hospitals in the Austrian Tirol, a total of 16 hospitals. 2.25 million packs are dispensed each year and services 4,898 beds. An analysis of the current operational dispensing time was compared to the additional burden required by the FMD. This showed that for the 80 orders that were dispensed a significant increase in time and workload was experienced as can be seen in Table 2.

**Table 2 Operational dispensing time under normal pre-FMD conditions compared to FMD conditions**

	Time to dispense medicines	Time to dispense medicines in the FMD environment
Hours per day	33.7	60
FTE per 365 days	4.21	7.5

Overall the increased number of FTEs based on processing 112,000 orders over one year equates to 3.5 FTEs or an increase of 78%.

By introducing automation there are systems that can dispense 2,000 - 4,000 packs per hour. Taking the Innsbruck dispensing load of 2.25 million packs per year then with automation a total of 1,125 hours would be required compared to the 3.5 FTEs (or approximately 5,250 hours – this is based on the German analysis of 1,500 hours per FTE described on page 10 of this report). This solution uses an image recognition system for robotic dispensing of packs and would need to run for 4-5 hours a day to accommodate the requirement. Such a solution can be extended to run for longer time periods providing the necessary staff are available to monitor the situation. This study reveals that for a large hospital then automation may provide a solution. The study also points out that an extended study period is required to enable more representative statements to be made.<sup>10</sup>

## German study

At the University Medical Center Freiburg research is ongoing to discover how best to introduce a robotic/automation authentication system namely:

- ★ Verification and decommissioning of numerous packs at Goods in via a one pass conveyor belt and camera bar code identifier
- ★ Verification and decommissioning at Goods out. Here the process is integrated into the picking of the packs. The system is designed to identify the codes at the last step of dispensing. However, these machines are not built to process larger size goods or medicines that need to be stored in a fridge. Which means that you have to employ several systems at the same time.



## Spanish data

The advances in the supply chain that are seen in the Spanish hospital setting are significant. For instance, more than 60% of Spanish hospital pharmacies have automated warehousing systems for inpatients and approaching 10% in the outpatient setting. In addition, 90% of the hospital pharmacies use barcodes at some point of the medication use cycle (currently mainly for dispensing) but an increase from 10.3% is being seen for the process of compounding. These two areas are regarded as the most critical points in patient safety.

Another point of difference in the Spanish hospital supply chain is that 98.6% of medicines are by direct acquisition and delivery from suppliers to the hospital pharmacy.

In terms of volume of packs through the hospital then the average smaller hospital (less than 100 beds) dispenses 1,658 packs day (approx. 600,000 packs per year). For larger hospitals (more than 500 beds) then 2,560 packs are dispensed per day (approx. 900,000 packs per year).

Today around 200 hospital pharmacies are verifying and decommissioning prescription packs. Given that the scanning time is three times longer than before the FMD came in to effect, then it is important that hospitals strive for more resources such as automation to support the flow of medicines to enable hospitals to realise efficiencies along with the inherent value of rich data seems to further enhance process efficiencies.



## UK study

The implementation of an authentication and verification system also has several potential “secondary” implications. A centralised end to end system storing data on all scanned medicines allows for simplified communication between supply chain actors and creates an incredibly rich source of information on how and when patients one and only access and respond to medicines.”<sup>11</sup> This important quote, taken from a study published in Hospital Pharmacy Europe (January 2016) entitled ‘EU FMD hospital pharmacy challenges and opportunities’ clearly highlights the advantages of an authentication system which are summarised below:

- ★ Reduction in wasted, expired medicines and medicine shortages
- ★ Increased opportunities from pharmacist engagement in patient care
- ★ More rapid and lower cost of product recalls
- ★ Reduced personnel time and costs assessing product due to tamper proof seals
- ★ Potential savings due to automated stock control and inventory management
- ★ Opportunities to identify improvements in pharmacy workflow
- ★ Support the monitoring of inappropriate anti-microbial prescribing

## 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:



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