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EDITORIAL

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# The EU Falsified Medicines Directive: key implications for dispensers

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**ABSTRACT**

The EU Falsified Medicines Directive (FMD) mandates the serialisation of prescription-only medicines using a two-dimensional (2D) barcode by pharmaceutical companies and the systematic verification of this 2D barcode in pharmacies. This European directive has ramifications for many stakeholders, including market authorization holders, wholesalers, parallel importers, and dispensers.

Focusing primarily on the impact on UK dispensers, the following questions are addressed in this article: Where should the affected medicines be scanned? and who will pay for the incoming changes to practice? The role of the EU FMD in terms of drug recalls, the preparation required for EU FMD compliance, and the potential for added healthcare value are also discussed.

Dispensers must prepare for the February 2019 EU FMD deadline date by choosing a point within their dispensing processes to scan medicines. Dispensers must also budget appropriately for the incoming costs associated with new hardware and processes.

**Keywords:** Falsified Medicines Directive, Medicine quality, Public health, Supply chain

## Introduction

In May 2017, the World Health Organisation (WHO) adopted the term substandard and falsified (SF) medicine in place of the previously used term, spurious/falsely-labelled/falsified/counterfeit (SFFC). The new term, SF, covers both substandard and falsified medicines. According to the WHO, substandard medicines or "out of specification" medicines, are authorised medical products that fail to meet either their quality standards or specifications, or both (1). Falsified medicines are "medical products that deliberately/fraudulently misrepresent their identity, composition, or source" (1) and exist in illegal international online markets, low- and middle-income countries (LMICs) as well as high income countries (HICs).

It is difficult to quantify the extent or the economic impact of medicine falsification in Europe due to sparse prevalence data. However, there have been many cases throughout Europe where falsified and substandard medicines have been identified in the legal supply chain. Some sources, such as the EU Falsified Medicines Directive (FMD) impact assessment, suggest that 0.005% (2) of medicines in the legal European supply chain are counterfeit/falsified while the European Union Intellectual Property office estimate that fake medicines cost the pharmaceutical industry €10.2bn annually (3). These economic impacts have contributed to the introduction of the EU FMD (4, 5), which involves the serialisation of medicines by manufacturers, and the systematic scanning of the unique identifier (UI) contained within the two-dimensional barcodes by dispensers. When a scan is performed, the product is decommissioned; that is, data on the medicine packet are transmitted to a national database where they are cross-checked against a database of known legitimate products, and is recorded as being dispensed. The information is then sent back to the terminal responsible for performing the scan. The terminal alerts the user to any warnings associated with that product. Warnings may include "medicine not found on the database," "medicine expired," "medicine soon to expire," "medicine recalled," "medicine has been falsified," or "medicine has been previously scanned elsewhere," which should prompt staff to quarantine the affected product. This editorial describes the key implications of the EU FMD on UK dispensers, and covers issues such as improving drug recalls, where to scan medicines, and who will pay for EU FMD changes.

## Drug recalls

The identification of SF medicines in HICs usually results in government-led product recalls. In the UK, there were 11 recalls of falsified medicines between 2001 and 2011 (6), and many more recalls relating to substandard medicines. However, not all SF medicines are identified by government bodies, and even when they are, even the most efficient

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product recall process can never recuperate all examples. In the UK, the current recall system involves email communication from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) directly to healthcare professionals and healthcare organisations. Historically, UK pharmacies or pharmacy departments within hospitals would print the MHRA email and attach it to a noticeboard or place it in the dispensary as a reminder, which results in staff searching for affected batches and having to remember the recall when checking medicines supplied by the pharmacy or brought into the healthcare facility by patients. In recent years, the process has been made more uniform, with pharmacies often documenting recalls and their actions taken, and discussing them in a monthly safety report. Even so, it is still very difficult to conduct patient-level recalls as specific medicine batches are not recorded when medicines are dispensed to individual patients. This gives rise to the opportunity for dangerous recalled medicines to be used by patients. Healthcare professionals currently do not have the data required to make patient-level recalls feasible; this alone puts patients at risk of taking an SF medicine. The EU FMD not only involves the identification of falsified medicines, but also the mandated technological approach must be able to identify to the pharmacist whether or not a medicine is expired or recalled at the point of dispensing to the patient. This will add an extra level of security beyond the current email alert system. Moving beyond this, if configured correctly, hospitals may be capable of attaching this UI serial code to a patient record. This would be a tremendous advantage to public health and would revolutionize the patient-level drug recall process.

## Primary and secondary care

Community pharmacies in Belgium, Italy, and Greece have been scanning medicines at the point of dispensing for many years with apparent success. However, the scanning of medicines in secondary care is a new concept, and each European country operates separately for legal reasons or due to variations in hospital size and the services they offer. Furthermore, primary care and secondary care have different systems for the dispensing, sale, and reimbursement of medicines. A number of key questions will need answering before EU FMD implementation, and two of the most practical and pertinent questions for dispensers relate to the operational impact and cost of implementation; namely, (i) Where to scan? and (ii) Who will pay?

## Primary care

### *Where to scan?*

The EU FMD states that the decommissioning of medicines (scanning) must be carried out at the point of dispensing in the community. Many government bodies have not made it clear if this means the point at which the medicine is dispensed, checked, bagged, or handed out to the patient. Using the UK as an example, authentication at any stage has downstream repercussions for the dispenser (Tab. I). This added step to the dispensing process is sure to disrupt work processes, at least initially, in the UK and European pharmacies.

**TABLE I -** The different stages within a community pharmacy dispensary where decommissioning could occur

| Stage | Advantages | Disadvantage |
|---|---|---|
| Labelling Stage | The terminal used to label the product may be used to perform the medicine scan, relinquishing the need for additional authentication terminals.<br>Unsuitable medicines are identified early in the process. This provides the pharmacy with a better chance of procuring a replacement medicine to satisfy the patients drug order, should the product in stock be identified as SF | Authenticating at this stage may slow down the labeling process by occupying a terminal for a longer period of time. If performed at this stage, this task may be performed by a less qualified member of staff, which may compromise the quarantine process |
| Dispensing Stage | Unsuitable medicines are identified early in the process. This provides the pharmacy with a better chance of procuring a replacement medicine should the product in stock be identified as SF | This staff grade may be less qualified to deal with SF medicines. Decommissioning at this stage may require a financial outlay for additional computer terminals for product decommissioning |
| Checking Stage | SF medicines are identified by highly trained registered professionals. Identification occurs closer to the patient, reducing the risk of adulteration between the moment of authentication and the moment of supply. | SF medicines are identified at one of the last points before supply to the patient. If the medicine is recalled and an alternative product is unavailable, this may cause disruption to patient supply. Medicines that are checked may be placed in storage for up to one month before collection, in which time a medicine could expire or be identified as recalled |
| Handing-Out Stage | Medicines are verified as safe at the final stage before reaching the public.<br>Authentication technology can be configured to send counselling alerts to the healthcare assistant, which facilitates patient education and counselling | Medicines identified as unsuitable for the public at this stage may cause inconvenience to patients if there is no replacement stock available. This step would be carried out by the least qualified staff members, which may increase the inadvertent supply of an SF medicine to a patient. |

SF = substandard and falsified.

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***Who will pay?***

The EU FMD states that manufacturers must pay for the medicines' authentication technology and national databases, but it will be the responsibility of the pharmacy itself to pay for staff education and hardware, such as scanners and additional computer terminals that may be required. Although most dispensers in the UK have scanners within their practice for scanning electronic prescriptions, some dispensers will not and others will require updating.

Mainland Europe differs to the UK as not all dispensers have electronic stock recording systems or patient medication record systems used for dispensing. It is likely that dispensers without an electronic dispensing system or record-keeping system will have to invest in a computer terminal and scanner to facilitate the decommissioning of medicines in compliance with EU FMD regulations. This will be a significant expense for those currently lacking this information technology (IT) infrastructure. Some UK pharmacies may have this infrastructure in place due to the electronic prescribing agenda in the UK, but in busy stores there may be a requirement for additional terminals and scanners.

Where the appropriate infrastructure is not present, there will be financial pressures. This will be in addition to reduced payments to many UK pharmacies from the phasing out of establishment payments (7), a reduction in the global sum (8), and a cut to category M reimbursement (9).

## Secondary care

Hospitals face a similar challenge to the community sector dispensers; however, these challenges are further complicated by the number and variety of companies that supply medicine to hospitals, the complexities of their work, and the diversity of drug movement within the hospital (10). The biggest difference between community and hospital EU FMD requirements relate to the point at which the medicine requires decommissioning.

***Where to scan?***

The EU FMD allows for the verification of a product's unique identifier at any stage of the drug supply chain in any sector. In contrast to the community pharmacy sector, where medicines must be decommissioned at the point of dispensing, the hospital sector is permitted to decommission at any point before dispensing the product to the patient (Tab. II) (4). However, the EU FMD includes an article which explains that all medicines decommissioned can only have their status reverted within 10 days of decommissioning. If medicines are 10 days past the point at which they are decommissioned, then those medicines can only be used within the healthcare institution that they have been decommissioned from and cannot be sold to another organisation. Although there is an option to decommission medicinal products when they are received from suppliers i.e "goods in stage", this would likely require the employment of further pharmacy procurement staff to conduct this exercise. Unless a two-stream product system was created (one stream for wholesaling and one stream for hospital patient requests), this would restrict hospitals that profit from wholesale dealing (e.g., to community hospitals, hospices, or other hospitals) as any medicine decommission greater than 10 days previously would not be permitted to be sold to any other organisation (10).

A study was conducted which identifies the checking stage of prescription processing as one of the most appropriate points in the hospital setting to decommission medicines (11), based on scanning compliance data. The study results explain that checking staff comply with the medicine authentication process a little better than their dispensing counterparts. This, coupled with the reality that all checking staff (accuracy-checking technicians and pharmacists) are trained and experienced with the identification of errors, and are all registered with a professional body (which brings with it the potential for professional repercussions for making errors), makes this a reasonable stage to consider for decommissioning in the hospital pharmacy.

***Who will pay?***

Generally speaking, hospitals will have to pay for the education and training of their staff, the adjustments to workflows, and the purchase of additional hardware to facilitate the EU directive. Each European government is likely to react differently, and it is anticipated that some governments may provide financial support to facilitate compliance; however, this is unlikely. For the most part, the cost of compliance will be shouldered by the pharmacy departments within hospitals in the UK and across the European Union.

## Preparation for the EU FMD deadline

***Verification technology***

Within the literature, there exists a study by Simoens (12), which assessed medicine authentication in the community pharmacy sector and showed that, in practice, the process can be effective. When we consider that Greece, Belgium, and Italy have been scanning medicines for several years, this is not surprising. A study published in 2016 by Naughton et al (11) demonstrates the effectiveness of the EU FMD mandated medicines decommissioning technology in a hospital environment, which assesses the authentication and detection rates. Naughton et al (11) places this research into the general context of health information technology and compares their findings with a systematic review by Shojania et al (13). Naughton explains how the concept of "Active" alerts identified in Shojania et al's study ties in with staff suggestions to add an "Active" alert to the proposed EU FMD technology to improve the detection rate of this approach (14). It is anticipated that the proposed medicine authentication technologies may not be suitable as a one-size-fits-all, and may require a level of customization to suit the different environments that they will be used in; namely, manufacturers, wholesalers, community pharmacies, and hospital pharmacies.

***National Medicines Verification Organisation (NMVO)***

Each EU country must create a not-for-profit organisation called the National Medicines Verification Organisation

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**TABLE II -** The different stages within a hospital pharmacy where decommissioning could occur

| Stage | Advantages | Disadvantage |
|---|---|---|
| Goods In | SF products are identified upon receipt from the wholesaler and issues can be rectified early in the drug supply chain. The decommissioning process is completed without an impact on frontline services | Scanning drugs by workers in the hospital pharmacy stores department would be a new process that may require further staff numbers to carry out the activity. Subsequent to scanning at goods in, medicines may be recalled or expire. As they would not be scanned again before dispensing to a patient, this would increase the risk of supplying a patient with an expired or recalled drug |
| Labelling Stage | As per Tab. I | As per Tab. I |
| Dispensing Stage | As per Tab. I. Also, some hospitals have a process where labels are not produced until the correct medicine is scanned. Incorporating the scanning of the 2D data-matrix at this point adds no additional time to that process while complying to the EU FMD | As per Tab. I |
| Checking Stage | As per Tab. I. Many UK hospitals are familiar with scanning prescriptions at this stage to facilitate prescription tracking in the hospital. Therefore, scanning medicines at the same time could be incorporated | As per Tab. I. Also, hospital dispensaries in the UK largely dispense for the same day and have less flexibility in managing their workload, unlike in community where monthly prescriptions can be dispensed in advance. Scanning drugs as part of the dispensing process may prove burdensome during busy periods |
| Handing-Out Stage | As per Tab. I. As hospitals deal with more specialist and often rarely used medicines supplied to outpatients, it can be difficult to remember counselling advice associated with these medicines. A scan at this stage may generate drug information to remind staff of specific, less frequent used specialist medicines advice. Handing out of medicines within hospitals in the UK is often conducted by accredited checking technicians and pharmacists, thus decreasing the likelihood of exposing less qualified staff to this task | As per Tab. I. Exception, lesser qualified staff do not routinely hand out medicines directly to patients. In addition, patients do not always collect medicines from the pharmacy department. Medicines can be collected by ward-based nurses or porters, which further complicates the process |

2D = 2-dimensional; EU FMD = European Union Falsified Medicines Directive; SF = substandard and falsified.

(NMVO). It is the responsibility of the NMVO to select a verification provider from the two available providers, Arvato Systems GmbH and Solidsoft Reply (15). These companies put themselves forward and were selected by the European Medicines Verification Organisation (EMVO) in 2015 to provide a blueprint system to comply with the EU FMD. This blueprint was developed based on the FMD and feedback from many different European pharmaceutical and healthcare stakeholders.

An NMVO is in place in 26 of the 28 European countries, and many have signed contracts with either of the two medicine authentication providers (16). These providers will work with the NMVO in each country to develop and deploy a national IT system to facilitate medicine verification. Each country will have its own individual database (referred to as the spoke), and this database (managed by the verification provider and overseen by the NMVO) will feed into a central European database (referred to as the hub), which is under the supervision of the EMVO. The verification providers and respective NMVOs have a tremendous task ahead. They are required to load serialized drug codes into the national medicines verification databases, and ensure that the technology is communicating to wholesalers and pharmacies around the EU before February 2019. Noncompliance will not be acceptable, but the deadline for enforcement has the potential to change. In the USA, we observe that the Drug Supply Chain Security Act manufacturer serialisation enforcement deadline date has been pushed back by one year, from November 27, 2017 to November 26, 2018 (17). As EU FMD preparation appears slow, we may yet see the same delay in Europe.

## Added value

The forward-thinking healthcare professional will be glad to know that the EU FMD does not signal all doom and gloom: there is value in the EU FMD. Some hospitals, such as the Oxford University Hospitals NHS Foundation Trust, are interested in getting as much value per scan as possible. These hospitals plan to look at using the proposed system for post-marketing surveillance, patient-led recalls, nurse-led scanning at the point of administration, patient safety, and better stock management. These advantages are important, and if time was in abundance the author would advise that all hospitals strive for these gains (18). Considering the time to compliance is less than 15 months from now, the best that can be expected is an authentication service that is built to facilitate the incorporation of added value in the future. Although the potential advantages and opportunities are unlikely to be implemented across the board in time for the February 2019 deadline, there is no reason why an individual organisation cannot build in "EU FMD value" themselves.

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## Conclusion

The EU FMD was first published in 2011; however, there was not much preparation by hospital and community pharmacies in the immediate years that followed. The road to compliance is now shorter than one would hope, and industry-wide compliance will be difficult before the 2019 deadline. Healthcare professionals can prepare by budgeting for the costs associated with the EU FMD, deciding on where to scan in their organisation and re-evaluating their dispensing workflows to facilitate the added decommissioning step. There may be a delay in the enforcement date, as seen in the USA; however, currently, there is no set plan for an extended deadline; therefore dispensers must aim for compliance by February 2019. Clear guidance to outline the expectations from European government organisations, such as the national medicines regulatory authorities and departments of health, would help tremendously to ensure that compliance is safely reached before the February 2019 deadline.

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