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POINT OF VIEW

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# Fighting counterfeit medicines in Europe: the effect on access to medicines

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**ABSTRACT**

The implementation of the Falsified Medicines Directive, and its Delegated Regulation with detailed specifications of safety features, will provide an additional obstacle for counterfeiters. The implementation of the Directive aims to prevent falsified medicines from reaching patients, and is in the interest of public health. However, the financial burden for manufacturers to implement these additional safety features, as well as the repository system that will allow the verification of authenticity of individual packs of medicine, may threaten the availability of medicines.

**Keywords:** Costs implications, European Commission, European medicines verification system, Falsified Medicines Directive, Generic medicines, Shortages

## Introduction

To counter the risk of falsified medicines, the European Parliament and European Council have released a Falsified Medicines Directive (FMD) (1), which aims at improving patient safety by mandating the marketing authorization holders and manufacturers to put in place a system to prevent falsified medicines from entering the legal supply chain.

In practice, pharmaceutical manufacturers will need to apply a unique identifier (i.e., serialization number) and a tamper verification feature to the outer package of medicinal products. In addition, by February 2019, a European medicines verification system (EMVS) will guarantee the verification of medicines throughout the supply chain and at the time of delivery to the patient. Products included in the scope of the FMD are all prescription products, with a few exceptions specified in the Delegated Regulation (2). The Directive also specifies that the cost of the system will be funded by the manufacturers of medicinal products.

The scope of falsification and counterfeiting in other sectors (e.g., clothing and electronics) is proven to be a problem that is driven by price and demand (3). The same drivers have been identified in the health sector. For example, a Pfizer-sponsored study demonstrated that the counterfeit medicines market in developed countries (which is almost exclusively via the internet) is mainly dominated by so-called "lifestyle" medicines, such as well-known erectile dysfunction and weight loss products, followed by oncology and influenza medicines (4).

In fact, there are very few problems of medicines being falsified in the legal supply chain. The prevalence of counterfeit medicines in the European legal supply chain is estimated to be only 0.005% (5). Establishing a medicines verification system for this very low prevalence is akin to using a sledgehammer to crack a nut.

The upgrading of pharmaceutical packaging lines to apply serialization and tamper verification features will have a huge financial impact on the generic medicines industry. There are 10,000 packaging lines in efficient operation to supply European patients with generic medicines (6). The upgrading of these lines to apply serialization and tamper verification features costs around €500,000 per packaging line (7). As the life-span of this new equipment (hardware and software) on a packaging line is 5 years on average, the application of safety features adds a cost of €1billion per year for the manufacturers of generic medicines. Each year in Europe, 10 billion packs of generic medicines are dispensed (8); the application of safety features on packaging adds €0.10 to the cost of goods per pack of generic medicines. In their impact assessment, the European Commission acknowledges that the financial impact of their legislation may be the greatest for the generic medicines industry and for small- and medium-sized enterprises (SMEs) (9).

At the same time, the industry is currently investing in the establishment of the EMVS, which will allow supply chain stakeholders to verify the authenticity of medicines. Also, the FMD dictates that the repositories system shall be paid for by manufacturers of medicinal products. This system will need to be in place and be operational by February 9, 2019. It will represent a further cost of around €100 million per year for medicines manufacturers.

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Medicines manufacturers are very concerned about these additional costs, which come on top of other existing costs of current regulatory requirements, while at the same time, payers and health insurers are only focused on lowering the prices of medicines. This widening gap on each side will increase the likelihood of medicines being withdrawn from the market as the commercial viability of several products will be brought into question. Shortages of medicines already seem to be occurring more frequently, and the root cause is no longer attributable only to manufacturing disruption; it is now becoming more of an economic issue (10).

However, having a repositories system in place to verify the authenticity of medicines could also create several advantages. More transparency in the supply chain could create more predictability for manufactures to manage their supply of medicines more efficiently; stock management could be improved; and the needs of the market could be addressed more precisely. Therefore, the system could be used in the prevention of medicines shortages.

## The generic and biosimilar medicines industry

Due to an ageing population and an increase in the cost of new innovative medicines, healthcare systems are faced with a significant financial burden, especially in times of budgetary constraints. At the same time, the European Union (EU) is committed to ensuring equal access to appropriate and high-quality healthcare for all European citizens (11).

The generic and biosimilar medicines industry is a cornerstone of healthcare, as 56% of the medicines dispensed in Europe today are generic (12). Generic and biosimilar medicines provide an outstanding opportunity to increase access to essential, safe, and effective medicines, while ensuring the sustainability of healthcare systems.

To support the governments in ensuring access to medicines for patients, while guaranteeing a stable healthcare budget and securing a sustainable future market, more can be done and should be done to increase the use of generic and biosimilar medicines, and to increase the efficiency of healthcare systems. The Organisation for Economic Co-operation and Development (OECD) (13), the European Commission (14, 15), and the European Council (16) have highlighted the importance of the timely availability of generic and biosimilar medicines for healthcare systems. To fully realize the potential of these medicines, European governments should encourage investment in the competitive off-patent pharmaceutical market.

## Cost of placing medicines on a highly regulated market

The off-patent medicines industry suffers from continuous pricing pressure from payers on the one side and increased regulatory cost on the other. Short-sighted and radical cost-containment measures (e.g., external reference pricing [ERP], tendering, payback/clawback policies and discounts), endanger the reliability of medicines supply and, ultimately, patients' health. Since generic medicines only contribute to 2%-3% of the healthcare costs, targeting this segment of the pharmaceutical market with cost-containment measures will only generate marginal savings. In contrast, increasing the use of generic and biosimilar medicines provides a unique opportunity for savings, while generating sustained benefits for all stakeholders over the long term.

Apart from the production cost of a medicine (i.e., the cost of goods sold), the pharmaceutical markets in Europe are highly regulated. Compliance with all these regulations comes with a significant cost. Looking only at the production cost does not fully reflect the truth, as the costs of several activities need to be considered.

- Development costs: The development of a new generic medicine involves several bioequivalence trials. These trials, together with several other development costs, are an important contributor to the total cost of a generic product. In addition, since there is no global development for generic medicines, companies are required to conduct multiple trials to meet different national requirements. For example, a generic medicine approved in the EU must fulfil different requirements to be approved in Switzerland.
- Regulatory costs: The marketing of a generic product can be accomplished only after the submission and approval of a marketing authorization application dossier to the relevant competent authority. The establishment of such a dossier is very resource intensive, particularly in highly regulated markets. In addition, there are many differences in regulatory standards. Navigating this global regulation patchwork has a significant impact on the cost of manufacturing, dossier submission, post-marketing surveillance, etc.
- Quality assurance (QA) costs: The pharmaceutical industry is a globalized industry that relies on supply chains, which are often very complex. To keep oversight of these supply chains and to guarantee the quality of the products manufactured throughout them, global QA and auditing of the various supply chains is very important, and it contributes to costs.
- Pharmacovigilance costs: The regulations relating to pharmacovigilance are becoming more arduous and stringent, and, consequently, more costly, as expensive skilled staff and information technology (IT) systems are required.
- Distribution costs: The regulations relating to supply chain management are becoming more laborious, rigid, and costly, with expensive skilled staff and IT systems required. Authorities impose these conditions on manufacturers to ensure patient safety.
- Legal costs: In a highly competitive market, where generic companies operate, it is very rare for a generic company to enter the market without undertaking litigation, or defending themselves from litigation (usually patent issues). These costs are particularly relevant, especially for the generic sector, and represent a significant burden.
- Cost of capital: Investors expect a return when they invest in a manufacturing concern. In basic terms, the cost of capital is what shareholders and lenders require as a return on their investment. Without profit expectations, very little investment would be available for pharmaceutical manufacturing.

## Costs of FMD

The implementation of the FMD will entail tremendous costs for the industry. This does not only involve packaging line hardware, but also a complete new software system, which will be needed for the serialization. Medicines for Europe has estimated costs for implementing the safety features (Tab. I).

A conservative estimate of the implementation cost will be about €500,000 per packaging line. As the generic medicines industry operates 10,000 packaging lines to supply European patients with high-quality generic medicines, the implementation cost will be €5 billion, or €1billion per year, since the life-span of these features (hardware and software) is estimated to be around 5 years.

This impact on the cost-versus-price ratio of medicines is highest for the generic medicines industry, which is continuously under pricing pressure, and for SMEs, which produce only a low volume of medicines. The added cost for the generic medicines industry is about €0.10 per pack; whereas, for companies placing a smaller volume of products on the market, the cost per pack might be much higher.

However, the European Commission was informed that the impact of this legislation would be contrary to the principle of cost effectiveness and proportionality, and would eventually lead to concentration of the industry, and companies going out of business. Nevertheless, the European Commission has quoted in its impact assessment "According to the impact assessment on the fees on pharmacovigilance (SWD [2013] 234 final), SMEs represent approximately 90% of the marketing authorization holders (MAH) in the EU. The micro enterprises represent 33% of the MAHs within the SMEs category. The European Generic medicines Association (EGA), also confirmed that the sector of generic medicines has a high number of SMEs. Due to their low production volume, SMEs could be potentially more affected by the costs of introducing the safety features than large pharmaceutical companies, which would benefit from economies of scale. However, Directive 2011/62/EU does not provide for exemption from bearing the unique identifier based on the size of the company, or on the classification as originator vs generic medicine, as this could compromise the protection of patients" (17).

**TABLE I -** Cost of FMD implementation per packaging line

| | |
|---|---|
| Laser printing with fume extractor | €90,000 |
| Vision system | €45,000 |
| Rejection system | €15,000 |
| Distribution line down time | Unknown |
| Qualification/validation per line | Unknown |
| Infrastructure costs (site) | €100,000 |
| Installation costs (engineer, technician, etc.) | €50,000 |
| Hardware for anti-tampering feature | €150,000 |
| Software (per line) | €50,000 |
| Total | €500,000 + unknown costs |

## Medicines shortages

### *Economical aspects of shortages*

Cost-containment measures, such as government-mandated price reductions, internal and ERP, and procurement through tendering, undermine the long-term sustainability of manufacturers while increasing the risk of medicines shortages, which ultimately affects patient health. This was also acknowledged by the World Health Organization, which stated that there are more appropriate pricing mechanisms for off-patent medicines than ERP (18). Similarly, most scientific articles reviewing shortages of generic medicines identify cost-containment measures and policies as the underlying root cause (19-33).

Generic manufacturing is a competitive business that aims at having efficient operations to minimize costs and to offer competitive prices to payers. To date, the main focus of healthcare policies around generic medicines has been on cutting prices instead of securing patient access to high-quality medicines. However, the real value of the introduction of generic medicines lies in gaining access to treatment where there was previously an unmet medical need, which leads to improved health outcomes (34, 35).

The most extreme examples of medicines shortages can be found in countries that have disproportionate pharmaceutical pricing policies on generic medicines. In Romania, due to inappropriate cost-containment measures (e.g., clawback tax, ERP, etc.), approximately 2,000 generic medicines have been withdrawn from the market over the last 2 years alone. As a result, Romania has suffered from chronic shortages of essential but inexpensive medicines, such as methotrexate.

Governments should put in place a predictable and sustainable pricing and reimbursement environment that will increase the number of players in the market to reduce the risk of medicines shortages. To ensure that societies continue to benefit from all medicines, including generic and biosimilar medicines, it is important to develop a sustainable market model (36, 37).

### *Increased regulatory costs*

The EU has high regulatory standards in place, which need to be complied with before a medicine can be placed on the market. Governments should consider that enhancing regulatory efficiency and fit-for-purpose regulatory measures can foster greater access to, and availability of, medicines. To increase efficiency and optimize the regulatory processes to reduce the administrative and cost burden of keeping the medicines on the market, regulators should recommend (i) implementing a flat fee structure for variations; (ii) optimizing the use of centralized and decentralized procedures for generic medicines; (iii) increasing flexibility to accept different pack sizes or multi-country packs to address market needs; (iv) increasing the use of telematics tools for the communication of changes currently requiring varied submissions in large portfolios; and (v) lowering fees/costs for older medicines that still serve a healthcare need.

### *Negative healthcare impacts of parallel trade*

Parallel exports from Eastern Europe to Western Europe contribute to availability problems, which undermines public health (38). Slovakia, Czech Republic, and Romania are proposing measures to address medicines shortages caused by parallel exports: if a medicine is at risk of experiencing a shortage, distributors will have to notify the relevant authorities who will decide whether the medicine can be exported.

While parallel trade is a genuine and lucrative business, it benefits from the possibility of buying medicines at extremely low prices. Cost-containment measures in Slovakia have driven medicines prices down, resulting in parallel exportation to countries where these medicines have higher prices. Furthermore, under the umbrella of Article 81 of Directive 2001/83/EC (39), and to avoid medicines shortages, the Slovakian government has issued a legal obligation to manufacturers to supply within 24 hours. In case manufacturers fail to supply, they are subjected to penalties of up to €1 million. The way in which these penalties are applied will lead to disproportionate fines amounting to multiple generic medicines industry sales, which will undermine the sustainability of the pharmaceutical industry and increase the risk of medicines shortages.

## The opportunity

In 2019, the EMVS will be established, which could support authorities and manufacturers in better managing the supply of medicines through managing the information available in the EMVS. The system has the potential to increase transparency in the supply chain. Manufacturers could potentially have information on the number of products that would still be active in the supply chain. This knowledge would lead to better management of manufacturing and supply to the market, and thereby prevent shortages.

However, any additional use of the EMVS depends on the agreement of all stakeholders managing it. These stakeholders are the representatives of retail pharmacists, full-line wholesalers, parallel distributors, and innovative and off-patent manufacturers. While such a telematics system may bring many opportunities that could strengthen the role of the pharmacist in becoming the primary point of care, there is currently no agreement on the additional use of the EMVS.

## Conclusion

Patient health and the availability of high-quality medicines are of the utmost importance to the pharmaceutical industry. The FMD will make it more difficult for counterfeiters to bring falsified medicines into the legal supply chain. Medicines that are considered by the legislation as nonprescription medicines are exempt.

The implementation of the hardware and software to apply safety features and the EMVS will come at a huge cost. Together with other increasing regulatory costs, and payers trying to cut more on prices, the availability of medicines is at risk. Manufacturers will no longer market medicines when they are not commercially viable.

There are multiple causes for medicines shortages, which can be divided into three areas: economic, business, and manufacturing/supply chain (quality issues throughout the supply chain are also included). When medicines shortages occur, patients may not receive their medication and this can result in clinical risks, such as disease progression (40-43).

The root causes of shortages of generic medicines, or the off-patent industry, are different from the causes of the unavailability of new, highly expensive, innovative medicines. While manufacturing issues can occur on both sides of the industry, the generic medicines industry is more sensitive to economic factors and cost-containment measures, and is more dependent on efficiency. While stimulating the uptake of generic medicines could bring sustainability to the healthcare system, payers tend to apply cost-containment measures that will eventually lead to the withdrawal of products from the market, resulting in the unavailability of medicines for European patients.

The industry is now heavily investing in the establishment of the EMVS, and the system could have many additional benefits. For the authorities, it can support access to the system for the purposes outlined in the FMD; the development of the outcome-based healthcare model; and value-based pricing (44). It also delivers the potential for pharmacists to increase their importance as the primary point of care by using the system to implement new services.

Patient safety is key for the pharmaceutical industry, but the industry today only faces the financial burden of the FMD and issues (e.g., drug shortages), which may occur due to the increasing cost. On the other hand, if the FMD brings about the anticipated increased transparency, this may act to reduce such shortages. However, until the FMD is in full operation, this remains to be seen.

## About Medicines for Europe

Medicines for Europe (formerly the European Generic Medicines Association) represents the generic, biosimilar, and value-added medicines industries across Europe. Its vision is to provide sustainable access to high-quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability, and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.

Medicines for Europe member companies across Europe are increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high-quality, effective, generic medicines, while also innovating to create new biosimilar medicines and bringing to market value-added medicines, which deliver better health outcomes, greater efficiency, and/or improved safety for patients in the hospital setting.

For more information please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.

## Abbreviations

| | |
|---|---|
| EGA | European Generic medicines Association |
| EMVS | European medicines verification system |
| ERP | External reference pricing |

| | |
|---|---|
| EU | European Union |
| FMD | Falsified Medicines Directive |
| IT | Information technology |
| QA | Quality assurance |
| SMEs | Small- and medium-sized businesses |

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