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# Update on the serialization process in Europe

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# Update on the serialization process in Europe

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# Final countdown towards the complete implementation of the EU falsified medicines directive

In our two last articles[1], we were discussing the growing EU and worldwide trend for safety features implementation on medicinal productmeant to fight counterfeiting while preserving the patient's safety; in addition to the EU, other countries representing the most important pharmaceutical markets are progressively implementing serialization, each of them with different requirements.

## 1. A general concern against counterfeiting and for patient security

The countdown till the safety features deadline, as introduced by the EU Directive 2011/62[2] on falsified medicines, also known as the "EU FMD", is getting closer. Deadline is fixed as of February 9th 2019 for medicines on the EU market (beyond that date, products will no longer be susceptible of being placed on the market if not compliant). It is to note that a supplemental delay till February 2025 exists for Member States already having their own national system, i.e. Greece, Italy and Belgium, even though Belgium chose to implement the directive no later than February 9th 2019.

As a brief reminder, the FMD implemented specific safety features in order to fight pharmaceutical counterfeiting while preserving the patients' safety in relation to medicine use, and preventing also social security fraud. Each manufacturer willing to sell medicine within the EU market will have to print on each sealable unit a unique identifier, and add an anti-tampering device on the packaging, before it leaves the manufacturer's facilities (i.e. the so called "serialization" process).

## 2. Implying several practical constraints for the supply chain actors

EU FMD 2011/62 has been adopted on June 8th 2011, and we were expecting the European Commission to vote the delegated regulation, as discussed in our last article, to give further clarification on a couple of points for the practical implementation of the aforementioned directive by every participant on the market.

Delegated Regulation 2016/161[3] has been adopted on October 2nd 2015; it clarifies some blackspots, amongst which the technical specifications of the unique identifier, the terms of the safety verification procedure and the national repository system, and details the products covered by the EU FMD. Regarding the unique identifier numbers, they will have to be human and machine readable (in 2D data matrix code, readable by the majority of the existing machines), and will be composed of, several identifiers, like the drug type, the manufacturer code, a unique serial number, and the expiration date of the product.

### Verification all along the supply chain

The verification procedure of the unique identifier and the anti-tampering device will go all along the product life cycle, from its manufacture until its delivery to the patient, even when returning medicine to the wholesaler. This way, everyone in the supply chain will be responsible for ensuring that the medicine issued is genuine. The unique identifier has to be identical to the one registered in national and EU repositories, and still be active. Should one supply chain member notice that the unique identifier corresponds to a deactivated one, or that the anti-tampering device is broken, it shall not deliver the drug, and immediately inform the competent authorities.

### Integrity guaranteed through national and transnational repositories

Data regarding unique identifiers are uploaded in corresponding national repositories, synchronized through the central information and data router European "hub", managed by a dedicated authority called the EMVO. National repositories are managed by nonprofit legal entities created by marketing authorization holders and manufacturers, meanwhile wholesalers and drug suppliers are entitled to participate, on a voluntary and cost-free basis. Costs of the national repositories are borne exclusively by manufacturers of the concerned drugs. Almost all Member States (including non EU members which chose to apply the FMD, such as Switzerland, Iceland, or Norway), already have their national repository system ready. You will find through the attached hypertext link[4] the list of all repositories in place and responsible contacts.

### A need for contractual clarification on the respective responsibilities of supply chain members

Manufacturers will have to place safety procedures on their product packaging, while marketing authorization holders will bear the responsibility of uploading identifiers in the repositories through their "On Boarding Partners".[5] Therefore marketing authorization holders uploading depend on the manufacturer's serialization tasks; that raises some important questions which will have to be clearly outlined in contractual clauses. Sharing of responsibilities will have to be precisely established between the manufacturer and the marketing authorization holder, moreover when the manufacturing tasks are outsourced by the marketing authorization holder, to allow each party to fulfill its obligations in a secured way.

## 3. Beyond the regulation's harmonization effect, national specificities will need to be considered

The purpose of the Delegated Regulation is to unify the serialization requirements within the EU market. However, national specificities may exist. Indeed, the required safety procedures are applicable to prescription drugs only, and some exceptions may exist regarding the products detailed in the Delegated Regulation's annexes; depending on the Member State, one drug can be subject to prescription somewhere while it is not somewhere else. Member States also have the option to expand the scope of the mandatory safety procedures to other drugs if found necessary. Last, the unique identifier may have to bear, in addition to the product code, serial number, batch number and expiry date, a reimbursement code if required by the Member State. All of these national specifications will have to be outlined in each national law where applicable; EMVO released along with its Master Data guide[5], an overview of all coding requirements in EU Member State[5], updated in September 2017[7], giving some useful specifications applicable to multi-market drugs.

Such national differences in serialization implementation make it necessary to keep production lines flexible enough to be able to cope with such national demands while following the EU framework, therefore potentially increasing the manufacturing costs of each box. These costs as outlined in the EU FMD shall be borne by the manufacturer, but, this might be the occasion for a renegotiation of the existing agreements due to substantial economic change. Under French law, all contracts concluded after October 2016 can be renegotiated provided that the alteration of the economic situation was unpredictable, and that the parties did not expressly accept to face it. In this context, we strongly recommend to adapt existing warranty, liability, insurance and termination clauses through the supply chain to anticipate February 9th 2019 under the best possible conditions. ■

1. See PHARMAnetwork magazines n°27 - n°29, 2015
2. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf
3. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf
4. https://emvo-medicines.eu/home/mission/emvs/
5. https://emvo-medicines.eu/wp-content/uploads/2017/08/EMVO_0077_OBP-On-boarding_Guideline_V4.0.pdf
6. https://emvo-medicines.eu/wp-content/uploads/2017/06/EMVO_0122_EMVS-Master-Data-Guide.pdf
7. https://emvo-medicines.eu/wp-content/uploads/2017/09/EMVO_Coding-Requirements-Tracker_201709.pdf

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Cécile Théard-Jallu is a partner at De Gaulle Fleurance & Associés, a French entrepreneurial independent law firm headquartered in Paris, with a recognised experience in all fields of law and a strong international practice, both on transactional and litigation matters for the benefit of private and public businesses, including actors of the pharmaceutical industry.

Cécile Théard-Jallu has developed in-depth expertise as an attorney in private practice representing multinational corporations, including major US and European firms and organizations in the R&D and healthcare sectors. Cecile helps clients on their complex transactions including IT, R&D and consortiums, technology transfers, licensing deals and other technological change related projects. She assists them with their responses to project offers in the R&D and innovation sector in the context of public funding. She also advises them on the structuring of their contractual flows as well as the design, drafting, negotiation and enforcement of their commercial or IT contracts. She is an expert in the field of building and implementing of digital health strategies, including with a personal data focus.

She worked in Washington DC as a seconded attorney in private practice at the law firm Covington & Burling LLP, and was also seconded to a global player in the medical equipment sector. She is a member of the IBA in the Healthcare and Technology practice. Cécile Théard-Jallu is ranked among the Best Lawyers in France in Biotechnology and Information Technology law (ranking published by the US publisher Best Lawyers in cooperation with the French newspaper Les Echos).

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**The authors of this article have published:**

*"Hit the serialization road"* - PHARMAnetwork magazine n° 27

*"Serialization in Europe: a decisive step about to be taken"* - PHARMAnetwork magazine n ° 29

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