What has changed with the new EU Falsified Medicines Directive EU/2011/62?

Logistics without risks or unintended consequences

The EU Falsified Medicines Directive EU/2011/62 will make it more difficult to falsify medicines in the future, but it also presents pharmaceutical manufacturers and logistics service providers with major challenges. Manufacturers have had to adapt their manufacturing processes to the new requirements since February 9, 2019 – the date on which the directive came into force in all member states of the European Union, and suppliers to the pharmaceutical industry are being asked to change their warehouse processes accordingly. This includes using a warehouse management system that not only meets the previous industry-specific requirements, but now also meets the requirements of the Falsified Medicines Directive.

The falsified medicines business is booming. The World Health Organization (WHO) estimates that one in two medicinal products sold on the Internet is not original. Around 25 million illegal tablets, capsules and ampoules, for example, were taken out of circulation in a worldwide campaign in 2017. However, falsified products are also found "offline" in the regular supply chain. In an article for SWR in February 2018, criminal expert Karlhans Liebl reported the results of a survey of pharmacists that he had conducted. In the survey, one in six pharmacists said they had encountered cheap imitations. For the gangs producing falsified products, it is a lucrative business – but the consumers of falsified medicines are taking a big risk, albeit unknowingly. The problem is that no one knows what the tablets, capsules and ampoules actually contain. Anything is possible, from missing or incorrect active ingredients, through pathogens, harmful substances and solvents, to baking powder, chalk and sawdust. In the worst case, taking a falsified product may even be fatal for the consumer.

The EU has therefore declared war on the crime of falsified medicinal products by implementing the Falsified Medicines Directive 2011/62/EU and Commission Delegated Regulation (EU) No. 2016/161, which clarifies the technical and organizational details of implementation. The aim is to prevent falsified medicinal products for human use from entering the legal supply chain, and therefore to protect patients. From February 9, 2019, Directive 2001/83/EC and, most recently, Commission Delegated Regulation (EU) 2016/161 have meant that medicinal products for human use may only be placed on the market if they have specific safety features.

Step 1: Generate a unique identifier

The new safety mechanism consists of a unique identifier and an anti-tampering device. The anti-tampering device refers to suitable ways to seal the product to demonstrate that the packaging of a medicinal product has been tampered with, such as a seal label at the end of the folding box, whereas the unique identifier is a serial number. This involves generating a unique serial number with a maximum twenty-digit sequence of numeric or alphanumeric characters that contain the medical product's product code, batch number, and the expiry date. The pharmaceutical manufacturers are responsible for generating the unique identifier. This procedure ensures that every pharmaceutical sales unit can be uniquely identified and assigned. The data carrier for the unique identifier is a data matrix code. Since February 9, 2019, every manufacturer of medicinal products subject to verification has had to attach this two-dimensional code to the relevant packaging units.

Step 2: Check against the central database

However, the unique identifier and anti-tampering device are only part of the large-scale medical product safety initiative in the EU. To guarantee the authenticity of medicinal products, the unique identifier must be counter-checked when the package is handed over to the patient. A central database is set up for this purpose, where pharmaceutical manufacturers must store their unique identifiers. When a pack of medicine is dispensed by a pharmacy or clinic, the attached code must be

checked in real time against the data stored on the system. If both sets of data match, the unique identifier can be dispensed. The EU talks about an end-to-end verification system. In Germany, the system is set up by the stakeholder organization, SecurPharm.

New directive also has consequences for logistics service providers

The procedure affects logistics service providers with the same status as a pharmacy or clinic. This depends on whether they are the last link in the supply chain before the medicine is delivered to the patient. Logistics service providers who deliver directly to a clinic are therefore legally obliged to run the code check. There are also suppliers who are not legally obliged to run the check, but with customers that require the scanning and checking process as a service. In this case, logistics service providers need scan the unique identifier in a specific logistics process, such as goods incoming, picking or packaging, and check the data, as described, via a web service. If a code turns out to be invalid, the affected package has to be quarantined – even if all that has happened is that the code has not been entered in the database. Companies that deliver goods to a pharmacy, however, are not directly affected by the EU regulation. The reason is that the pharmacy is then the last point in the supply chain. Exceptions, according to securPharm, are returns, distribution in non-EU countries, samples requested by authorities, and the destruction of affected medical products.

Aggregated scanning keeps performance at the same level

In practise, the EU Falsified Medicines Directive means that the warehouse scanner is making a comeback in pharmaceutical logistics. However, affected logistics service providers only have to make minor adjustments to their hardware. Commercially available scanning devices that meet modern standards can usually read a data matrix code. Aggregated scanning is allowed, so logistical processes can still be as effective, despite the additional effort. This method involves generating a master serial number that contains the codes of the individual packages. Logistics service providers then do not have to scan each box of medicine separately, but can enter an entire case with multiple single boxes.

Warehouse management systems therefore need to deliver this aggregated scanning process from February 9, 2019.

Functional scope of warehouse management systems has to be adapted

The Ehrhardt + Partner Group, for example, has responded to the new requirements and can appropriately adapt its LFS.wms warehouse management system, which is used by well-known pharmaceutical companies. In addition to existing functions of importance to the industry, such as serial number handling, best-before date monitoring, batch traceability, multi-order picking and connecting up pharmacy vending machines, LFS.wms can also handle communication with the central database. Communication is necessary to report the unique identifier and check it against the stored code. If an error message is returned, LFS.wms can initiate a process defined by the customer, such as removing the relevant pack of medicine from the flow of goods. The processes managed by LFS.wms are also certified according to the strict GAMP-5 criteria. This ensures that there is no negative impact on product quality, process control, or quality assurance. Logistics service providers therefore actively promote consumer protection by using an appropriate warehouse management system.

The key points of the new EU Falsified Medicines Directive 2011/62/EU

- The aim is to prevent falsified medicinal products for human use from entering the legal supply chain, and to protect patients.
- As of February 9, 2019, certain medicinal products must therefore have specific safety features.
- The unique identifier is a serial number applied to the packaging as a data matrix code.
- The manufacturers of medicinal products must save the unique identifier in a central database, so that the packaging code can be checked against the database.

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Photo captions

Photo 1: **The EU Falsified Medicines Directive EU/2011/62 will make it more difficult to falsify medicines in the future, but it also presents pharmaceutical manufacturers and logistics service providers with major challenges.**

Photo 2: **As of February 9, 2019, certain medicinal products must therefore have specific safety features.**

Ehrhardt + Partner Group

The Ehrhardt + Partner Group (EPG) is one of the world's leading logistics experts and offers a comprehensive solution for all industries in the form of the LFS software suite. LFS as a supply chain execution system is currently in successful use across five continents and allows all logistics processes to be managed and controlled across departments. The globally active E+P Group was founded in 1987 and now has more than 500 employees at 14 locations. More than 60,000 users all over the world use the LFS system for their supply chain management. The features offered by the LFS software suite include everything that is necessary for comprehensive logistics management: The LFS.wms warehouse management system for managing and controlling intralogistics, the LFS.mfc material flow calculator, the LFS.tms transportation management solutions for efficient tour handling and planning, and the LFS.iss international shipping system for processing shipping logistics. Radio data transmission solutions, warehouse planning and -consulting, private cloud and hosting services as well as warehouse seminars conducted at the LFS.academy round out the list of comprehensive solutions provided by the E+P Group. Together with in-depth consulting services for warehouse technology, extensive expert knowledge in the area of warehouse logistics and reliable technical support, this makes E+P a one-stop solution provider. At present, more than 1,000 customers across all industries can be found on our list of references.

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