Patient protection: actively combating counterfeit drugs

The safety and health of patients take top priority at Galenica. To ensure these, the company is actively involved throughout the entire value chain in protection against drug counterfeiting. Galenica is progressively implementing the European Commission's Falsified Medicines Directive, even though it is not mandatory in Switzerland.

Since February 2019, all prescription medication packaging in the European Union (EU) must have certain security features to protect against falsifications. These are, on the one hand, a so-called tamper-evident closure, so that it is immediately evident whether medication packaging has already been opened, and, on the other hand, a Datamatrix code with a unique serial number, which must be checked for authenticity before the pack is dispensed to the patient. This is to ensure that no falsified medicines are distributed.

For several years now, the World Health Organization (WHO), the Organisation for Economic Cooperation and Development (OECD) and the Swiss Agency for Therapeutic Products (Swissmedic) have observed a steady rise of global trade in falsified therapeutic products, i.e. medicines and medical devices. Falsifications not only affect lifestyle drugs such as those for erectile dysfunction or slimming aids but also life-saving products, including cancer drugs and antibiotics, and therefore pose a serious risk to patient health. Due to the strict licensing and authorisation procedures for medicines in Switzerland, the risk of falsified medicines reaching pharmacies or medical practices via official distribution channels is very low. However, the import of falsified medicines by individuals via the Internet is steadily increasing.

At the Galenica Group, all Business sectors face the challenges of protecting against falsification and are taking targeted measures to combat falsified medicines, for example by implementing the new EU Falsified Medicines Directive (FMD).

Ideally equipped for the future

As a pre-wholesaler, Alloga works on behalf of mainly international pharmaceutical manufacturers. As part of a joint project with Galexis, headed by Project Manager and Business Analyst Efkan Sahingöz, Alloga has integrated the EU FMD into its internal quality management and IT systems. New scanners have been introduced to read the two-dimensional Datamatrix code, and the software has been connected to the verification system. "We are getting Alloga ready on a technical level to meet FMD requirements for international partners," says the project manager. "Specifically, this means that Alloga can check the authenticity of pharmaceutical packaging labelled accordingly in Incoming Goods at the request of the pharmaceutical partner. If prescription medicines are returned by pharmacies, hospitals or physicians, Alloga will be able to check each individual pack and, if necessary, deactivate it in the database before the pack is destroyed." A Europe-wide networked database system ensures immediate verification of the medicine's authenticity.

Galexis also introduced new scanners in 2018 and updated its software system. "We are now working on a concept to develop solutions for integrating the new verification activities into our work processes, for example for incoming goods," explains Efkan Sahingöz. In contrast to Alloga, which works on behalf of mainly international partners, Galexis, as a wholesaler, is the owner of the medicines it distributes, and as a Swiss company, it is not affected by FMD. It has therefore not yet fully completed the implementation of the directive. The project manager points out, however, that Galexis is fully prepared to implement FMD entirely if it also becomes mandatory in Switzerland. Galexis would then also be equipped to verify the authenticity of a pack labelled accordingly when medicines arrive from suppliers or have been returned by customers.

Controlled disposal of original packaging

Blistering companies such as Medifilm face particular challenges with regard to falsified medicines and the EU directive. Markus Meier, Head of Medifilm, explains: "We buy medicines in the original packaging, open them and then repack the medications. The trust of our customers is all the more important because medicines are not delivered in their original packaging so they do not have a tamper-evident closure or a Datamatrix code as required by the EU

Falsified Medicines Directive." Medifilm is also implementing the EU directive in full. Medicines with a Datamatrix code can therefore be verified and deactivated in the database system before the original packaging is opened. This means that customers can be certain that only original products are repackaged. To ensure the original packaging can no longer be used, Medifilm carefully supervises the destruction and disposal of all packaging.

Serialisation along the value chain

The graphic shows how FMD affects the value chain of any prescription drug. At the start is the manufacturer who produces the medicine and assigns a unique serial number to each pack. This is printed on the folding box in the form of a Datamatrix code. The information in the code is transmitted to the European database. This makes every pack unique. In addition, a tamper-evident closure is affixed. In the next step, the manufacturer delivers the medicine to Alloga. At the manufacturer's request, Alloga scans the

medicine's Datamatrix code and checks its status. The medicine then goes to Galexis, where it can be checked against the database again if necessary. The next identification check is carried out by the pharmacy assistant when the goods are received by the pharmacy. Final verification takes place before the medicine is dispensed to the patient. The pharmacist also has to deactivate the medicine in the database system after it is sold. Safe dispensing of the medicine is therefore recorded.
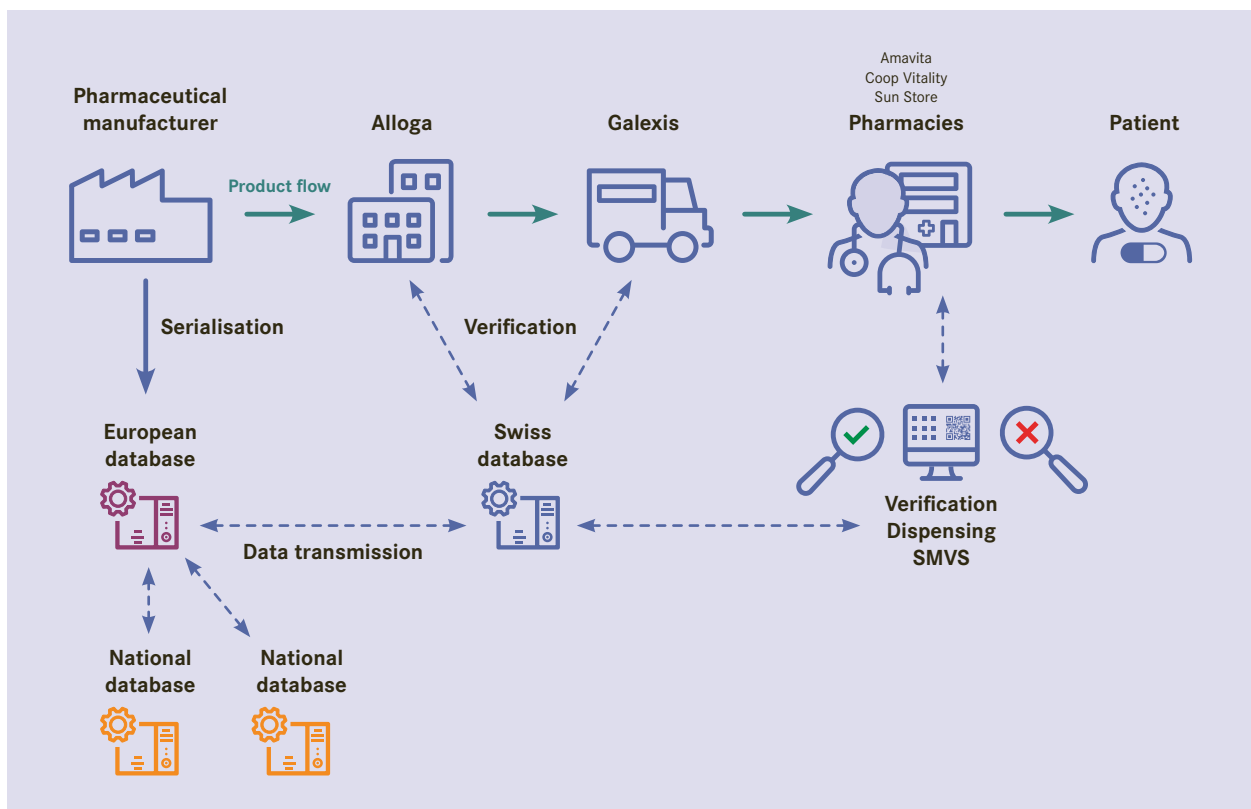
Continuous monitoring of medication effects

Verfora's quality management system ensures that no falsified medicines enter the supply chain. Any suspected cases are thoroughly investigated and documented. "Although we don't sell products that are traditionally targets for falsification, we will implement the required measures to protect against falsification as soon as the EU directive is legally binding in Switzerland. Only one of our products would be affected at present: Algifor® Junior, which requires a prescription," explains Daniel Steck, Relationship Manager Consumer Healthcare at Verfora.

Maximum safety when dispensing medicines

Pharmacies play a key role in patient safety and therefore in implementing FMD. According to the directive, all prescription medicines must be scanned and their authenticity checked by the pharmacist before they are dispensed to the patient. A visual inspection of the tamper-evident closure is also required. Galenica pharmacies are already subject to strict inspection guidelines. "The product number and expiry date of all medicines are checked on delivery and before they are dispensed to the patient. We also check the completeness and integrity of the packaging. If a pack had already been opened, it would be noticed immediately," explains Daniel Hugentobler, Head of Quality at Galenicare.

To further improve safety, Galenica pharmacies are also implementing the EU Falsified Medicines Directive. Daniel Hugentobler explains: "We are currently procuring new scanners for all pharmacies, making the necessary adjustments to our quality management system and training our employees." HCI Solutions has also integrated new functionalities into the Triapharm® pharmacy software to ensure technical compatibility with the national database. To guarantee data protection, only information from the Datamatrix code is sent to the national database. Patient data are only stored locally. Eric Rochat, Process and Security Specialist at HCI Solutions, confirms that data privacy is fully assured with the implementation of the EU directive.

Significant improvement in patient safety

Daniel Hugentobler also points out that in June 2019, all Galenica pharmacies will be ready to check the authenticity of prescription medicines in accordance with the EU directive. But what happens if the authenticity of the medicine is not confirmed during a check? "In this case, of course, the medicines will not be dispensed, and the internal quality unit will be informed so that it can establish the facts," says

Implementation of the Falsified Medicines Directive in Switzerland

Based on EU Directive 2011/62/EU, Switzerland has supplemented the Therapeutic Products Act (TPA) with provisions on safety features (Article 17a). Swiss manufacturers, wholesalers and persons licensed to dispense medicines can implement the new TPA article voluntarily. The Federal Council may, however, declare the article mandatory at any time. By founding the Swiss Medicines Verification Organisation (SMVO), the players in the healthcare sector have joined forces to implement the EU directive on a voluntary basis and to further improve patient protection. The Swiss Medicines Verification System (SMVS GmbH) has therefore been set up to ensure operational implementation of medicine verification in Switzerland and manage the Swiss database. The interests of Galenica are represented by various associations, which in turn are members of the SMVO.

Hugentobler. "Although checking every pack on delivery means additional work for our employees, this significantly improves patient safety. Because it is not just the authenticity of the drug that is checked by scanning the two-dimensional code. The expiration date and the batch number are checked too – and it was previously only possible to do that visually," says Hugentobler.