Your path to securPharm

At a glance for pharmaceutical companies

Strengthening patient protection

In order to protect patients even better from falsified pharmaceuticals in the legal supply chain, almost every prescription drug for human use has had to bear two safety features since 9 February 2019: a unique identifier (in a Data Matrix Code) and an anti-tampering device, e.g. a perforation or a seal. The legal basis for this additional protection is the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) No. 2016/161.

The role of pharmaceutical companies

During the production process, the marketing authorisation holder equips the pharmaceutical package with two safety features. He uploads the dataset of the unique identifier via the EU Hub to the database system of the pharmaceutical industry. This way, he creates the prerequisite for these data to be available in a timely manner, e.g. in a community pharmacy, at the time of dispense. The anti-tampering device is affixed to the pack in accordance with DIN EN 16679. Pharmaceuticals that are subject to mandatory verification and released by the marketing authorization holder after 9 February 2019 can only be sold if they bear these safety features.

securPharm e. V.

securPharm e.V. is the German organisation for the authentication of pharmaceuticals. Pharmaceutical companies connect to the securPharm system via the database system of the pharmaceutical industry. The operator of this database system is ACS PharmaProtect GmbH (ACS).

Your path to the securPharm system

Contracts and contractual partners

- Pharmaceutical companies need to conclude a contract with ACS in order to be able to connect to the securPharm system. The contractual partner is the marketing authorisation holder who markets his products in Germany or who has registered the pharmaceuticals as a supplier with Informationsstelle für Arzneispezialitäten GmbH (IFA). For more information, please visit www.pharmaprotect.de and www.ifaffm.de.
- For reasons of interoperability with other national systems of the EEA and the EU member states, it is necessary that the so-called onboarding partner (OBP) has also fully undergone and completed the technical and contractual onboarding at the EU Hub. The onboarding partner is either the marketing authorisation holder himself or a corporate part that belongs

to the group of companies. The EU Hub is operated by the European Medicines Verification Organisation (EMVO). For more information, please visit: www.emvo-medicines.eu

Legitimation

- In order to obtain legitimate access to the securPharm system, each marketing authorisation holder must undergo a one-time legitimation process as part of concluding the contract. Legitimation is performed by means of a PZN registered to the marketing authorisation holder as well as his (five-digit) IFA supplier (address) number registered with Informationsstelle für Arzneispezialitäten GmbH (IFA). To ensure that legitimation proceeds smoothly, the corporate information stored with Informationsstelle für Arzneispezialitäten GmbH (IFA) (commercial register excerpts, proof of marketing authorisation or manufacturing permits) must be up to date.

System connection

- Connection to the securPharm system: Each marketing authorisation holder whose products must bear the safety features has to upload his pack data to the database system of the pharmaceutical industry (MAH system). It is the task of the MAH system to hold the pack data for the German market in trust and to store them for verification by pharmacies or wholesalers. After the conclusion of the contract, ACS provides the contractual partner with access information for the web portal through which the marketing authorisation holder has local access to the MAH system.
- Connection to the EU Hub: For interoperability, the master data and the batch information of the affected products must be reported to the EU Hub by the onboarding partner. After the conclusion of the contract, the EMVO will provide the onboarding partner with the required access information.

Required data

- The basic prerequisite for the verification process is the complete and timely data transmission to the systems in question, i.e. to the securPharm system (MAH system) and the EU Hub. The product master data and the pack data must be transmitted.
- Product master data: The marketing authorisation holder stores the product master data listed in Article 33 of the Delegated Regulation (e.g. product code, marketing authorisation holder, name, common name, dosage form, strength, package type and package size, etc.) in the EU Hub. For products for the German market, the product code and the MAH ID are compared to the information reported to the IFA.
- Batch master data: The batch master data (batch designation, expiry date, relevant markets) must be stored in the EU Hub. Product master data and batch master data represent the basis for the ability to conduct verifications everywhere in the member states and the EEA states.
- Pack data: Pack data (product code, serial number, batch designation and expiry date) represent the basis for authentication. They must be stored in the NMVS of the relevant

markets. Pack data are exclusively uploaded via the EU Hub, which distributes these data to the relevant national systems. The function of also directly uploading pack data to the German system remains deactivated. As part of the planned harmonisation of the German system with the blueprint solutions in Europe, there are no plans to reactivate this function.

- Parallel importers also upload their pack data exclusively via the EU Hub.

IFA labelling

- The verification obligation for a given product must be reported by a marketing authorisation holder to Informationsstelle für Arzneispezialitäten GmbH (IFA) to ensure that merchandise that is subject to mandatory verification can be recognised by the software systems of the verifying entities (pharmacies, wholesalers). For each PZN affected by the Falsified Medicines Directive, the two so-called verification labels *Verification in mandatory operations after upload date* and *Verification in mandatory operations after expiry date* must be reported. In doing so, the IFA reporting deadlines must be observed. For more information, please visit www.ifaffm.de.

Coding

- Packs for the German market must be coded in accordance with the securPharm Coding Rules. For more information, please visit www.securpharm.de/codierung/.

Responsibility

- The marketing authorisation holder is responsible for the implementation of processes within the pharmaceutical company and the connection to the securPharm system and the EU Hub.

Costs

- The fee model of ACS PharmaProtect GmbH is based on a one-time set-up fee and a fee that is calculated based on annual turnover and the number of packages of the respective company's pharmaceutical that is subject to mandatory verification. Additional information can be obtained from ACS (www.pharmaprotect.de/de/kontakt).

- The costs for connecting to the EMVO must be settled between the marketing authorisation holder and the onboarding partner of the EMVO. For more information, please visit: www.securPharm.de.

Who will advise you?

- For questions regarding the connection to the securPharm system, pharmaceutical companies can contact ACS PharmaProtect GmbH at info@pharmaprotect.de or +49 (30) 577037900.
- For questions regarding the implementation of the Falsified Medicines Directive and the Delegated Regulation, pharmaceutical companies can also contact their trade association, e.g. BAH, BPI, Pro Generika or vfa.
- For questions regarding the connection to the EU Hub, pharmaceutical companies can contact helpdesk@emvo-medicines.eu. The phone number of the help desk is +372 611 90 44.