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 will have to bear two safety features after 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 (DVO).

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 to the database system of the pharmaceutical industry. This is 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 as of 9 February 2019 can only be sold if they bear these safety features.

securPharm e. V.

securPharm e.V. is the German non-profit 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). The securPharm system has been available to pharmaceutical companies for testing of the processes associated with serialisation since 2013.

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 with Informationsstelle für Arzneispezialitäten – IFA GmbH as a supplier. 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 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 IFA supplier number registered with IFA - Informationsstelle für Arzneispezialitäten GmbH. To ensure that legitimation proceeds smoothly, the corporate information stored with Informationsstelle für Arzneispezialitäten - IFA GmbH (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 data transmission to the systems in question, i.e. to the securPharm 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 during a local upload process via the MAH system. 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. The data of multi-market packs can only be uploaded via the EU Hub, which distributes these data to the relevant national systems. The data of packs that are exclusively destined for the German market can currently only be uploaded via the interface of the EU Hub as well. To avoid data inconsistencies, the direct data upload to the MAH system must be terminated transitionally at the end of 2018. It is planned that the direct data upload to the national system will become available again during the first half of 2019. System users will be informed by ACS when the national data upload is available again.
- 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 – IFA GmbH to ensure that merchandise that is subject to mandatory verification can be recognized by the software systems of the dispensing entities, e.g. pharmacies. 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.

Important to know

Scope

- With just a few exceptions, the requirements apply to prescription drugs for human use as well as for omeprazole (OTC) as a hard capsule in two sizes. Via the entries in the public part of the AMIS database, pharmaceutical companies can check whether their product must bear the safety features or is exempt from the obligation. Any required corrections can be reported at 1@bfarm.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/.

Data upload/clearance process

- The most frequent error source is that pack data are not available completely or on time in the MAH system prior to verification and/or dispense of the pharmaceuticals at the pharmacy. This was shown by experience from the testing operation. Therefore, the upload process of pack data should be integrated into the clearance process at the marketing

authorisation holder's place of business and be completed before the pharmaceuticals are transferred to saleable inventory.

Responsibility

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

Costs

- The costs for connecting to the securPharm system via ACS PharmaProtect GmbH are composed of a one-time initial set-up fee and, during the pilot phase, an annual operating fee and the fees per dataset. For a cost overview, please visit www.pharmaprotect.de/de/acs-gebuehrenmodell.html.
- The cost model for mandatory operations from 2019 onward is currently undergoing the final approval process and will be published at www.pharmaprotect.de.
- The costs for connecting to the EMVO must be settled between the marketing authorisation holder and the onboarding partner of the EMVO. https://emvo-medicines.eu/pharmaceutical-companies/

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.