Your path to securPharm

At a glance for marketing authorisation holders[1]

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 marketing authorisation holders

During the production process, the marketing authorisation holder (MAH) equips the pharmaceutical package with two safety features. The marketing authorisation holder shall ensure that the data set of the unique identifier is uploaded to the database system of the pharmaceutical industry via the EU hub. 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.

securPharm e. V.

securPharm e.V. is the German organisation for the authentication of pharmaceuticals. Marketing authorisation holders connect to the securPharm system via the database system of the pharmaceutical industry (PU-System). The operator of this database system is ACS PharmaProtect GmbH (ACS).

Your path to the securPharm system

Contracts and contractual partners

- Marketing authorisation holders need to conclude a contract with ACS in order to be able to connect to the securPharm system. 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

[1] This document deals with the Marketing Authorisation Holder (Zulassungsinhaber) and applies accordingly to parallel importers and parallel distributors as defined in the Delegated Regulation.

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 legitimation process as part of concluding the contract. Legitimation is performed by means of a PZN registered to the marketing authorisation holder and other documents such as commercial register excerpts and proof of marketing authorisation.

Technical system connection

- The marketing authorisation holder must connect to the EU hub either itself or via its OBP.
- For interoperability, the master data and batch information of the affected products must be reported to the EU Hub by the onboarding partner. Details on this can be found in the Master Data Guideline of the EMVO.
- The database system of the pharmaceutical industry (PU-System) will automatically take over the data uploaded by the marketing authorisation holder via the EU Hub. It is the task of the PU-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.

Overview of the required data

- The basic prerequisite for the verification process is the complete and timely data transmission to the PU-System via the upload in 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 of the pharmaceutical, common name, dosage form, strength, package type and package size, etc.) in the EU Hub.
- 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.
- Parallel importers and parallel distributors 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: https://emvo-medicines.eu/pharmaceutical-companies/

Who will advise you?

- For questions regarding the connection to the securPharm system, marketing authorisation holders can contact ACS PharmaProtect GmbH at info@pharmaprotect.de or +49 (30) 4000 484 00.
- For questions regarding the implementation of the Falsified Medicines Directive and the Delegated Regulation, marketing authorisation holders can also contact their trade association, e. g. BAH, BPI, Pro Generika or vfa.
- For questions regarding the connection to the EU Hub, marketing authorisation holders can contact helpdesk@emvo-medicines.eu. The phone number of the help desk is +372 611 90 44.