

European and German organisations for the protection of medicinal products set deadlines for system users

Frankfurt am Main, 24 April 2018 – The development of the European network against falsified pharmaceuticals is in full swing. From 9 February 2019 onwards, prescription drugs may only be circulated if they bear safety features. Pharmacies must verify these safety features before they dispense prescription drugs to patients. To ensure that all market participants can connect to the system on time when it officially starts, the European Medicines Verification Organisation (EMVO) and securPharm e.V. have announced deadlines for pharmaceutical companies for connecting to the protective system against falsified pharmaceuticals.

Pharmaceutical companies are required to start the contractual and technical connection to the protective system no later than by the end of June 2018. This had already been announced by the European Medicines Verification Organisation (EMVO) in January. Since not all companies have concluded the mandatory contract with the operating company of the EU Hub, this will be the only way to ensure that the contractual and technical connection to the protective system can be completed by the effective date of 9 February 2019. Via the EU Hub, the protective systems of the individual EU member states will be connected to form an EU-wide network that is meant to prevent the entry of falsified pharmaceuticals into the legal supply chain.

In Germany, it is securPharm that is building this protective system, with ACS PharmaProtect GmbH (www.pharmaprotect.de) as the operating company for the database system of the pharmaceutical industry. Since 228 pharmaceutical companies have already connected to the system in Germany, securPharm is able to set a shorter deadline than the European operating organisation. For contracts concluded by 30 September 2018, securPharm guarantees via ACS PharmaProtect that system access can be made on time as of 9 February 2019, provided that all contractual and technical prerequisites are met. As a result, securPharm is able to promise a timely connection until up to four month prior to before the implementation date.

The objective of the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) No. 2016/161 is the protection of patients from falsified pharmaceuticals in the legal supply chain. To accomplish this goal, the existing regulations and controls are supplemented by mandatory technical solutions. Starting 9 February 2019, pharmaceutical companies may circulate only prescription drugs bearing an individual serial number (used by the securPharm system) and an anti-tampering device to show that the package is intact. However, pharmaceuticals released into

circulation before this effective date may still be dispensed without the safety features until their expiry date.

About securPharm e.V.:

securPharm e.V. is a nonprofit stakeholder organisation that develops the authentication system for prescription drugs in Germany pursuant to the requirements of the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) No. 2016/161. The objective is to protect patients from falsified pharmaceuticals in the legal supply chain in Germany. securPharm e. V. is sponsored by the following associations of the pharmaceutical companies, wholesalers and pharmacists: BAH, BPI, vfa, PHAGRO and ABDA. securPharm has the goal of providing a system by the due date of 9 February 2019 that can be used by all market participants. securPharm sees itself as the German component in an EU-wide network working against falsified medicines.