

Press Release

securPharm e.V.

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Sprint to the finish line: Only one more year until the protection from falsification for pharmaceuticals becomes effective

Frankfurt am Main, 8 February 2018 – In one year only, the new protective system for pharmaceuticals will go live. Any pharmaceutical packs that are released by manufacturers from 9 February 2019 onward must bear safety features, which are verified by pharmacies prior to dispensation in order to protect patients from falsified pharmaceuticals even better. While securPharm e. V., the organisation that develops the system for the authentication of pharmaceuticals in Germany by means of a safety feature, is satisfied with the progress made last year in setting up the system, numerous market participants have yet to connect to securPharm.

The protective system for prescription drugs must be set up in most member states of the European Union as well as the countries of the European Economic Area by 9 February 2019. The core elements of the system are the use of packages with an anti-tampering device and labelling each pack with an individual serial number. The securPharm system ensures that this number can be checked for authenticity prior to the dispensation of each pharmaceutical pack. "We are absolutely on target with the set-up of the new protective system," said Dr. Reinhard Hoferichter, spokesman of the Board of Directors of securPharm e. V.

securPharm is already connected with the European hub, which enables the data exchange between the protective systems of the participating countries. But even independently of the fact how many countries are connected to the hub as of the effective date, the securPharm system will improve patient protection in Germany.

"The construction of a European network against falsified pharmaceuticals is a great challenge for all participants, which the system users can only master by connecting early and by conducting a corresponding training phase," said Hoferichter. Therefore, the securPharm system was available to users as early as 2013.

The users of the securPharm system are pharmaceutical companies, wholesalers, pharmacies and hospitals. The need to connect to the system in order to exchange data for the legally required authenticity check of pharmaceutical packs based on an individual serial number. "In 2017, we were able to observe that the complexity of conversion and the resulting need to take action were largely understood by the pharmaceutical sector," said Hoferichter. In 2017, more pharmaceutical companies than in previous years concluded a contract with securPharm. Currently, 200 pharmaceutical companies are on board, but numerous ones are still missing. "We recommend that companies, which have not yet set the course for affixing the safety features, absolutely

do this now, otherwise things could get tight for individual manufacturers,” Hoferichter added.

The connection process of community pharmacies and wholesalers is gaining momentum as planned. “The only situation we are watching with concern is the connection of hospitals,” Hoferichter said. “So far, only one hospital has connected to securPharm and tested working with the system. There is great time pressure there.” However, the responsibility for connecting lies with the users. “We will not relent and continue to point out how important it is to connect to the system in a timely manner and to test the processes of authentication to ensure that not only the system works smoothly on 9 February 2019, but also that all users will have connected.”

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. For this purpose, the existing regulations and controls are supplemented by obligatory technical solutions. From 9 February 2019 onward, pharmaceutical companies in Germany may only release prescription drugs that bear an individual serial number (used by the securPharm system) as well as an anti-tampering device that shows whether a pack is intact. However, pharmaceuticals released prior to that 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.

For more information, please visit: www.securPharm.de.