Press Release

securPharm e.V.

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Falsified Medicines Directive:
New safety features for pharmaceuticals to arrive in three years

Frankfurt am Main, February 9, 2016 – Today, the Delegated Regulation (EU) 2016/161 regarding the implementation of safety features on prescription drug packages was published in the Official Journal of the European Union. This marks the start of the three-year implementation period for all participants in the pharmaceutical supply chain. From February 9, 2019 onward, only prescription drugs that bear an individual serial number and whose intactness is clearly recognisable can be circulated in Germany.

“This is an important day for patient protection,” said Dr. Reinhard Hoferichter, spokesman for the board of directors of securPharm e. V., the stakeholder organisation, which is establishing a system for the authentication of pharmaceuticals in Germany. “Germany will continue to remain among the most secure markets for pharmaceuticals in the future. Starting now, the clock is ticking in terms of the implementation of these safety features.”

The objective of the Falsified Medicines Directive and the Delegated Regulation, which was published today, is patient protection. This will be accomplished with the new safety features to protect the legal supply chain against being penetrated by falsified pharmaceuticals. The Delegated Regulation complements the 2011 Counterfeit Medicines Directive with technical and organisational details for the implementation of the safety features.

The Delegated Regulation confirms the securPharm system in its cornerstones, such as the implementation by the national stakeholder organisations, the Data Matrix Code as data carrier, separate databases for pharmaceutical companies and pharmacies and an end-to-end verification system. For the end-to-end system, the pharmaceutical manufacturer generates the individual serial number during production of the pharmaceutical that renders each package unique and that will be verified in terms of its authenticity by wholesalers and pharmacies in the future. As of February 2016, more than 21 million packages have already been uploaded to the securPharm system.

While the requirements of the Delegated Regulation published today take into account the processes of the individual trade levels and identify pragmatic solutions, they also confront the **pharmaceutical companies** with technological and economic challenges. Management of the serial number, from generation and printing on the packaging to the successful transmission to the database, requires an adjustment of IT solutions and processes within the company.

Pharmaceutical wholesalers also play an important part in securing the legal supply chain. According to the Delegated Regulation, they are supposed to verify all pharmaceutical packages that are not supplied directly by the pharmaceutical companies or on their behalf. As a result, a wholesaler will authenticate each pharmaceutical package he purchases from another wholesaler or receives as a return from a pharmacy.

In many respects, the requirements of the Delegated Regulation published today take into consideration the day-to-day business of a **pharmacy**. For example, the Data Matrix Code includes the batch number and the expiration date, which can now be scanned together with the Central Pharmaceutical Number (PZN). In addition to the mandatory authenticity check prior to dispensing a pharmaceutical to the patient, pharmacists now also have the opportunity to check the package at goods in process. This has various advantages for pharmacists, e.g. the regular entry of batch number and expiration date into the merchandise management system and the clear assignment of non-dispensable pharmaceuticals to the supplier in question. Furthermore, the Delegated Regulation includes suitable deadlines for everyday business with regard to pharmaceuticals that were already booked out of the system but have not yet been dispensed. Within 10 days, a pharmaceutical can now be booked back into the system if it has remained in the pharmacist's possession. The speed of the data storage system for authentication has also been clearly stipulated. It must enable pharmacists to perform their job activities without significant time delays.

About securPharm e.V.

securPharm e.V. is an initiative to protect patients from falsified pharmaceuticals in Germany's legal supply chain. It is sponsored by a consortium of the following pharmaceutical companies`, wholesalers' and pharmacists' associations: BAH, BPI, vfa, PHAGRO, and ABDA.
Since 2011, securPharm e. V. has been developing a protective system from falsified medicines in compliance with the requirements of the EU Falsified Medicines Directive 2011/62/EU. This system has been tested in practice since 2013. The findings derived from testing are directly used in further system development. This unique collaboration of all stakeholders in the pharmaceutical supply chain makes it possible to optimally tailor the system to the business processes of all parties involved from the outset. One important element of securPharm is the use of separate databases for manufacturers and pharmacists in order to maintain the greatest possible data privacy for patients. Today, securPharm is the leading system in Europe for the implementation of future legal requirements regarding the authenticity verification of pharmaceuticals. It is the objective of securPharm to provide a system that can be used by all market participants when the Falsified Medicines Directive becomes effective.

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