securPharm

STATUS REPORT 2017

Status of the project to implement the
Falsified Medicines Directive

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.

This status report is available in German and English and can be requested at info@securPharm.de.

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1. Introduction

With Directive 2011/62/EU, the so-called Falsified Medicines Directive, the European Union has defined principles for preventing falsified medicinal products from entering the legal supply chain. These principles pertain to the verification of pharmaceuticals at the package level and the ability to ascertain their integrity. With the publication of the Delegated Regulation (EU) 2016/161 on 9 February 2016, which includes the technological and organisational requirements for implementing the Falsified Medicines Directive, the legislative process has come to an end. Pharmaceutical companies, wholesalers and pharmacies now largely have clarity regarding the technical and organisational details they will face during the implementation of the directive as well as the mandatory time horizon for implementation. In this respect, the Delegated Regulation confirms securPharm in its key cornerstones.

The German stakeholders have prepared for the implementation of the Falsified Medicines Directive early on. As early as 2012, the ABDA, BAH, BPI, PHAGRO and vfa established the securPharm e.V. organisation in order to set up the German verification system and to demonstrate how the verification requirements can be implemented in an efficient, industry- and pharmacy-friendly manner that is also viable for all parties involved in the pharmaceutical market.

1.1 Project context and limits

It is the objective of securPharm to provide a national verification system that can be used by all market participants in Germany. Since 2013, pharmaceutical companies, wholesalers and pharmacies have been able to use securPharm and practice their own processes. The securPharm project operates under real-life conditions of the German pharmaceutical market and takes into account the diversity of pharmaceutical companies, pharmacy software and pharmacy supplier relations.

The system, which was started four years ago as a pilot project, has been continuously improved and expanded since then. In this phase, the participants in the pharmaceutical supply chain can practice and further optimise their own processes, thereby optimally preparing for 9 February 2019, which is the date on which the requirements of the Delegated Regulation shall apply.

1.1.1 Delegated Regulation

The EU Commission submitted the final version of Delegated Regulation (EU) 2016/161 amending Directive 2001/83/EC to the European Parliament and the Council in October 2015 (referred to in abbreviated form as the "Delegated Regulation" in the text below). On 9 February 2016, it was published in the Official Journal of the European Union. As a result, the legislative process for the Delegated Regulation is concluded. The date of publication also started the implementation period of three years. At that time, the requirements of the Delegated Regulation must be fully implemented.

Starting 9 February 2019, only prescription drugs bearing an individual serial number and whose integrity is visibly recognisable may be circulated in Germany. Packages that were released for sale or distribution prior to this date (Article 48) are not limited in their marketability until their expiry date, even without the safety features.

Following an intensive review of the Delegated Regulation, we find securPharm well prepared. Overall, the Delegated Regulation confirms the securPharm system in its key cornerstones, such as implementation by a stakeholder organisation, end-to-end verification with risk-based checks by wholesalers, the Data Matrix Code as data carrier, parallel usage of two coding variations and separate databases for pharmaceutical companies and pharmacies.

The content of the Delegated Regulation creates clarity in a variety of respects as to how pharmaceutical companies, wholesalers and pharmacies must implement the requirements. However, there are still some unclarified details. In its dialogue with market participants and in the Q&A with the national and international authorities, securPharm makes a key contribution to clarifying open questions.

With a separate position paper entitled "Jointly for more safety in the pharmaceutical market", securPharm accompanies the implementation of the Delegated Regulation and promotes knowledge transfer between the parties involved.

1.1.2 Required safety features

The Delegated Regulation requires two safety features for all pharmaceuticals subject to verification and marketed after 9 February 2019 that are to be sold in the EU member states. The unique identifier represents the basis for authentication. It is a randomly generated serial number in connection with the product code in question, which renders each package unique.

Furthermore, the Directive requires an anti-tampering device, which facilitates verification as to whether the outer packaging of a pharmaceutical was manipulated. This safety feature must be implemented independently by each pharmaceutical entrepreneur. In order to create a joint and reliable basis for the manufacturing industry, specialists from industry, associations and government agencies have developed a uniform European standard under the umbrella of the German Institute for Standardisation (Deutsches Institut für Normung - DIN) and the European Committee for Standardisation (CEN) with the DIN EN 16679.

1.2 Key factors for project success

1.2.1 Stakeholder associations

It is the task of stakeholder associations to represent the interests of their members to the political arena and the public. As a result, they take opposing positions towards each other at times. The key insight is that opposing interests are inappropriate in view of the significance of patient

protection and the scope of the task at hand. What is important is to prove to both the public and the political arena that the associations can and will jointly assume responsibility for a safe pharmaceutical supply.

Upon closer scrutiny, it becomes apparent that it is not just pharmaceutical companies, wholesalers and pharmacists who are affected by the Directive but also a variety of others who are involved in the handling of pharmaceuticals. Therefore, it is necessary to describe their tasks precisely as well and to take into account their interests. In forming a stakeholder association to implement the Falsified Medicines Directive, the middle ground between the involvement of all stakeholders and everybody's ability to work must be found. Stakeholder associations that are not a member of this organisation must be credibly assured that their interests will be taken into account through the establishment of appropriate working groups.

1.2.2 Sequence of steps

The sequence of steps chosen by securPharm is tried and tested:

- Establishment of the securPharm stakeholder organisation as a non-profit organisation;
- Attraction and involvement of experts;
- Agreement on objectives and rules as part of a memorandum of understanding;
- Development of a working plan and budget, including start-up funding;
- Review of national conditions, including the
  - Availability of master data (see 1.2.5);
  - Availability of an internationally usable product number (see 1.2.6);
- Establishment of operating organisations;
- IT provider selection and implementation of the systems;
- Organisation of the collaboration with the national authorities in charge;
- Reporting operations pursuant to Article 37 (a) of the Delegated Regulation.

1.2.3 Organisational structure

With Directive 2011/62/EU and the associated Delegated Regulation (EU) 2016/161, the European Parliament and the Council have created the framework to be monitored by the national supervisory authorities. Based on this system, the founders of securPharm have decided on a three-level structure.

1. securPharm creates the prerequisites for implementing the Falsified Medicines Directive in Germany, describes the rules, organises the procedures and resolves conflicts. The latter includes that securPharm will operate a conflict management system (CMS) for documenting and settling any type of unexpected event during the verification of medicinal packs.

2. The operation of certain components is assigned to operating companies. The legal operators of the database of the pharmaceutical industry (ACS PharmaProtect GmbH) and the pharmacists' system (Avoxa – Mediengruppe Deutscher Apotheker GmbH) in turn commission the technical service providers that install and technically operate the required databases.

3. arvato Systems GmbH has already been commissioned to serve as provider for the pharmaceutical industry database.

In this respect, the national authorities in charge assume a special role. They are responsible for system oversight and check that the requirements of the Delegated Regulation and the Falsified Medicines Directive are met.

1.2.4 Data ownership and privacy

Experience from other projects such as the electronic patient file has shown that special attention must be paid to data ownership. Based on this experience, the concerns regarding data use for other purpose than the intended one by unauthorised market partners and the knowledge that data are already being used for advertising in other EU countries, the German stakeholders have first addressed the issue of data ownership. They agreed to store and manage the data of the pharmaceutical

companies and those of the pharmacies in physically separate databases. As a result, data ownership is organised clearly and in a manner that is understandable for everybody.

1.2.5 Centralised management of national master data

As early as 1967, the German stakeholder associations decided on the central management of master data for the products in demand at German pharmacies (both pharmaceuticals and non-pharmaceuticals). This marked the birth of today's IFA (Informationsstelle für Arzneispezialitäten). It is the organisation that assigns the classification code known as "Pharmazentralnummer" (PZN), which is without exception used by all market participants handling pharmaceuticals. The centralised assignment of the PZN guarantees its uniqueness as a classification code. If the assignment of product identification numbers is left to the pharmaceutical companies in other countries, the uniqueness of product numbers cannot be guaranteed, at least while there are no centrally stipulated rules and the implementation of rules is not centrally monitored.

Apart from data quality, centralised management of master data that relates to one member state and centralised assignment of product numbers offer another key advantage: While the product number is assigned to one specific product and pharmaceutical company, it need not contain a reference to the pharmaceutical company. This information can be flexibly looked up in a centrally managed database. As a result, a product number can be preserved even if the product's licence is sold. The party subsequently responsible for the old merchandise can be ascertained clearly at any time with the help of the centralised database.

1.2.6 Use of national product numbers in an international system

Just like the PZN in Germany, national product numbers are also used in other European countries. In this respect, they represent a national standard that could only be modified at great expense to all market participants, and they may even be governed by national law. For example: The extension of the German PZN from seven to eight digits was only feasible after 10 years of discussions and a technical lead time of three years. The complete exchange of a national product number system must therefore seem futile.

A possible alternative are container systems that envelop the national product number, i.e. preserve it for national use, and provide supplementary data to guarantee international usability. Since only one system was known in the past (NTIN by GS1) and GS1 individually decides on the use of the NTIN for each user nation, securPharm commissioned IFA with the development of its own container system – the Pharmacy Product Number (PPN). Since 2013, it has been globally available free of charge and is based on ISO/IEC. Since then, its applications have been extended from printing/labelling retail packages to tagging outer packaging, pallets and shipments. It can be used for multi-market packs and as UDI for medicinal products.

1.2.7 Reporting operations pursuant to Article 37 (a) of the Delegated Regulation

For each EU member state, there is to be a National Medicine Verification Organisation (NMVO) in the future that will establish the authentication system for pharmaceuticals subject to verification and connect it to the EU hub. To the authority in charge, securPharm has already declared its intent in terms of Article 37 (a) of the Delegated Regulation to physically set up the repository in conjunction with the systems of the pharmacists and pharmaceutical industry in the territory of the Federal Republic of Germany. This ensured early compliance with one of the key reporting obligations of securPharm as the legal entity in charge regarding system operations.

2. Coding agreement

2.1 General

Pursuant to Article 4 of the Delegated Regulation, the unique identifier includes the following data elements:

- Product code;
- Serial number;
- Batch number; and
- Expiry date.

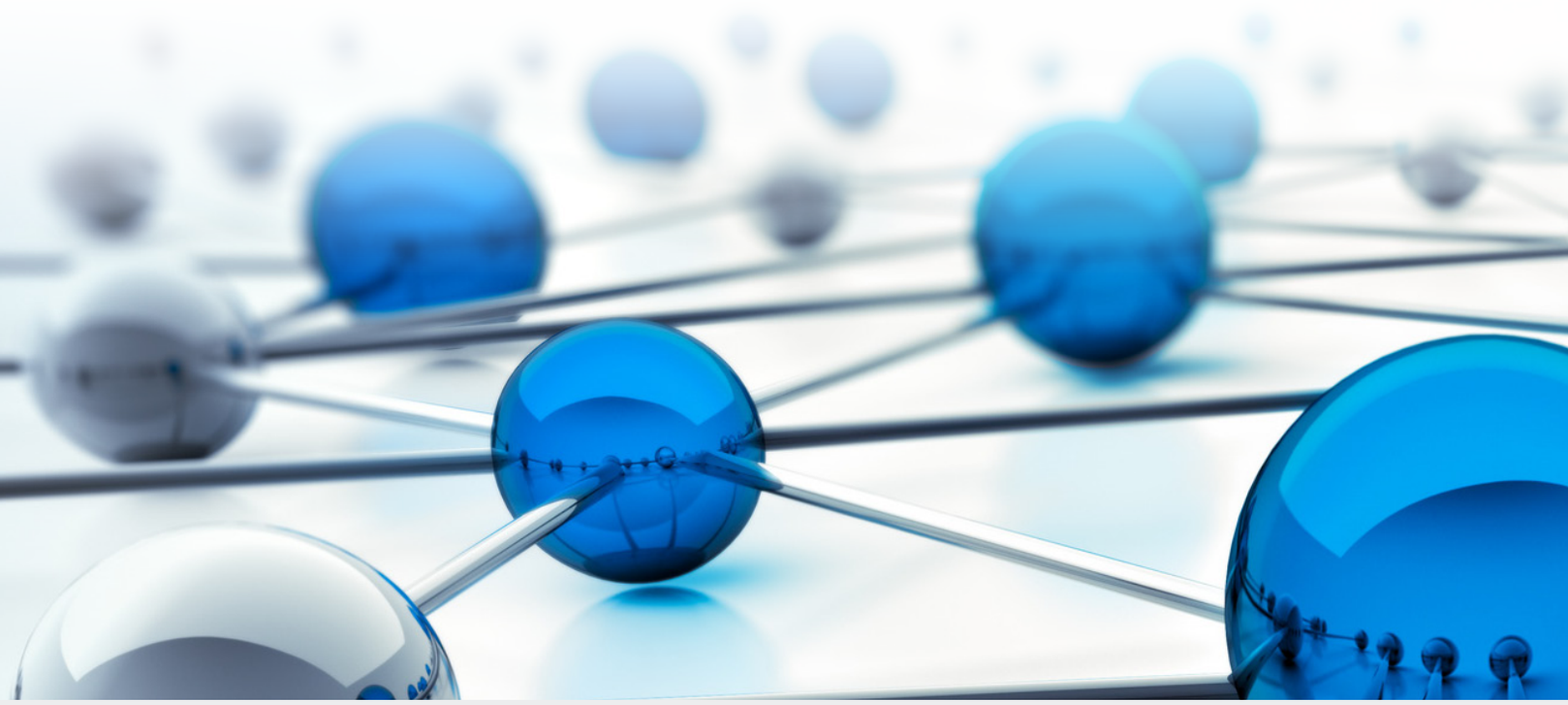
The national reimbursement number is mentioned as an additional element in Article 4. For pharmaceuticals meant for the German market, this number is already included in the product code in the form of the PZN and therefore need not be listed additionally. As a result, there is no so-called fifth element as far as Germany is concerned.
Coding is done in the Data Matrix Code in accordance with ISO/IEC 16022. This ensures that these data elements are machine-readable and form the technical prerequisite for implementing the EU Falsified Medicines Directive and additional expected legal requirements for the verification of pharmaceutical packages.

At the same time, the requirements from Article 5 of the Delegated Act ("Carrier of the unique identifier") are met.

2.2 Coding rules

For verification within the meaning of Article 4 (d) of the Delegated Act, an unambiguous product code on a Europe-wide scale is needed. To meet this requirement as well, the Pharmacy Product Number (PPN) and the National Trade Item Number (NTIN) were created, which are generated from the eight-digit PZN. The pharmaceutical company can choose between two above-mentioned product numbers while taking into account the respective licencing conditions. Existing databases and software systems can algorithmically generate a PZN from the PPN/NTIN or a PPN/NTIN from the PZN. For the retail segment, the PZN will remain the relevant product number and it will continue to be used for reimbursement. As a result, existing processes will be preserved without change.

The two-dimensional Data Matrix Code in accordance with ISO/IEC 16022 must be used as symbology for the data container. It has excellent characteristics regarding data density, data volume, geometric scalability and robustness. Additional rectangular versions of the Data Matrix Code in accordance with DIN 16587 (see www.dmre.info) make the packaging design easier. Pursuant to Article 5 of the Delegated Act, the coding rules generated by securPharm allow coding of information in compliance with the ASC format described in the IFA specification as well as the format of GS1. Both formats are in accordance with ISO/IEC 15434 and use the data designators in compliance with ISO/IEC 15418. This ensures an open market for pharmaceutical companies without additional, binding licencing fees.



All necessary details on coding and labelling of pharmaceutical packages are described in the securPharm "Coding Rules". Among others, this includes generation of the PPN and NTIN, code content with the associated data designators, code size, and printing quality (see www.securpharm.de/en/mah/coding.html). The securPharm Coding Rules contain the current requirements resulting from the Delegated Regulation.

3. The national verification system

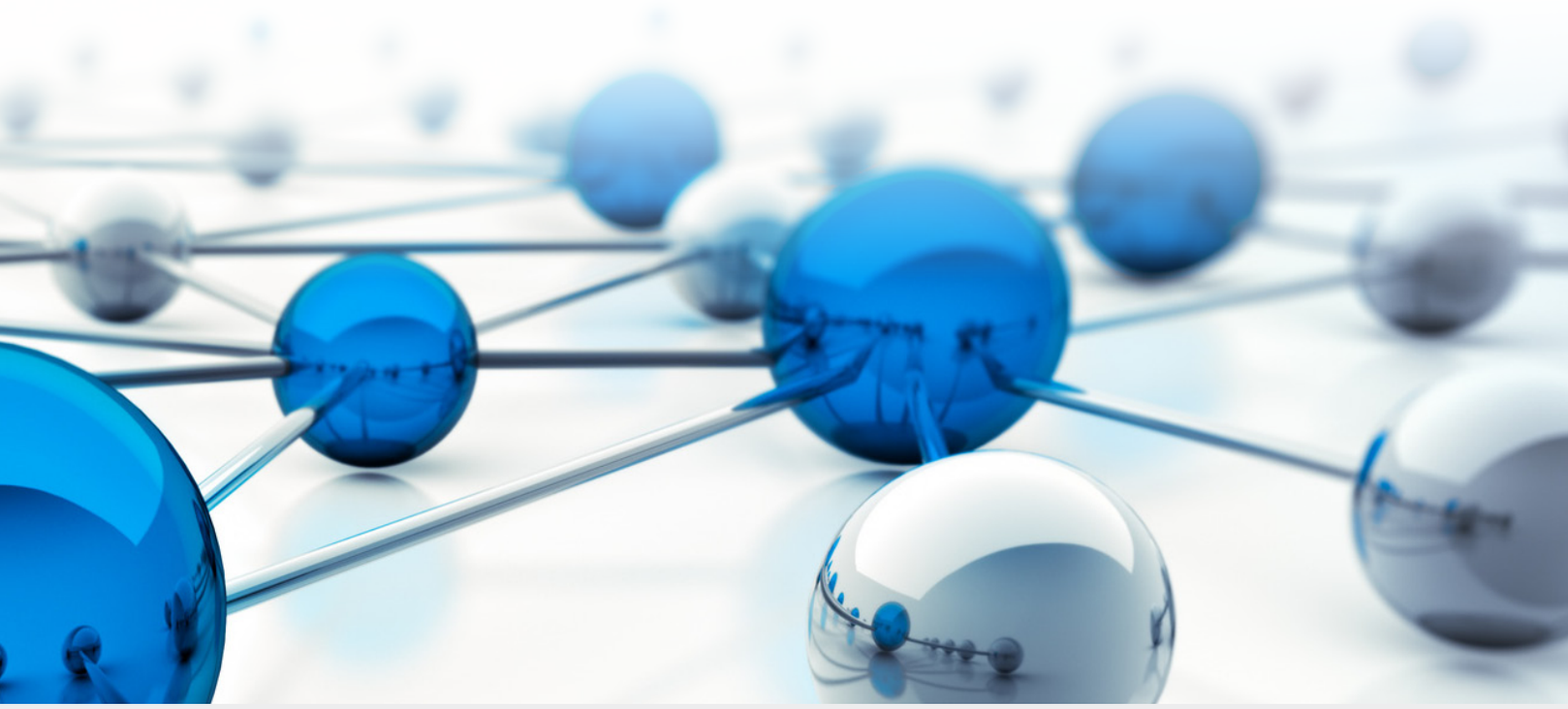
Following the requirements of the Falsified Medicines Directive, the German verification system of securPharm is based on the end-to-end principle during which both ends of the supply chain help ensure safety. The one end is the marketing authorisation holder who markets pharmaceuticals. The other end represents the dispense of pharmaceuticals to patients, i.e. at a community pharmacy. The national verification system is embedded in a European network in order to also safeguard patient protection across national borders.

3.1 The pharmaceutical verification process

During the production process, the marketing authorisation holder (MAH) equips each pharmaceutical pack that is subject to mandatory verification with an individual serial number. This serial number is applied to the pack together with a product code (a PZN enveloped as a PPN or NTIN), the batch number and the expiry date within the Data Matrix Code. In parallel, the pharmaceutical company uploads these data to the central database of the pharmaceutical industry (ACS MAH system).

Each pharmaceutical company reports to IFA the pharmaceuticals that bear the Data Matrix Code and can be verified in pharmacies. Via ABDA information services, the pharmacy software recognises the flag from the IFA database and controls the processes in the merchandise management system of the pharmacy accordingly.

To verify the authenticity of a product package, the pharmacy staff scan the Data Matrix Code of the package before dispensing it to the patient. The verification of serial number and product code against the data-base system of the pharmaceutical industry is running in the background. The package status as it is stored in the database is reported back to the pharmacy. If the status is correct, the package can be dispensed and the package status is simultaneously changed in the database to "dispensed". If the data check shows that the serial number is either not found in the database or has already been marked as dispensed, the pharmacy receives a corresponding warning, so that the necessary measures can be taken. This will prevent a negatively verified and possibly falsified pharmaceutical pack from being dispensed to the patient.
A model with a separate system is used to protect the data of the parties involved (see diagram). Verification inquiries from pharmacies are bundled via the centralised pharmacy system and directed to the database system of the pharmaceutical industry in anonymised form. This modularisation also results in higher efficiency, since both systems can specialise in the requirements of their respective user groups.



Before dispensing, pharmaceutical packages can be additionally verified by others, such as wholesalers or at goods in process at the pharmacy. This allows the verification of authenticity in the chain of distribution even before pharmaceuticals are verified when being dispensed to the patient.

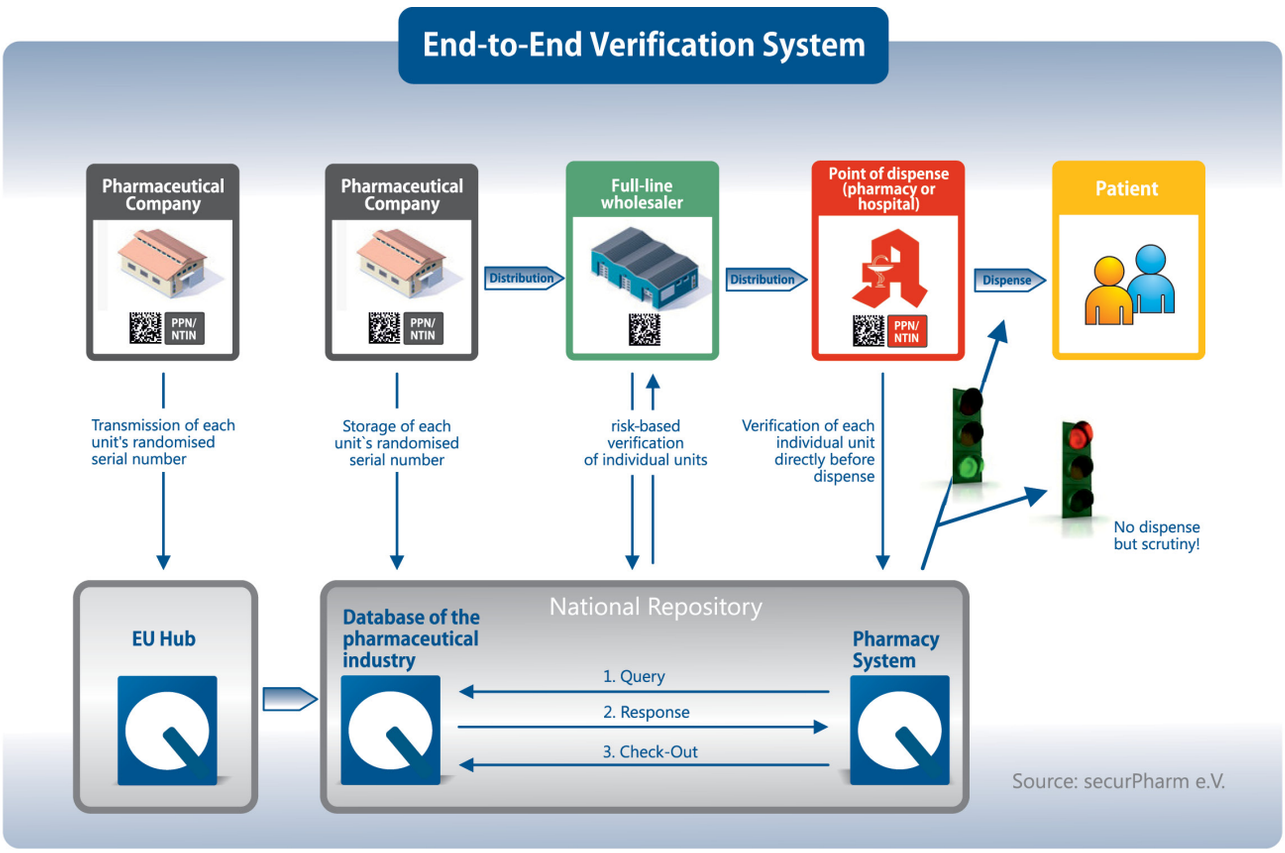
Since retail packages can bear multiple codes and additional two-dimensional codes increasingly appear on packages (e.g. codes with links to URLs), the abbreviation PPN in the Data Matrix Code provides the information that this code contains the data for pharmaceutical verification and must be scanned. The PPN abbreviation stands independent of the above-mentioned "envelope" of the PZN, since the PZN is extracted for merchandise management purposes and the NTIN envelope is transferred into the PPN envelope for verification anyway.

3.2 Integration into the European network

Since securPharm represents the German component for the security network of the European stakeholder associations (EMVO) for the protection against falsified medicines, the European hub has already been connected to the German verification system of securPharm. The interface to the hub is the database of the pharmaceutical industry (ACS MAH system). So far, Germany is the only country that has successfully connected to the European hub. This connection is continuously expanded and adjusted to new circumstances.

In its final version, the European hub will connect the verification systems of the individual member states with each other. As a consequence, it can be used to verify any pharmaceutical pack equipped with safety features in any pharmacy in Europe.

Furthermore, the European hub serves as an additional access point for pharmaceutical companies. They can choose whether to upload the pack data directly via the EU hub, which then routes the data to the corresponding national system. For multinational companies with multiple markets, this certainly is an interesting option. Alternatively, the companies can also directly upload the data of the pharmaceuticals destined for the German market to the national system of ACS. The decision of the pharmaceutical company has no impact on the other participants in the supply chain. Since the data are always stored nationally, patient protection is guaranteed in both cases.



4. Current status of the project

4.1 Structure of securPharm e.V.

securPharm e.V. is the higher-level institution developing the technical system for the authentication of pharmaceuticals subject to mandatory verification in Germany in accordance with the requirements of EU Directive 2011/62/EU and Delegated Regulation (EU) 2016/161. In this function, it has assigned operation of the two systems needed in the Germany arrangement to different operating companies. The database of the pharmaceutical industry is operated by ACS PharmaProtect GmbH (ACS). Via ACS, all pharmaceutical companies whose products are subject to mandatory verification can be connected to the national system for authentication. The pharmacy server is operated by Avoxa - Mediengruppe Deutscher Apotheker GmbH (Avoxa). Via Avoxa, wholesalers, retail pharmacies, hospital pharmacies and pharmacies supplying hospitals can connect to the system. The operators also serve as contacts for more specific issues regarding the connection to the system for authentication.

4.2 Involvement of the pharmaceutical industry

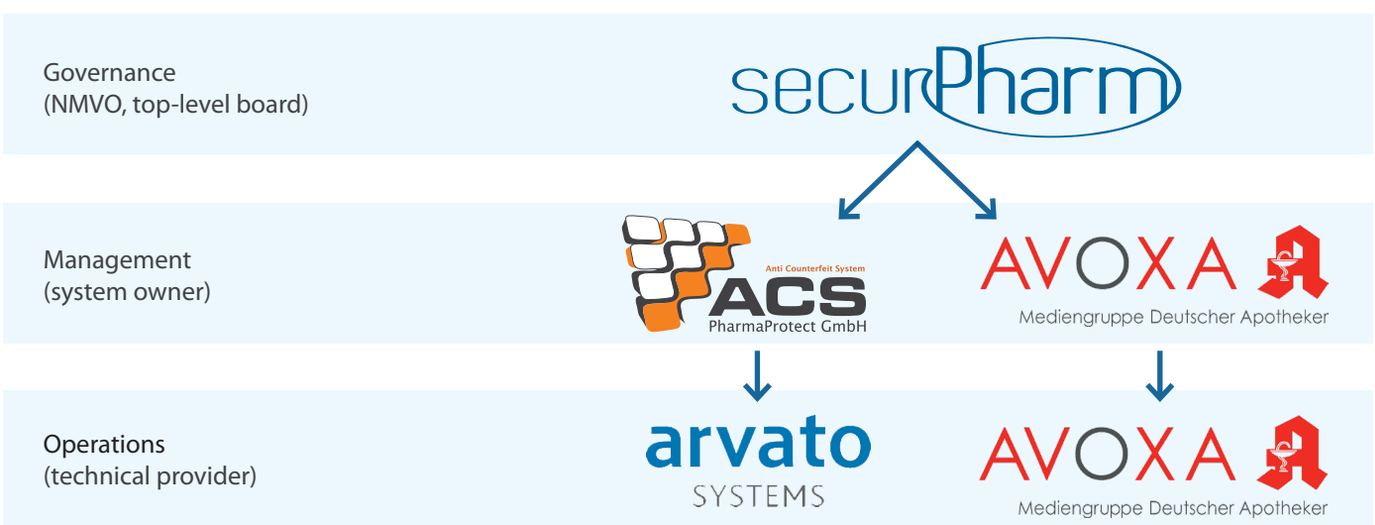
4.2.1 Pharmaceutical companies

As of December 2016, a total of 100 pharmaceutical companies are participating in the securPharm project. These include both large, globally active companies with extensive experience in serialisation or coding of medicinal products in other markets (e.g. Turkey, Korea or China), as well as small and medium-sized enterprises from Germany, many of which have been faced with these issues for the first time.

In addition, the participants include parallel importers, who are particularly affected by the EU Directive. On the one hand, they will function in the future system as dispensing agents who must therefore log out the products they will be distributing under their own name from the database system. On the other hand, they are currently already considered pharmaceutical companies which need to generate their own serial numbers and upload these to the database system of the pharmaceutical industry (ACS MAH system) directly or via the European hub.

Last but not least, companies manufacturing generic drugs, which will also require safety features pursuant to the EU Directive, now increasingly participate in the project as well. All in all, the project includes a representative cross-section of the pharmaceutical companies in the overall German pharmaceutical market.

Governance of the securPharm system



4.2.2 Operating company of the pharmaceutical industry's database

The operation of the database of the pharmaceutical industry was assigned to a separate operating company. The pharmaceutical industry associations established ACS PharmaProtect GmbH in Berlin for this purpose, which is in charge of specifying, setting up and operating the database system of the pharmaceutical industry in Germany (ACS MAH system). The associations also provide three of the managing directors for this limited liability company. In addition, the Board of Directors consists of representatives from the pharmaceutical companies.

With arvato Systems GmbH, securPharm and ACS are partnering with a company that develops, implements and operates the ACS MAH system, and processes product data via the interface to the pharmacy system. The company has a proven track record in IT services and demonstrated its efficiency during comparable projects.

One important concern of ACS PharmaProtect is knowledge transfer and passing on experiences gained by pharmaceutical companies during serialisation to those companies participating in the project. A regular exchange of experience takes place for this purpose, during which pharmaceutical companies that have already implemented the requirements of the Delegated Regulation communicate about their experience and provide support in the form of practical advice. Furthermore, ACS supports the pharmaceutical companies through webinars, guidelines, manuals and answers to FAQs. As a result, pharmaceutical companies can align their processes to serialisation even before the effective date in 2019 and practice those processes along the entire supply chain.

4.2.3 Connection to the system

All pharmaceutical companies that are marketing pharmaceuticals in Germany and are affected by Directive 2011/62/EU must conclude an agreement with ACS PharmaProtect GmbH to participate in securPharm. As soon as the agreement is concluded, the pharmaceutical companies receive access to the database system of the pharmaceutical industry (ACS MAH system). However, an additional contract with the European hub is required to ensure that the pharmaceutical company can be clearly identified during the data exchange between the ACS MAH system and the European hub (www.emvo-medicines.eu).

Pharmaceutical companies can choose from two methods for transmitting their data to the ACS MAH system. The companies can either transmit their data directly to the ACS MAH system or send their data to the European hub, which subsequently routes them to the ACS MAH system.
As part of the connection to the ACS MAH system, the submitted data are checked against data from the IFA database, among others. Therefore, it is particularly important for pharmaceutical companies to always keep their data up to date with IFA and to contact ACS PharmaProtect GmbH for any questions arising in connection with the necessary proof for the legitimacy check.

For details regarding ACS PharmaProtect GmbH or the fee model for pharmaceutical companies, please go to www.pharmaprotect.de.

4.3 Involvement of wholesalers

Pharmaceutical wholesalers are an important component in the pharmaceutical supply chain. As a result, they serve an important function in securing the supply routes. The Delegated Regulation (Article 20) of the European Commission has specified the wholesalers' obligation to verify packages in terms of a risk-based approach.

Accordingly, all returns from pharmacies and other wholesalers as well as all deliveries from other wholesalers that are neither the manufacturer nor the marketing authorisation holder nor a wholesaler who is designated by the marketing authorisation holder must be verified in the future. Regardless of this fact, he is authorised to check each pharmaceutical for authenticity.

4.3.1 Wholesalers verify via the pharmacy server

securPharm works with separate IT systems for pharmaceutical companies on the one hand and wholesalers and pharmacies on the other. Both databases are separate from each other and only exchange data for the verification processes in anonymised form.

Since the start of the project, PHOENIX Pharmahandel GmbH & Co KG with its German subsidiaries has been participating in securPharm, verifying securPharm items at goods in process in order to test the integration of wholesalers.

During the process, the securPharm system was tested for its everyday usability and its efficiency during the processing of larger amounts of verifications over short periods of time. In a second step, the verification of returns was also tested in PHOENIX' returns unit.

4.3.2 Machine-readable coding of batch number and expiry date

For pharmaceutical wholesalers, too, it is worthwhile to develop, implement and test the verification processes and the required reporting obligations at an early date in order to meet the requirements of the Delegated Regulation in 2019.

The Delegated Regulation now also provides clarity with regard to the machine-readable coding of batch number and expiry date. This new coding allows pharmaceutical wholesalers to capture these data in a fully automated manner, thereby supporting the wholesalers' legally required documentation obligation.

4.4 Involvement of community pharmacies

When it comes to discovering falsified pharmaceuticals, pharmacies play a key role, since they verify the authenticity of a pharmaceutical at the end of the supply chain. Before dispensing it to the patient, the pharmacist scans the Data Matrix Code of the pharmaceutical subject to mandatory verification, thereby testing the pack for authenticity. Since the start of the securPharm project, about 400 pharmacies have registered for participation.

4.4.1 The pharmacy system

The conceptualisation and implementation of the centralised pharmacy system is performed by Avoxa – Mediengruppe Deutscher Apotheker GmbH. The pharmacy system is a technical solution which, in a first step, renders the verification queries from pharmacies anonymous and then sends them to the database system of the pharmaceutical industry (ACS MAH system). When a positive response is generated by the ACS MAH system, the dispensing pharmacy initiates a second step in the process, which consists of (anonymously) checking the specific package out of the system. If no positive response is received from the ACS MAH system, the package is not dispensed to the patient but investigated instead. Compliance with the existing reporting protocols is mandatory.

4.4.2 Machine-readable batch number and expiry date

With the publication of the Delegated Regulation, there is now also clarity regarding the fact that the batch number and the expiry date must also be part of the Data Matrix Code. This provides pharmacists with the possibility of making their merchandise management more efficient, since the batch number and expiry date no longer need to be entered manually but can be scanned together with the PZN. Furthermore, they can conduct the authentication as early as during goods in process in order to recognise non-dispensable pharmaceuticals early on and assign them to the supplier in question.

4.4.3 Re-entry of deactivated serial numbers

During the everyday business of a pharmacy, it is possible that a pharmacist books out a pack but does not dispense it. The Delegated Regulation now clarifies that a pharmaceutical – as long as it is in the pharmacist's "physical" possession – can be re-entered for up to 10 days after deactivation.

4.4.4 Pharmacy software providers

In contrast to other countries, there is a variety of different software companies for the software used in pharmacies. The heterogeneity of the pharmacy software market is well represented in the project through the early involvement of five pharmacy software providers with a total of eight

merchandise management systems. After just a short time, it became apparent that the securPharm system works reliably, irrespective of what software package is used at the individual pharmacy.

All pharmacy software packages used in community pharmacies will have to offer the verification function through the securPharm system on time, by February 9, 2019, as per the Delegated Regulation.

In its database, IFA clearly indicates which pharmaceuticals already bear safety features and can therefore be verified at pharmacies. Products are labelled based on the PZN and therefore based on information provided by the pharmaceutical companies to IFA. Using these data, the pharmacy software alerts the dispensing pharmacy employee to perform the verification for a specific pharmaceutical.

4.5 Connection of hospital pharmacies and pharmacies supplying hospitals

At the start of 2016, securPharm established a Hospital Working Group. Representatives from hospital pharmacies and community pharmacies that supply hospitals jointly work with securPharm to develop a practice-oriented and practicable implementation of the Delegated Regulation in hospitals. The processes for verification at a hospital pharmacy or at a pharmacy that supplies hospitals are only partially comparable to those of a community pharmacy. Therefore, starting in the spring of 2017, securPharm offers hospitals to join a six-month pilot project for testing the specifics of verification in hospitals, based on a verification of individual packs, as provided by the Delegated Regulation. In contrast to community pharmacies, the legislature has made no stipulations regarding the location and time for the authentication and verification of packages.

The goal of the pilot project will therefore be to gather experiences, to make suggestions for the optimal location of the verification and to point out a solution for the quantity problem at hospitals. The achieved results are meant to help hospitals implement the Delegated Regulation in conformity with the law and in a practicable manner.

In autumn of 2016, securPharm succeeded in connecting the first hospital in Europe to the authentication system for prescription drugs. The first successful verifications of hospital merchandise at a clinic therefore marked the start for a successful securPharm pilot project at hospitals. As a result, securPharm is the first stakeholder organisation in Europe that practically addresses the specific issues of authentication at hospitals.

4.6 International exchange

All nations affected by the Directive face the same challenge of establishing an international and functional verification system that does not obstruct the movement of goods and safeguards patient protection. It is for this reason that securPharm pursues a lively exchange with the stakeholders of other European countries. Discussions typically include questions on system architecture, interactions between stakeholders, coding rules and pricing models. The project manager community established at the European level by the EMVO is a key factor in this respect and will intensify the exchange between the nations. Since Day 1, securPharm has been active in this international exchange and is also available for bilateral discussions to the organisations in the other countries.

4.7 Key indicators of the system

4.7.1 System performance

The Delegated Regulation stipulates requirements for the speed of the repository (Article 35 (f)) at which the query for authentication of a pharmaceutical must be made. This speed must enable wholesalers and pharmacists to "to operate without significant delay".

The overall system performance depends on the performance of the centralised manufacturers' database, the centralised pharmacy database and the individual pharmacy software in use, along with the connections between the various systems. However, naturally, the stakeholders have no influence on the data connection between pharmacies and the pharmacy system. The data packages transmitted during verification are small and therefore using an internet connection with small bandwidth does not represent a problem in terms of system speed. The critical factor for the system's speed in the verification process is how many other processes are simultaneously running via the internet connection. If the connection is at maximum capacity because of other processes (e.g. internet telephony or order processing), this can in some cases lead to verifications being processed within seconds instead of milliseconds.

So far, users are convinced of the system's speed. Deviations with delays in performance can be attributed to the individual pharmacy's implementation of the necessary technical infrastructure for the system. The reaction time of the centralised systems averages 100 milliseconds.

4.7.2 System availability

Another critical aspect of the securPharm system's everyday usability is its reliability, as expressed by system availability. For smooth pharmacy operations, the system must be consistently available at all times, since verifications must be possible even during night and weekend hours. As a result, the system must be available around the clock, 365 days a year.

So far, the securPharm system has proven robust and reliable overall. To keep availability at this high level, maintenance intervals in regular operations must be covered by redundant systems so that availability is not limited by maintenance activities.

4.7.3 Trends in package data

The pharmaceutical companies have been continuously uploading the serialisation data of their serialised and subsequently marketed products to the database system of the pharmaceutical industry (ACS MAH system) since the end of 2012.

Today, more than 28 million packages, which bear a safety feature that is compatible with the EU Falsified Medicines Directive, are secured by the Data Matrix Code, and the number of packages will consistently increase of the next weeks and months.

Participating companies

5. Conclusion

After an operating time of more than four years, the securPharm project is well on its way. While a variety of milestones have already been achieved, there will be several more for the project partners. The stakeholder associations have started a system for the verification of pharmaceuticals that meets the requirements of the EU Falsified Medicines Directives and works under real-life conditions. The Delegated Regulation confirmed the key cornerstones of the project:

- Implementation by a stakeholder organisation;
- End-to-end verification with risk-based testing by wholesalers;
- Data Matrix Code as data carrier;
- Parallel use of two coding variations; and
- Separate databases for pharmaceutical companies and pharmacies.

In view of the significance and scope of the requirements imposed on all stakeholders in the pharmaceutical supply chain by the Falsified Medicines Directive and the associated Delegated Regulation, they have shown that they are the right partners for implementing these important principles for patient protection.

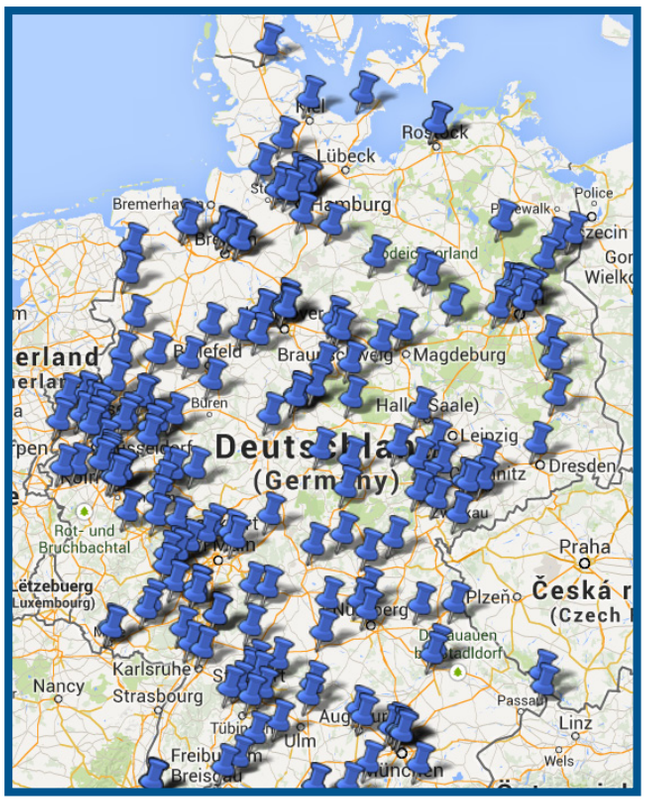
One of the other goals of the securPharm project, namely to realistically represent the heterogeneity of systems and the diversity of market stakeholders, necessitates a significant amount of coordination efforts between the involved parties. Any problems arising during project preparation and implementation were solved jointly and provided valuable insight for the further development of the system by all parties involved.

It was and still is extremely helpful that the stakeholders had agreed early on the basic tenets of their cooperation and the project in general. This has led to the results-oriented and practical resolution of issues (including organisational ones) arising within the project.

Over the past few years, the participating pharmaceutical companies have been able to gather comprehensive experience. At the start of the project, the printing of packages with the Data Matrix Code was a process that was subject to certain variations in quality. However, these difficulties have now been resolved by the companies and printing is a valid process in most cases. The generation, management and reliable transmission of serial numbers to the database system of the pharmaceutical industry is another challenge that has been solved by the participating companies through the systematic adjustment of IT solutions and processes within the company. The experience the participating companies were able to gather so far also shows how valuable it is to start the implementation early. Almost none of the tasks listed can be solved without the help of external partners such as the manufacturers of cameras, printing and packaging machines, the providers of software solutions and the producers of folding cartons. The only problem is that their capacities are ultimately not unlimited either.

For pharmaceutical companies, it is now a matter of great urgency to address the technical and organisational challenges associated with the implementation of the EU Falsified Medicines Directive. One of the greatest challenges is and will be the conversion of internal company processes, since almost all processes have to be adjusted.

By the end of 2017, pharmaceutical companies should have connected to the database of the pharmaceutical industry. From 2018 onwards, the participants in the supply chain have one more year for training their processes and workflows. This is all the more important, since processes run under real-life conditions during the training phase, but any errors that occur will not lead to business disruptions. So there is room for adjustments and corrections.



Pharmacies connected to the securPharm system

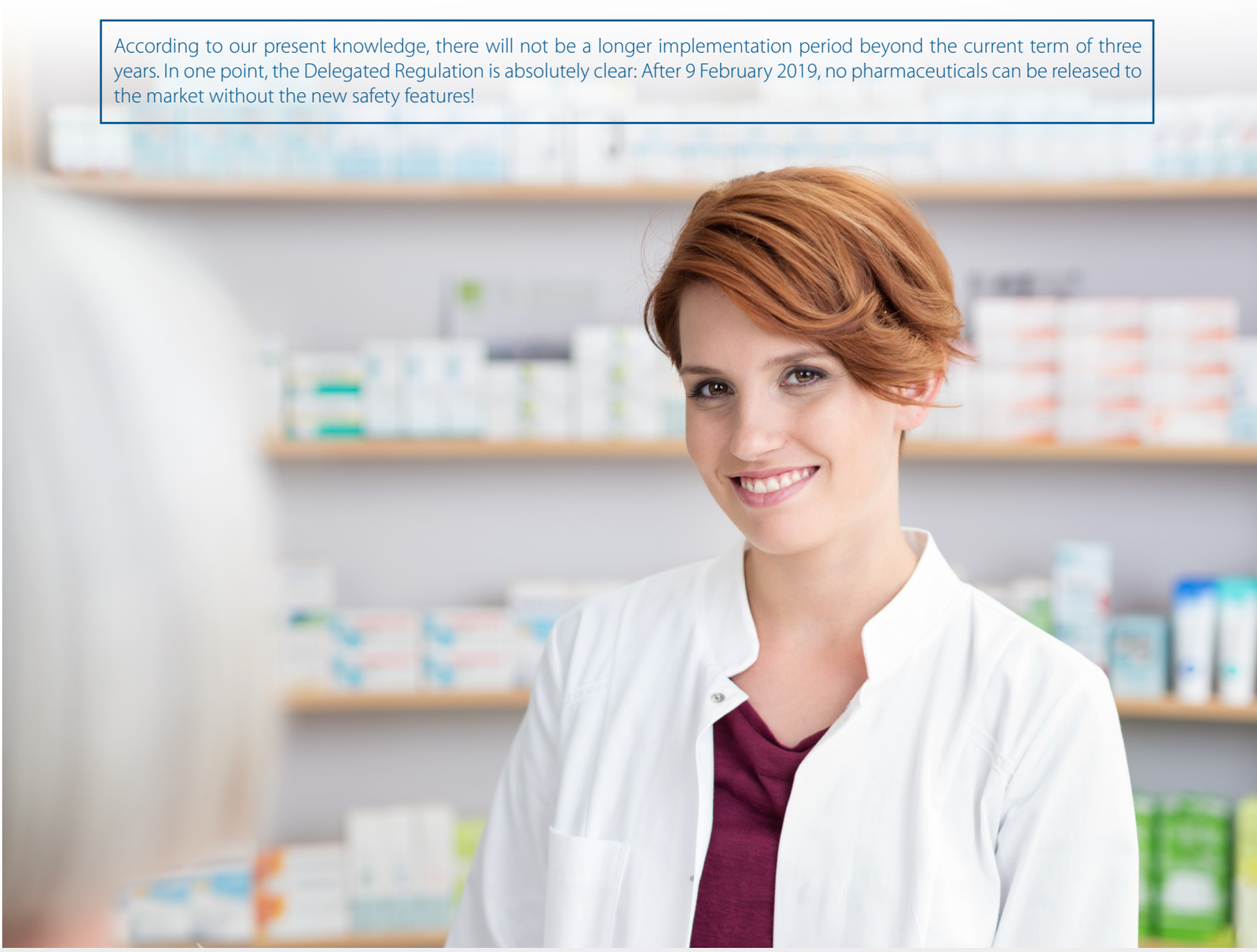
6. Outlook

The Delegated Regulation confirms essential assumptions of the securPharm project. Nevertheless, the remaining time must be used to continuously analyse and successively implement all details of the Delegated Regulation. This includes the following tasks, among others:

- Integration of additional user groups such as hospital pharmacies and pharmacies that supply hospitals.
- Analysis of exceptions and the systematic expansion of the corresponding conflict management process. Arising exceptions (suspected falsifications) must be solved or clarified according to precisely defined rules and under government supervision in cooperation with the market participants;
- Discussions with the authorities in charge have already been initiated.
- Efficient representation of international movements of goods and the further integration of the EU hub;
- Expansion of secure procedures for the legitimation of participants and the systematic improvement of system security;
- Set-up of a quality management system that clearly defines all cross-organisational processes, thereby facilitating smooth and lean business processes.

Last but not least, additional pharmaceutical companies, wholesalers and pharmacies will be connected to the securPharm system in the future in order to facilitate the smooth operation of all individual systems before the due date of 9 February 2019 stipulated in the Delegated Regulation.

According to our present knowledge, there will not be a longer implementation period beyond the current term of three years. In one point, the Delegated Regulation is absolutely clear: After 9 February 2019, no pharmaceuticals can be released to the market without the new safety features!



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This status report is available in German and English
and can be requested at info@securPharm.de.

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