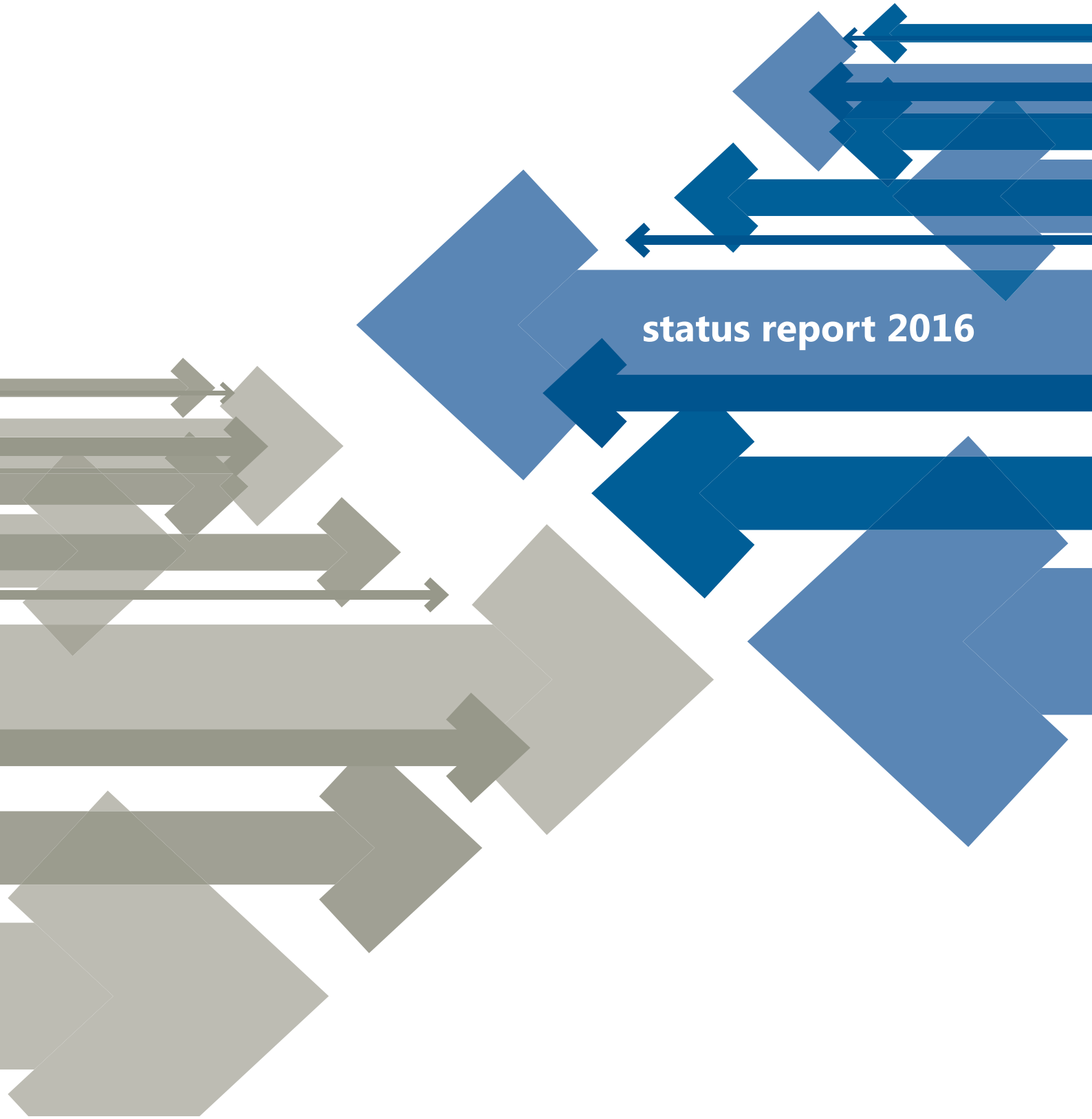
securPharm

status report 2016



ABDA

BPI Bundesverband der Pharmazeutischen Industrie e.V.

PHAGRO

Bundesverband der Arzneimittel-Hersteller e.V. B.A.H

vfa. Die forschenden Pharma-Unternehmen

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.

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 February 9, 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 three 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 further optimise their own processes, thereby optimally preparing for February 9, 2019, which is the date on which the requirements of the Delegated Regulation shall apply.

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 toward 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.

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 national operators of the pharmaceutical industry database (ACS PharmaProtect) and the pharmacy system (Werbe- & Vertriebsgesellschaft Deutscher Apotheker) commission the technology providers who will install and operate the required databases.
3. arvato Systems GmbH has already been commissioned to serve as provider for the pharmaceutical industry database.

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 also be used for multi-country packs and as UDI for medicinal products.

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 need therefore not be listed additionally. As a result, there is no 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 forms 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.[1] 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 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). Upon publication of the Delegated Regulation, the securPharm coding rules will be updated with those items for which the Delegated Regulation has provided more specific or supplementary information. This primarily concerns statements on human readable elements. Fundamental coding rules will remain unaffected.

[1] Footnote (as a sidebar):[1] Excerpt from the joint information of securPharm, IFA and GS1 from April 2012:
Usage of the GS1 NTIN is permanently free of charge for companies that are customers of GS1 Complete. For customers who do not yet use GS1 Complete, the GS1 NTIN is free for the duration of the pilot. Usage of the IFA PPN code is permanently free of charge for companies.

3. The verification process for medicinal products

The pharmaceutical company places an individual serial number on each package during the production process. Together with the PZN (via PPN or NTIN), batch number and expiry date, it is printed in a Data Matrix Code on the package. In parallel, the pharmaceutical company uploads these data to the central database of the pharmaceutical industry.

Each pharmaceutical company reports to IFA the pharmaceuticals that already 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 at 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 serial number and product number are checked against the database of the pharmaceutical companies 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".

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 pharmacy staff with 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.

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 non-verifiable and possibly falsified pharmaceutical from being dispensed to the patient.

Before dispensing, pharmaceutical packages can also be 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.

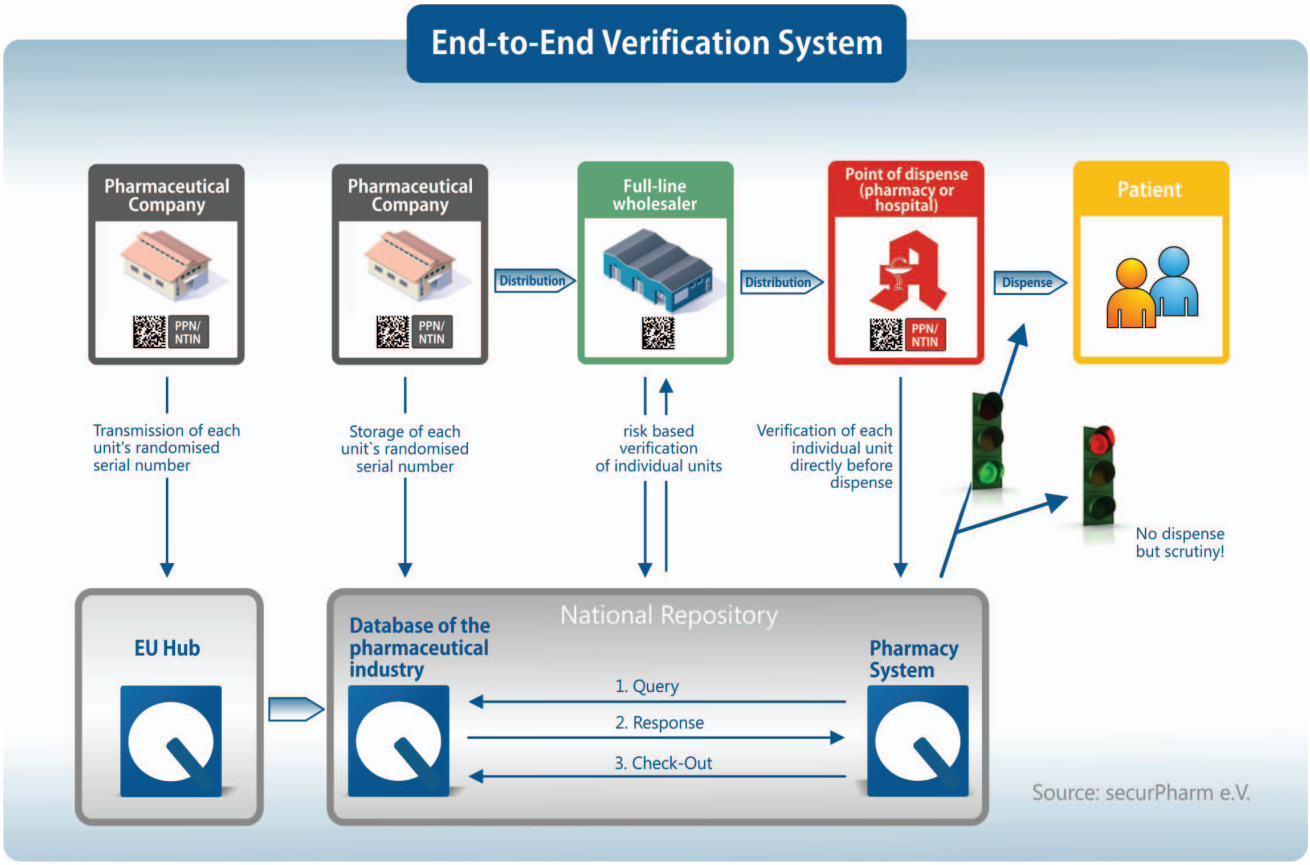
4. System structures

4.1 Design of the national system

securPharm is based on the concept of separate databases (see image). The pharmaceutical companies (marketing authorisation holders - MAHs) are responsible for uploading their serialised pack data to the database system of the pharmaceutical industry (ACS-MAH-System). In order to maintain this ACS-MAH-System, the associations of BAH, BPI and vfa established an operating company (ACS PharmaProtect GmbH), which is currently financed by these industry associations. Verification queries from pharmacies are collated and rendered anonymous by the centralised pharmacy server and sent to the ACS-MAH-System. The pharmacy server is maintained and currently financed by *Werbe- und Vertriebsgesellschaft Deutscher Apotheker mbH*. Wholesalers will also process their verifications through the centralised pharmacy server. This data segregation will prevent the stakeholders of the ACS MAH system from extracting data on procurement and sales volumes of individual pharmacies, thereby ensuring complete data privacy.

4.2 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 database of the pharmaceutical industry of securPharm. This connection is continuously expanded.



5. Current status of the project

5.1 Involvement of the pharmaceutical industry

5.1.1 Pharmaceutical companies

As of February 2016, 32 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, France 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.

The participants also 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. 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, 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.

5.1.2 Operating company of the pharmaceutical industry's database

The pharmaceutical industry associations established ACS PharmaProtect GmbH, which is in charge of specifying, setting up and operating the database system of the pharmaceutical industry in Germany (the ACS-MAH-System). The associations also provide three of the managing directors for this limited liability company. The administrative board is staffed with representatives from the companies of Boehringer Ingelheim Pharma GmbH & Co. KG and Berlin Chemie AG.

It was key for ACS PharmaProtect to bring arvato Systems GmbH on board – a company that would develop, implement and operate the ACS-MAH-System, process product data and operate the interface to the pharmacy system. The company had a proven track record in IT services and demonstrated its efficiency during comparable projects.

For more information on ACS PharmaProtect or details on the pricing model, please visit www.pharmaprotect.de.

5.2 Involvement of wholesalers

The EU Falsified Medicines Directives requires the verification of packages by pharmaceutical wholesalers. The Delegated Regulation 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 de-

liveries 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. In order to test the feasibility of wholesalers using the securPharm system, the company *PHOENIX Pharmahandel GmbH & Co KG*, including all of its German subsidiaries, participates in the project to verify securPharm projects according to a defined protocol.

PHOENIX uses the pharmacy system of securPharm and tests its everyday usability. In a second step, the securPharm system was also tested in PHOENIX' returns unit.

5.3 Involvement of community pharmacies

Since the start of the securPharm project, about 400 pharmacies have registered for participation.

5.3.2 Pharmacy software providers

The heterogeneity of the pharmacy software market is well represented in the project through the 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.

The software providers involved in the securPharm project currently have a 70% market share in the pharmacy market. However, all pharmacy software packages used in community pharmacies will have to offer the verification function through the securPharm system no later than February 9, 2019, as per the Delegated Regulation.

5.3.1 Pharmacy system

ABDATA Pharma-Daten-Service, a business unit of Werbe- und Vertriebsgesellschaft Deutscher Apotheker mbH, was responsible for the planning and implementation of the centralised pharmacy system. In a first step, the system renders the verification queries from pharmacies anonymous and then sends them to the database system of the pharmaceutical industry. 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.

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.

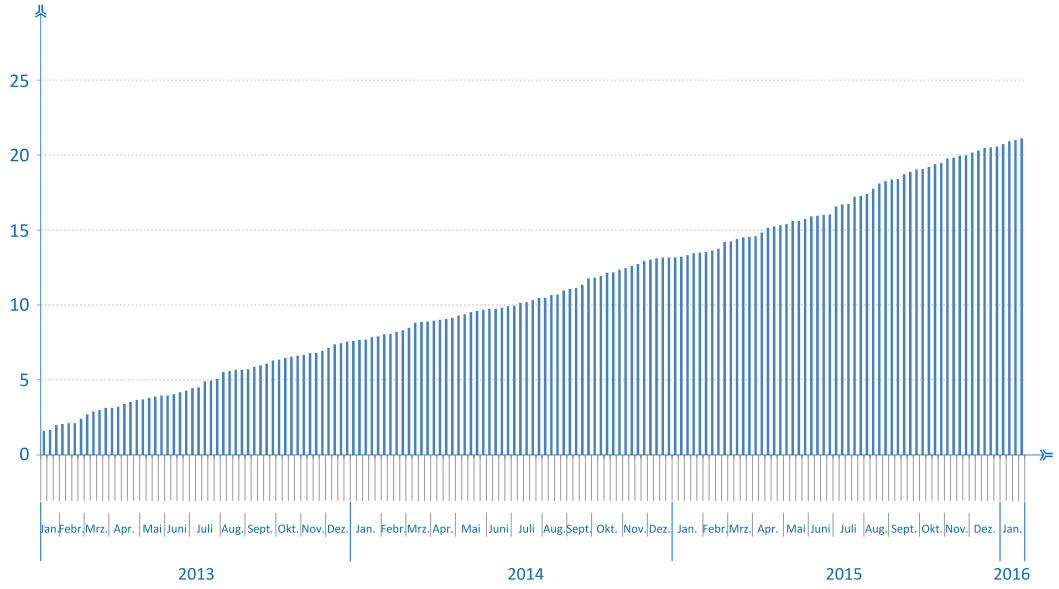
5.4 Participation of hospitals / hospital pharmacies

An initial connection of hospitals or their pharmacies to securPharm is planned before the end of 2016. Following the implementation of a hospital pilot project, a subsequent roll-out is planned. According to the Delegated Regulation, products at the hospital can be verified and booked out in goods in process. Ultimately, the hospital pilot project serves the purpose of testing the technical system at hospitals, to refine the technical requirements and to gather practical experience early on. Weaknesses should be identified and the resulting findings should be processed.

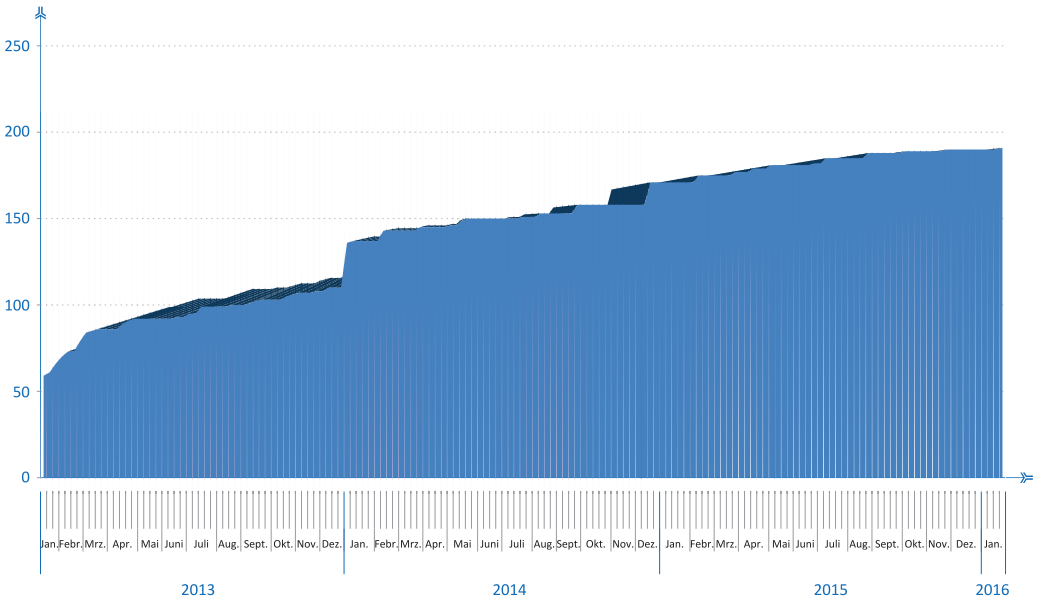
5.5 International exchange

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. An outstanding event was the International Information Conference in July of 2015, which was attended by representatives from 15 countries.

Number of units uploaded into the system (in Mio.)



Number of registered products in the system



5.6 Publication of the Delegated Regulation

On February 9, 2016, the EU Commission published the Delegated Regulation (EU) 2016/161 in the Official Journal of the European Union in the version of October 2, 2015. For the stakeholders in pharmaceutical care, this marks the start of the three-year implementation period. Starting February 9, 2019, only prescription drugs bearing an individual serial number and whose integrity is visibly recognisable may be circulated in Germany.

Following an intensive review of the 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.

securPharm will accompany the implementation of the Regulation with a separate statement, thereby continuing to promote the knowledge transfer between the parties involved.

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

To the competent authority, 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.

5.8 Key indicators of the system

5.8.1 Trends in package data

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

While there were 7.5 million serialised and coded packages in the German market in 2013, this number had increased to 13 million packages secured with the Data Matrix Code at the end of 2014. By February 2016, another increase brought the total to about 21 million packages bearing a safety feature that is compatible with the EU Falsified Medicines Directive.

However, this significant increase of serialised and coded packages is just one of several criteria for the success of securPharm. It is one of the more important goals of the organisation to use the continuously gained experience to optimise the system and to adjust it to the requirements and business processes of all parties involved in the pharmaceutical supply chain from the outset.

5.8.2 System performance

Simulated tests for system speed and its impact on processes at pharmacies brought the following results:

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. Even simulated verifications run on Internet connections with old modems with a bandwidth of 14,400 bits/second resulted in no significant delays.

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.

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 connection between pharmacies and the pharmacy system.

The measurements taken so far have demonstrated the system's fitness. 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.

To capture the subjective perception of the system's performance depending on Internet connection speed, two pharmacists – one with a high-speed Internet connection and one with a slower connection – were polled (see sidebar).

= Response time of the Server **% = Queries**

	X < 100ms	100ms ≤ X < 120ms	120ms ≤ X < 140ms	140ms ≤ X < 160ms	160ms ≤ X < 250ms	250ms ≤ X
%	20,87 %	57,11%	12,87 %	5,14 %	3,61 %	0,40%

Fastes response: 87ms | **Mean response:** 103ms | **Slowest response:** 3.312ms

Case studies:

System response times
as experienced by two pharmacies

"I've been participating in the pilot since January 2013. Everyone involved, including the software providers, appear to have done a good job. The Internet connection is stable, the server response times are negligible. As such, there are no negative effects on dispensing activities. Of course, in this phase, all the possible merchandise management features have not yet been implemented, but I anticipate possible relief regarding more onerous tasks such as management of expiration dates and recalls, aside from the main function of increasing drug safety."

Technical
test requirements
Bandwidth
6000 kBits/s

Excellent

"Typically, the verification process is pretty fast. I usually scan the package during the sale. My software checks whether this is a product that must be verified. If so, verification automatically runs in the background. The result is immediately displayed on my screen. Sometimes there is a slight delay, but this doesn't impact the processes at my pharmacy."

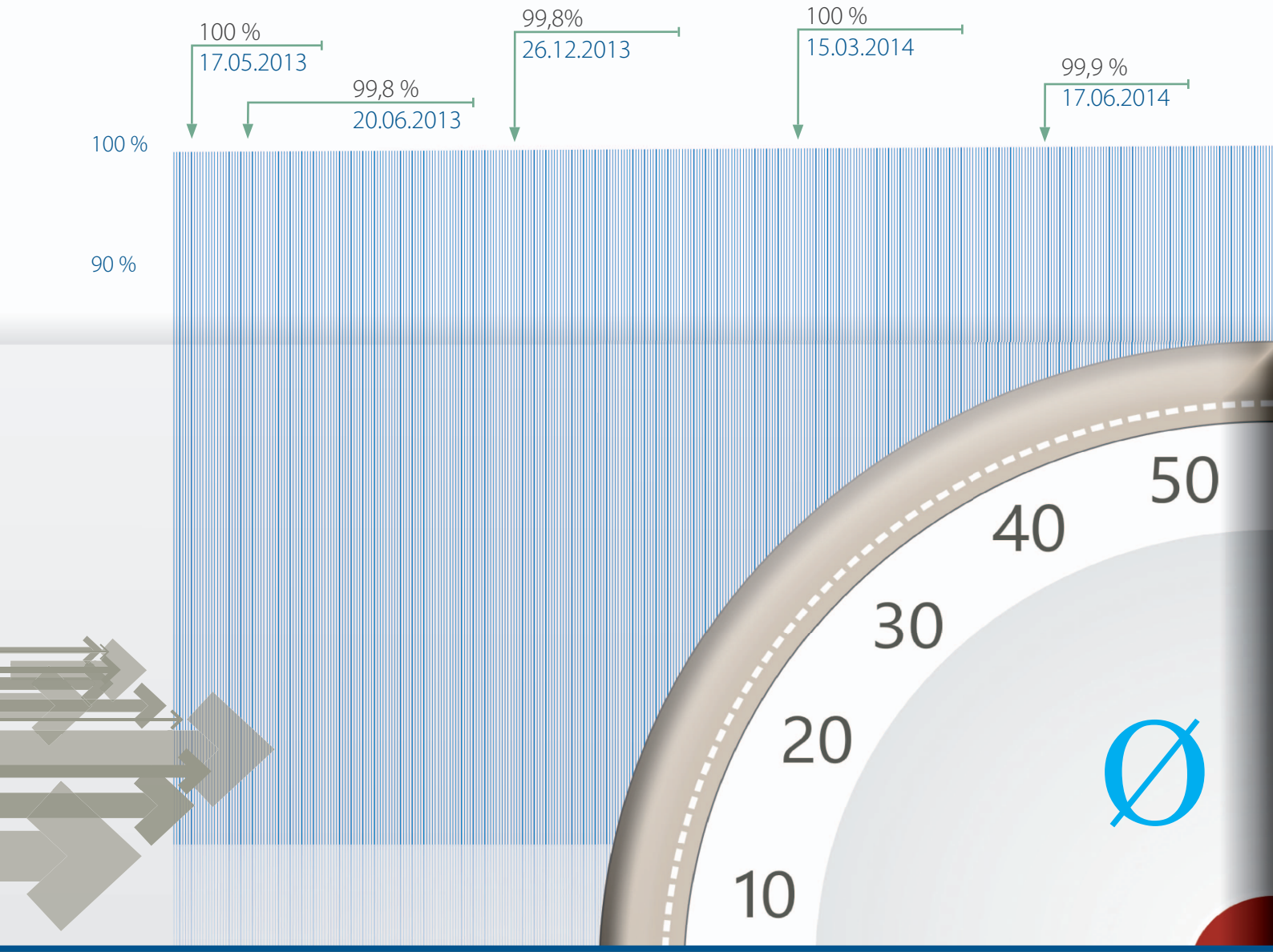
Technical
test requirements
Bandwidth
1000 kBits/s

good

5.8.3 System availability

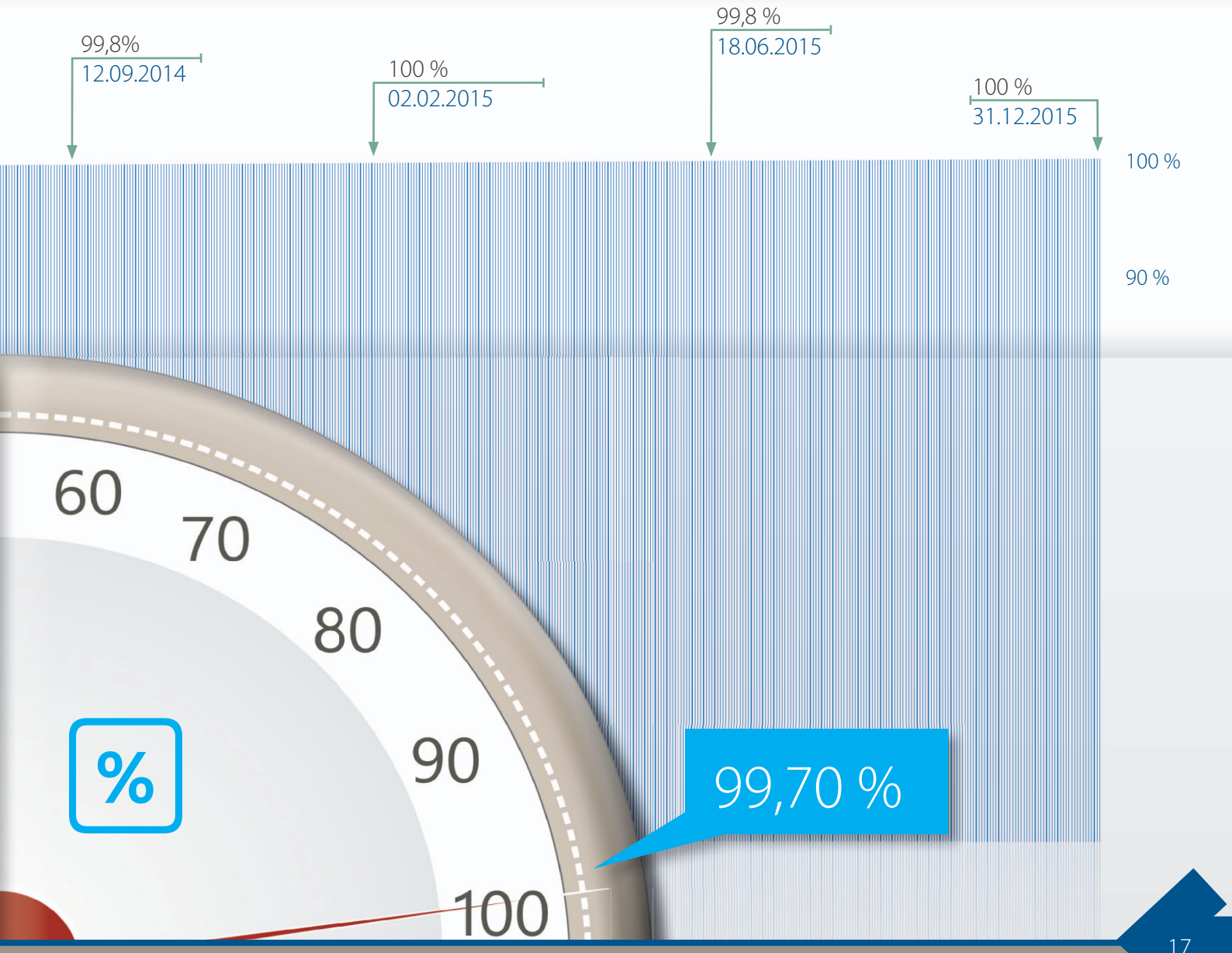
Another critical aspect of the securPharm system's everyday usability is its reliability, as expressed by system availability. For smooth pharmacy operations, the system must be consistently available at all times, since verifications must be possible even during night and weekend hours. As a result,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

System Availability



So far, the securPharm system has proven robust and reliable overall. The system's availability was consistently 100% or very nearly so, with the exception of necessary maintenance downtimes.

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.



6. Conclusion

After an operating time of more than three 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.

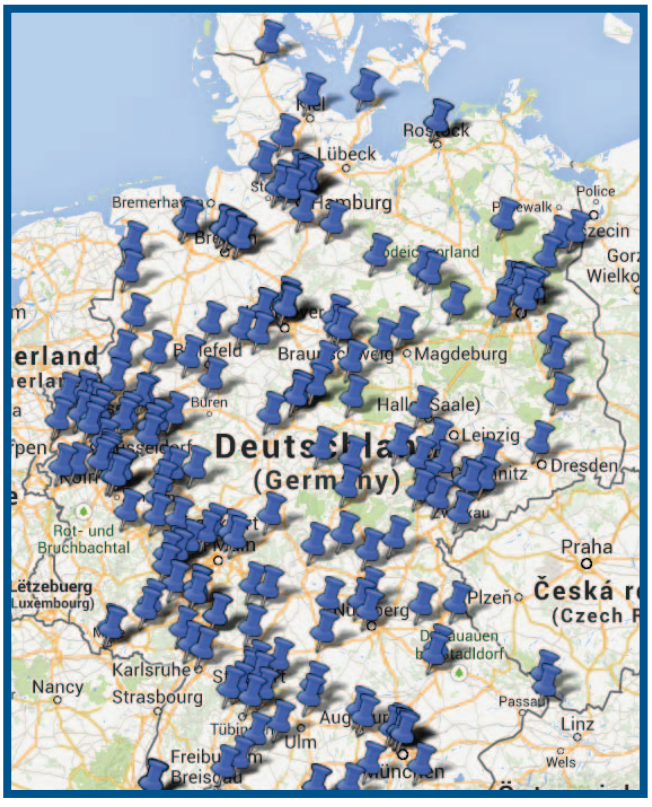
In view of the significance and scope of the requirements imposed on all stakeholders in the pharmaceutical supply chain by the Falsified Medicines Directive and the associated Delegated Regulation, they have shown that they are the right partners for implementing these important principles for patient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

Distribution of securPharm Pharmacies



7. Outlook

The Delegated Regulation confirms essential assumptions of the securPharm project. Nevertheless, all details of the Delegated Act must be analysed exactly and implemented successively over the next few months. This includes the following tasks, among others:

- Integration of additional user groups such as hospital pharmacies;
- 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;
- 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.

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

securPharm

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as of 01.02.2016

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