securPharm

German Medicines
Verification Organisation

2021 STATUS REPORT

Activity report of the German organisation
for the authentication of pharmaceuticals
and on the operation of the securPharm system

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ABDA

BPI Bundesverband der Pharmazeutischen Industrie e.V.

PHAGRO

Bundesverband der Arzneimittel-Hersteller e.V. B.A.H beraten • analysieren • handeln

vfa. Die forschenden Pharma-Unternehmen

About securPharm e.V.

securPharm e. V. is the German organisation for the authentication of pharmaceuticals and responsible for operating the authentication system for prescription drugs 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 is the German component in the EU-wide network EMVS against falsified pharmaceuticals.

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

This status report is available in German and English for downloading at www.securpharm.de.

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Foreword

Dear reader,

In 2020, the Coronavirus pandemic has created enormous challenges for Germany, Europe and the world at large. For the members of securPharm, who jointly represent a large part of Germany's pharmaceutical supply, patient care, the production of pharmaceuticals and, first and foremost, the search for a vaccine took centre stage during that time. These challenges have largely and rightfully eclipsed what a great achievement it is to set up a European protective system in which most European countries are networked. It is expected that the European protective system will continue to safeguard a supply of safe pharmaceuticals in which people can trust.

In its second year of operation, the securPharm system has proven to be robust, stable and resilient even at peak times. Nonetheless, the system continues to be in development. This concerns the processes surrounding the system much more than the technical protective function. As a result, the members of securPharm together with their stakeholders are committed to actively participate in the securPharm working groups as well as the working groups at the European level, because it is becoming apparent that many decisions regarding the further alignment of the protective system will be made at the European level. For example, reports to the authorities are uniformly designed in all of Europe. Future topics such as aggregation can also only be implemented within a standardised European framework. In order to protect the interests of the securPharm system and therefore the German pharmaceutical supply, an active representation of securPharm at the EMVO in Brussels is important. One important working area continues to be the reduction of false alarms that are predominantly due to handling errors or IT bugs in third-party systems. Many users of the securPharm system are still very much in need of information. Therefore, the securPharm members have intensified their information efforts regarding all aspects of the system and the associated processes. Another important progress is the evolution of convenience functions such as the securPharm-GUI.

Apart from system operation, the collaboration with the supervisory authorities is another important activity area of securPharm e.V. securPharm supports them in the resolution of cases of suspected falsification by providing the authorities with reports from the securPharm system, the so-called audit trails of individual packs. Currently, this occurs upon request and only for packs that were previously reported to the authorities by the market participants. The preparations for automating these requests by connecting the authorities to the securPharm system will be completed soon and can be expected in 2021.

On its own behalf, the organisation has also made progress in 2020. The organisational structures were streamlined and adjusted to the new responsibilities in mandatory operations. Furthermore, the establishment of an administrative board, on which the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Ministry of Health (BMG) will represent the authorities, is being initiated.

I would like to thank our members, their representatives in the working groups, and the operators of the individual databases for their tireless efforts in further evolving the protective system against falsified pharmaceuticals. We are all united in the joint objective of securing pharmaceuticals and protecting patients.

Yours sincerely,

Martin Bergen
Managing Director

1. The German organisation for the authentication of pharmaceuticals

1.1 The tasks of securPharm e. V.

Patients should be able to trust that they receive safe pharmaceuticals through the legal supply chain. Therefore, it is the foremost objective of all partners in pharmaceutical care to keep the distribution chain secure and to ensure that falsified pharmaceuticals are detected early. This is why prescription drugs are specially secured during production and verified for their authenticity with the securPharm system once more before being dispensed to patients. Besides many other measures taken by the participants in pharmaceutical care, this authentication is an important innovation in order to protect patients from falsified pharmaceuticals. Behind this digital protection are highly developed IT systems and complex processes on each level of the supply chain – from pharmaceutical companies and wholesalers to pharmacies.

securPharm e. V. is responsible for operating the securPharm system with which the authentication of pharmaceuticals based on the unique identifier and in accordance with the Falsified Medicines Directive 2011/62/EU and the Delegated Regulation (EU) No. 2016/161 is conducted. As the German organisation for the authentication of pharmaceuticals, securPharm also supports the authorities in charge in the investigation of cases of suspected falsification. For this purpose, it provides the authorities with the legally stipulated reports from the securPharm system, e.g. the so-called audit trails which contains the data from the securPharm system regarding the path of a package through the supply chain. Furthermore, securPharm e.V. serves as a platform for the representatives of the stakeholder groups in the supply chain in order to ensure that the requirements of the securPharm system take into account the concerns of all market participants.

The securPharm system is part of the EU-wide network EMVS against falsified pharmaceuticals.

1.2 Legal framework

The work of securPharm must be viewed in context with a series of measures of the European Union for the protection of patients from falsified pharmaceuticals in the legal supply chain with the corresponding legal regulations.

European regulations

Since 9 February 2019, prescription drugs for human use have been tagged with safety features that are subjected to an authentication process before the drugs are dispensed to the patient. The legal foundations are:

- The Falsified Medicines Directive 2011/62/EU and
- The Delegated Regulation (EU) 2016/161.

In addition, the following information from the EU Commission applies:

- Questions and Answers of the EU Commission on the Delegated Regulation
- EU measures for the protection of patients against falsified medicines in the legal supply chain

National regulations

The European regulations required the corresponding adjustments to the national law:

- Federal Law Gazette Part I, Year 2018 No. 24 Page 1080
- Federal Law Gazette Part I, Year 2019 No. 30 Page 1202

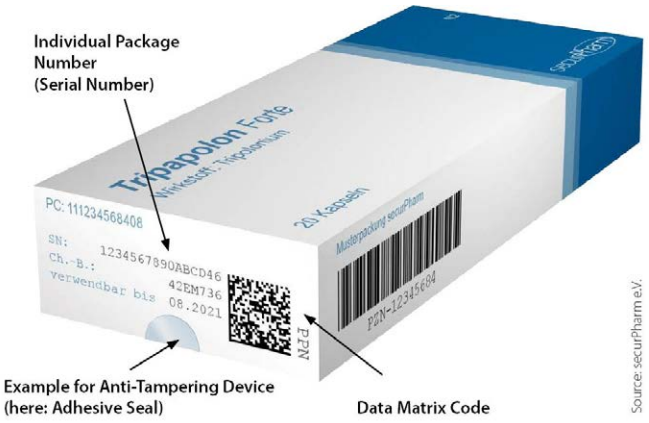
In addition, the following information applies:

- Announcement of the BfArM and PEI regarding the anti-tampering device (BAnz AT 26 April 2017 B3)

1.3 The safety features

Since 9 February 2019, only prescription drugs bearing a unique identifier and whose integrity is visibly recognisable have been allowed to be circulated in the member states of the European Union and the European Economic Area.

- The unique identifier is a randomly generated serial number in connection with the product code in question, which renders each package unique. The serial number clearly stands in the context of the product code. The unique identifier represents the basis for authentication through the securPharm system.
- The anti-tampering device (the so-called initial-opening protection) facilitates verification as to whether the outer packaging of a pharmaceutical was manipulated. Standard ISO 21976 is considered the joint, reliable basis for the manufacturing industry.



2. The 2020 operating year

2.1 Users

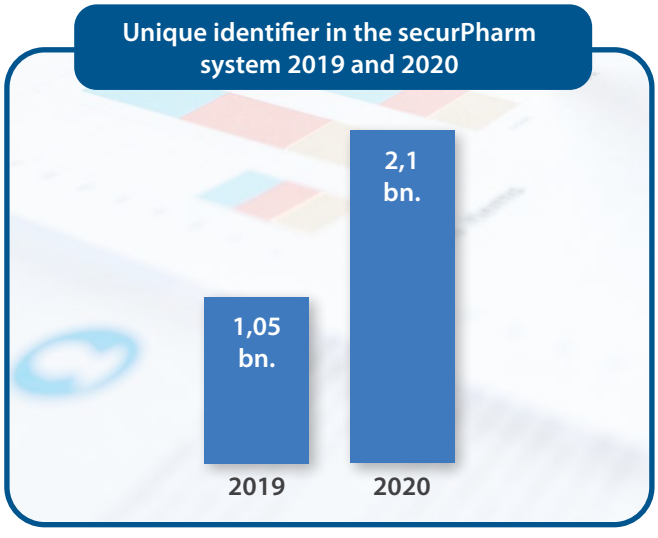
The users of the securPharm system are the market participants in German pharmaceutical care who connected to the securPharm system in order to implement the Falsified Medicines Directive and the Delegated Regulation. In the future, this will include the supervisory authorities in charge according to the German Medicinal Products Act.

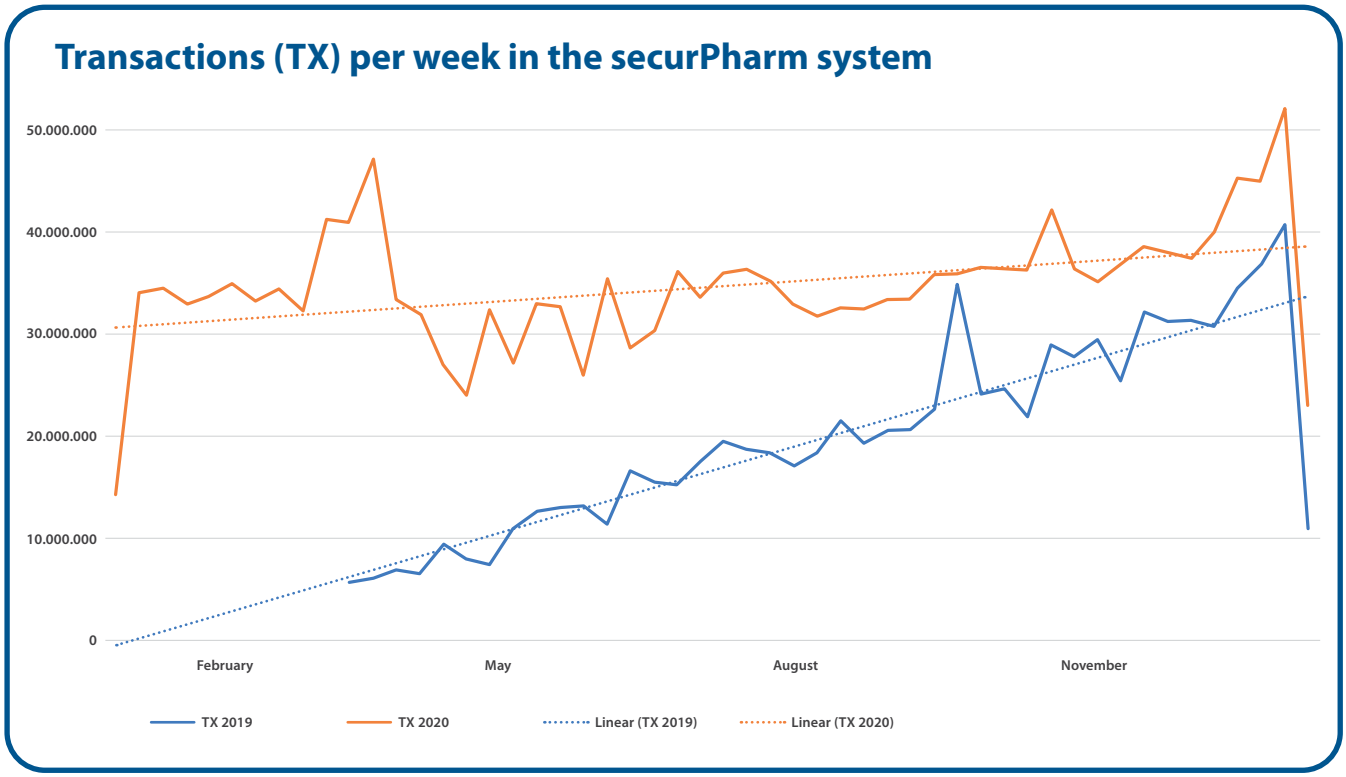
As of 31 December 2020, the following active users were connected to the system: 416 pharmaceutical companies, 708 wholesalers, 18,820 community pharmacies, 361 hospital pharmacies, 24 industrial blister companies, 25 compounding manufacturers and 14 centralised procurement departments. The number of users varies according to market dynamics with concentration processes, closures and newly established companies.

2.2 Key indicators of the system

As of 31 December 2020, there were 2,1 billion unique identifiers uploaded to the securPharm system (previous year: 1.05 billion). The transactions with the unique identifier in pharmacies and wholesale that were recorded in the system amount to 34 million per week on average (previous year: 20 million per week). The rate of alarms, which reflects the ratio of alarms and transactions, was significantly reduced over the year. While it was still at 0.42 percent at the end of 2019 (calendar week 51/2019), it had gone down to 0.15 percent in calendar week 52/2020. As for the previous year, it is therefore significantly lower than the European value of 0.46 percent in calendar week 52/2020.

The securPharm system is in compliance with the requirement of a data repository speed of 300 milliseconds in normal operation, as stipulated by the Delegated Regulation. However, the response time from the users' point of view is not only based on the efficiency of the securPharm system but is also impacted by the data connection between a verifying entity and the pharmacy system and the internal infrastructure within the verifying entity. As a result, the overall duration of the query can exceed the 300 milliseconds from the users' point of view in exceptional cases.





In 2020, more than 1,8 billion queries (transactions) reached the securPharm system. Even in peak times with up to 52 million transactions per week, the system ran in stable operation. Overall, reliability was significantly improved in 2020 as compared to the previous year, so that only a few brief system disruptions occurred. The system availability e.g. of the pharmacy server was 99.98 percent.

In order to create transparency regarding availability, securPharm provides an overview at www.securPharm-status.de. Information on system impairments is communicated on the securPharm website and by the operators of the partial systems.

2.3 Supervision and monitoring of securPharm

As the national authority in charge, the Detmold district government performed the initial inspection of securPharm e.V. in terms of the implementation of the Delegated Regulation on 18 November 2019.

The final meeting of the inspection did not result in any major deviations and only a few conspicuities, according to the compliance rating of the inspection report, which was generated and published by the EU Commission as a guideline for the monitoring of NMVOs:

(https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/inspectionreport_en.docx)

2.4 Change in the scope of the safety features

According to the Delegated Regulation, a product can be included in Annex 1, the so-called "White List", if a pharmaceutical has e.g. a low potential for falsification. In these cases, the regulatory agencies in charge must be contacted. They will then go through the Federal Ministry of Health to contact the European Commission for final investigation and inclusion in the "White List". In 2020, no new products were included in the White List and Black List. However, according to Article 46 (2) of the Delegated Regulation, the German Federal Ministry of Health has submitted to the European Commission an application for including "BioBag® Fliegenlarven" (fly larvae) in Annex I of the Delegated Regulation. The application is still being processed by the European Commission.

2.5 Report from the operating organisations

2.5.1 The NGDA – Operator of the pharmacy system

NGDA – Netzgesellschaft deutscher Apotheker mbH (NGDA), the operator of the pharmacy system, expanded the securPharm-GUI user interface with an alarm monitoring function

on 1 December 2020. This now provides the verifying entities with an overview of the alarms they triggered. It is visible on what day a query that triggered an alarm was made, the processing status and whether the problem was resolved. Apart from the pack data, information is now also available on the alarm type, the error code and the alarm ID, which is uniform in all of Europe. The expansion of the user interface and the associated user options were communicated by NGDA to its users. Plans for 2021 include an expansion of the alarm monitoring by one function based on which the verifying entity can anonymously transmit comments to the marketing authorisation holder.

In 2020, the first extensions of the N-Ident certificates, each of which is valid for 24 months, also occurred. These certificates are the prerequisites for access to the securPharm system. NGDA informed its users of this fact and provided instructions early on.

2.5.2 ACS Pharma Protect – Operating company of the database system of the pharmaceutical industry

ACS PharmaProtect GmbH (ACS), the operator of the database system of the pharmaceutical industry (MAH system) successfully rolled out its release 3.08 in November 2020. With this release, various adjustments and improvements were implemented. Among others, it created the prerequisite for an interface through which marketing authorisation holders can leave comments for the end users within the alarm monitoring section.

In the MAH system, the certificates as a prerequisite for access to the securPharm system also had to be renewed after two years. ACS supported its customers with materials and a webinar early on.

Furthermore, ACS implemented the annual exchange of experiences, this time in digital format. A total of 240 participants used the opportunity to obtain information on the securPharm system and to engage in an exchange.

2.6 Provision of audit trails

The authorities are legally entitled to receive reports from the securPharm system. Upon request, they are therefore provided with audit trails regarding cases of suspected falsification, which were previously reported to them by the market participants. During the 2020 operating year, securPharm processed 766 audit trail inquiries.

For 2021, direct access to the securPharm system is planned for authorities so that they can independently download the audit trails. Preparations in this respect, including the required agreement for system use and legitimation, were started in 2020. Pursuant to Art. 37 lit b) of the Delegated Regulation, only legitimised users will obtain access to the securPharm system.

2.7 Provision of reports for the authorities

Apart from the above-mentioned audit trails, the national authorities are also entitled to receive reports from the securPharm system regarding the monitoring of market participants as well as pharmacovigilance and pharmacoepidemiology. These so-called NCA reports have been developed at the European level between the authorities of individual countries as a subgroup of the Expert Group of the EU Commission and the EMVO. They are to be implemented uniformly in all countries. The implementation in Germany has started and is expected to conclude in 2021.

Overall, the supervisory authorities will have 28 reports available in the respective national systems. The purpose of these reports is to support the authorities in executing their duties in supervising the market participants. The reports provide

supporting information for the investigation of conspicuities, information as part of pharmacovigilance and pharmacoepidemiology as well as information regarding other questions. Among others, they may include actions a market participant has taken in regards to a certain unique identifier.

3. Handling of system notifications

Following the rules of the Delegated Regulation, unsuccessful verifications of the unique identifier are captured in the securPharm system and a so-called alarm is generated. This alarm is assigned an alarm ID, so that each alarm can be unambiguously referenced.

3.1 Warning of the participants: Immediate measure and investigation

First, the alarm is displayed to the system user who caused the alarm. Based on the requirements of the Delegated Regulation, said user must separate the package from the product inventory. With a few exceptions, a package with a deactivated unique identifier may not be distributed or supplied to the public.

To facilitate correction of the cause of the alarm, the marketing authorisation holder responsible for the product also receives the alarm. For this purpose, the alarm ID is sent from the securPharm system to the EU hub and from there to the onboarding partner who is connected to the hub and to whom this product is assigned in terms of data technology. The onboarding partner clarifies internally with his associated pharmaceutical companies who will be in charge of further processing the alarm. When using the national alert management tool, which ACS has provided to its contractual partners, the marketing authorisation holder in charge has seven calendar days to analyse the case and qualify it accordingly.

If it can be ascertained during this time period that the alarm is due to an internal handling error, e.g. an incomplete upload of the pack data to the securPharm system, the incident can be rated a false alarm and the corresponding entry can be made in the securPharm system. An alarm rated a false alarm is not subject to mandatory reporting. If there is no false alarm, the alarm is subject to mandatory reporting.

If the time period of seven calendar days expires without the corresponding feedback being entered in the system, the conflict is automatically rated a suspected falsification and the reporting obligations apply. If the marketing authorisation holder does not use the alert management tool, the seven-day deadline does not apply and the reporting obligation applies immediately.

3.2 Reporting obligations and pathways

The reporting obligation when a case is rated a suspected falsification applies both to the marketing authorisation holder and the system user with whom the alarm occurred. In this respect, the previous reporting pathways of the individual market participants remain in effect, i.e. the report goes to the respective supervisory authority in charge. The various reports regarding a suspected falsification can be classified by the authorities via the unique alert ID on a Europe-wide scale.

To ensure that a verifying entity is informed that an alarm was classified as either a false alarm or a case of suspected falsification, the user interface of the securPharm system (the securPharm-GUI of NGDA) was expanded by the corresponding function in December 2020. Among other things, users can now view the current processing status of a pack alarm. The marketing authorisation holder in charge of investigating the case of suspected falsification can communicate e.g. with the pharmacist via the unique alert ID. However, the pharmacist remains anonymous to the marketing authorisation holder.

It is planned that the securPharm system will automatically inform the Federal Institute for Drugs and Medical Devices (BfArM) via the authority portal as soon as an alarm has been classified as a suspected falsification in the securPharm system. Together with the Paul Ehrlich Institute (PEI), the BfArM then coordinates these cases, registers them in its own official database of falsifications and informs the supervisory authority in charge of the affected marketing authorisation holder. Nevertheless, it should be noted that the automatic notification through the securPharm system is an additional report that is not a substitute for the previous reporting obligations of the market participants. For a justified suspicion of falsification, the previous reporting obligations will continue to apply.

3.3 Alarms: Number, cause, measures

In 2020, securPharm has continued to dedicate special attention to reducing the number of alarms. The search for errors is still complex, since – due to the internationally networked systems – impacts of actions in other national systems must also be taken into account. Therefore, a working group at securPharm is intensively dealing with error analysis, root cause analysis and the definition of measures (see Chapter 3.3.2). Over the course of operating year 2020, the measures taken by securPharm have resulted in an alarm rate reduction.

As a result, the alarm rate was further reduced from 0.42 percent (in calendar week 3/2020) to 0.17 percent (in calendar week 53/2020) with a simultaneously increasing usage intensity. The annual alarm rate average was 0.28 percent. While this is a considerable development and a good value in a European comparison, the absolute number of alarms per day is still too high for qualified processing by the supervisory authorities.

At the European level, the alarm rate was also reduced from 0.76 to 0.41 percent, but here, too, the absolute number is still too high to be able to process individual cases. Since it has become apparent that these alarms are predominantly triggered through handling errors or bugs in third-party software, securPharm is currently investigating the use of additional technical filter solutions. The goal is to identify the actual cases of suspected falsification among the alarms, thereby facilitating tracking efforts by the authorities in charge.

3.3.1 Causes of alarms

The causes of alarms are predominantly handling errors or technical faults in third-party software. Specifically, some of the following causes of alarms were identified:

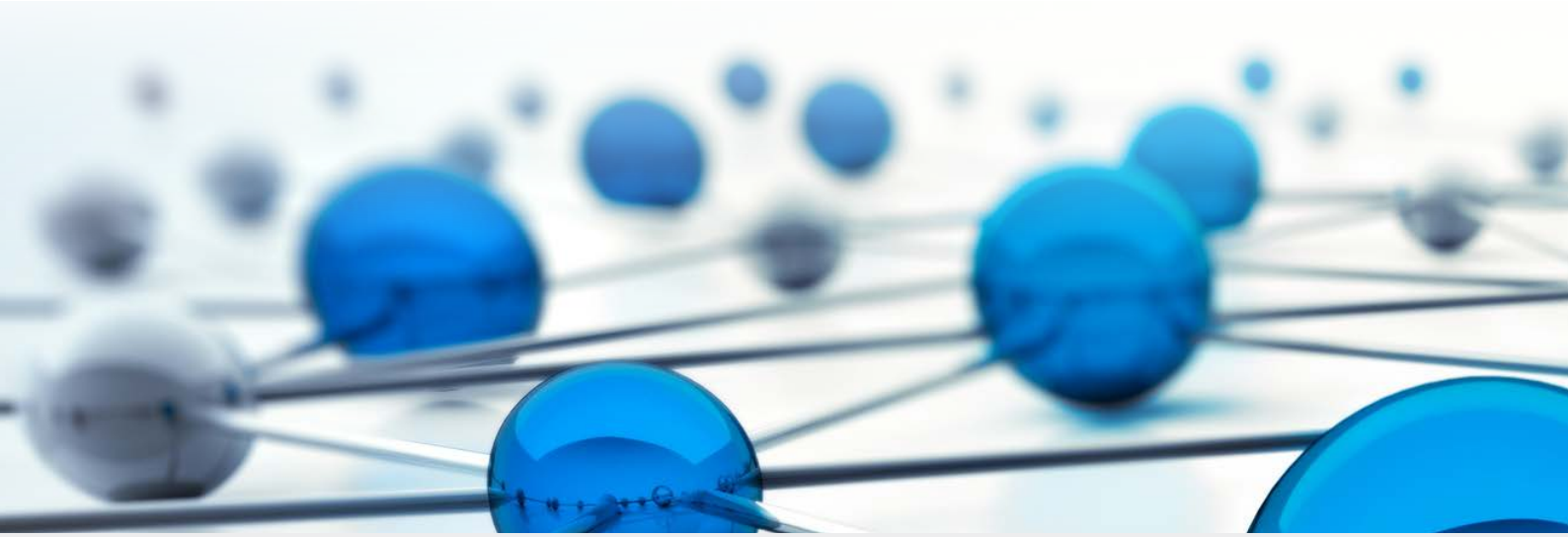
- Handling errors by system users
- Unpredicted system behaviour due to high complexity
- Missing or incomplete data upload
- Bugs in participating systems (EMVS, NMVS, user software)
- Faulty configuration in the participating systems

3.3.2 Measures by securPharm for reducing alarms

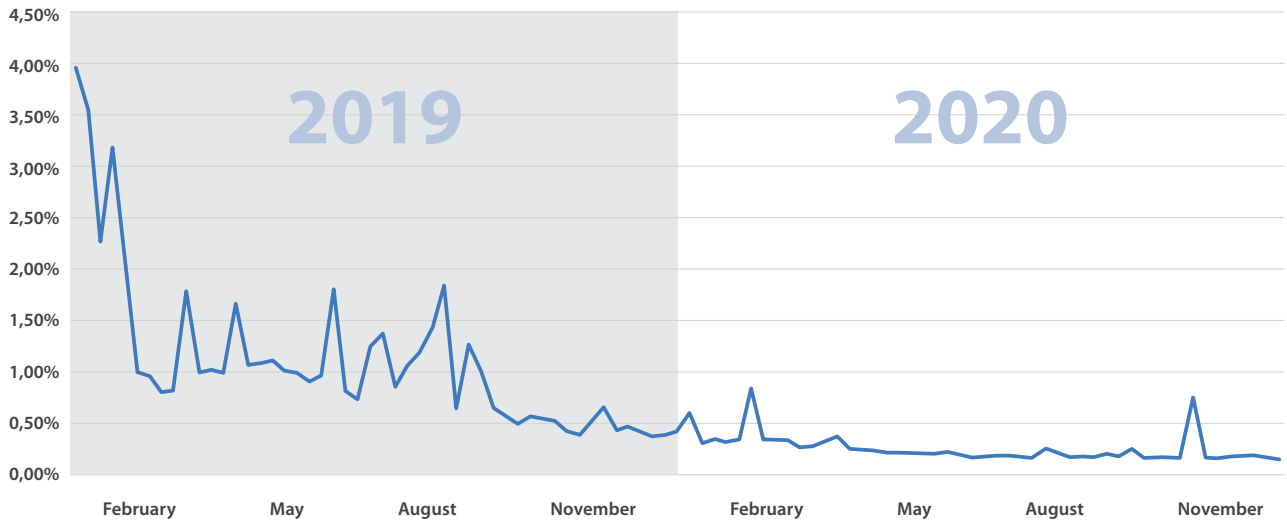
Besides personal contact, securPharm e. V., the members of securPharm and the operating companies have taken several measures to reduce the number of false alarms.

Intensive communication

Once more in 2020, the trade associations of the individual user groups have intensified their communications efforts regarding the causes and the elimination of handling errors. The ABDA and the Federal Pharmacy Chamber sent out several information letters to their members about the specific causes and on how to avoid false alarms. In working groups and information letters to members, the trade associations of the pharmaceutical industry and the wholesalers' association have also disseminated targeted information on the causes



Alertrate



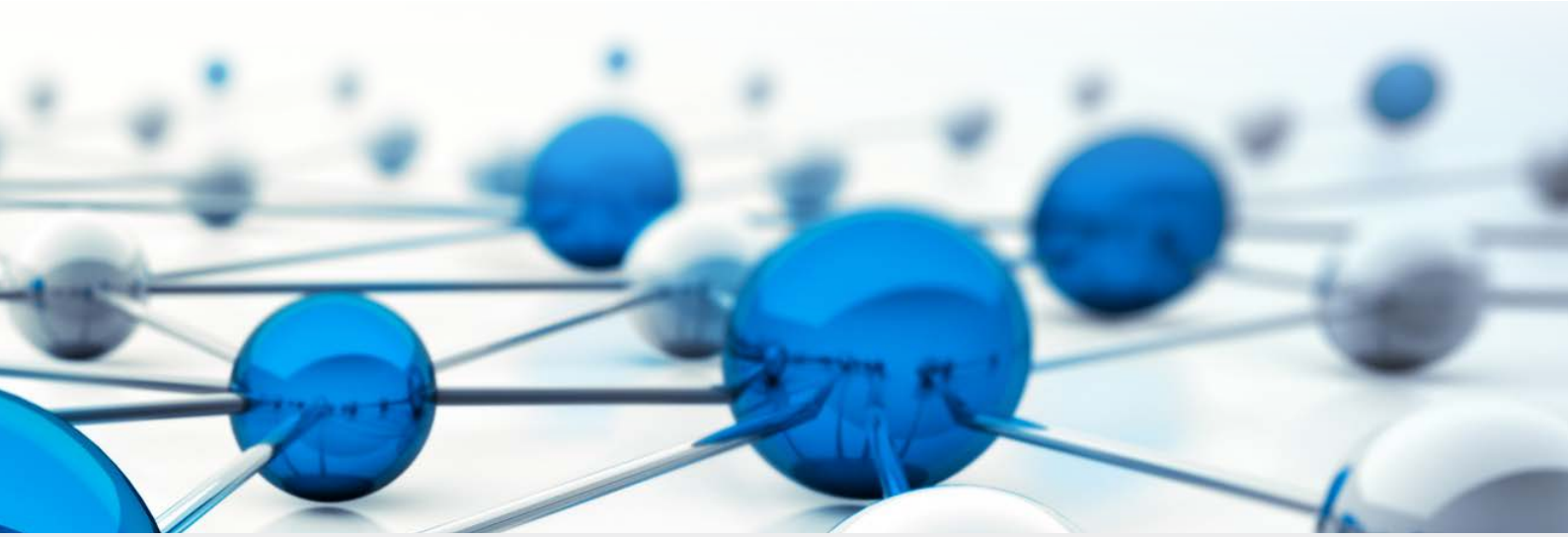
of false alarms. securPharm and the operating organisations have picked up this information as well. Most recently, during a digital event organised by ACS PharmaProtect, representatives of the various supply levels and about 230 pharmaceutical companies engaged in an in-depth exchange about the possibilities for reducing false alarms and other issues.

Detection of existing merchandise

Apart from root cause analysis and directly addressing the originators of alarms, securPharm has also implemented technical solutions for alarm reduction in selected cases. This concerns e.g. merchandise released prior to 9 February 2019. The Delegated Regulation provides that this merchandise remains marketable until its expiry date (Article 48). However, if this merchandise bears an affixed Data Matrix Code, the securPharm system can react with an alarm, either because coding was incomplete or the data were not uploaded to the MAH system. In this case, the securPharm system behaves technically correctly but generates a so-called false alarm. To ensure that false alarms do not result in a market impairment, securPharm has defined central filter rules, which interrupt the automatic escalation of reports to the authorities in these cases. The information about these packages is stored, so that it can be consulted by the authorities, if necessary.

Scanner test

In addition, securPharm and NGDA have provided verifying entities with a scanner test that can be used to verify if a scanner is configured in such a way that it reads the codes in a system-compatible manner.



Expansion of NGDA's securPharm-GUI
NGDA has added an alert management tool to the Web interface of the securPharm system. Previously, the Web interface could only be used for a manual verification of the unique identifier. Now, verifying entities (pharmacists, wholesalers, etc.) can use the page in order to obtain information on the processing status of an alarm on the part of the marketing authorisation holder. Furthermore, the marketing authorisation holder has the opportunity to leave a comment for the verifying entity. It is further planned that the verifying entity will also be able to transmit comments to the marketing authorisation holder via the alarm monitoring function in the future. The goal is an unambiguous communication process via the system, so that all parties involved can communicate with each other in a case-related manner.

In addition, the Web interface offers the possibility that verifying entities can download from the securPharm system a list of the errors that occurred at their facility. With this overview, the verifying entity can work on system handling and processes in a targeted manner or adjust the software solutions in order to avoid false alarms.

Verification during goods in process
securPharm continues to recommend that merchandise be scanned at the time of delivery. This additional voluntary check will help discover and limit complications early on.

Returns
When returning merchandise to wholesalers, it must not be deactivated in the securPharm system if it is to remain marketable. If merchandise was accidentally deactivated, the legislature has provided the possibility to undo this process within 10 days. However, this can only be done by the same facility.

4. Collaboration on the national and international level

4.1 National collaboration

An exchange and collaboration with the authorities are important for operating the securPharm system. Therefore, securPharm maintains a regular exchange with representatives from the authorities on current issues regarding the operation of the securPharm system. In the Federal and State Working Group on Falsified Pharmaceuticals (German: BLAG), securPharm also reports on the degree of implementation and current issues. The BLAG is coordinated by the Federal Ministry of Health. State ministries, supervisory authorities and the superior federal authorities send delegates to this round. The pharmaceutical expert circles are represented as well. As part of various events of the superior federal authorities and contributions to the Pharmaceutical Working Conference, the current status of the system was presented and questions and answers of the authorities' representatives were discussed. Furthermore, securPharm e. V. has established an administrative board on which the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Ministry of Health (BMG) will each have a seat.

4.2 International collaboration

Member states within the scope of the Directive face the challenge of establishing and evolving an international and functional verification system that does not obstruct the movement of goods and safeguards patient protection. Therefore, securPharm maintains an intensive exchange with the organisations of the other countries (NMVOs) for discussions revolving around questions of system development and improvement, interactions with each other and with the EMVO. The roundtable of project managers established at the European level by the European umbrella organisation EMVO is a key factor in this respect and is supplemented by various working groups from the areas of project management, technology and quality assurance. Since Day 1, securPharm has been active in this international exchange and is an important member of this community, e.g. in the so-called "Secretariat", a coordinating body of the Arvato customer group and a member on the EU Change and Control Board (EU CCB) where changes in the respective national protection systems and in the hub are coordinated and finetuned.

5. The NMVS – The National Medicines Verification System

The securPharm system 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.

5.1 Data ownership and privacy

Data ownership and privacy are a high priority at securPharm. As a result, the securPharm system consists of connected partial systems. The respective operation was assigned by securPharm e.V. to different operators in order to ensure data separation and data privacy, not just from a legal

but also from an organisational and technical standpoint. As a result, data ownership is clearly assigned and organised in transparent and reproducible fashion. This modularisation additionally results in higher efficiency, since the operators of the partial systems can specialise in the requirements of their respective user groups. securPharm e.V. as the NMVO monitors and controls the operating companies' compliance with the stipulated legal and agreed upon requirements.

The operators act as contractual partners of the system users and serve as contacts for technical and contractual questions regarding connection to the system. They provide the system users with different aids such as starter kits, checklists and guidelines, etc. Information is available at https://www.securpharm.de.

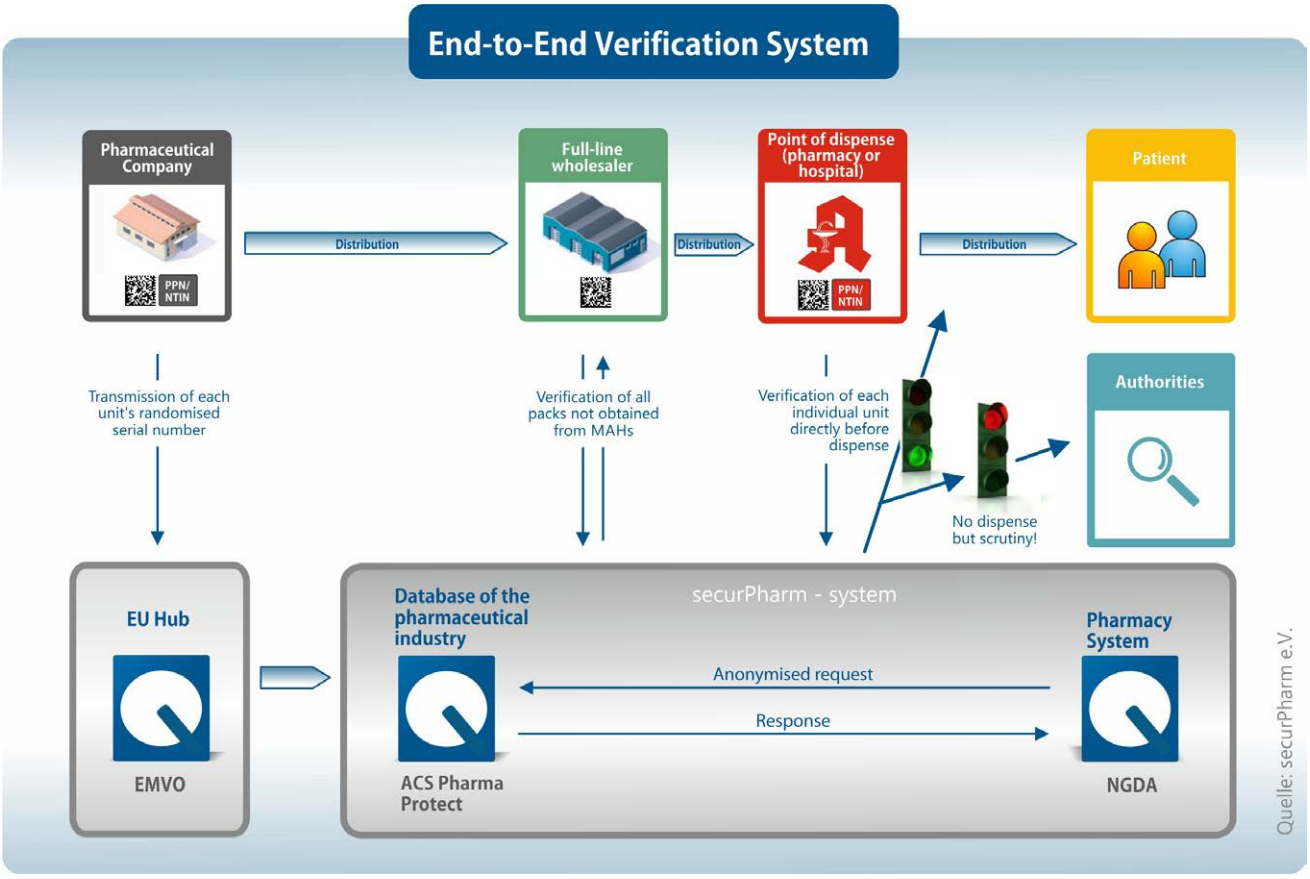
5.2 Developers of third-party software for system users

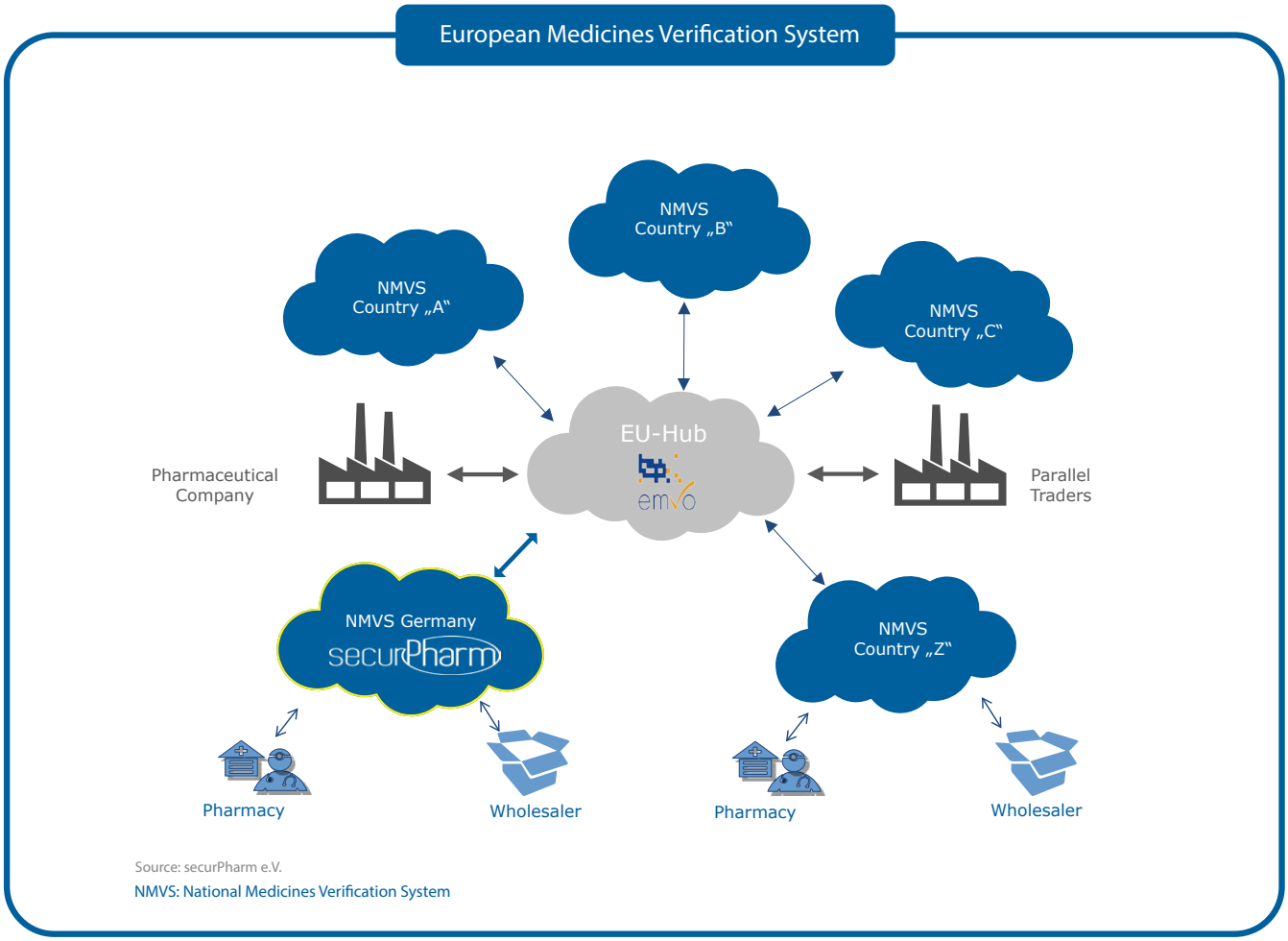
Technical access for system users to the securPharm system is made via interfaces the specifications of which are provided by the operating companies. The technical connection between the interface of the securPharm system and the software system of a user is set up by the user's software provider.

The implementation guidelines of ACS and NGDA regarding the use of the interface also contain recommendations for so-called convenience functions, which can e.g. make the capture of the serial number and product code easier during disruptions. Naturally, securPharm and the operating companies have no influence on the implementation of the recommendations by the software vendors.

5.3 Integration into the European network EMVS

Like the national verification systems of the other member states of the European Union and the European Economic Area, the securPharm system is connected to the European hub as the central data router. The connection of the securPharm system to the hub is made via the MAH system. The European Medicines Verification Organisation (EMVO) is responsible for the European hub. This way, the different so-called National Medicines Verification Systems (NMVS) and the European hub become the European Medicines Verification System (EMVS). The EMVS is continuously improved based on experience and insights from ongoing operations. These improvements are coordinated by the EU-CCB.





Source: securPharm e.V.

NMVS: National Medicines Verification System

Pharmaceutical companies upload the pack data via the European hub and the hub routes them to the corresponding national system.

Based on the networking of the national verification systems, any pharmaceutical pack equipped with the safety features can be verified in any pharmacy in Europe.

5.4 Coding requirements

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 https://www.securpharm.de/codierung/?lang=en). The securPharm Coding Rules contain the current requirements, which result from the Delegated Regulation and are binding for the German market and the use of the securPharm system.

5.5 System access

securPharm guarantees that only users whose identity, role and legitimacy has been checked have access to the securPharm system, based on requirements for the operating companies of the partial systems with regard to a safe, reliable and appropriate procedure for the authentication and legitimation of the user groups . For information about the contacts for contract conclusion, legitimation and connection, please visit https://www.securpharm.de. Membership in a trade association is not a prerequisite for system access.

6. Conclusion and outlook

During operating year 2020, the securPharm system has proven to be reliable and very stable from a technical standpoint and has also handled greater peaks very well. The number of uploaded unique identifiers has doubled and the number of transactions has also increased significantly. Both numbers show that the digital falsification protection through the securPharm system has become established in users' everyday lives. The main focus of securPharm has been and continues to be the number of alarms, which has decreased relatively but is still too high. Therefore, securPharm and its members have intensified their communications efforts regarding causes of and possibilities for avoiding errors as well as provided technical support for users. For example, an alarm monitoring function was added to the securPharm-GUI developed by NGDA. It makes communication between market participants easier and provides individual users with a possibility to deal with handling errors that occurred at their facility. Plans for 2021 include an expansion of the alarm monitoring by one function based on which the verifying entity can anonymously transmit comments to the marketing authorisation holder. This will also facilitate an exchange between the parties involved. Furthermore, it is expected that the authorities will be connected to the securPharm system in 2021. They will then be able to independently download audit trails for the unique identifiers reported by the market participants and to investigate the individual suspected cases without consulting with securPharm. Nonetheless, the interaction between securPharm and the authorities will continue to represent an important aspect in the work of securPharm. Also expected for 2021 is the completion of the Europe-wide uniform authority reports for Germany. They will enable the authorities to take a look at the interactions of individual market participants with the securPharm system. This will be yet another tool for completing the patient protection intended by the Delegated Regulation. The administrative board which was established by securPharm e.V. in 2020 pursuant to Article 44 (5) of the Delegated Regulation will also take up its work in 2021.

7. About Us

7.1 securPharm members as of 31 December 2020

ABDA – Bundesvereinigung Deutscher Apothekerverbände e.V.
http://www.abda.de

Avoxa – Mediengruppe Deutscher Apotheker GmbH
http://avoxa.de

BAH – Bundesverband der Arzneimittel-Hersteller e.V.
https://www.bah-bonn.de

BPI – Bundesverband der Pharmazeutischen Industrie e.V.
http://www.bpi.de

IFA – Informationsstelle für Arzneispezialitäten GmbH
https://www.ifaffm.de

PHAGRO – Bundesverband des pharmazeutischen Großhandels e.V. (German Association of Pharmaceutical Wholesalers)
http://www.phagro.de

vfa - Verband Forschender Arzneimittelhersteller e.V. (German Association of Research-based Pharmaceutical Companies)
https://www.vfa.de

7.2 Board of Directors

Dr. Eckart Bauer
Bundesvereinigung deutscher Apothekerverbände e.V.

Thomas Brückner
Bundesverband der Pharmazeutischen Industrie e.V.

Michael Dammann
Bundesverband des pharmazeutischen Großhandels e.V.

Dr. Herrmann Kortland
Bundesverband der Arzneimittelhersteller e.V.

Peter Krug
Verband Forschender Arzneimittelhersteller e.V.

7.3 Executive Management

Martin Bergen

7.4 Administrative Board

Members of the securPharm Board of Directors

Dr. Michael Horn
Bundesinstitut für Arzneimittel und Medizinprodukte
(Federal Institute for Drugs and Medical Devices)

Dr. Oliver Onusseit
Bundesministerium für Gesundheit
(Federal Ministry of Health)

8. Important links

Falsified Medicines Directive 2011/62/EU
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_de.pdf

Delegated Regulation (EU) 2016/161
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_de.pdf

Questions and Answers of the EU Commission on the Delegated Regulation: Version 18, August 2020
https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

Website on EU measures for the protection of patients against falsified medicines in the legal supply chain
https://ec.europa.eu/health/human-use/falsified_medicines_en

securPharm e.V. – the German organisation for the authentication of pharmaceuticals
https://www.securpharm.de

ACS PharmaProtect GmbH – The operating company of the database system of the pharmaceutical industry at securPharm
http://www.pharmaprotect.de

NGDA – Netzwerkgesellschaft Deutscher Apotheker mbH – The operating company of the pharmacy system at securPharm
http://www.ngda.de

EMVO – European Medicines Verification Organisation – The operating organisation of the European hub
http://www.emvo-medicines.eu

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2021 Status Report
As of February 2021

This status report is available in German and English
for downloading at www.securpharm.de.

www.securpharm.de

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Vereinsregister des Amtsgerichts Frankfurt am Main | Tel. 069 / 979 919 12 | info@securpharm.de