securPharm

German Medicines
Verification Organisation

STATUS REPORT 2022

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

2

ABDA

BPI Bundesverband der Pharmazeutischen Industrie e.V.

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 and pharmacists: BAH, BPI, vfa 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 readers,

Once again, our status report is overshadowed by the Coronavirus pandemic. During the second year of the pandemic, the challenges for research, the economy and society remain huge. Even under lockdown conditions, the members of securPharm, who jointly represent a large part of Germany's pharmaceutical supply, dedicate all their expertise to patient care and the production of pharmaceuticals. People in Europe can feel good about relying on the fact that the European protective system and the securPharm system in Germany dependably protect pharmaceuticals and vaccines against falsified products in the legal supply chain. Trust in the pharmaceutical supply is and remains a precious asset.

Protection against falsified pharmaceuticals is an international responsibility. As a result, the countries of the EU and the EEA collaborate via the European protective system against falsified pharmaceuticals, EMVS. The further alignment and standardisation of the protective system will increasingly be decided at the European level, in a joint exchange of the NMVOs and while safeguarding the specifics and needs of the national pharmaceutical markets. After all, in an economic area with free movement of goods, international tracking of data flows is also important. To ensure that securPharm's experiences are incorporated into the further development of the protective system, active representation of securPharm at the EMVO in Brussels is important. As a result, the members of securPharm together with their stakeholders are committed to actively participate in the working groups at the European level. The current focus is on standardising the alarm systems of the individual countries with the respective specific national additional functions. The goal is to enable more effective and standardised cooperation between individual countries and their NMVOs in international cases of suspected falsification. As part of these efforts, we will adapt the basic functions of our system to a European standard and harmonise it with the European system.

The securPharm system operated quickly and reliably in 2021, with an annual average availability of 99.9 percent for users of the pharmacy system. As a result, system performance has increased once again. The reduction of false alarms, most of which result from handling errors or incomplete data uploads, remains an important task. The need for information among individual users of the securPharm system remains high. Together with our members, we have therefore not only continued to provide information but also to expand the technical support functions in the alert management system for pharmaceutical companies and in the securPharm-GUI for verifying entities. These tools enable users to identify and minimise individual errors.

After we adapted our organisational structures to mandatory operations in 2020, the optimisation and development of the organisation continues. In 2021, we audited our operating companies with good results. ACS received the DIN EN ISO 9001 certification in December 2021.

There has been a change in the membership of the organisation for the first time since it was founded. The wholesalers association terminated its membership at the end of 2021. The change in the membership structure shows once again that the goal of establishing a European protective system against falsified pharmaceuticals has been achieved. Now the focus is on routine operations, further expansion and adjustments to future challenges.

securPharm and its members, their representatives in the working groups and the operators of our databases are ready to accept these challenges. I would like to thank them for their commitment to further developing our protective system against falsified pharmaceuticals. It is our joint objective to secure pharmaceuticals and to protect patients. That is what unites us – now and in the future.

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 verification trail 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:

- Falsified Medicines Directive 2011/62/EU
- Delegated Regulation (EU) 2016/161
- Delegated Regulation (EU) 2021/457 (Brexit)
- Delegated Regulation (EU) 2022/315 (Brexit)
- Delegated Regulation (EU) 2021/1686 (White List)

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:

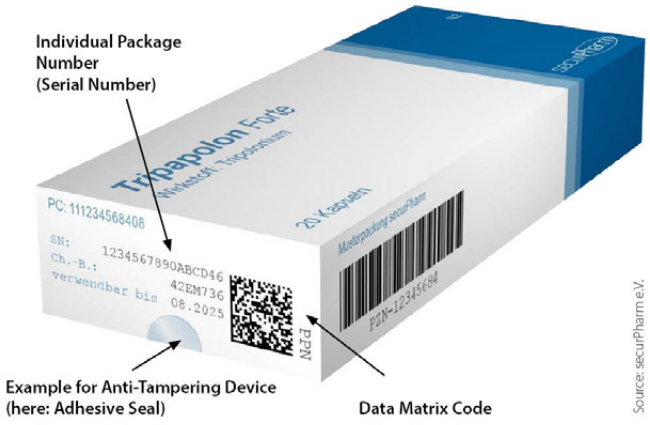
- Federal Law Gazette Part I, Year 2018 No. 24 Page 1080
- Federal Law Gazette Part I, Year 2019 No. 30 Page 1202

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.



Source: securPharm e.V.

- 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. The ISO 21976 standard is considered a common, dependable basis for the manufacturing industry.

2. The 2021 operating year

2.1 Users

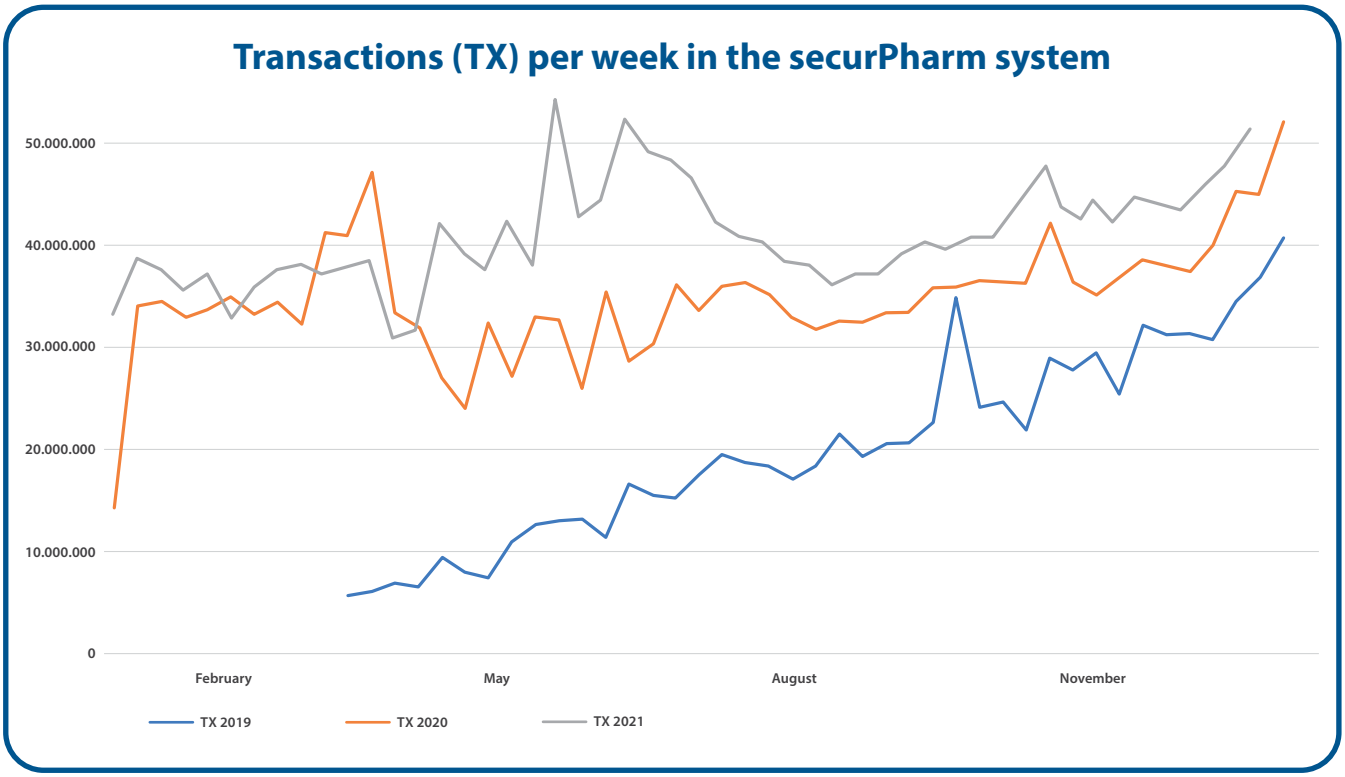
The users of the securPharm system are the market participants in German pharmaceutical care who connected to the securPharm system in order to implement the Falsified Medicines Directive and the Delegated Regulation. In the future, this will include the supervisory authorities in charge according to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

As of 31 December 2021, the following active users were connected to the system (the previous-year values are given in parentheses): 458 (416) pharmaceutical companies, 645 (708) wholesalers, 18,747 (18,820) community pharmacies, 345 (361) hospital pharmacies, 21 (24) industrial blister companies, 27 (25) compounding manufacturers and 11 (14) centralised procurement departments. In all of Europe, 115,000 users are currently connected to the system. The number of users varies according to market dynamics with portfolio adjustments, concentration processes, closures and newly established companies.

2.2 Key indicators of the system

As of 31 December 2021, approximately 900 million additional unique identifiers had been uploaded to the securPharm system. As a result, there were a total of 2.9 billion unique identifiers in the securPharm system as of 31 December 2021. It can be assumed that a plateau has been reached with this value. As expected, the number of unique identifiers marked as "dispensed" increased once again to over 740 million. Moderate increases can be expected in subsequent years until a plateau is reached here as well. The transactions recorded in the system with the unique identifier in pharmacies and the wholesale sector average 39 million (previous year: 34 million) per week, thus also showing a moderate increase.

The alarm rate, which expresses the ratio of alarms to transactions, was reduced once again over the course of the year, thereby continuing its positive downward trend. As an annual average, the alarm rate decreased by half from 0.28 percent in 2020 to 0.14 percent in 2021 as the intensity of usage



increased. It has become apparent that singular events can cause alarm spikes at any time.

The alarm rate of the entire European system (EMVS) was reduced by more than half over the course of 2021. After 0.46 percent in calendar week 52 of 2020, it was merely 0.21 percent in calendar week 52 of 2021. The annual average in the EMVS is 0.26 percent. The securPharm system compares well across Europe, even if the absolute number of alarms in the German system and in the EMVS is still too high. The target for the pan-European alarm rate is 0.05 percent. This corresponds to approximately 3,500 alarms per day in Germany. On the subject of alarm causes and measures for alarm reduction, see Chapter 3.3.

The Delegated Regulation stipulates that the speed of the data repository shall not exceed 300 milliseconds (from receipt of the query at the NGDA to feedback output to the system user). The securPharm system meets this quality requirement. However, the response time from the users' point of view is not only based on the performance of the securPharm system but also impacted by the data connection between a verifying entity and the pharmacy system as well as the internal infrastructure within the verifying entity, so that the overall duration of the query can exceed the 300 milliseconds from the users' point of view in exceptional cases.

More than 2.03 billion queries (transactions) were processed through the securPharm system in 2021. Even during peak loads of up to 51 million transactions per week, the system operated stably. Reliability was improved again in 2021 compared to the previous year, so that the system was permanently available, except for planned and announced maintenance work. System availability for users of e.g. the pharmacy server averaged 99.99 percent (previous year: 99.98 percent). The migration of the pharmacy server's data centre also went smoothly and without affecting system availability.

For a quick look at the current availability of the securPharm system, please visit www.securPharm-status.de.

2.3 Supervision and monitoring of securPharm

The possibility of an inspection of securPharm e.V. pursuant to Article 44 (1) of the Delegated Regulation (EU) 2016/161 was last used by the Detmold district government as the national competent authority on 18 November 2019.

The final discussion of the inspection revealed no major deviations and only a few conspicuities, according to the compliance rating of the inspection report, which the EU Commission has prepared and published as a guideline for the monitoring of NMVOs: https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/inspectionreport_en.docx.

In 2021, securPharm conducted an audit at each of the operating companies, ACS PharmaProtect and NGDA. No exceptions were noted. Furthermore, ACS received DIN EN ISO 9001 certification, which confirms the conformity of its quality management system to this internationally recognized standard for quality management systems.

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 2021, BioBag® fly larvae were included in Annex I of the Delegated Regulation. The Delegated Regulation (EU) 2021/1686 amending Delegated Regulation (EU) 2016/161 was published in the Official Journal of the European Union on 21 September 2021 and became effective on the 20th day following its publication.

2.5 Brexit: Impacts and legal adjustments

So far, Brexit has not had any impact on the securPharm system, such as an increase in the alarm rate. The EU Commission adopted amendments to Delegated Regulation (EU) 2016/161 (Article 22) based on Delegated Regulation (EU) 2021/457 of 13 January 2021. This is a temporary exemption from the obligation for wholesalers to deactivate the unique identifier of products exported to the UK. This regulation was valid for one year. It was extended by three years with Delegated Regulation (EU) 2022/315 of 17 December 2021 and supplemented by additional items.

2.6 Report from the operating organisations

2.6.1 The NGDA – Operator of the pharmacy system

After NGDA – Netzgesellschaft Deutscher Apotheker mbH (NGDA) had added the alarm monitoring function to the securPharm-GUI user interface in December 2020, another new function followed in 2021 with the Key Indicators module. In addition to an overview of the alarms triggered by them, verifying entities now also have the possibility to compare their own alarm rate to that of another facility of the same type. Anonymity is preserved in the process. The new function provides an overview of the time history of the alarms as well as clues to possible error causes. With the functional expansion implemented in 2020, system users already have all the information on alarms that have occurred at their facility, including for processing status, PZN, error codes, pharmaceutical companies or product names. Based on another functional expansion in 2021, the verifying entities are provided with an additional tool for detecting, resolving and avoiding internal error sources. Furthermore, the foundations were laid in 2021 for a fundamental overhaul of the alarm management system. In addition to the planned commenting function, which allows the verifying entities to anonymously send comments to the marketing authorisation holders regarding the alarms in question, a function for the transmission of image files is planned. This will make it even easier for the parties involved to resolve the causes of alarms and to deescalate alarms. In addition, 2021 set the stage for the securPharm system to comply with the new EMVO requirements and transmit a consistent end-user ID for intermarket transactions without revealing the identity of the endpoint. This function will be activated over the course of 2022.

In addition, the NGDA has expanded its interface and created a simplification for pharmaceutical wholesalers with the function "Query of Permit Holders (Designated Wholesaler)." This information can now be queried in an automated manner individually or collectively.

2.6.2 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 3.09 at the end of 2021. Among other things, this release contains a further development of the alert management system (AMS). In the future, it will be possible to change the status of an alert multiple times and to add multiple comments to an alert. In a further expansion stage, these functions will also be made available to the verifying entities so that they can communicate with the marketing authorisation holder in a case-related manner. Furthermore, ACS implemented the annual exchange of ex-

periences. Several hundred participants used the opportunity to exchange information on the use of the securPharm system. ACS received DIN EN ISO 9001 certification in 2021, which confirms the conformity of its quality management system to this internationally recognized standard for quality management systems.

2.7 Provision of verification trails

The authorities are legally entitled to receive reports from the securPharm system. Upon request, they are therefore provided with verification trails regarding cases of suspected falsification, which were previously reported to them by the market participants. During the 2021 operating year, securPharm processed 445 verification trail inquiries. The direct access to the securPharm system for authorities planned for 2021 has been technically implemented. It is expected that the agreement on system use and legitimation will also conclude the other access prerequisites in 2022. Authorities are granted access to the securPharm system to be able to download verification trails on their own. Previously, authorities have received verification trails from the securPharm executive office upon request.

Apart from the above-mentioned verification 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.

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 regard to a certain unique identifier.

3. Handling of system notifications

Unsuccessful verifications of the unique identifier are captured in the securPharm system and an 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 triggered 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 system, 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 system, 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.

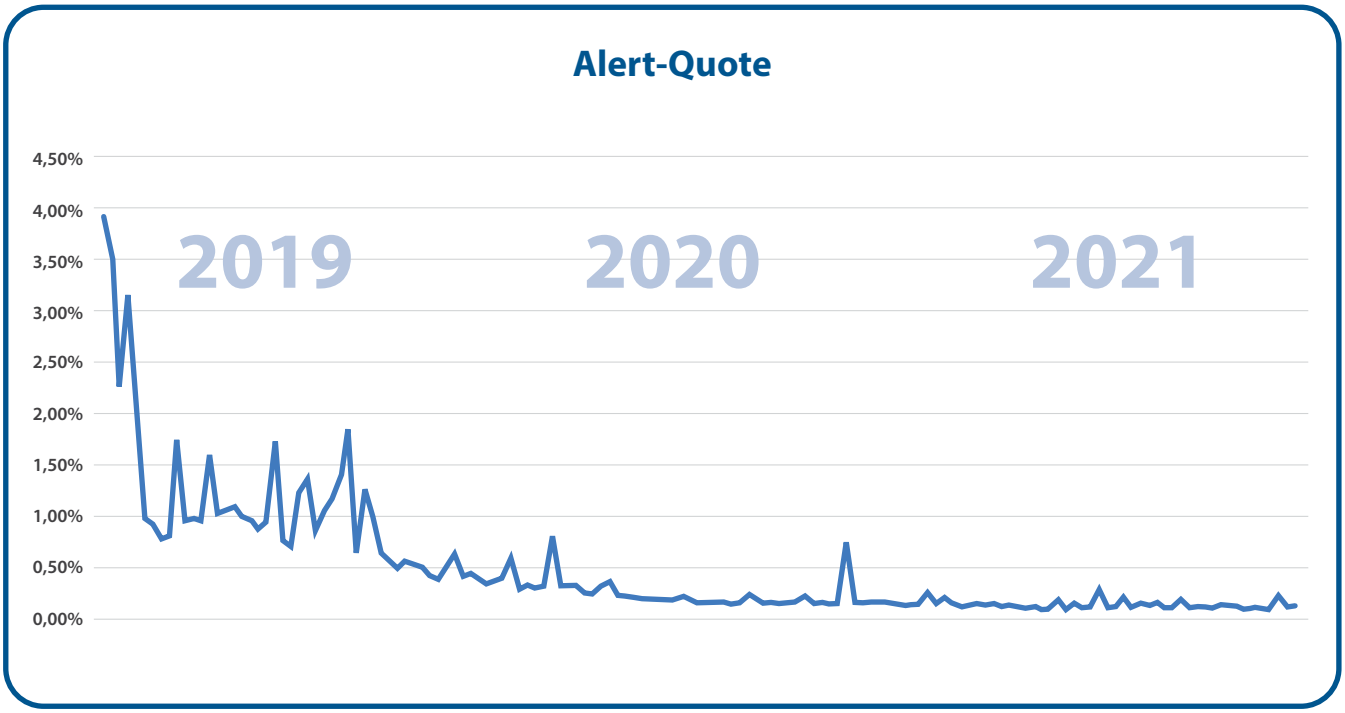
To ensure that a verifying entity is informed that an alarm was classified as either a false alarm or a case of suspected falsification, the user interface of the securPharm system (the securPharm-GUI by NGDA) has a corresponding function. Among other things, users can view the current processing status 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

As in previous years, securPharm continued to dedicate special attention to reducing the number and rate of alarms in 2021. A working group with representatives of securPharm members, operating companies and practitioners is intensively dealing with error analysis, root cause analysis, the definition of measures (see Chapter 3.3.2) and contact with individual users.

The measures taken so far to reduce false alarms have led to a 50% decrease of the average annual alarm rate. Meanwhile the usage intensity continues to rise. As a result, last year's positive trend continued, which also shows at the European level. Nevertheless, the absolute number of alarms per day is still too high for qualified processing of individual cases by the supervisory authorities. securPharm and the working group in charge have therefore defined and implemented additional measures to reduce alarms.



3.3.1 Causes of alarms

The causes of alarms are mainly handling errors due to incorrect operation or configuration or an incomplete data upload.

Specifically, some of the following causes of alarms were identified:

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

Typical solutions how users can avoid alarms can be found in the following examples:

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. The scanners at goods in process should also be tested to ensure they are set up correctly (see scanner test).

Procedure for 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.

Handling of expired products

As soon as a pack reaches its expiry date, the unique identifier of that pack is automatically deactivated in the securPharm system. Therefore, it is important that market participants do not attempt to additionally deactivate the unique identifiers of expired packs (e.g. by setting them to "Destroyed"). No additional status changes in the securPharm system are necessary. Potential other duties (e.g. documentation of disposal) remain unaffected.

However, a verification of the authenticity of the unique identifier of the pack will still be possible: In that case, the securPharm system will respond with the information that the expiry date has been exceeded and the pack must not be dispensed. The pack must be handled in accordance with the existing requirements.

3.3.2 Measures by securPharm for reducing alarms

securPharm e. V., the members of securPharm and the operating companies have taken various measures to support users in avoiding false alarms.

Intensive communication

In 2021, the trade associations of the individual user groups have further intensified their communications regarding the causes and the elimination of handling errors. For example, the ABDA and the Federal Pharmacy Chamber provided information in the form of member information bulletins about specific causes and how to avoid false alarms. In working groups and information letters to members, the trade associations of the pharmaceutical industry have also reported on the causes of false alarms. Several hundred pharmaceutical companies once again held an intensive exchange of ideas on e.g. ways to reduce alarms at an event organised by ACS PharmaProtect.

Detection of existing merchandise

In selected cases, securPharm has also implemented technical solutions to reduce alarms, so that false alarms do not result in a market impairment. The information about these packages is stored, so that it can be consulted by the authorities, if necessary.

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. The share of existing merchandise is declining, so this filter will likely be reassessed.

Scanner test in merchandise management

The scanner test, which was previously provided as a file, has now been integrated into the merchandise management system. Using a data matrix code, verifying entities can check whether the scanner used is reading package data correctly. Correct reading of the package data is a prerequisite for ensuring that a pack can be deactivated and that a false alarm does not occur. The result of the test can be displayed directly in the merchandise management system. securPharm expects a significant reduction in errors from this innovation.

Expansion of NGDA's securPharm-GUI

The web interface of the securPharm system provides an alert management system through which verifying entities (pharmacists, wholesalers, etc.) can obtain information on the processing status of an alarm by the marketing authorisation holder. Furthermore, the marketing authorisation holder has the opportunity to leave a case-related comment for a verifying entity.

The web interface also allows verifying entities to download a list of errors from the securPharm system 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. The Key Indicators view, which NGDA released in November 2021, allows users outside of merchandise management to easily track the number of verifications and deactivations performed, as well as the type and number of alarms within a freely selectable time period. The anonymized comparison of one's own facility with other facilities of the same type (pharmacy, wholesale or hospital) shows whether an above-average number of alarms are triggered in one's own facility. At the same time, a corresponding note appears in the display with references to further assistance. This should make it easier for participants in the securPharm system not only to deal with alarms but also to eliminate them in the long term.

As part of the further expansion of the securPharm-GUI, it is planned that the verifying entity will also be able to transmit comments to the marketing authorisation holder via alarm monitoring and that image files can also be exchanged in the future. The goal is an unambiguous communication process via the system to enable all parties involved to communicate with each other in a case-related manner.

More on the planned expansion of the securPharm-GUI of the NGDA can be found in Chapter 2.6.1.

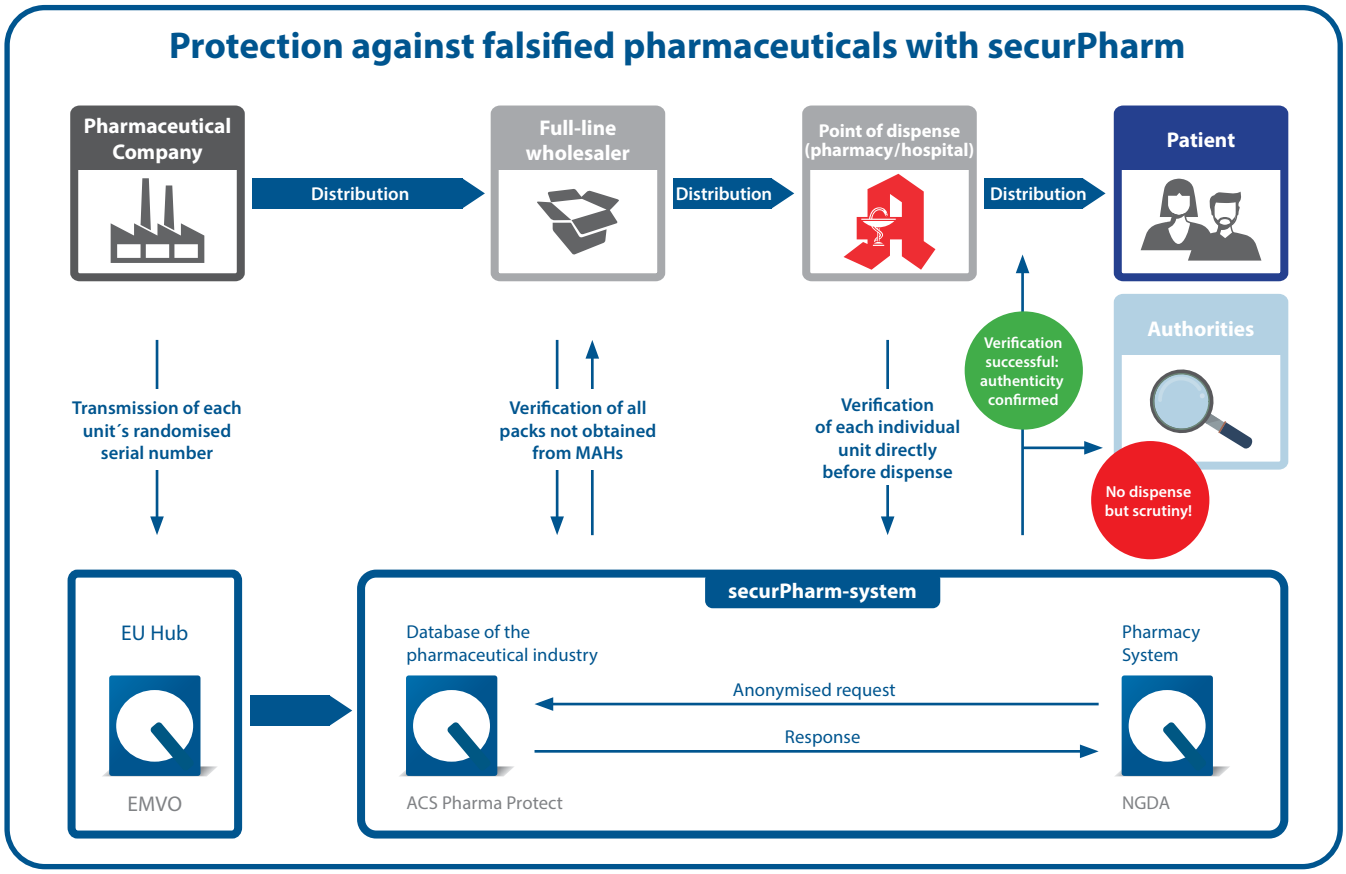
4. Collaboration on the national and international level

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. The securPharm Board of Directors, where the Federal Institute for Drugs and Medical Devices (BfArM) and the Federal Ministry of Health (BMG) each have a seat, started its work in 2021.

4.2 International collaboration

securPharm, as the German organisation for the authentication of pharmaceuticals (NMVO), maintains an intensive exchange with the organisations of the other EU and EEA 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

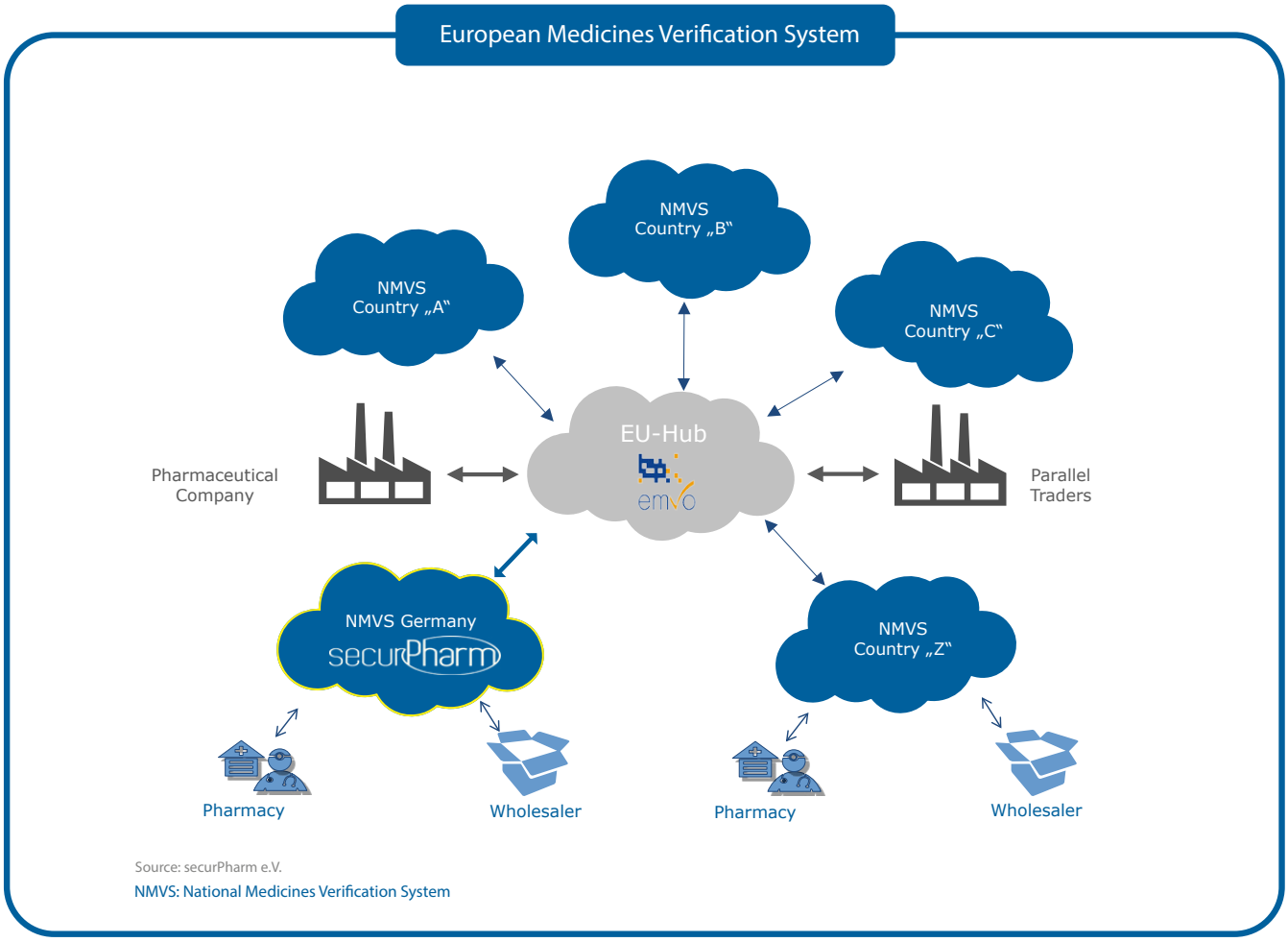
The securPharm system is based on the end-to-end principle during which both ends of the supply chain help ensure safety. The one end is the marketing authorisation holder who markets pharmaceuticals. The other end represents the dispense of pharmaceuticals to patients, i.e. at a community pharmacy. 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 www.securpharm.de.

The issue of the Java security vulnerability Log 4j, which became known in December 2021, has also occurred in the securPharm systems. It was closed within 24 hours.



Source: securPharm e.V.

NMVS: National Medicines Verification System

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.

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 currently 30 verification systems, any pharmaceutical pack equipped with the safety features can be verified in any pharmacy in Europe.

At the European level, work on a uniform European alert system is currently underway. The goal is to enable more effective and standardised cooperation between individual countries and their NMVOs in international cases of suspected falsification.

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. 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 www.securpharm.de. Membership in a trade association is not a prerequisite for system access.

6. Conclusion and outlook

During operating year 2021, the securPharm system has once again proven to be fast and reliable from a technical standpoint. The number of uploaded unique identifiers has increased once more and the number of transactions has also continued to grow. The average alarm rate was reduced by 50%, which rates as a success. However, the absolute number of alarms, most of them false alarms, is still too high. The main focus therefore remains on reducing the alarm rate. The most common causes of errors remain handling errors and incompletely uploaded pack data. Peaks caused by singular events will also be unavoidable in the long term. securPharm has further expanded technical support for system users and continued its intensive efforts to disseminate information. It remains to be seen whether this will translate into a further reduction in the alarm rate.

For the evolution of the securPharm system, the focus is not only on national issues but also on Europe. Here, work is being done to link the respective national alert systems via a standardized interface in order to meet the requirements of international flows of goods but also to enable internationally positioned companies to standardize their processes. The year 2022 also marks our anniversary, because securPharm e.V. was established 10 years ago on March 16.

7. About us

7.1 securPharm members as of 1 January 2022

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

vfa – Verband Forschender Arzneimittelhersteller e.V.
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.

Dr. Hermann Kortland
Bundesverband der Arzneimittelhersteller e. V.

Peter Krug
Verband Forschender Arzneimittelhersteller e. V.

7.3 Executive Management

Martin Bergen

7.4 Administrative Board

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

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

Members of the securPharm Board of Directors

8. Important links

Falsified Medicines Directive 2011/62/EU
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0062&from=de

Delegated Regulation (EU) 2016/161
https://ec.europa.eu/health/system/files/2016-11/reg_2016_161_en_0.pdf

Questions and Answers of the EU Commission on the Delegated Regulation: Version 19, December 2021
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
https://www.pharmaprotect.de

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

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

The links were last accessed on 22 February 2022.

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2022 Status Report
As of February 2022

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

www.securpharm.de

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