Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2024

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AN OPENING WORD

Last year brought significant recognition to the National Medicines Verification Organization (NMVO), confirming that the Czech Republic remains a European leader in medicine verification. The high level of compliance with the so-called Falsified Medicines Directive (FMD) is a testament to the excellent cooperation of all stakeholders governed by this legislation.

The past year not only saw another 366 days of stable system operation but also marked progress in innovation. Once again, the Czech Republic ranked among the top three countries with the fewest alerts across all medicine verification transactions — in other words, among those with the lowest number of failed verifications requiring further investigation. This success is largely due to the continuous development of our unique alert management system (CZAMS) and the implementation of alert "preanalysis", a form of support provided by CZMVO to help alerting entities better assess the root causes of alerts.

The Czech alert management model continues to stand out as one of the most advanced in Europe. It remains a unique tool within the European Medicines Verification System (EMVS), with no comparable equivalent in other countries. CZMVO regularly presents this innovation as a best practice at European summits — serving as an inspiration to others.

In 2024, we also focused on overhauling our internal systems. The result is the CZMVO Information System (CZMVO IS), which now integrates both the Alert Management System and other internal databases and support modules. This upgrade helps ensure our continued compliance with European anti-counterfeiting legislation and boosts operational efficiency.

However, the year also brought challenges. A key focus was mitigating the impact of the planned disconnection of the Northern Ireland system (including UK data) from EMVS, scheduled for 1 January 2025. Throughout 2024, both a European working group (with CZMVO representation) and our internal NIXIT team worked intensively to prepare for this transition. We proactively informed the Czech trade press — particularly pharmacists and distributors — about the change and its potential implications. Information was made available on the CZMVO website, and we also sent targeted communications to marketing authorization holders. We coordinated necessary steps with SIDC, who also shared the information on their platform.

CZMVO continued to collaborate closely with European partners — especially those using the same platform developed by Solidsoft Reply for the medicines verification system. We held a productive meeting in Slovakia with colleagues from the Slovak Organization for Medicines Verification (SOOL) to exchange experiences and share best practices. Similar discussions were held online with our Irish counterparts. Cooperation with SIDC also remained strong, reflected in the Czech Republic's continued high compliance with FMD requirements. Both organizations actively shared updates from national supervisory authority working groups with the European Commission and the EMVS.

There were no major structural changes within CZMVO in 2024. The Board of Directors, representing all five founding members, met quarterly, receiving detailed updates on CZMVO's operations and the current status of FMD both in the Czech Republic and within the EMVS.

In closing, we would like to thank all CZMVO staff and partners for their trust and collaboration over the past year. Together, we've upheld a system that professionals — and the public — can rely on. We are proud that CZMVO continues to operate smoothly and that the verification system remains almost "invisible" — a sign that the underlying processes are working exactly as they should.

Mgr. Filip VRUBEL
Chair of the Board of Directors

Mgr. Lenka NOVOTNÁ, MHA
Vice Chair of the Board of Directors

ABOUT THE NATIONAL MEDICINES VERIFICATION ORGANIZATION

The National Medicines Verification Organization, z. s. (NMVO/CZMVO), was established in 2017 to protect the legal supply chain from falsified medicinal products by creating and managing the national data repository – the National Medicines Verification System (NMVS).

NMVO is a national non-profit legal entity, founded in accordance with Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011, and Commission Delegated Regulation (EU) 2016/161 of 2 October 2015.

Directive 2011/62/EU amends Directive 2001/83/EC on the Community code relating to medicinal products for human use, with the aim of preventing falsified medicinal products from entering the legal supply chain. Regulation (EU) 2016/161 supplements Directive 2001/83/EC by establishing detailed rules for the safety features required on the packaging of prescription-only medicines for human use.

Founding regular members of the NMVO are as follows:

- **AEDL** – Asociace evropských distributorů léčiv z.s. (Association of European Distributors of Pharmaceuticals)
- **AIFP** – Asociace inovativního farmaceutického průmyslu (Association of Innovative Pharmaceutical Industry)
- **AVEL** – Asociace velkodistributorů léčiv – AVEL, z.s. (Association of Wholesale Distributors of Pharmaceuticals)
- **ČAFF** – Česká asociace farmaceutických firem (Czech Association of Pharmaceutical Companies)
- **ČLnK** – Česká lékárnická komora (Czech Chamber of Pharmacists)

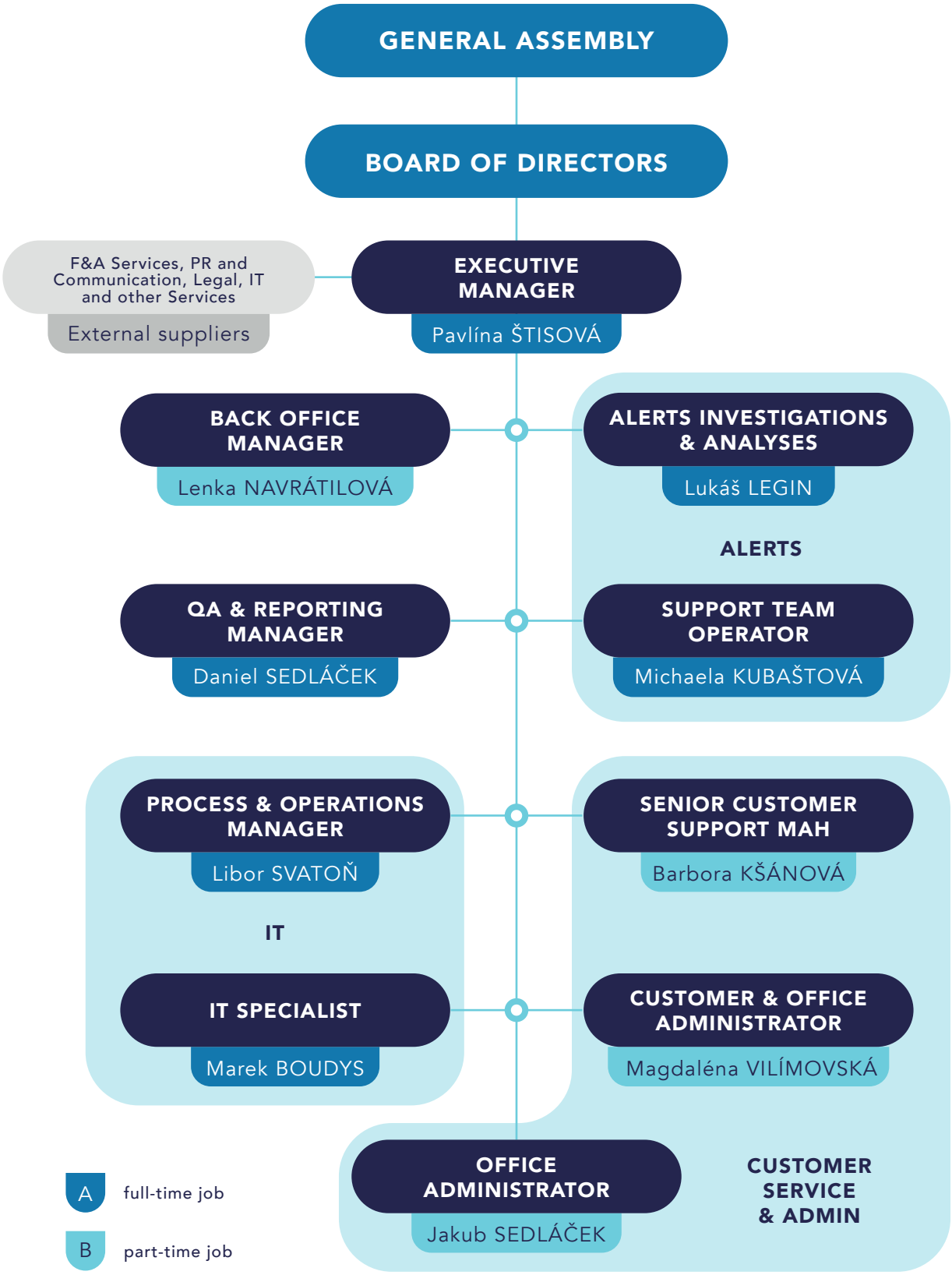
Associated members of the NMVO are as follows:

- Apatyka Servis s.r.o.
- Asociace provozovatelů lékárenských sítí (Association of Pharmacy Chain Operators)
- GS1 Czech Republic
- Lekis s.r.o.
- PharmaSwiss Česká republika s.r.o.
- Poskytovatelé lékárenské péče z.s. (Pharmaceutical Care Providers)
- Avenier a.s.
- Cyrmex, s.r.o.
- Unie distributorů léčiv z.s. (Union of Medicines Distributors)

CZMVO's full members, represented by their 11 delegates on the CZMVO Board of Directors and in the General Assembly, meet regularly and actively participate in overseeing the implementation of the Falsified Medicines Directive (FMD) in the Czech Republic.

The following sections provide an overview of CZMVO's key activities and developments in 2024.

ORGANIZATIONAL STRUCTURE



THE CZMVO'S TEAM IN 2024

Pavlína ŠTISOVÁ, MBA
Executive Manager

Ing. Lenka NAVRÁTILOVÁ
Back Office Manager

Ing. Libor SVATOŇ
Process & Operations Manager

Lukáš LEGIN
Alerts Investigations & Analyses

Marek BOUDYS
IT Specialist

Ing. Daniel SEDLÁČEK
QA & Reporting Manager

Ing. Michaela KUBAŠTOVÁ
Support Team Operator

Barbora KŠÁNOVÁ
Senior Customer Support MAH

Mgr. Magdaléna VILÍMOVSKÁ
Customer & Office Administrator

Bc. Jakub SEDLÁČEK
Office Administrator

OVERVIEW OF ACTIVITIES IN 2024

NATIONAL MEDICINES VERIFICATION SYSTEM (NMVS)

The primary responsibility of the National Medicines Verification Organization (CZMVO) is to develop and oversee the operation of the system for medicine verification. This core task was successfully fulfilled in 2024 as well. At the same time, the organization continued to reduce the incidence of non-conformities (alerts) arising during medicine verification by end-users through ongoing communication and support.

Czech National Medicines Verification System remained fully operational throughout the year. With only minor exceptions, there were no operational limitations or significant increases in response times for medicine verification and dispensing.

Regarding improvements to user functionality in CZMVS, the year 2024 did not bring any major functional changes. The updates focused primarily on enhancing system security and ensuring smooth operation. Nonetheless, the implemented changes improved processes for the registration of users, organizations, locations, and equipment, and contributed to simplifying and accelerating the investigation of incidents (alerts). Reporting changes introduced during the year have proven beneficial not only for CZMVO and end-users (pharmacies, distributors), but also for the State Institute for Drug Control (SIDC).

May 15th 2024 – CZMVS Release R14.0

- Discontinued the use of API version 2.3.
- Updated system components including system libraries, Service Fabric, Identity Server, and .NET. The CZMVS portal was migrated to Bootstrap version 5.
- Extended functionality in the CZMVS management portal, allowing end-users to manage Facilities, Devices, and Roles more effectively — while maintaining or enhancing CZMVO's oversight capabilities.
- Introduced several modifications to the software vendor self-certification process, particularly regarding testbook status handling.
- Enhanced the end-user response to transaction requests involving a lot ID mismatch (A68) or a missing serial number (A3), by including additional information that may help identify the root cause of the issue.
- A Level 3 exception event is now triggered if the location where a discarded pack is verified differs from the location where it was originally discarded. This event may be flagged by the SIDC as a potential case of medicinal product mismanagement.

November 6th 2024 – CZMVS Release R15.0

- Introduced a new alert code (A22) – *"The transaction cannot be completed because the pack is on the market, which is not part of the EMVS."* This alert is returned to end-users when an operation on a package results in the transaction being redirected outside the EMVS (in connection with the disconnection of the Northern Ireland and UK NMVS – the so-called NIXIT).
- Added a new mandatory field, **"Legitimacy information,"** to the Locations list in the CZMVS management portal. This field is used to enter a registration identifier (typically the SIDC location code).
- User reports are now also accessible via the CZMVS management portal (previously only available through the API). Reports can be filtered to show transactions for a specific location within an organization.
- Implemented several new features in preparation for Greece's upcoming integration into the EMVS, including support for national codes and connector functionality.

In 2024, the tradition of regular seminars organized by Solidsoft Reply, in cooperation with national medicines verification organizations and pharmacy/FMD system providers, continued. These seminars were consistently held approximately two months prior to each planned CZMVS release.

The medicines verification system, supplied by Solidsoft Reply, is used not only in the Czech Republic but also in 12 other European countries. Its development is carried out in close collaboration with all participating countries, and multi-level testing is conducted jointly before any changes are implemented.

CZMVO staff actively participate in selected testing phases, either as members of the international group of IT managers working with Solidsoft Reply, or as part of the quality managers' group.

CZMVO INFORMATION SYSTEM (CZMVO IS)

To support and simplify the handling of alerts generated within the CZMVS, the Czech National Medicines Verification Organization, in collaboration with a software vendor, developed its own Alert Management System (CZAMS) in 2020. While no major functional or user-facing changes were introduced in 2024, the system's architecture and internal component interconnections were completely redesigned. As part of this process, the internal systems and databases were overhauled, resulting in the creation of the CZMVO Information System (CZMVO IS).

CZMVO IS includes:

A. **MAH Administration** (in operation since 08/2024)
B. **End user management**
   (under development before completion)
C. **Alert management** (CZAMS module in operation)
D. **SW company records**
E. **SIDC data** (integration with SIDC data)
F. **Administration of CZMVO IS**
   (management of users, dials and parameters)

Additional modules are planned for future development, such as **Asset Registry, Ticketing System,** and others.
The operation of both CZMVS and CZMVO IS is overseen by a dedicated, independently developed **Monitoring Module.**

January – April 2024

A migration of PHP from version 7.xx to 8.xx was carried out across all test and development environments. Following successful verification, the migration was also completed in production environments. The process included comprehensive internal and external functionality testing.

February – May 2024

Several adjustments were implemented based on findings from a regular IT security audit reviewing the status of CZMVO's information systems.

These included, for example:

- Implementation of measures to prevent the upload of malicious files
- Elimination of cross-site request forgery (CSRF) vulnerabilities
- Fixes to address cross-site scripting (XSS) issues
- Introduction of a blocking mechanism for OTP in two-factor authentication (2FA)
- Replacement of a deprecated JavaScript library and implementation of regular update mechanisms

March – June 2024

A complete redesign of all CZAMS components, auxiliary databases, and the CZMVO website was completed. The primary objective was to separate the Alert Management System (CZAMS) from the public CZMVO website (www.czmvo.cz) and to move CZAMS monitoring tables/databases to a dedicated virtual server. This redesign aimed to strengthen security against external threats, eliminate redundancies, and simplify the architecture.

July – November 2024

Development and implementation of the MAH Administration module were completed. This module enables secure registration processes for MAHs and their representatives, including digital signing of relevant contracts with CZMVO.

Key features of the module:

- Efficient issuance of initial and annual invoices to MAHs and representatives
- Automatic monitoring of invoice due dates with automated notifications
- Integration with the external accounting firm's system (invoice export, balance import)
- Detection of any MAH activity on the Czech market without a signed contract with CZMVO

Future plans include implementing a validity check of MAH registration with the State Institute for Drug Control (SIDC).

December 2024

Development of the End-User Management module was initiated. This new module of the CZMVO Information System is designed to securely manage the registration and administration of end-users. It will also continuously verify the validity of an organization's or location's authorization using data from the SIDC.

SUPPORT TEAM – INFORMATION ABOUT ACTIVITIES

- In 2024, the team successfully built on the activities of previous years. Support for CZMVS users remained a core priority, with alert resolution continuing to be a key focus area. The active use of the CZMVO Alert Management System (CZAMS) contributed to an increase in the number of end-users (pharmacies and distributors) connected to the system, as well as in the number of alerts resolved directly by end-users.

- Particular emphasis was placed on resolving technical errors caused by end-users, and on enabling the resolution of procedural errors directly within CZAMS. In cases of procedural errors, dispensing of the medicinal product is possible after meeting specific conditions approved by the State Institute for Drug Control (SIDC). Regular monitoring of the most frequent end-user errors enabled further development of CZAMS, including the addition of new options for closing alerts resulting from such procedural mistakes.

- Following the detection of counterfeit Ozempic in several European countries and the United States, alerts related to this product were prioritized in agreement with SIDC. All such alerts arising in the Czech market were addressed with urgency, in so-called Emergency Mode.

- Due to frequent inquiries, the support team also focused on communication regarding unregistered medicinal products temporarily approved for distribution, dispensing, and use by a decision of the Ministry of Health. These products may trigger alerts during CZMVS verification. The aim was to inform end-users about the recommended procedures in such cases.

- The support team was also traditionally involved in assisting with end-user registration in CZMVS, verifying location settings, and onboarding new users to the CZMVO Alert Management System (CZAMS).

NIXIT

- In regard to the forthcoming disconnection of the Northern Ireland medicines verification system (NIXIT) from the European Medicines Verification System (EMVS), a European working group was active for most of 2024, in which CZMVO was represented. The disconnection of the Northern Ireland NMVS, which also contains UK medicines data, was scheduled for 1 January 2025.

- In parallel, CZMVO established an internal working group in the third quarter of 2024, which remained active until the end of the year. Its aim was to develop local mitigation measures to minimise the impact of the disconnection of the UK and Northern Ireland systems from EMVS. This represented a significant risk, with potential consequences across the entire EU. CZMVO's system provider, Solidsoft Reply, delivered an overview of the number of transactions with the UK repository in 2023 and 2024, enabling a meaningful risk assessment regarding the possible impact of NIXIT on the Czech pharmaceutical market.

- Extensive supporting documentation was subsequently prepared for all affected parties. Intensive communication efforts were launched in the Czech pharmaceutical trade press, targeting primarily pharmacists and distributors. Information about the upcoming change, required actions, and potential impacts was also published on the CZMVO website, including a video presentation. In addition, targeted email campaigns were sent to MAHs and CZMVS end-users. Activities were closely coordinated with the State Institute for Drug Control (SIDC), and additional information was shared via the SIDC website.

- As part of Release 15.0 of CZMVS, system modifications were implemented to introduce new operational and alert codes. These codes are displayed to end-users in cases where verification or attempted decommissioning involves a product pack registered only in the UK repository. Specific test scenarios were developed to ensure proper system functionality when handling such packs. Coordination with EMVO and other NMVOs continued throughout the preparation process to align approaches and share best practices.

WHAT ELSE WAS DONE IN THE NMVO IN 2024?

- The process of concluding version 4.0 of the Agreement on the use of the CZMVS by end users continued throughout 2024. The objective was to ensure maximum consistency across contracts and to enhance data security from the perspective of end-users. Updates to the contract reflect both the requirements raised by supranational European stakeholder representatives and the ongoing evolution of the system and applicable legislation. These changes strengthen data protection measures and improve the handling of data stored in CZMVS. The agreement also includes the Licence Conditions for the use of the Alert Management System (CZAMS).

- Intensive cooperation with counterparts in other European countries continued, particularly within the customer group using the Solidsoft Reply verification system. In Slovakia, a meeting was held with representatives of the Slovak National Medicines Verification Organization (SOOL) to share experiences and best practices. A similar session was held online with colleagues in Ireland. At the Operations Summit in Brussels, CZMVO presented its unique alert pre-analysis tool to IT managers and alert investigators from other national organisations. This tool supports entities that generate alerts in CZMVS by helping them better analyse the root causes of those alerts. The approach has since inspired similar initiatives in other NMVOs.

- CZMVO maintained strong cooperation with the State Institute for Drug Control (SIDC). This collaboration contributes to the high level of FMD compliance in the Czech Republic. There is continuous exchange of information between SIDC working groups and those of the European Commission, as well as regular updates from CZMVO on developments within the EMVS.

- The "Have you noticed?" section continued to feature regular educational articles, where CZMVO introduced users of CZMVS and CZAMS to useful functionalities of both systems, aimed at facilitating compliance with FMD legislation in the Czech Republic.

- The re-certification of IT software companies was successfully completed, with only three companies failing to pass re-certification in the previous year. Additionally, two new software providers and their systems used for FMD purposes were certified, allowing their software to be connected to CZMVS.

THE FMD'S STATE AT THE END OF 2024

MARKETING AUTHORIZATION HOLDERS (MAH)

The number of registered MAHs to use the NMVS: **394**
Of these, the number of MAHs eligible for a reduced user fee: **58**

NMVS END-USERS (PHARMACIES AND DISTRIBUTORS)

Number of connected subjects: **1,534***

Number of contracts with legal entities: **1,436***

** The difference is due to the company's activities being divided into two separate entities within the CZMVS system, in cases where it operates both as a pharmacy and as a distributor.*

Number of registration agreements concluded with legal entities during 2024: **67**

3,413 locations connected to the NMVS. Of this:

- Pharmacies: **2 964** – including **129** hospital pharmacies
- Warehouses (distributors' locations where medicines are verified): **449**

CHANGES IN ORGANIZATIONS CONNECTED TO THE NMVS DURING 2024

60 new entities connected, of which

- Pharmacies: **29**
- Wholesaleres: **31**

62 entities suspended, of which

- Pharmacies: **43**
- Wholesaleres: **19**

PRODUCT DATA IN THE NMVS

12,557 products uploaded in the EU HUB and the NMVS.
The number of uploaded batches: **148,684**
The total number of packs with data uploaded in the NMVS as of 31 December 2024: **1,375,201,846**

TRANSACTIONS IN THE NMVS

The number of transactions was stable at around **8.9** million transactions per week.
Of these, an average of **3.43** million packages were verified and marked as dispensed.

The highest number of transactions occurred in October this time – **41, 413,491** , followed by April – **41,118,798**
Over **41** million transactions occurred in November as well.

The number of of packs successfully decommissioned by end users was highest in week 51 of 2024 – **11,676,735**

CONNECTION OF SUBJECTS TO CZAMS

In 2024, the number of users of the Alert Management System (CZAMS) continued to increase.
461 entities were newly registered and/or connected.
At the end of 2024, **1,069** end users were connected to CZAMS.

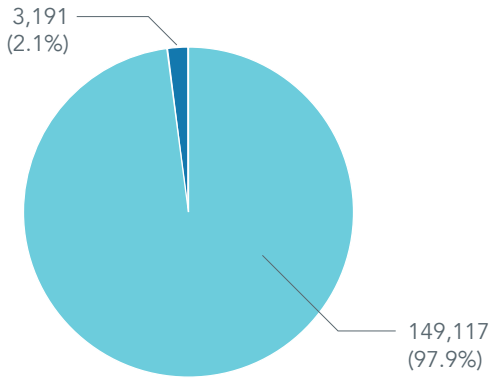
A total of **2,923** locations are connected, of which **2,685** are pharmacies and **238** are distribution warehouses. CZAMS was simultaneously used by **311** marketing authorisation holders, while another **85** MAHs could resolve alerts in CZAMS via a one-time limited access.

ALERTS RAISED DURING UNSUCCESSFUL VERIFICATION OF MEDICINAL PRODUCTS IN 2024

In total, **152,308** alerts were generated in CZMVS in 2024.
Share of alerts among completed transactions: **0.027%** (as of year-end)
The total number of closed alerts in 2024 was **149,117**, which represents **98%** of all alerts in 2024.

NUMBER OF CLOSED/UNCLOSED ALERTS

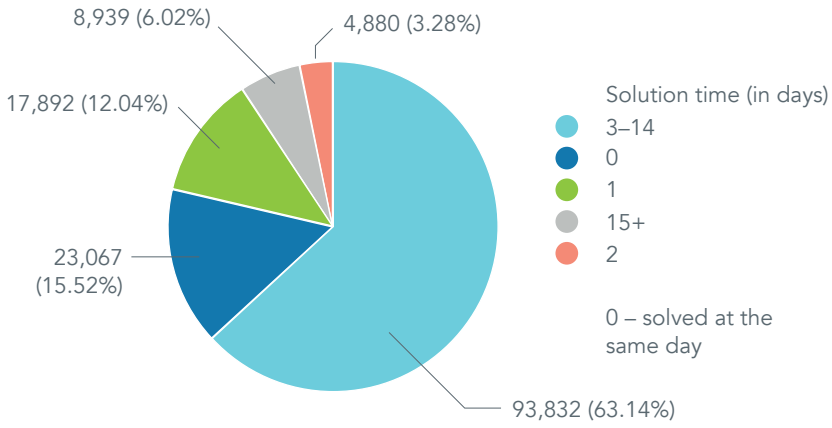
Alert status	Sum	%
Unclosed	3,191	2.10%
Closed	149,117	97.90%
TOTAL	152,308	100.00%



End-user transactions (pharmacies and distributors) resulted in **45,948** alerts, of which **44,849** were closed, which is also almost **98%**.

The average alert resolution time increased from **5.35** days to **7.58** days compared to last year. Most alerts were closed between 3 and 14 days. **94%** of all alerts were closed within the 14-day period defined by the Pharmaceuticals Act, after which the pack can be returned to distribution.

% OF THE ALERT CLOSING TIME ACCORDING TO THE TIME SCALE

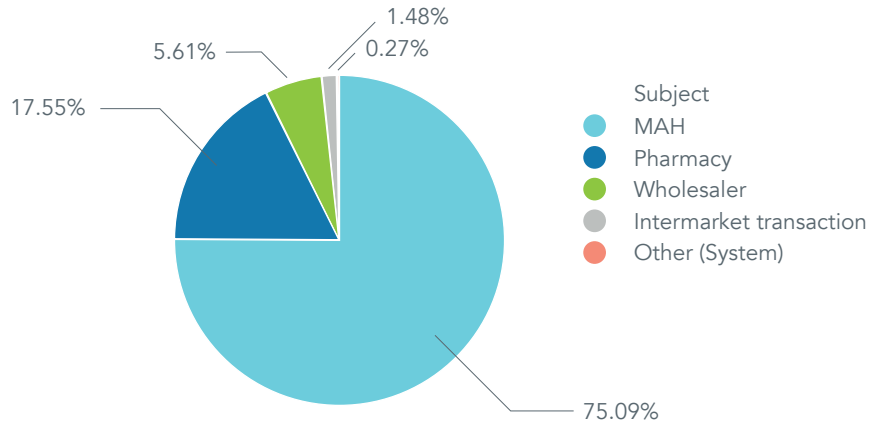


Total number of closed alerts	148,610
Median of resolution time	10.00
Average of resolution time	7.58

Most alerts (**75%**) were generated by Marketing Authorisation Holders (MAHs) and parallel distributors, who communicate with the CZMVS system via the EU Hub and are therefore classified in the same category. Their transactions resulted in a total of **106,000** alerts. One of the most significant incidents involved **over 70,000** alerts generated in a single day by the same MAH due to human error, where a verification request was submitted with an incorrect batch number. In another case, a different MAH mistakenly verified an entire batch of packs that had not been previously uploaded to the EMVS, resulting in **over 10,000** alerts.

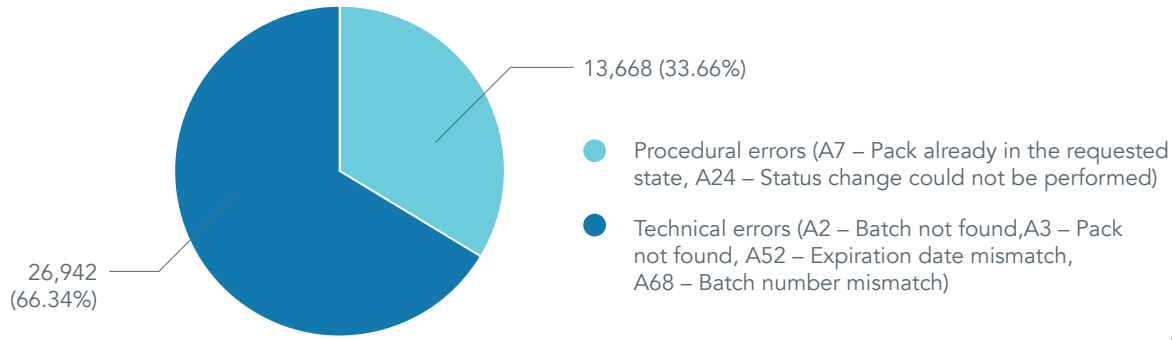
The highest number of alerts from end-users was recorded between April and June 2024, related to an unregistered medicinal product imported from Canada under a special permit issued by the Ministry of Health of the Czech Republic. In September, an issue was identified in the software of a hospital pharmacy, which caused more than **50%** of all end-user alerts for that month. In July, a distributor (identified by Client ID) had their access to CZMVS temporarily suspended due to their software repeatedly transacting over the same set of serial numbers. In another month, a different distributor experienced technical issues with their software, which led to **85%** of all alerts among distributors during that period.

CLOSED ALERTS ACCORDING TO ERRORS OF INDIVIDUAL SUBJECTS – 2024



Among end-users, technical errors prevailed over procedural ones. The most common cause of technical errors was a mismatch in the characters of the pack's serial number, typing errors, often due to active Caps Lock. In the case of procedural errors, the most frequent issue was the repeated decommissioning of a pack into a state other than "Supplied", such as "Destroyed" or "Stolen". Additionally, errors were identified in some end-users' software solutions that resulted in repeated supply operations being performed.

TECHNICAL AND PROCEDURAL ERRORS OF END USERS IN 2024

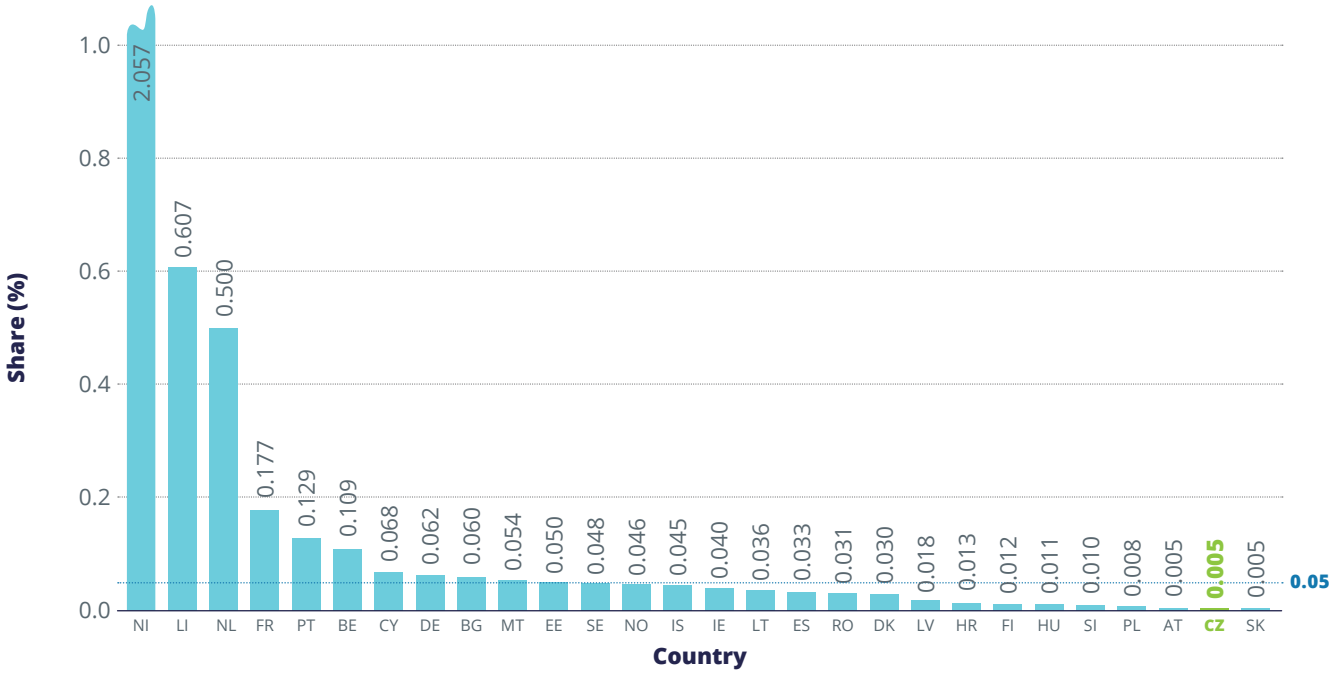


COMPARISON WITH OTHER EUROPEAN COUNTRIES IN TERMS OF ALERTS

The Czech Republic has consistently ranked among **the top-performing countries** in terms of the share of alerts relative to the number of transactions in the medicines verification system.

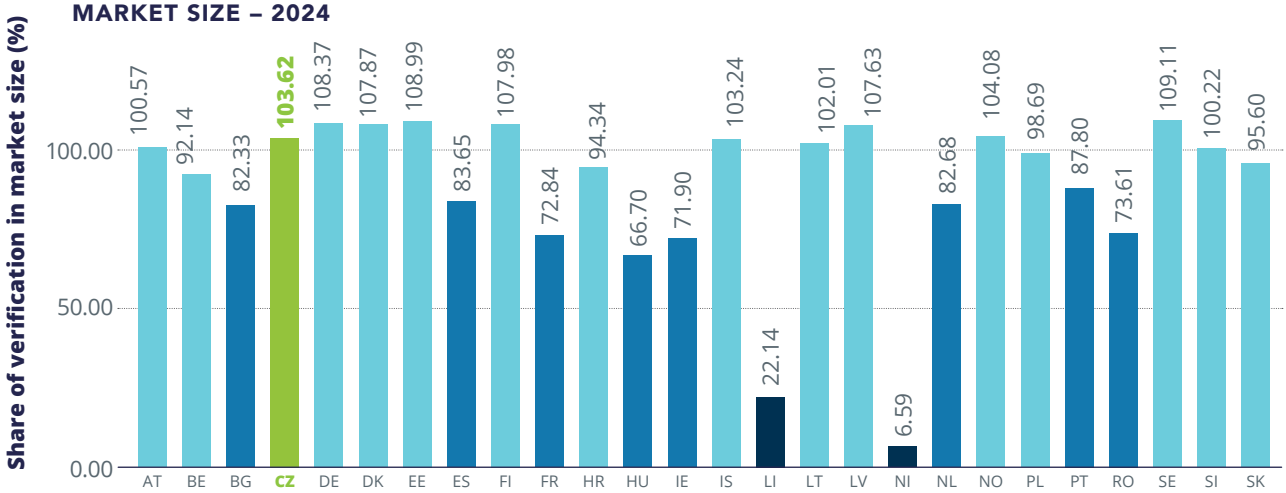
Out of 28 countries, **19** achieved the target threshold of **0.05%** or fewer alerts per transaction in the NMVS.

COMPARISON OF COUNTRIES IN DESCENDING ORDER BY THE SHARE OF ALERTS TO THE VOLUME OF TRANSACTIONS – DECEMBER 2024



All end-user systems are fully connected to the CZMVS, and the medicines verification in the Czech Republic is carried out by all entities as required by legislation.

COMPARISON WITH OTHER COUNTRIES – QUANTITY OF VERIFICATIONS RELATING TO AVERAGE MARKET SIZE – 2024



The data source for international comparison and for assessing the volume of verifications relative to market size is based on IQVIA data. The analysis includes only prescription medicines, measured in pack units. In some weeks or quarters, actual volumes may exceed 100% of the average reference value. It should be noted that the comparison baseline is lower than the current actual market size.

MEDIA AND PUBLIC RELATIONS IN 2024

The past year can be described as relatively calm from a media and public relations perspective. No crisis communication was necessary in 2024. However, targeted communication was directed at end-users and distributors to help prevent potential complications related to Northern Ireland's disconnection from the EU internal market (NIXIT).

At the end of February 2024, the Ministry of Health and the State Institute for Drug Control (SIDC) issued a warning regarding the potential circulation of counterfeit semaglutide (Ozempic) in the pharmacy network. An investigation conducted in Czech pharmacies revealed no presence of the counterfeit product. CZMVO responded by issuing a public warning against purchases from unverified sources.

In March 2024, CZMVO published a report titled "Five Years of Medicine Verification in the Czech Republic", featured for example in Medicína po promoci (1/2024), and made available in full on the CZMVO website (www.czmvo.cz).

In July 2024, the World Health Organization (WHO) released a report on the global occurrence of counterfeit Ozempic, highlighting cases in the USA, Brazil, the UK, and Germany. CZMVO published a related update confirming that no counterfeit Ozempic had been detected in the Czech Republic.

NIXIT COMMUNICATION

Since summer of 2024, CZMVO has been actively preparing for the disconnection of Northern Ireland from the European Medicines Verification System (EMVS) — known as NIXIT — and for the potential risks this change could pose to end users during the verification of medicines.

This communication was carried out in cooperation with SIDC and included:

- Warnings about the presence of dual-market packs intended for both the UK and EU markets,
- Notifications about new types of alert codes associated with NIXIT,
- Clear guidance on how to respond to such alerts.

Although follow-up communication was planned, the transition occurred without any serious complications.

PUBLISHING ARTICLES

- Czech and Slovak Pharmacy 4/2024 (Solen, November 2024)
- Pharma Profit 11–12/2024 (Atoz, December 2024)
- Web campaign – banners in the newsletter Pharma Profit (3× December–January)
- Website of the Czech Chamber of Pharmacies
- Website of the SIDC
- Detailed information, including a video presentation and FAQ on the CZMVO website.

Direct online communication regarding the issue was conducted with IT companies, pharmacies, and distributors. Crisis communication plans — including messages to be used in the event of counterfeit detections or medicine shortages — were prepared in advance, but fortunately did not need to be activated.

FINANCIAL MANAGEMENT REPORT

The National Medicines Verification Organization and the FMD implementation project were financed through registration and user fees paid by all MAHs using the medicines verification system in the Czech Republic.
In 2024, the annual user fee was EUR 4,250*. MAHs with an annual turnover of up to EUR 500,000 in the previous year were eligible for a reduced user fee of EUR 1,150*.
The one-time registration fee was EUR 4,856*.

**All fees are approved in EUR. The CZK equivalent is calculated using the Czech National Bank (CNB) exchange rate valid on the 1st day of the month in which the invoice is issued.*

SELECT DATA FROM THE FINANCIAL STATEMENTS (in thousands of CZK)

REVENUES IN 2024

Registration fees	2,199
User fees	37,450
Other revenues	2,113
(including foreign exchange gains: 897)	
Total revenues	**41,762**

EXPENSES IN 2024

Purchases including services	27,343
– Materials and energy consumption	409
– Purchased services	26,934
Personnel costs	11,504
Taxes and fees	-14
Other expenses	468
(including foreign exchange losses: 303)	
Depreciation	1,018
Income tax	236
Total expenses	**40,555**

The full version of the financial statement is available in the Collection of Deeds of the Associations Register kept by the Municipal Court in Prague, Section L, Insert 67982.

Profit in 2024 amounted to **1,206,785.66** CZK.

INDEPENDENT AUDITOR'S REPORT

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INDEPENDENT AUDITOR'S REPORT

on the financial statements as at 31 December 2024 of

Národní organizace pro ověřování pravosti léčiv, z.s.

Identification data:

Company name:	Národní organizace pro ověřování pravosti léčiv, z.s.
Registration number:	058 51 742
Company address:	Pobřežní 620/3, Karlín 186 00 Praha
Balance sheet date:	31 December 2024
Audited period:	from 1 January 2024 to 31 December 2024
Financial reporting framework:	Czech accounting regulations
Date of issue auditor's report:	22 May 2025
Auditor:	Erik Ďurkáň Licence No. 2407 Moore Audit CZ s.r.o. Licence No. 599

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Independent Auditor's Report for the Members of

Národní organizace pro ověřování pravosti léčiv, z.s.

Opinion

We have audited the accompanying financial statements of Národní organizace pro ověřování pravosti léčiv, z.s. (hereinafter also the "Company") prepared in accordance with accounting principles generally accepted in the Czech Republic, which comprise the balance sheet as at 31 December 2024, the income statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies and other explanatory information. For details of the Company, see Note 1. to the financial statements.

In our opinion, the financial statements give a true and fair view of the financial position of Národní organizace pro ověřování pravosti léčiv, z.s. as at 31 December 2024 and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech Republic.

Basis for Opinion

We conducted our audit in accordance with the Act on Auditors and Auditing Standards of the Chamber of Auditors of the Czech Republic, which are International Standards on Auditing (ISAs), as amended by the related application clauses. Our responsibilities under this law and regulation are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company in accordance with the Act on Auditors and the Code of Ethics adopted by the Chamber of Auditors of the Czech Republic and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other Information in the Annual Report

In compliance with Section 2(b) of the Act on Auditors, the other information comprises the information included in the Annual Report other than the financial statements and auditor's report thereon. The Board of Directors is responsible for the other information.

Our opinion on the financial statements does not cover the other information. In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. In addition, we assess whether the other information has been prepared, in all material respects, in accordance with applicable law or regulation, in particular, whether the other information complies with law or regulation in terms of formal requirements and procedure for preparing the other information in the context of materiality, i.e. whether any non-compliance with these requirements could influence judgments made on the basis of the other information.

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Based on the procedures performed, to the extent we are able to assess it, we report that:

- The other information describing the facts that are also presented in the financial statements is, in all material respects, consistent with the financial statements; and
- The other information is prepared in compliance with applicable law or regulation.

In addition, our responsibility is to report, based on the knowledge and understanding of the Company obtained in the audit, on whether the other information contains any material misstatement of fact. Based on the procedures we have performed on the other information obtained, we have not identified any material misstatement of fact.

Responsibilities of the Company's Board of Directors for the Financial Statements

The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the Czech Republic and for such internal control as the Board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the above mentioned laws and regulations will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with the above law or regulation, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors.
- Conclude on the appropriateness of the Board of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required

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to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Board of Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Prague, 22 May 2025

Moore Audit CZ s.r.o.
Licence No. 599
Karolinská 661/4
186 00 Praha 8

Represented by Erik Ďurkáň

Erik Ďurkáň
Statutory auditor, Licence No. 2407

CONTACT AND IDENTIFICATION INFORMATION

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TIN: CZ05851742

Web: www.czmvo.cz

E-mail: info@czmvo.cz

Tel.: +420 224 834 153

Národní organizace pro ověřování pravosti léčiv, z. s.
registered in the Associations Register maintained by the Municipal Court in Prague, Section L, File No. 67982

Národní organizace
pro ověřování
pravosti léčiv