Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2023

TABLE OF CONTENTS

AN OPENING WORD

Last year was for the National Medicines Verification Organization (NMVO) a year of many interesting events, but contrary to the past, it was not necessary to respond to dramatic circumstances concerning the entire society.

Thanks to the NMVO, the Czech Republic belongs among the most active EU Member States, and its Alert Management System (CZAMS) is a model for other members of the European Medicines Verification System (EMVS). We continue to be one of the best in Europe in handling alerts thanks to improved escalations and notifications, as well as expanding CZAMS functionalities. The Czech Republic has had a very low percentage of alerts in the long run (0.01%) with respect to the number of transactions, which is considerably less than the recommended 0.05%. In comparison to other EU Member States, the Czech Republic has belonged for two years now among the three most successful countries where the so-called anti-falsification legislation (Directive 2011/62/EU and Commission Delegated Regulation (EU) 2016/161} was implemented.

The National Medicines Verification System (NMVS) has been stable for a long time, its availability last year was 99.94%.

Security in the NMVS was increased during the year, as well as in the CZAMS. Two-step authentication for access to the CZAMS interface was implemented and there was a switch to the protocol OAuth 2.0 for users communicating with the Alert Management System from their applications through API.

In February 2023, on the 4th anniversary of the launch of the EMVS, the NMVO set up its own support team that helps to improve outputs and support for NMVS and CZAMS users in handling alerts. Moreover, as a part of NMVO team, it provides good-quality feedback.

The NMVO moved to a bigger and much more suitable space in the International Business Center Building in May 2023, which made it possible to expand and strengthen the IT infrastructure.

A counterfeit version of Ozempic detected in the EU during 2023 fulfilled the main mission of the "anti-falsification directive." The NMVO immediately responded and issued a recommendation for end-users with an instruction on how to proceed in case they come across a suspect pack. The NMVO team continued to monitor the situation, and in the end no falsified Ozempic was reported in the Czech Republic.

The NMVO regularly communicated all changes and important notifications mainly with experts and in particular with NMVS end-users.

In conclusion, I am very pleased to say that the excellent and close cooperation of the NMVO with its oversight authority – the State Institute for Drug Control (SÚKL; Czech NCA), - continues.

The NMVO would like to sincerely thank all partners for their cooperation in the successful year 2023.

Mgr. Filip VRUBEL
Chair of the Board of Directors

ABOUT THE NATIONAL MEDICINES VERIFICATION ORGANIZATION

Národní organizace pro ověřování pravosti léčiv, z. s. (National Medicines Verification Organization – NMVO) was founded in 2017 to protect the legal supply chain against falsified medicinal products by creating and managing the regional data repository – the National Medicines Verification System (NMVS).

The National Medicines Verification Organization is a national non-profit legal entity founded in compliance 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, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Regulation 2016/161 supplements Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of prescription-only medicinal products for human use.

Founding regular members of the NMVO are as follows:

- **AEDL** – Asociace evropských distributorů léčiv (Association of European Distributors of Pharmaceuticals)
- **AIFP** – Asociace inovativního farmaceutického průmyslu (Association of Innovative Pharmaceutical Industry)
- **AVEL** – Asociace velkodistributorů léčiv (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:

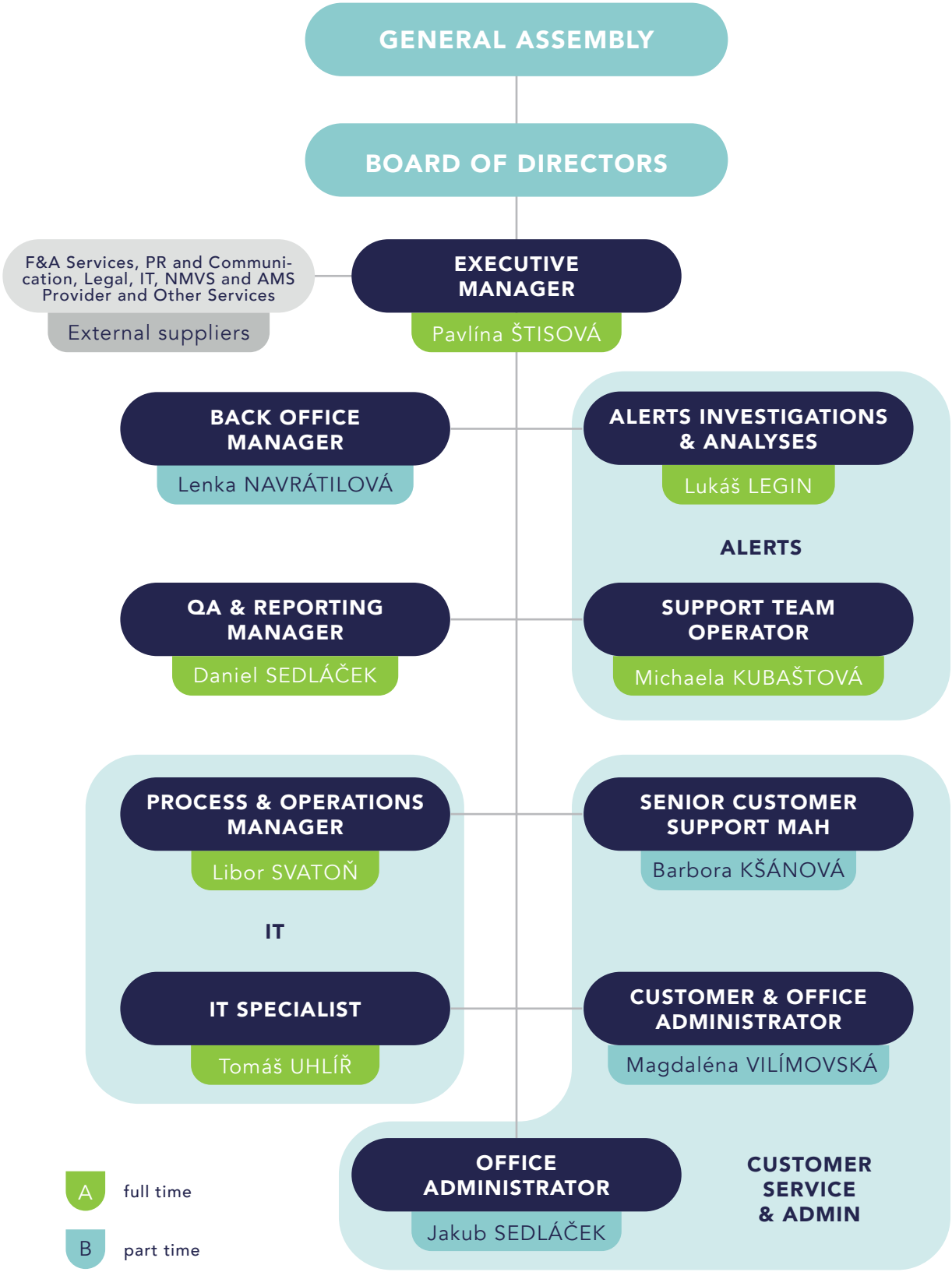
- Apatyka Servis
- Asociace provozovatelů lékárenských sítí (Association of Pharmacy Chain Operators)
- GS1 Česká republika
- Lekis
- PharmaSwiss
- Poskytovatelé lékárenské péče (Pharmaceutical Care Providers)
- Avenier
- Cyrmex
- Unie distributorů léčiv (Union of Medicines Distributors)

The NMVO's regular members regularly meet via their 11 representatives in the NMVO's Board of Directors and General Assembly and help to supervise the FMD in the Czech Republic.

The NMVO also closely collaborates with the State Institute for Drug Control (SÚKL), the Ministry of Health of the Czech Republic, the European Medicines Verification Organization (EMVO) and other stakeholders.

The following chapters describe in detail the NMVO's activities in 2023.

ORGANIZATIONAL STRUCTURE



THE CZMVO'S TEAM IN 2023

Pavlína ŠTISOVÁ, MBA
Executive Manager

Ing. Lenka NAVRÁTILOVÁ
Back Office Manager

Ing. Libor SVATOŇ
Process & Operations Manager

Lukáš LEGIN
Alerts Investigations & Analyses

Ing. Daniel SEDLÁČEK
QA & Reporting Manager

Mgr. Tomáš UHLÍŘ
IT Specialist

Ing. Michaela KUBAŠTOVÁ
Support Team Operator

Barbora KŠÁNOVÁ
Senior Customer Support MAH

Mgr. Magdaléna VILÍMOVSKÁ
Customer & Office Administrator

Jakub SEDLÁČEK
Office Administrator

OVERVIEW OF ACTIVITIES IN 2023

NATIONAL MEDICINES VERIFICATION SYSTEM (NMVS)

The NMVO's primary responsibility includes the development and supervision of the NMVS. These primary tasks were successfully performed in 2023 as well.

The NMVS was stable throughout the entire year and only very rarely was its operation limited or the response to requests of end-users (pharmacies, distribution warehouses) too long.

The year 2023 did not bring any major changes in terms of improving user functions, the system development has focused on increasing security and traffic flow. Implemented modifications also improved the registration of users, organizations and locations and facilitated alerts investigation. New information outputs (reports) about the behavior of users and the movement of medicines benefited not only the NMVO but also the State Institute for Drug Control (SÚKL).

22 May 2023 – NMVS Release R12.0

- **The use of API version 2.2 was terminated.** It is necessary to use API 2.5 to generate reports.
- System libraries were updated. The NMVS was upgraded to version.NET 7, OS Windows was migrated on MS Server 2022. Reports were migrated to Databricks (from Azure Data Lake).
- The transfer of a location from one to another organization of the same type is possible without the need to change the settings of client devices.
- There were changes in reports for the State Institute for Drug Control and small changes in the web interface to improve NMVS administration.

6 November 2023 – NMVS Release R13.0

- **Self-service Qualification Test-book.** A new section on the management portal that makes it possible for authorized SW providers to create independently the Qualification Test-books, to refresh test data and to submit them to the NMVO for checking.
- **Bulk intermarket transactions of end-users.** The NMVS started to support intermarket transactions (IMTs) as part of bulk transactions of medicine packs. So far **only for the pharmacy-type users.**
- End-users will receive **an indication about the number of transaction attempts concerning a pack;** transaction – dispense or decommissioning of unique identifier.
- **Two new reports for the State Institute for Drug Control.**
  S.1.4 Supervision Report for OBP Batch Upload – it shows how many packs of a specific medicine were uploaded and when.
  1.6 Decommissioning activity for batches – it shows a list of locations that successfully decommissioned packs of a specific batch.
- **Changes in the NMVS web portal.** Reports for end-users are now also available on the NMVS portal. There are tables and charts of activities also on the level of end-users' devices, a list of on-boarding partners (OBP) and their marketing authorization holders (MAHs) whose products are recorded in the system. Managed access for client authorizations based on the roles for organization-managed client authorizations.
- **Security modifications**
  JavaScript libraries update. Service Fabric Cluster update to the latest version. System libraries update.

Regular seminars organized by Solidsoft Reply together with the NMVOs for SW providers for end-users continued in 2023 as well. They always took place about two months before the scheduled release of new functionalities.

The Medicines Verification System, which is provided by Solidsoft Reply, is designed in the Czech Republic the same way as in other 12 European countries. The system development and all necessary functionalities are verified in cooperation with all these countries; testing before implementation of changes is done jointly as well. As part of the common European structures, there is also cooperation in interoperability testing between the Arvato system and the Solidsoft Reply system before individual changes are implemented into the production environment of given systems.

ALERT MANAGEMENT SYSTEM (CZAMS)

To support and simplify the handling of alerts generated in the NMVS, the NMVO created in 2020 its own Alert Management System (CZAMS) that underwent a number of major functionality and design changes during the year 2023. These changes were targeted to improve system security and stability, to increase user comfort in alert investigating and closing, to shorten the time-limit for alert investigations and to eliminate the number of alerts incorrectly closed by users.

MAY – OCTOBER 2023 – TWO-STEP WEB INTERFACE AUTHENTICATION

A two-step authentication was implemented to access the CZAMS web interface. An e-mail address is used primarily as the second factor, potentially also Google Authenticator. The second (or additional) factor is set up by the user in the user administration of the given organization. The authentication was implemented in two steps; it was first tested in a pilot operation and then all CZAMS users gradually accessed it. The switch was completed on 31 October 2023.

15 May 2023 – AMS Release R6.0

This release focused mainly on security and stability and included the following main modifications:

- **Users' access to CZAMS.** A limited number of inquiries per given time. API authentication via OAuth 2.0. **Two-step authentication.**
- **CZAMS security improvement.** Security improvement for adding attachments. A time-limit for login via web portal. User account lock after several failed attempts. An unpredictable session ID. A change in cookies setting. Error messages unification upon login.

26 May 2023 – CZAMS Release R7.A

This release responded to changes in the NMVS (R12) and included the following main modifications:

- **New fields in alert e-mails.** The loading script was updated. The fields "Client ID" and "Transaction Code" are now directly taken from the alert e-mail into the alert record log. New fields with specifying information were added to e-mails. **Modifications in the Daily Snapshot automatic report processing.** The "Batches" sheet now includes three new columns. This information must be now entered by MAHs when uploading their product data. These data are then used in CZAMS for pre-investigations in alert processing (the length and format of the SN chain).
- **Automatic closing of pending alerts that are older than one year.**
- **Correction of possible misclassification of technical errors as procedural errors and vice versa.** The user cannot close **A7 and A 24 alerts** as technical errors. On the other hand, if A7 and A 24 are not errors, the alert cannot be closed as a procedural error.

26 November 2023 – CZAMS Release R7.B

- **Both standard and anonymous groups were completely redone**
  a) The period for creating both groups was shortened to 24 hours by default.
  b) The option to modify this period for a specific group by the user was added.
  Optional period: 1–90 days.
  c) The overview of standard and anonymous groups displays all available information related to the group (what it consists of, creation date and time, closure date and time, error code) as well as select information about each alert in the group (current status, PC, SN, batch).
  Anonymous groups can now be used by end-users as well (before only MAHs/OBPs).
- **Changes in procedural workflow and pre-investigation process**
  A54 alerts are automatically closed. An A52 alert pre-analysis was added. Improvement of the pre-analysis of end-users' procedural errors (own or not-own location is identified from NMVS reports).
- **Design modifications**
- Alert indications – **the number of days/hours left until a status change is enabled/enforced.**
  The heading of each alert displays an indication for the given role and status, the days left until the given condition expires (provided that such condition exists for the given alert, status and role). Sets of charts were added to the Dashboard for the end-user role to visualize the status of alerts of the given organization.
- **Improvement of the system of information about changes, news and notifications.**
  a) A new row "Overview of Changes in the CZAMS" was added to the "Documentation" column in the main overview.
  b) A new row "News" was added to the "Documentation" column.
  c) A better use of the pop-up window.
- **The system of notifications and escalations was completely redone**

WHAT ELSE WAS DONE IN THE NMVO IN 2023?

• At the beginning of February, the NMVO's own support team was created. In addition to providing continuous support to NMVS users, the team is helping to spread shared experience from the FMD and to develop the CZAMS to satisfy all users as much as possible.

• In June, an online webinar for marketing authorization holders and distributors took place. Its main goal was to provide them with new information concerning the use and development of the CZAMS and the handling of alerts in the Czech Republic and with important information about how they are resolved.

• "Training videos" about alert handling and new notifications in the CZAMS were created and CZAMS and NMVS user manuals were regularly updated and posted on the NMVO's website (in Czech and English).

• Quarterly workshops and meetings with representatives of the State Institute for Drug Control focused on informing all participants about the state of the FMD in the Czech Republic, about planned changes in the entire EMVS and about related activities of the NMVO and the State Institute for Drug Control.

• Participation and active involvement in solving joint all-European topics, such as the identification of risks and the strengthening of the EMVS's cyber security, strategic initiatives of the Solidsoft Reply's Customer group, cooperation to improve medicines verification systems and responses to legislative changes, such as the fact that Northern Ireland left the EMVS.

• Regular educational articles for the "Did You Know" section, where the NMVO, among other things, acquainted NMVS and CZAMS users with useful functions of both systems that will facilitate the application of the FMD in the Czech Republic.

• The NMVO's team moved to a new and more suitable space and was expanded for an IT specialist who was in charge of activities related to the NMVS operation and internal infrastructure.

VERSION 4.0 OF THE CONTRACT ON THE USE OF THE NMVS BY END-USERS

The NMVO started to sign version 4.0 of the contract on the use of the NMVS with all end-users, i.e. pharmacies or distributors, in 2022 and continued to do so in 2023. Some modifications in the contract address certain requirements formulated by the transnational representatives of European stakeholders, some modifications respond to the development of the system and legislation. These modifications are improvements for end-users in terms of the protection of their data and the handling of data contained in the NMVS. The contract also includes the License Terms and Conditions for Using the Alert Management System. More than 1400 companies have been gradually switching to the new version since July 2022, with nearly 1120 of them already having the new version of the contract with the NMVO in place at the end of 2023. When the new version of the contract is signed, information about end-users, their contact details and location is updated.

A VISIT TO A PARALLEL DISTRIBUTOR

The NMVO's representatives visited a small parallel distributor to learn about the FMD-related processes in this type of organization, in particular about the processes related to the repacking and decommissioning of medicinal products and their uploading into the national repository, including the handling of potential alerts.

Thanks to the helpfulness of the company management, the NMVO's team received a lot of interesting information about potential pitfalls of this activity. The company sometimes has problems with the unavailability of the OBP portal during certain daytime hours. The NMVO was surprised that the data uploaded into the repository were not checked. The visit definitely met its purpose and provided many ideas about how to improve the NMVS and to set up processes in "our" CZAMS.

RECERTIFICATION OF IT COMPANIES

In 2023, the Czech Republic had **34 different software programs** connected to the NMVS. They all were **recertified to version API 2.4** during the first six months of the year.

THE FMD'S STATE AT THE END OF 2023

MARKETING AUTHORIZATION HOLDERS (MAH)

The number of registered MAHs to use the NMVS: **393**
Of this, the number of MAHs eligible for a reduced user fee: **62**

NMVS END-USERS (PHARMACIES AND DISTRIBUTORS)

1 432 contracts with legal entities

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 2023

71 new entities connected
76 entities disconnected and **63** entities suspended

PRODUCT DATA IN THE NMVS

11 647 products uploaded in the EU HUB and the NMVS. The number of uploaded batches: **61 144**
The number of packs with data uploaded in the NMVS as of 31 December 2023: **1 134 252 254**

TRANSACTIONS IN THE NMVS

There were about 8.7 million transactions per week. Of this, **3.43 million** packs were verified on average and marked as dispensed.

This time, most transactions took place in June – **41 754 888** and then in March – **41 588 430**.
Over **40 million** transactions also took place in May, October and November.

The so-far biggest number of packs successfully decommissioned by end-users was in the 50th week of 2023 – – **11 209 389**. Over 10 million transactions were carried out in the week before and after – 10 100 410 in the 49th week and 10 045 019 in the 51st week.

ALERTS GENERATED DUE TO FAILED MEDICINES VERIFICATION

The percentage of alerts of the total number of transactions amounted to **0.039%** during the 1st week of 2023 and to **0.007%** during the 15th week of 2023.

In 2023, the Czech medicines verification system generated a total of 149 806 alerts, which may seem rather high, but over 93 thousand alerts were caused by a single error made by a marketing authorization holder, which generated almost one million alerts in the EMVS because the pack was a multimarket batch and was uploaded into several national repositories. If we disregard this extreme situation, the total number of alerts in 2023 was 56 158, which is almost 30 thousand less than in 2022.

ENTITIES CONNECTED TO THE CZAMS

The number of CZAMS users significantly increased in 2023.

483 new entities were registered and/or connected.

844 end-users were connected to the CZAMS as of the end of 2023.

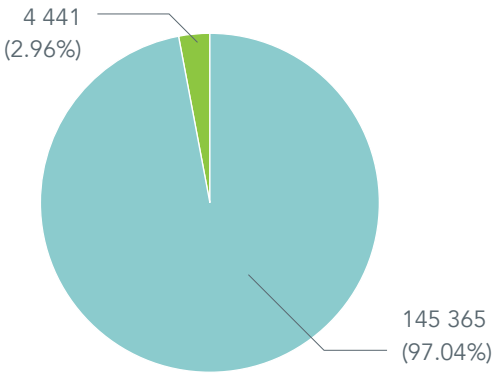
A total of **2 462** locations are connected: of this **2 268** pharmacies and **194** distribution warehouses.
A total of **300** marketing authorization holders used the CZAMS and another **91** MAHs were able to handle alerts in the CZAMS, using one-off limited access.

ALERTS IN 2023

The number of alerts of end-users (pharmacies and distributors) in the Czech Republic keeps decreasing in the long run. The number of alerts includes all alerts per pack – several alerts are often generated for the same serial number, i.e. the number of packs is much lower. It is very rare for one location to have a higher increase in alerts during 24 hours.

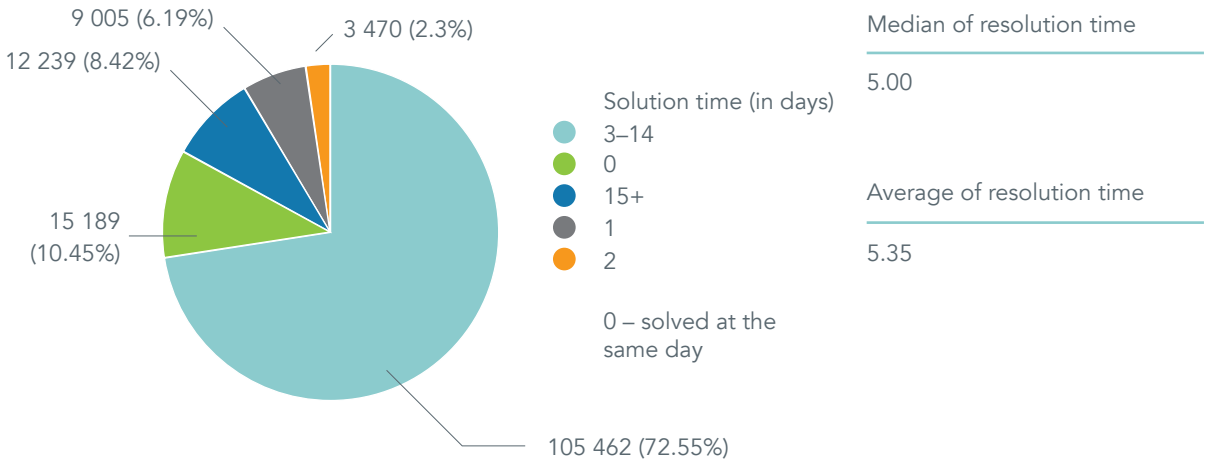
NUMBER OF CLOSED/UNCLOSED ALERTS

Alert status	Sum	%
Unclosed	4 441	2.96%
Closed	145 365	97.04%
TOTAL	149 806	100.00%



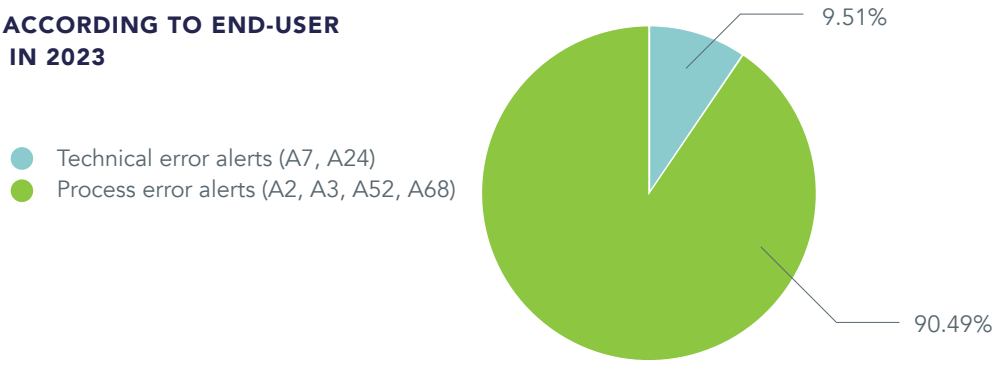
- The average time of resolving alerts significantly decreased from 17.6 days in 2022 to 5.35 days in 2023. Most alerts were usually closed within 3 to 14 days. Almost 98% of all alerts were closed within the statutory 14-day time-limit defined in the Pharmaceuticals Act. After its expiry, the packs can be sent back to the distributor.

% OF THE ALERT CLOSING TIME ACCORDING TO THE TIME SCALE



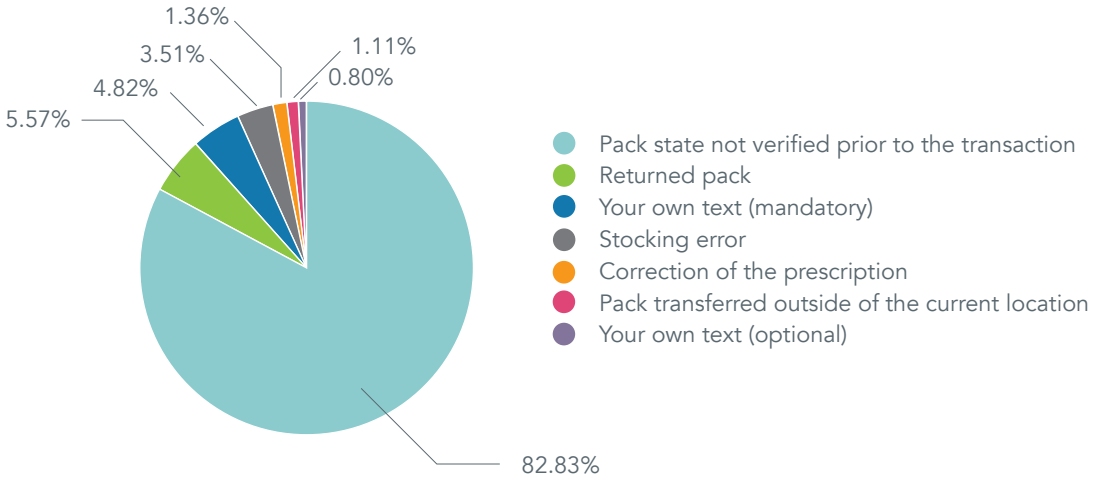
- Technical alerts were prevalent among end-users and were caused, for example, by incorrect keyboard settings, poor scanner quality or manual entry errors.
- Procedural alerts, which are a result of repeated or unauthorized transactions concerning already decommissioned packs, accounted for nearly 10% of alerts.

ALERTS ACCORDING TO END-USER ERRORS IN 2023



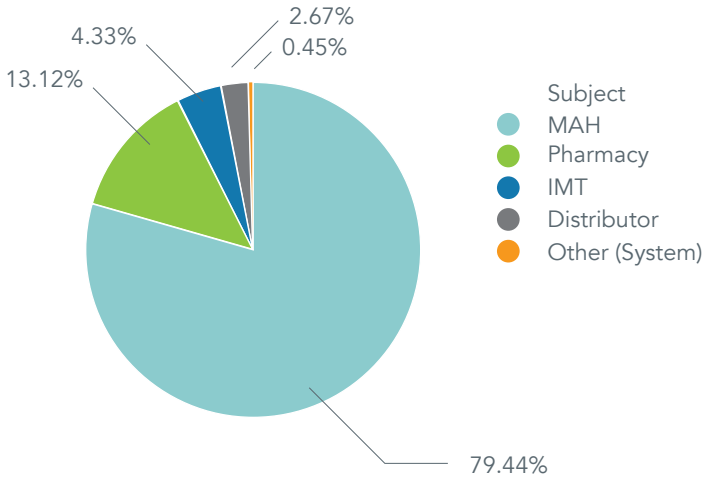
- End-users started using more the tool for closing alerts directly in the CZAMS where it is possible to select a specific cause of an error from predefined options and to confirm an affidavit, which allows the CZAMS to close the alert and potentially dispense the appropriate pack to the patient. (Note: If the location that caused the procedural alert is not the one that originally decommissioned the pack, the NMVO will enter the investigation process and close the alert).
- The non-verification of the current pack status was the most frequent procedural error, which means that the location made a request to change the status of the pack unique identifier without checking the actual status. These errors were made mostly due to a request to reactivate the pack or a request to decommission the pack to a status other than "Dispensed", e.g. "Destroyed."

SPECIFYING THE OCCURRENCE OF PROCEDURAL ERRORS IN 2023



- In 2023, alerts were mostly caused by marketing authorization holders (MAHs) and parallel distributors. Almost 80% of all MAH alerts were generated in a single day due to a wrong transaction concerning a multimarket batch, which generated almost 1 million alerts in the EU's national repositories. A MAH tried to decommission a pack to the "Exported" status, but all packs had already been decommissioned this way. The MAH confirmed its error and assured the NMVO that it was not a counterfeit. The alerts were then closed. Parallel distributors' most frequent error was a repeated transaction due to the fact that the 24-hour time-limit for the system's response was not observed or due to a human process error.

CLOSED ALERTS ACCORDING TO ERRORS OF INDIVIDUAL SUBJECTS – 2023



Percentage distribution of closed alerts in 2023 by groups

Type (group)	% of alerts in 2023
MAH – Marketing autorization holder	79.44%
Pharmacy	13.12%
IMT – Intermarket transaction	4.33%
Distributor	2.67%
Other (System)	0.45%
Total	**100.00%**

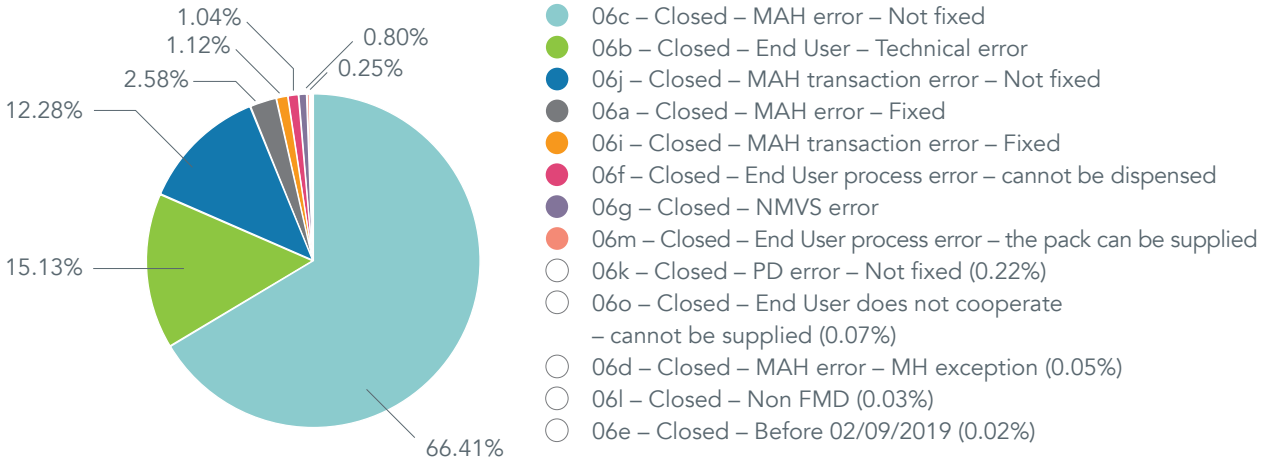
- The highest total number of alerts generated by end-users occurred once again in the largest pharmacy chains; however, considering the large number of their pharmacies, the final average number of alerts per pharmacy was only around 17 alerts for the entire year.

- Alerts generated by end-users were most frequently caused by the fact that the pack serial number was not found in the system due to different technical errors in pharmacy and distribution information systems. The biggest percentage of these technical errors was caused by confusing upper-case letters with lower-case letters and vice versa.

- Distributors caused alerts mainly due to a repeated "Destroyed" transaction when destroyed packs that had already been decommissioned in the system. Almost 40% of the distributors' alerts were caused by MAH, usually due to the fact that MAH did not upload data into the repository.

- The number of exceptions granted by the Ministry of Health of the Czech Republic for individual medicine batches in connection with the FMD keeps decreasing in the long run; however, any alert that is generating under such exception, is automatically closed in the CZAMS.

% SHARE OF CAUSES FOR CLOSED ALERTS



- The NMVO handled only a few suspected counterfeit packs. But these suspicions were immediately disproved, and the alerts were closed.

SUPPORT TEAM – INFORMATION ABOUT ITS ACTIVITY

In 2023, the support of NMVS users mainly focused on handling alerts, on an active use of the CZAMS. The emphasis was on providing information about handling procedural errors directly by end-users in the CZAMS where a medicinal product can be dispensed even after the end-user (pharmacy, distributor) made a procedural error, provided that the conditions approved by the State Institute for Drug Control were met.

After the two-step authentication for the web interface was implemented and API authentication was set up in pharmacy software in the CZAMS, the support team actively provided support to CZAMS users in setting up this security improvement.

As soon as the new system for sending notifications and escalations was launched, end-users' inquires temporarily increased and were successfully handled.

Throughout the entire year 2023, the support team also helped with registering end-users in the NMVS, checking the setting of locations in the NMVS and entering new users in the CZAMS.

COMMUNICATION

The year 2023 was very calm for the NMVO in terms of the media since it was not necessary to start any crisis communication. Media outputs concerning medicinal products, their availability, shortages and potential counterfeits were permanently monitored.
Operational changes concerning the NMVS and the NMVO as well as the position of the Czech Republic among other EU Member States based on the EMVO's reporting were communicated. The NMVO issued a warning when a counterfeit version of Ozempic was identified.
Reports were posted on the NMVO's website and sent mostly to professional media (in the case of the counterfeit also to the select lay media) and to end-users.

THE NMVO ISSUED THE FOLLOWING REPORTS:

- The signing of new contracts (targeted communication – professional press)
- The 4th anniversary of the FMD – published in PharmaProfit
- The most frequent SW errors (targeted communication)
- Procedural errors - published in PharmaProfit
- Changes in the support team (targeted communication)
- The NMVO's statement on the unavailability of certain medicines
- A warning about a counterfeit version of Ozempic in the EU (November 2023)

REGULAR AND TARGETED COMMUNICATION:

- News about the CZAMS (e.g. the two-step authentication, changes in the CZAMS interface)
- Information about the state of the NMVS, the number of alerts according to the ENMVO's reporting
- Importance of being connected to the CZAMS

TARGET MEDIA:

- Pharma Profit (printed magazine and e-newsletter)
- lekarnici.cz (Czech Chamber of Pharmacists' web)
- czmvo.cz (web NOOL), – best practice – "Did You Know?"
- Praktické lékárenství
- Direct communication: Freedcamp – designed for IT SW companies

FINANCIAL MANAGEMENT REPORT

The National Medicines Verification Organization and the FMD implementation project were financed with registration and user fees of all MAHs using the medicines verification system in the Czech Republic. In 2023, the user fee was 4 000 EUR; MAH, whose turnover was up to 500 000 EUR in the previous year, paid a reduced user fee of 1 100 EUR. The one-off registration fee was 4 856 EUR.

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

Revenues in 2023

Registration fees	2 079
User fees	34 277
Other revenues (including foreign exchange gains: 982)	1 363
Total revenues	**37 719**

Expenses in 2023

Purchases including services	**27 272**
– Materials and energy consumption	390
– Purchased services	26 882
Personnel costs	10 985
Taxes and fees	35
Other expenses (including foreign exchange losses: 332)	918
Depreciation	1 057
Income tax	0
Total expenses	**40 267**

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.

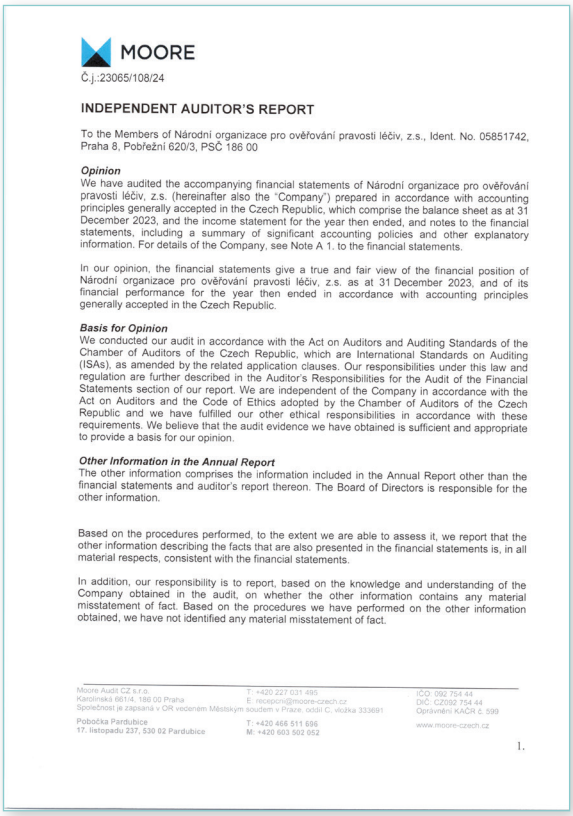
Loss in 2023 amounted to **2 548 481.13 CZK.**

INDEPENDENT AUDITOR'S REPORT

THE AUDITOR'S OPINION: UNQUALIFIED 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 2023, and 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 A1, 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 2023, and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech Republic.



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INDEPENDENT AUDITOR'S REPORT

To the Members of Národní organizace pro ověřování pravosti léčiv, z.s., Ident. No. 05851742, Praha 8, Pobřežní 620/3, PSČ 186 00

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 2023, and 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 A 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 2023, 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
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.

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.

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.

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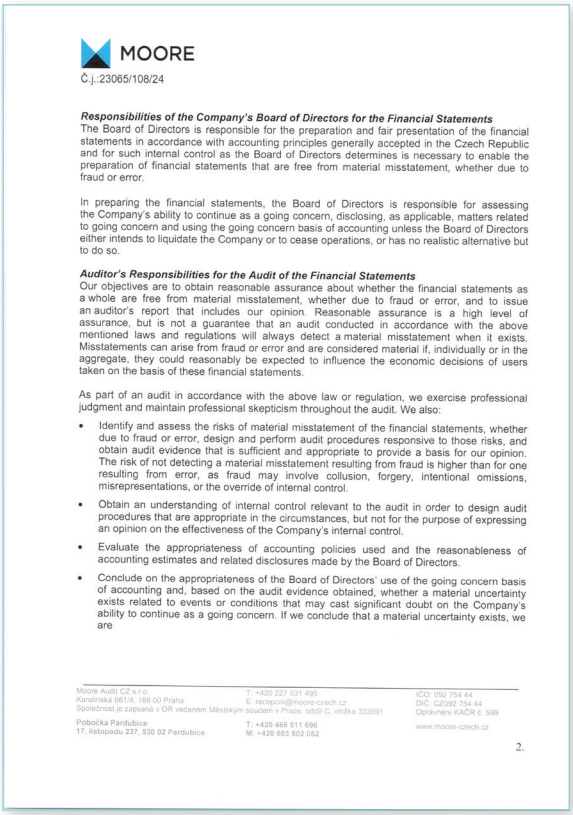

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Responsibilities of the Company's Board of Directors for the Financial Statements
The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted 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 has 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 skepticism 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

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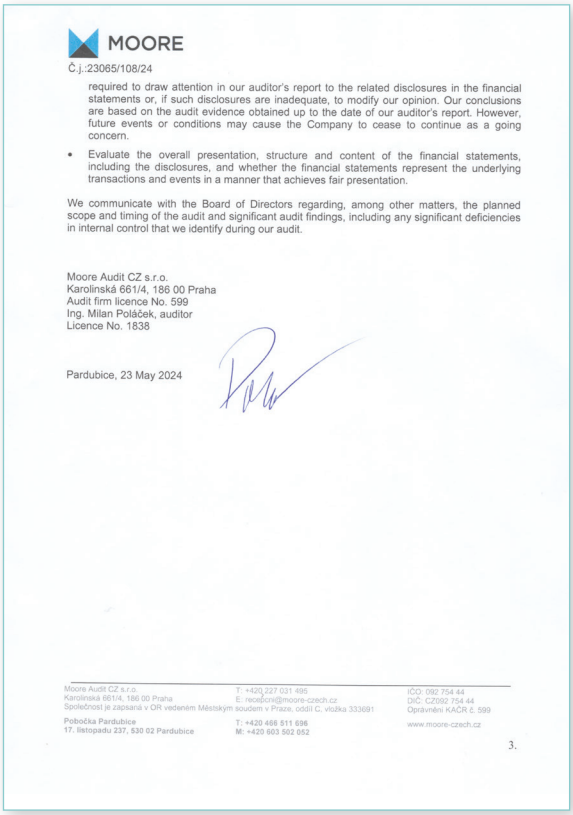

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required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our 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.

Moore Audit CZ s.r.o.
Karolinská 661/4, 186 00 Praha
Audit firm licence No. 599
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 23 May 2024

Moore Audit CZ s.r.o.
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3.

CONTACT AND IDENTIFICATION INFORMATION

NÁRODNÍ ORGANIZACE PRO OVĚŘOVÁNÍ PRAVOSTI LÉČIV, z. s.

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TIN: CZ05851742

Web: www.czmvo.cz
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Národní organizace pro ověřování pravosti léčiv, z. s.
entered into the Federal Register kept by the Municipal court in Prague, Section L, file 67982

Národní organizace
pro ověřování
pravosti léčiv