Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2022

Experts In the Morse code alphabet will have no problem to read the message in the image on the front page.

AN OPENING WORD

Medicines verification has become commonplace and is routinely carried out at all locations where medicines are dispensed and randomly at the locations where medicines are distributed. There was no counterfeit or serious incident during 2022, and the National Medicines Verification System (NMVS) worked smoothly. It was stable, a blanket outage occurred only briefly on 1 January 2022, and its average availability was 99.89% for the entire year.

9 February 2022 marked the 3rd anniversary of the launch of the European Medicines Verification System (EMVS), the purpose of which is to ensure patient safety and to protect them against the risk of taking counterfeit medicines in the legal distribution chain. The NMVS is an integral part of an all-European solution implemented in 29 countries. The Czech Republic held up in this challenging project perfectly. In a very short time and despite initial partial problems, 100% of pharmacies and distributors joined the National Medicines Verification System. The Czech Republic was among the three most successful countries in terms of the percentage of false positive alerts (0.007-0.02%) throughout 2022. It is also encouraging that more than 96% of alerts were closed.

The year 2022, especially the first six months, was still partly marked by the ongoing Covid-19 pandemic, although rather by the continuing need to prioritize SARS-COV-2 vaccine alerts than by any restrictions or limitations. Since the outbreak of the war in Ukraine on 24 February, there has been an urgent need to supply medicines to the people of the invaded country. The National Medicines Verification Organization (NMVO) has issued a guidance on how to delete the unique identifier of medicinal products from the NMVS for the export of medicines, which are subject to the FMD, to a non-EU Member State. The National Medicines Verification Organization strongly condemns the Russian attacks on Ukraine.

During the year, the concluding of contracts on the use of the NMVS by end-users, version 4.0, was launched. This administratively very demanding project involves approximately 1600 organizations and strives to improve the position of end-users in terms of protecting their data and the NMVO's work with data in the NMVS and to conclude the terms and conditions for using the NMVO's Alert Management System (AMS).

The unique Czech Alert Management System (AMS) has become a model for the European alert management platform, where predefined messages are used to advantage at both ends of the system - with end-users and marketing authorization holders (MAHs) and on-boarding partners (OBPs). During the year 2022, the system was stabilized, promoted among users and developed especially based on the lessons learned from several years of using the AMS.

Communication activities were primarily aimed at sharing experiences with the NMVS's operation and medicines verification and at promoting new things in the NMVS and AMS, including through the "Did You Know?" articles on the NMVO's website.

The year 2022 was the third in a row among the most challenging ones. As the Covid-19 pandemic receded, war was unleashed in Europe, triggering an economic crisis and inflation. The shortage of some essential medicines at the end of the years made the work of pharmacists more difficult. My sincere and heartfelt thanks to all partners of the NMVO for handling their role (not only) in the verification of medicines and the tasks associated with it during this exhausting year.

Mgr. Filip VRUBEL
Chair of the Board of Directors

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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:

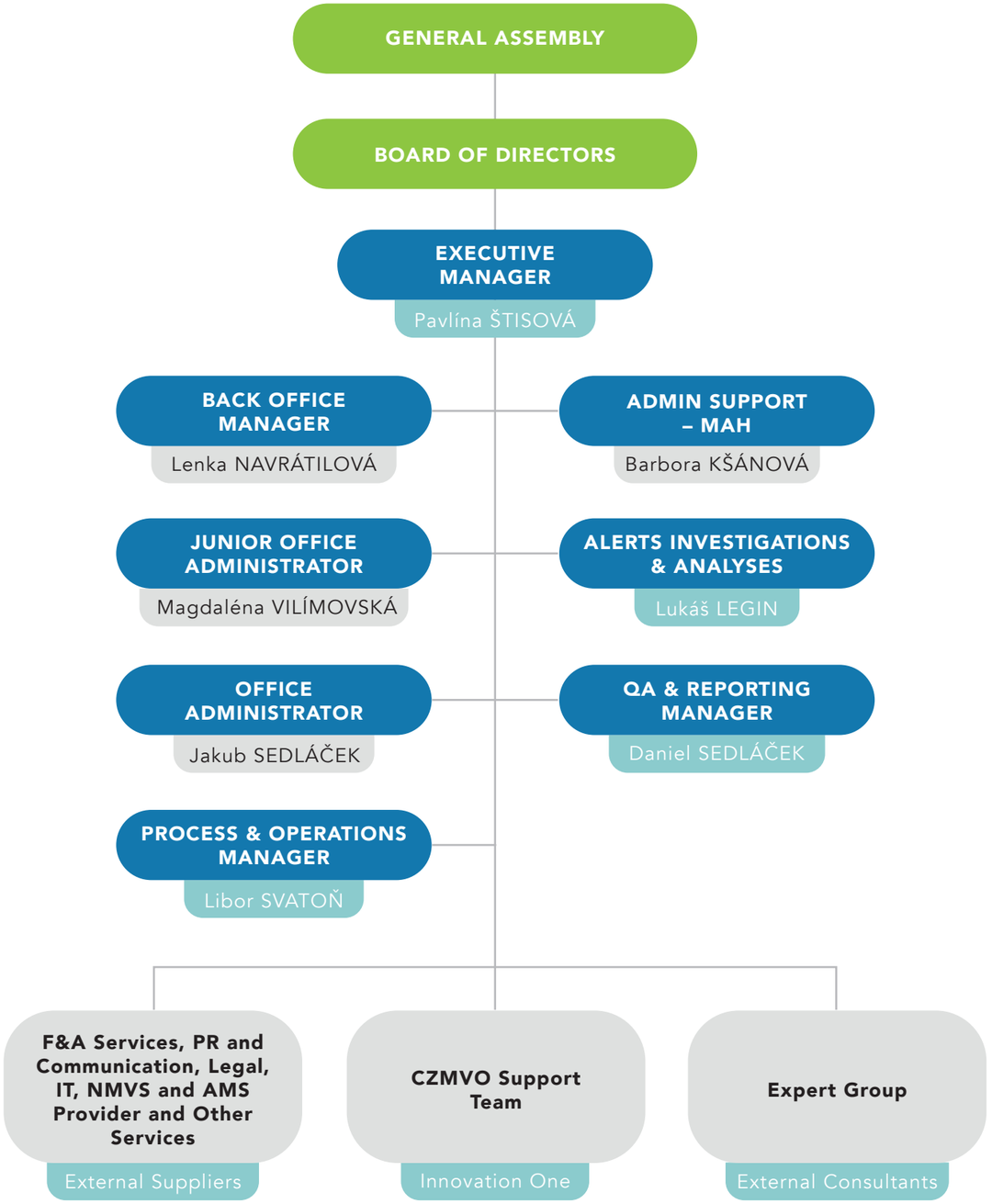
- Apatyka Servis
- Asociace provozovatelů lékárenských sítí (Association of Pharmacy Chain Operators)
- GS1 Česká republika
- Lekis
- PharmaSwiss
- Poskytovatelé lékárenské péče (Pharmaceutical Care Providers)
- Avenier
- Cyrmex
- Unie distributorů léčiv (Union of Medicines Distributors)

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; Czech NCA), 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 2022.

ORGANIZATIONAL STRUCTURE



THE CZMVO'S TEAM IN 2022

Pavlína ŠTISOVÁ, MBA
Executive Manager

Ing. Lenka NAVRÁTILOVÁ
Back Office Manager

Lukáš LEGIN
Alerts investigations & Analyses

Ing. Daniel SEDLÁČEK
QA & Reporting Manager

Ing. Libor SVATOŇ
Process & Operations Manager

BK

Barbora KŠÁNOVÁ
Admin Support – registrations/MAH

Bc. Magdaléna VILÍMOVSKÁ
Junior Office Administrator

Jakub SEDLÁČEK
Office Administrator

ACTIVITIES IN 2022

PROVIDING THE 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 2022.

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 2022 did not bring any major changes in terms of improving user functions, the system development focused mainly on increasing the system security and stability. Regular modifications to the entire system also included the implementation of improvements to further facilitate alert investigations. This was particularly welcomed by the State Institute for Drug Control (SÚKL; Czech NCA), the NMVO and all users (pharmacies, distributors, MAHs, manufacturers).

11 April 2022 – NMVS Release 10.0

- The use of API version 2.0 was terminated.
- New operation codes with more detailed messages were added.
- Information about whether the user has the option to reactivate a deactivated pack was added to verification responses.
- "Product Name" was added to the API response (so that the end-user can check whether the product that the end-user holds is the one that was verified).

18 October 2022 – NMVS Release 11.0

- The use of API version 2.1 was terminated.
- In the case of an alert, the response to the end-user also includes "Alert Code" (Axx) and indicates that it is an IMT transaction.
- API version 2.4 now includes operation codes related to the upcoming "White Paper" (non FMD codes).
- Local transactions of end-users containing invalid GSI features should no longer generate an alert.
- National organizations were provided with an option to export details concerning all organizations of end-users on their market.

In 2022, a regular seminar organized by Solidsoft Reply together with the NMVO for IT SW system providers for end-users was implemented. It always took place about one month before the scheduled release of new functionalities.

The Medicines Verification System, which is provided by Solidsoft Reply, is designed the same way as in other 11 European countries. Its development and the verification of all necessary functionalities takes place together during all testing and implementation phases. 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.

DEVELOPMENT OF THE ALERT MANAGEMENT SYSTEM

To support and simplify the handling of alerts generated in the NMVS, the Alert Management System (AMS) was created in 2020 and underwent a number of major functionality and design changes during the year 2022. These changes were to significantly increase user comfort in alert investigating and closing as well as to shorten the time-limit of alert investigations and to reduce the number of incorrectly closed alerts.

11 March 2022 – AMS Release 4.2

- After the first logging to the AMS on behalf of an organization (EU/MAH/OBP), it is necessary to confirm approval with the terms and conditions related to the use of the AMS.
- MAHs' consent to delegate the management of their alerts – upon registration of a new MAH/OBP, a new query related to alerts management will appear on the web form. MAHs can delegate the management of their alerts to another MAH or OPBs.
- A new option in the main menu: "*Dashboard*," this page also serves as the "Main Page" after logging to the AMS. The dashboard contains:
  - Flow and pie charts of alerts generated during a selected period;
  - Information window about the number of alerts and a lot of other information, based on the user's setting.
- The AMS introduced an automatic/manual export of reports available in the NMVS. This enables autofill of additional data for pre-investigations, further options for automatic closing of alerts and a fast export of needed reports (e.g. audit trail) for the given alert.
- One-off access to the AMS for MAHs/OBPs not connected to the AMS was provided. It is designed for MAHs/OBPs that do not have access to the AMS. A notification e-mail containing a link with a token valid for 90 days is randomly generated to enable access to the alert details via the AMS. One-off access temporarily provides MAHs/OBPs with all functions and options of the AMS, except for multiple modifications.
- A number of minor modifications were performed in the AMS (filters - the "Note" field was added for end-user and NMVO roles, import of status changes was modified, user removal option was added, administration of user notifications can be checked, date formats were modified...).

April 2022 – AMS Release 4.3.A, Release 4.3.B

R.4.3.A – A response to changes in the NMVS (a change in automatic processing of data from Daily Snapshot (Organizations, Establishments, Product Catalogue)), a significant expansion of displayed information as requested by the State Institute for Drug Control.
R.4.3.B – Automated processing of data from the State Institute for Drug Control (Pharmacies, Distributors), an automatic retrieval of Exceptions from the State Institute for Drug Control's data together with manual checking, a revised retrieval of the EMVO's monthly reports on MAHs.

26 October 2022 – AMS Release 5.0

- The option to close process errors of end-users was implemented in cooperation with the State Institute for Drug Control.
- Alert processing time was cut down from 5-10 minutes to several seconds.
- The process workflow was modified by including a number of logical checks.
- A workflow pro the call center was created.
- Pre-investigation algorithms were modified and expanded.
- The NMVS's monitoring improved, and the AMS now provides charts and notifications.
- The processing of monthly reports for the State Institute for Drug Control is now automated.
- The design of the web interface for users improved.
- The processing of level 3 exceptions (A1,A5,...) does not so far require any investigation. Preparation is underway in cooperation with the State Institute for Drug Control.

By the end of 2022, **361** end-users were connected to the Alert Management System (AMS), i.e. a total of **1647** establishments – **1504** pharmacies and **143** warehouses.

WHAT ELSE WAS DONE IN THE NMVO IN 2022?

- Regular workshops and meetings with representatives of the State Institute for Drug Control helped to resolve some problematic areas in terms of the FMD (a specific treatment program, ome entities' non-cooperation in handling alerts) or to reach a common agreement on changing some processes. The whole process of investigating and closing alerts caused by process errors has been set up; the medicinal product can be dispensed once the State Institute for Drug Control's requirements are met. The State Institute for Drug Control regularly spoke in favor of using the AMS and supported its promoting as part of the FMD in the Czech Republic.

- Participation and active preparation of joint meetings in Europe - FMD workshops once a quarter in the presence of representatives of all European stakeholders; newly introduced workshops with representatives of European supervisory authorities – including the State Institute for Drug Control.

- Review of the NMVS in terms of meeting the GAMP5 requirements at the transnational level. Joint activities of national organizations using the NMVS provided by Solidsoft Reply.
The result has confirmed that the system setup and operation meet all the main requirements.

- Regular webinars for marketing authorization holders and pharmacists about AMS development and other FMD news. AMS and NMVS user manuals were regularly updated and posted on the NMVO's website (in Czech and English).

- The NMVO organized a workshop with IT SW companies, during which recommendations regarding the settings of SW end-users and news concerning the FMD and the AMS were provided and individual suppliers shared their experience.

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

- The internal audit of the NMVO's quality management system (QMS) concluded that the NMVO applied approved internal regulations and identified no critical shortcomings in the NMVO's quality management system.

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

In the middle of 2022, the NMVO started the process of concluding a new version of the contract on the use of the NMVS by all end-users, i.e. pharmacies or distributors. 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 (AMS). More than 1600 companies have switched to the new version of the contract since July 2022, with nearly 650 of them already having the new version of the contract with the NMVO in place at the end of 2022. When the new version of the contract is signed, information about end-users, their contact details and establishments is updated.

HANDLING OF PROCESS ERRORS

End-users were allowed to close A7 and A24 alerts in the AMS caused by process errors, where the unique identifier has already been eliminated and no additional transaction in the NMVS was allowed. Up until R 5.0 AMS, the given packs of medicinal products had to be quarantined and eventually returned to the distributors. The alert could be closed by both marketing authorization holders (MAHs) and end-users; however, it was impossible to dispense the medicinal product to the public.

The new AMS release allows end-users to handle process errors directly in the AMS. Although the pack cannot be successfully verified in the NMVS, end-users can close the alert and possibly even dispense the pack, subject to certain conditions set by the State Institute for Drug Control.

Therefore, end-users have nine days after the alert to investigate, document the cause and provide an affidavit to the AMS through the AMS web interface or their pharmacy or warehouse application. All necessary steps can be easily completed with a few clicks of the mouse. The AMS will direct NMVS end-users and provide instructions on how to handle the pack.

The entire process of handling process errors has been consulted and approved by the State Institute for Drug Control.

VISITS TO END USERS

The NMVO's selected employees made two visits to end-users and thus had the opportunity to learn about current FMD practice after some time, including FMD practice in the demanding operation of a large pharmacy and a parallel importer.

It was good to see that, with just few exceptions, there were no problems with the response time when a medicine dispensing was requested. The NMVO's representatives created several artificial alerts, and it took a very short time to receive an information e-mail about the alert – it was almost instantaneous; the actual processing in the AMS ranged from 8 to 10 minutes after the alert was generated.

It has been confirmed that the pharmacy system in use is of high quality even in terms of the FMD. It also helps the pharmacy staff in dealing with potential alerts and in releasing medicines from quarantine.

Random scanning errors (especially in the case of a high scanning frequency) and the fact that manufacturers often unnecessarily use negative 2D Matrix codes (white on the black background), which complicates and prolongs scanning, are still a problem. Staff also pointed out the confusion about the correct procedure in eliminating lost or illegible packs (SN is unknown) and the problem with packs that patients bring back to the pharmacy as sales returns. In such a case, they cannot invalidate the newly dispensed pack because the original pack has already been dispensed against the prescription. As a result, the new pack dispensed to the patient remains active in the NMVS.

LEVEL 3 ALERTS

AMS R5.0 also introduced the monitoring of level 3 alerts, which includes situations where the product code of a medicinal product is unknown in any European national repository (alert A1) or there is an attempt to reactivate a pack in an establishment other than the establishment where the pack was eliminated (alert A5). However, these alerts are so far for information only and do not require any activity on the part of the pharmacy, distributor or MAH/OBP; nevertheless, this topic is interesting for the State Institute for Drug Control, and discussions on how such alerts should be handled are ongoing.

THE FMD'S STATE AT THE END OF 2022

MARKETING AUTHORIZATION HOLDERS (MAH)

Number of registered MAHs to use the NMVS: **382**
Of this, the number of MAHs eligible for a reduced user fee: **55**

NMVS END-USERS (PHARMACIES AND DISTRIBUTORS)

1,772 registration contracts with legal entities

3,532 establishments connected to the NMVS. Of this:

- Pharmacies: **3,107**, including **137** hospital pharmacies
- Warehouses (distributors' locations where medicines are verified): **425**

CHANGES IN ORGANIZATIONS CONNECTED TO THE NMVS DURING 2022

42 new entities connected
99 entities disconnected

PRODUCT DATA IN THE NMVS

10,946 products entered in the EU HUB and the NMVS.
The number of packs with data uploaded in the NMVS as of 31 December 2022: **890,756,508**

TRANSACTIONS IN THE NMVS

There were about **8.6 million** transactions per week.
Of this, **3.36 million** packs were verified on average and marked as dispensed.

Most transactions take place every March – **41,507,912**
Over **40 million** transactions also took place in June and November.

The so-far biggest number of packs successfully eliminated by end-users was in the 50th week of 2022 – **10,765,386** – and right behind in the 49th week of 2022 – **10,446,303**.

ALERTS GENERATED DUE TO FAILED MEDICINES VERIFICATION

o The percentage of alerts of the total number of transactions amounted to **0.017%** during the 1st week of 2022 and to **0.006%** during the 40th week of 2022. During the entire year, the percentage of alerts of the total number of transactions was below **0.02%**.

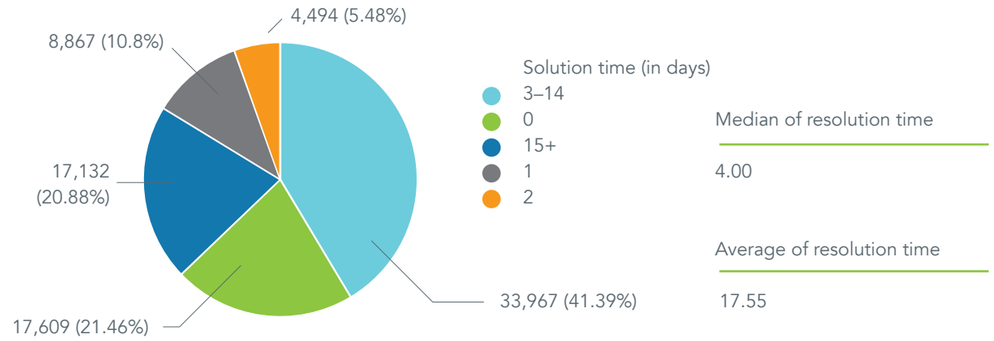
In 2022, a total of **84,916** alerts were generated, which means that the authenticity of medicines could not be successfully verified. As compared to the previous year, the number of alerts dropped by almost half – only **54.04%** of generated alerts; their number keeps decreasing in the long run. (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).

NUMBER OF CLOSED/UNCLOSED ALERTS

Alert status	Sum	%
Unclosed	2,879	3.39%
Closed	82,037	96.61%
TOTAL	84,916	100.00%

The average time of resolving an alert became longer (almost 17.6 days), but an alert was usually resolved and closed within four days, and 79.12% of all alerts were closed within 14 days. The time-limit for keeping medicines in quarantine while alerts are being investigated and before a medicine pack can be sent back to the distributor, which is stipulated in the Medicines Act, was mostly observed.

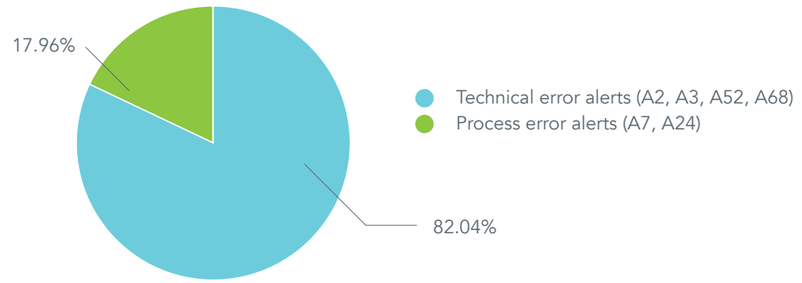
% OF THE ALERT CLOSING TIME ACCORDING TO THE TIME SCALE



Technical alerts were prevalent among end-users and were caused, for example, by incorrect keyboard settings, poor scanner quality or manual entry errors.

Process alerts, which are a result of repeated or unauthorized transactions on already eliminated packs, accounted for nearly 18% of alerts.

ALERTS ACCORDING TO END-USER ERRORS



In 2022, alerts were mostly caused by marketing authorization holders (MAHs) and parallel distributors. More than one third of all MAH alerts were generated in a single day due to a faulty EU HUB response. An MAH repeated the "Exported" transaction involving 14 500 pack serial numbers. Several thousand alerts were generated earlier in 2022 also due to an MAH's repeated attempt to change the pack status to "Exported." Packs that were uploaded to multiple markets as part of multi-market batches had been dispensed by end-users in other markets. The alerts were subsequently closed as an MAH error. Parallel distributors' most frequent error was a repeated transaction due to the fact that the 24-hour time-limit for the system response was not observed or due to a human process error.

PERCENTAGE DISTRIBUTION OF CLOSED ALERTS IN 2022 BY GROUPS

Type (group)	% of alerts in 2022
MAH	61.39%
Pharmacy	26.51%
Wholesaler	8.24%
IMT	3.40%
Other (system)	0.46%

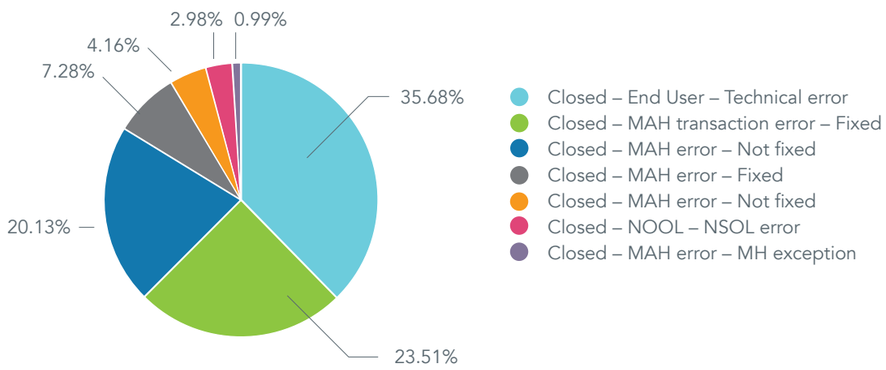
The highest total number of alerts generated by end-users occurred once again in the largest pharmacy chains; however, considering the large number of their pharmacies, the final average number of alerts per pharmacy was only around 13 alerts for the entire year.

A large number of alerts were caused by the distributor eliminating packs that had already been eliminated in the system. The incident was caused by an error in the distributor's system. Distributors caused alerts mainly due to a repeated "Destroyed" transaction.

No pack serial number found in the system due to various technical errors in the pharmacy or distribution information systems was the most frequent cause of end-user alerts.

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 over time; however, any alert that falls under such exception is automatically closed in the AMS.

% 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.

Covid-19 vaccines had only three alerts, which were resolved immediately thanks to the process in place.

ALERT MANAGEMENT SYSTEM (AMS)

NUMBER OF USERS CONNECTED TO THE AMS

- Pharmacies: **1504**
- Distributors: **143**
- MAHs: **282** – production environment, **15** – testing environment

SUPPORT TEAM

In 2022, the support team focused in particular on the following:

- Implementation and use of the Alert Management System (AMS) - support and education of pharmacies, distributors and MAHs with the goal to effectively manage and handle alerts.
- Support for communication between end-users and MAHs, in the case that one of the parties does not use the AMS; the acquisition of NMVS users for connecting to the AMS.
- Handling process errors by end-users, where a medicinal product can be dispensed even after a process error of the end-user (pharmacy, distributor), once the State Institute for Drug Control's requirements are met.

Just like last year, the main activities included:

- Communication with entities and handling inquiries concerning anti-counterfeiting legislation.
- Investigation of alerts at MAHs' request and providing additional information about the cause of alerts from end-users, especially in the case of process errors. Verification of audit trails, education of end-users in using correct procedures for handling medicines in compliance with the FMD and assistance in eliminating technical errors caused by incorrect software and scanner settings.
- Processing e-mail and phone inquiries that usually concerned specific alerts, user registration, contracts with end-users and setting up establishments in the NMVS.
- Collecting practical suggestions to improve the AMS for easier alert resolving and listing frequently asked questions and incorrect procedures to eliminate alerts.
- Education of end-users - an effort to minimize the number of alerts; collecting suggestions for support materials posted on the NMVO's website, e.g. "Frequently Asked Questions," "Did You Know ..." section; monitoring technical errors caused by end-users to communicate them to IT SW companies.

COMMUNICATION

The fading away pandemic, the war in Ukraine, inflation and the rising price of energy, raw materials and food completely overshadowed the attractiveness of medicines verification for the general Czech media. Fortunately, the significant shortage of certain medicines on the Czech pharmaceutical market at the end of the year was not blamed on medicines verification, which was carried out without any problems throughout the year. Therefore, we focused on targeted communication about ongoing and planned changes in the media for pharmacists/distributors. No (even potential) counterfeit medicine was caught, so we did not have to use any crisis communication tools.

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

TOPICS IN 2022

FEBRUARY

The 3rd anniversary of the European Medicines Verification System (Czech/English)
Pharma Profit, lekarnici.cz, czmvo.cz

Recertification of IT companies providing FMD solutions
Pharma Profit, lekarnici.cz, czmvo.cz

MARCH

Changes in the members of the Board of Directors
czmvo.cz, lekarnici.cz

A donation to Ukraine
czmvo.cz, lekarnici.cz

APRIL

Webinar for IT SW companies on R10.0

MAY

News: Use of Alert Management System (Czech/English)
Pharma Profit, lekarnici.cz, czmvo.cz

Good Distribution Practice Conference

JUNE

Updated information: Users, transactions and alerts in 2022

lekarnici.cz, czmvo.cz

JULY/AUGUST

Signing of the new contract
Pharma Profit, Praktické lékárenství, lekarnici.cz, czmvo.cz + ads

SEPTEMBER

Webinar for IT SW companies on R11.0

OCTOBER

A new version of the NMVO's Alert Management System – AMS R5.0
czmvo.cz

NOVEMBER

Interview with Pavlina Štisová, MBA
Lekis (interview requested)

THROUGHOUT THE ENTIRE YEAR 2022

The publicity of pharmaceutical topics, especially in relation to medicines verification, the AMS, the NMVS and the FMD, was continuously monitored and evaluated.

The year 2022 was calm in terms of the media; information was provided in a balanced manner.

The National Medicines Verification Organization communicated ongoing and planned changes in a targeted manner, and there was no negative reaction on the part of the media.

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.

Select data from the financial statements (in thousands of CZK)

Revenues in 2022

Registration fees	2,511
User fees	34,472
Other revenues (including foreign exchange gains: 194)	198
Total revenues	**37,181**

Expenses in 2022

Purchases including services	**33,145**
– Materials and energy consumption	352
– Purchased services	32,793
Personnel costs	8,091
Taxes and fees	0
Other expenses (including foreign exchange losses: 1,574)	1,724
Depreciation	835
Income tax	0
Total expenses	**43,795**

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.

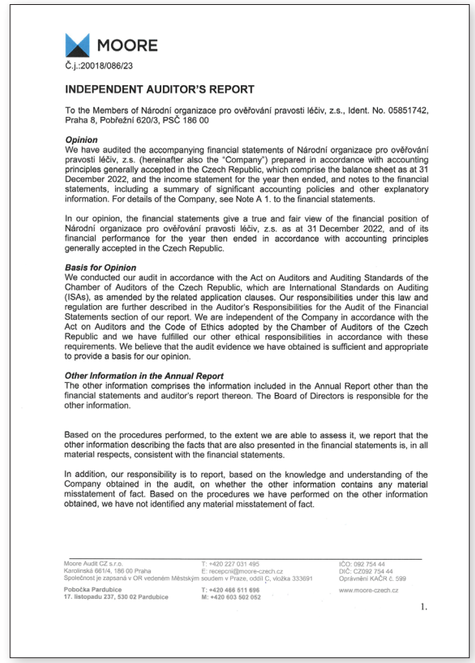
Loss in 2022 amounted to **6,614,247.21** CZK.

INDEPENDENT AUDITOR'S REPORT

AUDITOR'S UNQUALIFIED OPINION

We audited the attached financial statements of Národní organizace pro ověřování pravosti léčiv, z. s. (hereinafter also as the "Organization") prepared based on the Czech accounting regulations and consisting of the balance sheet for the year ended 31 December 2022, the profit and loss account for the year ended 31 December 2022 and the notes to the financial statements which include the description of applied major accounting methods and other additional information. The information about the Organization is provided in the notes to the financial statements.

In our opinion, the financial statements provide a true and fair picture of the assets and liabilities of the Organization as of 31 December 2022 and of the expenses, revenues and profit (loss) for the year ended 31 December 2022 in compliance with the Czech accounting regulations.



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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 2022, 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 2022, 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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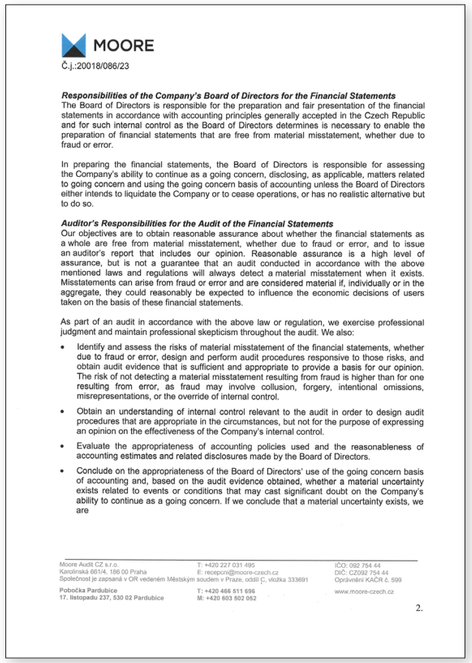

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Responsibilities of the Company's Board of Directors for the Financial Statements
The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted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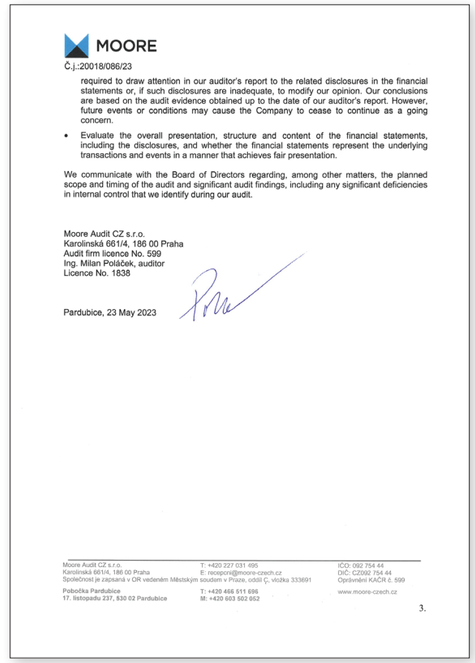

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required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our 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 2023

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CONTACT AND IDENTIFICATION INFORMATION

NÁRODNÍ ORGANIZACE PRO OVĚŘOVÁNÍ PRAVOSTI LÉČIV, z. s.

Address: Pobřežní 620/3, 186 00 Prague 8

IN: 05851742
TIN: CZ05851742

Web: www.czmvo.cz
E-mail: info@czmvo.cz
Tel.: +420 224 834 153

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