Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2021

AN OPENING WORD

The National Medicines Verification System (Czech NMVS/CZNMVS) has been stabilized and its functionalities are being adjusted on an ongoing basis. In 2021, medicines continued to be successfully verified in spite of the ongoing the SARS-CoV-2 pandemic. In addition, the transitional period, where pharmacists could dispense medicinal products despite an error message (alert), ended on 1 January 2021. In January 2021, the pharmaceutical media wondered whether this would jeopardize the availability of medicines for Czech patients. The National Medicines Verification Organization (Czech NMVO/CZMVO) explained that the verification of medicines was not Czech official institutions' "bureaucratic necessity" but that it stemmed from DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011; abbreviated as the FMD, Falsified Medicines Directive).

The importance of medicines verification became apparent during the spring (March) 2021, when the European Medicines Verification Organization (EMVO) issued warnings about the source of SARS-CoV-2 vaccines and recommended to distributors and other authorized institutions to take vaccines from official and well-proven sources only. There were attempts to sell vaccines without the proof of their origin. This suggests that there may have been an illegal trade with stolen, counterfeit vaccines or vaccines from non-approved manufacturers without a guarantee of quality control and good manufacturing practice.

The implemented medicines verification is also justified by the detection of counterfeits in the distribution chain.

It is very gratifying that the Czech Republic is consistently among the top three European countries in terms of the implementation of the FMD (100% of end-users are connected to the system) and had a very low share of alerts of the total number of performed transactions (0.01-0.04%) throughout the year 2021.

To facilitate alert investigations, the CZMVO has developed the unique Alert Management System (AMS) that supports alert investigations and makes investigation findings available to end-users (pharmacies or distributors). It provides direct two-way anonymous communication between an end-user and a marketing authorization holder (MAH) during an alert investigation, without the need for CZMVO support-center staff to arrange such communication, which speeds up alert investigations.

The advantage of the AMS is that it removes the language barrier in anonymized communication between an MAH and an end-user, as it offers predefined messages. A clear advantage of the AMS is that it shows the alert status and makes it easier to obtain and enter detailed information about the alert. The AMS also allows pharmacists to release the medicine from the quarantine and to dispense it to the patient once the alert had been resolved and the medicine pack verified. Early identification of the alert status and cause, i.e. the place of its occurrence (e.g. an error of an end-user or MAH), will also limit the number of non-recognized medicine returns in the case that an error was caused by an end-user or in the case that an alert caused by an MAH is eliminated during the 14-day quarantine. On the other hand, in the case of uncorrectable errors caused by MAHs or alerts handled after 14 days, it will be possible to arrange medicine returns with the distributor as part of standard procedures (in 2021, 87.92% of alerts were closed within 14 days).

In 2021, the National Medicines Verification Organization continued to closely collaborate with MAHs and CZNMVS end-users and their software solution providers in training, providing additional information and solving alerts, all this with an emphasis on the new functionalities of the system and on connecting to the AMS in particular. With the exception of the first quarter, communication took place in the form of direct mailing and on-line seminars.

I would like to thank all those who participated in the successful implementation of the FMD in this difficult year, i.e. pharmacists, distributors, MAHs and their partners. In particular, I would like to take this opportunity to thank Jakub Dvořáček, former Chairman of the Board of Directors of the National Medicines Verification Organization, who stood at the birth of the Czech NMVO and has proactively worked to successfully implement the Anti-Counterfeiting Legislation in the Czech Republic.

Mgr. Filip VRUBEL
Chairman 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/Czech NMVO/CZMVO) 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 Czech 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 Czech NMVO are as follows:

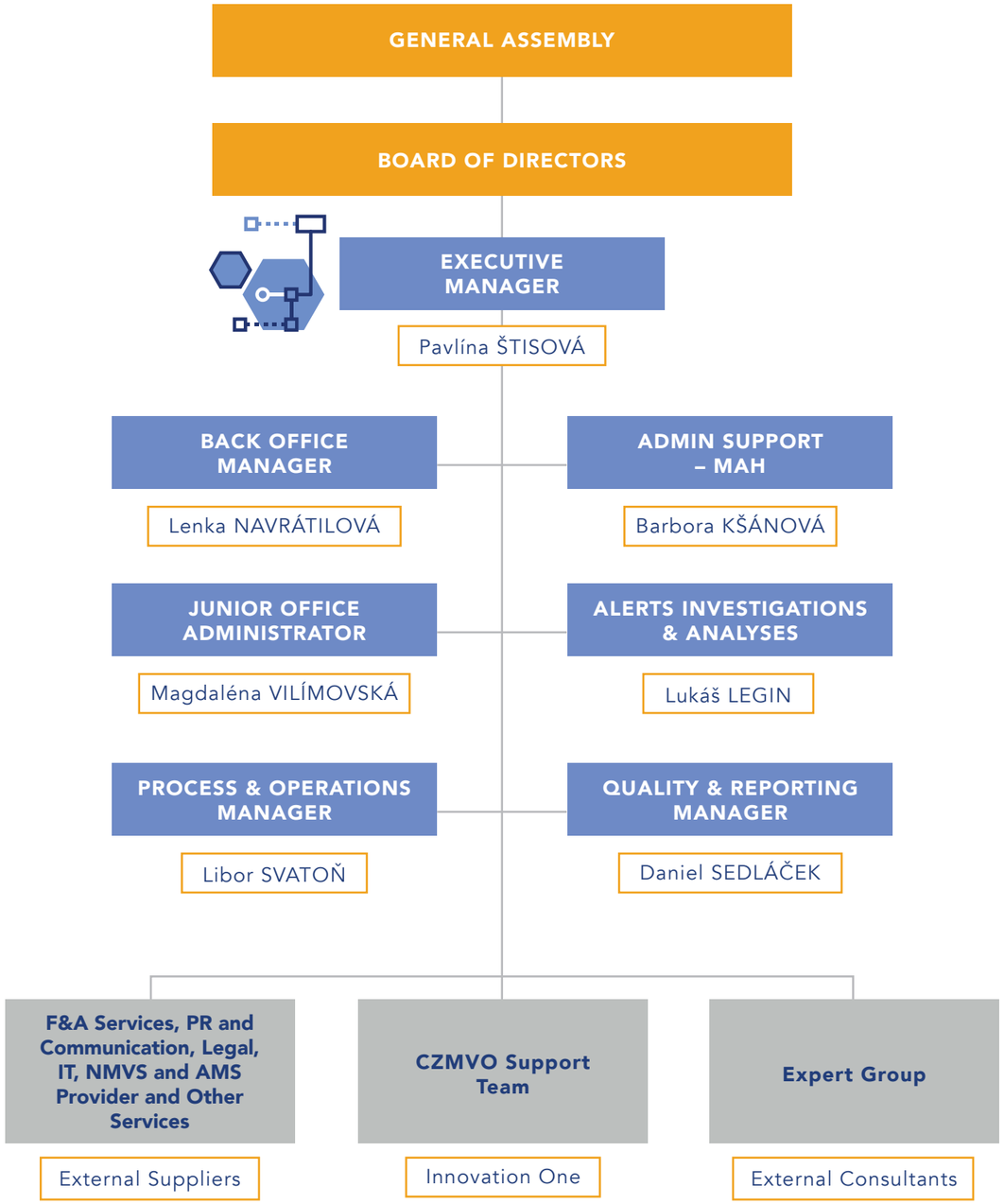
- Apatyka Servis
- Asociace provozovatelů lékárenských sítí
(Association of Pharmacy Chain Operators)
- GS1 Česká republika
- Lekis
- PharmaSwiss
- Poskytovatelé lékárenské péče
(Pharmaceutical Care Providers)
- Avenier
- Cyrmex
- Unie distributorů léčiv
(Union of Medicines Distributors)

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

The CZMVO 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 CZMVO's activities in 2021.

ORGANIZATIONAL STRUCTURE



THE CZMVO'S TEAM IN 2021

Pavlína Štisová, MBA
Executive Manager

Ing. Lenka Navrátilová
Back Office Manager

Ing. Daniel Sedláček
Quality & Reporting Manager

Ing. Libor Svatoň
Process & Operations Manager

Barbora Kšánová
Admin Support – registrations/MAH

Bc. Magdaléna Vilímovská
Junior Office Administrator

Lukáš Legin
Alerts investigations & Analyses

ACTIVITIES IN 2021

The CZMVO's primary responsibility includes the operation of the Medicines Verification System in the Czech Republic, which can be considered successful especially in terms of its accessibility. The CZNMVS was stable throughout the entire year and, with some exceptions, was available and responded quickly. In 2021, the CZNMVS development **did not bring any major functionality changes**, but focused on **improving the system security and stability**. It also provided end-users, the CZMVO and SÚKL with some minor improvements facilitating the investigation of alerts.

27 April 2021 – CZNMVS release R8.0

- API 2.0 support was terminated
- Some security protocols (Cipher Suite) with known security errors were removed
- Support for security protocol TLS 1.3 was added
- Zip codes became required information (it concerns end-users locations added to/updated in the CZNMVS)

26 October 2021 – CZNMVS release R9.0

- The use of API version 1.5 was terminated
- The authentication API was expanded for a new operation for uploading the current system status (Ping interface) = a mechanism to check whether the system is available
- The system supports security protocols TLS 1.2 and 1.3.; some potentially weak protocols (Cipher Suite) with known security errors were removed from TLS 1.2

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 systems of Arvato, Solidsoft Reply and EU Hub before individual changes are implemented.

To support and simplify the handling of alerts generated in the CZNMVS, the CZMVO Alert Management System (AMS) was created. It began to be used in 2021 not only by marketing authorization holders but also by end-users (pharmacies, distributors) and it underwent **a number of major functionality changes** during 2021. These changes significantly increased user comfort in alert investigating and closing and were also made based on user feedback; for example, in 2021, we managed to significantly improve the work with alert groups thanks to end-users' and MAHs' suggestions.

During 2021, it became obvious that the AMS contributes to greater proactivity of end-users, e.g. thanks to the possibility to close an alert, if they identify and correct their own error, or to inform the MAH via a message in the AMS.

22 January 2021 – CZMVO AMS release R2.4

- **The option to verify the functioning of API communication with the AMS was added**
- **It was made possible for end-users to change the alert status**
- **It was made possible for end-users to communicate** (sending of predefined texts and attachments) (without being asked by MAHs)
- **List of alerts** – new filters were added

3 September 2021 – CZMVO AMS release R4.0

- **A new process workflow managed by the CZMVO's administrator was set up**
- The work with alert groups was redone (a change in the status of open alerts in the group)
- **MAHs' requests sent to end-users** (improvement and two-way information provision)
- **Logging in the web interface was redone**
- **Change logging** (a more detailed change in the alert status, other changes in editable fields; everybody, except for the CZMVO, sees only its own information)
- **Alert pre-investigation was created – alerts are investigated before they are sent to alert solving experts, which facilitates the follow-up investigation of the alert and its cause**
  - **a) To determine whether it is an MAH's/OBP's transaction or a parallel distributor's transaction**
  - **b)** If **it is not** an MAH's/OBP's transaction:
    - ba) **To determine whether it is an end-user's intermarket transaction**
    - bb) **To determine whether the MAH is known** – if not, it must be investigated by the CZMVO
    - bc) **To analyze the end-user's technical/process error**
    - bd) **To check the database of exceptions of the Ministry of Health of the CR**
  - **c) To send a notification e-mail about a new alert**
- **It was made possible to add a file even without request** (MAHs, the CZMVO or end-users can enter a file with respect to all alerts that do not have the flag "ARCHIVE")
- **Communication with the CZMVO** through an internal messenger, answers in the AMS
- **Reopening of an already closed alert** requires **a reason for reopening**
- **Closing of an alert by the CZMVO** due to errors caused in the CZNMVS
- **Confirmation of a manually made status change** by a notification e-mail containing alert closing details
- **The system of escalations and alert status setting was redone**
- **New escalations if an MAH does not act for 10 days** – an alert has the status "New" for more than 10 days
- **It was made possible to display an informative text after logging in the web interface** (it is used to provide information about what's new or about an AMS shutdown, etc.)

24 November 2021 –CZMVO AMS release R4.1

- **User management of users and notifications**
- **User management (and recovery) of access passwords**
- **Pre-investigation modification,** small changes in algorithms, for more specific results
- **Bulk import of status changes**
- **UTC is used everywhere** (i.e. Central European Time – 1–2 hours)
- **Change in offered predefined messages**
- **New filter – "NMVO message"** (predefined options of communication between MAHs and the CZMVO or between end-users and the CZMVO)
- New alert status **"Closed – end-user does not cooperate – it cannot be dispensed"** (the MAH asked the end-user to cooperate, but the end-user does not respond in spite of the MAH's reminder and warning, it can be closed nine days after the first inactivity escalation)
- The time of inactivity, about which an MAH was reminded, was **shortened** from seven days to five days

WHAT ELSE WAS DONE IN THE CZMVO IN 2021?

Proactive alert handling and monitoring during the year, including an increased occurrence of alerts at specific pharmacies, parallel distributors and marketing authorization holders. After a careful analysis was performed and information from audit trails received, the user was always contacted to provide detailed information and to prove corrective and preventive measures.

SARS-CoV-2 vaccine verification – these vaccines were typically verified in the CZNMVS, which was one of 11 systems in the EU to which data were uploaded for all other countries. There were only 59 alerts that were handled immediately; they had high priority; it was mostly a process or technical error.

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, some entities' non-cooperation in handling alerts) or to reach agreement on changing some processes. As a result, we made it possible for end-users to handle and close alerts identified by them as a technical error, to release a medicine from quarantine and to dispense it to the patient after it was successfully verified. We also discussed the whole process of investigating and closing alerts with process errors, etc. 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 workshop once a quarter in the presence of representatives of all European stakeholders; newly implemented workshops with representatives of European supervisory authorities - including the State Institute for Drug Control.

Review of the CZNMVS 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.

As part of communication, regular webinars were held for marketing authorization holders and pharmacists about the AMS development and other news concerning the FMD. At the same time, a regular update of user manuals for the AMS and CZNMVS was carried out, which were subsequently published on the CZMVO's website Czech and English.

The CZMVO organized a workshop with IT SW companies that allows to share recommendations regarding the setting of SW end-users and to share experiences between individual providers. We also started a regular webinar for all IT SW providers of end-user systems in the countries that use the NMVS from Solidsoft Reply - the webinar was organized by Solidsoft Reply together with national medicines verification organizations.

THE FMD'S STATE AT THE END OF 2021

MARKETING AUTHORIZATION HOLDERS (MAH)

Number of registered MAHs to use the CZNMVS: **373**
Of this, the number of MAHs eligible for a reduced user fee: **55**

CZNMVS END-USERS (PHARMACIES AND DISTRIBUTORS)

1,667 registration contracts with legal entities

3,452 end-users locations connected to the CZNMVS

Of this:
Pharmacies: **3,061** – including **115** hospital pharmacies
Warehouse – distributors locations where medicines are verified: **391**

PRODUCT DATA IN THE CZNMVS

9,893 products entered in the EU HUB and the CZNMVS
Number of packs with data uploaded in the CZNMVS as of 31 December 2021: **646,591,007**

TRANSACTIONS IN THE CZNMVS

There were about **8.2 million** transactions per week.

Of this, **3.2 million** packs were verified on average and marked as dispensed.

MOST TRANSACTIONS take place every March – **40,983,903**

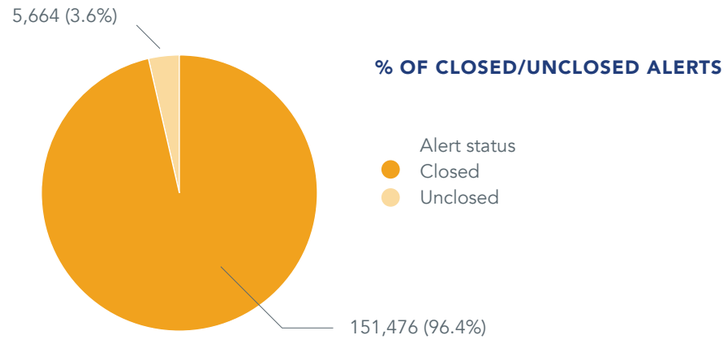
THE SO-FAR BIGGEST NUMBER OF PACKS SUCCESSFULLY ELIMINATED BY END-USERS was in the 50th week of 2021 – **10,203,810.** Up until and since then, the number of eliminated packs has not exceeded 10 million per week.

THE PERCENTAGE OF ALERTS OF THE TOTAL NUMBER OF TRANSACTIONS amounted to **0.04%** during the 1st week of 2021 and to **0.01%** during the 51st week of 2021. During the entire year, the percentage of alerts of the total number of transactions was below 0.05%, which was set as a target for all European medicines verification systems in connection with the implemented Anti-Counterfeiting Legislation.

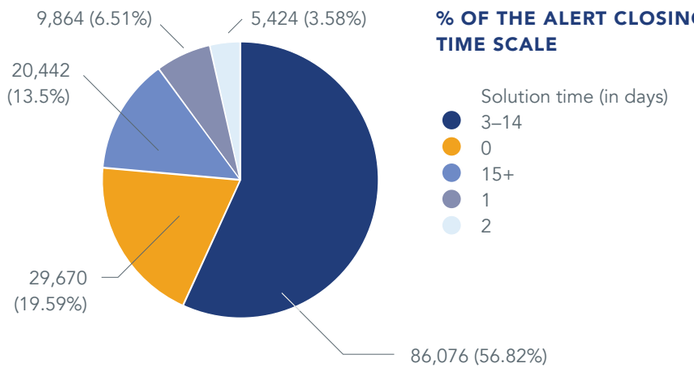
ALERTS GENERATED DUE TO FAILED MEDICINES VERIFICATION
In 2021, a total of 157 140 alerts were generated, which means that the authenticity of medicines could not be successfully verified. This represents only 36.36% of generated alerts compared to the previous year. Their number keeps decreasing in the long run. (The number of alerts includes all alerts per pack - the same serial number – several alerts are often generated, i.e. the number of packs is much lower.)

Number of closed/unclosed alerts

Alert status	Sum	%
Closed	151,476	96.40%
Unclosed	5,664	3.60%
Total	157,140	100.00%



The average time of resolving an alert was longer (almost 12 days), but an alert was usually resolved and closed within four days, and 86.5% 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.



In 2021, alerts were mostly caused by marketing authorization holders and parallel distributors.

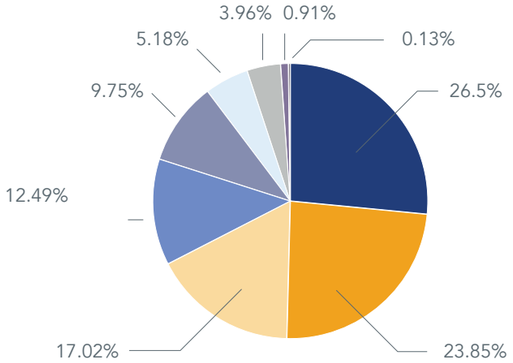
In March and September, the CZNMVS experienced two big swings in alerts caused by marketing authorization holders. In the first case, there were at once 18 thousand alerts caused by a human error and a repeated attempt to place packs in the status "Exported." The second case concerned the SARS-COV-2 vaccine where the MAH made a bulk transaction of the entire batch, of which a large number of packs has already been supplied abroad.

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 2021 by groups	
Type (group)	**% of alerts in 2021**
Intermarket operations	**1.56%**
MAH/Paraller Distributor	**68.40%**
Other (system)	**6.60%**
Pharmacy	**18.58%**
Wholesaler	**4.85%**

The highest total number of alerts generated by end-users naturally occurred in the largest pharmacy chains; however, considering the large number of their pharmacies, the final average number of alerts per pharmacy was only around 20 alerts for the entire year. The highest number of alerts was generated by one pharmacy – almost 3,000 alerts. As a result of incorrectly set SW, it generated almost 1,700 alerts in a single day by its multiple attempts to dispense a medicine. Alert solving assistance provided to the end-user included repeated communication and training. Its SW was also updated. Thanks to these measures, the number of alerts then rapidly dropped.

The number of exceptions granted by the Ministry of Health of the Czech Republic for individual medicine batches in connection with the FMD has decreased over time; however, any alert that falls under such exception is automatically closed in the AMS.



% SHARE OF CAUSES FOR CLOSED ALERTS

- Closed – PD error – Not fixed
- Closed – End User – Technical error
- Closed – MAH error – Not fixed
- Closed – MAH transaction error – Fixed
- Closed – MAH error – MH exception
- Closed – MAH error – Fixed
- Closed – End User process error – cannot be dispensed
- Closed – MAH transaction error – Not fixed
- Closed – Released prior to 02/09/2019

COUNTERFEIT IDENTIFICATION AND HANDLING in 2021 in the Czech Republic and neighboring countries – during the year, several alerts were identified by MAHs in the AMS as a suspected counterfeit. However, the investigation, which took place immediately, always revealed that the suspicion was false, and the alert was closed. In December, however, a real counterfeit was discovered in the system, which started with an electronic offer of a medicinal product from a supplier abroad sent to a distributor in the CR. The offer included photographs of the pack and 2D codes. In violation of the Regulation, the distributor verified the pack from the photographs. The scanned codes caused alerts in the CZNMVS, and the distributor did not purchase the medicinal product. The MAH identified the alerts as a suspected counterfeit and, as part of the alert investigation, asked the distributor to send the actual pack to the production plant. This, however, was not possible since the distributor did not have the pack. The CZMVO also informed SÚKL. After a thorough investigation, the case of counterfeiting was confirmed by the MAH. In compliance with the Regulation, the CZMVO informed the European Commission and the European Medicines Agency.

CZMVO ALERT MANAGEMENT SYSTEM (AMS)

The Alert Management System was operated and developed throughout the entire year 2021, while its advantages were promoted.

NUMBER OF USERS CONNECTED TO THE AMS

- Pharmacies: **1,302**
- Distributors: **95**
- MAHs: **209** – production environment, **29** – testing environment.

SUPPORT TEAM – INFORMATION ABOUT ACTIVITIES IN 2021

Just like last year, the main activities included in particular:

- Communication with entities and handling inquiries concerning Anti-Counterfeiting Legislation
- Assistance to AMS users concerning alert management and system administration as part of the implementation and use of the CZMVO AMS; support and training 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 processing of e-mail and phone inquiries that usually concerned specific alerts, user registration and setting up end-users locations in the CZNMVS.
- Collecting practical suggestions to improve the AMS for easier alert resolving and listing frequently asked questions and incorrect procedures to eliminate alerts
- 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
- Providing feedback on alerts caused by parallel distributors and providing MAHs with an explanation of the cause in an anonymized form
- Regular communication with MAHs with unclosed alerts
- Education of end-users - an effort to minimize the number of alerts; collecting suggestions for support materials posted on the CZMVO's website, e.g. "Frequently Asked Questions," "Have you noticed...?" section; monitoring technical errors caused by end-users to communicate them to IT SW companies

IN 2021, THE SUPPORT TEAM HANDLED:

2,434
phone calls,
primarily with pharmacies

26,803
e-mail communications and investigation assistance

284
messages
that the support team received and handled through the AMS messenger

COMMUNICATION

In 2021, all media still focused on the ongoing and tedious SARS-CoV-2 pandemic. Our communication was similar: our on-line information concerned only topics closely related to the COVID-19 pandemic and vaccination. Topics concerning the FMD, CZMVO and AMS were communicated in the professional media or in the form of direct mailing.

During the first semester, we ran ads on the following topics:
- Transitional period is over, the verification of medicines is mandatory
- Connect to the Alert Management System (AMS)
- Advantages of the AMS.

Target media: Praktické lékárenství, Sortiment, PharmaProfit, Medical Tribune, lekarnici.cz – they cover 100% of pharmacies and distributors.

Any important information was regularly posted on the National Medicines Verification Organization's website (www.czmvo.cz)

January 2021
- The CZMVO's/AIFP's statement on ČLnK's report about a potential unavailability of medicines due to the FMD
- Reminder – medicines cannot be dispensed if there is an alert

January – February 2021
ADS
- Transitional period is over
- Connect to the AMS
- Advantages of the AMS
  (PharmaProfit, Praktické lékárenství)

February 2021
- Report on the 2nd anniversary of the FMD

March 2021
- Press release – the EMVO's warning against SARS-CoV-2 vaccines from unverified sources (a very broad coverage in dailies and on-line)

June – September 2021
MAH: DIRECT MAILING
- New functionalities – what the system can do
- The AMS vs. clicking e-mails (they are no longer developed and supported)

June 2021
- Praktické lékárenství: What worked in 2020 + connect to the AMS
- Remedia: Information about the CZMVO + the importance of the AMS with graphics (hospital pharmacies – connect to the AMS through API or a web interface, advantages of alert solving, less phone calls).

July 2021
- Recommendations of the National Medicines Verification Organization and the State Institute for Drug Control
- Notification of the CZMVO: 48 hours for alert investigation

August 2021
- Report: Implementation of the Falsified Medicines Directive in the Czech Republic in 2021 (for the EMVO)

October 2021
- Report of the FMD Working Group (for the web)
- CZNMVS users' alert solving procedure
  (in compliance with Directive 2001/83/EC of the European Parliament and of the Council, 2011/62/EU and Commission Delegated Regulation (EU) 2016/161)
- FAQ about the AMS
- The AMS and the CZNMVS: News and new functionalities

November 2021
- Pavlína Štisová: the CZMVO AMS provides many advantages (an interview for Medical Tribune)

December 2021
- SÚKL's report: Information about falsified Imbruvica (Medical Tribune)

Throughout the entire year 2021

Many educational materials were available to users on the CZMVO's website - regular articles based on information and experience from the field and so-called best practice. We were able to identify and gradually eliminate more and more misunderstandings and causes of false-positive alerts. It is worth mentioning, for example, that alerts caused by incorrectly working with a delivery note now occur rather sporadically.

CZMVO employees directly communicated with, and provided assistance to, a number of end-users in solving problems concerning alert verification and management, marketing authorization holders in checking uploaded data and distributors in handling certain product returns.

Marketing authorization holders were asked during the entire year to close alerts from the year 2020. At the end of the year, the number of unclosed alerts from 2020 was minimal.

During the year, we organized several on-line seminars for IT providers of end-user systems, as well as for pharmacists, distributors and marketing authorization holders.

FINANCIAL MANAGEMENT REPORT

The National Medicines Verification Organization and the FMD implementation project were financed from several sources:

- Membership fees of the regular members;
- Registration and user fees from each MAH using the medicines verification system.

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

Revenues in 2021

Received membership fees	50
Registration fees	2,128
User fees	49,909
Other revenues (including foreign exchange gains: 420)	425
Total revenues	**52,512**

Expenses in 2021

Purchases including services	**33,539**
– Materials and energy consumption	175
– Purchased services	33,364
Personnel costs	6,819
Taxes and fees	0
Other expenses (including foreign exchange losses: 3,141)	3,282
Depreciation	606
Income tax	1,407
Total expenses	**45,653**

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 after tax in 2021 amounted to **6,858,849.37** CZK.

Profit after tax in 2020, which amounted to 9,037,597.81 CZK, was distributed as follows:

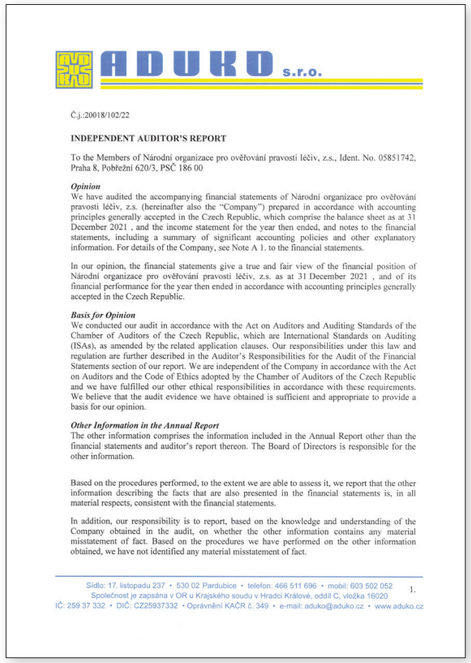
- 5,000,000.00 CZK were used for additions to the Future Risks Fund in compliance with the Statute
- 4,037,597.81 CZK were used for additions to the Provisions and Development Fund in compliance with the Statute

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 2021, 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 2021, and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech Republic.



ADUKO s.r.o.

Č.j.:20018/102/22

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 2021 , 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 2021 , 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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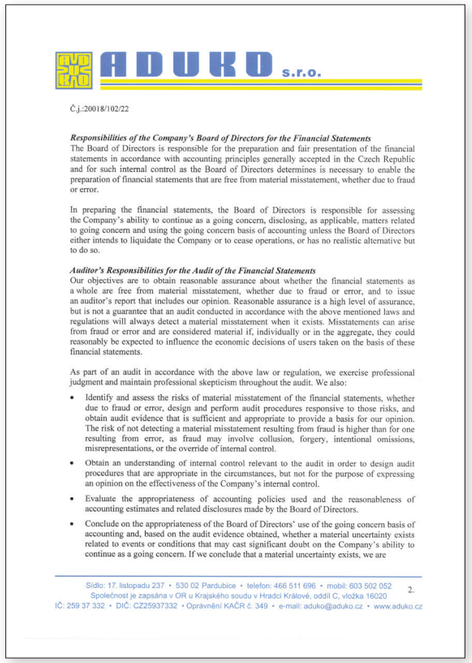

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Responsibilities of the Company's Board of Directors for the Financial Statements
The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted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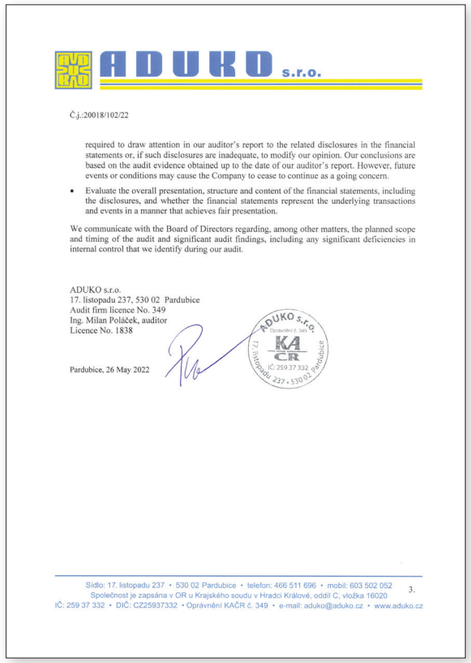

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required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our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

ADUKO s.r.o.
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Audit firm licence No. 349
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 26 May 2022

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CONTACT AND IDENTIFICATION INFORMATION

NÁRODNÍ ORGANIZACE PRO OVĚŘOVÁNÍ PRAVOSTI LÉČIV, z. s.

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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