Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2020

AN OPENING WORD

The year 2020 will forever be remembered as the year of the coronavirus crisis, which affected society as a whole, but most of all those who were in regular contact with patients actually or potentially infected with SARS-CoV-2, i.e. all healthcare professionals and pharmacists. The verification of medicines continued despite all the obstacles caused by COVID-19. All the essentials of the correct process stipulated in legislation were fulfilled, but in order to ensure the availability of medicines in this difficult epidemiological situation, it was possible to dispense them to patients even if their authenticity could not be successfully verified, i.e. after an alert was generated.

A big thank-you goes to the pharmaceutical companies, marketing authorization holders (MAHs), that, in a very short time, developed and prepared for approval effective vaccines and promising medicines against COVID-19 and actively participated in educational campaigns.

All crises pose an increased safety risk. This is also true about the risk of falsified medicines entering the European market. Some falsified vaccines against the SARS-CoV-2 infection have already been seized. Thus, the Falsified Medicines Directive (DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011; hereinafter as the FMD) is still needed and justified even two years after it came into effect. Compliance with the FMD effectively protects Czech patients.

In 2020, the National Medicines Verification Organization (NOOL) stabilized the systems and searched for activities that would reduce the number of generated false alerts, for which the unique identifier on the packs of medicinal products could not be verified against data in the system. During the year 2020, the National Medicines Verification System (NSOL) as well as the follow-up systems were modified based on the experience from the first year's live operation: errors were eliminated and minor inaccuracies in settings were debugged.

NOOL also focused on improving the Alert Management System (AMS) and all processes related to handling alerts generated both on the part of marketing authorization holders (MAHs) and end-users (pharmacies, distributors). The AMS enables direct two-way anonymous communication between a pharmacy and an MAH during the investigation of an alert, without the need to involve the NOOL support center, which speeds up the investigation of alerts. The AMS removes the language barrier in communication between an MAH and a pharmacy.

The Alert Management Center closely worked with marketing authorization holders and NSOL end-users in training, providing additional information and cooperating in handling alerts. Communication was mainly targeted at specialized pharmaceutical media to provide them with factual reports concerning changes and settings of the AMS.

Thanks to the "extended transitional period" for dispensing medicines despite alerts, all entities in the Czech Republic that are obliged to verify the authenticity of medicines based on the FMD had the opportunity to further practice the verification of medicines and to reduce the number of errors caused by unfamiliarity with the processes.

It can be considered a great success that the number of alerts in 2020 was stabilized at 0.05%, which places the Czech Republic - with 100% of the connected end-users – among the European elite. European data and comparisons are taken from regular reports of the European Medicines Verification Organization (EMVO).

We would like to thank all those who participated in the successful implementation of the FMD in this difficult year.

Mgr. Jakub DVOŘÁČEK, MHA, LL.M.
Chairman of the Board of Directors

Mgr. Martin MÁTL
Vice-Chairman of the Board of Directors

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ABOUT THE NATIONAL MEDICINES VERIFICATION ORGANIZATION (NOOL)

Národní organizace pro ověřování pravosti léčiv, z. s. (National Medicines Verification Organization (NOOL) was founded in March 2017 by the following regular founding members:

- **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:

- 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).

NOOL 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.

NOOL was founded to protect the legal supply chain against falsified medicinal products by creating and managing the regional data repository – the National Medicines Verification System (NSOL). The NOOL's goal is to coordinate collaboration among its members, NSOL users and competent entities and authorities in implementing the Falsified Medicines Directive (FMD).

The regular member companies regularly met via their representatives in the NOOL's Board of Directors and General Meeting and helped to supervise the implementation of the FMD in the Czech Republic.

NOOL's activities are described in detail in the following chapters.

In 2020, NOOL also closely collaborated 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.

MEMBER COMPANIES

AVEL asociace velkodistributorů léčiv

Česká lékárnická komora

ČAFF Česká asociace farmaceutických firem

aifp Asociace inovativního farmaceutického průmyslu

AEDL Asociace evropských distributorů léčiv

AFFILIATED COMPANIES

GS1 Czech Republic

Asociace provozovatelů lékárenských sítí

Poskytovatelé lékárenské péče

APATYKA SERVIS Pharmacy Software a PHOENIX company

PharmaSwiss Choose More Life

Lekis

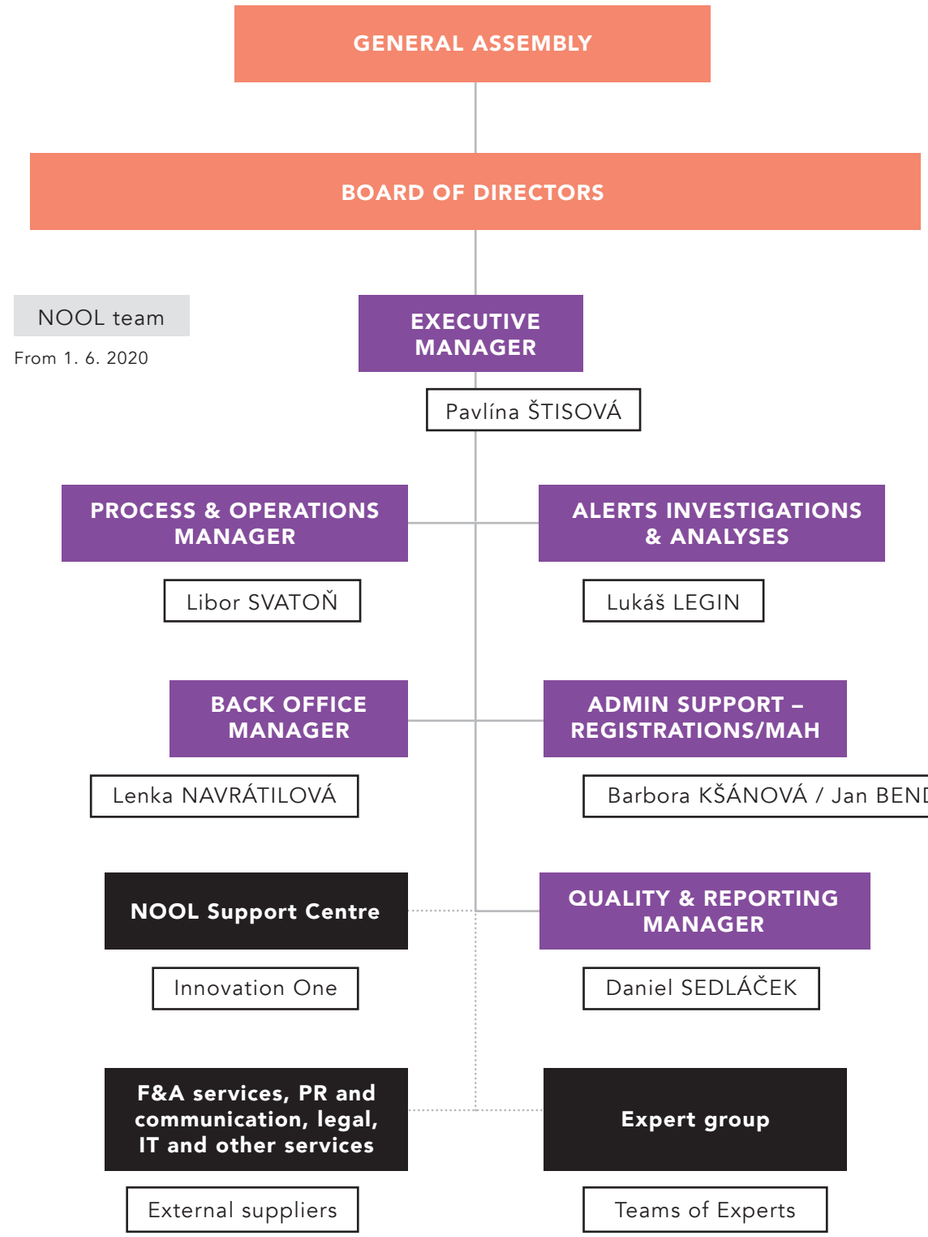
AVENIER

CYRMEX

Unie distributorů léčiv

(Union of Pharmaceutical Distributors)

ORGANIZATION STRUCTURE



NATIONAL MEDICINES VERIFICATION ORGANIZATION TEAM IN 2020

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. Jan Bendl
Admin Support – registrations/MAH

Lukáš Legin
Alerts investigations & Analyses

ACTIVITIES IN 2020

The year 2020 can be characterized as a year of searching for the right solutions to surprising and complex problems. For NOOL, it was rather about learning and setting up cooperation with all entities involved in the verification of medicines, handling and reducing the number of alerts generated during verification and in particular about improving the Alert Management System (AMS) developed and managed by NOOL. NOOL also modified and improved the National Medicines Verification System and cooperated within European anti-counterfeiting structures.

NOOL's main activities in 2020 focused in particular on stabilizing processes and handling alerts in the case that medicinal products could not be successfully verified, although the transitional period continued during the entire year and it was possible to dispense medicines even if an alert was generated. These activities also included the development and modification of the NOOL Alert Management System (AMS), which is extremely useful for communication support and for identifying alert causes.

THE MOST IMPORTANT ACTIVITIES INCLUDE IN PARTICULAR:

1. The modifications and development of the National Medicines Verification System in cooperation with its provider Solidsoft Reply and other countries using the system of the same provider.
2. Cooperation and intensive communication with providers of end-user IT systems regarding updates, changes and partial modifications before their planned implementation in the NMVS.
3. Daily contacts and cooperation with pharmacists, distributors and marketing authorization holders concerning anti-falsification legislation; sharing best practices and experiences in investigating alert causes as well as preventive measures to reduce the number of alerts.
4. Setting up the process of implementation of changes and relevant structures in the entire European Medicines Verification System (EMVS) in cooperation with other countries using Solidsoft Reply, Arvato and European HUB systems.
5. Informing and educating NSOL end-users (pharmacists and distributors) about the Alert Management System and the benefits of using the AMS in handling alerts generated during the verification of medicines; direct contact and education through the NOOL support team.
6. Cooperation, within European structures, with other countries using the same NMVS provider and with other EU Member States, as well as coordination of activities with the EMVO.

7 Monitoring the trend of error messages (alerts) from NSOL and searching for false alert causes and for ways to prevent false alerts. These long-term activities made it possible to reduce the percentage of error messages from almost 0.4% at the beginning of 2020 to less than 0.05% during the last months of 2020, which also led to the decision of the Ministry of Health of the Czech Republic to abolish the possibility to dispense medicines that were not successfully verified.

8 Communication with the Ministry of Health of the Czech Republic and the State Institute for Drug Control and continuous provision of current information, including monitoring the functioning of NSOL using the NOOL's website www.czmvo.cz.

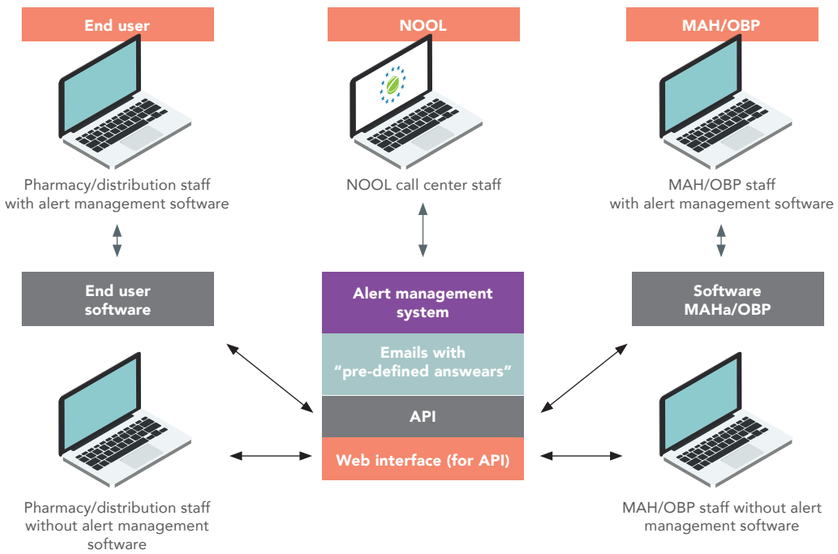
9 Regular meetings of the members of the NOOL Board of Directors and two General Meetings.

The NOOL Alert Management System is a unique solution that ensures the maximum automated processing and exchange of data information, i.e. it provides end-users and marketing authorization holders (MAHs) with the following benefits:

- immediate access to the current status of alerts;
- a simplified and completely anonymous exchange of messages among MAHs, the NOOL and end-users (i.e. the establishment, the place where the alert originated);
- the possibility to detect and change the status of alerts automatically or manually;
- data integration with MAH and end-user applications.

The National Medicines Verification Organization investigates, through the AMS, alert causes and closes alerts in cooperation with both MAHs and end-users. The AMS also makes it possible to detect and signalize a too slow response or the absence of activity in handling alerts, and thus the impending unnecessary return of medicines from pharmacies to distribution. The challenge for the year 2021 is to train both MAHs and end-users as much as possible in order to reduce the number of error messages and to streamline the handling of generated alerts caused by errors on the part of MAHs, pharmacists or distribution personnel.

All-European monitoring, which is regularly provided by the EMVO, shows that the Czech Republic successfully implemented the FMD in 2020 as well. The Czech Republic has long been one of the best countries in terms of activity, i.e. the number of verifications (transactions) in relation to its market size, as well as in terms of the number of alerts and their percentage on the total number of transactions, which keeps decreasing.



The NOOL Alert Management System was expanded in 2020 thanks to several releases of new functionalities, which mainly include:

Release 2.0 – 3/2020

- **Access and management of users and their roles** and management of organizations;
- **Design modifications and the option to export** to xlsx;
- **The alert display has been expanded with new details** (*"Manual Entry"*, *"Note"*, *"Expiration Date"*, *"Error Code"*);
- **"Anonymous groups" have been created** (alerts generated by the same end-user are grouped);
- **New statuses** have been added (*"Probably End-User's Error"*, *"NMVS's Error"*);
- **Activities now include Data Import** – mass update, uploading of attachments to an alert and an alert group;
- **The code list of messages sent by end-users to MAHs** has been expanded with other options from practice (*"Dispensed to the Patient – No Proof,"* *"Confirmed End-User Error"*) and **vice versa from MAHs to end-users** (*"Message with Uploaded Attachment – No Activity of End-User Is Required"*).

Release 2.1 – 4/2020

- The option to also include files **from central administration** – alert.czmvo.cz

Release 2.2 – 8/2020

- **The support team's response is recorded in the case that the end-user requests the MAH's cooperation:** the support team enters the end-user's **e-mail** response in the text field and an e-mail with the text is sent to the MAH's e-mail address. The same applies to a group response;
- **Corrections and additions in messages and filters;**
- **Reports for individual AMS users based on access rights** that include a complete report on a detail in the alert or alert groups, a report of the audit log by the alert, a summary report for the given period or since the last change.

THE FMD'S STATE AS OF THE END OF 2020

MARKETING AUTHORIZATION HOLDERS (MAHS)

Number of MAHs registered to use the NMVS: **360**
Of this, the number of MAHs eligible for a reduced user fee: **58**

NMVS END-USERS (PHARMACIES AND DISTRIBUTORS)

1 565 registration contracts with legal entities.
3 204 total establishments connected to the NMVS. Of this:
Pharmacies: **2 767** (100 %) – including **116** hospital pharmacies (100 %)
Warehouse – distributors' locations where medicines are verified: **437**

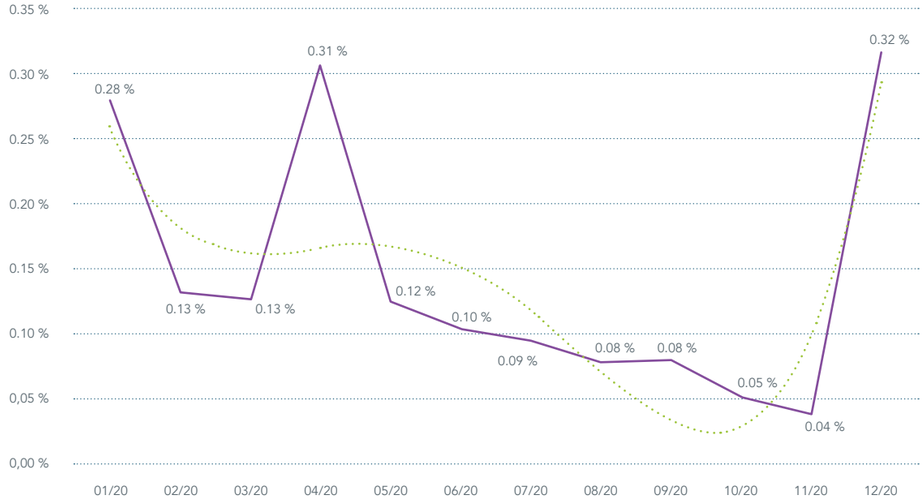
PRODUCT DATA IN THE NMVS

8 767 products entered in the EU HUB and NSOL
Number of packs with data uploaded in the NSOL as of 31 December 2020: **412 145 529**

TRANSACTIONS IN NSOL

There were about **8.5 million** transactions per week.
Of this, **3.3 million** packs were verified on average and marked as dispensed. During the first week of 2020, alerts amounted to 0.28% of all transactions; they dropped to 0.04% in the 51st week of 2020.

Count of alerts in relation to the count of transactions in NSOL (% of alerts) period 01/2020-12/2020

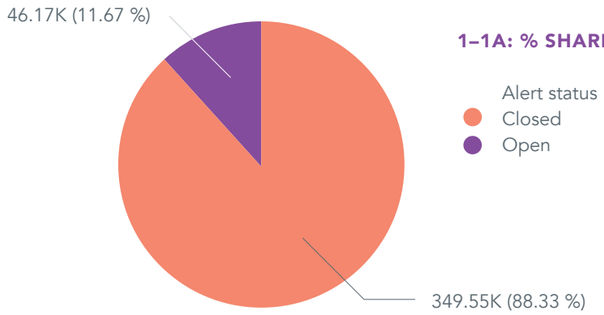


ALERTS GENERATED DURING AN UNSUCCESSFUL VERIFICATION OF MEDICINES

Count of closed / open alerts for 2020	
Alert status	**Sum**
Open	**52 048**
Closed	**380 166**
Total	**432 214**

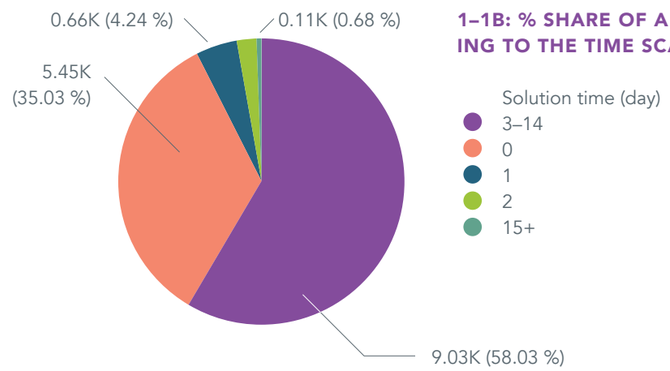
During 2020, a total of **432 214** alerts were generated, which represented only **42%** compared to 2019. (The number of alerts includes all alerts per pack – the same serial number – several alerts are often generated, i.e. the number of packs is much lower.)

In 2020, it was still possible in the Czech Republic to dispense prescription-only medicines to patients, even if an alert was generated; at the request of the State Institute for Drug Control, all alerts generated in 2020 had to be checked and closed. This was primarily done in the NOOL Alert Management System, where all alerts are registered. As of 31 December 2020, **88.33%** of all alerts were investigated and closed.



1–1A: % SHARE OF CLOSED / OPEN ALERTS

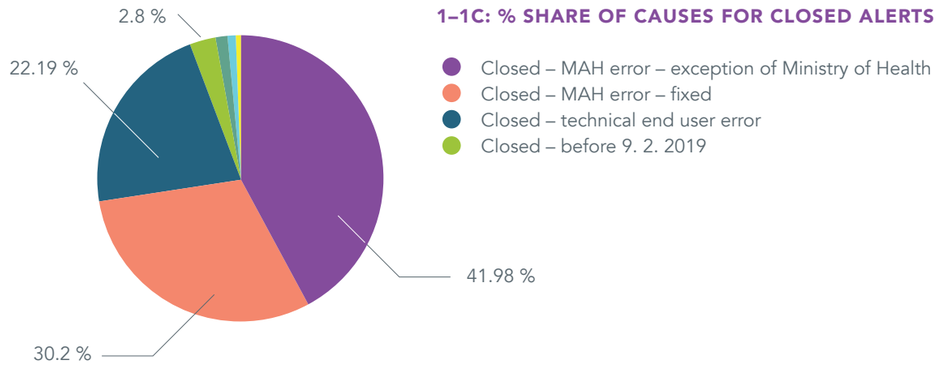
During the year 2020, alerts were closed retrospectively even for the previous year. During the last month of 2020, alerts were most often checked and closed within **six days** of their generation; the average time required to resolve an alert was 4.14 days. A total of **97.3%** of alerts closed in December were resolved **within 14 days**, which is the time-limit for the so-called medicines quarantine stipulated in the Medicines Act, during which it is possible to search for and eliminate alert causes.



1–1B: % SHARE OF ALERT RESOLUTION TIME ACCORDING TO THE TIME SCALE IN THE MONTH 12/2020

The investigation of the reasons for a failed verification of medicinal products showed that:

- **30.2% of the closed alerts were caused by correctable errors** made and removed by **MAHs**;
- **41.98%** of the closed alerts concerned medicinal products that were granted an **exemption** by the Ministry of Health of the Czech Republic (according to Section 11r of the Medicines Act), which stipulates the conditions under which medicinal products can be dispensed to patients in spite of incompliance with the FMD;
- less than **1%** of the alerts were closed due **to uncorrectable errors** made by **MAHs**;
- **end-users' errors** amounted to **22.1%**, of which 89% of errors were made in pharmacies and 11% in distribution;
- **2.8%** of the closed alerts were confirmed by MAHs as **medicines released from production before 9 February 2019.**



1–1C: % SHARE OF CAUSES FOR CLOSED ALERTS

THE KEY ACTIVITIES OF THE SUPPORT CENTER INVOLVED:

- Handling inquiries about the processes related to "anti-counterfeiting legislation" and the Alert Management System (the creation of the AMS, intermarket operations, procedures for handling different types of alerts);
- Alert investigation requests of MAHs, verified audit trails and communicated with Solidsoft Reply and other NMVOs;
- Provision of additional information about the cause of alerts from end-users - communicated with pharmacies, confirmed the cause of alerts and educated end-users in order to eliminate alerts (software and scanner settings, checking the status of medicines in the system, correct procedures in handling medicines in compliance with the FMD).

IN 2020, THE SUPPORT TEAM HANDLED:

2 000
phone calls
– primarily with pharmacies

1 263
requests in the AMS
– end-users' feedback communicated to MAHs

5 920
e-mail communications and investigation assistance

over
100 th.
manually closed alerts at MAHs' request

1 277
false alerts

COMMUNICATION

The communication platform was also affected by the COVID-19 pandemic, the public (professionals and non-professionals) focused almost entirely on the pandemic and its unsuccessful/successful handling. This is why we targeted exclusively professional media to provide pharmacists with key information about ongoing changes.

After the February press conference held in person on the first anniversary of the FMD, we exclusively communicated electronically (with the exception of June and July when we held personal meetings with media representatives). We regularly prepared and updated crisis communication documents.

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

January 2020

Graphical design of the verification system – for the NOOL's press release on the first anniversary of the FMD, preparation of the press conference.

February 2020

Press conference on the first anniversary of the FMD (Participants: Mgr. Storová, Mgr. Dvořáček, Mgr. Mátl, PharmDr. Kopecký).

Outputs: Medical Tribune (print and web), Apatykář, TevaPoint, PharmaProfit, Sortiment.

March–April 2020

Campaign – advertising: "Are you sure that you and your scanner are able to verify medicines?"

Medical Tribune web, PharmaProfit, Sortiment.

May–September 2020

Campaign "A Message for IT" (about a new release)

TevaPoint, PharmaProfit, Sortiment.

October 2020

A key interview (Face to face on the cover page) with Pavlína Štisová in PharmaProfit.

October–December 2020

Campaign – "The quarantine will be over one day, connect to the AMS (API)"

PharmaProfit, Sortiment, Praktické lékárenství, TevaPoint.

November 2020

Medical Tribune – An interview with Mgr. Dvořáček on vaccines (and verification)

An interview with Ing. Rohrbacher (the FMD did not complicate distribution)

December 2020

Crisis communication preparation – the transitional period ended.

FINANCIAL MANAGEMENT REPORT

The National Medicines Verification Organization is financed from several sources:

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

NOOL continues to be financed only by registration fees (in the case of new registered MAHs) and user fees charged for using the NMVS in the given year. In 2020, the NMVO paid off the loan, including interest, provided by AIFP.

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

Revenues in 2020	
Received membership fees	50
Registration fees	2 950
User fees	51 772
Other revenues (including foreign exchange gains: 2 029)	2 034
Total revenues	**56 806**

Expenses in 2020	
Purchases including services	**37 987**
– Materials and energy consumption	271
– Purchased services	37 716
Personnel costs	6 082
Taxes and fees	0
Other expenses	1 447
Depreciation	334
Income tax	1 918
Total expenses	**47 768**

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 2020 amounted to **9 037 597.81** CZK.

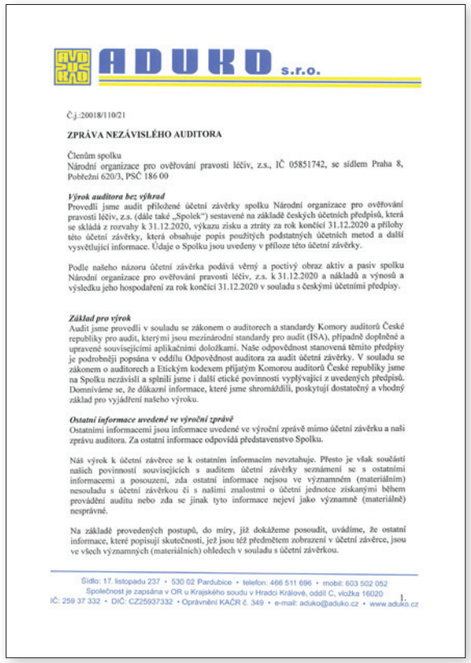
Profit after tax in 2019 = 20 590 912.29 CZK was distributed as follows:
- 4 321 092.50 CZK were used for additions to the Future Risks Fund in compliance with the Statute;
- The remaining profit was kept as retained profit from 2019 to be used in the future.

INDEPENDENT AUDITOR'S REPORT

THE AUDITOR'S OPINION: UNQUALIFIED OPINION

We have audited the attached financial statements of Národní organizace pro ověřování pravosti léčiv, z. s. (hereinafter also as the "Association") that were prepared in compliance with Czech accounting regulations and consist of the balance sheet for the year ended 31 December 2020, the profit and loss account for the year ended 31 December 2020 and the annex to these financial statements, which contains a description of the used major accounting methods and other explanatory information. Details about the Association are provided in the annex to these financial statements.

In our opinion, the financial statements provide a true and fair picture of the assets and liabilities of Národní organizace pro ověřování pravosti léčiv, z. s. as of 31 December 2020 as well as of its expenses, revenues and profit (loss) for the year ended 31 December 2020 in compliance with Czech accounting regulations.



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Čj.:20018/110/21

ZPRÁVA NEZÁVISLÉHO AUDITORA

Členům spolku
Národní organizace pro ověřování pravosti léčiv, z.s., IČ 05851742, se sídlem Praha 8, Pobřežní 620/3, PSČ 186 00

Výrok auditora bez výhrad
Provedli jsme audit přiložené účetní závěrky spolku Národní organizace pro ověřování pravosti léčiv, z.s. (dále také „Spolek") sestavené na základě českých účetních předpisů, která se skládá z rozvahy k 31.12.2020, výkazu zisku a ztráty za rok končící 31.12.2020 a přílohy této účetní závěrky, která obsahuje popis použitých podstatných účetních metod a další vysvětlující informace. Údaje o Spolku jsou uvedeny v příloze této účetní závěrky.

Podle našeho názoru účetní závěrka podává věrný a poctivý obraz aktiv a pasiv spolku Národní organizace pro ověřování pravosti léčiv, z.s. k 31.12.2020 a nákladů a výnosů a výsledku jeho hospodaření za rok končící 31.12.2020 v souladu s českými účetními předpisy.

Základ pro výrok
Audit jsme provedli v souladu se zákonem o auditorech a standardy Komory auditorů České republiky pro audit, kterými jsou mezinárodní standardy pro audit (ISA), případně doplněné a upravené souvisejícími aplikačními doložkami. Naše odpovědnost stanovená těmito předpisy je podrobněji popsána v oddílu Odpovědnost auditora za audit účetní závěrky. V souladu se zákonem o auditorech a Etickým kodexem přijatým Komorou auditorů České republiky jsme na Spolku nezávislí a splnili jsme i další etické povinnosti vyplývající z uvedených předpisů. Domníváme se, že důkazní informace, které jsme shromáždili, poskytují dostatečný a vhodný základ pro vyjádření našeho výroku.

Ostatní informace uvedené ve výroční zprávě
Ostatními informacemi jsou informace uvedené ve výroční zprávě mimo účetní závěrku a naši zprávu auditora. Za ostatní informace odpovídá představenstvo Spolku.

Náš výrok k účetní závěrce se k ostatním informacím nevztahuje. Přesto je však součástí našich povinností souvisejících s auditem účetní závěrky seznámení se s ostatními informacemi a posouzení, zda ostatní informace nejsou ve významném (materiálním) nesouladu s účetní závěrkou či s našimi znalostmi o účetní jednotce získanými během provádění auditu nebo zda se jinak tyto informace nejeví jako významně (materiálně) nesprávné.

Na základě provedených postupů, do míry, jíž dokážeme posoudit, uvádíme, že ostatní informace, které popisují skutečnosti, jež jsou též předmětem zobrazení v účetní závěrce, jsou ve všech významných (materiálních) ohledech v souladu s účetní závěrkou.

Sídlo: 17. listopadu 237 • 530 02 Pardubice • telefon: 466 511 696 • mobil: 603 502 052
Společnost je zapsána v OR u Krajského soudu v Hradci Králové, oddíl C, vložka 16020
IČ: 259 37 332 • DIČ: CZ25937332 • Oprávnění KAČR č. 349 • e-mail: aduko@aduko.cz • www.aduko.cz
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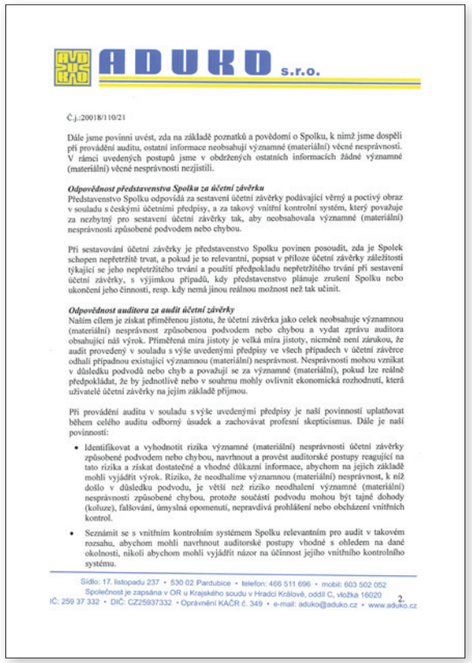

ADUKO s.r.o.

Čj.:20018/110/21

Dále jsme povinni uvést, zda na základě poznatků a povědomí o Spolku, k němž jsme dospěli při provádění auditu, ostatní informace neobsahují významné (materiální) věcné nesprávnosti. V rámci uvedených postupů jsme v odvozených ostatních informacích žádné významné (materiální) věcné nesprávnosti nezjistili.

Odpovědnost představenstva Spolku za účetní závěrku
Představenstvo Spolku odpovídá za sestavení účetní závěrky podávající věrný a poctivý obraz v souladu s českými účetními předpisy, a za takový vnitřní kontrolní systém, který považuje za nezbytný pro sestavení účetní závěrky tak, aby neobsahovala významné (materiální) nesprávnosti způsobené podvodem nebo chybou.

Při sestavování účetní závěrky je představenstvo Spolku povinen posoudit, zda je Spolek schopen nepřetržitě trvat, a pokud je to relevantní, popsat v příloze účetní závěrky záležitosti týkající se jeho nepřetržitého trvání a použití předpokladu nepřetržitého trvání při sestavení účetní závěrky, s výjimkou případů, kdy představenstvo plánuje zrušení Spolku nebo ukončení jeho činnosti, resp. kdy nemá jinou reálnou možnost než tak učinit.

Odpovědnost auditora za audit účetní závěrky
Naším cílem je získat přiměřenou jistotu, že účetní závěrka jako celek neobsahuje významnou (materiální) nesprávnost způsobenou podvodem nebo chybou a vydat zprávu auditora obsahující náš výrok. Přiměřená míra jistoty je velká míra jistoty, nicméně není zárukou, že audit provedený v souladu s výše uvedenými předpisy ve všech případech v účetní závěrce odhalí případnou existující významnou (materiální) nesprávnost. Nesprávnosti mohou vzniknat v důsledku podvodů nebo chyb a považují se za významné (materiální), pokud lze reálně předpokládat, že by jednotlivě nebo v souhrnu mohly ovlivnit ekonomická rozhodnutí, která uživatelé účetní závěrky na jejím základě přijmou.

Při provádění auditu v souladu s výše uvedenými předpisy je naší povinností uplatňovat během celého auditu odborný úsudek a zachovávat profesní skepticismus. Dále je naší povinností:

- Identifikovat a vyhodnotit rizika významné (materiální) nesprávnosti účetní závěrky způsobené podvodem nebo chybou, navrhnout a provést auditorské postupy reagující na tato rizika a získat dostatečné a vhodné důkazní informace, abychom na jejich základě mohli vyjádřit výrok. Riziko, že neodhalíme významnou (materiální) nesprávnost, k níž došlo v důsledku podvodu, je větší než riziko neodhalení významné (materiální) nesprávnosti způsobené chybou, protože součástí podvodu mohou být tajné dohody (koluze), falšování, úmyslná opomenutí, nepravdivá prohlášení nebo obcházení vnitřních kontrol.
- Seznámit se s vnitřním kontrolním systémem Spolku relevantním pro audit v takovém rozsahu, abychom mohli navrhnout auditorské postupy vhodné s ohledem na dané okolnosti, nikoli abychom mohli vyjádřit názor na účinnost jejího vnitřního kontrolního systému.

Sídlo: 17. listopadu 237 • 530 02 Pardubice • telefon: 466 511 696 • mobil: 603 502 052
Společnost je zapsána v OR u Krajského soudu v Hradci Králové, oddíl C, vložka 16020
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- Posoudit vhodnost použitých účetních pravidel, přiměřenost provedených účetních odhadů a informace, které v této souvislosti představenstvo Spolku uvedlo v příloze účetní závěrky.
- Posoudit vhodnost použití předpokladu nepřetržitého trvání při sestavení účetní závěrky představenstva a to, zda s ohledem na shromážděné důkazní informace existuje významná (materiální) nejistota vyplývající z událostí nebo podmínek, které mohou významně zpochybnit schopnost Spolku nepřetržitě trvat. Jestliže dojdeme k závěru, že taková významná (materiální) nejistota existuje, je naší povinností upozornit v naší zprávě na informace uvedené v této souvislosti v příloze účetní závěrky, a pokud tyto informace nejsou dostatečné, vyjádřit modifikovaný výrok. Naše závěry týkající se schopnosti Spolku nepřetržitě trvat vycházejí z důkazních informací, které jsme získali do data naší zprávy. Nicméně budoucí události nebo podmínky mohou vést k tomu, že Spolek ztratí schopnost nepřetržitě trvat.
- Vyhodnotit celkovou prezentaci, členění a obsah účetní závěrky, včetně přílohy, a dále to, zda účetní závěrka zobrazuje podkladové transakce a události způsobem, který vede k věrnému zobrazení.

Naší povinností je informovat představenstvo spolku mimo jiné o plánovaném rozsahu a načasování auditu a o významných zjištěních, která jsme v jeho průběhu učinili, včetně zjištěných významných nedostatků ve vnitřním kontrolním systému.

ADUKO s.r.o.
17. listopadu 237, 530 02 Pardubice
Evidenční číslo auditorské společnosti: 349
Ing. Milan Poláček, auditor
Evidenční číslo auditora: 1838

V Pardubicích 19. května 2021

ADUKO s.r.o. Společnost č. 349 KAČR IČ: 259 37 332 17. listopadu 237 • 530 02 Pardubice

Sídlo: 17. listopadu 237 • 530 02 Pardubice • telefon: 466 511 696 • mobil: 603 502 052
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3.

CONTACT AND IDENTIFICATION INFORMATION

NÁRODNÍ ORGANIZACE PRO OVĚŘOVÁNÍ PRAVOSTI LÉČIV, z. s.

Address: Pobřežní 620/3, 186 00 Praha 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