Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

Czech Medicines Verification Organization

2019

INTRODUCTORY REMARKS

There are still indications of the possible entry of falsified medicines, in terms of their identity, history or origin, into official distribution chains. That is why the European Commission has launched a project to protect the legal distribution chain against this threat, as summarized in DIRECTIVE 2011/62 / EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 (the Falsified Medicine Directive, or FMD).

The Delegated Regulation (EU) 2016/161 came into force by 9 February 2019. Directive 2001/83 / EC of the European Parliament and of the Council is supplemented by laying down detailed rules for the protection of medicinal products for human use subject to medical prescription in the Delegated Regulation.

Since that time, marketing authorization holders have been required to market medicines equipped with safety features. At the same time, it obliges manufacturers to enter data of serialized medicine packs in uniform format into the European Medicines Verification System (EMVS). This pan-European system includes national databases which enable the verification and authentication of the packaging of medicines before they are dispensed to the patients. Before dispensing medicines, the end users (pharmacies and distributors in certain specific cases) must verify them and check unique identifier that must be decommissioned from the system.

Czech Medicines Verification Organization (CZMVO; NOOL) manages and ensures the operation of the National Medicines Verification System (CZMVS, NSOL). A non-profit organization was founded by AEDL, AIFP, AVEL, ČAFF and ČLnK in March 2017. Since that time NOOL managed to implement FMD to ensure the readiness of all stakeholders to launch the comprehensive medicine verification project.

Since the beginning of 2019, contracts negotiated in the preceding year have been concluded with end users and marketing authorization holders.

Czech Medicines Verification System was implemented in strict accordance with EU legislation on 9 February 2019, and the system was tested as part of a "pilot project" before launch. Since its launch, NSOL has been operational, with the exception of brief outages in May and June 2019.

During the entire year of 2019 the transition period was in place to enable all processes were running smoothly when verifying the authenticity of medicines and so all stakeholders could learn to properly verify the authenticity of medicines and eliminate any possible errors in the system settings and readers.

Czech national medicines verification system just like systems in practically all other EU countries, initially reported a high number of false positive alerts, which were reduced thanks to the efforts of all stakeholders involved. During the first days of full operation, the CZMVS generated alerts for up to 10% of all transactions. By the end of 2019 the share of alerts in the national medicines verification system had fallen to 0.39 %.

Great attention was devoted not only to communicating with pharmacists, marketing authorization holders and distributors, but also with state institutions (Ministry of Health of the Czech Republic, State Institute for Drug Control) and the lay public.

*An **Alert Management Center** was created to ensure mutual information on the status (resolution) of the alert, i.e. both for end users and manufacturers. Information about the current state of NSOL and other related topics is posted at www.czmvo.cz.*

Czech Medicines Verification Organization was the first among EU member states to create a system to manage alerts along with the NOOL support center, which cooperates with marketing authorization holders and end users to investigate alerts and carry out additional related activities. Since 9 February 2019 the alert management system has provided auditable records and results from the investigation of alerts generated. In the summer, improvement of the alert management system begun so that it could be accessed in an open interface (API) in both the system of end users and marketing authorization holders. The system is intended to allow Marketing Authorization Holders (MAHs) and end-users to check the status and results of an alert investigation through their systems or web interface and to send other information necessary to examine the alert, such as a picture of the package.

2019 was a year of great hopes and ambitions, a year of introducing a completely unique, demanding and comprehensive project. The Czech Republic ranks among those countries that managed the situation very well. Thanks to everyone involved in the project.

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

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

CONTENTS

ABOUT CZECH MEDICINES VERIFICATION ORGANIZATION (NOOL)

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

- **AEDL** – Association of European Distributors of Pharmaceuticals
- **AIFP** – The Association of Innovative Pharmaceutical Industry
- **AVEL** – Association of Wholesale Distributors of Pharmaceuticals
- **ČAFF** – Czech Association of Pharmaceutical Companies
- **ČLnK** – Czech Chamber of Pharmacists

Affiliate members:

- Apatyka Servis,
- Association of Pharmacy Network Operators,
- GS1 Czech Republic,
- Lekis,
- PharmaSwiss,
- Pharmacy care providers,
- Avenier,
- Cyrmex,
- Union of Pharmaceutical Distributors.

NOOL is a national non-profit legal entity founded in accordance with Directive 2011/62 / EU of the European Parliament and of the Council of 8 June 2011 and Commission Delegated Implementing Regulation (EU) 2016/161 of 2 October 2015. Directive 2011/62 / EU amends Directive 2011/83 / EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry of falsified medicinal products into the legal supply chain. Delegated Regulation 2016/161 supplements Directive 2001/83 / EC of the European Parliament and of the Council by laying down detailed rules for the protection of prescription-only medicinal products for human use.

NOOL was founded to ensure the protection of the legal supply chain against falsified medicinal products by implementing and managing a national database (NSOL). The objective of NOOL is to coordinate cooperation between members, NSOL users, relevant entities and bodies in the implementation and enforcement of FMD.

The regular member companies met periodically and helped supervise implementation of the Directive and the associated Delegated Regulation through their representatives in the board of the Czech Medicines Verification Organization. They also drew up and approved the budget and decisions related to FMD implementation. The project manager continuously monitored readiness through reports providing information to the statutory body.

During the course of 2019 NOOL facilitated close communication with end users in particular and provided information to both the professional and lay public (see the Communication section). NOOL support center was set up for targeted and direct communication with end users. Support Center can be contacted by telephone or through a contact form on the internet (www.czmvo.cz).

NOOL also intensively cooperated with the State Institute for Drug Control (SÚKL) and the Ministry of Health of the Czech Republic, as well as with the European Medicines Verification Organization (EMVO) and other stakeholders, including IT system providers in 2019.

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 z. s.

APATYKA SERVIS Pharmacy Software a PHOENIX company

PharmaSwiss Choose More Life

Lekis

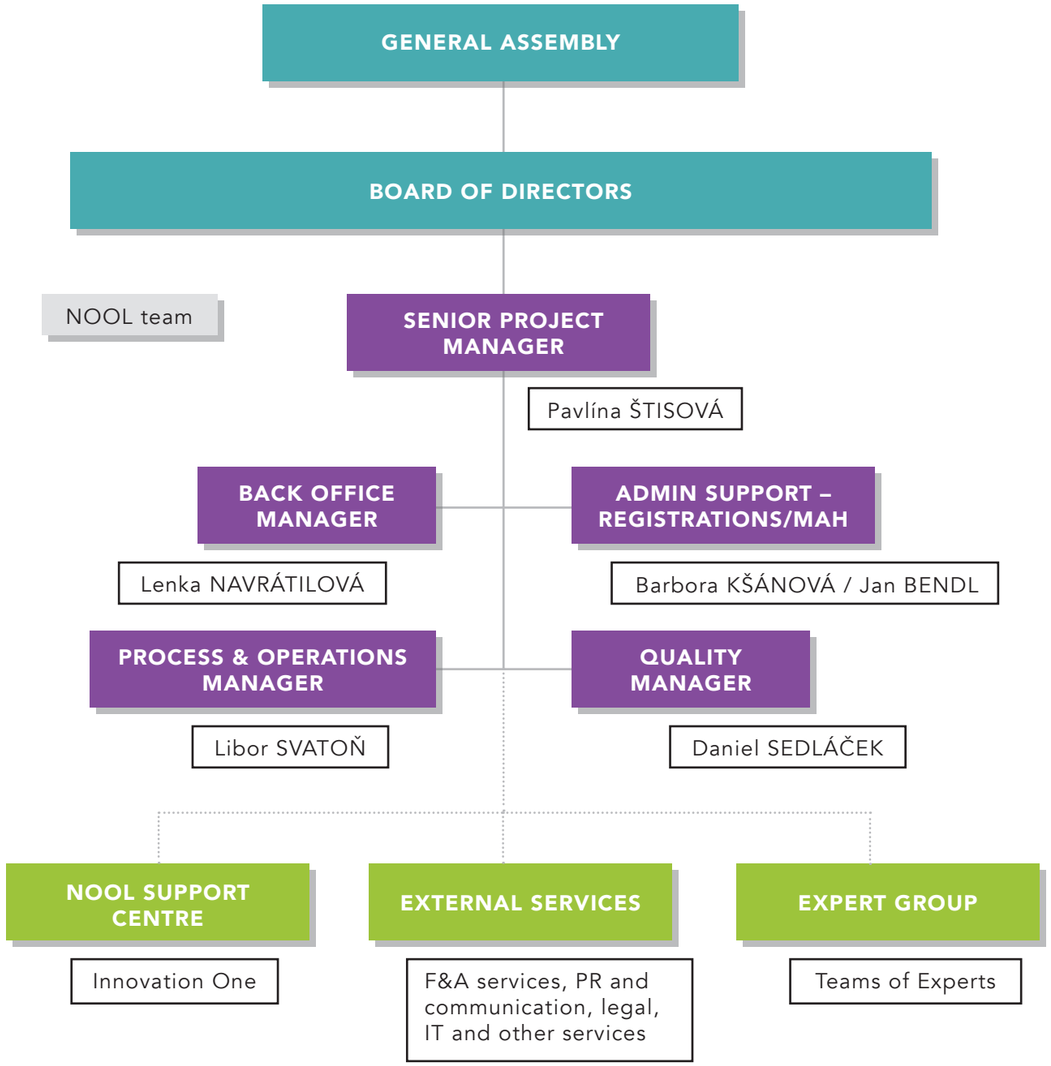
AVENIER

CYRMEX

Unie distributorů léčiv

(Union of Pharmaceutical Distributors)

ORGANIZATIONAL STRUCTURE



NATIONAL MEDICINES VERIFICATION ORGANIZATION TEAM IN 2019

Pavlína Štisová, MBA
Senior Project Manager

Ing. Lenka Navrátilová
Back Office Manager

Ing. Libor Svatoň
Process & Operations Manager

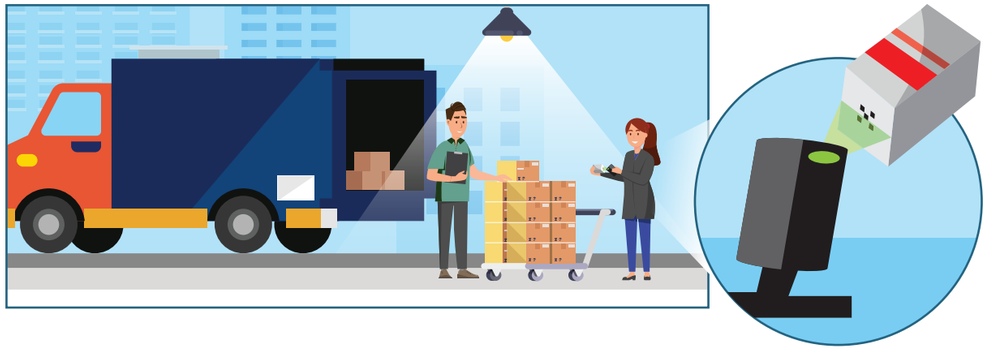
Barbora Kšánová
Admin Support – registrations/MAH

Bc. Jan Bendl
Admin Support – registrations/MAH

Ing. Daniel Sedláček
Quality Manager

OVERVIEW OF ACTIVITIES IN 2019

2019 was a stress test of readiness for NOOL, in all aspects. The project to implement a system to verify the authenticity of medicines and commence full operations in the Czech Republic was scheduled to launch on 9 February, 2019. At the same time, throughout the year NOOL continued to prepare and develop support systems, provide maximum support and information to end users and marketing authorization holders, and focus on stabilization of the system.



At the end of 2018 an amendment was passed to Act on pharmaceuticals No. 378/2007 Coll., which was approved by the Chamber of Deputies and then the Senate of the Parliament of the Czech Republic. This amendment specified the transition period during which end users were required to verify the authenticity of medicines before dispensing them to patients, but considering the minimal risk of false medicines appearing in brick-and-mortar pharmacies, during this time it was possible to dispense medicines in good faith, even if unverified. The transition period ended by 31 December 2019.

This legislative measure enabled a large number of transactions to take place, gaining experience with the system by most end users and their IT systems providers, without endangering the availability of medicines for Czech patients.

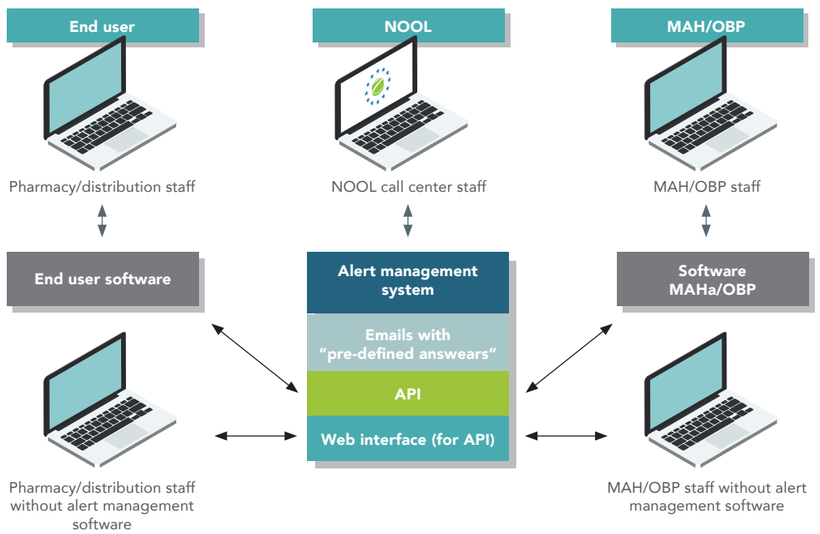
The amendment to the Pharmaceuticals Act states: Art. 1 paragraph 4 Section 8 is supplemented with a new paragraph 9, which including the notes under no. 106 says:

"**(9)** In a situation where it is not possible to verify the safety features of a medicinal product, to the extent provided for in Article 10 of directly applicable European Union legislation specifying detailed rules for the protective features on medicinal products for human use (hereinafter referred to as the "Falsified Medicines Directive") due to the fact that this medicinal product does not meet the requirements of this Regulation after production, the Ministry of Health may exceptionally temporarily authorize the distribution and dispensing of this medicinal product by a decision issued at the request of the marketing authorization holder. In such case, marketing authorization holders, manufacturers of medicinal products, distributors and persons authorized to dispense shall fulfill their obligations under the FMD in an appropriate manner. Liability for defects in medicinal products under special legislation is not affected. The Ministry of Health will inform the State Institute for Drug Control regarding the issue of this measure. The Ministry of Health will post the issued measure on its official bulletin board and the State Institute for Drug Control will publish it in a way that allows remote access."

Throughout the transition period, NOOL worked intensively to develop an alert management system and focused on other activities related to establishing and operating the database system as specified in Commission Delegated Regulation (EU) 2016/161. Overview of NOOL's main activities in 2019* not in order of importance:

- Final conclusion of contracts between NOOL and end users or marketing authorization holders.
- Communication with the providers of end user IT systems; there was also ongoing certification of end user IT systems before they were connected to NSOL.
- Modification and development of the medicines verification system in cooperation with the supplier, Solidsoft Reply, and other countries using the same supplier's system. Coordination and provision of a single storage database in cooperation with the European Medicines Verification Organization (EMVO).
- Ensuring awareness of the importance of medicines verification, the need and manner of connecting to NSOL, and explaining related topics.
- The fully operational launch of NSOL on 9 February was preceded by a pilot project with selected representatives of manufacturers, marketing authorization holders, distributors and pharmacists from May to December 2018.
- The creation and launch of the Alert Management Center = NOOL Support center, which facilitates communication with end users (about the alert status) and enables manufacturers to obtain more detailed information about the medicines triggering the alert.
- Monitoring alerts from the NSOL system and looking for causes of false alerts and ways to prevent them enabled us to reduce the nearly 10% incidence of erroneous alerts in the initial days of operation to 0.4% in the final week of 2019.
- Intensive communication and cooperation during May and June with SolidSoft Reply, the provider of the medicine verification system in the CR, led to the elimination of system errors which appeared with the growing number of transactions and slow response times which, in some cases, made it impossible to verify a medicine.
- Monitoring of NSOL functionality and information for system users is constantly updated and available at www.czmvo.cz
- Communication with the Ministry of Health of the Czech Republic and the State Institute for Drug Control.
- Regular meetings with members of the NOOL Board of Directors and two sessions of the General Meeting.

The European-wide monitoring regularly carried out by EMVO enables us to keep tabs on the success of the Czech Republic, which has been among the best countries in implementing FMD, both in terms of number of end users connected, marketing authorization holders connected, number of transactions in relation to market size and steady reduction in number of alerts. We would like to heartily thank all those who have contributed to this European success.

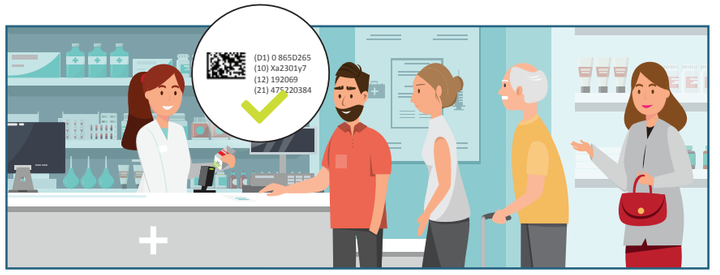


PROJECT STATUS AT THE END OF 2019

The status of the project at the end of the year is best reflected by data on number of entities* connected as of 31 December, 2019, unless listed otherwise.

MARKETING AUTHORIZATION HOLDER (MAH)

Number of MAHs registered to use NSOL: **366**
Of these: number of MAHs entitled to a reduced fee for using the system: 57



END USERS

1,565 registration contracts with legal entities.
Of these: Pharmacy: 1,269, Distributor: 163, Pharmacy and distributor: 133

3,104 total workplaces connected to NSOL.
Of these: Pharmacy: 2,697 (100 %), Hospital pharmacies: 116 (100 %), Warehouse – distributor: 407

DATA ON PRODUCTS IN NSOL

7,549 products entered in EU HUB and NSOL.
Number of packages with data recorded in NSOL as of 31 December, 2019: **209,891,350**

Number of daily transactions 11 February, 2019: **69,996** and 18 December, 2019: **1,839,844**
Share of alerts in transactions at the 11th week **4.23 %**, at the 52nd week of 2019 it fell to **0.39 %**.

Total number of transactions from 9 February to 31 December, 2019: **183,100,377**

COMMUNICATION

During the year in which full FMD operations were launched, NOOL communications focused mainly on informing end users and, in select cases, also the lay public (typically reactive communication, with the targeted provision of information associated related to anti-falsification issues).

NOOL EVENTS FOR PROFESSIONAL PUBLIC

JANUARY

- Information in Sortiment Magazine: "How to connect to NSOL" and an informative leaflet distributed to pharmacies (Aliance HealthCare)
- Series of articles in PharmaProfit Magazine following a panel discussion at the autumn congress on drug verification.

FEBRUARY

- **PRESS RELEASE ON THE LAUNCH OF FULL OPERATIONS FOR THE MEDICINE VERIFICATION SYSTEM SENT TO THE FOLLOWING MEDIA OUTLETS**
  - – Sortiment no. 2 and 3/2019
  - – PharmaProfit 8. 2.
  - – I60 9. 2.
  - – PharmaProfit 11. 2.
  - – Zdravotnický deník 12. 2.
  - – Apatykář 15. 2.
  - – Medical tribune 19. 2.
  - – Czech Television 1 – live broadcast SAMA DOMA
  - – Zdravé zprávy 28. 2.
  - – Zdravotnictví medicína 28. 2.
  - – Czech Television 1 Studio 6: 28. 2.
  - – Apatykář 1. 3.
- Preparation of crisis communicatio

MARCH

- **PHARMAPROFIT CONGRESS 28. 3.**
  - – Presentation and participation in a panel discussion.
  - – Article in PharmaProfit Magazine: Current state of verifying the authenticity of medicines.

KEY MEDIA

- PharmaProfit
- Sortiment
- Apatykář.cz
- Medical Tribune
- Remedia
- Czech News Agency
- TevaPoint
- Zdravotnický deník.cz

MAY

- Appeal to marketing authorization holders regarding exemption requests for un-verifiable batches.
- **CRISIS COMMUNICATION:** System failure and long NSOL response times when verifying medicines. Subsequent daily communication with the media to prevent the spread of distorted information.
  - – Detailed information for the Czech Press Agency
  - – Blesk news – following information that the availability of medicines has not changed, article not published
  - – Issue of NOOL press release after partial resolution of the problem
  - – Press release published in Medical Tribune, TevaPoint, PharmaProfit

  ARTICLES
  - – What independent pharmacies and distributors face, Medical Tribune 13. 5.
  - – Problems in the medicine verification system are slowing dispensing in pharmacies – Czech Press Agency 23. 5.
  - – Problems in the medicine verification system are slowing dispensing in pharmacies – Zdravotnický deník 23. 5.
  - – NOOL's response to problems with the verification system, TevaPoint 29. 5. 2019, Medical Tribune 31. 5., PharmaProfit 30. 5.
  - – Online medicine verification systems have encountered outages across Europe, Apatykář 26. 5.
  - – Anti-falsification directive in the eyes of distributors and pharmacists – Sortiment June 2019
- **KONFERENCE „SPRÁVNÁ DISTRIBUČNÍ PRAXE LÉČIVÝCH PŘÍPRAVKŮ" 30. 5.**

OCTOBER

- Topic "Do you know how to verify your reader?"
- **PRESS RELEASE 10 MONTHS AFTER THE LAUNCH OF FULL OPERATIONS**

  ARTICLES
  - – PharmaProfit + advertisement with graphic
  - – TevaPoint
  - – Remedia
  - – Medical Tribune
- **PHARMAPROFIT CONGRESS 8. 10.**
  - – Presentation and participation in a panel discussion.

NOVEMBER

- Preparation of communication for Call Center employees at the end of the transition period, crisis communication for the end of the transition period and press conference to celebrate the first year of NSOL operations.

MANAGEMENT REPORT

The National Medicine Verification Organization and the FMD implementation project were financed from the following sources:

- member contributions from the founding members
- loans from the AIFP and ČAFF associations, possibly through gifts directly from members of these associations – IMPLEMENTATION PHASE
- registration and user's fees from every marketing authorization holder that uses the medicine verification system – IMPLEMENTATION AND PRODUCTION PHASE

The implementation phase of the FMD project ended on 9 February, 2019. Subsequently, NOOL operations were funded entirely from registration fees (from newly registered users) and user fees for using the NSOL system in the given year. In 2019, the loan was repaid with interest to the Czech Association of Pharmaceutical Companies (ČAFF).

SELECT DATA FROM THE FINANCIAL STATEMENT (in thou. CZK)

Revenue for 2019

Total contributions received	**63**
– contributions received – gifts	13
– member contributions received	50
Sales	68,858
Other revenue	146
Total revenue	**69,067**

Costs for 2019

Consumed purchases inc. services	**37,584**
– consumption of material, energy	305
– purchases services	37,279
Personnel costs	4,711
Taxes and fees	0
Other costs	1,501
Depreciation	97
Income tax	4,583
Total costs	**48,476**

The complete financial statements are published in the Collection of Documents in the Federal Register kept by the Municipal Court in Prague, Section L, file 67982.

The financial result in 2019 was an after-tax profit of **20,590,912.29 CZK.**

Profit from 2018 after tax = 8,678,589.83 CZK was distributed:
- 678,907.50 CZK to create the Fund to cover future risks pursuant to the Statutes
- 989,974.73 CZK payment to cover losses from previous years

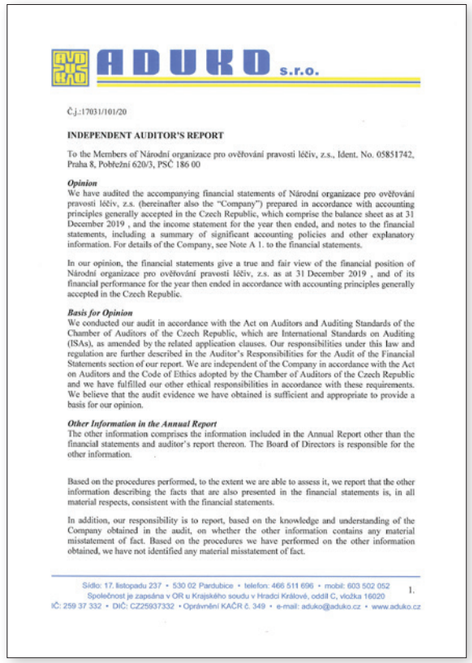
The remaining portion of profit was left as unallocated profit for 2018 to be used in future years.

INDEPENDENT AUDITOR'S REPORT

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 2019, 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 2019, and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech Republic.



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INDEPENDENT AUDITOR'S REPORT

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

Opinion
We have audited the accompanying financial statements of Národní organizace pro ověřování pravosti léčiv, z.s. (hereinafter also the "Company") prepared in accordance with accounting principles generally accepted in the Czech Republic, which comprise the balance sheet as at 31 December 2019 , 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 2019 , 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.

Sídlo: 17. listopadu 237 • 530 02 Pardubice • telefon: 466 511 696 • mobil: 603 502 052 1.
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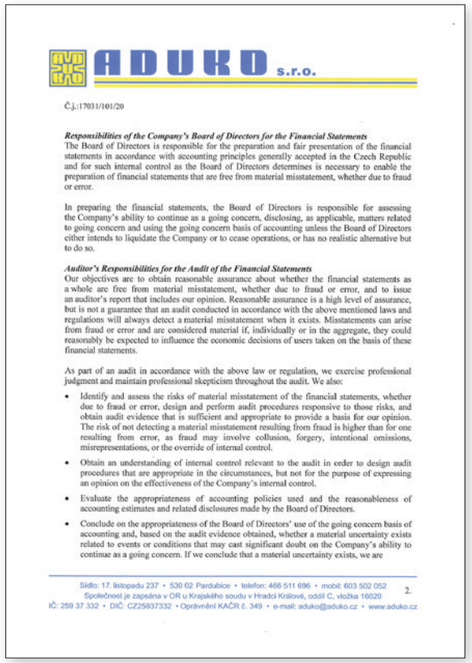

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Responsibilities of the Company's Board of Directors for the Financial Statements
The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted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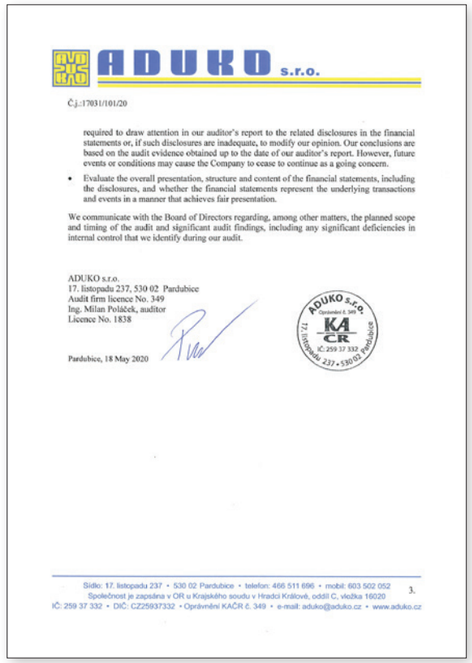

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required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our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

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17. listopadu 237, 530 02 Pardubice
Audit firm licence No. 349
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 18 May 2020

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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