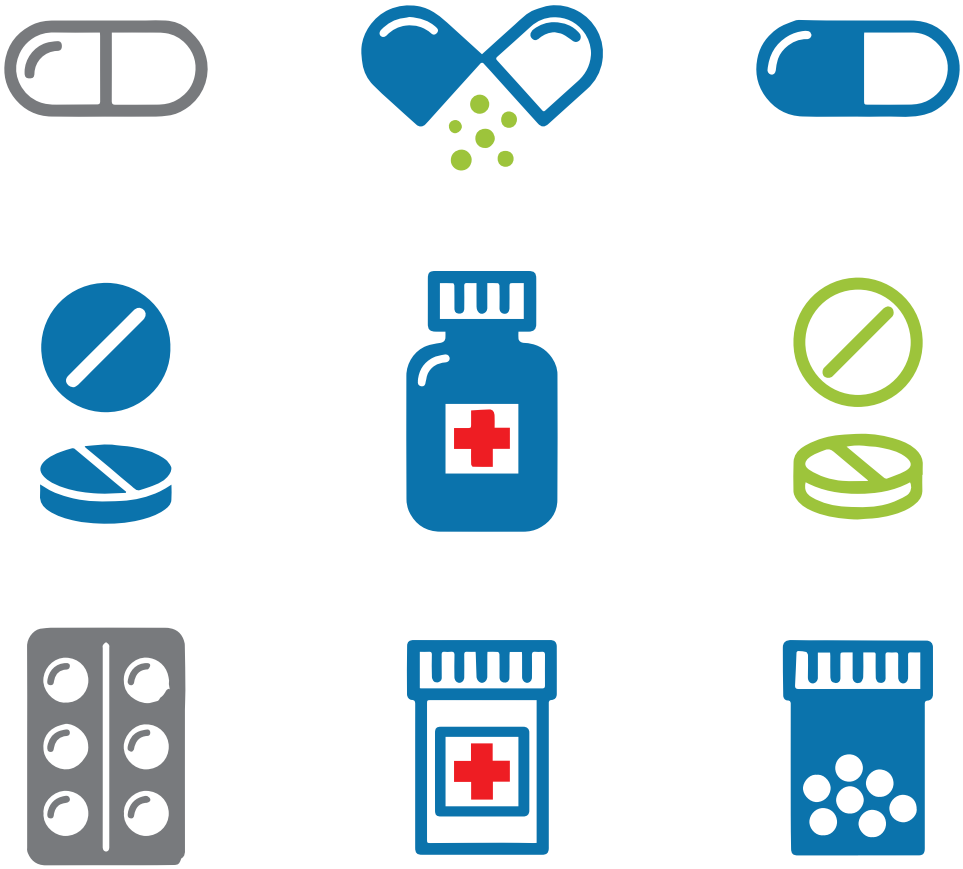
Národní organizace
pro ověřování
pravosti léčiv



ANNUAL REPORT

National Medicines Verification Organization

2018

AN OPENING WORD

Since there is a real risk of falsified medicines entering the European market, it has become necessary to adopt Directive 2011/62/EU on falsified medicines (Falsified Medicines Directive or FMD). It requires that prescription-only medicine packs include safety features (i.e. a unique identifier together with anti-tampering device) and manufacturers enter the data of serialized medicines into the European medicines verification system (EMVS). The Europe-wide system includes national repositories that allow to verify and authenticate the packs of medicines before they are dispensed to patients.

The functioning of the National Medicines Verification System (NMVS) is ensured by the non-profit National Medicines Verification Organization (NOOL) founded by the Association of European Distributors of Pharmaceuticals (AEDL), the Association of Innovative Pharmaceutical Industry (AIFP), the Association of Wholesale Distributors of Pharmaceuticals (AVEL), Czech Association of Pharmaceutical Companies (ČAFF) and Czech Chamber of Pharmacists (ČLK) in March 2017. Since then NOOL has been working on getting ready the launch of the National Medicines Verification System, while informing the stakeholders about the FMD. During the entire year of 2018, NOOL worked on the implementation and in particular on the launch of the National Medicines Verification System.

The pilot project of medicines verification started in May 2018 in collaboration with the main providers of information systems for NMVS end users and with 40 representatives from pharmaceutical industry including marketing authorization holders, distributors and pharmacies. In spite of a small number of batch medicine packs, it was possible to verify the basic functioning of the system and to identify some problematic areas in the system. While the pilot project was running, additional system functionalities were released. In 2018, contracts with marketing authorization holders (MAHs) and end users were signed so that the project could be launched, just like in other EU Member States, on 9 February 2019. In the last quarter, all users were gradually connected to the NMVS, and marketing authorization holders uploaded the data of serialized medicines into the system. The National Medicines Verification Organization paid a lot of attention to communicating the status of the system implementation and important matters concerning the FMD to all stakeholders.

Mgr. Jakub Dvořáček, MHA
Chairman of the Board of Directors

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

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ABOUT THE ORGANIZATION

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

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

NOOL is a national non-profit legal entity founded in compliance with Directive 2011/62/EU of the European Parliament of the Council and Commission Delegated Regulation (EU) 2016/161 of 2 October 2015. Directive 2011/62/EU of the European Parliament of 8 June 2011 isamending 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. Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 is supplementing 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 medicinal products for human use.

NOOL was founded to protect the legal supply chain against falsified medicinal products by creating and managing the national data repository (NMVS). The goal of NOOL is to achieve collaboration among members, NMVS users, competent entities and authorities in implementing the Directive and adapting the Commission Delegated Regulation.

The representatives of regular member companies regularly meet via their representatives in the Board of Directors of the National Medicines Verification Organization and help to monitor the implementation of the Directive and the Commission Delegated Regulation, to prepare and approve the budget and to make decisions concerning the implementation of the NMVS. Readiness is regularly monitored by board of directors via reports prepared by the project manager.

As of 31 December 2018, NOOL had the following associated members: Apatyka Servis, the Association of Pharmacy Chain Operators, GS1 Czech Republic, Lekis, PharmaSwiss, Pharmaceutical Care Providers, Avenir, Cyrmex and the Union of Medicines Distributors. The representatives of these companies attend NOOL's General Meetings and have the right to comment on NOOL's activities.

In 2018, 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.

We would like to thank all these entities for the opportunity to consult with them the entire anti-falsification matter in the Czech Republic as well as for their support and collaboration in 2018.

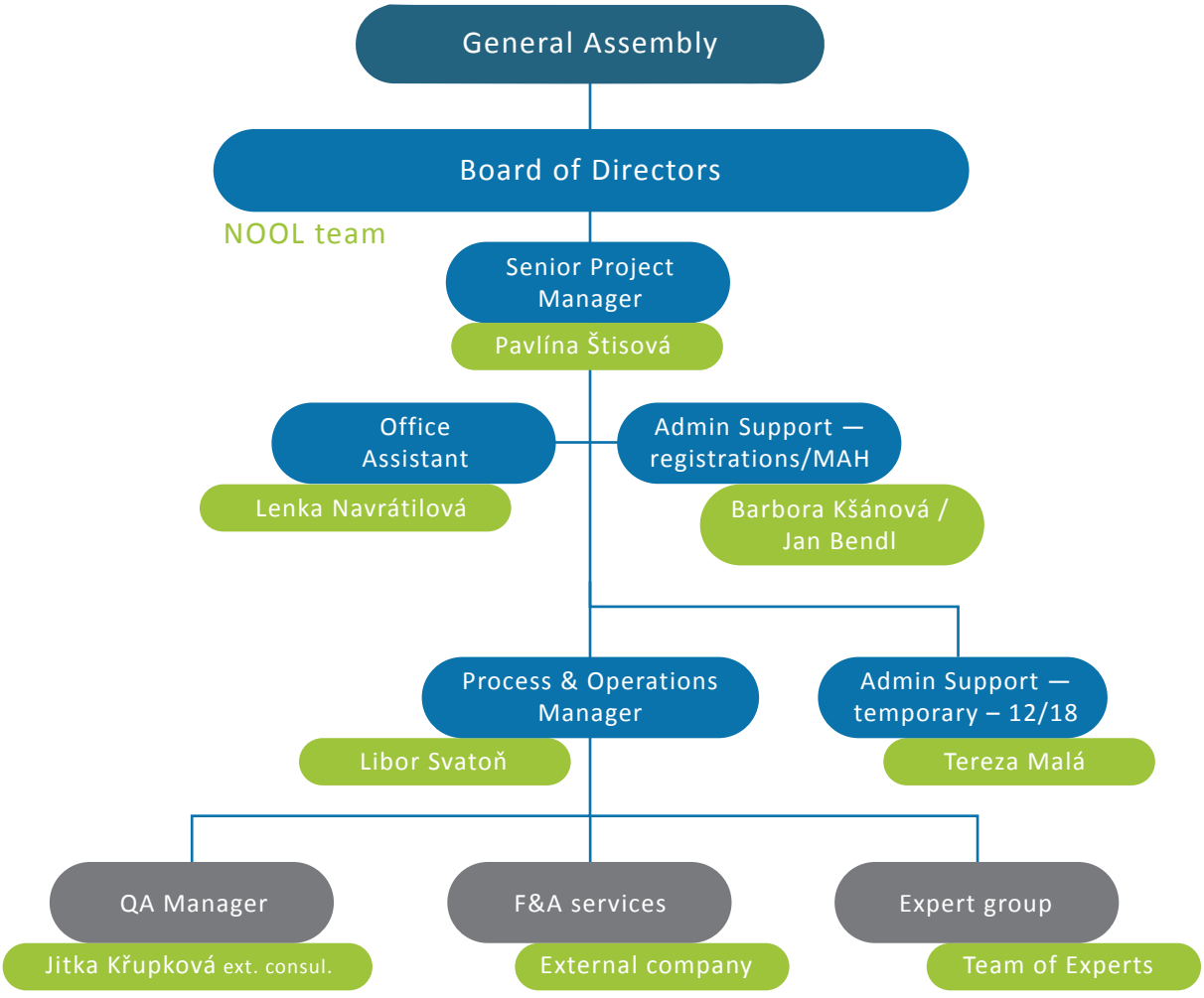
MEMBER COMPANIES

ASSOCIATED COMPANIES

Unie distributorů léčiv

NOOL ORGANIZATIONAL STRUCTURE

As of 31st December 2018, NOOL had five employees and collaborated with external companies and other persons based on a work agreement in order to ensure services necessary for the running of the organization and for the preparation of the system.



NOOL TEAM IN 2018

Pavlína Štisová, MBA
Senior Project manager

Ing. Lenka Navrátilová
Office Assistant

Ing. Libor Svatoň
Process & Operations Manager

Barbora Kšánová
Admin Support – registrations/MAH

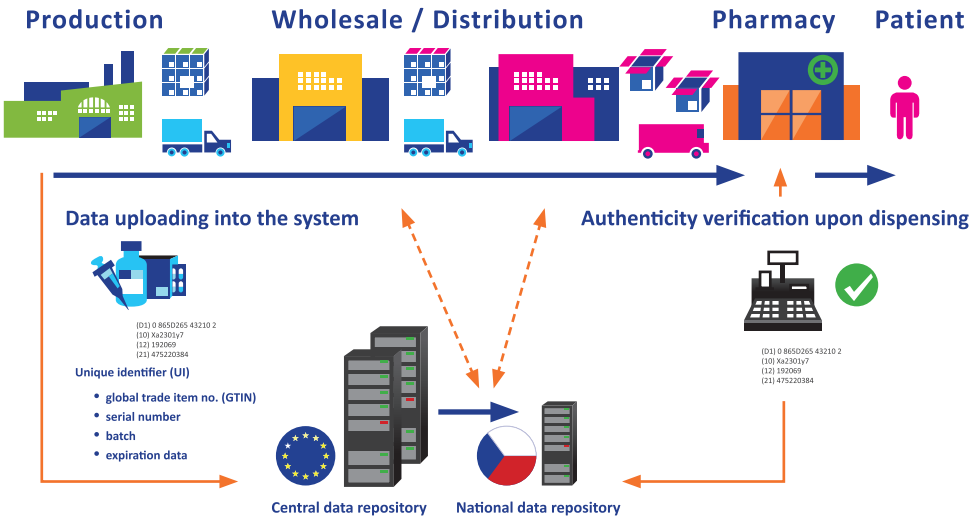
Bc. Jan Bendl
Admin Support – registrations/MAH

ACTIVITIES IN 2018

Since its foundation on 6th March 2017, NOOL, Národní organizace pro ověřování pravosti léčiv, z.s. has mostly focused on and managed activities concerning the preparation of the National Medicines Verification System in the Czech Republic, while paying attention to preparing and raising awareness of all stakeholders that are subject to the rules of anti-falsification legislation.

At the beginning of 2018, a lot of attention was paid to the validation of the NMVS by the European Medicines Verification Organization, which was the condition for connecting the system in the production environment to the European HUB. The Czech Republic was one of the first Member States to achieve this goal, i.e. the NMVS was the fifth successfully certified system; it was connected to the EU HUB on 25th April 2018. Thanks to this success, it was possible to start the pilot phase of the project and to gradually assess, together with selected entities, every process in terms of anti-falsification legislation. The results were continuously monitored and shared not only with pilot participants but also with other stakeholders, including those in other countries using the system from Solidsoft Reply.

EUROPEAN MEDICINES VERIFICATION SYSTEM



Regulation effective in February 2019

During the second half of 2018, there were also additional three releases of new functionalities of the NMVS to ensure compliance with the FMD's requirements for the medicines verification system prior to 9 February 2019. In the last quarter, NOOL concentrated on registering and connecting end users, i.e. mostly pharmaceutical services providers and distributors, to the NMVS, while registering and signing contracts with MAHs. The certification of the individual systems of end users was a very important activity as well.

PROJECT STATUS AS OF THE END OF 2018

Implementation of the project in 2018 continued according to the approved project plan that specified project milestones, risks were managed as well. The project status and its progress were regularly monitored and reported to all stakeholders and monthly reports were posted on NOOL's website.

The Czech medicines verification system was put into operation very soon and connected to the European HUB in the first half of 2018, which made it possible to start the pilot project in May and placed the Czech Republic among first Member States to implement the NMVS.

Current activities on the FMD project

During the entire year of 2018, the National Medicines Verification Organization closely collaborated with the representatives of individual stakeholders as well as with competent national authorities involved in FMD and in the implementation of the medicines verification system. Consultations with the representatives of the State Institute for Medicines Verification and the Ministry of Health of the Czech Republic were some of the steps leading to the implementation of the NMVS in compliance with the requirements of European legislation.

It was very important to sign contracts between NOOL and the entities that will use the medicines verification system starting on 9 February 2019, i.e. marketing authorization holders (MAHs) and end users. A draft contract on the use of the NMVS by end users (pharmacies, distributors) was discussed and approved, and in the first half of 2018, a draft cooperation agreement between MAHs and NOOL was approved. The follow-up information campaign targeting these entities was to inform them about these contracts and mainly about the process of registration with the National Medicines Verification Organization. NOOL specified an annual user fee for 2019 (flat fee model) and one-off registration fee for the creation and launch of the medicines verification system to MAHs that will use the NMVS. MAHs whose revenues in the previous year amounted to less than 500,000 EUR (or the equivalent in CZK) were allowed to request a reduced user fee. The registration and contract signing on registration portals created for end users and MAHs continues in 2019 as well.

The delivery of a solution - a medicine verification system was carried out in the cooperation with Solidsoft Reply. The system implementation also included three releases of new system functionalities during 2018 to make sure that the system meets the requirements concerning the FMD defined in the Directive and the Commission Delegated Regulation by 9 February 2019. These releases into the system's production environment were always thoroughly tested first in collaboration with the system provider, and acceptance tests were always attended by the representatives of the NMVO. The system implementation was supported through regular collaboration with the NMVS provider, i.e. Solidsoft Reply, and the technical and project part of the system implementation was regularly supervised by a top-quality team of external consultants from EY.

The setup of the quality management system (QMS), which is an integral part of the NMVS, a requirement for the validation of the NMVS by EMVO and necessary for the future management of NOOL and for the running of the NMVS, took the entire year. Preparations for a QMS audit of the NMVS provider, i.e. Solidsoft Reply, and for an audit of the NMVS's information security took place before the end of 2018. Both audits were scheduled for January 2019.

The certification of end users' systems that had to pass self-certification tests began soon once the release of NMVS into the production environment on 25 April 2018. It was possible to connect individual systems to the production environment of the national repository after that, provided that the pharmaceutical services providers or distributors using the IT SW completed their registration and signed end-user contract with NOOL.

Approximately 40 entities from all parts of the medicine distribution chain were actively involved in the pilot phase and both the NMVS and the processes affecting the new implemented measures protecting the market against falsified medicines were tested in the real operation and with medicines dispensed to patients. The purpose of the pilot was, among other things, to identify the areas that need to be changed or modified in collaboration with individual stakeholders. The pilot phase of the project was finished in December 2018 and then evaluated.

There were different activities concerning the drafting of an amendment to the Pharmaceuticals Act (no. 378/2007 of Coll., on pharmaceuticals) and commenting by the representatives of individual stakeholders during the year. The government and the House of Deputies of the Parliament of the CR approved an amendment regulating anti-falsification.

COMMUNICATION

Communication projects of NOOL in 2018

A successful implementation of the FMD depended on intensive communication to ensure the awareness of all stakeholders. NOOL participated in many media activities and presented the importance of the FMD and the progress of its implementation to healthcare professionals in particular during the year 2018. The general public was informed through the media, for which two press conferences were held.

Press conference

13 March 2018

Falsified medicines will have no chance. The pilot project of the medicines verification system is starting.

9 November 2018

The medicines verification system will be launched in three months. Deputies promised to pass the amendment on time.

Communication targeting healthcare professionals

12 April 2018

A presentation at the Pharma Profit conference – The medicines verification system is about to start

25 April 2018

MF Partnership – Pharmacist of the Year (announcement)

31 May 2018

A presentation at the 8th Spring Conference of Hospital Pharmacists – Implementation of the "Anti-Falsification Directive" – eight months to go

June 2018

- Remedia 3/2018 – A pilot project for detecting falsified medicines has started
- Advertising and information at FAEI.cz 1/11 2018–30/4 2019
- Advertising and information in the journal Pharma Profit 25/18

9 October 2018

- A traditional meeting of the PHOENIX Group with manufacturers – Readiness of the Czech Republic for the FMD as viewed by NOOL
- An IT workshop of NOOL and SÚKL for IT SW firms working on the systems for end users

11 October 2018

Pharma Profit Congress in Olomouc

FINANCIAL MANAGEMENT REPORT

The registered non-profit organization and the FMD implementation project are financed from several sources:

- Membership fees of the founding members;
- Loans from AIFP and ČAFF or donations from the members of these associations – IMPLEMENTATION PHASE;
- Registration and user fees from every marketing authorization holder that uses the medicines verification system – IMPLEMENTATION AND PRODUCTION PHASE.

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

Revenues in 2018

Total received contributions	**3 227**
Received contributions – donations	3 177
Received membership fees	50
Revenues	**22 690**
Other revenues	**106**
Total revenues	**26 023**

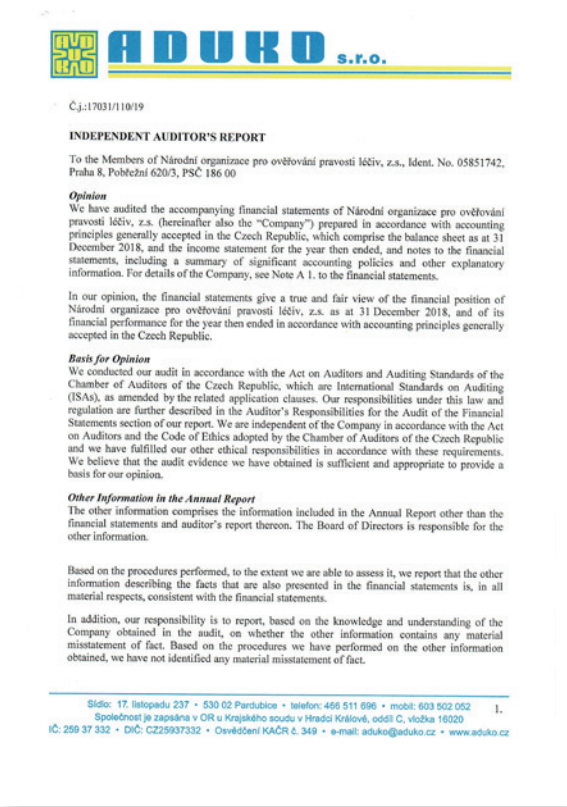
Expenses in 2018

Purchases	**10 988**
Materials and energy consumption	320
Purchased services	10 668
Personnel costs	**3 356**
Taxes and fees	**10**
Other expenses	**955**
Depreciation	**11**
Income tax	**2 024**
Total expenses	**17 344**

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 2018 was CZK 8,678,589.83.

INDEPENDENT AUDITOR'S REPORT



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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 2018, 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 2018, 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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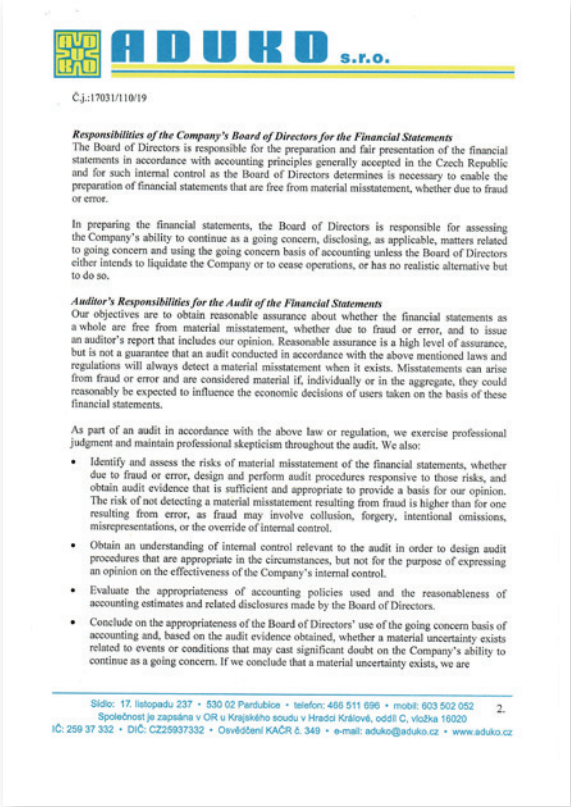

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Responsibilities of the Company's Board of Directors for the Financial Statements
The Board of Directors is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted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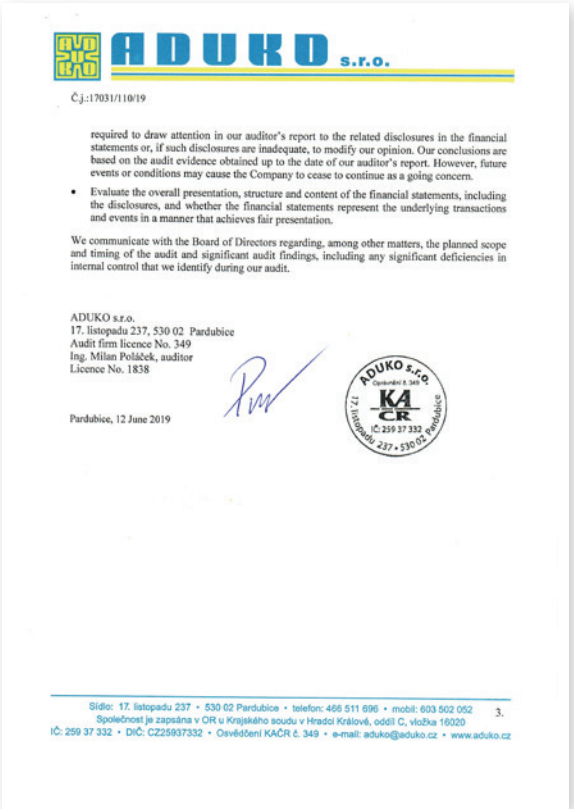

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Č.j.:17031/110/19

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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Audit firm licence No. 349
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 12 June 2019

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Opinion

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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 2018, and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech Republic.

CONTACT AND IDENTIFICATION DATA

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

Národní organizace pro ověřování pravosti léčiv, z. s.
Registered in the Associations Register kept by the Municipal Court in Prague under ref. No. L 67982

Národní organizace
pro ověřování
pravosti léčiv

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