Národní organizace
pro ověřování
pravosti léčiv

ANNUAL REPORT

National Medicines Verification Organization

2017

AN OPENING WORD

A lot of attention is now paid in Europe to falsified medicines. There is a considerable risk that people will buy a falsified medicine especially if they buy it outside the official distribution network or on the Internet. However, such a medicine may also find its way into the official distribution network. Falsified medicines are mostly found in Asia and America, but the number of falsified medicines reported in Europe keeps growing as well. In the best case, these medicines are ineffective, in the worst case, they contain substances harmful to health.

This situation led to the adoption of Directive 2011/62/EU on falsified medicines (Falsified Medicines Directive or FMD) that requires that prescription-only medicine packs include safety features (i.e. a unique identifier together with features providing evidence of tampering), manufacturers enter medicine batch numbers into the European medicines verification system and national electronic systems allowing the verification and authentication of these packs are implemented.

For these purposes, European stakeholders - EAEPC (parallel distributors), EFPIA (innovative manufacturers), GIRP (wholesalers), Medicines for Europe (generics manufacturers) and PGEU (community pharmacists) - collaborated in creating the European Stakeholder Model or ESM). This system forms a European central hub that provides a portal for entering manufacturers' codes and is connected to many national/regional information databases or repositories that serve as verification platforms that pharmacies or other authorized parties can use to check a pack's authenticity before being decommissioned from the system prior when dispensed to patients. The European stakeholders have founded a non-profit legal entity, the European Medicines Verification Organization (EMVO), that is to launch the ESM by establishing the central European hub and to support national stakeholders in establishing competent national organizations. EMVO's current president – Hugh Pullen (EFPIA's representative) – took over the leadership from PGEU representing community pharmacists within the EU. All stakeholders came up with, and defined, the entire solution against falsified medicines together.

The non-profit National Medicines Verification Organization (NOOL) founded in the Czech Republic by the Association of European Distributors of Pharmaceuticals (AEDL), the Association of Innovative Pharmaceutical Industry (AIFP), the Association of Wholesale Distributors of Pharmaceuticals (AVEL), the Czech Association of Pharmaceutical Companies (ČAFF) and the Czech Chamber of Pharmacists (ČLK) in March 2017 is in charge of setting up a functioning national medicines verification system. Since its foundation NOOL has been working hard on preparing the launch of the national medicines verification system and on informing the stakeholders about the matters concerning FMD as much as possible.

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 and of the Council of 8 June 2011 amending 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 and Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 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 implementing 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 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 means of reports prepared by the project manager of the statutory body.

As of 31 December 2017, NOOL had the following associated members: Apatyka Servis, the Association of Pharmacy Chain Operators, GS1 Czech Republic, Lekis, PharmaSwis and Pharmaceutical Care Providers. These companies attend NOOL's General Meetings and have the right to comment on NOOL's activities.

NOOL also closely collaborates with national and European authorities, such as the State Institute for Drug Control (SÚKL), the Ministry of Health of the Czech Republic, the European Medicines Verification Organization (EMVO) and other stakeholders.

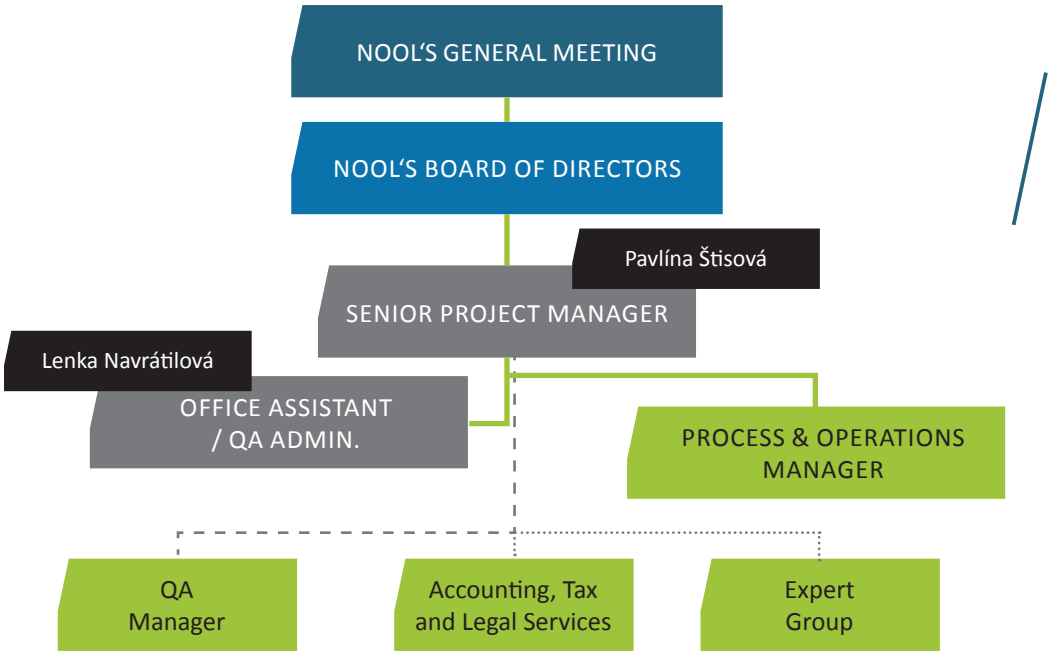
We would like to thank all these entities for their support and collaboration as well as for the opportunity to consult with them the entire anti-falsification matter in the Czech Republic.

MEMBER COMPANIES

ASSOCIATED COMPANIES

NOOL'S ORGANIZATIONAL STRUCTURE

As of 31 December 2017, NOOL had two employees and collaborated with external companies in order to ensure services necessary for the running of the organization and for the preparation of the system.



NOOL'S TEAM IN 2017

Pavlína Štisová, MBA
Senior Project manager

Ing. Lenka Navrátilová
Office Assistant

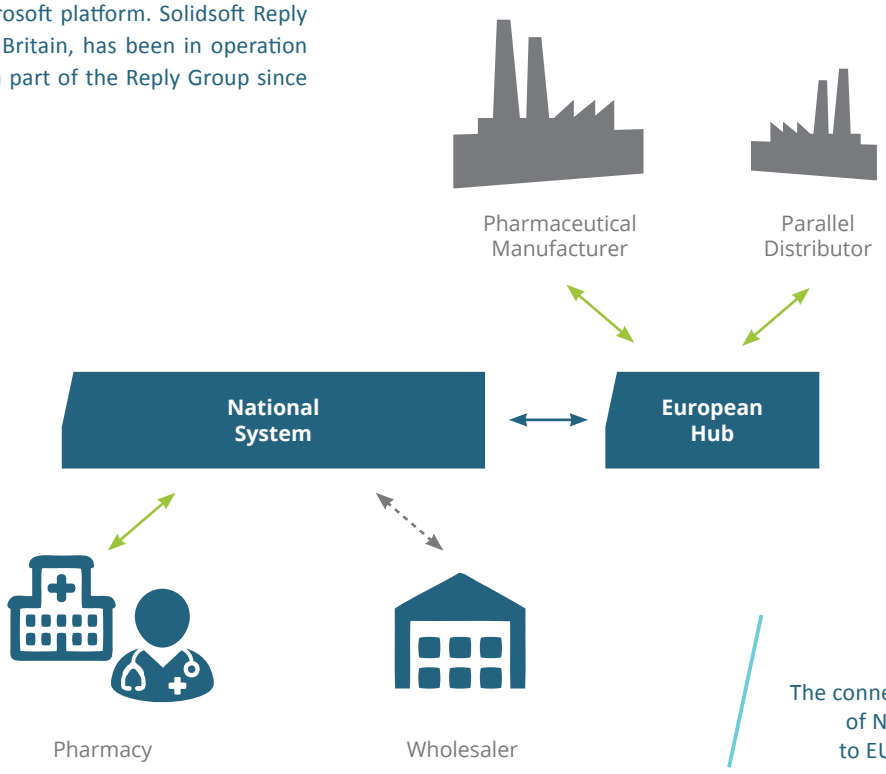
ACTIVITIES IN 2017

Since its foundation on 6 March 2017, the non-profit National Medicines Verification Organization (NOOL) has mostly focused on preparations of the national repository. Shortly after its foundation, the organization selected, in collaboration with external consultants, a provider of IT services, the so-called blueprint solution, based on a call for tenders for a specified IT system.

Based on its previous evaluations, EMVO recommended contacting Aegate, Arvato and Solidsoft Reply. Solidsoft Reply Ltd. won the tender, and NOOL and Solidsoft Reply Ltd. signed a cooperation contract in June 2017. The company was asked to create, commission and ensure the proper functioning of a Czech repository, i.e. the national medicines verification system.

Solidsoft Reply Limited is a part of the Reply Group that operates worldwide and provides consultations, system integrations and digital services. It focuses on the concept, design and implementation of solutions built on new communication technologies and digital media in collaboration with key firms on the market. It received the award "leader in architecture-oriented services and business process management" on the Microsoft platform. Solidsoft Reply Ltd. is registered in Great Britain, has been in operation since 1993 and has been a part of the Reply Group since 2013. In 2017, Solidsoft Reply had 65 employees (the Reply Group had over 5,500 employees). The Reply Group's turnover in 2015 was 28,224,362 GBP.

Collaboration on the project with other countries and the European Medicines Verification Organization's coordination in implementing a comprehensive solution of the medicines verification system continued throughout the entire 2017.



The connection of NMVSs to EU HUB

In the Czech Republic, a great deal of our activities focused on informing professionals about the Directive and the duties laid down in the Directive. Together with the State Institute for Drug Control (SÚKL) and the representatives of individual stakeholders, NOOL organized many seminars and lectures for pharmacists, distributors, manufacturers and pharmacy and distrution SW providers and provided information from the media on a regular basis.

- A seminar introducing FMD (falsified medicines) – the representatives of NOOL, SÚKL, pharmacies, distributors and manufacturers. The seminar was attended by 109 representatives of manufacturers, distributors and pharmacists.
- 3 IT WS – with the representative of Solidsoft Reply and pharmacy and distribution SW providers. The WS was attended by 75 representatives of IT SW companies, MAHs and distribution firms.
- 3 WS for the management of hospitals and hospital pharmacists – representatives of the MH of the CR, SÚKL, NOOL, Porta Medica and hospital pharmacists. There were about 120 representatives from hospitals and pharmacies.

PROJECT STATUS AS OF THE END OF 2017

The implementation project started in 2016 with preparations for the establishment of the National Medicines Verification Organization. The project status and progress were regularly monitored, reported to all stakeholders and posted on the organization's website. Throughout the year 2017, the implementation progress was approximately the same as that in other countries; the Czech Republic was actually one of the leading countries in some areas of preparations.

Current situation of the FMD project

During the first quarter, collaboration with all stakeholders continued, a memorandum of understanding was signed, NOOL's statutes were approved and the organization was founded and registered in the Associations Register on 6 March 2017.

Solidsoft Reply Ltd. won the tender for the development, delivery and management of the NMVS and the contract was signed in June 2017. The implementation of the selected solution started with joint workshops and the setting up of collaboration rules. During the year, a contract between EMVO and first countries was discussed and signed for the system implementation phase and a more intensive collaboration concerning FMD was set up with the State Institute for Drug Control and the Ministry of Health of the CR. A draft contract between NOOL and NMVS end users (pharmacies, distributors) was discussed and approved.

A project plan and time schedule with clear milestones was prepared and approved together with project risks and their fulfillment was regularly monitored. A project team led by the project manager was appointed, a Quality Assurance team monitored the fulfillment of individual tasks independently from the project team.

The technical activities were mainly performed to support the implementation of the system and to prepare all entities for the launch of the entire solution and for the real operation of the NMVS. The intensive collaboration with Solidsoft continued. Workshops for IT firms providing SW to NMVS end users were held and records and instructions from these seminars were made available for future use by other IT firms. An integrated testing environment was launched and made available to all registered pharmacy and distribution SW providers in October.

Communication to start collaboration with participants of the project pilot testing through the web was launched in the fall. 52 entities were interested in participating in the pilot testing; most of them signed a memorandum of collaboration with NOOL. Based on the original plan, the pilot testing should take five months and end in the third quarter 2018. The representatives of all stakeholders signed up for the pilot testing, which included eight manufacturers (mostly from the innovative industry), two parallel distributors, six distribution companies, two public pharmacy chains, two groups of pharmacies together with other two public pharmacies and 17 hospital pharmacies, including five university hospitals. The providers of SW solutions for NMVS users as well as the State Institute for Drug Control also participat in the pilot testing.

Preparations necessary for the validation of the medicines verification system, including documentation concerning processes and the quality management system, were started before the end of 2017.

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 registration holder that uses the medicines verification system – IMPLEMENTATION AND PRODUCTION PHASE.

NOOL's budget for the implementation phase during 2017–2018

Total implementation costs 33 552 000 Kč

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

Revenues in 2017

Total received contributions	6 154
• Received contributions – donations	6 104
• Received membership fees	50
Total revenues	**6 154**

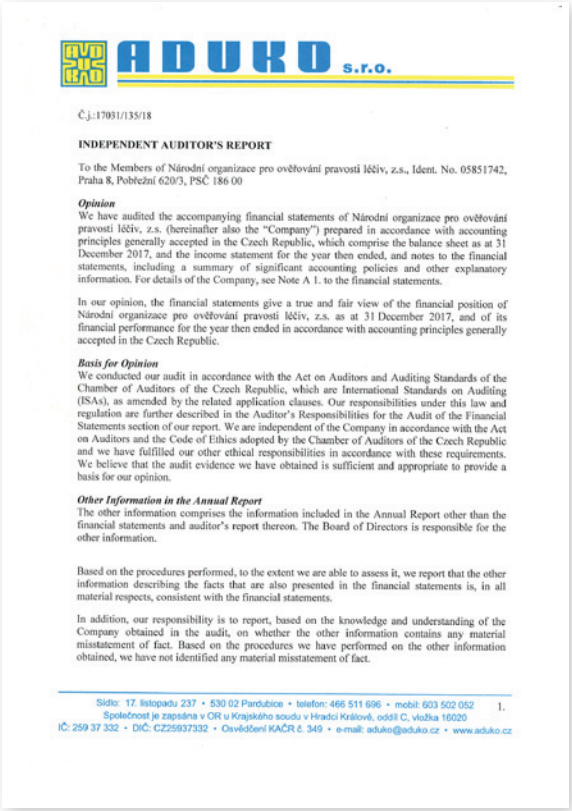
Expenses ink 2017

Purchases	5 674
• Materials and energy consumption	284
• Repairs and maintenance	21
• Travel expenses	73
• Cost of representation	82
• Other services	5 214
Personnel costs	1 275
Taxes and fees	10
Other expenses	185
Total expenses	**7 144**

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.

In 2017 NOOL had a loss of 989 974,73 CZK.

INDEPENDENT AUDITOR'S REPORT



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Č.j.:17031/135/18

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 2017, 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.

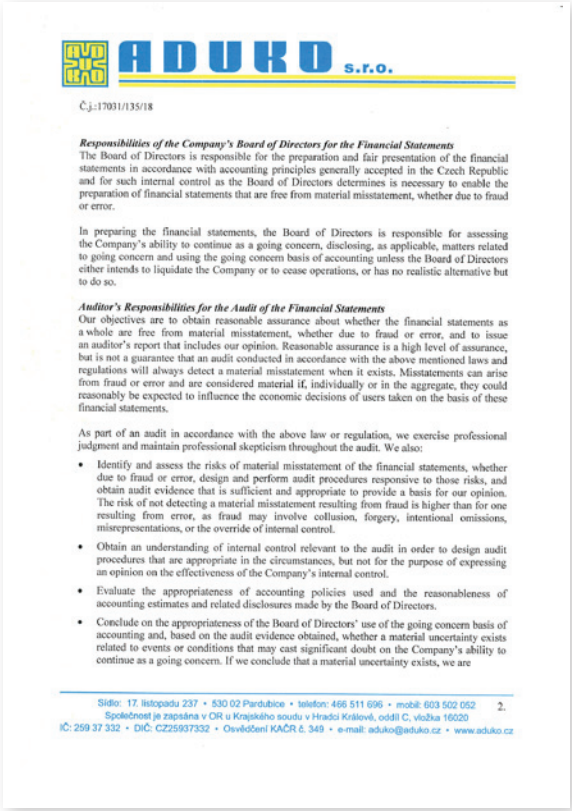
In our opinion, the financial statements give a true and fair view of the financial position of Národní organizace pro ověřování pravosti léčiv, z.s. as at 31 December 2017, and of its financial performance for the year then ended in accordance with accounting principles generally accepted in the Czech 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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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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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.
17. listopadu 237, 530 02 Pardubice
Audit firm licence No. 349
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 6 August 2018

ADUKO s.r.o. Oprávnění č. 349 KA ČR IČ: 259 37 332 17. listopadu 237 • 530 02 Pardubice

CONTACT AND IDENTIFICATION DATA

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IN: 05851742
TIN: CZ 05851742

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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