aifp

Asociace inovativního farmaceutického průmyslu

Association of Innovative Pharmaceutical Industry

Annual Report 2022

CONTENTS

INTRODUCTION

Dear colleagues,

The year 2022 was a very successful from the perspective of our Association. The Czech Republic successfully held the Presidency of the Council of the European Union. It opened up and advanced several issues related to the direction of healthcare at the EU and national level.

One of the topics concerned the implementation of the Pharmaceutical Strategy for Europe. Current European pharmaceutical legislation has contributed to many achievements, for example, improving the situation of patients suffering from rare diseases and pediatric patients. The adopted European regulations have helped to significantly increase the number of pediatric clinical trials and new orphan medicines.

It is essential to build on this positive trend, and not only in terms of pediatric medicines and orphan drugs. The forthcoming European legislation is a great opportunity to support the research of modern medicines and improve the EU's overall competitiveness and attractiveness on a globalised medicines market where it has recently lost its privileged position. It is also a milestone that, together with other legal regulations, will determine Europe's healthcare for the next two decades.

The European Health Data Space (EHDS) was also an important topic. This proposal represents an unprecedented opportunity to set up the future data and digital ecosystem in healthcare. Suppose the EHDS is well set up and unanimously interpreted and implemented in all EU Member States in the upcoming years while guaranteeing the protection of intellectual property rights and trade secrets, it will not only benefit patients but also boost Europe's attractiveness for innovative investments.

In the Czech Republic, I would like to highlight the groundbreaking amendment to Act no. 48/1997 Coll., on Public Health Insurance, which came into force on 1 January 2022. This most significant change in health legislation in many years and the most progressive legislation in the EU, which our Association helped to draft, has proven its benefits during the past 12 months. The first medicinal products have already been included in the public health insurance system, more are expected to follow in the upcoming months.

Last but not least, I would like to highlight the contribution of innovative medicines and vaccines. Every year, modern products give thousands of Czech patients and their families hope of a prolonged and significantly better life, whether it is preventive protection against serious illnesses, a complete cure, a slower disease progression, a shorter hospitalisation, a delayed disability retirement or an earlier return to work and everyday life.

I am confident that the entire healthcare sector and our Association will be able to build on the achievements from 2022. AIFP will continue to work hard to increase the availability of modern medicines for Czech patients and support the urgent reform of the Czech healthcare system. AIFP will also promote an accelerated digitalisation of healthcare, as the availability of up-to-date comprehensive data about the population's health condition should become the basis for effective decision-making in healthcare, political and economic domains in the future.

MUDr. Pavel Sedláček
Chair of the Board of Directors

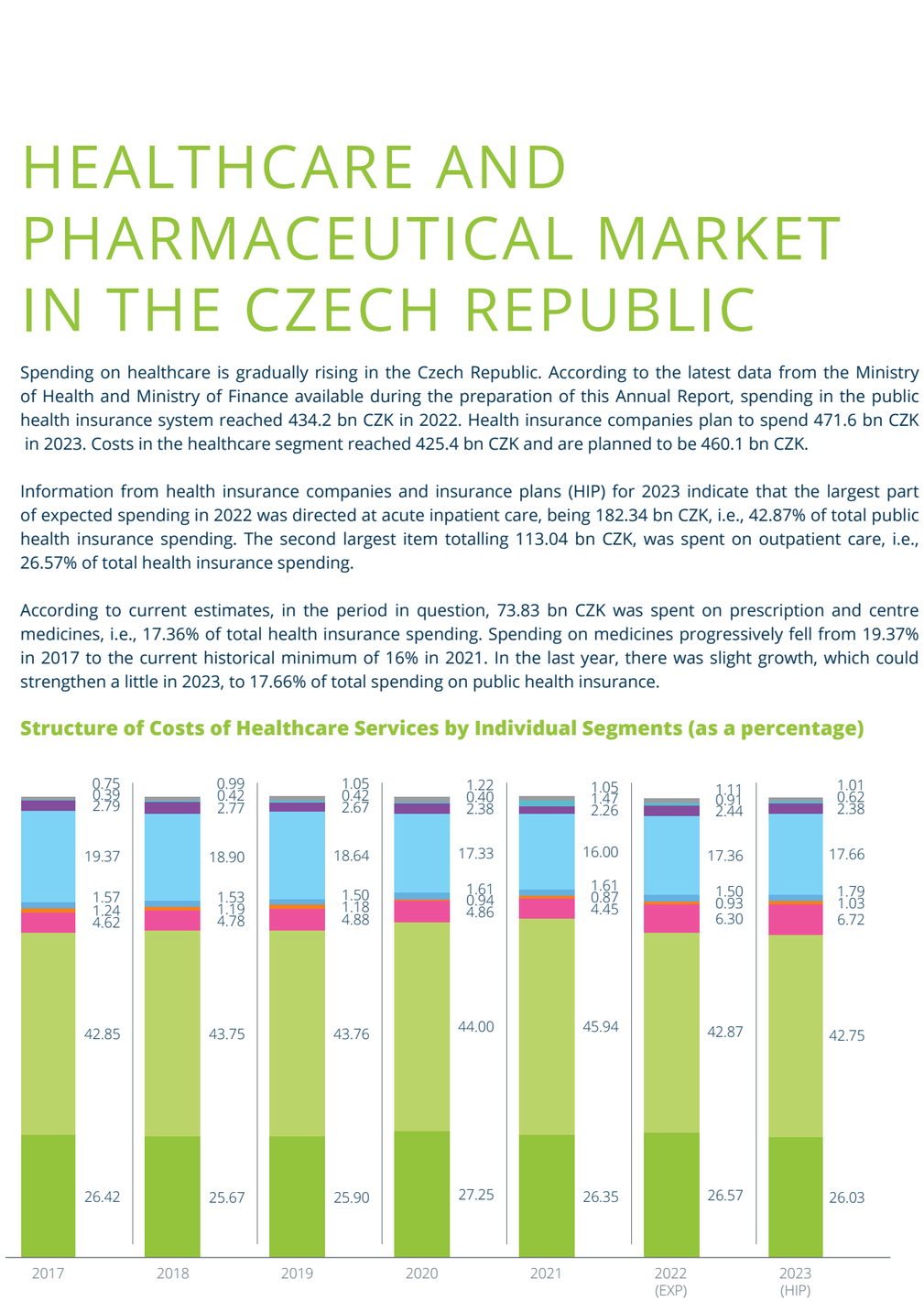
HEALTHCARE AND PHARMACEUTICAL MARKET IN THE CZECH REPUBLIC

Spending on healthcare is gradually rising in the Czech Republic. According to the latest data from the Ministry of Health and Ministry of Finance available during the preparation of this Annual Report, spending in the public health insurance system reached 434.2 bn CZK in 2022. Health insurance companies plan to spend 471.6 bn CZK in 2023. Costs in the healthcare segment reached 425.4 bn CZK and are planned to be 460.1 bn CZK.

Information from health insurance companies and insurance plans (HIP) for 2023 indicate that the largest part of expected spending in 2022 was directed at acute inpatient care, being 182.34 bn CZK, i.e., 42.87% of total public health insurance spending. The second largest item totalling 113.04 bn CZK, was spent on outpatient care, i.e., 26.57% of total health insurance spending.

According to current estimates, in the period in question, 73.83 bn CZK was spent on prescription and centre medicines, i.e., 17.36% of total health insurance spending. Spending on medicines progressively fell from 19.37% in 2017 to the current historical minimum of 16% in 2021. In the last year, there was slight growth, which could strengthen a little in 2023, to 17.66% of total spending on public health insurance.

Structure of Costs of Healthcare Services by Individual Segments (as a percentage)



Source: Annual reports of health insurance companies, HIP for 2023

With the growing availability of innovative medicines for Czech patients and the development of specialised centres intended, in particular, for treating oncological, metabolic, cardiovascular and neurological diseases in recent years, there has been higher use of centre-based treatment. Information from health insurance companies indicate that these costs were 30.98 bn CZK in 2022, whereas the costs for 2023 are estimated to be 36.22 bn CZK. Together with the development of modern medicine, it can be predicted that the volume of new products and the costs of centre treatment will progressively rise. There could be a solution in the form of new risk-sharing payment models and decentralisation of selected medicinal products, which is currently being discussed, for example, in oncology.

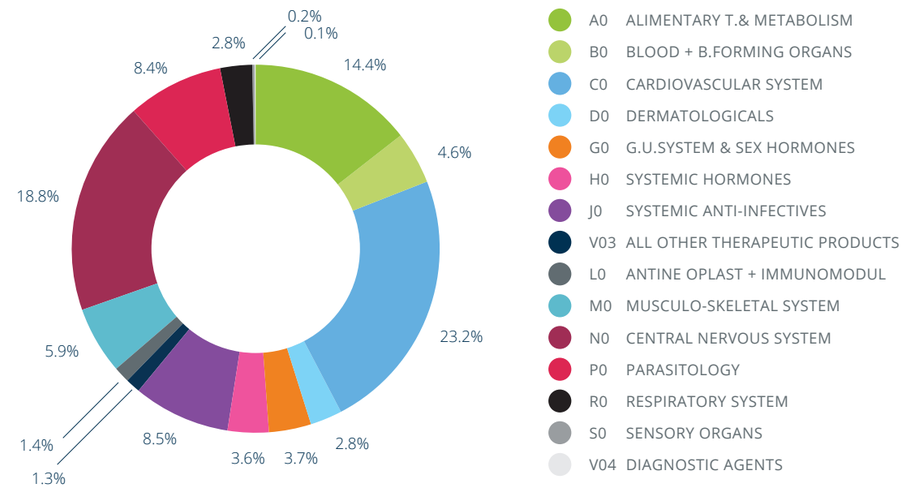
The last analysis, the *EFPIA Patients W.A.I.T. Indicator*, from April 2023, indicated that 99 new modern medicines intended to treat oncological, rare, and several other diseases are available in the Czech Republic. The Czech Republic was better off than the other V4 countries in terms of the availability of modern medicines. Still, it was behind some Western European countries, e.g., France, Austria and Germany. It is, however, necessary to consider that it is an indicative result because it only compares the number of new medicines that entered the system, as it omits their indication and prescription restrictions, which differ from country to country.

From the view of sales of medicinal products, in 2022, there was a slight increase in the number of packages of medicinal products sold by 3.76%. In financial terms, this represented 7% growth.

MARKET	2021	2022	GR
Packages (+000)	175,532	182,138	3.76%
Financial terms (millions CZK)	82,769	88,575	12.46%

Let's look at the sales of medicines from the viewpoint of their ATC group, i.e., the anatomical therapeutic chemical classification, based on data from IQVIA. The largest shares comprise of medicines for treating the cardiovascular system (23.2%), the nervous system (18.8%) and the alimentary tract and metabolism (14.4%). We present a complete overview in the chart below.

Distribution of Packages in ATC Groups (2022) – Market Share



In 2022, 18 innovative medicines entered the Czech reimbursements system, a similar number to the previous year. However, as stated above, the mere availability of medicine does not mean that Czech patients have a real opportunity to access a new treatment. A significant role here is played by indication and prescription restrictions that limit which patients can get medicine at what stage of their treatment. From our Association's viewpoint, it is necessary to proceed *lege artis* and in accordance with the valid SPC for a medicinal product.

Molecules Newly Included in Reimbursement System (2021 and 2022)

	2021	2022
Total innovative molecules	18	18
Orphan molecules	4	5

Last but not least, it is necessary to mention new legislation, specifically the amendment to Act No. 48/1997 Coll., on Public Health Insurance, which in 2022 brought a new entry path to the price and reimbursement system for orphan products and highly innovative medicinal products. Sixteen orphan products requested the determination of reimbursement by the new legislation in the past year, and one was approved in the same year. It is expected that in the forthcoming period, this option will be used by other products intended to treat previously untreatable or hard-to-treat diseases.

THE INNOVATIVE PHARMACEUTICAL MARKET IN THE CZECH REPUBLIC

Let's look now specifically at the pharmaceutical industry: in the Czech Republic, it is an industry with a relatively effective appreciation of investments compared to other sectors. The added value of AIFP member companies in the Czech economy is manifested through an economic multiplier calculated based on an analysis done by the advisory company EY at 2.30 CZK.[1] Every 1 CZK spent by AIFP members generates 2.30 CZK in the Czech economy through payments and investments. For comparison, the automobile industry in the Czech Republic is at a value of 1.69 CZK, and telecommunication services at 1.70 CZK.

2.30 CZK

1 CZK spent by AIFP members generates in total 2.30 CZK in the Czech Republic's economy.

[1] Source: EY, Macroeconomic Analysis of Innovative Pharmaceutical Industry in the Czech Republic, April 2023. The data stated relate to 2021.

Annual investments by AIFP members in the Czech Republic are 18.5 bn CZK. These costs are further used and generate the added value of 43 bn CZK in the form of VAT.

The total costs incurred in the Czech Republic by AIFP members in 2021

18.5 bn CZK

The costs were further utilised in the economy and generated additional added value with an impact of

43 bn CZK as a part of GDP (an increase of over 1 bn CZK compared to 2018).

AIFP members are also significant employer that creates job opportunities with high-added value. Jobs in the pharmaceutical industry require a high degree of expertise, a university education and long experience. The overall employment generated by AIFP members in the Czech Republic corresponds to 13,900 jobs (direct, indirect and induced employment).

A significant activity is the realisation of clinical trials of innovative medicines, which a chapter of the Annual Report is devoted to. In this place, we only mention that savings in the healthcare system, thanks to the realisation of clinical trials, reached 3.4–3.5 bn CZK alone in 2021.[2]

[2] Source: EY, Clinical Evaluation of Innovative Medicines and Their Impact on the Czech Economy, April 2022

CLINICAL TRIALS

Research of new medicines, so-called clinical trials (CTs), is a prestigious, complicated process carried out around the world, including in the Czech Republic. EY's regular analysis from 2022, which mapped the local research activity of pharmaceutical companies, showed that AIFP member companies conducted 396 clinical trials of new medicines, particularly in the area of oncology, infectious diseases, and nervous system diseases.

Last year, more than 16,000 Czech patients and almost 2,000 medical teams participated in clinical trials. As a result, the total savings of the healthcare system generated by AIFP member companies' clinical trials amounted to 3.4–3.5 billion CZK. Compared to 2019, this is an increase of more than 100%. The resulting savings represent approximately 1.1% of all funds spent by health insurance companies on healthcare in 2020.

AIFP's clinical trials in the CR (2021)

396
conducted CTs

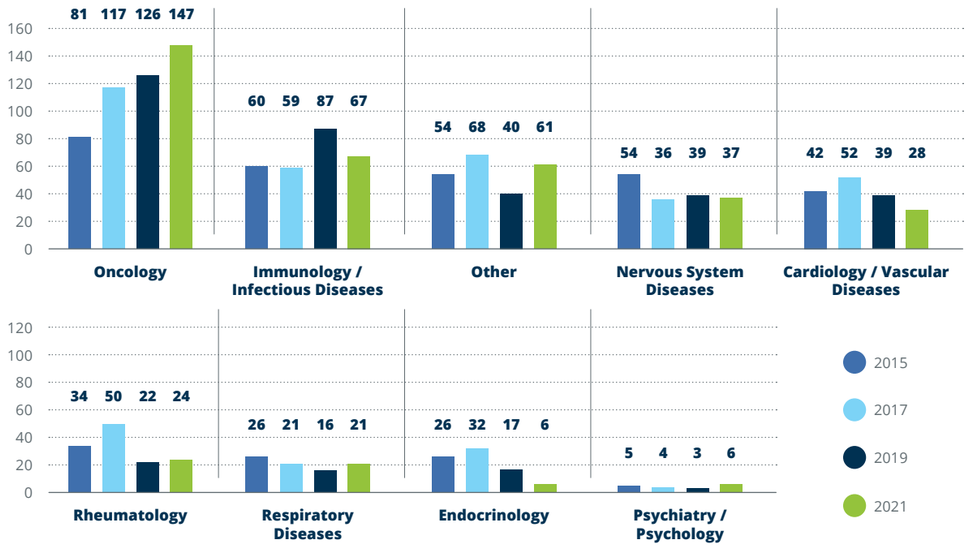
16 069
participating patients

1 891
participating research teams

2.6
billion CZK
member companies' annual CT costs

3.4–3.5
billion CZK
savings of the healthcare system

Total number of CTs conducted by AIFP members during 2015–2021 by area



FIVE STEPS FOR IMPROVEMENT

Clinical trials in the Czech Republic today are highly fragmented – each healthcare facility has different rules, different guidelines, and the administrative burden is enormous. This often slows down the start of clinical trials, which is problematic given that clinical research is conducted worldwide. Therefore, pharmaceutical companies sometimes turn to researchers from other countries where it is easier to conduct clinical trials.

To continue to conduct clinical trials in the Czech Republic and to increase competitiveness with other countries and regions, AIFP proposes the following steps:

1. **CT prioritisation and professionalisation in healthcare facilities in the Czech Republic:** It is necessary to support the establishment of *Professional Research Centers of Excellence* in selected healthcare facilities, which will interconnect CT research teams and specialists.

2. **Shortening the process of starting clinical trials in hospitals (so-called start-up):** It is necessary to support the issuance of a methodological guideline of the Ministry of Health, which would establish two basic CT requirements for hospitals, namely a one-month deadline for CT request approval and the requirement to set up the position of clinical trial coordinator.

3. **Electronization:** It is necessary to prepare a CT module in the hospital information system, including the option of remote access, electronic signature, and electronic document entering. It should be possible to retrieve electronic medical records from the system.

4. **Expansion of the current form of home care** for the option to perform relevant procedures that are part of clinical trials in the patient's home.

5. **Active support for meetings of the complete platform** of all key CT stakeholders.

> *IT SHOULD BE EMPHASISED THAT CLINICAL TRIALS AND RESEARCH ACTIVITIES, IN GENERAL, HAVE A LONG TRADITION IN THE CZECH REPUBLIC AND ARE CONSIDERED PRESTIGIOUS, HIGHLY PROFESSIONAL MEDICAL ACTIVITY. UNIVERSITY AND TEACHING HOSPITALS, AS ORGANISATIONS DIRECTLY MANAGED BY THE MINISTRY OF HEALTH, SHOULD CARRY ON THIS TRADITION, INCLUDING THROUGH THE EMERGING CENTRES OF EXCELLENCE. AIFP IS READY TO ACTIVELY PARTICIPATE IN CREATING AN ENVIRONMENT FOR IMPLEMENTING CLINICAL TRIALS BY PARTICIPATING IN ALL STAKEHOLDERS' DISCUSSIONS AND IMPLEMENTATION PLATFORMS. OPEN DIALOGUE AT A COMPETENT AND EXECUTIVE LEVEL IS THE WAY FORWARD.*
>
> **MUDr. Beata Čečetková, Ph.D.**
> TWMA

CZECH PRESIDENCY OF THE COUNCIL OF THE EUROPEAN UNION

The second half of 2022 was the time of the Czech Presidency of the Council of the European Union. On this occasion, our Association, with the support of the European Federation of Pharmaceutical Industries and Associations (EFPIA), prepared the project **"2022: Health of Europe"**, the goal of which was to open up and discuss major European healthcare topics in a broad debate of stakeholders. In addition, it included roundtables and conferences focusing, for example, on protecting intellectual property rights, implementing the Pharmaceutical Strategy for Europe, Europe's Beating Cancer Plan, and the European Health Data Space (EHDS). Recordings of all events are available on the AIFP website.

ROUNDTABLE: PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

The first event of the project, "2022: Health of Europe", was a roundtable on the protection of intellectual property rights in the development of new medicines. The topic came to the forefront of European interest during the coronavirus pandemic in connection with new vaccines. The existing IP protection helped Europe to provide vaccines and treatment for its population very quickly.

Any potential change in the scope of this protection could significantly affect the European and local investment and research environment in the future. Diminished attractiveness and research could reduce the number of clinical trials and, thus, the availability of modern treatment.

Instead of loosening the IP protection that is being discussed in the European Parliament and other institutions, it would be better to focus on finding systematic ways of effectively solving current problems – for example, the optimisation of free trade rules, the solution of obstacles in the distribution and supply chain of medicines and raw materials or solidarity between the world's rich countries and poor regions.

The roundtable organised by Zdravotnický deník took place on 6 April at the Chamber of Commerce of the Czech Republic. The speakers included representatives of the Ministry of Industry and Trade, the Ministry of Health, the Industrial Property Office, EFPIA and the Institute of Organic Chemistry and Biochemistry of the CAS.

"THE AREA OF INTELLECTUAL PROPERTY PROTECTION IS A KEY AREA FOR THE DEVELOPMENT OF NEW MEDICINES. THE ROUND TABLE, WHICH TOOK PLACE IN APRIL 2022, WAS IMPORTANT FOR PROMOTING THIS ISSUE AND BROUGHT A LOT OF NEW INFORMATION BOTH AT THE NATIONAL AND EUROPEAN LEVELS. I AM VERY GLAD FOR THE OPPORTUNITY TO PRESENT OUR EXPERIENCE AND DISCUSS THE CHALLENGES FACING DRUG DEVELOPMENT IN ACADEMIA."

prof. Ing. Martin Fusek, CSc.
Deputy Director for Strategic Development,
Institute of Organic Chemistry and Biochemistry of the CAS

EXPERT MEETING: UNEQUAL ACCESS TO ONCOLOGICAL CARE

The next expert meeting was dedicated to one of the main topics of the Czech Presidency in the Council of the European Union – oncology. The roundtable discussed, in particular, the availability of oncological care to patients in the context of two strategic documents – Europe's Beating Cancer Plan and the National Cancer Plan of the Czech Republic. The experts agreed that Czech cancer care was very good, but there were inequalities in its availability, mainly in the regions or individual cancer diagnoses. To improve cancer care availability, it is necessary to share medical data, interconnect the health and social systems, improve the evaluation of the quality of provided care, develop multidisciplinary teams providing care to cancer patients and support the further development of comprehensive cancer centres in the regions. It is also important to improve patient awareness.

The roundtable organised by Zdravotnický deník took place on 5 May. The speakers included representatives of the Ministry of Health, the General Health Insurance Company, the Association of Health Insurance Companies, the Czech Oncological Society, the Czech Hematological Society, the Masaryk Cancer Institute Brno, the Oncology Clinic of the 2nd Faculty of Medicine of Charles University in Prague and the Motol University Hospital, and Cancer Patients' Voice.

INTERNATIONAL CONFERENCE: REVIEW OF THE EU LEGISLATION ON ORPHAN AND PEDIATRIC MEDICINAL PRODUCTS

In May, the Health Committee of the Senate of the Parliament of the Czech Republic and AIFP organised an international conference on rare diseases and pediatric medicines.

The Orphan Medicinal Products Regulation (OMP) adopted in the European Union in 2000 initiated significant progress in treating patients with rare diseases. This achievement can be illustrated by the increase in the number of newly approved orphan medicines. Between 2017 and 2020 alone, the European Medicines Agency (EMA) approved more than 160 orphan medicines. This represents an 88% increase compared to previous years. However, despite the tangible success of the OMP Regulation and related incentives, many patients suffering from rare diseases in EU Member States do not have full access to proper treatment.

To continue the trend that started with the adoption of the OMP Regulation and, in particular, to meet the needs of patients, the new pharmaceutical legislation currently discussed in the EU should incorporate every successful experience of the past two decades. Therefore, discussing the planned changes in pharmaceutical legislation concerning rare diseases and pediatric indications with all stakeholders, including patients, professionals and technology providers, is essential.

The expert discussion in the Senate of the Parliament of the Czech Republic held on 17 May was attended by experts from the Czech Republic and abroad, representatives of the public administration, regulators, health insurance companies, patients and the pharmaceutical industry.

THE CZECH REPUBLIC IS VERY STRONG IN THE FIELD OF RARE DISEASES. OUT OF 24 EUROPEAN REFERENCE NETWORKS (ERNS) FOR INDIVIDUAL DIAGNOSTIC GROUPS, WE ARE INVOLVED IN 22. OUR TWO SPECIALISED CENTRES AT THE UNIVERSITY HOSPITALS IN MOTOL AND BRNO ARE AMONG THE TOP 20 IN EUROPE. WE HAVE AN EXCELLENT INFRASTRUCTURE, AN ESTABLISHED SYSTEM OF CARE, AND EXPERTISE. FURTHER DEVELOPMENT OF PATIENT CARE REQUIRES, AMONG OTHER THINGS, THE APPROVAL OF THE NATIONAL STRATEGY FOR RARE DISEASES 2022–2030 BY THE MINISTRY OF HEALTH AND THE FULL IMPLEMENTATION OF OUR PARTNER SITES OF THE EUROPEAN REFERENCE NETWORKS INTO OUR HEALTHCARE SYSTEM. IT IS ALSO NECESSARY TO ENSURE THEIR FUNDING BEYOND THE "FLAT RATE" OF DIRECTLY MANAGED ORGANISATIONS OF THE MINISTRY OF HEALTH IN DIAGNOSIS AND TREATMENT. AT THE EUROPEAN LEVEL, THEN, THE ADOPTION OF THE RARE DISEASES ACTION PLAN, THE IDEA OF WHICH WAS TAKEN UP BY THE CZECH EU PRESIDENCY ITSELF AND SUPPORTED BY THE MAJORITY (21/27) OF EU MEMBER STATES.

prof. MUDr. Milan Macek, DrSc., MHA
2nd Faculty of Medicine, Charles University and Motol University Hospital – National Coordinating Centre for Rare Diseases

INTERNATIONAL CONFERENCE: PHARMACEUTICAL STRATEGY FOR THE EU

In June 2022, the Health Committee of the Senate of the Parliament of the Czech Republic and AIFP organised an international conference on implementing the Pharmaceutical Strategy for Europe. The meeting was attended by representatives of the European Commission, the European Medicines Agency, local public administrations, regulators, health insurance companies, patients and the innovative pharmaceutical industry.

The EU's new pharmaceutical legislation being drafted as part of implementing the mentioned strategy will determine, together with other laws, the healthcare and drug research landscape in Europe for the next 20 years. Furthermore, the recent pandemic has shown that Europe needs a strong, competitive, resilient and sustainable pharmaceutical industry to improve the health of European citizens and to meet healthcare challenges. It is, therefore, necessary to promote a competitive and sustainable industry that will maintain or further improve the European Union's position on the global pharmaceutical market.

Current pharmaceutical legislation has achieved a lot, for example, improving the situation of patients suffering from rare diseases and pediatric patients. The new legislation should build on these achievements and help Europe move forward in making medicines available and develop its innovation potential. This topic was discussed in greater detail at the follow-up international conference "Pharmaceutical Strategy for Europe – Implementation, Achievements, Challenges," which took place in Brussels in September 2022.

I SEE THE GREATEST CONTRIBUTION OF THE PHARMACEUTICAL STRATEGY FOR EUROPE IN THREE AREAS IN PARTICULAR, NAMELY IN ACCELERATING THE ENTRY OF NEW MODERN THERAPIES INTO EUROPEAN COUNTRIES AND FOR EUROPEAN PATIENTS. FURTHERMORE, IN INCREASING THE RESILIENCE AND OVERALL IMPROVEMENT OF THE UNION'S PREPAREDNESS FOR CRISES AND, LAST BUT NOT LEAST, IN REDISCOVERING MAXIMUM SELF-SUFFICIENCY IN THE PRODUCTION OF MEDICINES AND MEDICAL DEVICES.

MUDr. Roman Kraus, MBA
Chairman of the Senate Committee on Health of the Parliament of the Czech Republic

INTERNATIONAL CONFERENCE: PHARMACEUTICAL STRATEGY FOR EUROPE – IMPLEMENTATION, ACHIEVEMENTS, CHALLENGES

In September, AIFP organised, under the auspices of the Czech Presidency of the Council of the EU, another expert international conference as part of the project "2022: Health of Europe" that discussed the Pharmaceutical Strategy for Europe. The goal of the meeting was to learn in detail the needs of the different parts of the healthcare system, which will help to create a new, sufficiently robust, sustainable and balanced legislative framework.

The speakers' presentations and the subsequent discussion underlined the importance of the new pharmaceutical legislation, identified its weaknesses and highlighted the need for all stakeholders to work together to find a compromise. The speakers agreed that the goals set out by the legislation were attainable but differed in how to achieve them.

In general, we can say that it will be critical to strike a balance between the requirement to make the European Union as attractive as possible for investment in the research and development of new medicines, which is linked to the pharmaceutical incentive system, and the protection of intellectual property rights, and the requirement for rapid access to new treatments for patients in EU Member States, which is co-determined not only by European legislation but also by different conditions for entering the market in individual EU Member States and their economic situation.

The attendees agreed that finding a balance between these two requirements would be crucial for the success of the legislation and would require an open and responsible approach by both politicians and the industry. It is essential that patient representatives, whose role is indispensable, are also invited to these discussions.

On 30 September, over 100 representatives of the Permanent Representations to the European Union, the European Commission, the European Parliament, the Czech public administration, the patient and professional community and the innovative pharmaceutical industry attended the conference held in Brussels.

> *THE CONFERENCE WAS A VERY IMPORTANT MOMENT TO HEAR AND SHARE VIEWS AMONG STAKEHOLDERS ON WHAT WE NEED TO ACHIEVE FOR PATIENTS IN EUROPE VIA THE PHARMACEUTICAL STRATEGY. AS AN INDUSTRY, THE PORTION OF THE STRATEGY DEDICATED TO THE REVISION OF THE ENTIRE PHARMACEUTICAL LEGISLATION IS AN IMPORTANT OPPORTUNITY FOR EUROPE TO UPDATE THE 20-YEAR-OLD LEGISLATIVE FRAMEWORK AND TRY TO CLOSE THE COMPETITIVENESS GAP THAT HAD BEEN GROWING BETWEEN EUROPE AND THE US. EUROPE NEEDS TO EQUIP ITSELF WITH A FUTURE-PROOF REGULATORY SYSTEM AND STRONGER INCENTIVES TO ATTRACT INVESTMENTS INTO INNOVATION BACK TO EUROPE AND ENSURE WE ARE ABLE TO RESEARCH, DEVELOP AND MANUFACTURE THE TREATMENTS AND VACCINES CITIZENS NEED. IN PARALLEL AND OUTSIDE THE LEGISLATIVE REVISION, WE URGENTLY NEED A COORDINATED APPROACH AMONG STAKEHOLDERS TO TACKLE ACCESS DISPARITIES IN EUROPE BASING ACTIONS ON AN AGREED ANALYSIS OF THE MULTIFACTORIAL ROOT CAUSES OF THE DISPARITIES.*
>
> **Nathalie Moll**
> Director of the European Federation of Pharmaceutical Industries and Associations (EFPIA)

INTERNATIONAL CONFERENCE: WHAT SHOULD THE NEW REGULATION FOR ORPHAN AND PEDIATRIC MEDICINES LOOK LIKE?

Another international conference under the auspices of the Czech Presidency of the Council of the European Union took place in October and focused on promoting orphan and pediatric medicines. The goal of the conference was to provide a holistic view of orphan and pediatric medicines for the new European medicines legislation that is being drafted, including the vision of the Czech Presidency and the innovative pharmaceutical industry.

FIVE MAIN CONCLUSIONS:

1. Open discussions among all stakeholders – EU Member States, the European Commission, patient representatives, professionals and the industry – are a prerequisite for legislation that will improve the situation of European patients.
2. Discussions should lead to a compromise that would not diminish the attractiveness of the European Union for science and research while ensuring that patients in all EU Member States would benefit from the results of this research.
3. The role of patients cannot be overlooked. Their representatives should be involved not only in discussions but also in decisions about reimbursements for new medicines.
4. Available and high-quality health data are a prerequisite for the further development of healthcare.
5. It is essential to use all data, including those beyond standard clinical trials and patients' experiences and preferences.

The successful conference held on 21 October in Brussels was attended by over 80 people, mainly representatives of the Permanent Representations to the European Union, European institutions, the Czech public administration, healthcare providers, the patient and professional community and the innovative pharmaceutical industry.

> *THE NEW FORM OF THE EUROPEAN LEGISLATIVE FRAMEWORK FOR ORPHAN DRUGS IS CRUCIAL FOR ALL PATIENTS WITH THESE DISEASES, INCLUDING PATIENTS FROM THE CZECH REPUBLIC. I AM GLAD THAT WE WERE ABLE TO ADDRESS IT AT THE CONFERENCE. IN SETTING UP THIS FRAMEWORK, WE SHOULD BE ABLE TO THINK OUTSIDE THE BOX AND, FOR EXAMPLE, IN ACCESS TO TREATMENT FOR PATIENTS WITH EXTREMELY RARE DISEASES, CONSIDER THE OPTION OF ENHANCED EUROPEAN COORDINATION, INCLUDING THE FUNDING SYSTEM, SO THAT WE ARE TRULY ABLE TO DELIVER TREATMENT TO PATIENTS WHO URGENTLY NEED IT IN A TIMELY MANNER, IN ALL EU COUNTRIES.*
>
> **Bc. Anna Arellanesová**
> President, Czech Association for Rare Diseases (ČAVO)

INTERNATIONAL CONFERENCE: EUROPEAN HEALTH DATA SPACE – AN OPPORTUNITY FOR INNOVATION AND ECONOMIC GROWTH – A DISTANT VISION OR REALITY?

The European Health Data Space (EHDS) was the subject of an international conference organised by the Czech Chamber of Commerce in cooperation with our Association on 15 November. The EHDS is a significant healthcare milestone based on creating a single EU data environment that will facilitate patients' access to their electronic health records while accelerating the research environment, increasing the EU's competitiveness and helping EU Member States save money.

The European Commission's proposed new legislation responds to Europe's deteriorating innovation and investment potential in research of new medicines and technologies. The data are clear: 48% of all new innovative medicines and medical innovations are developed in the US. US investments amount to tens of billions of USD. In Europe, it is only 22% of new medicines, and the gap between the two continents continues to grow. The situation was the other way around 25 years ago; the EU used to be at the forefront of research and development of new therapeutics. The revision of European pharmaceutical legislation, of which the EHDS is an important part, should help to reverse this situation.

The conference was held under the auspices of the Czech Presidency of the Council of the European Union. It was attended by representatives of the European Commission, the European Parliament, the Ministry of Health, the Ministry of Industry and Trade, the Ministry of Science, Research, and Innovation, national electronization authorities of EU Member States, local research institutes and the innovative pharmaceutical industry.

> *THE CONFERENCE CONFIRMED THE GREAT POTENTIAL OF THE EHDS DATA TOOL NOT ONLY FOR PATIENTS BUT ALSO FOR MORE EFFICIENT TARGETING OF RESOURCES OR THE DEVELOPMENT OF INNOVATIVE MEDICINES IN THE EU.*
>
> **Ing. Ondřej Knotek**
> Member of the European Parliament

PROJECTS AND EVENTS

In 2022, the Association successfully organised several professional meetings, seminars and conferences and continued with its long-term projects. Below is a list of the most exciting things of the year.

ACADEMY OF PATIENT ORGANIZATIONS

In 2022, the Academy of Patient Organizations (APO), an AIFP educational and development project for patient organisations, celebrated ten years of its foundation. Since its very beginning, APO has been supporting the transformation of patient groups from more or less informal groups of volunteers into professional, independent, and transparent organisations. The original small project, in which 30 patient organisations participated, now includes 100 patient groups.

Throughout its existence, APO has organised over 180 all-day seminars, provided 600 hours of individual consultations, held several patient meetings, workshops and conferences and mapped 900 grants. APO continued with these support activities during 2022 as well. APO has been repeatedly recognised not only by patient organisations but also by representatives of the Czech public administration, healthcare payers and foreign institutions.

THE FUTURE DIRECTION OF APO

Over the past ten years, patient organizations have become a partner that is actively involved in decision-making and evaluation processes in the Czech healthcare system. However, the question of long-term sustainable financing remains a pressing issue. Therefore, the next step is to find a suitable solution. The Ministry of Health has already announced that it is taking concrete steps in this matter in cooperation with other ministries, representatives of payers, professionals, and patients.

APO will continue helping patient organisations. It will support their professionalisation and offer a platform for experience sharing, cooperation and education in the Czech Republic and Europe (e.g. through the EUPATI project).

THE ACADEMY HAS STEERED US TOWARDS A PROFESSIONAL APPROACH TO WORK IN PATIENT ORGANIZATIONS. ITS PROGRAM AND LECTURERS HAVE OPENED UP AND CONTINUED TO OPEN UP FOR US A WORLD OF NEW KNOWLEDGE, INFORMATION, AND SKILLS NECESSARY FOR EFFECTIVE PATIENT ADVOCACY AND CREATING CONDITIONS FOR LIVING WITH A CHRONIC DISEASE (IN OUR CASE, DIABETES). GAINING INSIGHT IS THE GREATEST BENEFIT TO ME FOR OPTIMAL COLLABORATION AT ALL LEVELS.

Vlastimil Milata
Chair of the Patient Council of the Czech Minister of Healthcare
and Chair of Diaktiv Czech Republic

Certifikace reprezentantů

CERTIFICATION OF PHARMACEUTICAL SALES REPRESENTATIVES

The Sales Representatives Certification Project, established in 2013, is about training all sales representatives of member companies in pharmacology, pharmaceutical law, and ethics basics so that they would be able to professionally convey information about medicinal products in terms of content and form. In addition, the project aims to ensure that member companies and their sales representatives are trustworthy when promoting and interacting with healthcare professionals and provide only correct information.

The project includes an e-learning course, during which the participants improve their knowledge about the regulation of advertising concerning medicines for human use, the protection of personal data, pricing and reimbursement mechanisms for medicinal products, the protection of competition, medical information, pharmacovigilance, clinical trials as well as the rules of the AIFP Code of Practice.

In 2022, nearly 400 sales representatives of AIFP member companies attended the course and received their certificates. A total of 2,448 certificates of successful course completion have been issued since the beginning of the project.

TERAPIE BUDOUCNOSTI

THERAPIES FOR THE FUTURE

Therapies for the Future is the Association's educational project to familiarise professionals and non-professionals with the latest treatment trends and options. In April, the third seminar for healthcare professionals was held in cooperation with the Czech Medical Society of Jan Evangelista Purkyně.

The presentations of Prof. Štěpán Svačina, MD, DrSc., MBA, Assoc. MUDr. Jana Haberlová, Ph.D., and MUDr. Aleš Kmínek, MBA, MHA, focused on gene therapy. The recording of the webinar as well as the recordings of previous webinars on CAR T-cell therapy and treatment and prevention by mRNA therapy, are available on the website of the Czech Medical Society of Jan Evangelista Purkyně.

"THERE HAVE BEEN SIGNIFICANT CHANGES IN PHARMACOTHERAPY IN THE LAST 20 YEARS, WHICH ARE ACCELERATING. IN PARTICULAR, THERE ARE NEW PROCEDURES USING MOLECULAR BIOLOGY PRINCIPLES, INFLUENCING DNA AND RNA, BUT ALSO VIRAL CARRIERS OR MODIFICATION OF THE REMOVED CELLS. UNFORTUNATELY, THE PRINCIPLES OF MODERN PHARMACOTHERAPY ARE ONLY SOMETIMES WELL UNDERSTOOD BY PHYSICIANS. I AM, THEREFORE, PLEASED THAT WE HAVE BEEN ABLE TO DEVELOP THE THERAPIES FOR THE FUTURE PROJECT WITH AIFP. INDIVIDUAL LECTURES CAN BE WATCHED IN REAL-TIME ONLINE OR RECORDED ON THE WEBSITE OF THE CZECH MEDICAL ASSOCIATION. THE PROJECT STARTED WITH A LECTURE ON CAR-T, FOLLOWED BY A SERIES OF LECTURES FOCUSED ON NEW PHARMACOLOGICAL PROCEDURES, E.G., IN ONCOLOGY, CARDIOLOGY OR NEUROLOGY. I AM GLAD THIS JOINT PROJECT OF THE ČLS JEP AND THE AIFP HAS BEEN SUCCESSFULLY REALISED AND FURTHER EXPANDED."

prof. MUDr. Štěpán Svačina, DrSc., MBA
President of the Czech Medical Society of Jan Evangelista Purkyně

ROUNDTABLE: VACCINATION IN THE CZECH REPUBLIC: THE IMPORTANCE OF VACCINATION POLICY IN THE HEALTHCARE SYSTEM, CURRENT ISSUES AND AN OUTLINE OF FUTURE DEVELOPMENTS

Vaccination is one of the most accessible and cost-effective prevention tools with high added value. It is also one of the most critical health innovations of the last centuries. However, vaccination against a number of diseases is still insufficient in the Czech Republic; this is why the Association organised a roundtable of professionals at the end of June to present the current status quo in vaccination, to share experience from other countries, to present visions of vaccination strategies and their position on healthcare policy and to identify the necessary changes in the short and long term.

The roundtable was attended by representatives of the Health Committee of the House of Deputies of the Parliament of the CR, the Czech Society of Vaccinology of the Czech Medical Society of Jan Evangelista Purkyně, the Institute of Health Information and Statistics, the State Institute of Health, health insurance companies, general practitioners for adults, children and adolescents and other professionals.

Let's not forget that vaccination was also one of the main topics of the Czech Presidency of the Council of the European Union. In December 2022, the conclusions of the Council of the EU on vaccination as one of the most effective tools for preventing diseases and improving public health were published. These conclusions call for a joint EU-wide effort to strengthen cooperation in the fight against vaccine-preventable diseases, building on the lessons learned during the coronavirus pandemic.

OTHER VACCINATIONS WERE SOMEWHAT FORGOTTEN DURING THE COVID-19 PANDEMIC. IT IS APPROPRIATE TO ASK HEALTH INSURANCE COMPANIES AND THE GOVERNMENT WHETHER THE VACCINATION RATE COULD IMPROVE IF SOME VACCINATIONS WERE COVERED BY INSURANCE, BECAUSE VACCINATION IS THE MOST EFFECTIVE AND CHEAPEST WAY OF PREVENTING SELECTED INFECTIOUS DISEASES.

MUDr. Tom Philipp, Ph.D., MBA
Deputy of the House of Deputies of the Parliament of the CR
Source: Vaccination in the CR: vaccination rate, vision of electronisation and prevention investments, 11 July 2022

EXPERT MEETING: SECONDARY PREVENTION, HEALTHCARE QUALITY AND CARDIOVASCULAR HEALTH DATA

Cardiovascular diseases are the most common cause of death in the Czech Republic. Out of heart diseases, chronic ischemic heart disease, heart failure, and acute myocardial infarction show the highest mortality rates in both men and women. Based on available data, the Czech Republic has the third worst incidence of cardiovascular diseases in Europe. The number of cardiac patients continues to increase due to the ageing of the population, while the mortality rate of patients is gradually decreasing yet, there is a risk of its increase. What needs to be done to ensure that the predicted increase in mortality does not materialize? What changes need to be made?

These and other issues were discussed at the AIFP roundtable organised in collaboration with Zdravotnický deník in early November. Key topics discussed included the standardization of shared data, patient trajectory through the system, centre-based healthcare, healthcare quality, the use of innovative technologies in practice and adverse demographic trends contributing to the increasing prevalence of (not only) cardiac diseases.

All participants agreed on the need to strengthen secondary and primary prevention. They repeatedly said that the healthcare system should be changed so that patients can see a specialist just for some time and then return back to their general practitioner. It would also be appropriate to adjust prescribing restrictions so that essential medicines, even in the secondary prevention of cardiovascular diseases, could be prescribed by general practitioners.

The discussion was attended by representatives of the Parliament of the CR, the Czech Society of Cardiology, the Ministry of Health, the Institute of Medical Information and Statistics, the Association of General Practitioners of the CR, the Association of Health Insurance Companies, the General Health Insurance Company, the Health Insurance Office and Diagnóza FH, z. s.

OVER THE LAST THIRTY YEARS, THE CZECH REPUBLIC HAS MANAGED TO REDUCE CARDIOVASCULAR MORBIDITY AND MORTALITY CONTINUOUSLY. HOWEVER, THIS POSITIVE TREND NO LONGER CONTINUES, AND THE CURRENT DATA ARE NOT VERY OPTIMISTIC. IN FACT, WITHOUT ANY FURTHER MODIFICATION OF RISK FACTORS AND INNOVATIVE TREATMENTS, THERE IS NOW A REAL RISK THAT CARDIOVASCULAR MORBIDITY AND MORTALITY COULD RISE BY UP TO 40% OVER THE NEXT 20 YEARS. IF WE DO NOTHING AND CONTINUE TO TELL OURSELVES HOW GOOD WE ARE, CARDIOVASCULAR MORBIDITY AND MORTALITY WILL RISE BY TENS OF PER CENT.

prof. MUDr. Aleš Linhart, DrSc.
Chair of the Czech Society of Cardiology
Source: We need to get back on a trajectory of lowering cardiovascular mortality, 23 February 2023

PANEL DISCUSSION: EXPERIENCE WITH THE AMENDMENT TO ACT NO. 48/1997 OF COLL. CONCERNING PHARMACEUTICALS

In January 2021, an amendment to the Public Health Insurance Act came into force, bringing the most significant change to the local healthcare legislation in 13 years. One of its most important benefits is that it facilitates the availability of medicines for patients with rare diseases who previously depended on individual treatment approval by health insurance companies. The amendment also made possible for patients and professional societies to participate in the decision-making process concerning the entry of new orphan drugs through a new advisory body that evaluates medicines based on ten comprehensive criteria stipulated by law.

Experts at the event, organised in cooperation with Zdravotnický deník, evaluated the functioning of the amendment after almost a year. They agreed that it was still too early for a detailed evaluation of the new way of obtaining reimbursement from public health insurance. However, it is clear that the amendment has the potential to improve the availability of orphan drugs for patients and their attending physicians. Therefore, it is necessary to persevere and gradually overcome and discuss the new issues that arise from the various drug assessments; the internal decision-making rules of the minister's newly established advisory body are also crystallising.

The event was attended by representatives of the Ministry of Health, the State Institute for Drug Control, the Czech Medical Society of Jan Evangelista Purkyně, the General Health Insurance Company, the Association of Health Insurance Companies of the CR, the Czech Association for Rare Diseases, our Association and Value Outcomes.

> *I AM CONVINCED THAT THE AMENDMENT TO THE PUBLIC HEALTH INSURANCE ACT HAS A PERMANENT PLACE IN THE CZECH LEGAL SYSTEM. ITS BENEFITS, NOT ONLY FOR PATIENTS WITH RARE DISEASES BUT ALSO FOR THEIR FAMILIES, ARE UNDISPUTABLE AFTER ONLY ONE YEAR SINCE IT CAME INTO FORCE. WE WILL SEE MORE IN THE COMING MONTHS WHEN NEW INNOVATIVE MEDICINES WILL ENTER THE CZECH HEALTHCARE SYSTEM.*
>
> **Mgr. David Kolář**
> Executive Director of the Association of Innovative Pharmaceutical Industry

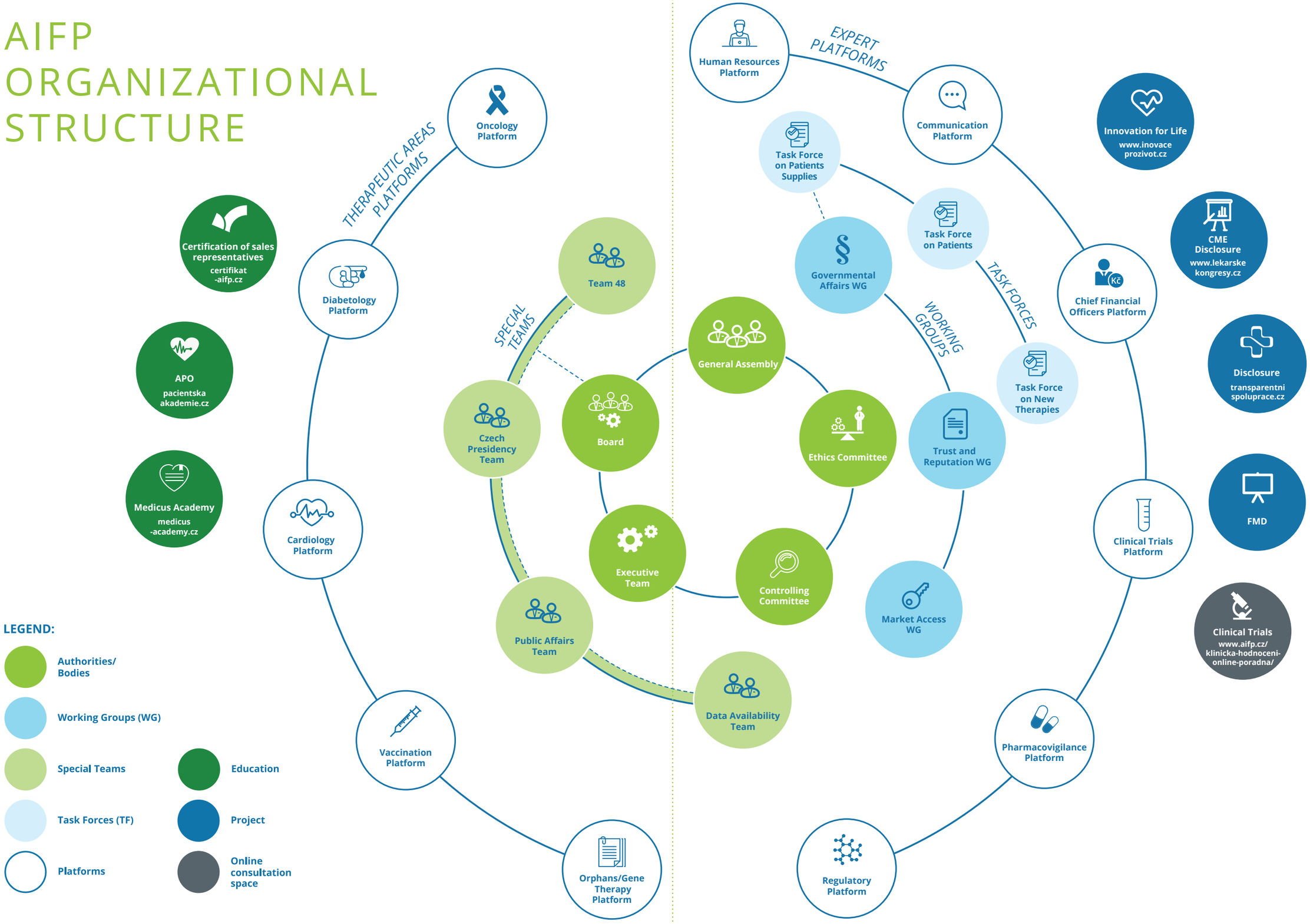
MEDICUS ACADEMY

COURSE: GCP AND SPECIFICS OF CLINICAL TRIALS IN CZECH HEALTHCARE FACILITIES

The Association also focuses on educational activities for healthcare professionals and those interested in clinical trials, medicines regulation, marketing, advertising and other areas related to the pharmaceutical industry, pharmaceuticals and technology. For them, the Association, in cooperation with ACRO-CZ, Charles University in Prague and Masaryk University in Brno and under the guarantee of doc. MUDr. Regina Demlová, PhD., head of the Institute of Pharmacology at the Faculty of Medicine of Masaryk University in Brno, has been providing lectures and courses as part of the Medicus Academy project since 2016. In November, the Association organised a course on Good Clinical Practice for investigators and clinical trials team members called: GCP and Specifics of Clinical Trials in Czech Healthcare Facilities.

The course was designed primarily for physicians, investigators, co-investigators, nurses and all clinical trials team members. The course was organised in compliance with Regulation No. 16 of the Czech Medical Society and was awarded with continuing medical education credits of the Czech Medical Society.

AIFP ORGANIZATIONAL STRUCTURE



AIFP BODIES

GENERAL ASSEMBLY

The General Assembly is the supreme steering body of the Association, which decides the Association's strategic direction. It comprises of representatives of member companies (usually CEOs). It elects members of the Board of Directors, approves the budget and decides about changes or amendments to the statutes and the Code of Practice.

BOARD OF DIRECTORS

The Board of Directors is the statutory body of the Association. It decides about all matters that do not fall under the remit of the General Assembly or any other body of the Association.

Chair of the Board of Directors
MUDr. Pavel Sedláček
CEO of Pfizer CR

First Vice-Chair of the Board of Directors
Ing. Daniela White, CSc.
CEO of Novo Nordisk CR

Second Vice-Chair of the Board of Directors
Kieran Leahy
CEO of Takeda CR and SR
(until 7 November 2022)

Member of the Board of Directors
Carolyn Sousa
CEO of Novartis CR
(until 30 June 2022)

Member of the Board of Directors
Miha Kline
CEO of Eli Lilly CR

Member of the Board of Directors
Ing. Luděk Patočka
CEO of UCB CR

Member of the Board of Directors
MUDr. Miloš Živanský, MBA
CEO of Eisai CR

Member of the Board of Directors
Emilie Grand-Perret,
CEO of Novartis CR
(starting 10 August 2022)

BODIES OVERSEEING THE ASSOCIATION'S OPERATION

ETHICS COMMITTEE

The Ethics Committee checks and supervises the compliance of the Association's activity and members with the Code of Practice.

Office term 03/2020 – 03/2022

Members:
- MUDr. Miloš Živanský, MBA, Eisai
- PharmDr. Helena Rösslerová, MBA, Lundbeck
- MUDr. Vojtěch Kotrč, Pfizer
- Mgr. Vendula Knappová, Sanofi
- Ing. Eva Sovová, MBA, Novartis
- MUDr. Silvia Přitasilová, Amgen
- MUDr. Pavel Kovář, MHA, Takeda
- RNDr. Milada Brabcová, MBA, Eli Lilly
- MUDr. Karel Rychna, CSc., Novo Nordisk
- prof. MUDr. Petra Tesařová, CSc., external member
- MUDr. Milan Šikut, MBA, external member
- Mgr. David Ondráčka, M.A., external member

Office term 03/2022 – 03/2024

Chair of the Ethics Committee
Mgr. Patrik Kastner

Members:
- Neil McDonald, GSK
- MUDr. Mgr. Filip Fremund, LL.M., BMS
- MUDr. Pavel Kovář, MHA, Takeda
- RNDr. Milada Brabcová, MBA, Eli Lilly
- MUDr. Vojtěch Kotrč, Pfizer
- MUDr. Silvia Přitasilová, Amgen
- Ing. Eva Sovová, MBA, Novartis
- MUDr. Karel Rychna, CSc., Novo Nordisk
- Mgr. Vendula Knappová, Sanofi
- MUDr. Milan Šikut, MBA, external member
- Mgr. Ladislav Loebe, external member
- Ing. Milan Eibl, external member (until May 2022)
- JUDr. Adam Jareš, PhD., external member (starting September 2022)

CONTROLLING COMMITTEE

The Controlling Committee supervises the Association's financial management and submits its audit report at the meeting of the General Assembly.

Office term 02/2020 – 02/2022, 02/2022 – 02/2024

Chair of the Controlling Committee:
PharmDr. Adriana Funderáková Beňová
MA Chapter Head Bayer for CEE

Members:
- Bc. Petr Janíček, Lundbeck
- Mgr. Petr Zelený, Sanofi

AIFP TEAM

The executive team headed by the executive director is in charge of the Association's activity.

Mgr. David Kolář
Executive Director
(starting February 2022)

Mgr. Lenka Novotná, MHA
Attorney

Ing. Katarína Eibl
Public Affairs / Relationship Manager (starting June 2022)

Ing. Markéta Kolanová, MA
PR Manager

Ing. Miluše Kaudersová
Project & Event Manager

Mgr. Zuzana Komárková
Financial Coordinator / Manager of the Academy of Patient Organizations project / HR & Office Manager

Tereza Wiederová
Executive Assistant
(starting June 2022)

Karolína Puldová
Legal Assistant

Tereza Růžičková
Legal Assistant

Mgr. Sabina Alijagićová
PR Specialist

Jakub Nikl
Project Assistant

Bc. Barbora Šalamoun
Assistant of the Academy of Patient Organizations project

Lucia Hvizdáková
Office Assistant
(starting May 2022)

The following people were also members of the executive team during 2022: Mgr. Jakub Dvořáček, MHA, LL.M. (until January 2022), Valerie Sixtová (until April 2022), Marie Šolcová (until June 2022), Mgr. Jan Sádlo (until June 2022) and Mgr. Denis Drahoš (until September 2022).

MEMBER COMPANIES

The Association of Innovative Pharmaceutical Industry had **34 member companies** in 2022.

abbvie
AMGEN
Angelini Pharma
astellas — Leading Light for Life
AstraZeneca
Bayer
BERLIN-CHEMIE MENARINI
Biogen
Boehringer Ingelheim
Bristol Myers Squibb
Eisai
GILEAD
GSK
IPSEN — Innovation for patient care
janssen
KYOWA KIRIN
LEO
Lilly
Lundbeck
MERCK
MSD
NOVARTIS
novo nordisk
Pfizer
Pierre Fabre Médicament
Roche
sanofi
Santen
SERVIER
sobi
STALLERGENES GREER — Life beyond allergy
Takeda
ucb
VERTEX

THE OUTLOOK TO 2023

Dear colleagues,

at the end of the Annual Report, I would like to highlight several topics that, from my viewpoint, will resonate significantly in 2023.

The first of them will be the search for a long-term systemic solution to ensure the stability of supplies of medicines for Czech and European patients. The problems with the availability of some medicines we started to encounter in the second half of 2022 cannot be prevented entirely, given their nature. With regard to the interconnectedness of the European space, it is therefore essential that solutions are sought at the European level as a part of open discussion by all stakeholders, i.e. representatives of the state administration, regulatory authorities, the professional community, the pharmaceutical industry and patients. Only then we will be able to minimise the impacts of medicine shortages on patients in the future.

Another topic is the worsening economic situation in connection with the ongoing war in Ukraine and the repercussions of the coronavirus pandemic. Therefore, it will be necessary to effectively allocate public health insurance funds for healthcare to the current and, ideally, an improved extent. In this context, I would like to highlight the quite necessary digitisation of healthcare, the availability of anonymous data about the population's medical condition, and the necessary setup and ongoing monitoring of the quality of care.

This is closely related to the diversification of health insurance resources, which are unsustainable over the long term in their current form. Therefore, in the coming period, it will be necessary to look for new sources of income and discuss a higher amount of co-participation from patients themselves. In addition, it would be suitable that, with the same detail as medicines, all expenses on the part of health insurance companies are assessed in the same way.

A significant topic in 2023 will be the issue of financing patient organisations. Patient organisations have come a long way in the last ten years. Thanks to their endless efforts, they have become an irreplaceable partner whose role in Czech healthcare is constantly growing. However, their financing is an ongoing acute problem. The Ministry of Health has stated that it will take specific steps in cooperation with the other departments, representatives of healthcare payers, and the professional and patient public. I hope that 2023 will bring the outlines of possible solutions.

At the legislative level, I hope that 2023 will bring changes at the level of the Act on Advertising Regulation concerning medicinal products. The fifteen-year-old legislation has not corresponded to today's digital times for a long while, not only due to the limitation on information provided by medicine manufacturers to the general public but also to nurses and other non-medical healthcare workers. I believe that healthcare staff should have available information about current treatments and treatment options. In the same way, I am convinced that if, in pre-set conditions, medicine producers are enabled to share a more comprehensive framework of information with the general public about the medicines they are developing and bringing to the market, it will contribute to an increase in the medical literacy of Czech patients.

Last but not least, 2023 is essential not only for the Czech healthcare system and the Czech Republic itself but also for our Association, which will celebrate its 30th anniversary. I am very pleased that the Association, which groups 35 international pharmaceutical companies with their own medicine research and development, has become an important, respected partner in the Czech healthcare system in the last three decades.

The anniversary of our establishment gives us the opportunity to consider the successes of innovative treatment, as well as the Association's activities and projects in the last three decades. It also provides a chance to formulate long-term visions for the future of modern patient treatment in the Czech Republic. We will be paying attention to these topics and others over the year.

In conclusion, I would like to thank you all for your cooperation and the beneficial discussions in the past year.
I am sure next year will bring several opportunities for joint meetings concerning essential topics
in Czech healthcare.

Mgr. David Kolář
Executive Director

ACKNOWLEDGEMENTS TO JAKUB DVOŘÁČEK

As of January 2022, Mgr. Jakub Dvořáček, MHA, LL.M. ceased to hold the position of Executive Director of AIFP, which he had held since 2011. During his tenure at the Association, a number of projects aimed at promoting the availability of innovative medicines in the Czech Republic, cultivating the Czech healthcare system or the necessary sectoral cooperation have been implemented. Over the past years, the Association has become a strong and respected partner for the Ministry of Health, health insurance companies, professional societies, patient organisations and many other stakeholders. We would like to thank Mr Dvořáček for his excellent achievements on behalf of the entire AIFP team, working groups and platforms and wish him every success in his personal and professional life.

REPORT ON FINANCIAL MANAGEMENT

The non-profit organisation AIFP is a voluntary Association of legal entities.

It is primarily financed from contributions by member companies.

Selected Data from Financial Statements (CZK '000)

REVENUES FOR 2022

Contributions received	**34,774**
• membership contributions received	26,565
• membership contributions received on APO side	8,209
Other revenues	**1,962**
• revenues on services – workshops, courses, specialist events	1,711
• additional other revenues	200
• revenues on sale of fixed assets	46
• interest	1
• FX gains	4
Total	**36,736**

COSTS FOR 2022

Purchases consumed	**22,831**
• consumption of material and energy	861
• repairs and maintenance	30
• travel expenses	966
• costs of representation	2,271
• other services	18,703
Payroll costs	**12,311**
Taxes and charges	**8**
Other costs	**409**
• FX losses	243
• gifts	95
• interest expense	0
• additional other costs	71
Depreciation, amortisation, and fixed assets sold	**340**
Contributions provided	**804**
Income tax	**0**
Total	**36,703**

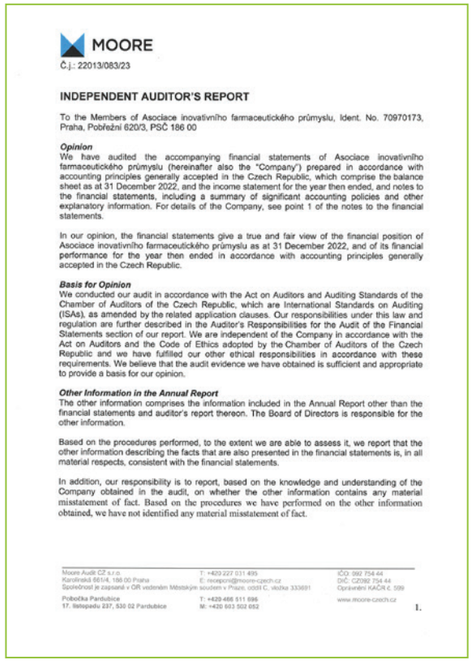
The complete financial statements are published in the Collection of Documents at the Associations Register maintained by the Municipal Court in Prague, Section L, entry 58517.

The profit for 2022 was 33,305.43 CZK, which, after approval by AIFP's General Meeting, will be transferred to the retained earnings (deficit) account.

Retained earnings total **604,823.64 CZK**

An auditor's opinion is an integral part of this annual report.

AUDITOR'S REPORT



MOORE

Č.j.: 22013/083/23

INDEPENDENT AUDITOR'S REPORT

To the Members of Asociace inovativního farmaceutického průmyslu, Ident. No. 70970173, Praha, Pobřežní 620/3, PSČ 186 00

Opinion
We have audited the accompanying financial statements of Asociace inovativního farmaceutického průmyslu (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 2022, 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 point 1 of the notes to the financial statements.

In our opinion, the financial statements give a true and fair view of the financial position of Asociace inovativního farmaceutického průmyslu as at 31 December 2022, 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.

Moore Audit CZ s.r.o. Karolinská 661/4, 186 00 Praha Společnost je zapsaná v OR vedeném Městským soudem v Praze, oddíl C, vložka 333691 | T: +420 227 031 495 E: recepce@moore-czech.cz | IČO: 092 754 44 DIČ: CZ092 754 44 Oprávnění KAČR č. 599 | Pobočka Pardubice 17. listopadu 237, 530 02 Pardubice T: +420 466 511 696 M: +420 603 502 652 www.moore-czech.cz 1.

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Č.j.: 22013/083/23

Responsibilities of the Company's Board of Directors, Supervisory Board 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.

The Supervisory Board is responsible for overseeing the Company's financial reporting process.

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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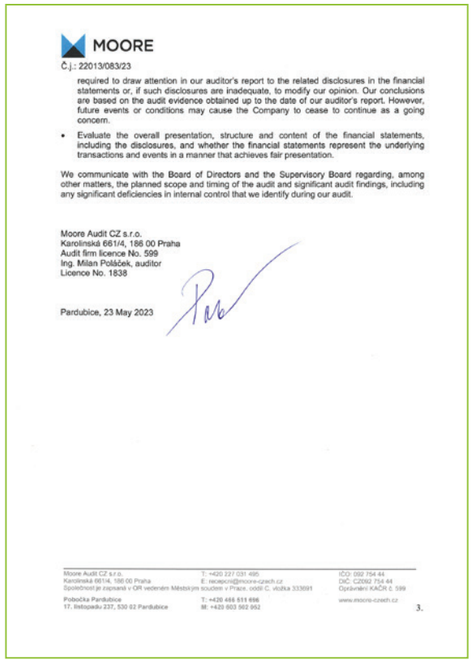

MOORE

Č.j.: 22013/083/23

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 and the Supervisory Board 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.

Moore Audit CZ s.r.o.
Karolinská 661/4, 186 00 Praha
Audit firm licence No. 599
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 23 May 2023

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CONTACT DETAILS

ASSOCIATION OF INNOVATIVE PHARMACEUTICAL INDUSTRY

Building IBC – Pobřežní 620/3
186 00 Prague 8

+420 277 004 291

www.aifp.cz

Founded on:	24 November 1993
Legal form:	A special-interest association of legal entities
ID No.:	70970173
TIN:	CZ70970173

Registered with the Associations Register maintained by the Municipal Court in Prague, Section L, file 58517

aifp
Asociace inovativního farmaceutického průmyslu