



Asociace inovativního
farmaceutického průmyslu

Association of Innovative Pharmaceutical Industry
Annual Report 2020

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A WORD OF INTRODUCTION

In 2020, the pharmaceutical industry responded to the new challenge in the form of the Covid-19 pandemic by an accelerated development, and its first vaccines were available within several months. I would like to thank all AIFP member companies for their help on the local level and their collaboration both with a number of academic institutions and many specialists and volunteers. The result of our work are safe and effective vaccines as well as the first medicinal products against the new type of coronavirus that significantly improve patients' survival and quality of life.

Speaking of the pandemic, let's not forget the many patients who suffer from serious diseases that have not only a higher mortality rate, but also serious effects on the quality of their life. The healthcare system in the CR must effectively respond to their current needs and to pay attention to patients whose life is at risk as well as to patients who have chronic or rare diseases. It is because due to the Covid-19 pandemic, some patients had to wait for their treatment or already scheduled surgery. It is evident that the availability of medicinal products and the treatment rate significantly mitigate the negative impact of the pandemic. A population with access to good-quality healthcare responds better to unexpected pandemics such as the SARS-CoV-2 pandemic. It is therefore crucial to amend Act no. 48/1997 of Coll., on public health insurance, which will allow a timely entry of innovative medicinal products and their blanket availability. It is also necessary to change the cooperation of the pharmaceutical industry and health insurance companies and to respond to new types of medicinal products. This is why we must work together on new contractual schemes that will reduce the uncertainty of both healthcare payers and patients.

We should also reevaluate how the Czech Republic cooperates within Europe and how its cross-border cooperation is set up and we must be able to quickly respond in terms of logistics to make sure that medicinal products for Czech patients are given to Czech patients. The availability of healthcare and treatment affects the national economy in a fundamental way. The treatment rate of the population and a speedy response to vaccination needs, testing and diagnostics have a major impact on the Czech economy and employment. Moreover, the Czech economy is interconnected with the global economy in terms of logistics and supplies, and a failure to quickly respond to healthcare needs and challenges will have a major negative impact both on the competitiveness of the Czech economy and on employment, and in the end on healthcare financing as well.

Every year the pharmaceutical industry of the CR spends approximately 2 billion CZK on the implementation of clinical trials, and to increase competitiveness the Czech Republic should create an agile and transparent environment that would facilitate an effective transfer of know-how from the academic sphere to the pharmaceutical industry as well as applied research and the implementation of clinical trials in healthcare facilities. Patients and physicians could thus benefit from clinical trials even more. This is why a higher availability of approved medicinal products can guarantee the continuity of modern healthcare.

The Czech Republic has interesting pharmaceutical research and development, but their further progress depends on the ability to sign contracts, on an adequate response to ideas coming from the pharmaceutical industry as well as on the development of digitalization, interconnection and work with medical data not only in research and development. I believe that in the future we will be able to create a more open and flexible environment that will become a vital solution for the development and cultivation of healthcare in the CR.



MUDr. Martin Minarovič, MBA
Janson CEO for the Czech Republic,
Chair of the AIFP Board of Directors



Mgr. Jakub Dvořáček, MHA, LL.M.
AIFP Executive Director

THE PHARMACEUTICAL MARKET 2020

Methodology:

Due to the absence of data on the website of the State Institute for Drug Control (SIDC), we analyzed IQVIA's data from 2019 and 2020. These data are shown in units (packs) and in values without margins and VAT and are based on distributors' reports. Therefore, the data do not include confidential discounts provided between MAHs and health insurance companies.

Results:

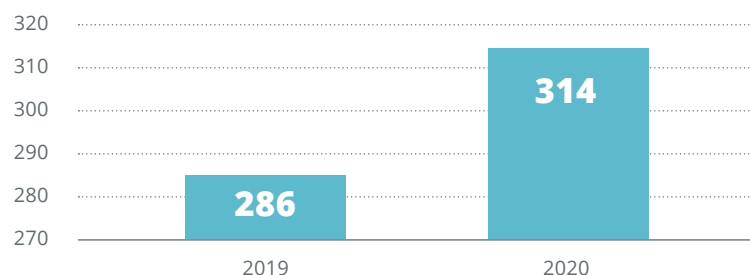
Last year, the overall market (including infusion solutions) dropped by 4.5% in packs and went up by 4.96% in values.

The overall pharmaceutical market in 2020 vs. 2019

MARKET	2019	2020	GR
Units (+000)	324,763.54	310,157.73	-4.50%
Values (+000)	92,900,649	97,504,204	4.96%

The average price per pack shows a 9.9% year-on-year increase – from 286 CZK in 2019 to 314 CZK in 2020.

The trend in average price per pack (2019 and 2020)



The OTC market dropped in terms of both the number of packs and values. The drop in the number of units is about double as compared to the percentage drop in values.

The OTC market 2020 vs. 2019

OTC	2019	2020	GR
Units (+000)	114,771.34	107,734.36	-6.13%
Values (+000)	11,924,512	11,548,689	-3.15%

The Rx market slightly dropped in terms of the number of units, but went up by 6.2% in terms of values.

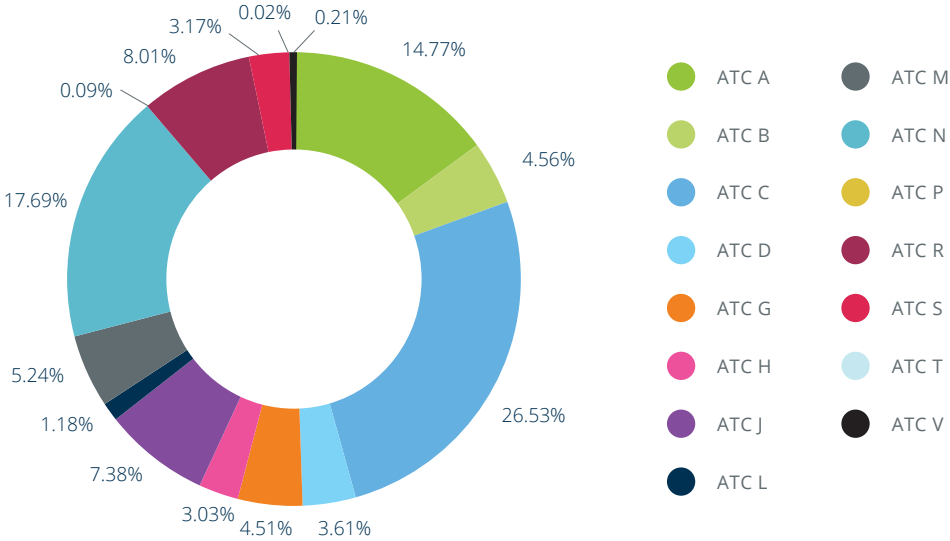
The Rx market 2020 vs. 2019

Rx	2019	2020	GR
Units (+000)	209,196.55	201,756.17	-3.56%
Values (+000)	80,605,568	85,601,408	6.20%

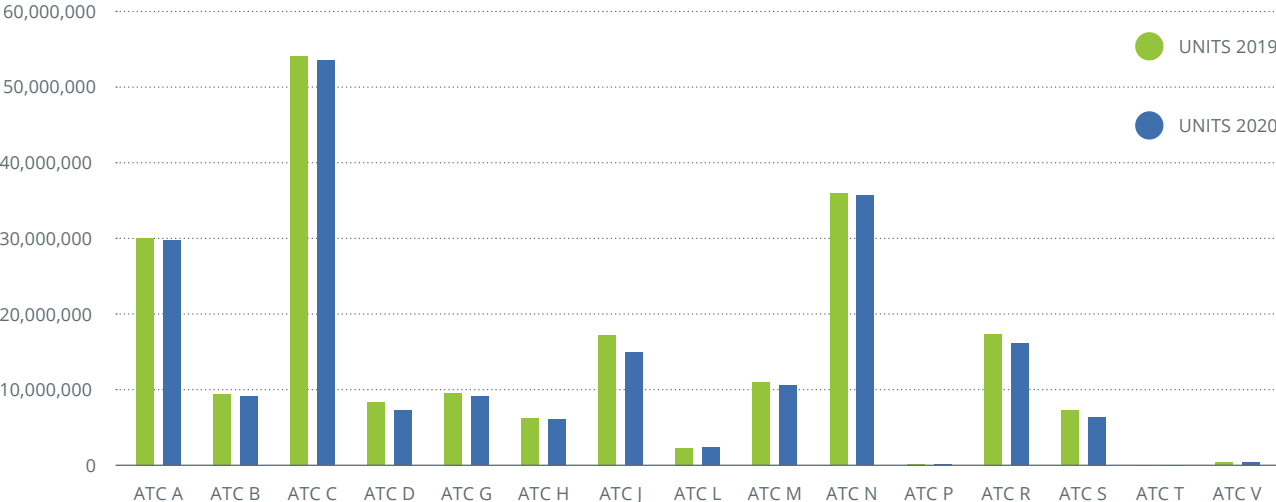
The number of units in individual ATC groups between 2020 and 2019 dropped, with the exception of group L that shows a slight increase (+3.6%). We can see a major drop in the number of units in group J (-13.6%) and in group D (-12.2%).

The table below shows the distribution and size of individual ATC group in terms of the number of units in 2020. The highest number of packs shows group C (26.5%), group N (17.7%) and group A (14.8%).

The distribution of units by ATC group (2020)

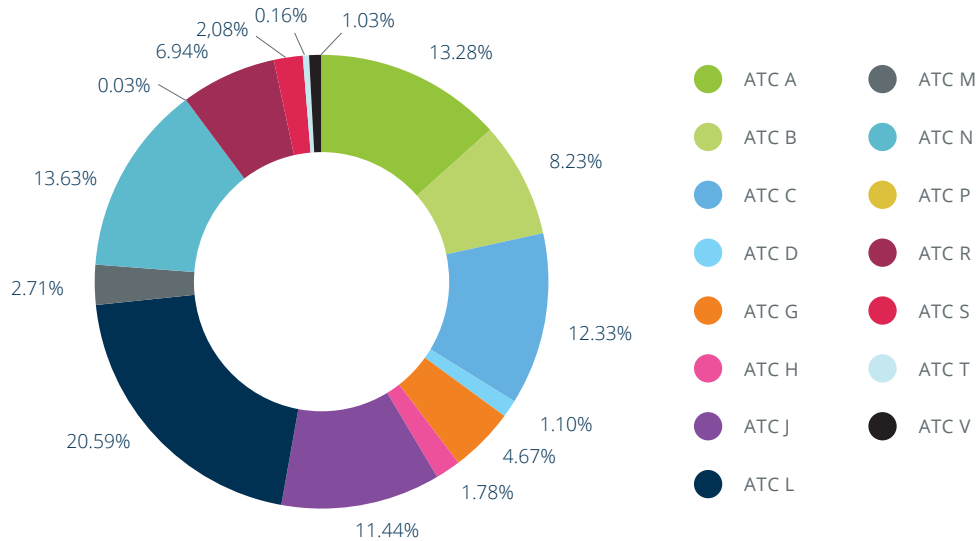


The number of units in 2020 vs. 2019 by ATC group



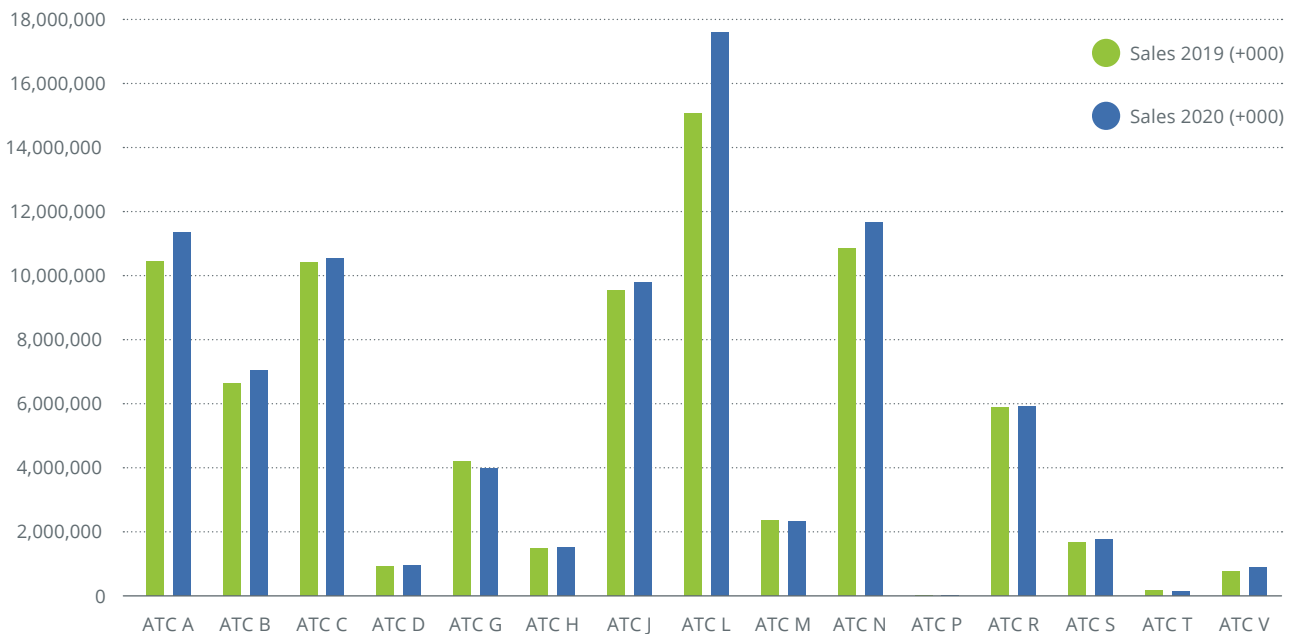
The biggest group in terms of values (CZK+000) was group L representing 20.6% of the overall market. It was followed by group N (with its 13.6% market share), group A (13.3%) and group C (12.3%).

The distribution in values by ATC group (2020)



A major year-on-year increase shows group L (16.8%), group V (14.8%) and group A (8.6%)¹. Other groups show either an increase that is lower than that of the overall market or a decrease.

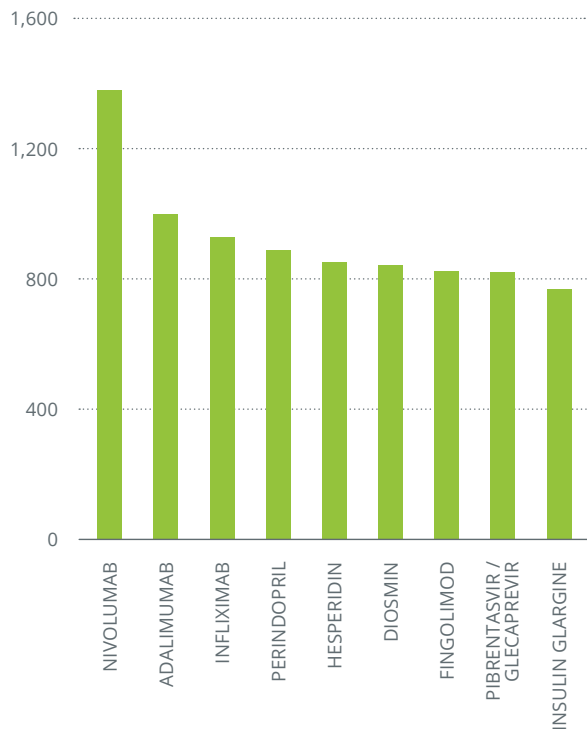
Sales in CZK by ATC group 2020 vs 2019



¹ The year-on-year change in CZK does not include confidential agreements between MAHs and health insurance companies. Therefore, the growth may be overestimated.

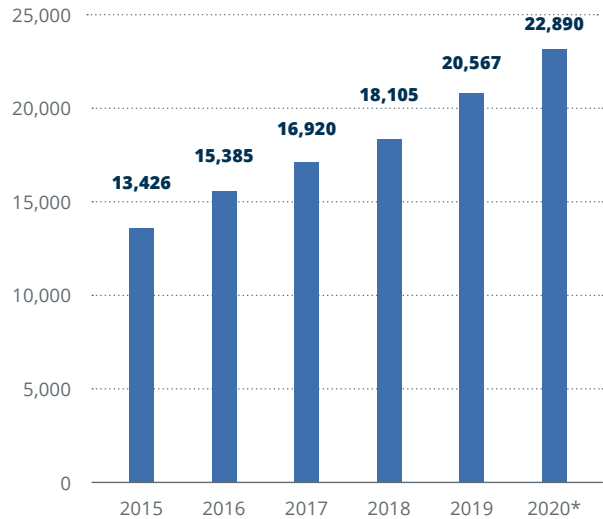
The first 10 molecules represent 9.6% of the overall Rx market.

TOP 10 molecules in CZK in 2020



The increase in medicinal products used in “centers with a special agreement” continues. It was about an 11% increase.

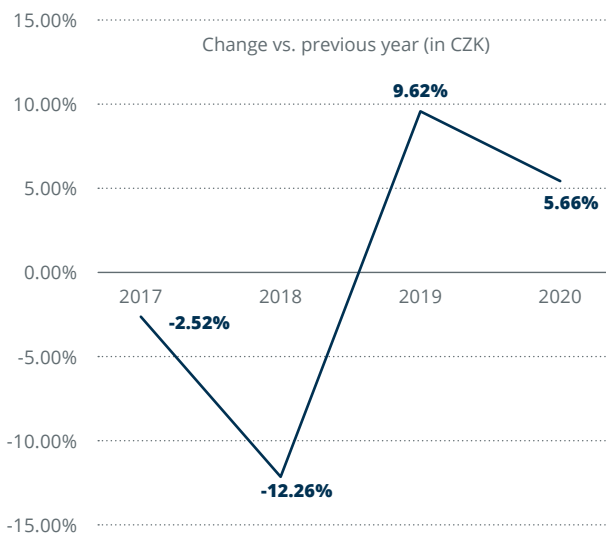
The cost of treatment in centers with a special agreement in 2015–2020



* Estimated costs based on available data

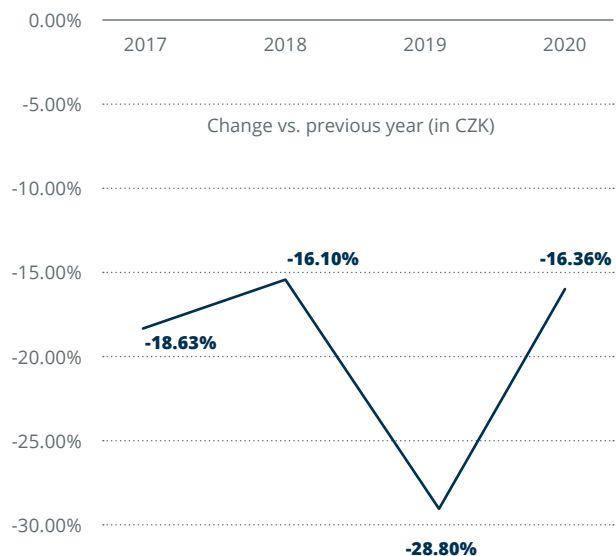
Parallel exports have been stagnating at about 4 billion CZK since 2016.

A year-on-year change in parallel exports in 2016–2020 (source: Sprinx)



Parallel imports have been decreasing since 2016. In 2020 they are estimated at 136 million CZK. A considerable part of parallel imports includes non-reimbursed medicinal products (e.g. hormonal contraceptives).

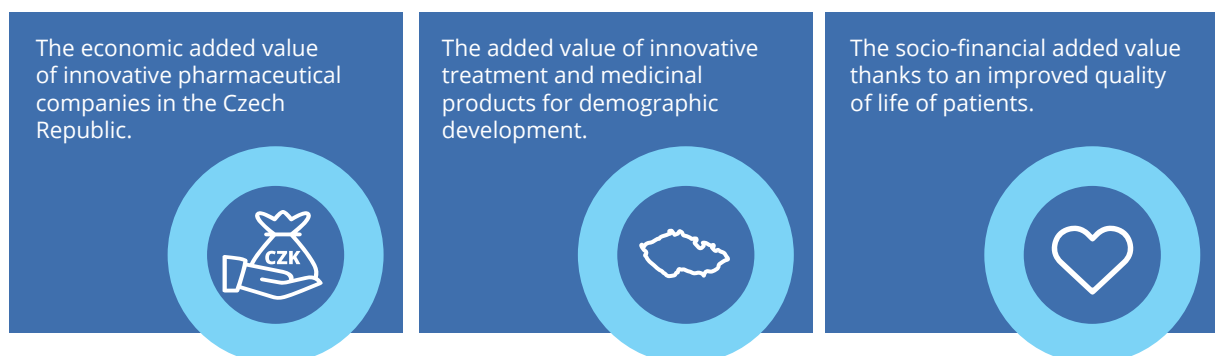
A year-on-year change in parallel imports in 2016–2020 (source: Sprinx)



THE IMPACT OF THE INNOVATIVE PHARMACEUTICAL INDUSTRY IN THE CR

“MEDICINAL PRODUCTS CANNOT BE CONSIDERED A ONE-OFF EXPENSE, BUT RATHER AN INVESTMENT. IT IS IMPORTANT TO HAVE A REALISTIC VIEW OF THE WHOLE SPECTRUM OF EXPENSES – NOT ONLY HEALTHCARE EXPENSES, BUT ESPECIALLY EXPENSES IN TERMS OF THE SOCIAL SECURITY BUDGET AND PENSION INSURANCE.”

Mgr. Jakub Dvořáček, MHA, LL.M.,
executive director of the Association of Pharmaceutical Industry (AIFP).



The economic benefits of the innovative pharmaceutical industry have significantly increased in the past years in terms of both its contribution to the GDP and the employment rate.









“THE ECONOMIC IMPACT OF THE INNOVATIVE PHARMACEUTICAL INDUSTRY SIGNIFICANTLY INCREASED BETWEEN THE YEARS 2010 AND 2018 IN TERMS OF BOTH ITS CONTRIBUTION TO THE GDP AND EMPLOYMENT. WITH ITS ACTIVITIES AND INVESTMENTS, THE INNOVATIVE PHARMACEUTICAL INDUSTRY GENERATES A TOTAL TURNOVER OF 42 BILLION CZK WITH A RELATIVELY HIGH MULTIPLIER EFFECT.”

Ing. Miroslav Zámečník,
a macroeconomist and a former member of the National Economic Council of the Government (NERV)

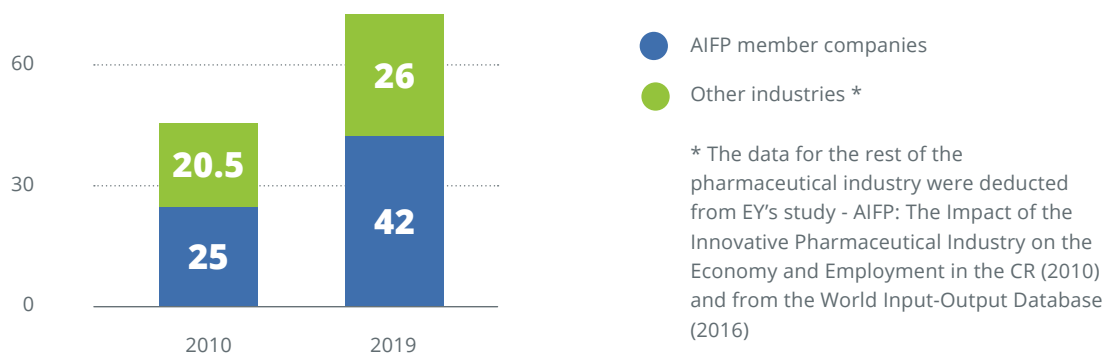
The multiplier effect of the pharmaceutical industry is 2.4. Every Czech Crown spent by innovative pharmaceutical companies generates an additional 2.4 Czech Crowns in the national economy. The contribution of the innovative pharmaceutical industry is thus comparable to that of information technologies (coefficient 2.3), chemicals production (coefficient 2.5) and telecommunications (coefficient 2.1).

A COMPARISON OF ECONOMIC MULTIPLIER EFFECTS WITH OTHER INDUSTRIES IN THE CZECH REPUBLIC

Financial services		→	4.3	Production of computers, electronics and optical machines and equipment		→	2.3
Chemical production		→	2.5	Architectural and engineering services		→	2.2
Pharmaceutical industry		→	2.4	Telecommunications		→	2.1

THE ECONOMIC PRODUCTION OF AIFP MEMBERS HAS ALMOST DOUBLED SINCE 2010

Induced turnover of the entire pharmaceutical industry in the CR (in millions of CZK)

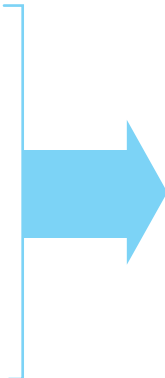


The pharmaceutical industry **has a potential to drive the Czech economy** twice as fast as in comparison to the nominal growth of the GDP. The transformation of the sector from production and marketing to **research and development** could fuel the further growth of the pharmaceutical industry.

AIFP MEMBER COMPANIES' COSTS EXCEED 18 BILLION CZK JUST IN THE CR

Costs put up by AIFP member companies in the CR in 2019

- Employee costs 7.3 billion CZK**
- Payments to the state 3.1 billion CZK**
- Services 3 billion CZK**
- Marketing and sale 1.3 billion CZK**
- Other costs 3 billion CZK**



The total costs put up in the CR in 2019 amounted to 18 billion CZK

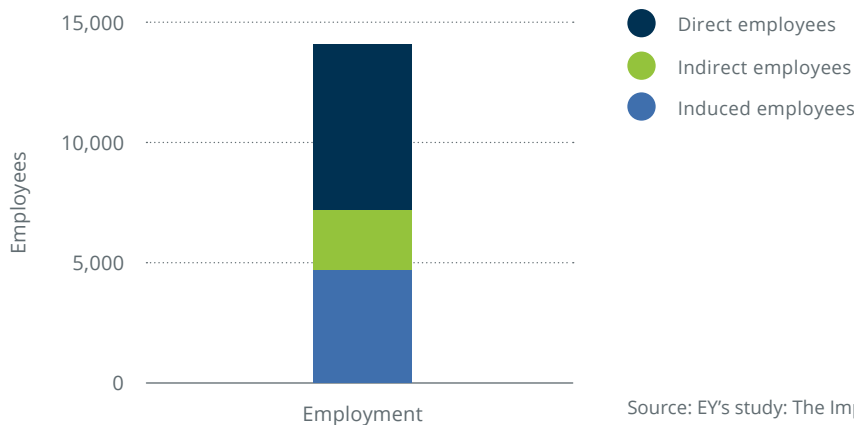


This sum was reflected in the economy and created an additional turnover of 42 billion CZK in the Czech Republic.

The innovative pharmaceutical industry creates about **14,500 jobs**, and more jobs are being created. Of these, more than **7,000 are direct jobs**, another **7,000 are indirect jobs** (employees of the suppliers of AIFP member companies) and **induced jobs** (jobs created based on expenditures of direct, indirect and state employees).



THE INNOVATIVE PHARMACEUTICAL INDUSTRY CREATES ABOUT 14,500 JOBS

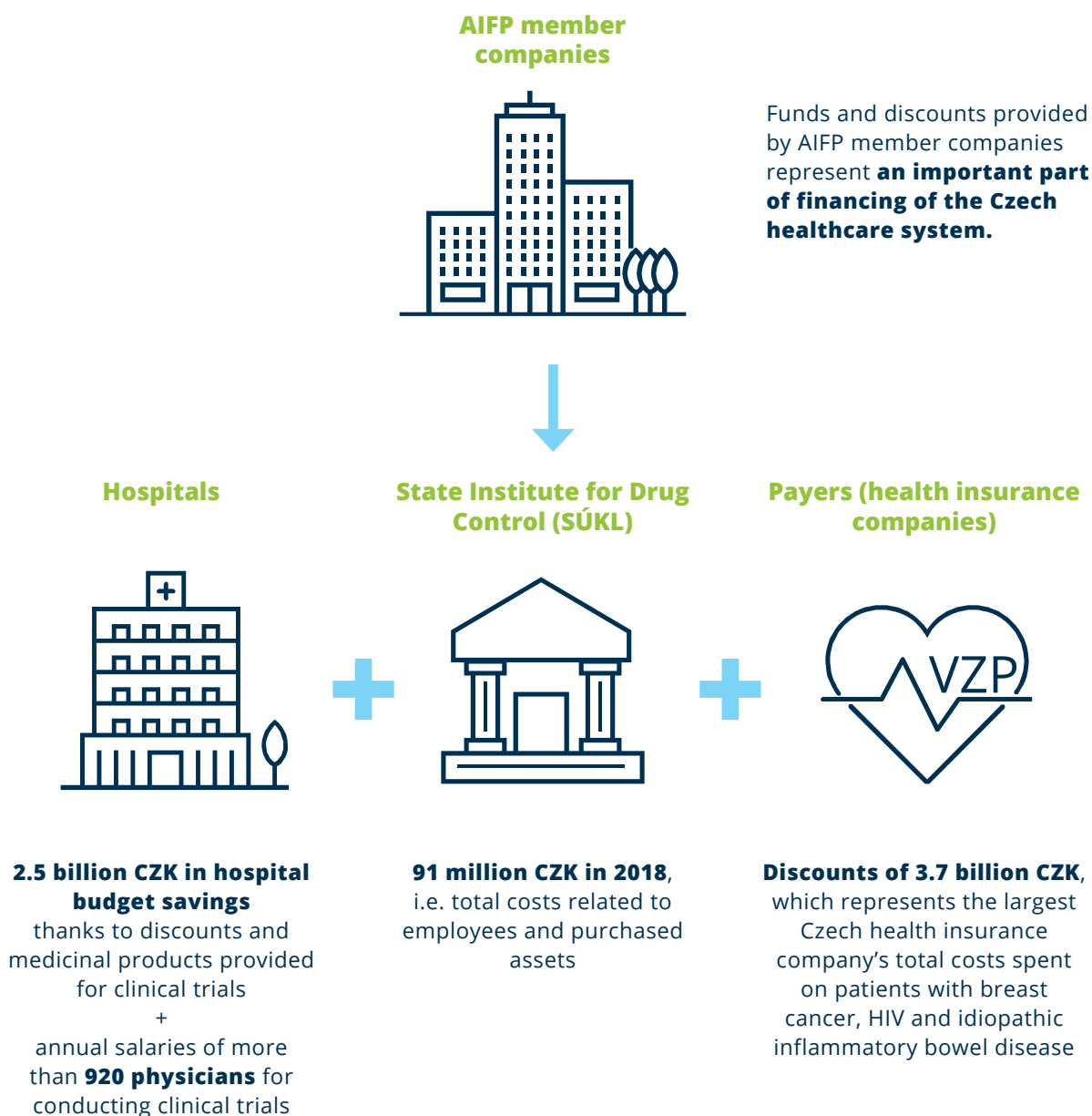


Source: EY's study: The Impact of the Innovative Pharmaceutical Industry on the Economy and Employment in the CR (2019)

Innovative activities also have an impact on other stakeholders, such as hospitals, health insurance companies and the State Institute for Drug Control (SÚKL). Actual costs, discounts and support measures of innovative pharmaceutical companies represent an important supplementary source of their financing.

AIFP MEMBER COMPANIES GENERATE BENEFITS FOR HEALTHCARE PARTICIPANTS

Actual costs, discounts and support measures of innovative pharmaceutical companies in connection with their activities represent an important source of financing of Czech hospitals and healthcare.



CHALLENGES AND OPPORTUNITIES IN INNOVATIVE TREATMENT



CHALLENGES

Most applications for marketing medicinal products are not decided on by the deadline stipulated by law, and the availability of innovative medicinal products thus diminishes, specifically less than 40% of applications are decided on time.

Obsolete legislation regulating the entry of medicinal products in the reimbursement system, as well as the growing number of patients who depend on individually approved reimbursement based on Section 16, creates pressure on finding a new way of entry for innovative medicinal products.

The number of newly started clinical trials conducted in the Czech Republic in 2019 went up on a year-on-year basis. The number of new clinical trials started by local entities went up from 67 in 2017 to 85 in 2019.

The number of newly started clinical trials conducted in the Czech Republic is slowly decreasing. The number of new clinical trials started by local entities dropped from 81 in 2015 to 67 in 2017.



OPPORTUNITIES

The regulatory environment for research and development is undergoing major changes related to necessary changes in laws.

The quality of the research infrastructure keeps improving, and the number of R&D workplaces keeps increasing.

The Czech education system and the scientific community produce the most recognized specialists.

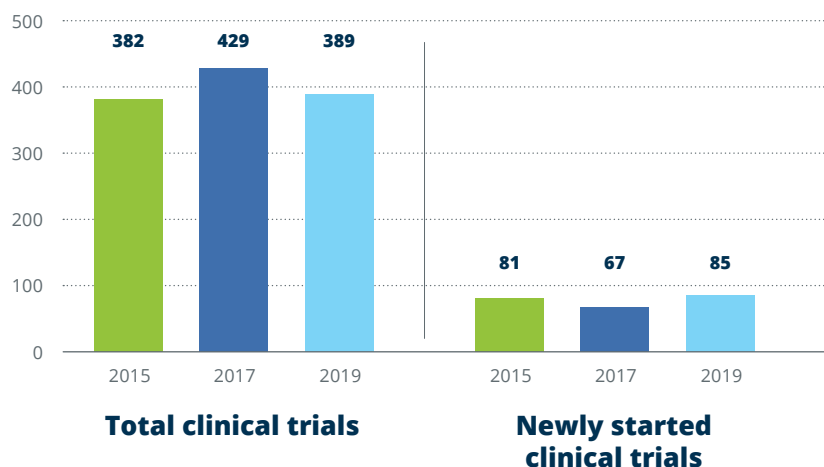
CLINICAL TRIALS

“THE TOTAL NUMBER OF CLINICAL TRIALS DROPPED, BUT THE PERCENTAGE OF CLINICAL TRIALS FOCUSED ON PERSONALIZED TREATMENT WENT UP. THE SUCCESSFUL IMPLEMENTATION OF COMPLICATED CLINICAL TRIALS REQUIRES BIGGER INVOLVEMENT OF HOSPITALS. THE STATE SHOULD SUPPORT THE COOPERATION OF HOSPITALS AND PHARMACEUTICAL COMPANIES BY PROVIDING A FRAMEWORK THAT WILL CREATE CONDITIONS FOR FASTER APPROVAL OF CLINICAL TRIALS.”

Mgr. Jakub Dvořáček, MHA, LL.M.,
executive director of the Association of Pharmaceutical Industry (AIFP)

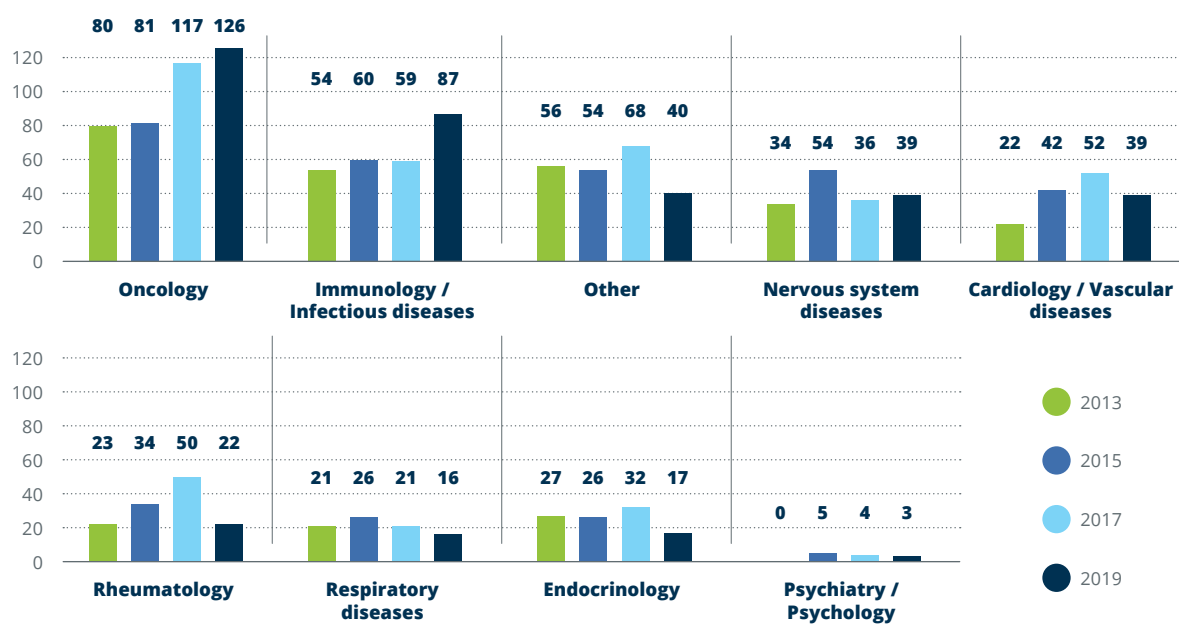
The total number of conducted clinical trials went down from 429 in 2017 to 389 in 2019, which represents an almost 5% year-on-year drop. Just like between 2015 and 2017, the total average number of clinical trials per company continued to drop – by one clinical trial. On the other hand, the number of new clinical trials went up by 12.6% as compared to 2017. The percentage of new clinical trials on the total number exceeded 20% just like in 2015, which is a positive trend.

Clinical trials conducted in the CR

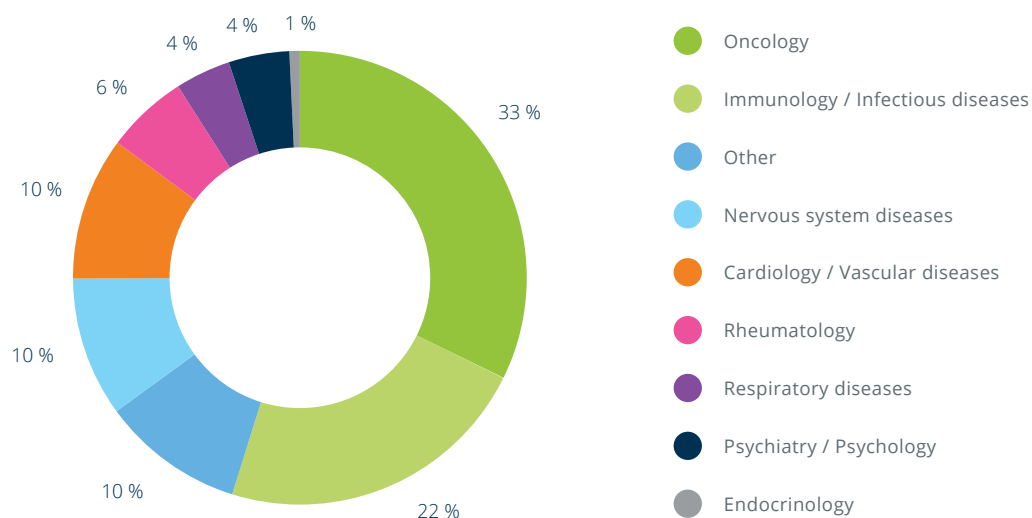


The nature of clinical trials in the CR has been changing for some time now. Clinical trials of blanket therapeutic areas shifted toward clinical trials focused on highly specified diagnoses and personalized treatment. This is reflected in an increase in clinical trials in oncology and immunology, where research focuses on rare diseases or diseases requiring a personalized approach.

Total conducted clinical trials by therapeutic area during 2013–2019



The structure of conducted clinical trials by therapeutic area in 2019

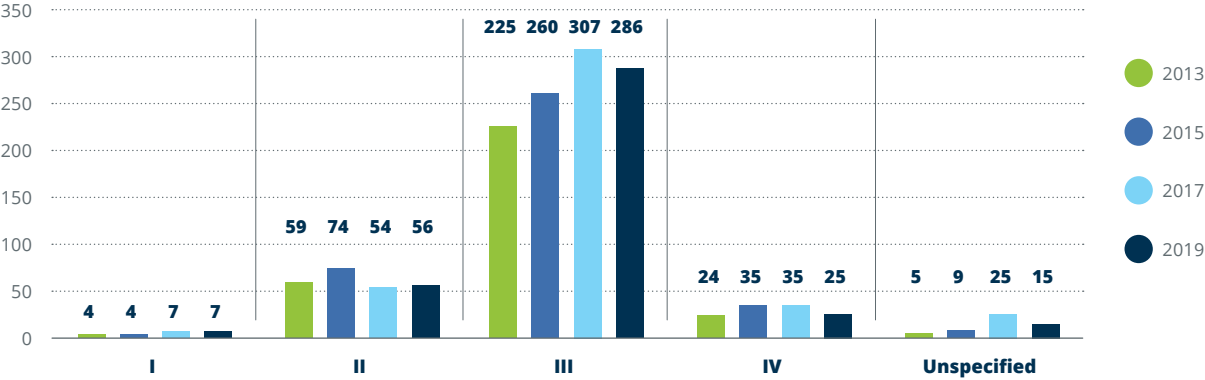


“ONCOLOGY AND IMMUNOLOGY SURPASS THE REST OF THE THERAPEUTIC AREAS IN TERMS OF THE NUMBER OF CLINICAL TRIALS. IN 2019, ONCOLOGY TRIALS REPRESENTED ONE-THIRD OF ALL CLINICAL TRIALS AND, TOGETHER WITH IMMUNOLOGY AND INFECTIOUS DISEASES TRIALS, AMOUNTED TO 55% OF ALL CLINICAL TRIALS IN THE CR.”

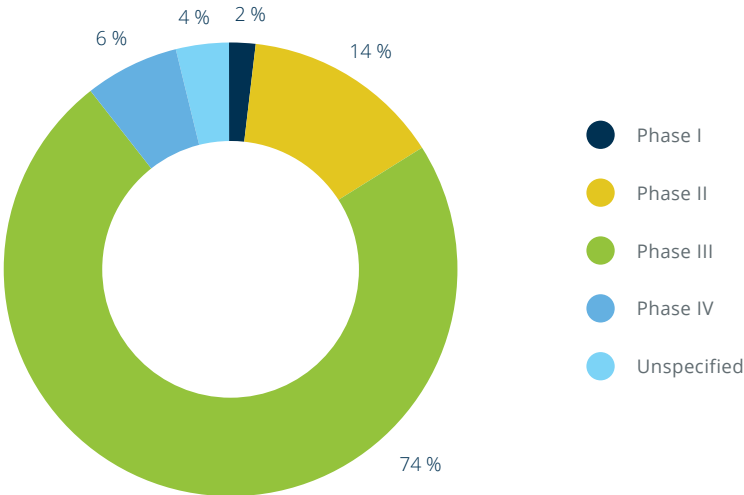
Mgr. Jakub Dvořáček, MHA, LL.M.,
executive director of the Association of Pharmaceutical Industry (AIFP)

Phase III still remains by far the most common phase in terms of the total number of clinical trials in the CR. Although its number of clinical trials dropped as compared to 2017, its percentage on the total number in the given year keeps increasing in the long run. Phase I and Phase II stagnated as compared to 2017.

The number of conducted clinical trials by phase during 2013-2019

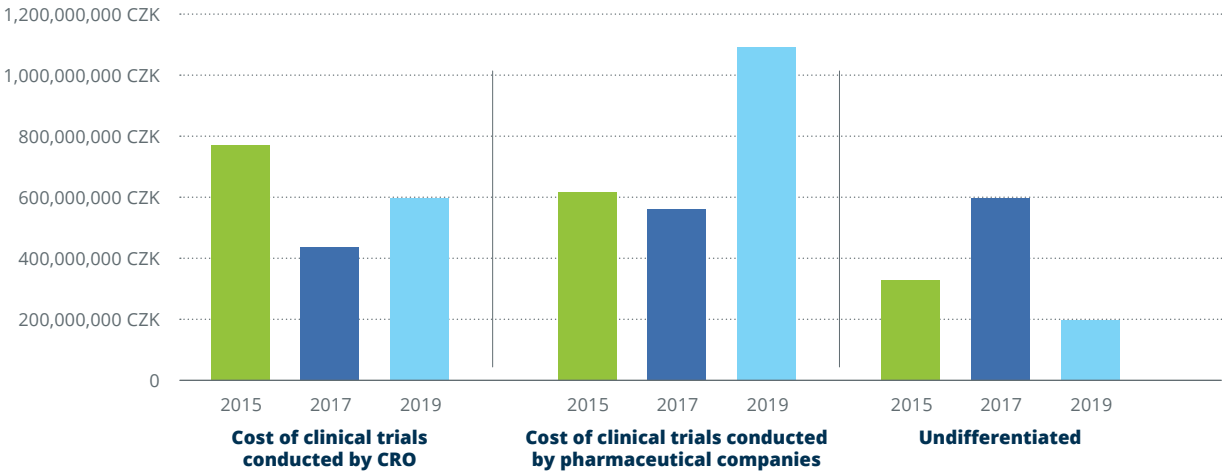


The structure of conducted clinical trials by phase in the CR during 2019



The cost of clinical trials went up as compared to 2015 and 2017.

The cost of clinical trials



The activity of AIFP member companies saved 305 million CZK in the cost of treatment paid from public budgets. This however concerns only a part of the mentioned clinical trials. **If we extrapolate this number based on the total number of patients, the total costs saved thanks to the involvement of patients in clinical trials will amount to about 1.5 to 1.6 billion CZK.**

Saved treatment costs

**1.5 to 1.6
billion CZK**



STEPS NECESSARY TO SUPPORT THE DEVELOPMENT OF CLINICAL TRIALS IN THE CR

“CLINICAL TRIALS PROVIDE HOSPITALS WITH MANY BENEFITS THAT CAN BE EVEN HIGHER IF THE IMPLEMENTATION OF CLINICAL TRIALS IS REGUALTED BY THE MINISTRY OF HEALTH’S INSTRUCTION. IT IS IMPORTANT TO CONSIDERABLY SHORTEN THE TIME OF FINALIZATION OF THE CONTRACT BETWEEN A HEALTHCARE FACILITY AND THE PHARMACEUTICAL INDUSTRY. TO MAKE CLINICAL TRIALS IN THE CR COMPETITIVE, IT IS NECESSARY TO FURTHER DEVELOP THE ELECTRONIZATION OF CZECH HEALTHCARE AND TO COOPERATE IN CONNECTING IT WITH THE PHARMACEUTICAL INDUSTRY.”

Mgr. Jakub Dvořáček, MHA, LL.M.,
executive director of the Association of Pharmaceutical Industry (AIFP)

1

The state support in the form of an implemented practical procedure – a methodological instruction that would define the start and execution of clinical trials.

2

The definition and implementation of the clinical Project Management Office in hospitals that would be in charge of organizing clinical trials.

3

An effective dialog with representatives of healthcare facilities, in particular with university hospitals and specialized centers.

4

The effort of pharmaceutical companies in the CR to assume the execution of clinical trials that, due to Covid-19 pandemic measures, could not be conducted in other states.

ACADEMY OF PATIENT ORGANIZATIONS



100+
patient organizations



18
APO seminars



4
mentors
of individual
consultations



26
patient
organizations



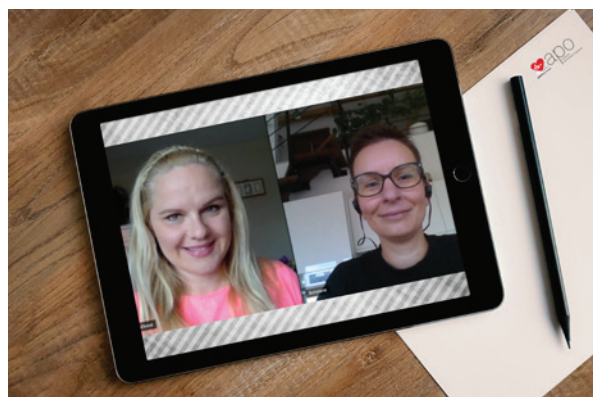
95
hours
in total

The Academy of Patient Organizations (APO) is an educational and networking project designed for Czech patient organizations. Even though the year 2020 was very much affected by the global Covid-19 pandemic, the APO was able to quickly adapt to the new situation and to move its support of patient organizations and the majority of its activities, seminars, individual consultations and conferences from offline to online. The AIFP hosted in July a personal networking meeting of patient organizations associated in the APO called “International Cooperation Benefits” and in August a round table discussion, during which the results of the analysis “The Role of Patient Organizations in Czech Healthcare”, including the impact of the Covid-19 pandemic on these organizations, were presented.

Thanks to the wonderful IT support, it was possible not only to hold all events scheduled for 2020 but also to add other seminars on topical pandemic-related issues, such as “Digital Transformation,” “How to Work with the Teams Platform” and many others. And so even in 2020, patient representatives were able to obtain help and support in handling many problems and pitfalls concerning fundraising, PR, non-profit organization management, accounting, law and also international cooperation.



Online seminars



Online individual consultations

APO NETWORKING II

On 31 July 2020, the AIFP hosted a networking meeting of patient organizations associated in the APO called "International Cooperation Benefits." It was also possible to participate online. Representatives of patient organizations presented their international cooperation and its benefits. They shared their experience with contacting foreign experts, using the sources and expertise of foreign organizations and organizing or participating in international projects.

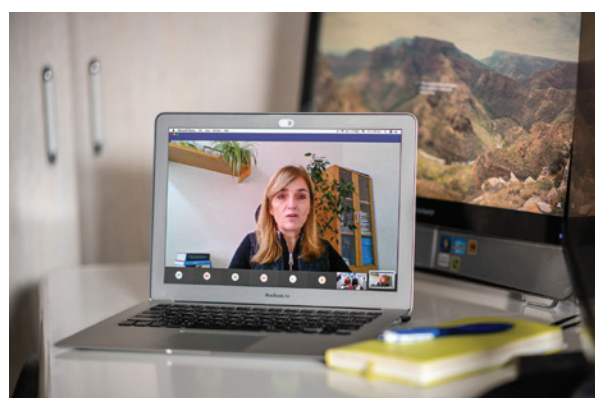
A ROUND TABLE ABOUT THE FUTUE OF PATIENT ORGANIZATIONS IN THE CR

On 25 August 2020, the Healthcare and Social Policy Committee of the Czech Parliament (Senate) organized a round table discussion, during which the results of the analysis "The Role of Patient Organizations in Czech Healthcare", including the impact of the Covid-19 pandemic on patient organizations, were presented. The analysis was conducted by Ernst & Young based on the request of representatives of the Patient Council of the Ministry of Health of the CR.



APO ONLINE CONFERENCE "TELEMEDICINE"

The Academy of Patient Organizations organized a unique online conference which took place on 27 November 2020 and during which the aspects, legislative framework and practical use of telemedicine were discussed. The APO will continue with the telemedicine topic in 2021 as well.



GOALS

Support of independence of Czech patient organizations

Facilitation of the long-term development of patient organizations

Assistance with an effective acquisition of funds from Czech and European sources

Improvement of presentation and negotiation skills of patient organizations

Improvement of the quality of internal processes and financing transparency

Effective use of the Internet and social media

Explanation of legal procedures, patient rights and obligations

The activity of the APO in the AIFP is organized and coordinated by Manager Mgr. Zuzana Komárková.



www.pacientskaakademie.cz



Akademie pacientských organizací

COMMUNICATION WITH THE PUBLIC

THE AIFP IN THE MEDIA IN 2020

644

citations
in media
articles



36

citations
in television
broadcasting



35

citations
in radio
broadcasting



114

citations
in printed
media



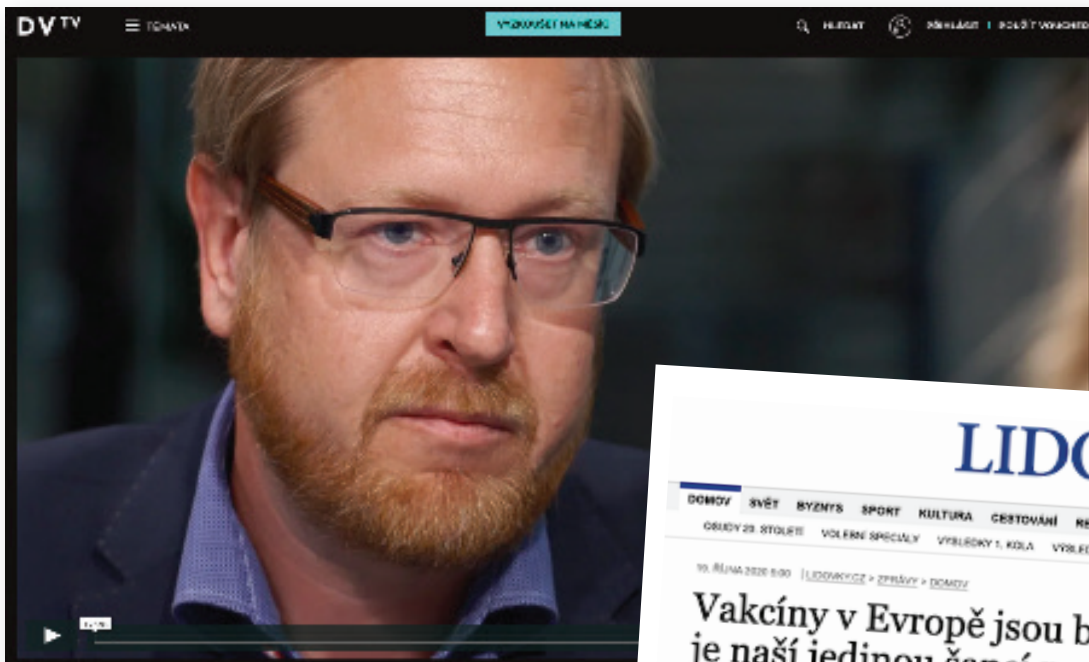
5

organized
press
conferences



1. Medicinal products for rare diseases – scleroderma + cystic fibrosis
2. Prostate and breast cancer
3. Diabetes
4. Vaccines – a drop in vaccination due to Covid-19
5. Rheumatoid arthritis





LIDOVKY.cz

DOMOV SVĚT BYZNYS SPORŤ KULTURA CESTOVÁNÍ RELAX DESIGN DOBRÁ CHUŤ MÁZOKY LIDÉ VIDEO

OBLEDY 20. STOLETÍ VOLBY SPECIÁLY VÝSLEDKY 1. KOLA VÝSLEDKY 2. KOLA ARCHIV ZPRÁV LN PŘED 100 LETY SAMIZDAROVÉ

10. ŘÍJNA 2020 9:00 | LIDOVKY.cz > ZPRÁVY > DOMOV

Vakcíny v Evropě jsou bezpečné, očkování je naší jedinou šancí proti viru, tvrdí šéf farmaceutického průmyslu Dvořáček

JAKUB DVOŘÁČEK (44) VEDE OD ROKU 2011 ASOCIACI INOVATIVNÍHO FARMACEUTICKÉHO PRŮMYSLU. FOTO: TWITTER/ANGEL DVOŘÁČEK, REPRÓ-FOTO

Když se nám povede proočkovat 75 až 80 procent populace, koronavirus potlačíme, říká v rozhovoru pro Lidovky.cz šéf Asociace inovativního farmaceutického průmyslu Jakub Dvořáček. Vakcína přitom funguje podobně jako rouška – nechrání jen naočkovaného, ale i ostatní. Třeba onkologicky nemocné, kteří vakcinaci podstoupit nemohou.

ČTK ČESKÉ NOVINY

KORONAVIRUS: Zprávy Milníky epidemie v ČR Foto z ČR Foto

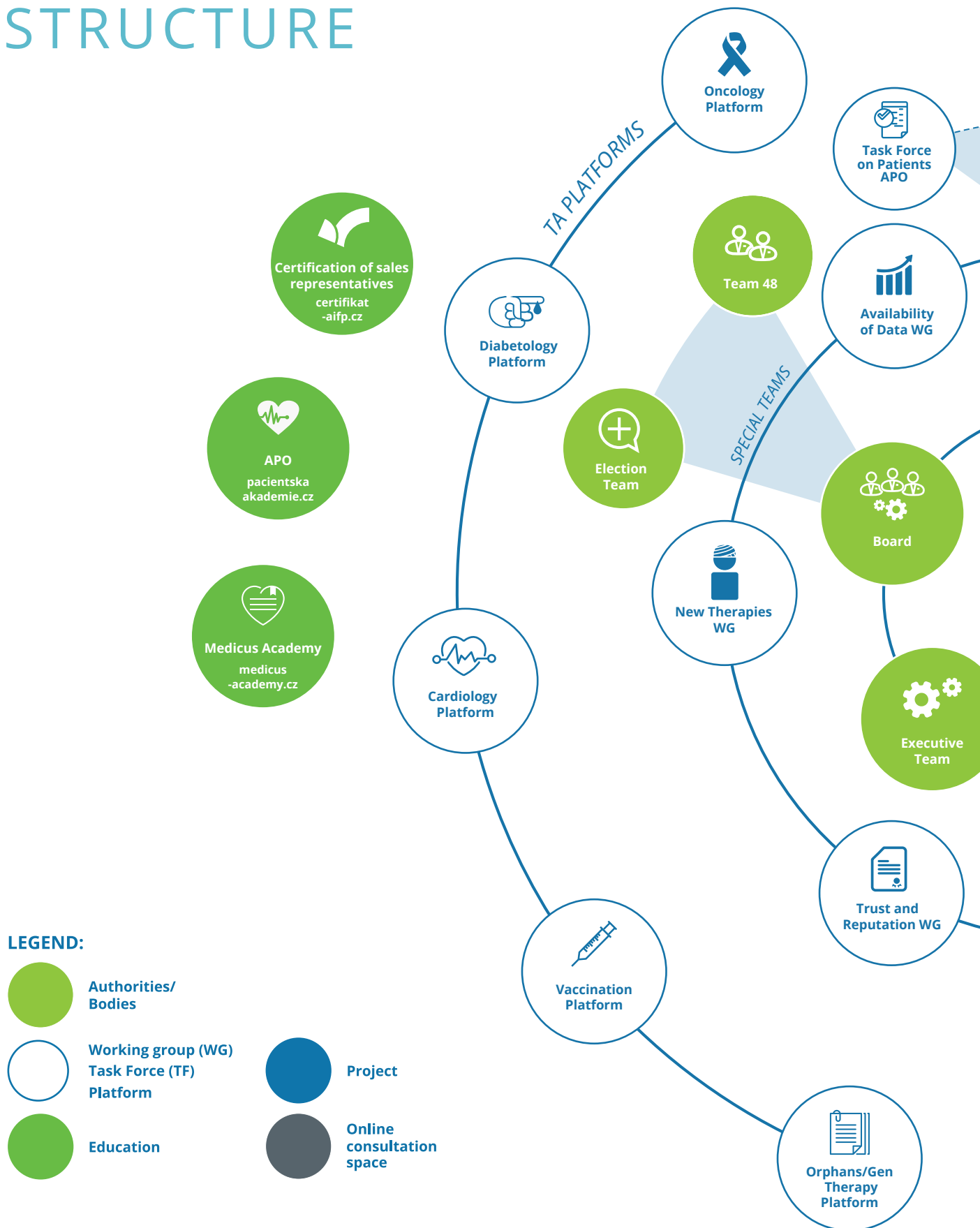
Budou letos léky pro vzácná onemocnění dostupnější?

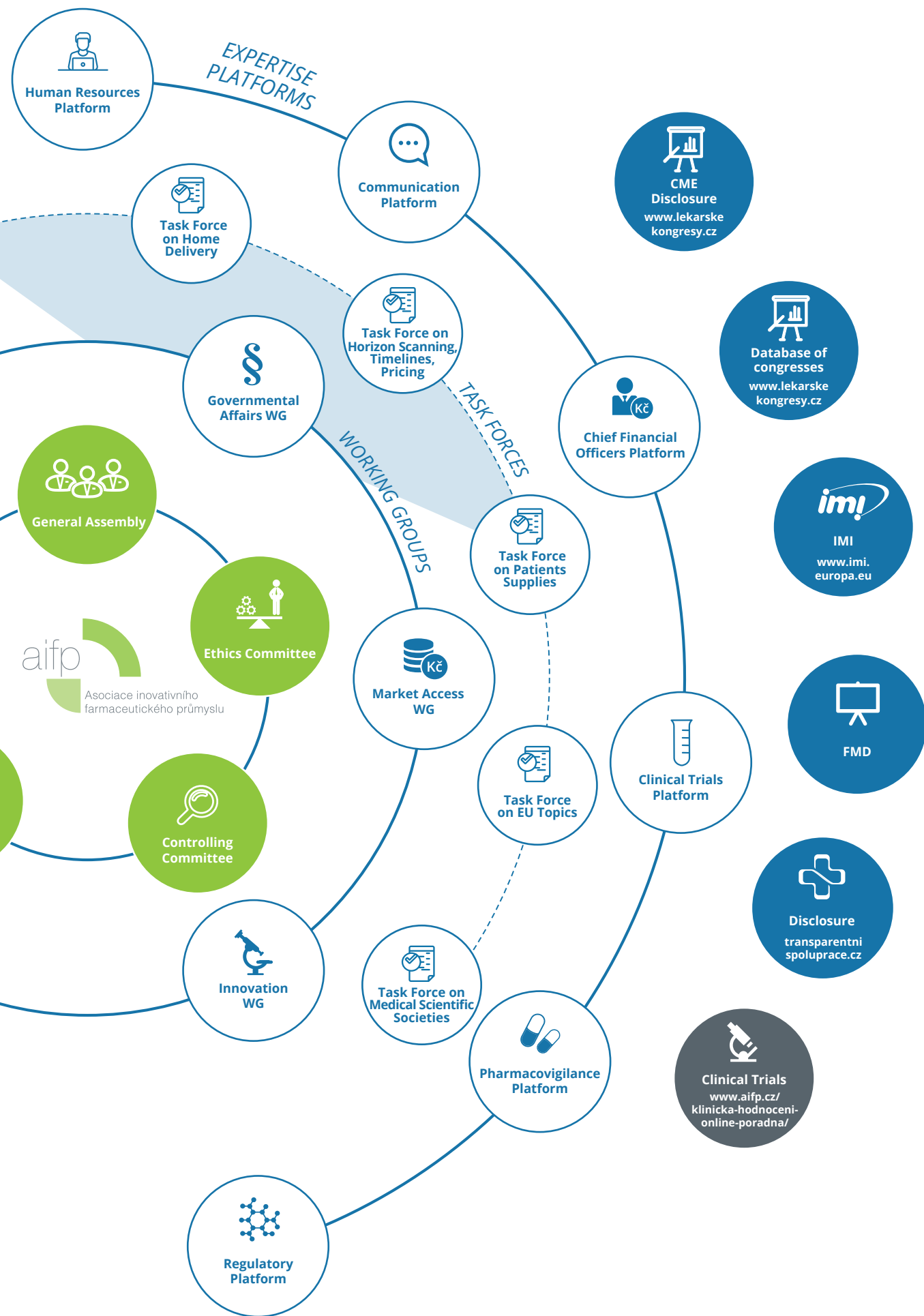
Aktualizace: 22.01.2020 11:01 Vydáno: 22.01.2020, 10:55

PR/

Léčivé přípravky na vzácná onemocnění jsou vysoce inovativní, nákladné léky pro úzké skupiny pacientů. Každoročně jich jsou ve vývoji desítky, jejich dostupnost je však pro české pacienty komplikovaná a mnohdy omezená. Díky aktuálně projednávané vládou novele zákona o veřejném zdravotním pojištění se k nim dostanou transparentní cestou, snáze a především dříve. Nově navíc přinese zapojení lékařů a pacientů do procesu schvalování léčiv, které je ve střední a východní Evropě zcela unikátní.

AIFP ORGANIZATIONAL STRUCTURE





AIFP BODIES



GENERAL ASSEMBLY

The General Assembly is the supreme steering body of the Association, which decides about the Association's strategic direction. It consists of representatives of member companies, usually of CEOs for the Czech Republic or Central Europe, and elects members of the Board of Directors.



BOARD OF DIRECTORS

The Board of Directors is an elected executive body of the Association, which meets once every two weeks. It makes decisions about important matters and implements the strategy laid down by the General Assembly.



Chair of the Board of Directors

MUDr. Martin Minarovič, MBA
(Janssen)



First Vice-Chair of the Board of Directors

MUDr. Pavel Sedláček
(Pfizer)



Second Vice-Chair of the Board of Directors

Ing. Daniela White, CSc.
(Novo Nordisk)



Miha Kline (Eli Lilly)



MVDr. Tomáš Březina, MBA
(Amgen)



Emmanuelle Boishardy (GSK)
– until May 2020



Carolyn Sousa (Novartis)
– since June 2020



Emelie Antoni (AstraZeneca)
– until November 2020



Ing. Luděk Patočka (UCB)
– since December 2020

BODIES OVERSEEING THE OPERATION OF THE AIFP



ETHICS COMMITTEE

The Ethics Committee checks the compliance with the Code of Ethics, the Patient Code, the Disclosure Code and other standards of the AIFP. It regularly checks non-intervention clinical trials commissioned by AIFP member companies as to whether or not all requirements were observed during these trials.

Office term 03/2020 – 03/2022



Chair of the Ethics Committee

Mgr. Patrik Kastner

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)



CONTROLLING COMMITTEE

The Controlling Committee supervises the financial management of the AIFP, checks the minutes from General Assemblies and submits recommendations to the Board of Directors.

Office term 02/2020 – 02/2022



Chair of the Controlling Committee

PharmDr. Adriana Funderáková Beňová
(Bayer)

Members:

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



EXECUTIVE TEAM

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



Executive Director

Mgr. Jakub Dvořáček, MHA, LL.M.



Executive assistant

Bc. Barbora Šalamoun
– until May 2020



Executive assistant

Marie Šolcová
– since May 2020



Office manager, financial coordinator

Ing. Miluše Kaudersová
– since August 2020



APO project manager, HR manager, financial coordinator

Mgr. Zuzana Komárková



Office assistant

Bc. Eliška Cermanová



Attorney, Association's secretary

Mgr. David Kolář



Legal assistant

Václav Krudenc
– until September 2020



Legal assistant

Vojtěch Pour
– since September 2020



Attorney

Mgr. Lenka Novotná, MHA



PR manager

Ing. Markéta Kolanová, MA



PR manager

Mgr. Denis Drahoš



PR assistant

Mgr. Denisa Průšová

AIFP MEMBER COMPANIES

The Association of Innovative Industry (AIFP) associates pharmaceutical companies that are able to develop and market new, more effective and safer medicinal products. The AIFP is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and closely cooperates with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

34 regular members and one affiliated (as of December 2020).



Any legal entity – pharmaceutical or biotechnological company that has its registered office and place of business in the Czech Republic and, directly or through a group of companies to which it belongs, researches, develops, produces or distributes original medicinal products – can become a member of the Association. <https://www.aifp.cz/en/aifp-member-companies/>

GILEAD	an affiliated member from December 2019 and a regular member since December 2020
SOBI	a regular member since August 2020
VERTEX	a regular member since July 2020
ANGELINI	an affiliated member since May 2020

FINANCIAL MANAGEMENT REPORT

The AIFP is a non-profit, voluntary association of legal entities. It is fully financed from the contributions of its member companies.

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

REVENUES IN 2020

Received membership fees	28,583
• Received membership fees	27,332
• Received membership fees for "AIFP footprint"	708
• Received financial contributions for APO	543
Other revenues	356
• Revenues for provided services – seminar	49
• Other revenues	201
• Received interest	89
• Foreign exchange gains	17
Total	28,939

EXPENSES IN 2020

Consumed purchases	16,008
• Consumption of materials and energy	651
• Repairs and maintenance	40
• Travel expenses	137
• Representation expenses	502
• Other services	14,678
Personnel costs	10,693
Taxes and fees	2
Other expenses	224
• Bad receivables – write off	1
• Foreign exchange losses	21
• Donations	40
• Paid interest	87
• Other expenses	75
Depreciated fixed assets	565
Provided contributions	727
Income tax	0
Total	28,219

The full format of the financial statements is available in the Collection of Deeds in the Associations Register kept by the Municipal Court in Prague, Section L, Insert 58517.

In 2020, the AIFP had a profit of CZK 720,482.94 that will be transferred to the account "Retained Profit, Unpaid Loss from Previous Years" once approved by the AIFP General Assembly.

The retained profit from previous years amounts to

CZK 220,889.07

The auditor's statement constitutes an integral part of the annual report.

ANNEX TO 2020 FINANCIAL STATEMENTS

A significant impact of the Covid-19 pandemic during the accounting period

The accounting entity did not close any premises and did not limit its production or provided services during the 2020 accounting period. The accounting entity did not use any subsidies or incentives in connection with the Covid-19 pandemic.

Major events after the balance sheet day

The AIFP's management did not experience any major impact of the Covid-19 pandemic on the activity of the accounting entity after the balance sheet day, but the situation keeps changing and this is why it is not possible to predict the future impact of this pandemic. The AIFP's management will continue to monitor the potential impact and will take all necessary steps to mitigate any negative effect on the AIFP and its employees.

The AIFP's management evaluated the potential impact of Covid-19 on its activities and business and concluded that it had no major effect on the going concern assumption. For this reason, the financial statements for the year ended 31 December 2020 were prepared based on the assumption that the Association will be able to continue with its activity.

AN INDEPENDENT AUDITOR'S REPORT



Č.j.:20019/98/21

INDEPENDENT AUDITOR'S REPORT

To the Members of Asociace inovátivního farmaceutického průmyslu, Ident. No. 70970173, Praha, Pohřební 620/3, PSC 186 00

Opinion

We have audited the accompanying financial statements of Asociace inovátivního 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 2020, 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 Asociace inovátivního farmaceutického průmyslu as at 31 December 2020, 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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Č.j.:20019/98/21

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

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Č.j.:20019/98/21

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 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.

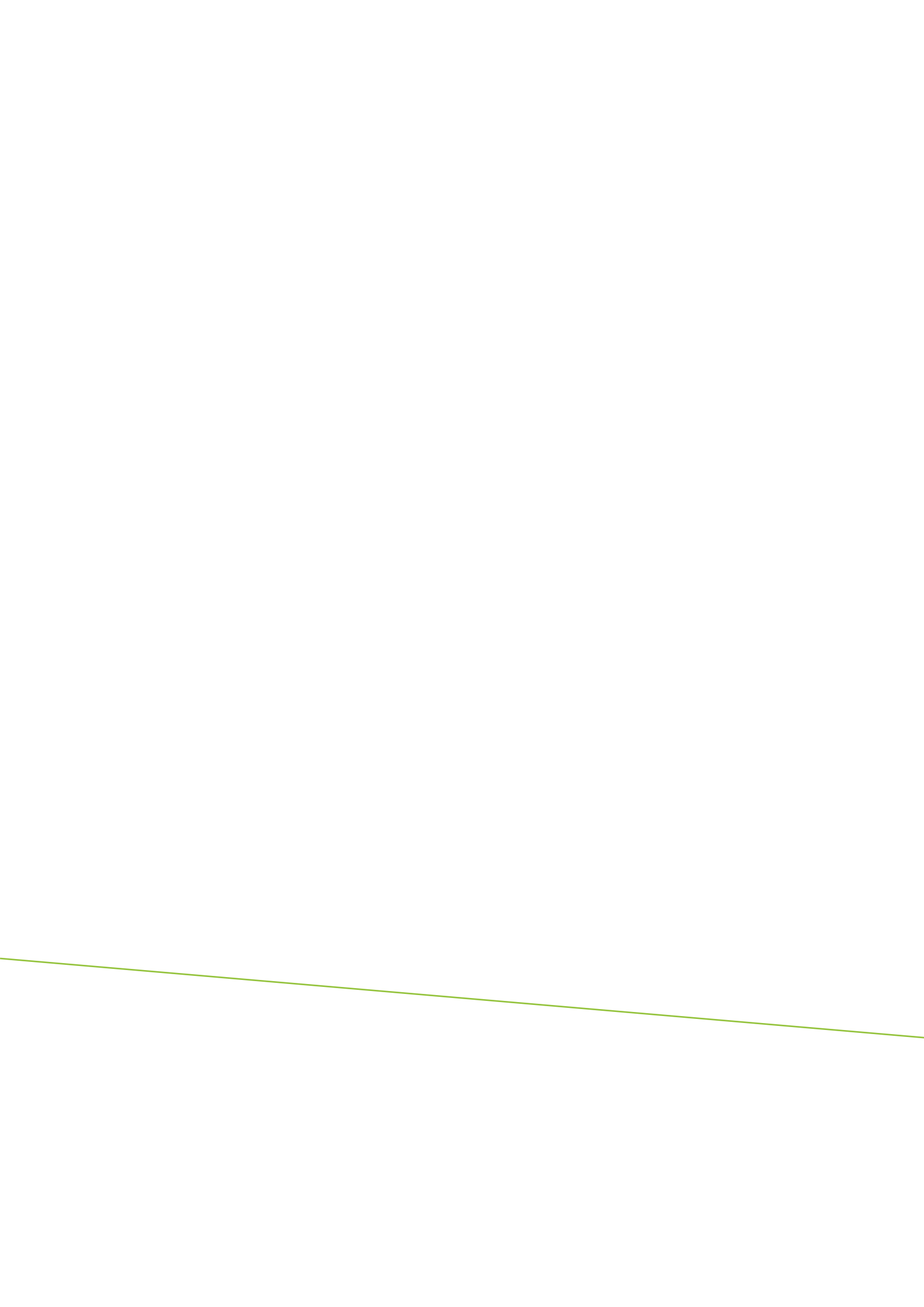
We communicate with the Board of Directors and the Supervisory Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

ADUKO s.r.o.
17. listopadu 237, 530 02 Pardubice
Audítorská firma licence No. 349
Ing. Milan Poláček, auditor
Licence No. 1838

Pardubice, 7 May 2021



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CONTACT AND IDENTIFICATION DETAILS

ASSOCIATION OF INNOVATIVE PHARMACEUTICAL INDUSTRY



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186 00 Prague 8



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www.aifp.cz



Founded on:	24 November 1993
Legal form:	A special-interest association of legal entities
IN:	70970173
TIN:	CZ70970173

Registered with the Associations Register kept by the Municipal Court in Prague, file no. L 58517



Asociace inovativního
farmaceutického průmyslu