aifp
Asociace inovativního farmaceutického průmyslu

ANNUAL REPORT

Association of Innovative Pharmaceutical Industry

2015

A WORD OF INTRODUCTION

2015 was marked by various activities bearing the common denominator of patient benefit. Drug safety and availability, along with support for science and research leading to the faster development of innovative medicines, represent just a fraction of our work. But for patients to receive quality care, the entire healthcare system must function well. Our activities therefore have a more far-reaching aim, which is to make the system more stable and effective. We cultivate the environment through the introduction of standards for ethics and transparency, we educate patient organizations that are an essential component of modern healthcare, and we promote cooperation between the public and private spheres so that innovative medicines can get to those who need them as quickly as possible.

A great deal of work has been carried out over the past few years and we can see gradual changes as the system shifts to a more patient-oriented model. Nevertheless, Czech healthcare still has many challenges to overcome before meeting West European standards. For us to achieve these goals, it is essential for discussion on healthcare legislation and changes to involve all stakeholders who observe and are impacted on a daily basis by all weak areas of the system. It is therefore the responsibility of the innovative pharmaceutical industry to continue to move the discussion forward.

PharmDr. Monika Horníková
Chair AIFP
GSK

Mgr. Jakub Dvořáček, MHA
Executive Director
AIFP

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INTRODUCING THE ASSOCIATION

The Association of Innovative Pharmaceutical Industry (AIFP) associates pharmaceutical companies that develop new, more effective and safer medicinal products and thus provide Czech patients with access to modern treatment. The AIFP is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and closely cooperates with the Pharmaceutical Research and Manufacturers of America (PhRMA). In 2015, the AIFP had 33 members.

"Each year the pharmaceutical industry pushes the boundaries of medicine further. It comes up with more effective and safer drugs to treat chronic and regular diseases. These innovative medicinal products bring patients new hope and better quality of life. Our goal is to make these medicines available to the greatest number of people who need them. We are also actively working on the cultivation of Czech healthcare by establishing ethical obligations, increasing transparency and incorporating patient organizations into the system."

Mgr. Jakub Dvořáček, MHA

THE PHARMACEUTICAL MARKET IN THE CR

55 billion CZK

Total sales

hospital market
30 billion CZK

pharmacy market
23 billion CZK

other distribution channels
2 billion CZK

44 billion CZK

Value of innovative drugs on the market

52 %

Share of Rx products on the pharmacy market

2 billion CZK

Spent on research and development

17,900

People employed in the sector

Source: EFPIA statistics questionnaire 2015

33 MEMBER COMPANIES

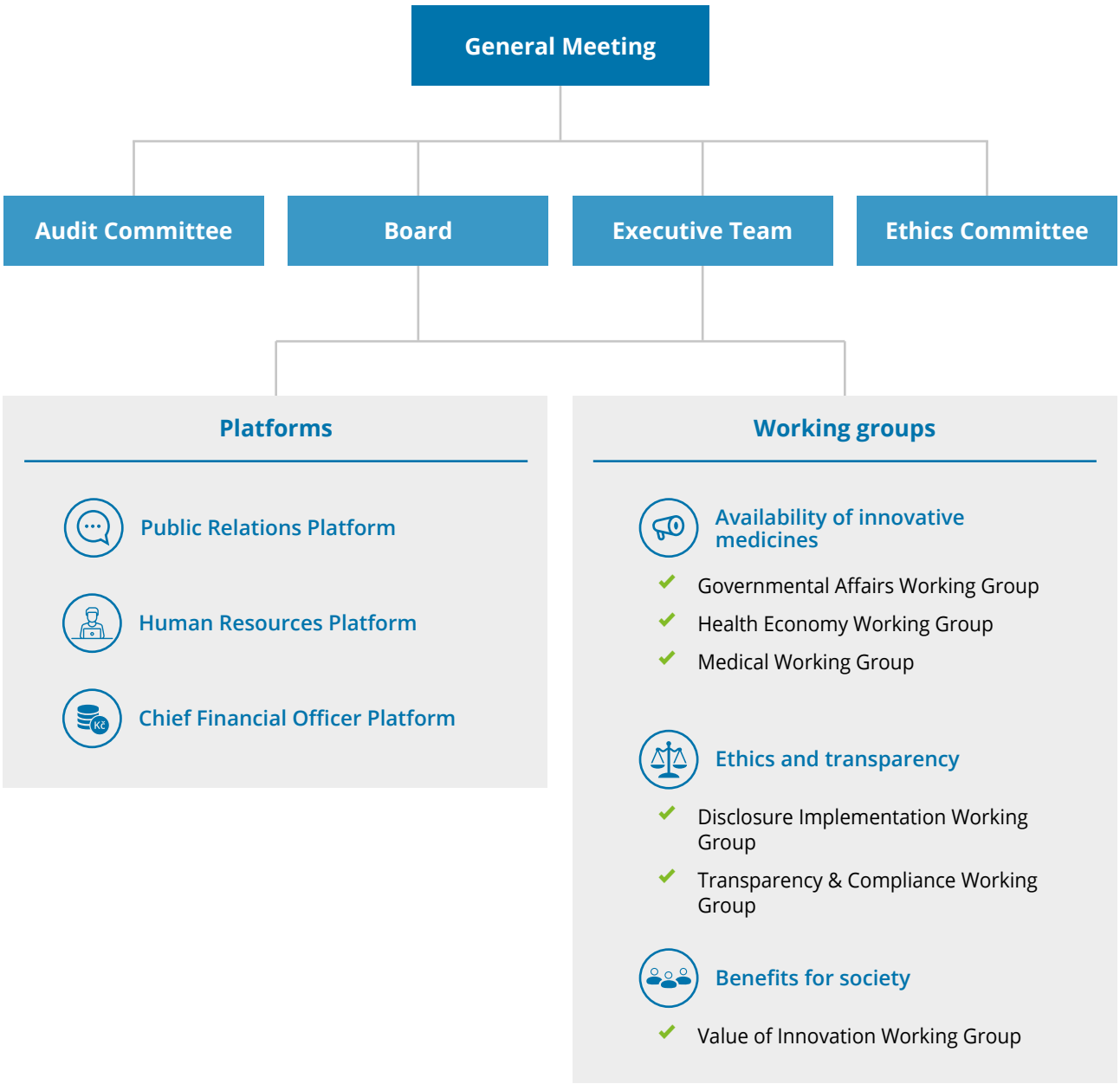
Member companies

abbvie
ACTELION
AMGEN
astellas
Leading Light for Life
AstraZeneca
Bayer
BERLIN-CHEMIE MENARINI
Biogen
Boehringer Ingelheim
Bristol-Myers Squibb
Celgene
Eisai
Lilly
FERRING PHARMACEUTICALS
gsk
IPSEN
Innovation for patient care
janssen
Lundbeck
MERCK
MSD
mundipharma
NOVARTIS
novo nordisk
Pfizer
Pierre Fabre Médicament
Roche
SANOFI
SERVIER
Shire
STALLERGENES GREER
Life beyond allergy
Takeda
ucb

Affiliated companies

Santen

ORGANIZATIONAL STRUCTURE



FUNCTIONING AND ACTIVITY OF THE ASSOCIATION

General Meeting

The supreme steering body of the Association is the General Meeting, which decides about the Association's strategic direction. In 2015, the General Meeting examined proposals aimed at contributing over the long term to the cultivation of Czech healthcare. At its sessions the General Meeting discusses prices, reimbursement and regulation, analyzes the results of individual working groups, and also examines changes in Czech healthcare and its impact on patients. Intensive attention was also devoted in 2015 to implementing changes to the Code of Ethics and bringing the Transparent Cooperation Initiative to the Czech environment.

In 2015, there were five sessions of the General Meeting, which were attended by the representatives of all member companies of the AIFP.

Board

The Board is the Association's executive body. The Board decides on all Association matters that do not fall under the competence of the General Meeting. In addition to long-term tasks such as the acceptance of new members, strategic direction of the Association and strengthening of its position, its objective in 2015 was to intensify discussions with key government officials, professional medical associations and other parties to establish closer cooperation and provide patients modern and safe medicines.

The seven-member Board regularly met twice a month in 2015. Its members are presented below.

2015 by the numbers

+3

new AIFP member companies

524×

mentions of AIFP in the media

301

working group members

9

working groups and platforms

Monika Horníková
Chair, GlaxoSmithKline

Monika Horníková has worked in the pharmaceutical industry since the beginning of the 1990s. In 1995, she became the head of GlaxoWellcome's branch office in Slovakia and, after its fusion with SmithKline Beecham in 2001, the CEO of the new company GlaxoSmithKline (GSK). In 2006, she also managed the branch offices in Latvia and Estonia. She has been the CEO of GSK's Pharmaceuticals Division in the Czech Republic since 2007 and is responsible for the management of its Oncological Division for Central Europe. Under her leadership, GSK regularly places among the best in the TOP Responsible Company in the category of Most Generous Donor.

From 2003 – 2006, Monika Horníková was the president of the Slovak Association of Pharmaceutical Companies (SAFS) and has held this position in the Czech Republic since 2010. She is the chair of the AIFP's Board, a member of the Supervisory Board of the Czech Healthcare Forum, the honorary chair of the Board of the GSK Endowment Fund and an honorary member of the Board of Elpida, v.o.s.

Michaela Hrdličková
First Vice-Chair, Biogen Idec

Michaela Hrdličková has worked in the pharmaceutical industry since 1995. Her career started at Wyeth where she held different positions and gained valuable experience over her 17 years there. She then worked at Novartis as Market Access, Public Affairs and Pricing Manager and was hired by Biogen Idec in May 2010 as Country Director.

Michaela Hrdličková represents the AIFP in the interdepartmental working group for Age Management, the goal of which is to demonstrate the important role of innovative medicinal products and the pharmaceutical industry in the area of prevention and early effective treatment to help maintain people's health and long-term productivity while reducing the state's social services expenditures. This topic resonates with one of the EFPIA's main priorities expressed in the Health & Growth strategic document.

Lenka Poleková (January - August)
Second Vice-Chair, Celgene

Lenka Poleková has worked in the pharmaceutical industry since 1995 and has been Country Manager for various innovative pharmaceutical companies (Wyeth, Nycomed, Octapharma and Celgene) since 2001. She has long focused on biotechnology in pharmaceuticals and support for cancer patients.

Jean-Philippe Duc (January – June)
Board member, Amgen

Jean-Philippe Duc has been Country Director of Amgen Czech Republic since June 2011. He has chaired the AIFP's Audit Committee for the past three years and became a member of the Board in November 2012. Jean-Philippe Duc has worked for Amgen since 2002 and held many marketing and sales positions at Amgen International Headquarters and in Amgen, France.

John M. Raney
Board member, Pfizer

John Raney has been Country Manager for Pfizer Czech Republic since October 2011. Prior to that, he was Senior Regional Manager in Established Products for Latin America. From 2010 to 2011, he worked in the Emerging Markets Business Unit and during the years of 2007 - 2010 as Senior Director of Sales Operations and Personnel Manager in the Emerging Markets Business Unit.

Beata Hauser (January – July)
Board member, Ipsen Pharma

Beata Hauser joined the pharmaceutical industry in 1993 and spent the following 12 years at GlaxoSmithKline Czech Republic, where she held different sales and medical positions. She then worked as Director of GSK's European Governmental Affairs in Brussels and Italy. She has been Ipsen Pharma's Vice-President for the Czech Republic and Slovakia since 2008.

Heidrun Irschik-Hadjieff
Board member, Novartis

Heidrun Irschik-Hadjieff started as Sales Manager at CIBA. Later on, she had an opportunity to work in different positions at Novartis Austria - from marketing all the way to management in the Ophthalmology and Neurology Divisions. At the end of 2012, she became the CEO of Novartis s.r.o. in the Czech Republic. She is in charge of coordinating the individual companies of the Novartis Group and is responsible for managing the General Medicine Division. High ethical standards in the pharmaceutical industry are her priority.

2015 by the numbers

34

newsletters sent out by AIFP

707

recipients

4

Association activities managed by the four-member Executive Team

AIFP now on social networks

_DvoracekJakub

akademiepacientskychorganizaci

In December 2015 a new Board was elected to lead AIFP for the next two years, i.e. through November 2017. The new Chair is **Martin Minarovič** (Janssen-Cilag), the First Vice-Chair is Michaela Hrdličková (Biogen) and the Second Vice-Chair is Heidrun Irschik-Hadjieff (Novartis). Other members of the Board are Daniela White (Novo Nordisk), Monika Horníková (GlaxoSmithKline), Miloš Živanský (Eisai) and Rong Yang (Bayer HealthCare Pharmaceuticals).

Daniela White
(as of September 2015)

Miloš Živanský
(as of September 2015)

Martin Minarovič
(as of December 2015)

Rong Yang
(as of December 2015)

Executive Team

The Association of Innovative Pharmaceutical Industry is represented by an executive director. This position has been held be **Jakub Dvořáček** since 2011.

Prior to joining the AIFP, Jakub Dvořáček worked in the Investments Division of CzechInvest, a public-benefit organization of the Ministry of Industry and Trade of the CR that supports business and investments. He was primarily responsible for the direct inflow of foreign investments to the Czech Republic and for the administration of the network of CzechInvest's foreign offices. He was also an advisor to the Minister of Education, Youth and Sports of the Czech Republic.

Before 2009, he held managerial positions at the Charity of the Czech Republic and was responsible for managing extensive public awareness campaigns and humanitarian development projects around the world.

Jakub Dvořáček
Executive Director

Additional members of the Association's Executive Team in 2015 were:

Zuzana Komárková
APO Project Manager and Office Manager

Aneta Dostálová
(July – December)
Association secretary and lawyer

Andrea Ringelhánová
PR Manager

The Association also worked with the following external contractors:

- **Martin Pospíšil**, Project Manager
- **Martin Michalov**, Project Manager (January – June)
- **Vladka Laštůvková**, Legal Assistant
- **David Kolář**, Legal Assistant (December)
- **Zuzana Hanibalová**, PR Assistant (January – August)
- **Markéta Černá**, PR Assistant (September – December)
- **Simona Blažková**, Office Assistant (January – August)
- **Loan Nguyen**, Office Assistant (September – December)

Ethics Committee

In 2015, the Ethics Committee randomly checked some of the non-intervention studies conducted by the AIFP's member companies, decided disputes of member companies concerning potential breaches of the Code of Ethics, interpreted and amended the Code of Ethics and expanded upon the frequently asked questions concerning the Code of Ethics. In addition, it actively addressed questions related to the "Transparent Cooperation" project. In September of 2015 it issued specific interpretations of the rules concerning ethical standards for sponsoring travel and meetings of AIFP member companies.

Patrik Kastner
Chair

***Committee members**: Martin Cikhart, Marco Forestiere, Heidrun Irschik-Hadjieff, Eva Koňáková, Patrik Kastner, Pavel Kovář, Helena Rösslerová, Karel Rychna, Milan Šikut, Václav Špičák, Petra Tesařová and Miloš Živanský.*

Audit Committee

The Audit Committee supervises the financial performance of the Association and observance of the Association's directives and statutes, reviews the minutes from plenary meetings and submits recommendations to the Board. The Audit Committee met six times in 2015.

***Committee members:** Jiří Locker, Petr Janíček and Petr Zelený.*

Jiří Locker

Governmental Affairs Working Group

Goal: to beneficially influence drug policy legislation, in particular pricing and reimbursement regulations aimed at increasing the availability of innovative medicinal products to patients and improving the business environment in the CR.

The Governmental Affairs Working Group, headed by Lenka Poleková (until mid-2015), continued in 2015 to focus mainly on creating a new policy for the pricing and reimbursement regulation of medicinal products in the Czech Republic.

The group also focused on legislative proposals concerning parallel exports, public contracts and the reference basket used to create the prices of medicinal products and the substitution of biological medicinal products. In this regard, AIFP expressed its official standpoint of AIFP in the form of position documents and amendment proposals. It actively addressed the issue of drug formularies issued by insurance companies, compliance with statutory deadlines by the State Institute for Drug Control, and the manner of deducting surcharges when determine prices and reimbursement. It worked together with the Health Economy Working Group to create a position document proposing changes concerning highly innovative medicinal products and prompted the Ministry of Health to issue another recommendation saying that the Czech prices of medicinal products should not be referenced by foreign regulatory authorities and drug agencies due to the artificial foreign exchange intervention of the Czech National Bank. Finally, it took part in analyzing the length of administrative proceedings for pricing and reimbursement, the impact of new legislative requirements established by the Contract Register Act, and new amendments to the Advertising Regulation Act.

Group members: *Alena Blechová, Markéta Budkovská, Lenka Bulejová, Anna Černá, Pavel Černý, Petr Diviš, Filip Dostál, Filip Dvořák, Hana Dvořáková, Hana Foitová, Zbyněk Gregor, Jiří Helcl, Jiří Hladík, Pavel Holík, Michaela Hrdličková, Heidrun Irschik, Kristýna Jašková, Pavel Karásek, Lenka Kaška, Aleš Kmínek, Jolana Kubátová, Filip Mavrov, Pavol Mazan, Mirek Patek, Pavlína Pavlíková, Kateřina Pechová, Lucie Pomajslová, Martin Pour, Helena Rösslerová, David Skalický, Robert Sýkora, Jiří Šlesinger, David Šmehlík, Juraj Šutovský, Jana Tvarohová, Eva Vaverková, Šárka Veselá, Magdalena Vyhnánková and Klára Zachová.*

Health Economy Working Group

Goal: to increase the awareness of healthcare professionals and key stakeholders about the value of pharmaceutical innovations and to set up transparent conditions for their entry in the healthcare system.

This working group, led since June 2015 by Martin Minarovič, was primarily engaged with the issue of highly innovative medicinal products. In this regard, it initiated discussions with association representatives of select European countries (Belgium, Netherlands, Italy, Sweden) on the most suitable manners and legislative tools to ensure prompt entry of costly medicinal products into the reimbursement system, and subsequently drafted the AIFP position document summarizing the proposed changes to the process of determining prices and reimbursement for highly innovative medicinal products. In addition to this, it also discussed the current manner of reimbursing medicinal products used for facility care, including shortcomings and risks.

Group members: *Martin Brunclík, Lenka Bulejová, Petr Diviš, Jan Doležel, Filip Dostál, Hana Dvořáková, Hana Foitová, Leoš Fuksa, Zbyněk Gregor, Petr Hájek, Jiří Helcl, Pavel Karásek, Jiří Klimeš, Alešl Kmínek, Jolans Kubátoá, Jiří Lamka, Martin Minarovič, Pavlína Pavlíková, Kateřina Pechová, Lucie Pomajslová, Karel Rychna, David Skalický, Robert Sýkora, David Šmehlík, Juraj Šutovský, Jana Tvarohová, Šárka Veslá and Miloš Živanský.*

Value of Innovation Working Group

Goal: to increase the awareness of the general public about the benefits of pharmaceutical innovations for Czech patients, the healthcare system and the economy of the CR.

The working group was led in 2015 by Michaela Hrdličková. Key projects of the working group included the Patient Organization Academy (POA) and the Innovative Medicines Initiative (IMI). In 2015, the POA established a Governing Board consisting of representatives of patients, physicians, and other stakeholders. In late April of 2015, IMI held an international conference to support the joint research and development of new medicines. In keeping with the Health & Grow strategic document of the EFPIA, a brochure was created for members of the group that examined the aging population of the Czech Republic.

Group members: *Jan Cimprch, Jiří Hladík, Michaela Hrdličková, Lenka Kaška, Eva Koňáková, Radek Korbel, Pavel Kříž, Jolana Kubátová, Filip Mavrov, Juraj Šutovský and Magdalena Vyhnánková.*

Medical Working Group

Goal: to beneficially influence legislation concerning registration, pharmacovigilance and clinical trials, which will speed the entry of innovative medicinal products in the healthcare system of the CR.

The working group was led in 2015 by Beáta Hauser. The group continued to work on the issues of individual subgroups (clinical trial, pharmacovigilance and regulators). The subgroups also actively took part in collaboration and meetings with representatives of the State Institute for Drug Control.

Subgroup members: *Petr Abrman, Tomáš Adamec, Daniel Alexander, Ivo Apetauer, Paolo Bajcic, Marek Barger, Hana Bartošová, Radek Běla, Olga Bernardová, Jana Blahniková, Iva Budařová, Ivan Cimprich, Jana Čačaná, Beata Čečetková, Anna Černá, Stanislava Daňková, Daniela Davidová, Jana Doksanská, Milena Dufková, Simona Dzudza-Kováčiková, Vladimíra Filipová, Kateřina Habrdová, Magdalena Hejrová, Jiří Hladík, Jarmila Hladíková, Mira Hojdarová, Jitka Hošťálková, Lenka Hrubišková, Patricie Chromá, Thomas Johansson, Eva Kalíšková, Monika Knapíková, Iva Kosatíková, Petr Krokavec, Anna Křížová, Ivana Kudynová, Libuše Kupková, Katarina Kužmová, Jarmila Léblová, Hana Macáková, Denis Majcher, Vlasta Marčanová, Stanislav Matějek, Luboš Melichar, Rastislav Molnár, Monika Němcová, Helena Nováková, Hana Novotná, Bibiana Oktavcová, Lucie Otčenášková, Lukáš Pachman, Marie Palkosková, Marie Pilařová, Martina Poučová, Simona Procházková, Silvia Přitasilová, Naděžda Puskarova, Martin Rek, Zuzana Rothová, Jana Rusová, Eliška Salátová, Vladimír Sedláček, Radka Srbená, Josef Svoboda, Zuzana Šebestová, Iva Šenkapoulová, Radka Šíchová, Olga Šípková, Beti Tanevská, Karel Tichý, Irena Trněná, Vlasta Trojanová, Radka Troníčková, Jan Turek, Jiří Urban, Jitka Urbánková, Lenka Věčorková, Matěj Voskovec-Vaksman, Magdalena Vyoralová, Bohumil Zlámal, Zdeněk Zmeškal and Miloš Živanský.*

Clinical Trial Subgroup

In 2015, the Clinical Trial Subgroup mainly focused on a new study analyzing the economic impact of clinical studies conducted in the Czech Republic in 2014. In this regard it prepared a new study method and representatives of the subgroup took part in preparing a press conference on this matter. In May of 2015 it drafted the AIFP position document on clinical trials, where it emphasized the need for quality backing to conduction individual clinical trials. The subgroup further helped organize an international seminar on Risk-Based Management which was held on October 13th, 2015 in Prague. With respect to new clinical trial legislation it actively commented on proposed amendments to the Pharmaceuticals Act. It also commented on the new KLH-22 methodological guidelines of the State Institute for Drug Control, prepared a project to create clinical trial advisory centers in the Czech Republic and discussed the possibility and format of a uniform contract for conducting clinical trials.

Pharmacovigilance Subgroup

The Pharmacovigilance Subgroup primarily examined the impact of the PHV-7 methodological guidelines of the State Institute for Drug Control. It discussed the protection of personal data during pharmacovigilance activities, the education of health care professionals with respect to reporting suspected adverse effects of drugs, and inspections in the area of pharmacovigilance. It also actively promoted the public awareness campaign of the State Institute for Drug Control.

Regulatory Subgroup

The Regulatory Subgroup primarily discussed the reporting of adverse effects, the review of Czech SPC, PIL and packaging information, and the uniform approach of assessors at the State Institute for Drug Control. It also examined cost reimbursement for professional activity of the State Institute for Drug Control and annual maintenance fees, and actively addressed the changes that will accompany implementation of European anti-counterfeiting legislation.

Transparency and Compliance Working Group

Goal: to actively support the wider application of ethical standards specified in the AIFP's Code of Ethics by all companies and to prepare implementation of the Transparent Cooperation Initiative. The working group cooperates with ethics bodies of other organizations and also regularly communicates with professional medical associations.

In 2015, the Transparency & Compliance Working Group, led by John Raney, primarily focused on the implementation of the Transparent Cooperation Initiative. The working group's agenda also included the Medical Representative Certification Project, which significantly contributes to the cultivation of the pharmaceutical environment in the CR. Members of this working group helped AIFP to prepare an informational Q&A brochure regarding the Transparent Cooperation Initiative.

Group members: *Milada Brabcová, Lucie Burešová, Vendula Knappová, Pavel Kovář, Jan Ledecký, Tereza Ošancová, Zuzana Příborská, Silvia Přitasilová, John Raney, Eva Sovová, Jaroslav Vydlák and Miloš Živanský.*

Disclosure Implementation Working Group

Goal: This group was created in 2014 to smoothly implement the Transparent Cooperation Initiative at Association member and non-member companies. The goal of the group is to achieve a uniform approach to project implementation.

In 2015 there were a total of six meetings of working group members that addressed technical issues, the sharing of know-how, and project communication. Representatives of both AIFP member and non-member companies are represented in the DIG group. Transparent cooperation will be implemented in the Czech Republic by a total of 41 pharmaceutical companies. Select regular meetings were also attended by third-party stakeholders who shared their know-how with the group.

Group members: *Daniela Břišťálová, Lucie Burešová, Jana Buršíková, Michaela Cibulová, Jaroslav Černý, Stanislava Daňková, Jana Doksanská, Helena Dolejšová, Milena Dufková, Vladimír Dvořák, Hana Foitová, Radoslav Furman, Hynek Heisig, Tomáš Hettych, Michaela Hrdličková, Hana Hrubá, Lenka Huslarová, Petr Janíček, Pavel Jičínský, Jiří Kalousek, Radka Kejzarová, Vendula Knappová, Vojtěch Kotrč, Pavel Kovář, Andrea Krajčiová, Petr Králíček, Dušan Křiva, Jan Ledecký, Pavlína Libusová, Jiří Locker, Jana Mádlová, Vlasta Marčanová, Vít Marek, Jitka Mašková, Jana Maudrová, Filip Mavrov, Marcel Michenka, Monika Mojžíšová, Alexander Myslík, Monika Němcová, Eva Obořilová, Milan Opršal, Tereza Ošancová, Vladimír Pacholík, Mirek Pátek, Lucie Pomajslová, Jan Popluhár, Martina Poučová, Zuzana Příborská, Silvia Přitasilová, Adriana Slavíková, Radek Smítka, Romana Smolková, Andrea Svobodová, Milan Šikut, Eliška Štrosová, Martin Vácha, Petr Vlach, Klára Zachová, Vilém Zvoníček and Miloš Živanský.*

OVERVIEW OF THE MOST INTERESTING PROJECTS

In 2015, the Association carried out numerous activities for both healthcare professionals and the general public. In accordance with the strategic pillars and goals of individual working groups, it brought attention to current problems and potential solutions, promoted patient education and supported innovation.

Highlighting current problems

The problem of parallel export and availability of innovative medicines for patients in the CR.

Parallel exports of drugs from the CR is a long-term problem. As a result, certain medications are not available to patients in the CR. The common objective of all AIFP members is to ensure maximum availability of medicinal products for Czech patients. AIFP analysis shows that drugs valued at 5 billion CZK were exported from the CR in 6.3 million packs. The most commonly exported drugs last year were medications to treat rheumatoid arthritis, Crohn's disease, epilepsy, heartburn, as well as anticoagulants. A large portion of the drugs frequently exported, up to 25%, are used in oncology.

Implementation of European-wide legislation

European Medicines Verification System (EMVS)

Beginning in 2019, European Union regulations will require all prescription medications to be checked to make sure they are not counterfeit or otherwise problematic. Therefore, preparations were made during 2015 for the implementation of the European-wide medicines verification system in the Czech Republic under the auspices of AIFP. EMVS will mark medicine packs with a special 2D code that will enable electronic verification of the authenticity of the drug in a European database. In addition to AIFP, project participants include the Czech Association of Pharmaceutical Companies (ČAFF), the Association of European Pharmaceuticals Distributors (AEDL), the Association of wholesale distributors of pharmaceuticals (AVEL) and the Czech Chamber of Pharmacists (ČLnK). Implementation of the system will be overseen by the State Institute for Drug Control (SIDC). In 2016, implementation will continue through the National Organization for Medicines Verification that will ensure the creation of the Czech part of the system. The system will be funded by drug manufacturers and marketing authorization holders.

Support for the education of Czech patients

"I know my medications" online advisor

In 2015, Czech patients continued to receive online advice from the "I know my medications" website. This website helps people detect serious interactions and redundancies among the medications, foods and herbs they are currently using. In the year and a half of its existence the advisor has responded to over 29,000 inquiries and detected over 2,650 drug interactions. These most frequently involved the cardiovascular system, with certain drug combinations and contraindications directly threatening patient lives. In addition, 10% of all inquiries were found to reveal drug duplicity, mostly in cardiovascular system treatment.

AIFP is cooperating in the project with students of the Pharmaceutical Faculty of Charles University in Hradec Králové, along with experts from the Infopharm Company.

29,000
inquiries answered

2,650
serious interactions

2,780
duplicities

3 degrees of serious drug interactions

1 Necessary to change dosage, monitoring certain laboratory tests and symptoms recommended.

2 Very serious drug interaction, administration of both drugs should generally be avoided.

3 Contraindications are life-threatening.

Most frequent interactions

- Cardiovascular system
- Nerve system
- Musculoskeletal system
- Blood and blood-forming organs
- Digestive tract and metabolism

Most frequent duplicities

- Cardiovascular system
- Nerve system
- Digestive tract and metabolism

Transparency and compliance with ethical rules

The Transparent Cooperation Project

2015 was an important year for preparation of the Transparent Cooperation Initiative, supported by the Ministry of Health of the Czech Republic and the leadership of the Czech Medical Society of Jan Evangelista (CMA JEP). The Association prepared the platform on which it will publicly run. A brochure of the Transparent Cooperation Project was prepared to explain the way values can be exchanged between the interested parties.

Science and Research Support

Innovative Medicines Initiative

In 2008, the Innovative Medicines Initiative (IMI) was created as part of the cooperation of the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI is an example of public and private partnership (PPP). Since 2014 the second phase, IMI 2, has been underway with an allocation of 90 billion crowns for the support of research projects. The European Union provides funding through the Horizon 2000 program with 45 billion allocated, while EFPIA provides 39 billion.

The priority of IMI 2 is to speed the development of a new generation of vaccines and drugs such as new antibiotics and treatments for Alzheimer disease. The goal is to ensure a 30% increase within 5 years in the success of clinical trials of priority medications of the World Health Organization, clinically verify the concept of immunological, respiratory, neurological and neurodegenerative diseases, get the approval of new diagnostic markets for four of these disease and develop at least two new medications.

In 2015 scientific teams were requested to submit proposals for the three IMI 2 calls. The primary topics were Alzheimer's disease, biomarkers for diabetics with renal disease, inflammation, toxicology quantification to improve the safety of new drugs, infection by a respiratory virus, use of big data in medicine, antimicrobial resistance and more. A major topic for all of 2015 was Ebola, leading to the special Ebola+ program. At the beginning of the year the first eight consortiums of this project took place, focusing on the development of vaccines and diagnostics. One of the consortiums was successfully joined by a research team of Mendel University in Brno from the Laboratory of Mettalomics and Nanotechnology, which works under the guidance of Prof. Adam.

During the course of an entire year AIFP monitored new IMI 2 calls. It then actively supported the participation of Czech researchers in the program by disseminating and promoting current opportunities for research financing.

Conference Industry Meets Academia

AIFP organized a conference called the IMI CEE Conference: Industry Meets Academia, which was held on April 30th, 2015. The one-day conference focused on promoting the Innovative Medicines Initiative (IMI) and providing information about opportunities for scientific teams to participation in projects and grants. The third annual conference has a regional theme, focusing on Central Eastern Europe. The conference was held in the National Technical Library and Institute of Organic Chemistry and Biochemistry on the campus of the Czech Technical University in Prague (ČVUT) in Dejvice.

129

guests visited Industry Meets Academia

33

prominent representative actively represented Stakeholders

61 representatives of academic and scientific institution

15 NGO representatives

representative of the Senate/Parliament of the CR

48 4epresentatives of industry

4 representatives of foreign regions of association members such as AIFP Poland or Romania.

Educational activity

Certification of sales representatives

In the context of improving ethical standards in health care, AIFP places high ethical demands not only on pharmaceutical companies as a whole, but also their individual employees. The certification project aims to instruct sales representatives in specialized areas as well as legal and ethical matters. Since 2013 this project has endeavored to guarantee greater transparency and supervision over the quality of the relationships between doctors and pharmaceutical company representatives. The goal is for the professional and lay community to view prescriptions as a transparent and qualified decision for prescribing the particular medicine for the patient, with the choice being made only on the properties of the product and the medical condition of the patient. In 2015 the project continued successfully and another 117 sales representative obtained their certification.

1,500

certified sales representatives

Patient Organization Academy

The Patient Organization Academy has successfully developed under the AIFP banner since 2012. It remains the only comprehensive program in the country where representatives of patient organizations can gain knowledge to enable them to function independently and effectively.

2015 met with unprecedented interest. The number of participants compared to last year increased by 14, and the project was attended by a total of 71 organizations, more than double compared to the first year. A total of 24-day long seminars provided reps with information and practical skills in the areas of management, fundraising, legislation, EU grants, communication and negotiation or using social networks. So as not to lag behind in this field and to more easily provide news and meeting dates, the academy Facebook profile was launched in June, 2015 (www.facebook.com/akademiepacientskychorganizaci).

The program of the Academy of patient organizations had a new twist in 2015, summer school. During the one-day event representatives of patient organizations met with representatives of Czech medical societies and the Ministry of Health. The aim was to bring together all parties and facilitate mutual collaboration. In the autumn, the Academy culminated in the APO Alumni meeting at the British Embassy in Prague. A special guest was President of the European Patient Forum, Nicola Bedlington, who spoke about the importance of patient organizations for the health care system. Also in attendance was Lenka Teska Arnoštová, Deputy Minister.

24

seminars

71

patient organizations

93%

satisfaction of participants

CONTACT AND IDENTIFICATION DETAILS

Association of Innovative Pharmaceutical Industry

Budova IBC – Pobřežní 3
186 00 Prague 8

+420 224 832 553

www.aifp.cz

Date established: November 24th, 1993
Legal form: A special-interest association of legal entities
ID no.: 70970173
Tax ID no.: CZ70970173

Registered with the City Hall of the Capital City of Prague, Trade Licensing and Civil Law Department, under No. 99/98.

BALANCE SHEET

In 2015, AIFP generated a profit 467,256,00 CZK. This profit will be transferred to a profit and loss account. The decision to transfer this profit was approved at the AIFP General Meeting.

The Association is a non-profit organization completely funded by the contributions of member companies. The annual budget of the Association is 16 mil. CZK. Half of this is overhead for the daily operations of the Association, employee wages, lease of offices, etc. The other half goes to Association activities and the activities of individual working groups and AIFP projects. An integral part of AIFP work is the creation of education materials www.aifp.cz/cs/aktuality/brozury/. A significant portion of financing (10 %) goes to membership of the Association in the EFPIA, the Union of Employer Unions, and the Confederation of Industry of the CR. The AIFP budget is approved by the AIFP General Meeting by a majority of votes. Individual projects are approved by a majority vote of the Board. The budget, statues and Code of Ethics are always approved by the AIFP General Meeting.

Part of the Annual Report is the Auditor's Statement.

AUDITOR'S STATEMENT

Auditor's statement

In our opinion, the financial statements provide a true and fair view of the assets, liabilities and financial situation of the Association of Innovative Pharmaceutical Industry, IBC, Pobřežní 3, Prague 8, IN: 70970173 as of 31 December 2015, and of its expenses, revenues and profit (loss) for the year 2015 in compliance with the accounting regulations effective in the Czech Republic.

Report on the Annual Report

We have also audited the compliance of the annual report with the aforesaid financial statements. The statutory body of the Association of Innovative Pharmaceutical Industries, Prague 8, is responsible for the correctness of the Annual Report. Our responsibility is to express an opinion on the compliance of the Annual Report and the financial statements based on our audit.

We conducted our audit in accordance with International Auditing Standards and the related application guidelines of the Chamber of Auditors of the Czech Republic. Those standards require that the auditor plan and perform the audit to obtain reasonable assurance that the information included in the Annual Report describing matters that are also presented in the financial statements is, in all material aspects, consistent with the relevant financial statements. We believe that our audit provides a reasonable basis for our statement.

In our opinion, the information included in the Annual Report is consistent, in all material aspects, with the financial statements referred to above.

AUDIT IB, s.r.o., license No. 146
Janovského 12, 170 00 Prague 7
Responsible auditor:
Ing. Ivana Podhráská, license No. 564

In Prague, on 21 April 2016

Association of Innovative Pharmaceutical Industry

www.aifp.cz +420 224 832 553 IBC Pobřežní 3, Prague 8, 186 00