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The Global Newsletter on Pharmaceutical Medicine

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Introducing BADI, the Bulgarian Association for Drug Information

BADI was founded in 2010, headed by its chairperson Prof. Tatyana Benisheva MD, PhD, MDRA. The mission of the Association is to foster a constructive dialogue between the members from pharmaceutical companies, competent authorities, scientific societies, the pharmaceutical industry, healthcare professionals, and patient organisations in Bulgaria to continuously improve their knowledge, qualification, and professional competency. BADI has over 90 individual and more than 70 corporate members.

Since 2010 BADI organised more than 75 training events in the area of regulatory affairs, with over 5,000 participants. The lecturers in BADI events are scientists, experts from competent authorities, representatives of the pharmaceutical industry, healthcare professionals, patient organisations, academia and consultants from Bulgaria and the EU with over 375 renowned experts (German Association of Drug Regulatory Affairs (DGRA), UK, Norway, France, Austria, Hungary, Portugal, Denmark, Switzerland, Poland, and Finland). Over the years BADI built a functional network of experts and the Association is a society of regulatory affairs specialists who actively communicate among themselves.

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With great effort and enthusiasm in the regulatory sector, BADI was established as NGO in 2010, following the example of the German Association (DGRA): examples were also ISPOR and DIA. Over the years BADI has emerged as an independent platform for all stakeholders involved in the entire pharma chain - from development to marketing, market access and maintenance of the drugs, including all controlled processes.

"BADI activities can support society, create knowledge and try to impose rules that work. Together with the Board of Directors and especially with my colleagues from the Faculty of Public Health we invested a lot of efforts and personal time in order to achieve these results over the years" outlines Prof. Benisheva.

"I am pleased to say that Prof. Dobriyana Sidzhimova was proactively involved in BADI activities and in disseminating information about our events, for which I am very grateful. We are also extremely grateful to Prof. Barbara Sickmüller and many other German lecturers from DGRA such as Axel Thiele, and also Dr Peter Bachmann from the German competent authority (BfArM), who supported us over many years."

BADI provides opportunities for the development and enhancement of the expertise of their members by organising training events, professional conversations and discussion studios, regulatory e-newsletters with news from Bulgaria and the EU, forming working groups on specific drug issues, developing opinions, presenting an opportunity for the members to report on professional topics, in which they have great expertise, to other stakeholders in the health sector and many others. The Association participates in the development, discussion, expert evaluation and analysis of draft normative acts, guidelines and instructions regarding the activities in the area of public health, nationwide and in the EU. The vision of the Bulgarian Association for Drug Information is to span a bridge between the different disciplines in the pharmaceutical sector.

Prof. Tatyana Benisheva, MD, PhD, MDRA, President of BADI, is a professor of the Faculty of Public Health at the Medical University, Sofia (Bulgaria). After receiving an EC-CADREAC scholarship she completed a Master degree in "Drug Regulatory Affairs" (2004/2005) at the University of Bonn, Germany, and in 2010 a Master degree in "Public Health" at the Medical University of Sofia. She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has more than 10 years of experience at the Bulgarian Drug Agency (BDA). As the first President of the National Council on Price and Reimbursement and Health Technology Assessment (HTA) of Medicinal Products from 2013 to 2014 she involved the institution in an EU project for elaboration of an electronic database and e-submissions. Prof. Benisheva is a member of both the DIA and DGRA and was a Board member of the Europe, Middle East and Africa Regional Advisory Council at the DIA Europe in 2017-2019. Her 25 years' experience in drug regulatory affairs are complemented by more than 100 publications in the regulatory science area of medicines.



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A Tribute to DR HERMAN LAHON (1928-2018)



Dr Herman Lahon, Honorary Life President of IFAPP, whose picture has been displayed on the front page of the past three issues of "IFAPP TODAY" had passed away on 16 July 2018 at the age of 89 years. Herman was the quintessential Pharmaceutical Physician. Born and raised in Belgium, he was truly a man of the world.

Herman was the founding President of IFAPP in 1975 and served continuously within our Federation until 2009, acting as President, Secretary or Treasurer on occasion. He was elected as Honorary Life President of IFAPP at the International Conference of Pharmaceutical Medicine in 2004 in Geneva, Switzerland. He was also a senior member of the Belgian College of Pharmaceutical Medicine. His contributions to our discipline and profession have been remarkable.

Herman received his medical degree from the University of Brussels and a degree in Tropical Medicine in Antwerp in 1954. With a sense of adventure, he went off to practise tropical medicine in Africa in what was then the Belgian Congo (now the Democratic Republic of the Congo) and gained a profound realization on the relevance of the patient-physician relationship and the proper use of medicines by well-trained professionals gearing public health. Herman returned to Belgium in 1960 and started a long and productive career with Pfizer, initially as Medical Director for his country and then as Medical Director for Eastern Europe and finally as Vice President, Medical Director, Pfizer Europe. His career at Pfizer lasted for 23 years.

Herman was a pioneer in establishing education in pharmaceutical medicine and medicines development. Herman was a key driver in the process to harmonize requirements for education in pharmaceutical medicine. He was the founding chair of the former IFAPP Council of Education in Pharmaceutical Medicine (whose responsibilities are currently under the IFAPP Education Working Group) and within the initiative to gain EU recognition of pharmaceutical medicine as a specialty.



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He was also intimately involved with the Postgraduate Courses in Pharmacology and Pharmaceutical Medicine and participated in the foundation of the PHARMED post-graduate program in Pharmaceutical Medicine and Medicines Development Sciences in Belgium.

Herman was a founding member of the Belgian College of Pharmaceutical Medicine and Honorary President for life of the Belgian Association of Pharmaceutical Medicine Professionals (BeAPP).

He was also for many years Board member of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom and was the first Chair of its International Committee.

Herman was a great leader and source of inspiration for many pharmaceutical physicians worldwide. He willingly gave his time, unique talents and resources to support numerous initiatives aimed to advance Pharmaceutical Medicine in Europe and beyond. Those of us who were fortunate to have known and worked with him will fondly remember his wisdom, integrity, compassion, engaging personality, limitless energy and passion to positioning Pharmaceutical Medicine as a distinct medical specialty.

In recognition to Herman's efforts to advance education in Pharmaceutical Medicine both the IFAPP Academy and IFAPP Board of Directors have agreed with the creation of the Herman Lahon Scholarship to be offered to young pharmaceutical physicians/drug development scientists from the emerging world willing to participate in the Professional Certification Program on Medical Affairs in Medicines Development offered by the IFAPP Academy and King's College London from 2019 and beyond.

Please visit [IFAPP Academy website](#) for further information.



A publication about MSL in Japan

Proposal of Standard for Medical Science Liaison (MSL) Profession in Japan: A Viewpoint from the Japanese Association of Pharmaceutical Medicine (JAPhMed); M.Tomiyasu et al, Pharmaceutical Medicine Vol34, p.315-326, (2020). Please click [here](#) to read the publication.

Since the introduction of MSL in the pharmaceutical industry, this profession has been discussed without establishment of a standardized definition of their expertise, roles and responsibilities. The concept of MSL in Japan was adopted first in a few foreign-based pharmaceutical companies as a distinct profession with scientific expertise to discuss with investigators and leaders but its implementation in the field was not easy due to the ambiguity in their positioning within the organization.



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In Japan, a series of scandals related to the clinical development of Diovan® (valsartan) was disclosed in the early 2000s, and the interaction between investigators and the pharmaceutical industry was fiercely criticized. As a result, several measures were devised to restructure the clinical research and development environment and a legislation was introduced to educate investigators, audit clinical studies, and strictly limit interactions with the industry. In Japan, the development of MSL as an independent profession was a turning point and many companies started to assign the title of MSL to their employees. Without social consensus of what MSL are, however, Japan may still be at risk of developing another series of scandals and losing social trust. This article was developed as a joint effort of professionals working in the medical departments of the pharmaceutical industry. They made regular industry surveys for years and identified common concerns and potential terms to define MSL as independent scientific professionals. The difficulties and values of their attempts can be shared by international readers as a working model of developing shared goals among all stakeholders.

Kyoko Imamura, MD, PhD, DrMedSci

Past president of IFAPP

Project professor, Social Cooperation

Program of IT Healthcare, The Graduate School of Pharmaceutical Sciences, The University of Tokyo

IFAPP at a BADI virtual event

The presentation posted at the enclosed [link](#) was given at a training meeting of the Bulgarian Association for Drug Information (BADI) on 27 November 2020 and describes the activities of the Ethics Working Group of IFAPP (<https://ifapp.org/working-groups/ethics-and-professionalism>). The members would be delighted if colleagues were interested to join and contribute actively.

Presentation of IFAPP activities at the Annual Symposium of SwAPP and SGPM

The enclosed [presentation](#) was given by Varvara Baroutsou, IFAPP President elect, at the 25th Annual Symposium in Pharmaceutical Medicine of SwAPP (Swiss Association of Pharmaceutical Medicine) and SGPM (Schweizerische Gesellschaft für Pharmazeutische Medizin) on November the 25th, 2020. The theme of the Symposium was "How does Personalized Medicine Impact Healthcare?" Achievements and technologies in personalised medicine and their consequences for the health care system, the individual patient, all key stakeholders and the drug development process were covered during this single day virtual event.



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The first IFAPP webinar on COVID-19 in Brazil

On December 1, 2020, thanks to the collaboration among IFAPP, IFAPP Academy and SBMF (the Brazilian Association of Pharmaceutical Medicine), the IFAPP Communication Working Group managed to go live with the first webinar on the impact of the COVID-19 pandemic in Brazil.

The webinar, the first of a series, was organized by SBMF and in particular by Dr Helio Osmo (President of SBMF) and Dr Eduardo Motti. They were able to have the collaboration of Prof Celso Granato, Infectious Disease Professor at the Federal University of Sao Paulo, Mr. Gustavo Mendes, General Manager for Medicines at ANVISA (Brazilian Agency of Regulation of Medicines and Food), and Dr Paulo Chapchap, CEO at the Hospital Sirio-Libanês.

The first speaker gave an overview of the epidemiology of COVID-19 in Brazil, taking into consideration the socio-economic environment, which – especially in large cities – had a great impact on the dissemination of the pandemic. The second speaker gave an overview of the activities implemented at ANVISA in support of new clinical trials, which were authorized in an average interval of two days. Finally, the last speaker commented on the hopes that a mass vaccination will keep the pandemic under control.

The webinar was a great success: it was followed by 152 participants from 18 countries: of course, about 50% of them were from Brazil, but we had several participants from Asia, North America and Europe. It is interesting to underline that we had also participants from countries where no Association of Pharmaceutical Medicine exists (i.e. India, Ukraine, Russia, Argentina, Poland): this is an interesting finding, as professionals in Pharmaceutical Medicine identified our webinar as an interesting reference for their domestic activities.

This event was also a significant demonstration of a fruitful collaboration between two global bodies (IFAPP and IFAPP Academy) and a National Member Association (SBMF). We will continue to promote the collaboration with National Associations, and new webinars are being planned in the near future: join us for an update of your professional competences.

The IFAPP Communication WG



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THE FLAG

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IFAPP is the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

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