IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

THIS ISSUE

The IFAPP Communication Working Group Welcomes a New Member

I am a cardiologist and have a post-graduate degree in nutrology and forensic medicine as well as an MBA in Health Economics. Currently, I am the President of SBMF (Associação Brasileira de Medicina Farmacêutica) for the term 2020 – 2021. Last year I was awarded a Global Fellow in Medicines Development by IFAPP.

I have been working in the pharma industry since 1988, starting as a CRA at former Rhone-Poulenc (today Sanofi). Then I moved to Roche as a Medical Manager where I worked from 1992 – 2000. In 2000, I joined Danone Nutrition as Medical Director, and in 2006 I moved to Pfizer, finally in 2010 to Zambon Pharma. Today I am a Medical Director of Zambon Brazil.

HELIO OSMO, MD, MBA

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In SBMF we have many educational initiatives related to clinical research, compliance, Medical Science Liaison (MSL), pharmacovigilance and medicines access. We are the scientific arm of INTERFARMA (Brazilian Research Pharma Industry Association) collaborating in educational campaigns, courses and meetings for politicians, meetings and discussions about laws involving medicines, clinical research and access.

1st IFAPP Asian Regional Meeting on 30 October 2021

Join us for the Asian Regional Meeting planned to take place on Saturday 30 October, 2021.
The regional meeting will focus on current topics and issues in Pharmaceutical Medicine in various countries in the region. The Asian Meeting will be positioned as a Regional IFAPP Meeting and will hold discussions on Pharmaceutical Medicine in countries that have national member associations (NMAs) in Asia, i.e., Japan, Korea, the Philippines and Singapore.

Since the IFAPP Board members were updated in June this year, we would like to introduce the new IFAPP Board of Officers and the newly established Working Groups, and hope to collaborate with all other IFAPP NMAs based on the current situation in Asian countries.

This meeting is held as part of the annual congress of JAPhMed (Japanese NMA).

Venue: Zoom meeting
Date: 30 October 2021 (Sat), at 12:40-13:40 (Tokyo time).

The proposed agenda will read as follows:
1) Introduction of the new Board of Officers and IFAPP in general
2) Materials available for NMAs: e.g., IFAPP TODAY, webinars on the COVID-19 situation in various countries
3) Expectations from IFAPP (participants from Asian NMAs/Individual Affiliates)
4) Discussion
5) Any other proposals for discussion

Please try to participate in the Asian Regional Meeting as above.

Author:
Kotone Matsuyama, R.Ph.
Professor, Department of Health Policy and Management, Deputy Director, Center for Strategic Research Initiative, Nippon Medical School Director, Board Certified Member of JAPhMed, Chair of IFAPP Ethics WG

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5th Pan-Hellenic EL.E.F.I. Congress Summary Report

We are delighted to report that the 5th Pan-Hellenic Congress of EL.E.F.I. held online from 28 to 30 June 2021, happening every other year, completed with great success its goal, to combine what's new in Pharmaceutical Medicine and Clinical Research by covering the full range of developments in R&D, Innovation, New Technologies, and Medicine Developments, not only considering the pandemic challenges but also forecasting evolution of biomedical research in the post-pandemic era with a focus on patient-centeredness.

During the official opening of the congress, the Health Authorities and National Medicines Agency, academic and clinical researchers, the Greek Patients Association, the institutional bodies of the pharmaceutical industry (PIF, SFEE, PEF, SAFEE) as well as the Hellenic Association of CROs (HACRO) contributed proposals for the "Next Day" in clinical trials and offered substantial collaborative solutions to make the country a hub for research, innovation and a competitive pole of clinical trials.

Additionally, the achievements of the Greek innovation clusters, start-ups and Pfizer Global Digital Innovation Hub in Thessaloniki gave a strong success signal of a vibrant research ecosystem.

The President of EL.E.F.I., Dr. Varvara (Barbara) Baroutsou, outlined the horizon of clinical research, highlighting the ongoing need to accelerate the procedures for clinical trials through the use of new technologies, remote monitoring of patients in clinical trials, the digitisation of the ecosystem and the coordinated cooperation of the institutional partners with the integration of Real-World Data – RWD/Big Data/Electronic Health Records - EHR in the research strategy.

The necessity of further investment on continuous modernisation of research infrastructure and digital transformation was emphatically underlined, so that Greece becomes a preferred partner in the international stage of biomedical research.

Seventy-seven (77) distinguished scientists from Greece and the international community joined the congress as speakers, moderators, and session presidents.

Our colleagues were given the opportunity to present their research activity at oral presentations and poster slots. A total of 298 registered members and participants attended the congress, with a high level of engagement that shaped a fruitful online dialogue and enriched learnings.

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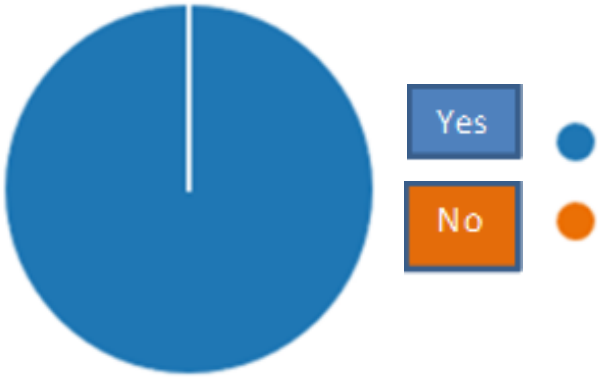
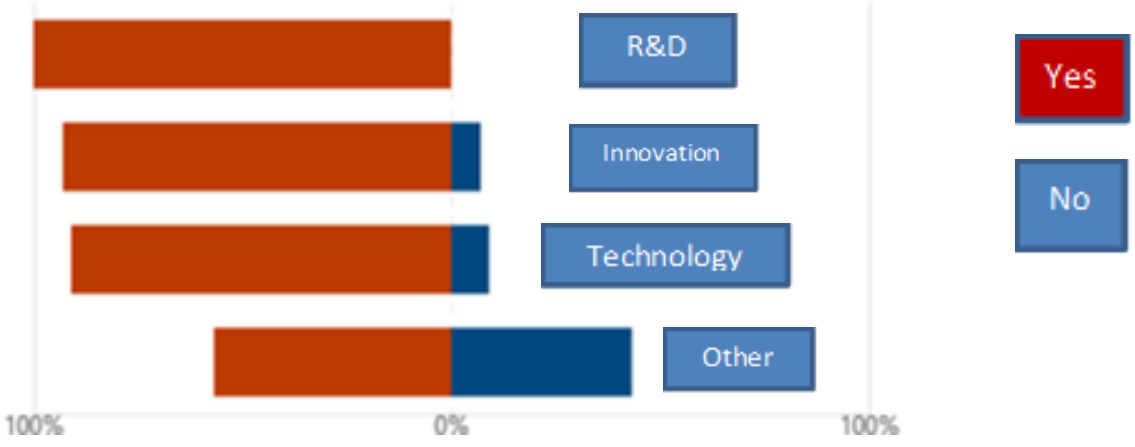
The program of the congress included the Keynote Speech by Professor and President of the Medical School of Athens, P. Sfikakis, who presented the research projects of the Center for New Biotechnology and Precision Medicine pMedGR of the Medical School of the National and Kapodistrian University of Athens, 8 Round Tables, 10 Lectures, 2 Symposia, 3 Workshops, with the release of important new data of the Phase III clinical trial 'Save More' (suPAR-guided Anakinra treatment for Validation of the risk and Early Management Of seveRE respiratory failure by COVID-19) of the Hellenic Institute for the Study of Sepsis by Prof. E. Giamarellos-Bourboulis. The congress was framed by the participation of scientists and executives of the National Medicines Agency, of Dr. Xavier Kurz from the European Medicines Agency and prominent pharmacoepidemiologists from McGill University, and the Democritus University of Thrace as well as by the members of the Scientific Committee of the congress and the Working Groups of EL.E.F.I.

Our attendees were invited to evaluate the congress and made it clear that their expectations were met based on below key feedback: Did the programme of the online 5th Pan-Hellenic Congress of EL.E.F.I. meet your scientific expectations?



Have you gained new knowledge in the following areas?



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The holding of the 5th Pan-Hellenic Congress of the Greek Society of Pharmaceutical Medicine was supported by the sponsorships of the Organisations: Biomedicine Group, Association for Clinical Studies of Greece (HACRO), Qualitis, Creative Pharma Services, CORONIS, the Pan-Hellenic Association of Pharmaceutical companies, Phocus and MEDWORK.

We are grateful to all contributors, and we look forward to the continued scientific exchange on emerging challenges and developments in the upcoming EL.E.F.I. events that you will find on our website www.elefi.gr.

On behalf of the Members of the EL.E.F.I. Board
Varvara (Barbara) Baroutsou, MD, PhD, GFMD, EMAUD
Consultant Internal Medicine
Consultant Pharmaceutical Medicine
EL.E.F.I. President
IFAPP President Elect

Career Paths in Pharmaceutical Medicine

Pharmaceutical Medicine offers a challenging multidisciplinary environment and one of great complexity. Careers in Pharmaceutical Medicine can be very varied and can be challenging, exciting, fulfilling and rewarding.

On June 15, 2021 an event "Career Paths in Pharmaceutical Medicine" was held as a live stream in cooperation with the Medical University Vienna Alumni Club. Three representatives from the fields of science and research, industry and life-science start-up described their careers and answered the numerous questions of the virtually present audience.

The event was opened by Univ. Prof. Dr. Harald Sitte, President of the MedUni Vienna Alumni Club and moderated by PD Dr. Johannes Pleiner-Duxneuner, President of the Austrian IFAPP member association of pharmaceutical physicians GPMed (Gesellschaft für Pharmazeutische Medizin e.V.) and board member of the MedUni Vienna Alumni Club.

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The broad spectrum of opportunities and career paths was illustrated by the following three panelists:

- Dr. Sylvia Nanz, MD, Medical Director at Pfizer Corporation Austria
- Univ.-Prof. Dr. Tanja Stamm, PhD, habilitated health scientist, Professor for Outcomes Research at MedUni Vienna
- Dr. Lukas Zinnagl, MD, co-founder of Diagnosia, entrepreneur, and business angel

In line with this diversity, the topics of the audience questions were also widely spread:

What is the importance of networks? Are mentors important and how do you find the "right" ones for yourself? What opportunities do you have for your own career if you want to stay in research? And how important are stays abroad or international collaboration? How does one get the idea of becoming an entrepreneur? And when or how do you know whether a business idea is mature and you can take that step? What makes you decide not to become a doctor involved in patient care after studying medicine? What are the right or necessary requirements to work in the pharmaceutical industry? What are possible entry-level jobs? What does one do in the areas of clinical research or medical affairs?

In the discussion, it quickly became clear that for all three participants, very different factors were decisive in having taken a certain step at a certain time. All three agreed that key is to be ready for something new, to gather experience, to try things out, to strive for continuing learning, and, if necessary, to acquire additional qualifications. In the end, the real difference is one's own satisfaction, the feeling of being able to make a difference, of having an impact. If you can close a "positive account" for yourself here, then ultimately the issue of work-life balance is also in balance.

The recording is available at https://www.meduniwien.ac.at/web/alumni-club/karrierewege/ or directly on MedUni Vienna's YouTube channel https://www.youtube.com/watch?v=j8xFEfHl1ko

Authors:

Dr. Sylvia Nanz MD, Medical Director at Pfizer Corporation Austria and GPMed board member,
PD Dr. Ghazaleh Gouya-Lechner, Chair of the IFAPP Communication Working Group, GPMed (Austrian IFAPP member association) Board member and founder of Gouya Insights

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The New EU Medical Device Regulation

Background

The new European law, Regulation (EU) 2017/745 on Medical Devices (MDR) (1) was published in the Official Journal of the EU on 5 May 2017. As a Regulation rather than a Directive, it is directly applicable in all European Union (EU) member states without having to be transposed into national laws. The Medical Devices Regulation (Regulation (EU) 2017/745) applies since 26 May 2021, following a four-year transition period.

Previously, the European landscape for the medical device market was claimed to make innovative medical technology available and to be the fastest in the world (2). But although the conditions in the EU might have been more favourable to the industry, they were not the best for patients. Despite the lack of transparency in existing clinical data on safety and efficacy, decisions on market authorisation for medical devices including of high-risk devices were made by privately run notified bodies rather than government agencies which might not be rigorous enough in checking how safely or well a device works (3).

According to an analysis (4), in the past European citizens have had earlier access to the most important new treatments compared to US ones. However, devices approved first in the EU were associated with a 2.9-fold greater rate of safety alerts and recalls (HR: 2.9, 95% CI: 1.4–6.2; p = 0.005) than devices approved first in the United States. Moreover, results of pivotal trials were published only for 37 (49%) of the 75 devices defined as "major innovations", and median time to publication from first regulatory approval, in the United States or EU, was approximately 3 years (37 months; range 0–118 months).

The MDR has been debated in the industry arguing that innovation will reach the market with a delay, cause late access to new technologies, and would be linked to a "human cost" compared to the time before MDR, though increased requirements in clinical development, transparency in safety and efficacy data, training and oversight of notified bodies and mandatory post-market clinical surveillance will increase the safety of medical devices for patients.

Several medical devices on the EU market have been approved previously by showing equivalence to other marketed products. The MDR only allows comparison under equivalence with one device. Using the equivalence approach to clinical evaluation will be much more difficult to achieve as manufacturers must have contracted access to the full technical documentation of the product with which they claim equivalence. There is an increased responsibility of manufacturers to document the effectiveness, safety, and quality of their own devices.

What is New in the MDR?

The scope of Regulation (EU) 2017/245 (MDR) has changed to include a broadening of the range of products that are subject to the new requirements. MDR 2017/245 covers devices that previously fell under two separate European directives, the Medical Devices Directive (MDD 93/42/EEC) and the Active Implantable Medical Devices Directive (AIMDD 90/385/EEC).

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Some of the major changes are related to the following elements:

- Expanded definition of the term "medical device" that now will include products aimed to perform prediction and prognosis of diseases as well as those which don't have a direct medical intent (e.g., disinfection and sterilisation products, fillers, condoms, software, or implanted devices used for aesthetic and cosmetic purposes).
- Reclassification of some categories of devices to Class III (e.g., surgical meshes and spinal disc replacement implants) and increased assessment for IVD (in-vitro diagnostics) medical devices.
- New (stricter) designation requirements and roles for notified bodies to assure they have required capabilities and competences.
- New (more rigorous) procedures for the notified bodies for the assessment of high-risk (Class III) medical devices; equivalence to already existing devices will be possible only in some cases and only if the manufacturer has full access to the technical documentation of the claimed equivalent device.
- Improved availability of clinical investigation data: Results of clinical investigations will be available on the European database for medical devices (EUDAMED), which will be available to the public, within 1 year from the end of the investigation or within 3 months from its early termination or halt, whichever is earlier.
- Improved traceability of medical devices by a Unique Device Identification number and implant card for certain implantable devices.

Medical devices in the EU must undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments. The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device.

Summary

Perhaps the most significant change from the MDD to the MDR is the increased focus on clinical evaluation, access to data and post-market surveillance. This places a greater burden upon manufacturers and their representatives. All medical devices regardless of their classification must be evaluated according to Article 61 for their safety and performance. European regulators are continuously preparing many guidance documents for manufacturers and notified bodies on important aspects of the legislation such as sufficient clinical evidence, equivalence, safety, and clinical performance. The time and monetary burden of clinical development will re-shape the medical device landscape with the need of increased funding, training on clinical evaluation and new business models for covering the increased MDR demands.

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5. Medical Device Coordination Group Documents: https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Author: PD Dr. Ghazaleh Gouya-Lechner,
Chair of IFAPP Communication Working Group,
GPMed (Austrian IFAPP member association) Board member and founder of Gouya Insights

Health Economics and Pharmacoeconomics Opportunities for German - African Cooperation

WORKSHOP

30–31 October 2021

PROGRAMME COMMITTEE:

- **Nathalie Dehne**, Head of Deanery, Faculty of Health Sciences Brandenburg, Potsdam, Germany
- **Cornelius Frömmel**, Dean and Professor, Faculty of Health Sciences Brandenburg, Potsdam, Germany
- **Ntobeko Mpanza**, Director, Pharmaceutical Economic Evaluations Directorate, National Department of Health, South Africa
- **Günter Peine**, Advisor Transfer und Translation, Faculty of Health Sciences Brandenburg, Potsdam, Germany
- **Bernd Rosenkranz**, President, Fundisa African Academy of Medicines Development, Cape Town; Professor emeritus, Division of Clinical Pharmacology, Stellenbosch University, South Africa; Charité Universitätsmedizin Berlin, Germany
- **Michael Thiede**, Director, Scenarium Group GmbH and Professor of Business Economics and Health Care Management, International University of Applied Sciences, Berlin, Germany
- **Praneet Valodia**, Adjunct Professor, University of the Western Cape; Director, Praneet Valodia Consulting, Cape Town, South Africa
- **Tryphine Zulu**, Senior Manager, Government Employees Medical Scheme (GEMS), Pretoria, South Africa

VENUE: Hybrid workshop – University of Potsdam, Germany (Auditorium Maximum), plus online participation. Attendance is free, but registration is required.

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Africa is one of the world's fastest-growing economic regions. In addition to multinational companies active on the African continent, an increasing number of local companies engage in the development, production and marketing of medicines, medical devices and diagnostics across Africa. There are many examples of successful partnerships between German and African stakeholders.

Health technology assessment (HTA) plays an increasing role in decision-making in product development, licencing, pricing and reimbursement. Pharmacoeconomic modelling methods are also used as bridging tools between clinical phase 3 efficacy data and "real world" outcomes. It is therefore important that pharmaceutical companies engaged in Africa have an understanding of this "fourth hurdle" to market access in order to optimise the potential of their medicines in this region. HTA also plays an essential role in decision-making as well as designing policies on the use of medical devices with a view to the efficient use of resources in health care.

At this workshop, recognised experts from Europe and Africa will explore potential use and applications of pharmacoeconomic tools for medicines, medical devices and diagnostics.

The workshop will emphasise upcoming trends in HTA in light of health systems strengthening towards universal health coverage. The format will provide an opportunity for networking between various stakeholders and for capacity building.

ENQUIRIES AND REGISTRATION: info@fundisa-academy.com

WORKSHOP OBJECTIVES:

Awareness of methodologies, outcomes and implications of health technology assessments for medicines, medical devices and diagnostics

Opportunity for networking between experts from industry, academia, and health technology assessment agencies

Capacity building for young scientists

Cooperation between German and African partners

TARGET AUDIENCE:

Experts in health economics from industry (medicines, medical devices and diagnostics), academia, funders/payers, and health technology assessment agencies

Government officials

Experts in medicines regulation

Consumers (patient organisations)

Postgraduate students

Click here for more information and the programme.

CO-HOSTED BY:

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First Announcement of Next Free IFAPP Webinar on Regional COVID-19 Updates

COVID-19 in Sub-Saharan Africa

IFAPP is honoured to announce the next free webinar on regional COVID-19 in collaboration with Fundisa African Academy of Medicines Development. This webinar will be presented on **Thursday, 18 November 2021**, at 2.00 pm CET.

Prof Rhoda Wanyenze, Dean of Makerere University School of Public Health (MakSPH), Kampala, Uganda, will talk about "*COVID-19 - Experiences from Uganda, Democratic Republic of Congo, Senegal, and Nigeria*".

Prof Charles Wiysonge, Director of Cochrane South Africa, Medical Research Council, Cape Town, SA, will speak about "*Vaccine Policy, Usage and Vaccine Hesitancy in SA*".

A third speaker will be confirmed soon.

The moderators will be **Dr med Bernd Rosenkran**z, FFPM, Prof. em. (Stellenbosch University), President, Fundisa African Academy of Medicines Development, Visiting Scientist Institute for Clinical Pharmacology and Toxicology, Charité Universitätsmedizin, Berlin, Germany, and **Professor Wolfgang Preiser**, Head, Division of Medical Virology, Faculty of Medicine and Health Sciences, Stellenbosch University and National Health Laboratory Service (NHLS), Tygerberg, South Africa.

Registration details will follow soon.

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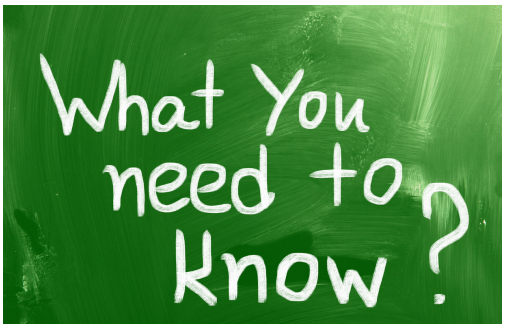
Need to Know



- **New IFAPP Board**
  At the IFAPP House of Delegates on 28 June 2021 a few new members of the Board of Officers were elected. You will find the new composition of the board at IFAPP's website.

- **House of Delegates Meeting**
  The next IFAPP House of Delegates Meeting will take place on **Thursday, 11 November 2021** at 1:00-2:30 pm CET, 7:00-8:30 am EST, 8:00-9:30 pm JST

- **NMA Survey**
  A survey on IFAPP benefits has been distributed to IFAPP National Member Associations and individual affiliates. Please complete, it will only take a few minutes.

- **Call for Working Group membership applications extended to 30 September 2021**
  The call for application for new members of the IFAPP Working Groups has been extended to 30 September! Please take a look at IFAPP's website for more information.

THE FLAG

IFAPP secretariat - Leidsestraatweg 41d - 3443 BP Woerden - The Netherlands
Chamber of Commerce 30224375 – VAT number NL817747321B02
Phone: (+31) 6 2291 1039 – e-mail: secretariat@ifapp.org – website: www.ifapp.org

IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Rodelio Bito, Brigitte Franke-Bray, Kotone Matsuyama, Helio Osmo, Johanna Schenk, Peter Stilting.

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

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