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The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

Italian Society of Pharmaceutical Medicine (SIMeF), Solid Historical Roots and an Eye Towards the Future

It is with great pleasure that we take the opportunity, offered by IFAPP, to host ourselves in IFAPP TODAY to illustrate the various Working Groups (WGs) and their activities within the Italian Society of Pharmaceutical Medicine (SIMeF) which this year celebrates the sixtieth anniversary of its foundation:

Institutional Affairs

It proposed itself with an operational and proactive mode in some areas, and reactive (or supportive) to inputs coming from the other WGs or from the world around us. The interest is focused on retrospective observational research and the implications in terms of General Data Protection Regulation (GDPR), up to the

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ethical use of healthcare big data. It promotes the identification and interaction with institutional stakeholders such as the Italian Drug Agency (AIFA), the Ministry of Health, the National Institute of Health, the Regions, the Universities, the National Research Council (CNR), the General Managers of Hospitals and Patient Associations. It wants to play a fundamental role in supporting SIMeF and its WGs, as well as being an engine for the progress of Pharmaceutical Medicine in Italy.

Legal Affairs

Born in 2009, it has had the opportunity to deepen, from a legal point of view, many aspects including, by way of example, Privacy, the national "CRO Decree", compassionate use, non-profit, insurance aspects, the Medicrime Convention and the counterfeiting of health products, e-consent and conflict of interest in clinical trials. Several inputs are proposed, including those relating to intellectual property: today, in fact, SIMeF has its own trademarks and, in general, its own copyright policy.

Medical Devices

Founded in 2008, it has taken the form of a series of events and educational and informative publications, thanks to the involvement of external stakeholders from the academic, institutional and clinical worlds, which have contributed to the multi- and inter-disciplinary character, with a view to defining roles, skills and perspectives not only in the development but also in the use of MDs. Since 2021, thanks to the presence in the group of a patient expert in EUPATI research and development, attention has also been focused on the figure of the "patient user" and her/his practical approach to their best use.

Pharmacovigilance "E. Montagna"

Started in 1995, it has always pursued the goal of raising awareness and spreading the culture of Pharmacovigilance among its members. With a strong aim to a greater visibility of the Pharmacovigilance Department, also outside the companies, it has planned, following the incoming regulatory changes, a series of events and initiatives on the greater involvement and inclusion of patients and healthcare professionals in the transparency of safety documents. The close interaction with the other WGs, such as RICMA and GIQAR, continues, to share the common points of view that involve Pharmacovigilance itself.

Young People

The result of a collaborative work between former students of the Master in "Pre-Clinical and Clinical Drug Research and Development" and the SIMeF Board of Directors, it was born in 2016 from the need to create a link between the universities and the world of work and allow the comparison and exchange of opinions between colleagues. Young people, up to 35 years of age, are welcomed in a space dedicated to them, to discuss with colleagues of different ages and work experience, propose ideas and issues and collaborate with other WGs. There are three themes that guide the activities of this WG: communication and leadership in the pharmaceutical field; gender medicine and women's health; professional guidance, i.e., collaborations with universities and research groups, with young people from other scientific societies, with associations of young students and with recent graduates in the pharmaceutical sector.

GIQAR (Italian Group of Quality Assurance and Research)

It began operating in 1989 when Quality Assurance in Italy felt the need to meet to discuss issues related to quality and the role and activities of Quality Assurance. Currently one of the largest WGs, it aims to provide the exchange of experiences and information and thus facilitate the acquisition, dissemination and use of Quality Assurance concepts also through dedicated meetings, seminars and training courses. It is composed of three subgroups:

GLP, GCP, QA in PV. The cornerstone of the activities that the Group as a whole has always been engaged in, is precisely the analysis of the regulations, assessing their applicability and sending their comments to the Competent Authorities.

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IBIG (Italian Biostatistics Group)
It promotes and organises several events aimed at the entire Italian statistical community, within which reflections and analyses of scientific articles of great international interest are proposed. Given the growing return to Bayesian statistics applied to clinical research, both in the context of randomised and observational trials, it is focusing particularly on this aspect and on that of causal Inference.

Food Supplements
Since 2015 it has been organising meetings and developing projects such as "training in pills" or questionnaires devoted to the various operators in such a market, touching on topics ranging from the quality of raw materials to the safety of finished products, to correct communication to consumers and specialists, to experimentation, phytosanitary surveillance, safety and efficacy of natural principles and of finished products. In those activities, active collaborations have been consolidated, among others, with the Ministry of Health, the Italian Society of Pharmacology, the Federation of Associations of Hospital Internists Managers, the Italian Society of General Medicine and Primary Care and with consumer associations.

Market Access & Health Technology Assessment
Since 2009 it has aimed to demonstrate the Value of the Drug through Pharmacoeconomic Analysis, promoting and spreading its culture, deepening the methodological knowledge of Clinical Pharmacoeconomics and acting as an interlocutor towards the institutions on the aspects of Price and Reimbursement of Drugs. Then came the idea of evolving the WG in the direction of working on the new skills for Market Access and on the recognition of the value of the drug at 360° by decision-makers, including all the activities and skills necessary to bring a drug to the patient, from early access to regional access, to value-based procurement.

Patient Partnership
Established in 2019 with the aim of enhancing virtuous alliances within the healthcare supply chain between the world of research, the pharmaceutical industry and that of citizens, patients, caregivers and their associations, testifying to the requests of the latter within the processes of health sustainability, the research and development path of the drug and facilitating their involvement in the decision-making boards of the health system. The paths that guide the activities are the dedicated training and information, the involvement of patient associations and the monitoring of trends in the evolution of the health organisations.

RICMA (Clinical Research and Medical Affairs)
Since the end of the 90s, it has been the spokesperson for the new scientific, technological and regulatory trends that revolve around pharmaceutical development and wants to be a place for open scientific debates where all actors can have the space to express themselves and where members can have the opportunity to listen to the most authoritative voices, promoting the technical and scientific culture of clinical research through specific training programs.

Observational Studies and Real-World Evidence
Established in 2004, it has dedicated its skills and energies to developing the discipline of observational research and, more recently, of Real-World Evidence (RWE), essentially pursuing three objectives: that of training members, scientific dissemination outside the SIMeF (in collaboration with other scientific societies and university institutions) and that of improving the national regulatory environment, in particular by interacting with the Italian Medicines Agency and

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the national Ministry of Health. It is still constantly pursuing its mission which is to contribute to ensuring the scientific and ethical quality of observational research and to make it more efficient through the development of appropriate evaluation and approval processes.

Hoping to have given a concise but relevant image of our activities, we thank you for your attention and we express our satisfaction in being part of the great family represented by IFAPP and wishing you and all of you to spread and develop more and more!

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On behalf of all WG members:

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Embracing a Future of Excellence: A Vision for the Hellenic Society of Pharmaceutical Medicine (EL.E.F.I.)

Stepping into the role of President EL.E.F.I., I am honoured and excited to outline my vision for the society's future. In this article I would like to introduce myself and my vision for the future of EL.E.F.I.

I was graduated from the Medical School University of Athens and specialised in Endocrinology. Since 2008 I am practising as a private physician and simultaneously joined the pharmaceutical industry where for more than 15 years I gained significant experience in Pharmaceutical Medicine.

The field of Pharmaceutical Medicine is at the forefront of scientific innovation and our society plays a crucial role in fostering collaboration between health authorities, researchers, pharmaceutical industry, health care professionals, contract research organisations (CROs), patients and all other stakeholders, in order to advance research and ensure the highest standards in medical practise. With a commitment to excellence and a focus on inclusivity, I aim to lead our society into a new era of growth and innovation in order to contribute to the broader health care ecosystem.

Promoting Collaborative Research:
One of our primary objectives is to further develop the interdisciplinary collaboration among health authorities, academia, researchers, CROs, industry experts and health care providers to accelerate the development of new medicines and therapies. Through dialogue and joint initiatives, we can address industry challenges, explore innovative solutions and collectively advance the standards of Pharmaceutical Medicine practise.

Enhancing Education and Professional Development:
In order to stay at the forefront of the latest scientific innovations, technological advancement and professional development, continuous education is mandatory. While we are organising workshops, seminars and conferences to cover a wide range of topics, we will explore opportunities for collaboration with academic institutions to provide our members access to cutting-edge knowledge. Through joint programmes and initiatives, we can enrich educational experience and provide access to diverse perspectives and expertise.

Embracing Technological Innovation:
The pharmaceutical landscape is evolving rapidly, driven by technological advancements. Artificial intelligence, advanced data analytics and digital health applications are some examples of new tools to enhance the efficiency of clinical trials and drug development processes, patient outcomes and patient care and contribute to the evolution of personalised medicine. Our society will invest in building relevant skills, to embrace these innovations and stay relevant and effective.

Advocating for Ethical Practises:
EL.E.F.I. traditionally reinforcing dedication to ethical standards and transparency in research, drug development and clinical practise. This includes promoting integrity in research, ensuring patient confidentiality and advocating for responsible and sustainable pharmaceutical development. By upholding these principles, we can build trust between the industry, health authorities, patients and public, fostering a positive reputation for the society and its members.

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Empowering Patients by Collaborating with Patient Advocacy Groups (PAGs):
Our society has a strong focus on promoting patient rights, ensuring that the needs and perspectives of patients are at the forefront of decision-making processes. PAGs play a pivotal role in the health care landscape, acting as powerful voices for individuals facing various medical conditions. In coming years, the concept of patient-reported outcomes (PROs) will emerge as a dynamic force in enhancing patient care and shaping health care policies, as PROs will become a prerequisite for the assessment of new treatments by health technology assessment bodies. EL.E.F.I. will continue and enhance further the close collaboration with PAGs, not only to advocate for guidelines and practises but also to include actively patients' opinion in decision-making in all steps of drug development and access to innovative treatments for the well-being and interests of patients.

Global Outreach and Collaboration:
Our society is fostering partnerships with other scientific societies and international organisations such as the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and collaborating on research projects with institutions from around the world in order to align our standards with international best practises, enhance our members' exposure to diverse perspectives and the presence of EL.E.F.I. in the global landscape.

Diversity and Inclusion Initiatives:
Diversity is a driving force behind innovation. I am dedicated to promoting diversity and inclusion within our society, ensuring that all voices are heard and valued. Recognising the richness that diversity brings to scientific endeavours, there are plans to implement initiatives that promote equal opportunities for professionals from all backgrounds and creating a welcoming space for professionals at all career stages. By fostering a diverse and inclusive environment, we can harness the full spectrum of talent and expertise within our membership, driving progress and excellence.

In conclusion, my vision for EL.E.F.I. is rooted in a commitment to excellence, foster active collaboration of all stakeholders and innovation. By promoting collaborative research, enhancing education, embracing technological innovation, advocating for ethical practises, empowering patients, expanding global outreach and prioritising diversity, we can position our society at the forefront of Pharmaceutical Medicine.

Together, we can shape a future where our contributions lead advancements in medical science, improve patient outcomes and drive Pharmaceutical Medicine professionals to excellence in their field.

Grigorios Rombopoulos, MD, Endocrinology, Diabetes & Metabolism
President of the Hellenic Society of Pharmaceutical Medicine

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Update on the 2024 IFAPP Fellowship Awards

The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) has launched its annual recognition programme for outstanding professionals in Pharmaceutical Medicine with the 2024 Fellowship Awards.

These prestigious awards recognise scientific excellence, leadership and contributions to the advancement of pharmaceutical research, education and patient care.

The three fellowship categories and application requirements for the 2024 IFAPP Fellowship Awards were published in IFAPP TODAY, November/December 2023, Number 39, Pages 4-6 and their titles are highlighted below:

1. **Scientific Leadership in Pharmaceutical Medicine (PM) for Senior Candidates** (experience > 15 years in PM roles)
2. **Scientific Excellence in Pharmaceutical Medicine (PM) for Mid-Career Candidates** (experience of > 10 years and ≤ 15 years in PM roles)
3. **Rising Star in Pharmaceutical Medicine (PM) for Early Career Candidates** (experience of > 3 years in PM)

For more information, please refer to the above-mentioned IFAPP TODAY reference.

Following the official announcement of the 2024 IFAPP Fellowship Awards mid November 2023, twenty-six applications were received from Europe, Asia and Australia regions by the due date of 26 January 2024.

The IFAPP Fellowship Award Committee evaluated and found all applications valid in February 2024 and interviews with candidates were conducted in March 2024.

Each candidate was interviewed by two members of the IFAPP Fellowship Award Committee. For reasons of neutrality, IFAPP Fellowship Award Committee members were assigned to interview candidates who were not members of their country of origin.

The final assessment of all candidates will be made by the IFAPP Fellowship Award Committee during the months of April and May 2024.

Candidates will be informed of the outcome of their application by the end of June 2024 at the latest.

The IFAPP Awards Reception, where all award winners will be honoured and receive their Certificate, is scheduled to take place at the International Conference of Pharmaceutical Medicine (ICPM) 2024 to be held in Amsterdam on 18-20 September 2024.

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On behalf of the IFAPP Board of Officers and the IFAPP Fellowship Award Committee Members, I would like to thank all applicants of the IFAPP community and respective National Member Associations and Individual Affiliates for their participation in this important process which recognises excellence in Pharmaceutical Medicine professionals and promotes their scientific careers.

Dr Varvara (Barbara) Baroutsou
IFAPP President

Swiss Round Table on Antibiotics – Effective Antibiotics for the Swiss Health Care System

About the Swiss Round Table on Antibiotics

The Swiss Round Table on Antibiotics is a multi-disciplinary, non-profit Swiss association founded in 2019. It brings together stakeholders from the fields of health care, academia, politics, and industry. While the focus of our activities is on Switzerland we are also involved in international initiatives. We are committed to measures that promote the development of antimicrobial technologies and ensure the continued availability of antibiotics in the market to safeguard the future functioning of health care systems.

Problem Statement

Antimicrobial resistance (AMR) stands as one of the most pressing global public health concerns, ranking among the top ten health threats worldwide (WHO and European Centre for Disease Prevention and Control (ECDC), 2023). As resistance continuously erodes the effectiveness of antibiotics, bacterial infections can become challenging or even impossible to treat. This trend is underscored by the growing number of fatalities, with about 1.27 million lives lost each year globally due to AMR, including around 300 in Switzerland (Eidgenössisches Departement des Innern und Bundesamt für Gesundheit, 2022; Murray et al., 2022). While these figures suggest an urgent need for new effective antibiotics the global level of innovation is inadequate (WHO, 2021). The last marketing authorisations for new chemical classes of antibiotics were granted 20 years ago. Further, the supply of existing antibiotics is characterised by shortages and market withdrawals of existing products, both in Switzerland and globally (Bundesamt für wirtschaftliche Landesversorgung BWL, 2023). The innovation shortfall does not stem from a lack of ideas or technological barriers, but rather from a dearth of incentives. The prevailing economic and regulatory challenges in the infectious disease field make it more lucrative to redirect resources to other medical fields like oncology.

Pull Project

Aspiring to secure more new antibiotics for the Swiss market and retain existing antibiotics there, the Swiss Round Table on Antibiotics launched its “pull” project in 2022. The project aims to have an innovative or “pull” incentive implemented in Switzerland to reimburse selected antibiotics. Pull incentives apply to antibiotics after they have gained marketing authorisation. Different pull designs have been developed internationally, all sharing the intention of allowing manufacturers to achieve a reasonable revenue even if sold product volumes are low. Such measures, leveraged

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by similar initiatives pursued in other countries, should motivate pharmaceutical manufacturers to invest more resources in antibiotic research & development (R&D) again.

In a first step, we evaluated various pull-incentive models for potential implementation in Switzerland.

The outcome of this evaluation is summarised in a white paper (refer to image 1) which was published on 25 March 2024 (Swiss Round Table on Antibiotics | Downloads (roundtableantibiotics.ch)).

Image 1: Cover of the White Paper "Effective antibiotics for the Swiss health care system: today and in the future".

It concluded that a so-called subscription model is most suitable for implementation in Switzerland. Not only can its adoption draw on substantial real-world evidence from pilot projects in Europe. Its design is well tuned to the specific characteristics of antimicrobials in that it enables a reasonable revenue while not incentivising drug use beyond clinically justified levels - a major driver of resistance build-up. The subscription model entails a contractually agreed fixed annual remuneration per antibiotic that is decoupled from the sales volume. The remuneration amount should not only reward the antibiotic treatment of individual patients, but also the benefits it generates for public health, for example by preventing the transmission of pathogenic germs to other people, de-risking surgeries or being immediately available like a fire brigade in the still relatively rare cases where standard antibiotics have failed. Remunerating the full value of new antibiotics improves their business case while its decoupled design slows the development of resistance, thus preserving their effectiveness longer.

Given that not all antibiotics with a marketing authorisation in Switzerland will be remunerated under a subscription model, it becomes imperative to prioritise antibiotics by the extent they address the highest unmet medical needs in Switzerland. The next step in the pull project focuses on the elaboration of eligibility criteria for antibiotics to qualify for a remuneration under a subscription model.

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World Health Organization (WHO), "2021 Antibacterial agents in (pre-)clinical development (infographic)." 27.05.2022.

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From EMA for Pharma SMEs: Updated User Guide

On 23 January 2024, the European Medicines Agency (EMA) released a major revision of its user guide for micro, small and medium-sized enterprises (SMEs) in the pharmaceutical sector. The revised guide offers a comprehensive view on the European Union (EU) legislative framework for medicines, outlining requirements for the development and authorisation of medicines for human use. Take a look at the new important sections/sub-sections.

Clinical Trials Information System (CTIS)

There is an extensive chapter providing an overview of the clinical trials regulation and Clinical Trials Information System (CTIS), which now harmonises the assessment and supervision of clinical trial applications throughout the EU/EEA member states. Each member state retains the responsibility for the trial, while EMA is responsible for the maintenance of CTIS, and the European Commission (EC) ensures oversight and control of the implementation of the Clinical Trials Regulation.

CTIS has become the single-entry point for the submission, supervision, and authorisation of clinical trial applications for human medicines in the EU/EEA, with secure workspaces for sponsors and authorities, including a public website to search for information on clinical trials. Deferral procedures can apply, under which sponsors can request a deferral of certain information related to the clinical trial in the public domain.

CTIS together with other EMA IT tools also supports the coordinated assessment of safety reporting in clinical trials. SMEs should be aware that if the final formulation differs from that of the IMP used in earlier clinical trials, the relevance of the earlier material compared to the product tested in later phases should be described. Special consideration should be given to changes in quality parameters with potential clinical relevance (e.g., in vitro dissolution rate).

Borderline products

The new user guide offers advice on borderline products which have regulatory framework uncertainty. Such products englobe medicinal products, medical devices, cosmetics, biocidal products, herbal medicines, and food supplements. National competent authorities classify borderline products either as medicinal products or, for example, as medical devices on a case-by-case basis, and this determines the applicable regulatory framework. Applicants who are unclear on the correct classification of their product, should consult a national competent authority and provide information on the product's composition, constituents, mode of action and its intended purpose. If scientific questions arise, then EMA's Innovation Task Force (ITF) can give further support.

Environmental Risk Assessment (ERA)

This new sub-chapter defines requirements to investigate potential environmental risks of a medicinal product following its use in patients. The ERA is mandatory for all marketing authorisation applications, although in some cases it can consist of a justification for not submitting data. As such, this evaluation is now a stepwise approach. The first part of the investigation estimates the exposure of the environment to the active substance and the potential for bioaccumulation, and persistence in the environment. As such, based on an action limit, the assessment of environmental risk may be terminated at this stage. Above this limit, the fate of the substance in the environment and its associated effects should be investigated in a second phase of investigation. Some product classes (e.g., endocrine active agents) require this second part irrespective of the predicted environmental exposure.

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How to use big data for decision-making

In the context of medicines regulation, big data includes Real-World Data (RWD) such as electronic health records, registry data and health insurance data, pooled clinical trials data, datasets from spontaneously reported suspected adverse drug reaction reports, and genomics, proteomics, and metabolomics datasets. In line with the agency regulatory strategy for 2025 and the European Medicines Regulatory Framework (EMRF), the aim is to establish a better integration of RWD and Real-World Evidence (RWE). As such, alongside the gold standard of controlled trials, the wish of EMA is to include RWD/RWE into regulatory decisions on the development, authorisation, and supervision of medicines. Projects are being piloted as we speak, to enable the use and establish the value of RWE and individual patient data from clinical trials.

"EU-M4all"

This procedure is designated to support the access to high-priority medicines for patients outside of the EU. Products eligible for this procedure include for example vaccines used in the World Health Organization (WHO) Expanded Programme on Immunization, or for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria, dengue, and tuberculosis. Cooperation with WHO and regulators from countries where the products are expected to be used, enriches the epidemiology and local disease expertise, facilitates a benefit-risk assessment tailored to the intended non-EU population, streamlines the WHO prequalification programme, and facilitates national registration in target countries. As such, EMA welcomes parallel applications for a centralised EU marketing authorisation and an opinion under the EU-M4all pathway. For a medicine to be eligible for a parallel evaluation, the active substance(s) must be identical in both applications, with comparable indications, although the formulation, pharmaceutical form or route of administration may be different in the two applications.

The "OPEN" Initiative

EMA collaborates with medicines regulators outside the EU in the scientific evaluation of certain medicines, within a framework called 'OPEN' (opening procedures at EMA to non-EU authorities). Within this framework, several regulators evaluate a medicine in parallel with EMA, remaining scientifically and procedurally independent from one another while sharing information, expertise, and approaches during the evaluation. The WHO is a partner in the initiative, which aims to accelerate registration and availability of certain medicines in low- and middle-income countries.

Links to EMA's SME user guide and respective annex:

1https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/user-guide-micro-small-and-medium-sized-enterprises_en.pdf

2https://www.ema.europa.eu/en/documents/other/annex-national-provisions-smes-applicable-pharmaceutical-sector_en.pdf

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JAPhMed-PhRMA-MAPS Japan Medical Affairs Summit 2024

The theme of the Summit is **Digital Innovations in Medical Affairs: Transforming Patient Outcomes**. This theme reflects continuously expanding the impact that new digital innovations are having on all disciplines within the Medical Affairs (MA) functions. The entire objective of the conference is to highlight the latest developments in digital and technology as it applies to key areas of MA's ordinary efforts and discuss how to leverage these innovations for greater impact on patient outcomes. All the moderators, speakers and panellists are crème de la crème. Other interesting topics are how to make the authorities aware of the significance of the existence of Medical Science Liaisons (MSL) in Japan, Medical Leader roundtable discussion and MA Career Development Workshop.

This summit will be generally held on-site (https://medicalaffairs.org/japan2024/#agenda).

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IFAPP Webinar in Co-operation with PTF and FPM

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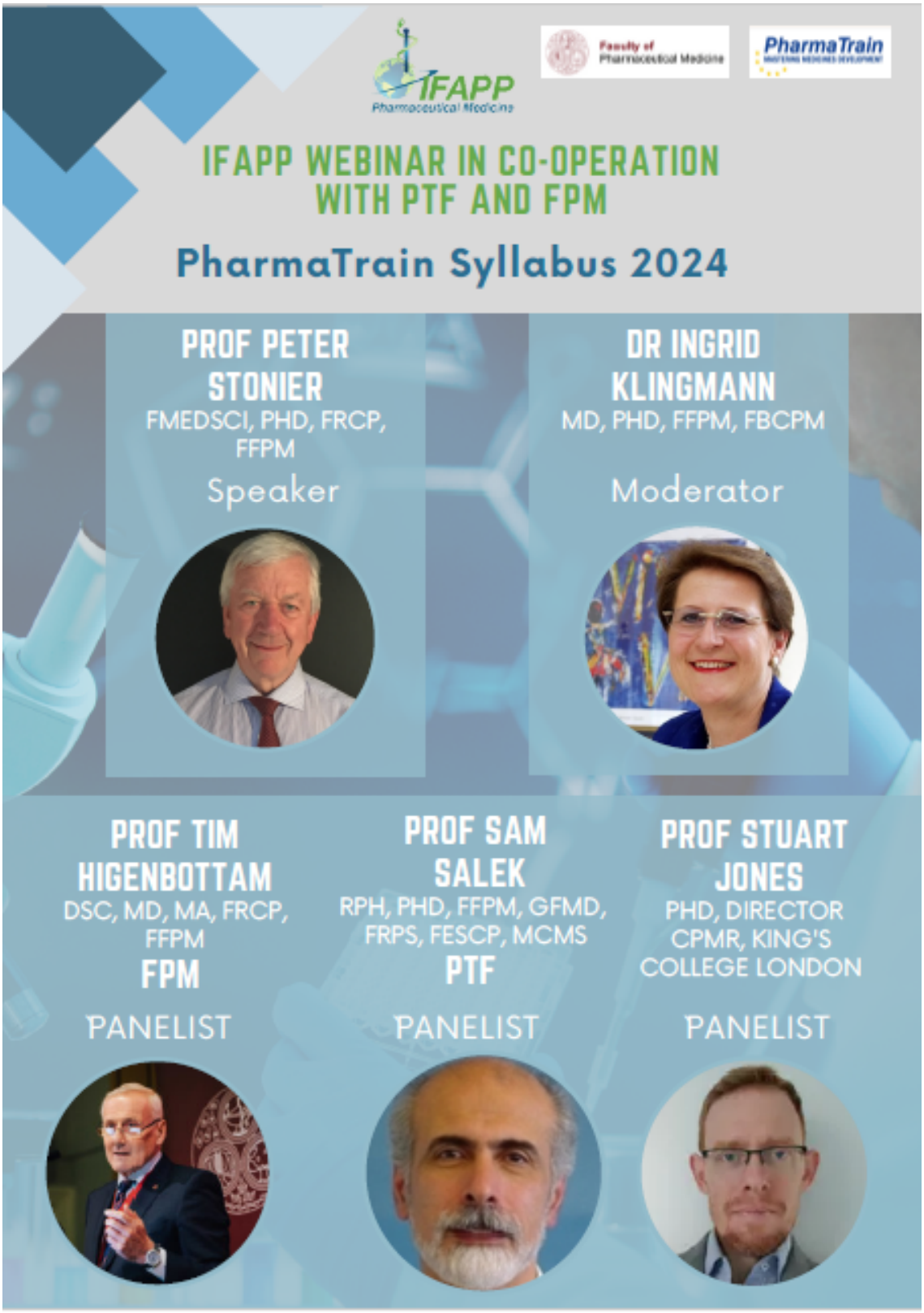

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Join us!! “IFAPP Asian-Pacific Regional Meeting” on 27 July 2024

Join us for the Asian-Pacific Regional Meeting planned to take place on 27 July.

The regional meeting will focus on current topics and issues in Pharmaceutical Medicine in various countries in the region. The Asian-Pacific 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, Australia and Singapore.

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

Venue: Zoom meeting
Date: 27 July 2024 (Sat), at 14:10-15:10 (Tokyo time).

The proposed agenda will read as follows:
1) Welcome message from IFAPP
2) Introduction of Patient Public Involvement activities in Asian-Pacific countries
3) Latest updates on the Declaration of Helsinki Amendment (2024)
4) Update on IFAPP ICPM2024
5) Any other proposals for discussion

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

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Web address (Japanese only, English in preparation)
https://japhmed.jp/japhmed2024/index.html

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