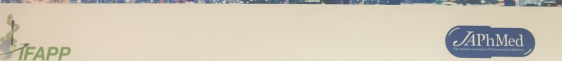




The 19th International Conference on Pharmaceutical Medicine (ICPM 2018)
 第9回日本製薬医学会年次大会

Main Theme
The Future of Medicines Development

• Date: September 27(Thu)~28(Fri), 2018(ICPM&JAPhMed)
 September 29(Sat)~2018(JAPhMed)



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The Austrian Society for Pharmaceutical Medicine (GPMED)

The Summary

The Austrian Society for Pharmaceutical Medicine (Gesellschaft für Pharmazeutische Medizin), founded in 1992, is a medical-scientific forum for physicians, scientists and health professionals from academia, industry, government agencies and other institutions involved or interested in the clinical development of pharmaceuticals. The goal of GPMed is promoting science and research by establishing and continuously developing a high professional standard, competence and ethical integrity in this specialty. The focus of activities is on training and continuous development in clinical research in a highly dynamic environment with internationally competitive standards. GPMed's international profile offers unique communication among the key stakeholders in clinical development to foster clinical research in Austria as a leading life sciences location.

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Top left to right every row: Assoc. Prof. Dr. Gerhard Garhöfer (Univ.-Klinik für Klinische Pharmakologie, Medizinische Universität Wien), PD Dr. Johannes Pleiner-Duxneuner (Roche Austria, President elect GPMed), Assoc.Prof. PD Dr. Markus Zeitlinger (Univ.-Klinik für Klinische Pharmakologie, Medizinische Universität Wien), Mag. Bernhard Mraz (Novartis Pharma GmbH, DI Christoph Noe (Amgen GmbH), Prof. Dr. Robert Mader (Comprehensive Cancer Center der Medizinischen Universität Wien), Dr. Sylvia Nanz (Pfizer Corporation Austria GmbH), PD Dr. Ghazaleh Gouya Lechner (Gouya Insights KG), Dr. Dejan Baltic (Amgen GmbH), Univ.DoZ.Dr. Martin Brunner (Univ.-Klinik für Klinische Pharmakologie, Medizinische Universität Wien), Dr. Alexander Barousch (AOP Orphan Pharmaceuticals AG), Dr. Barbara Grohmann-Izay (BIZness – Clinical Consulting), Mag. Doris Schweighofer (Bayer Austria GmbH), Univ.Prof. Dr. Bernd Gilma ((Univ.-Klinik für Klinische Pharmakologie, Medizinische Universität Wien).

GPMed

GESELLSCHAFT FÜR PHARMAZEUTISCHE MEDIZIN E.V.

GPMed was aimed as an industry-independent critical forum for education and training of professionals in pharmaceutical medicine. Already in 1997 GPMed joined IFAPP to drive the international collaboration, with the former president Prof. Dr. Gerfried Nell who was also IFAPP President in the years 2008-2011. The independent character of this society enables a close public private collaboration and a critical discussion with the regulatory agency to strengthen Austria as a hub in life science and clinical development.

GPMed Vision

As a competent workforce of professionals in clinical research in Austria, GPMed will continue to offer high-quality opportunities for education and training. Furthermore, GPMed will be contributing to shape the environment for clinical trials in Austria in a partnership-based exchange with authorities, research centers, academia and industry.

GPMed Mission

GPMed would like to support, to inform and to raise awareness about the challenges that may arise from the new, existing and upcoming regulations for academic as well as industry-sponsored studies. GPMed is committed to promote infrastructures in clinical research and to enable a close communication to various national and international stakeholders to translate the need of clinical development into high-quality deliverables.



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GPMed Working Groups

The ClinOps Circle

The ClinOps Circle provides a platform to exchange information and thus jointly identify the best solutions of potential obstacles, gain higher expertise and better experience values.

Participants include heads of clinical operations departments of pharmaceutical companies, hospital operators, research organizations and university hospitals, in order to include academic research.

Founded by the end of 2013, regular meetings with professionals in clinical operations have been held. This proactive group has jointly touched high demanding topics in clinical operations and developed standards and tools to optimize ClinOps across both academic and industry sponsored research. With a fast-increasing interest based on positive feedback, the outcome of the ClinOps Circle is considered valuable by setting standards across disciplines. The overall goal of this multidisciplinary group is to guarantee Austria as a valuable and reliable partner in clinical research.

Medical Affairs Circle

The Medical Affairs (MA) Circle was founded in 2019 and provides a forum to discuss and to drive relevant topics from the area of Medical Affairs, which is an independent and important function in the pharmaceutical industry. The main responsibilities of MA include Medical Information & Communication, Training & Education, Establishing of Networks with Healthcare Professionals, Medical Planning & Operations, Interventional & Non-Interventional Trials, Gathering of Insights and many more.

The currently 17 members of the GPMed MA Circle are coming from Austrian affiliates of different global pharmaceutical companies and are meeting on a regular basis on topics like the role of MA in drug research & development or the interactions with different internal and external healthcare stakeholders. The first deliverable of the MA Circle has been the publication of "Recommendations on Medical Affairs Job Roles in Austria" on our [homepage](#) in German language in November 2019.

FACTS

- 1992 GPMed founded
- Since 1997 IFAPP member
- 2008 Foundation of biennial Best Inspectee Award for Clinical Sites (collaboration between AGES and GPMed)
- Since 2011, 15 Board members equally composed from industry and academia
- 150 GPMed members
- Working Groups: ClinOps Circle and Medical Affairs Circle
- Quarterly Newsletter GPMedium
- Quarterly Educational Events in close collaboration with the Austrian Regulatory Agency AGES
- Website: GPMed | Gesellschaft für Pharmazeutische Medizin e.V., www.gpmed.at.



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A Message from the IFAPP President - Marco Romano

Dear IFAPP Members,

I am writing to you as I would like to thank all National Member Associations (NMAs) and Individual Affiliates (IAs) for their support and participation in the activities and events arranged by our International Federation on a regular basis. One of the goals and objectives of my Presidency is to further increase the number of NMAs and to strengthen the relationship between IFAPP and its members. One way to reach these goals is to expand our current Working Groups (WGs) with new active participants. We need new colleagues in the working groups with innovative thoughts and representing various cultures.

The Chairs of the WGs need the help and support from members who are keen to contribute to our growth by providing their professional experience. As you know, at present we have the following WGs:

- The Certification WG with the primary objective to create a career path in Pharmaceutical Medicine and medicines development.
- The Communication WG responsible, among other tasks, for the development and publication of IFAPP TODAY, our monthly newsletter. Its members have also embarked now in the creation of webinars and started with a series on COVID-19 in different countries.
- The Education and Competencies WG aiming at providing training programs meeting the needs of the NMAs and individuals on a career path in medicines development.
- The Ethics and Professionalism WG which deals with specific ethical issues relevant to Pharmaceutical Medicine.
- The External Affairs WG which is in contact with other professional Associations and Institutions.



This year it is time to elect new Chairs of our WGs and we herewith ask you for nominations of potential candidates. Also, the role of Treasurer and Secretary are open for election this year.

I would also like to launch a new WG dedicated to young members from the various NMAs. The primary purpose would be to allow colleagues under the age of 40 years to develop a global community of "rising stars" who can deal with evolving aspects of Pharmaceutical Medicine including fit-for-future education, exchange of ideas and best practices, global visibility, career path, networking, digital innovations, and so on. I would be delighted to receive your impressions of this potential new initiative, its feasibility from your perspective, your recommendations. Do you think there are young professionals in your associations who might be interested in joining this new WG? Are there any volunteers to chair such a new WG?

Please address your responses, i.e., nominations for Chairs of the WGs, nominations for the board roles of Treasurer and Secretary as well as nominations to chair a potential new WG for the upcoming generation to secretariat@ifapp.org.

I look forward to receiving many nominations and thank you all for your attention and cooperation.

Marco Romano MD GFMD
IFAPP President



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IFAPP COVID-19 Webinar Series #2: Voice from Japan

On February 25, 2021, the IFAPP COVID-19 webinar was presented by JAPhMed (Japanese Association of Pharmaceutical Medicine, Japanese member association of IFAPP) as the second in the series. The program was co-chaired by Dr Stewart Geary (Eisai) and Prof Kyoko Imamura (University of Tokyo).

Dr Kazuya Iwamoto, President of JAPhMed, kicked off with his opening remark and briefly introduced the association's history and current activities.

The first speaker, Professor Kotone Matsuyama (Nippon Medical School, IFAPP Secretary), presented a brief overview of the COVID-19 pandemic in Japan. The Japanese situation was introduced with information on the national health insurance system, reporting system, medical care provision and case registry.

The second speaker, Dr Atsushi Tsukamoto (Daiichi Sankyo), introduced the current situation and challenges in COVID-19 treatments and vaccines development. Based on his observation of the Japanese efforts in drug development and devising preventive countermeasures, Japanese strengths and weaknesses were discussed together with potential cultural and social reasons which may have contributed to the success in infection containment but slow drug development.

The third speaker, Mr Naoki Tsutsumi (University of Tokyo), presented sustainable ethical review and quality assurance, based on the results of the international comparative study in Korea and Japan in the use of remote ethical review, followed by his experiments in comparing remote auditing methods with conventional visit-style auditing.

The discussion with the speakers was based on the questions addressed by the participants online (186 in total), ranging from the curiosity of low morbidity and mortality of COVID-19 in Japan, social impact on medical practice, effective risk management, and adoption of innovative technology such as remote auditing to continue and accelerate drug development even amidst this difficult time.

The event was closed by Dr Marco Romano, IFAPP President, with thanks to all speakers and chairs, participants, leadership of JAPhMed, and support by IFAPP Academy. The third IFAPP COVID-19 webinar has been planned as a collaboration among European member associations and its details will be announced soon.

Kyoko Imamura, MD, PhD, DrMedSci, GFMD, Past President of IFAPP, Project Professor, Social Cooperation Program of IT Healthcare, The Graduate School of Pharmaceutical Sciences, The University of Tokyo



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Pharmacovigilance and COVID-19 Vaccines

The Greek Pharmaceutical Medicine Society - EL.E.F.I. convened an expert virtual meeting on Pharmacovigilance management of COVID-19 vaccines on the 25th of February 2021. The event was co-chaired by Eleonora Sarikou and Anastasia Sideri, members of EL.E.F.I. Pharmacovigilance Working Group. Giannis Petrovas, General Secretary of EL.E.F.I., welcomed the participants on behalf of the Board and heightened the significance of Pharmacovigilance aspects of COVID-19 vaccines for an efficient and safe national vaccination.

Dr Varvara (Barbara) Baroutsou, President of EL.E.F.I. and President-elect of IFAPP, gave the opening speech on the rapid COVID-19 vaccines R&D, highlighting how this achievement was made possible in a record time with the joint Pfizer/BioNTech first approved vaccine becoming available in less than 9 months from their clinical trials start. The unique circumstances that led to this extraordinary outcome pertain to:

- New platforms for vaccine delivery were **already researched in preclinical studies**
- **Rapid gene sequencing** of the virus allowed for rapid development of antigen sources for inclusion in the vaccine
- Vaccine **development steps** were **executed in parallel**
- **High disease prevalence** allowed trials to rapidly show a beneficial effect from the vaccines
- **High trial enrollment**
- **Vaccines were produced in parallel** with clinical trials

The second speaker, Dr Stefanos Tarazis (Director Pharmaceutical Research & Studies National Medicines Agency of Greece-EOF), presented a rigorous causality assessment of suspected adverse reactions by the National Pharmacovigilance Committee and Agency Pharmacovigilance department. He also confirmed that COVID-19 vaccines' ADR rates remain within the expected safety profile and range. No deaths were related to COVID-19 vaccination and no rare serious ADRs were confirmed so far in Greece following 857,306 vaccinations.

The panel discussion of pharmacovigilance experts, Maria Polydorou PharmD, George Christias MSc and Dr Nicolas Tsiakkas, introduced the current pharmacovigilance plans, RMP responsibilities and challenges with COVID-19 vaccination. Based on EMA guidelines, the panelists presented the adverse event following immunization (AEFI) cause-specific definitions and their implication in the COVID-19 context, the transparency of suspected and confirmed side effects of the vaccines in the EudraVigilance database and European Centre for Disease Prevention and Control sources as well as Local Regulatory awareness efforts.

Dr Aikaterini Syrigou, Allergologist, Head of Allergology Department and COVID-19 Reference Vaccination Centre of General Hospital in Athens, summarized the vaccinees information, follow-up process and 24-hour helpline plus the clinical safety data from the first cohort of 1,110 vaccinated Health Care Professionals that were quite reassuring.

Dr Syrigou underlined the importance of medical history (particularly of past allergy) and patient medication use to be assessed thoroughly for safe vaccination.



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The dialogue with the speakers was triggered by the audience interest around patients' vaccination information, vaccination Healthcare Professionals education aspects, anxiety as underlying cause for adverse event occurrence, differences of ADRs by gender, by System Organ Class and anaphylactic reactions.

The meeting was concluded by E.L.E.F.I. Board gratitude to speakers, chairs, participants and the Pharmacovigilance Working Group members.

Varvara (Barbara) Baroutsou, MD, PhD, GFMD
E.L.E.F.I. President and IFAPP President-elect



Is Pharmaceutical Medicine Missing from Your Skills List in Your LinkedIn Profile?

Over the years it has become apparent that among those professionals who have years, if not decades, within the field of Pharmaceutical Medicine, very few list this specialty as a Skill within their LinkedIn profiles. Even those who have lectured on postgraduate Master Courses in Pharmaceutical Medicine leave it out.

It is much more common to find lists of subspecialties, such as clinical trials, clinical development, pharmaceutical industry, medical affairs, pharmacovigilance, regulatory submissions, ICH GCP or medical writing, to name but a few. The term Pharmaceutical Medicine, which unites this multifaceted discipline under one heading, however, is not included.



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Having received the “Hero in Pharmaceutical Medicine” award in 2020 from IFAPP, I would be honoured to help developing a stronger professional identity of our specialty by endorsing this Skill in your profile, once you let me know that you have added it.

Dr. med. Johanna Schenk FFPM GFMD
Member of the IFAPP Communication Working Group

THE FLAG

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

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