IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

IFAPP President Message - Fall 2023

Dear Colleagues,

I hope that you enjoyed a restful and pleasant summer. I want to welcome you all to a re-energised start of the fall quarter of 2023. For me, September brings a sense of wonder at how to seize promising opportunities for IFAPP members. I feel optimistic when I reflect on the important insights, ideas and works our delegates, panelists and experts shared during the IFAPP 2023 Regional Meetings in Amsterdam (European -June 29-30) and Tokyo (Asia-Pacific - July 30) to tackle challenges and change for the better. In June, we debated our 2023-2024 strategic plan and path to inclusive excellence. This work clarifies our mission and vision and outlines our institutional values around generation continuum, next generation leaders and benefits for young, middle career and senior IFAPP members.

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I wish to underline that one of those values – the value of community – is precious for IFAPP going forward. Community means that we are unifying around our mission and vision, while supporting and celebrating each other in our mutual successes!

My responsibility as President is not just a position-related task but a personal commitment to lead the IFAPP community successfully to innovative possibilities.

Furthermore, and foremost, I would like to share that the Executive Board Officers spent the summer reviewing the IFAPP performance, finalising recommendations for the September 2023 Board of Officers Meeting and preparing to start up with awards and distinctions for our colleagues, Individual Affiliates and National Members Associations.

We examined our policies & procedures along with our operational plans, reviewed our progress of the organisation, and came up with solutions to move the organisation forward.

Our active Scientific Officers - Working Group Chairs - have been busy putting together a schedule of scientific events, public consultations with stakeholders and collaborative initiatives, including new working groups, that will provide more advantages for members to network, promote continuing education and professional development of them.

I am also excited about the last quarter of this year that we will have so many opportunities and projects to connect with you.

To learn more about IFAPP offerings, I encourage you to visit our news and events calendar on www.ifapp.org, to follow us on LinkedIn https://www.linkedin.com/company/65277832/, and to read the IFAPP TODAY Journal.

Our largest community event, the ICPM 2024, is in its early planning stages.

IFAPP is an incredible organisation for networking, education, and professional development.
I look forward to seeing what we – as a **community** – can accomplish and build together for a lasting IFAPP impact!

I hope to see you at our upcoming events and wish all of you a productive season.

Sincerely yours,

Varvara (Barbara) Baroutsou
IFAPP President

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FiAPP - The Finnish Association of Pharmaceutical Physicians

The Finnish Association of Pharmaceutical Physicians (FiAPP) is a non-profit professional organisation that operates under the umbrella of the Finnish Medical Association. FiAPP was founded in 1990, and the main purpose is to facilitate and promote networking and professional training needs of Finnish physicians working in the pharmaceutical field. In addition, FiAPP aims to create visibility and communicate about opportunities in the pharmaceutical field in the Finnish physician community and maintains oversight and training requirements for the “Special Competence in Pharmaceutical Medicine” programme. Currently, FiAPP has approximately 90 members including 12 board members. Membership can be applied for by physicians who are licensed in Finland and working in the pharmaceutical field, such as the pharmaceutical industry or regulatory authorities.

The key activities of FiAPP include two annual meetings, which are organised in connection with an educational symposium with external speakers and discussion around relevant scientific and/or professional topics. Recent topics for the educational symposium include, for example, Development of COVID-19 vaccines, Advanced Therapy Medicinal Products, New EU Clinical Trials Regulation, Personalised Medicine and Drug Development, and Real-World Evidence and Biobanks. The annual meetings provide FiAPP’s primary platform for networking and professional training. Other regular tasks of FiAPP include maintaining the association’s website, managing finances and legal obligations and communicating about external training opportunities, such as the webinars organised by IFAPP.

FiAPP is also responsible for maintaining and regularly updating the training programme for ”Special Competence in Pharmaceutical Medicine” in Finland. This is a 2-year training programme for physicians working in the pharmaceutical field and consisting of formal training, literature, mentorship programme, on-the-job training, and final exam. The up-to-date formal training requirements are available on the website of the Finnish Medical Association. Physicians completing the programme will receive a certificate of “Special Competence in Pharmaceutical Medicine”, granted by the Finnish Medical Association.

As the newly elected chair of FiAPP, and together with other board members, we are looking forward to further develop the activities of our association. I was happy to join the IFAPP European meeting for the first time in June 2023, and I hope to bring back new ideas and a lot of inspiration for the next annual meeting of our local association.

Silva Koskinen, MD, PhD
Chair of FiAPP, Janssen EMEA

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IFAPP Webinar on Reports from Regional Meetings and Updates from Young Professionals Working Group and Communication Working Group

Date: Thursday September 28th, 2023
Time: 2.00 - 3.00 PM CET

Moderator: Dr Birka Lehmann, Lead of Education and Certification WG at IFAPP

Speakers:

- Dr Varvara (Barbara) Baroutsou, IFAPP President, will present the highlights of the IFAPP European Regional Meeting taken place in the Netherlands and the IFAPP Asian Regional Meeting in Japan.
- Nikos Tsokanas BSc, MSc, MBA, IFAPP Treasurer and member of the Young Professional Working Group (WG) of IFAPP, will present the lessons-learned related to the way to attract and engage young professionals with the IFAPP organisation.
- Dr Ghazaleh Gouya, Lead of the Communication WG at IFAPP, will give an update on what goes on in the Communication WG and why it is important to contribute to IFAPP TODAY.

Dr Birka Lehmann
Moderator

Dr Varvara Baroutsou
Speaker

Dr Ghazaleh Gouya
Speaker

Nikos Tsokanas
Speaker

Registration:

- This webinar is free to everybody
- Click here for registration

After registering, you will receive a confirmation e-mail containing information about joining the webinar.

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Discussion in Amsterdam on Data-driven Research and the WMA Declaration of Helsinki

Collaboration with the WMA

IFAPP, collaborating with the World Medical Association (WMA), provided "IFAPP & WMA Workshop on the Revision of the Declaration of Helsinki focusing on Data-Driven Research", on June 29, 2023, during our European Regional Meeting, Amsterdam, the Netherlands. More than 20 delegates of European National Member Associations participated in person, with speakers and approximately 30 additional audience who participated online.

This event followed IFAPP's previous initiative based on the Memorandum of Understanding (MoU) with the WMA, a series of articles (1, 2) in IFAPP TODAY on the revision of the WMA Declaration of Helsinki (DoH) (3), and a scientific paper (4) on linking the DoH and the Declaration of Taipei (DoT) (5) for health databases and biobanks. WMA's workgroup for the revision of the DoH was set up in 2022. At ICPM in October 2022, IFAPP organised a workshop with Dr. Jack Resneck, the President of the American Medical Association/workgroup chair for the DoH, and Dr. Otmar Kloiber, WMA Secretary General in attendance (6). The author participated in two subsequent WMA regional meetings in Tel Aviv and Sao Paulo (7).

For the event in Amsterdam, Prof. Dr. Daniel Fu-Chang Tsai, National Taiwan University, a member of the workgroup for the revision of the DoH, and Dr. Jeppe Berggreen Høj, an advisor at the Danish Medical Association were recommended by the WMA as speaker/commentator. A special guest, Prof. Jerry Menikoff, the former Director of the Office for Human Research Protections, Department of Health and Human Services, United States, also gave valuable comments. The session was opened by Kotone Matsuyama, Chair of the Ethics Working Group (EWG) of IFAPP, and introductory remarks were provided by Chieko Kurihara, a member of the EWG.

Prof. Dr. Daniel Fu-Chang Tsai, National Taiwan University

Dr. Jeppe Berggreen Høj, advisor for Danish Medical Association

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Prof. Jerry Menikoff, the former Director of the Office for Human Research Protections, Department of Health and Human Services, United States; Professor of the National University of Singapore

Prof. Kotone Matsuyama, Nippon Medical University

Prof. Chieko Kurihara, Kanagawa Dental University

Speaker/commentators and moderators of the IFAPP & WMA Workshop

Presentation from Professor Tsai on "Data Science Ethics"

Taiwan has a well-established legal system of biobanks especially to protect rights of vulnerable, indigenous populations. Prof. Tsai provided his analysis in his presentation entitled "Ethical considerations of data-driven research: some thoughts on the revision of DoH" characterising the era of data-driven research, suggesting the need for "Data Science Ethics". The DoH requires informed consent of a person to provide human material or data, with some exceptional cases when consent would be impracticable, to be approved by the research ethics committee (Article 32). For research using data or biological material, requiring the re-consent or opt-out procedure would raise administrative burden, thus, he recommends recognising ownership and usage rights of health professionals to the data generated by their contribution of professional expertise (as in Taiwan's Medical Care Act), also recognising patients' various rights regarding their own medical records. He also cautioned that increasing restriction in data use can potentially hinder research related to vulnerable populations, leading to a lack of scientific foundation for them.

He raised the idea of "ethical obligation of research participation" of citizens serving public good, based on fair reciprocity, where universal healthcare system has been implemented.

Comments of Dr. Jeppe Berggreen Høj from European perspectives

Dr. Jeppe Berggreen Høj, PhD in philosophy, Senior Advisor on Medical Ethics and Secondary Use of Health Care Data at the Danish Medical Association, discussed about the issue of multiple use of personal data in the environment of European General Data Protection Regulation (GDPR). He contributed to the creation of the DoT and now to the revision of the DoH.

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He appreciated the insightful overview by Prof. Tsai and expressed agreement with the points of IFAPP that DoH and DoT must be linked together and that these documents should be the ethical foundation of research and data use. He suggested that it needs discussion whether two separated consent processes (for research participation and for future secondary use) could be helpful. It is important to keep the DoH to be a high-level document, avoiding too much description. Because the landscape of data use has been updated frequently, DoT would be updated more frequently, instead of updating the DoH.
He stressed the importance to focus on upcoming "European Health Data Space (EHDS)" (8), proposed by the European Commission, which will dramatically change making far less variety of national contexts, keeping the privacy protection, and maximising data use including commercial purpose.

Comment of Prof. Jerry Menikoff from a US research ethics perspective
In the following, Prof. Jerry Menikoff provided valuable comments based on his experience at the US Government office. After 14 years of contribution until 2022 as the Director of Office for Human Research Protections (OHRP), he is now a Professor of the National University of Singapore. He explained that the United States 45 Code of Federal Regulations 46 for Human Subject Protection (called "Common Rule") does not cover secondary research with individual non-identified biological specimens. When revision of this Common Rule was proposed to cover research using such biological specimens, strong objections have been raised. Considering the recent landscape of AI research, big data analysis as well as real-world evidence, the balance seems to be shifting from "autonomy" to "beneficence". It is important to educate the public about the importance of data-driven research and to maintain public trust, figuring out the valuable characteristics of such research.

Discussion with the audience

- **Benefit sharing**

Responding to a question from the audience, Prof. Tsai explained that the intellectual property right (IPR) ordinarily belongs to the researcher and/or sponsor (including funding agency), which should be mentioned in the informed consent process, while loss of time or other expenses of patients would be compensated.
Kurihara mentioned that there are very rare cases that patient's contribution deserves to IPR and DoT requires to have a clear policy and governance framework. While it is not patient right to gain financial profit directly from research participation, "benefit sharing" among the patient community and researcher would be the important point in the situation of shifting from autonomy to beneficence.
Prof. Tsai explained that Taiwan Biobank Law requires each Biobank to establish clear rules regarding policies of benefit sharing, how they return making good outcome to participants, the patient groups or in a broader society. Biobank must disclose the relevant evidence of the return to patient groups.

- **Access right of patients**

Responding to the question from the venue, Kurihara mentioned about data control right of a patient. In Japan patients cannot easily access their medical record.
Prof. Tsai introduced the situation in Taiwan, where patient can apply for a full copy of their entire medical record paying charge for service and using a mobile app for access to blood test results and other medical records.

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- **Next step of European legislation**

Prof. Varvara Baroutsou, the IFAPP President, congratulated on the excellent discussions of the panel and requested Dr. Berggreen Høj for instruction on the timeline and expected major changes of the European legislation.

Dr. Berggreen Høj explained that the proposal from the EC will be discussed at the European Parliament over the coming months and further in negotiations between Parliament, Council, and Commission most likely around the new year. The intent is for it to be adopted before the election of the new Parliament, which would be June of the next year. Various aspects of major changes have to be still negotiated but one critical point is the possibility of waiver of consent for secondary use on some conditions of governance and limitation of purposes. Or otherwise, opt-out option as the right of data subject may be introduced. Impact of the results would be different up to the country.

Background history and future perspective

It was 2000 that the DoH came to cover the individual identifiable data and samples responding to the concerns for fast progress of genetic analysis and commercial use of data, expressed by the then President (9) and National Members (10). For two decades, the DoT was issued to cover the activities of "health databases" and "biobanks" remaining "research" using data/material in the scope of the DoH. CIOMS 2016 guidelines (11) cover all these disciplines and suggested the idea of "broad informed consent", instead of re-consent or opt-out, obtained based on sufficient information of the possibility of future use of personal data, differently from traditional "broad consent". To promote data-driven research worldwide, we should watch the consequence of European legislation as well as the DoH as the international consensus.

Chieko Kurihara*, BSocSc., Specially-appointed Professor, Kanagawa Dental University, Kanagawa, Japan and member of the Ethics Working Group, IFAPP

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The Japanese Translation of CIOMS Report "Patient involvement in the development, regulation and safe use of medicines" and Expectations on Pharmaceutical Medicine Professionals

CIOMS (Council for International Organizations of Medical Sciences) Working Group XI published the report in 2022 summarising their years-long research and discussions among stakeholders such as representatives of patients, patient advocates, regulators, academics, and industry, developed as a pragmatic handbook to share 'how to' of sorts, for involving patients in the drug development and safe use of medicines. Ample cases are described as 'best practice' which can be recommendable as a guide, not expected to be adopted in their entirety, but to prompt readers to review and select those which may fit well in their environment.

Inspired by this report, the Japanese team led by Dr Noriko Fujiwara was set up to translate it into Japanese language to help sharing with diverse readers in Japan and stimulate discussions to advance patient involvement (to be posted at http://cont.o.oo7.jp/51sup39/ciomsPPI.pdf). Patients and patient advocates, as well as the representatives of industry and academia, have participated in the translation process and provided valuable input by answering online questionnaires asked for as public comments.

As is recognised by the authors of the CIOMS Working Group XI, research on the impact of patient and public involvement is sparce, and qualitative and quantitative research is needed. This is particularly true in Japan, as a variety of efforts already taken are not much introduced in this report except regulation-related matters such as a scheme to invite patients into scientific committees and risk minimisation as compared to EU and Japan. However, Japanese patients were not fully aware of such regulations and the possibility of participation in discussion. Even if patients are invited to regulatory meetings, such opportunities are often dominated by the same personnel suggesting the limitation to submit diverse patient voices.

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To make patient and public involvement as ethical and democratic principle, the opportunities should be open to those who know the disease best. Also, education of patients and patient advocates can help them understand the development process, and better address their unmet medical needs. At present, such educational opportunities had not been open to patients in Japan. Against this backdrop, the Japanese Institute for Public Engagement (Ji4pe) started to provide educational courses on this field in 2020. Ji4pe is the recognised Centre of Excellence (CoE) by the PharmaTrain Federation (PTF) and promoting Pharmaceutical Medicine in Japan with IFAPP and its Japanese member association JAPhMed (Japanese Association of Pharmaceutical Medicine). Japanese SMDs (Specialists in Medicines Development) awarded by PTF and IFAPP (https://www.pharmatrain.eu/smd-programme-japan) are now lecturing patient and patient advocates in Ji4pe courses.

The situation could be different in each country, but the future promotion of patient and public involvement should be expected elsewhere. Professionals in Pharmaceutical Medicine are expected to pave the way with a passion to advance future drug development with patients and public.

Dr Kyoko Imamura, MD, PhD, President of Japanese Institute for Public Engagement (PharmaTrain Centre of Excellence), IFAPP Past President (2018-2020)
Dr Noriko Fujiwara, RN, PhD, SMD, CRN-BC, Affiliated Hospital of The Institute of Medical Science, The University of Tokyo

Translators of CIOMS Working Group XI Report

Translated by:
Noriko Fujiwara, Kikuo Tsukahara, Naoki Tsutsumi, Chikako Toyooka

Supervisors of translation:
Kyoko Imamura, Chieko Kurihara, Kotone Matsuyama, and Ji4pe patient and public review working group (led by Keiko Inoue)

To be posted at:
http://cont.o.oo7.jp/51sup39/ciomsPPI.pdf

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The Postgraduate Diploma Course Cycle in Pharmaceutical Medicine 2023-2025 at the Basel ECPM

The history of drug discovery and development goes back several thousand years. It started with the use of herbals in China and India and in many other parts of the world. Later, there was evidence of medicinal practice in Egypt. Hippocrates in Greece started to transform medicine from art to science. The foundation of scientific medicine was then developed over two thousand years and many discoveries and achievements came out of Basel.

Modern drug discovery started to emerge by the end of the 20th century with the arrival of organic chemistry, the discipline of pharmacology and germ theory. Subsequently, industrial technology made it possible to manufacture high-quality medicines. By introducing genomics, the Human Genome Project enabled advances in molecular and genomic medicine in the year 2000. Tremendous progress occurred in the last 30 years, but we still have a limited understanding of disease pathology and progression. Cutting-edge technologies emerged, e.g., as humanised models in toxicology or gene sequencing. These help to predict and personalise the clinical success of drug candidates. Algorithms, machine learning, artificial intelligence and other in silico tools assist to study molecules in a dynamic state, even within a single cell.

High-throughput technologies and digital devices produce an exponential amount of data. Hence, it is important that such data is transformed to high-quality information and subsequently turned into actionable knowledge. In all parts of this process, skills, and talents of the individuals along the value chain are key. Our aim is to support research and educate professionals in drug discovery and development, especially at the interface of disciplines.

ECPM® European Center of Pharmaceutical Medicine

Thrilling news for those passionate about drug development and the latest advances! We are delighted to announce that the next cycle of our esteemed Postgraduate Diploma in Pharmaceutical Medicine programme has started:

Module 1 Start Date: 28 August 2023

Programme Duration: 6 modules spread over 2 years

Learning Method: In-person in the Biozentrum in Basel

Key Insights:

- Over 2000 accomplished graduates to date
- 100+ participants per course cycle
- Internationally acclaimed faculty with years of industry experience

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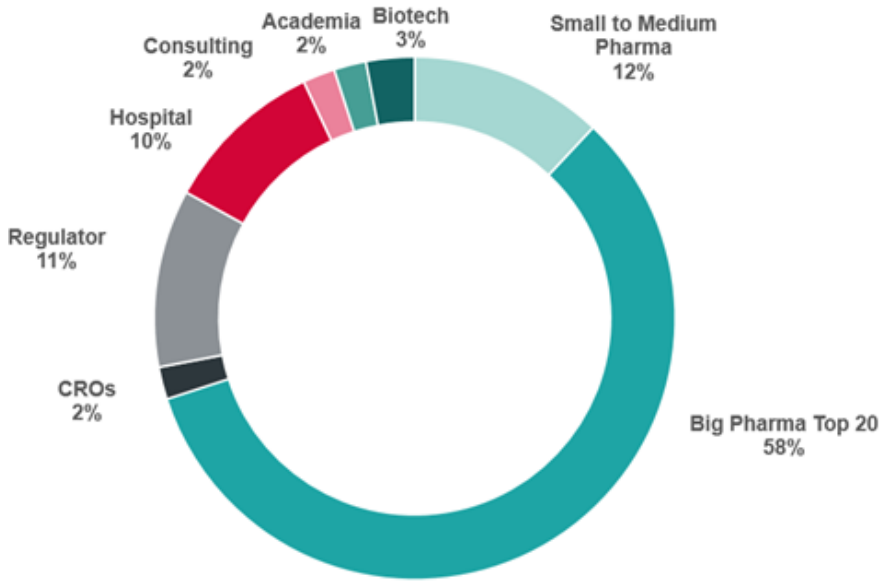
Participants Statistics for 2023-2025:

- Workplace:



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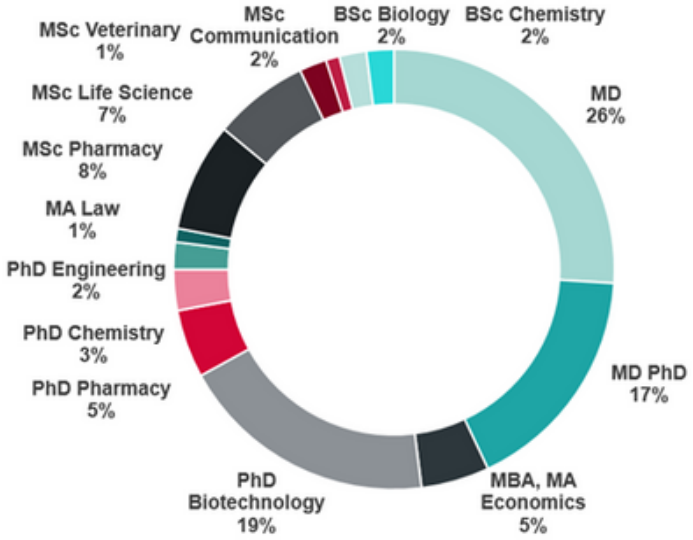

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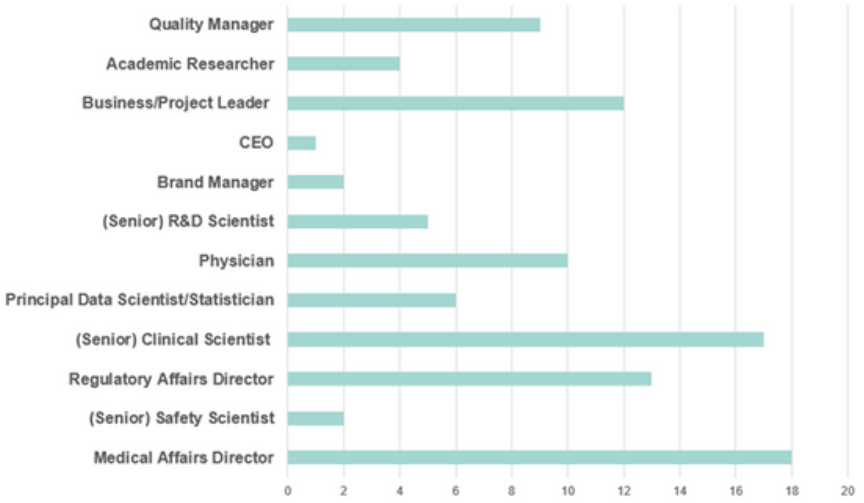

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For those who were not able to join us for Module 1, we are excited to reveal that you can jump on board in **Module 2** or register your interest for the next course cycle.

- **Module 2 Start Date: 05 February 2024**

Please contact Nikki Liversidge at ecpm@unibas.ch.

Moreover, we're pleased to present short **Continuing Professional Development (CPD) Courses** tailored to professionals eager to elevate their competence in the pharmaceutical domain. These courses are a great opportunity to enhance skills and stay abreast of the latest industry breakthroughs. The CPD Courses on offer include:

- Project Management in the Life Sciences Industry
- Scientific Medical Writing
- Mastering the Art of Persuasive Communication
- Fundamentals in Health Economics

Please note that the ECPM is a PharmaTrain recognised Centre of Excellence (https://www.pharmatrain.eu/pharmatrain-course-providers .

Do you want to turn the Diploma into a Master in Pharmaceutical Medicine? You can combine the diploma modules with further courses and a thesis to achieve the Master qualification. We are happy for you to contact us for further information at ecpm@unibas.ch.

Warm regards from the ECPM (European Center of Pharmaceutical Medicine) Team - Professor Thomas D. Szucs, Dr Annette Mollet, Nicola Liversidge, and Nastazja Laskowski.


Thomas Szucs


Annette Mollet


Nicola Liversidge


Nastazja Laskowski

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IFAPP Webinar: Pharmaceutical Medicine in the Philippines: Beginnings, Transitions and Future Directions

Date: Thursday October 26th, 2023
Time: 2.00 - 3.00 PM CET

The Philippine College of PharmaceuticalMedicine (PCPM) was established to maintain high standards of practice and professionalism in the discipline in their country. The webinar will give an overview of how this journey started, the organization's experiences and challenges, and share how it continues to develop towards its goal in an international context. One of their ongoing programs is the Diploma Course in Pharmaceutical Medicine and Management, whose syllabus is based on recognized international standards. The PCPM Diploma course is planned for evaluation and course recognition.

Speaker: Dr Jose Rodolfo Dimaano Jr, Board Member, PCPM

Panelists:
Dr Herbert Ho – President, Philippine College of Pharmaceutical Medicine (PCPM)
Dr Milagros Tan - Vice President PCPM
Dr Jonas Policarpio - Past President, PCPM ED

Dr Jose Rodolfo Dimaano
Speaker

Dr Herbert Ho
Panelist

Dr Milagros Tan
Panelist

Dr Jonas Policarpio
Panelist

Registration:

- This webinar is free to everybody
- Click here for registration

After registering, you will receive a confirmation e-mail containing information about joining the webinar.

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- **28-09-2023** IFAPP Webinar on Report from the Regional Meetings and Updates from Young Professionals WG and Communication WG
- **26-10-2023** Webinar on Pharmaceutical Medicine in the Philippines: Beginnings, Transitions and Future Directions
- **07-11-2023** IFAPP House of Delegates Meeting & General Assembly

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

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