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The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

New Curriculum for Pharmaceutical Medicine Training in Ireland

The Pharmaceutical Medicine Higher Specialist Training (HST) Programme in Ireland, along with the Basic Specialist Training (BST) training from an approved list of recommended specialties in Ireland, aims to deliver expert pharmaceutical physicians with a broad range of skills needed for the continually developing specialty.

The Outcome-Based Education (OBE) curriculum makes the transition from the previous minimum requirements model of training, to become better aligned with international best practices and standards around the globe. This involves a substantial change to the structure of the curriculum, but most of the curriculum assessments and objec-tives remain the same -

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to produce well-rounded specialists with the ability to practise independently, while supporting the development of subspecialty expertise and interests. Training goals are aligned to key areas of practice. Trainees will demonstrate proficiencies in each outcome matched to the level of their training, progressing to independent competence in each.

Development of the Outcome-Based Education (OBE) curriculum started in early 2023. It was decided that a hybrid model of curriculum review would be the best use of time for the subject matter experts in the Specialist Training Committee (STC). A series of initial live online reviews and drafting of the core and specialty modules for each of the 6 core sections took place. A full-day workshop then took place at the Royal College of Physicians of Ireland (RCPI) with the whole STC membership, to collate the review deliverables, where multiple perspectives were discussed, captured, and consensus reached. The final version, combined with the mandatory modules from RCPI, was reviewed and signed off by all STC membership, and thereafter underwent official approval by the Institute of Medicine (IOM) at RCPI in July 2023. The author would like to thank the entire STC here for their expertise, time, and effort throughout the process.

Fulfilment of the HST requirements will result in the award of a Certificate of Satisfactory Completion of Specialist Training (CSCST) in Pharmaceutical Medicine by RCPI. Trainees completing this HST programme will acquire a breadth of experience and be fully prepared for independent practice in Ireland.
This new style curriculum will also serve as the basis for the re-accreditation of the specialty in 2024 by the Irish Medical Council.

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BADI 2023 Annual Course of Drug Regulatory Affairs – an Update in Three Modules

The Bulgarian Association for Drug Information (BADI) is the only non-governmental organisation in Bulgaria which, for 13 years, has consistently worked to create a regulatory society within the pharmaceutical sector. It provides a platform for constructive dialogue and partnership between interested parties in Bulgaria.

BADI is an organisation with over 60 corporate and over 90 individual members and supports science research, education and regulatory activities in the field of medicinal drugs, medical devices, nutritional supplements, cosmetics and other products relevant to public health.

For the period October to December 2023 the Association has organised the Annual Course of Drug Regulatory Affairs – an Update in Three Modules:

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M**odule 1**
6 October 2023 - Pharmacovigilance Update | Online Event

Reminder: During internal pharmacovigilance audits and also during inspections from regulatory bodies, experts in the field of drug regulation must annually certify their professional qualifications in the fields in which they work, that they have been undergoing training for the relevant calendar year. Through the certificate that BADI issues you certify your current professional qualification.

Module 2
3 November 2023 - Round Table Discussion - Hot Regulatory Issues | Hybrid Event

- **Discussion of the new upcoming pharmaceutical legislation**
- **EU HTA implementation**

Changes to the new pharmaceutical legislation will be discussed. The new legislation refers to authorisation procedures, variations and renewals, product information, intellectual property, clinical trials, safety and HTA. Such global changes have not been made for 20 years, therefore, experts need to receive regular training to be up-to-date in their knowledge.

Module 3
1 December 2023 - Regulatory Update | Online Event

Speakers are renowned experts from the Bulgarian Drug Agency (BDA) as well as experts from other EU countries.

The registration form for participation and the programme are published on www.badibg.org or on link: https://www.badibg.org/2023/REGISTRATION_FORM_09_23_ENG.2.doc

To note: ***Members of IFAPP receive a 25% discount.***

Discussion in Japan on Patient Engagement in Research Ethics Reviews - Conference Report from Japan

This report is to follow up on the IFAPP webinar held on 7 December 2022, informing of the Japanese efforts to expand education in medicines development to all stakeholders. Here is the abstract of the symposium entitled 'Research Ethics Review - Butterfly Effect of Education and Training of Layperson Reviewers' presented on September 16th at the 23rd Conference on CRC (Clinical Research Coordinator) and Clinical Trials 2023 held in Okayama, Japan. According to the official announcement, more than 3,000 research professionals participated in-person and virtually.

- C**urrent Issues of Patient Engagement in Research Ethics Review in Japan**

First, Prof. Ayako Kamisato (Institute of Medical Science, University of Tokyo) gave an overview of the recent national activities to promote participation of laypersons in research ethics review committees.

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Chairpersons:
L) Dr Noriko Fujiwara
R) Dr Kyoko Imamura

Speakers (from left to right):

- *Ms Akemi Tamaura*
- *Ms Noriko Iwaya*
- *(participated remotely) Ms Keiko Inoue*
- *Ms Kaori Yukiyoshi*
- *Prof Dr Ayako Kamisato*

Like the ICH GCP requirement of institutional review committees, all clinical research projects in Japan are to be reviewed by an Ethics Committee (EC) asking for at least two or more laypersons represented as review members. In their study (Kamisato, A., Hong, H. and Okubo, S. Public Awareness of Medical Research Terminology in Japan, and the Accuracy of Physicians' Predictions regarding that Awareness. ABR (2023)), wide gaps between public awareness and physicians' predictions were observed. In general, public awareness of medical research terminology is low and physicians might overestimate their understanding. Although the participation of layperson reviewers is expected to fill the gap, many of them are not sure if they can speak out in the presence of professional experts in the committee and feel lack of medical knowledge to understand informed consent explanations. They also found out about 60 % of them did not receive education prior to initiate their participation in a review committee. As a result of their effort funded by the Japan Agency for Medical Research and Development (AMED), e-learning materials (REC education, https://sites.google.com/view/receducation/for-commissioner?authuser=0) are developed and open to the public.

Second, Ms Kaori Yukiyoshi (Okayama University Hospital) presented the development of a training course for ethics review committee members by Ji4pe (Japanese Institute for Public Engagement, https://ji4pe.tokyo/index_en.html). Ji4pe is the Centre of Excellence recognised by the PharmaTrain Federation (PTF, https://www.pharmatrain.eu/pharmatrain-course-providers), and SMDs (Specialists in Medicines Development, https://www.pharmatrain.eu/smd-programme-japan) awarded by PTF and IFAPP including Ms Yukiyoshi, are lecturing and leading education and training of laypersons since 2021. In their survey, layperson reviewers, although they are highly motivated and received introductory education, are feeling the need of systematic education including informed consent, roles, and responsibilities of an EC, and basic knowledge of clinical trials. Ji4pe E-Course is made of four weekend lectures and workshops (20 hours in total), using case studies, speaker trainings, and a mock review meeting led by active chairperson and review members to test their achievements. Successful participants are certified and registered to be recognised by ECs seeking layperson reviewers.

- **Experiences of Patients and Carers as Research Ethics Reviewers**

Two presenters described their experience in participating in ECs as layperson members, one at an academic centre and the other at medical institutions.

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Ms Keiko Inoue, a cancer survivor and a board member of the society of medical malpractice victims, has received education provided by AMED, university, REC-education, Ji4pe and others. Being an EC member for a national centre reviewing advanced research protocols, she introduced her ongoing effort to better understand the meeting exchanges and her continuous learning. She is also thankful for a variety of support provided by EC staff to encourage her understanding and the good conduct of EC discussions led by the chairperson.
The presentation was followed by Ms Noriko Iwaya, whose son is a rare disease patient. While she developed a patient group inviting other patients and families suffering from the same disease, she learned at Ji4pe courses to better understand drug development and potential contributions to the society. She shared her journey as an EC member, how she felt, studied, spoke at EC meetings, wondered if she performed right, etc. She said continuous learning can keep her aware of the expected role and responsibility as EC member.

- **Survey Results of the Impact of Layperson Members on Ethics Committee Review**

Ms Akemi Tamaura (National Center of Neurology and Psychiatry) presented the reorganisation of their EC to improve quality of their ethics review by refreshing the members and invite layperson reviewers fully trained and willing to participate in the review process. As a result, the quality and quantity of EC reviews is considerably improved and more vital by diversified viewpoints.
Ms Tamaura and her team also surveyed how other ECs are recruiting laypersons and educate them. According to their survey, occupation of laypersons is topped by educational professionals, corporate employees, and housewives. 42% of them are serving five and more years, reflecting the difficulty in recruitment of laypersons as new members. Gender representation was less considered, and new members are likely to be chosen from the closed communication such as referral by institutional staff or recommendation by current members. Continuous education is preferred with emphasis on speaking on behalf of patients and gain more confidence without feeling intimidated.
As a future prospective, roles and responsibilities of layperson reviewers should be clearly recognised, more discussions on points to consider should be facilitated, and the development of a pool of educated laypersons is highly aimed at.
After these presentations by five speakers, the chairs moderated the discussion. Speakers discussed that EC members from different perspectives, including laypersons, should work as a team to protect research participants and research integrity. Lay reviewers, in particular, play an essential role in promoting the trustworthiness and quality of research by acting as a bridge between research and the public. Although education and training opportunities for lay reviewers are essential, those are not yet sufficient. Small actions can make a big difference. We hope to see more educational opportunities in the future.

- **Conclusion**

Despite national promotion of more opportunities for patient engagement, their representation at national conferences, public hearings and institutional reviews are still limited. As well-educated and dedicated ethics review personnel is critical to improve the quality of clinical research, a coordinated effort to provide education and training should help laypersons to play their roles and accelerate patient engagement.

Authors:
Session co-chair: Dr Kyoko Imamura, MD, PhD, President of Japanese Institute for Public Engagement (PharmaTrain Centre of Excellence), IFAPP Past President (2018-2020)
Session co-chair: Dr Noriko Fujiwara, RN, PhD, SMD, CRN-BC, Affiliated Hospital of The Institute of Medical Science, The University of Tokyo
Session organiser: Dr Naoki Tsutsumi, PhD, CCRA, President of Tutti Quality Assurance Network

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Digital Health Africa, the Future of Healthcare on the Continent

//Digital Health Africa 2024

23-24 February 2024
Biomedical Research Institute
Stellenbosch University, Cape Town
digitalhealthafrica.org

We would like to draw your attention to a workshop about

Digital Health Africa, the Future of Healthcare on the Continent

(www.digitalhealthafrica.org)

This will be a hybrid event, so virtual attendance is possible.

This workshop will offer an overview on recent advancement in digital health, telemedicine and artificial intelligence within Africa's healthcare sector and their transformative potential on the future of healthcare in Africa. This event is designed to be a dynamic forum for collaboration and networking among local stakeholders and international partners to promote knowledge exchange and mutual growth.

Registration will open soon, just follow the link above. The registration fee is expected to be about R 6,000 (approximately € 200) for commercial participants, free for all others.

An invitation for sponsorship is available here. It provides some details about the event.

Also check another important link with regard to the activities of Fundisa, the African Academy of Medicines Development, http://www.fundisa-academy.com/.

The Evolving Landscape of Pharmaceutical Medicine in Dubai: A Promising Future

Dubai, a global hub of innovation and development, has emerged as a prominent player in the field of pharmaceutical medicine. With its robust infrastructure, strategic location, visionary leadership and commitment to innovation, Dubai presents a promising landscape for the advancement of healthcare and pharmaceutical research. In this opinion article, the growing significance of Dubai in the realm of pharmaceutical medicine and the potential it holds for the future is being explored.

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Skyline, Dubai, UAE image (Pixabay cartojos)

A Hub of Medical Excellence and Investment in Research and Development:

Research, Healthcare, Medicine image. (Pixabay geralt)

Dubai's healthcare sector has witnessed remarkable growth over the years, bolstered by state-of-the-art medical facilities, skilled healthcare professionals, and a strong regulatory framework. The city has become a sought-after destination for medical tourism, attracting patients from around the world seeking high-quality healthcare services. This influx of patients has created a diverse patient pool, ideal for conducting clinical trials and research studies.

Dubai's commitment to fostering innovation is evident in its substantial investments in research and development. The government, in collaboration with renowned educational institutions and research centres, is actively promoting research initiatives, aiming to position Dubai as a centre for cutting-edge pharmaceutical research. These efforts are attracting leading researchers and pharmaceutical companies, propelling the growth of medical knowledge and therapeutic advancements within the region.

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Regulatory Excellence, Collaboration and Knowledge Exchange

Healthcare Medicine
(Pixabay ar130405)

Dubai's regulatory agencies are dedicated to ensuring patient safety and maintaining high standards of quality in pharmaceutical medicine. The Dubai Health Authority (DHA) and the Ministry of Health and Prevention (MoHAP) have implemented stringent regulations and guidelines that govern the approval, import, and distribution of pharmaceutical products. This commitment to regulatory excellence provides a robust framework for conducting clinical trials and ensures the reliability and efficacy of medicines available in the market.

Dubai's ambition to become a global centre for pharmaceutical medicine is further fuelled by its emphasis on collaboration and knowledge exchange. The city hosts numerous international conferences, symposiums, and workshops that bring together experts, researchers, and industry professionals from around the world. These platforms facilitate the exchange of ideas, promote interdisciplinary collaborations, and foster innovation in pharmaceutical research and development.

While Dubai's progress in pharmaceutical medicine is commendable, a few challenges remain. The recruitment and retention of skilled professionals, ensuring equitable access to healthcare for all residents, and further streamlining regulatory processes are areas that require continued attention. By addressing these challenges and building upon existing strengths, Dubai has the potential to become a global leader in pharmaceutical medicine.

Dubai's ascent as a prominent player in the field of pharmaceutical medicine is a testament to its unwavering commitment to healthcare excellence. The city's investment in infrastructure, research, and collaboration, combined with robust regulatory frameworks, paves the way for remarkable advancements in pharmaceutical research and patient care. As Dubai continues to evolve, it holds the promise of reshaping the landscape of pharmaceutical medicine in the region and beyond.

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The Basel Center for Health Economics: at the Interface of Economics and Healthcare Systems

Inaugural Event

At the University of Basel, the interdisciplinary Basel Center for Health Economics (BCHE, https://bche.ch/home.html) has recently been founded. The BCHE involves three university faculties and is led by Prof Dr Stefan Felder (Managing Director, Faculty of Business and Economics), Prof Dr Günther Fink (Swiss Tropical and Public Health Institute, Faculty of Natural Sciences and Faculty of Business and Economics) and Prof Dr Matthias Schwenkglenks (Faculty of Medicine). On September 13, the BCHE invited the interested public to celebrate its inaugural event (Figures 1-3). The event assembled about 180 participants from academia, public administration, healthcare, health insurers and industry. After introductory speeches by Prof Torsten Schwede, Vice Rector Research of the University, and Dr Lukas Engelberger, Health Director of Canton Basel Stadt, the BCHE research and teaching activities at the interface of economics and healthcare systems were presented. Subsequent parallel session addressed pending changes to the German system of hospital financing (keynote: Prof Jonas Schreyögg, Hamburg Center for Health Economics) and experiences from a malaria trial revealing policy implementation issues in an African context (keynotes: Aita Signorell und Manuel Hetzel, Swiss Tropical and Public Health Institute). The event ended with a panel discussion, led by Prof Marcel Tanner, President of the Swiss Academies of Arts and Science, exploring possible contributions of science and research to efficiency in healthcare.

Prof Stefan Felder introduces the BCHE

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Why is the BCHE needed?

Rising costs and limited resources in the health sector have spurred demand for health economics research over the last decades. Historically rooted in the fields of economics, medicine and public health, health economic research uses a range of quantitative tools to identify the most efficient ways to improve health systems. Core areas of health economic studies include research of the functioning and governance of health service delivery, research on conditions for successful pharmaceutical innovation, research on access to and sustainability of essential medicines and medical technologies, research on optimal provider and patient incentives and behaviour, as well as research on data systems and research on health financing. At the interface with the pharmaceutical industry, cost-effectiveness and budget impact studies play a key role. Pricing and reimbursement of pharmaceuticals have become additional topics of major relevance, which we will study at the Center, particularly in light of the rise of personalised medicine, targeted treatment and gene therapies.

Current areas of activity

Research at the Faculty of Business and Economics has traditionally focused on three core areas: markets and competition, regulation in health insurance and healthcare markets, and priority setting for medical services. During 2024, Prof Dr Armando Meier will join the Faculty and the BCHE as a new colleague with a research focus on the intersection of health and behavioural economics. Research at the Swiss TPH has mostly focused on identifying the most suitable policies and interventions to reach vulnerable populations in Switzerland and globally. The institute's core expertise lies in the measurement and modelling of infectious as well as chronic diseases and the economic assessment of a range of disease control strategies, including large-scale eradication campaigns. The Swiss Tropical and Public Health (TPH) also has extensive experience in randomised controlled trials and longitudinal cohort studies. The Health Economics Facility (HEF) and European Center of Pharmaceutical Medicine (ECPM) at the Department of Public Health of the Medical Faculty have long-standing experience in the performance of cost-effectiveness, cost-utility, cost-minimisation and budget impact analyses, alongside clinical data collections and based on decision-analytic modelling. This occurs across a wide range of medical indications. Links between health economics and implementation science are increasingly established, e.g., in the rapidly growing areas of nursing science, public health, and health systems research. Further areas of activity include the wider field of health technology assessment, research on patient-reported outcomes and health services research. The HEF and ECPM also have strong experience with the analysis of health insurance claims data and other data, with a strong interest to increasingly apply causal inference methods to such data.

Prof Günther Fink

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Prof Matthias Schwenkglenks

Vision and Aims

The BCHE envisions becoming one of the leading European centres for research in health economics, leveraging its unique strategic position within a large economic, public health and life science cluster in North-Western Switzerland. Through independent research on health systems in an increasingly digital and interdisciplinary context, the centre aims to provide cutting-edge scientific evidence, to provide a networking hub linking research with industry and policy makers to address real-world translation, and to spur innovations that will improve health systems and well-being locally as well as globally.

Aims for the mid-term are to further leverage, strengthen and extend existing research capacity embedded and linked in the current research infrastructures of the University of Basel, to engage in methods development and to acquire joint, larger-scale research projects. We will also increase local knowledge and health economics capacity through providing extended teaching offers, and stimulate the exchange between researchers, stakeholders and the public, e.g., through outreach events addressing topics of public interest.

Contact

Interested parties are invited to contact the BCHE through https://bche.ch/contact.html.

Author:

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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 Pharmaceutical Medicine (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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- **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

THE FLAG

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