

Education and Certification WG

Concept Paper (final version of 17th March 2022)

Introduction

The Education and Certification Working Group (ECWG) will work on the delivery of educational training courses for professionals within the field of **Pharmaceutical Medicine/Medicines Development Sciences (PM/MDS)**. A second goal is to co-develop the network of course providers with the PharmaTrain Federation¹ and to foster different educational formats and degrees in Pharmaceutical Medicine.

The scope of the ECWG is based on IFAPP's overall strategy and mission to promote PM/MDS with regard to the discovery, development, research and use of medicines by enhancing the knowledge, expertise and skills of pharmaceutical physicians and other professionals involved in the development of medicinal products.

One of the corner stones of the ECWG will be, in co-operation with the Young Professionals Working Group (YPWG), to raise awareness in young people at the beginning of their careers, of the discipline and post-graduate education possibilities in the field of PM/MDS.

Basis/Background

The training programmes are based on the PharmaTrain Syllabus v2.0 and will be updated in line with future PharmaTrain Syllabus versions.

(https://www.pharmatrain.eu/resources/download/180101%20PharmaTrain%20Syllabus%20V2.0_Din_al.pdf).

The content of the concept paper is based on *the IFAPP Constitution, Article 2:*

- *'by enhancing the knowledge, expertise and skills of pharmaceutical physicians and other professionals involved in all scientific disciplines involved in the discovery, development, processing and usage of medicines as well as experimental and clinical research'*
- *'to foster the development of undergraduate and postgraduate education as well as continuing professional development programs in pharmaceutical medicine and medicines development;'*
- *'to assist National Member Associations in developing such programs'*
- *'to disseminate information on developments in Pharmaceutical Medicine and Medicines Development.'*

IFAPP Education and Certification Programme

The IFAPP education and certification programme comprises three corner stones:

1 Continuing Professional Development (CPD)

Members from National Member Associations (NMAs) and Individual Affiliates (IAs) are in need to systematically and continuously gain and update knowledge, independent of their educational background and career level. IFAPP aims at providing the global framework for continuous learning and exchange of experience for and from within its membership.

1a Short courses in pharmaceutical medicine/medicines development sciences and related disciplines

Such post-graduate education and training courses, covering any topic(s) of the PharmaTrain Syllabus or beyond, are provided by IFAPP, and the organising NMA is responsible for the quality of content and delivery of the courses as well as their financial and technical management. The length of a course is at the discretion of the organiser.

National and international education and training courses, either set up ad hoc or as continuously updated courses, preferably provided in English, will be published under a specific icon on the IFAPP website and will be announced in IFAPP TODAY.

1b NMA and international IFAPP Webinars

Ad hoc webinars will be provided to ensure that IFAPP members are aware of fast evolving developments such as, options and challenges of Real-World Evidence (RWE) data, Modelling and Simulation, Artificial Intelligence, licensing and monitoring developments, advanced therapies, new developments in Health Technology Assessment (HTA) and regulatory obligations, current health topics like acute infections, etc. Experts from all involved stakeholder groups like academia and scientific societies, life science companies, service providers, governmental bodies, or patient organisations will present newest developments and provide opportunities for exchange of experience, questions and discussions.

The webinars will be conducted in close cooperation with or by the NMAs with the intention to fill gaps and/or update the members' knowledge. There will also be short webinars addressed at young professionals in collaboration with the YPWG.

The IFAPP CPD webinars will all be presented and promoted within the "IFAPP CPD Network" icon on the IFAPP website with the aim to enable IFAPP members to select CPD topics from a broad, global scope of interesting offerings on different topics and in different languages.

2 Development and support to Diploma, Master and Certificate Courses in PM/PMDS

IFAPP is supporting existing and newly developed post-graduate courses that enable the trainees to receive a certificate, diploma or master in PM/MDS for physicians and other academic disciplines involved in the development of new medicines or medical devices as well as in related disciplines if they are offered by a NMA or a university/training organisation in a NMA and if they adhere to the PharmaTrain standards for syllabus, modular curriculum and their quality criteria. Such course standards were jointly developed between 2009 and 2014 by PharmaTrain and IFAPP within a project enabled by the public-private partnership IMI (Innovative Medicines Initiative²). Since 2014 course providers can apply for a PharmaTrain Federation assessment of their course(s) leading to the international recognition of "PharmaTrain Centre of Excellence", "PharmaTrain Centre" or "PharmaTrain Course" and thus becoming a member of the global network of course providers committed to continuously increasing quality and harmonisation of education in PM/MDS and related disciplines. IFAPP is supporting such course providers in achieving the respective recognition and by promoting their courses on the IFAPP website and newsletter.

Examples are the following courses for which IFAPP negotiated a fee reduction for IFAPP members (in the NMAs and for Individual Affiliates):

- GPMed, Austrian Society for Pharmaceutical Medicine: Certificate/Advanced Certificate Course in Medical Affairs and Pharmaceutical Medicine
- University of Basel/ECPM⁵'s Diploma Course in Pharmaceutical Medicine/Medicines Development Sciences.

3 Specialist of Pharmaceutical Medicine/Medicines Development Sciences

Currently, academically qualified people working in pharmaceutical research and development are trained on the job, undertake CPD, and participate in university training courses to achieve a

secondary diploma and/or master degree. This leads to an individual acquiring a certain array of competencies across multiple domains. Based on the existing national concepts for a specialisation of physicians in pharmaceutical medicine in some European countries, PharmaTrain and IFAPP jointly developed a global certification programme for physicians and non-physicians leading to the “Specialist in Medicines Development” (SMD). Trainees who successfully completed a PharmaTrain-recognised diploma or master course in PM/MDS apply their acquired knowledge and skills in a mentored, 2-4 years on-the-job training programme to achieve the required competence for this specialist certification. Successful completion of the programme is verified and recognised by the global PharmaTrain Certification Board (gPCB) consisting of IFAPP and PharmaTrain experts.

The SMD programme currently exists in Japan and Italy. In close collaboration with PharmaTrain IFAPP supports NMAs and course providers in encouraging trainees to join this certification programme, in providing mentors and in facilitating job opportunities suitable for achieving this degree in more and more countries.

Global Fellow in Medicines Development

IFAPP will continue to offer the award of the title Global Fellow in Medicines Development (GFMD) to those colleagues who already have many years of experience in Pharmaceutical Medicine and who can demonstrate their expertise. To apply for this award, a specially designed questionnaire should be completed, as used previously. The results of a recently conducted survey have shown clearly that this title is highly appreciated by the IFAPP membership.

A call for applications will be sent out during the course of 2022.

Summary

To summarise, training and education in PM/MDS cover a competency-based, work-centred education and training in all areas of medicines development. Competency and continuing professional development are key for working in a rapid changing and challenging environment.

The participation in the above listed courses, webinars and certification programmes will improve knowledge and competencies. The different options should be used in a strategic way by combining national and international training offers.

IFAPP will cooperate with CIOMS³ to support the global approach for PM/MDS. In this regard IFAPP will also work with the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom (FPM⁴) in the Global Forum (*FPM Global*).

A call for applications for the title *GFMD* will be sent out soon.

¹ PharmaTrain Federation <https://www.pharmatrain.eu/>

² Innovative Medicines Initiative <https://www.imi.europa.eu/>

³ CIOMS Council for International Organizations of Medical Sciences <https://cioms.ch/>

⁴FPM <https://www.fpm.org.uk/>

⁵ ECPM <https://ecpm.unibas.ch/>