

The Faculty of Pharmaceutical Medicine – Foundation, function and future

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Abstract: The Faculty of Pharmaceutical Medicine was established in the United Kingdom (UK) in 1989 to develop and maintain competence, ethics and the highest professional standards of practice in the discipline. This article charts the founding principles and history of the Faculty, details its composition and membership, and outlines the major functions and achievements of the organisation in the context of the development of the discipline of pharmaceutical medicine. The recognition of pharmaceutical medicine as a medical specialty in the UK is described together with the associated certification programme Pharmaceutical Medicine Specialty Training, which enables pharmaceutical physicians to become certified practitioners in the specialty with the UK General Medical Council (UK GMC).

Keywords: Pharmaceutical Medicine; membership; standards; ethics; training; examinations; advocacy

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1. Founding Principles and Aims

The Faculty of Pharmaceutical Medicine (the Faculty) is a standard-setting body for the medical specialty of pharmaceutical medicine and a professional membership organisation for pharmaceutical physicians and those with a professional interest in the specialty. Founded in 1989, it is a faculty of the three Royal Colleges of Physicians of the United Kingdom: The Royal College of Physicians of London, The Royal College of Physicians of Edinburgh, and The Royal College of Physicians and Surgeons of Glasgow.

Although the Faculty has a strong affiliation with its parent colleges and shares their overall aims, the organisation is self-governed and independent. The Faculty is a registered charity and therefore exists for the benefit of patients and the public. It was founded with the mission: “*To advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public.*”

2. History and Development

Medicines have a central role in clinical practice, and the need for the medical profession to be closely involved in their development and surveillance was recognised by the pharmaceutical industry in the mid-1950s, when a small but increasing number of doctors were employed as medical advisers.

In 1963, in the wake of the thalidomide disaster, the setting up by the government of the Committee on Safety of Drugs (The Dunlop Committee) and the subsequent formation of the Committee on Safety of Medicines, one of the advisory committees established by The Medicines Act 1968, reinforced the need for specially trained doctors in the pharmaceutical industry, academic departments of medicine and the Department of Health and Social Security. In 1976, the Diploma in Pharmaceutical Medicine was established to be gained by examination.

The rapid evolution of the role of pharmaceutical physicians, and the developing interface between pharmaceutical medicine and other medical disciplines, led to the proposal to create a faculty of the Royal Colleges of Physicians, so that criteria could be established leading to specialist certification of practitioners, and with

it the public recognition of the ethical and professional practices which ensured that new medicines are developed, approved and monitored to the highest standards. The Faculty of Pharmaceutical Medicine was established in 1989, and at the time of its inauguration comprised 400 members. Today, the Faculty has over 1,600 members in over 40 countries. Members are pharmaceutical physicians who work to develop medicines and vaccines both in the UK and across the world.

3. Pharmaceutical Medicine

The Faculty was established within a distinct medical scientific discipline, pharmaceutical medicine, which for over 40 years has advanced in the area of discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and the health of the public. Pharmaceutical medicine occupies common ground between the clinical and healthcare professions, pharmaceutical industry and government. Whilst the boundaries of pharmaceutical medicine are indistinct, at its centre is the clinical testing of medicines, translation of drugs into new medicines, the safety and well-being of research participants in clinical trials, and a pursuit of understanding of the safety of medicines and their benefit-risk balance.

Pharmaceutical medicine is a discipline that takes its place alongside other medical specialties; it has developed its own professional ethos; it has established a distinct body of knowledge based primarily on clinical science; its practitioners represent a cohesive group of professionals and specialists with common goals and aspirations. Pharmaceutical physicians work with industry, medicines regulatory authorities, clinical research organisations and academic centres. They have close affinities with medical colleagues in primary and secondary healthcare and in universities. As a postgraduate medical discipline, pharmaceutical medicine has a recognised international syllabus, training courses and examinations with qualifications and certification, its own research methodologies, and embraces new technologies and regulations in pursuit of proof of efficacy, safety, quality and effectiveness of medicines.

Pharmaceutical medicine is a listed medical specialty in the UK, in Ireland, and in Switzerland, but around the world this remains a work in progress. This official recognition is underlined by accredited education and training of pharmaceutical physicians in the specialty, and of the establishment and maintenance of standards of practice and professionalism in the competency, care and conduct applied to their work, and of growing public recognition and accountability.

In April 2002, pharmaceutical medicine was officially recognised as a medical specialty in the United

Kingdom. Trainees undertaking Pharmaceutical Medicine Specialty Training (PMST) have a 4-year programme of in-work competency-based training in early characterisation of potential medicines, clinical development, safety and risk management and medical affairs within the healthcare marketplace, together with general interpersonal, management and leadership skills. On successful completion of PMST, trainees are entitled to apply to be on the UK GMC's specialist register in pharmaceutical medicine. PMST is described in greater detail below.

4. A Functioning Faculty

Although the Faculty is based in the UK, it has an extensive international membership, with currently around 25% of its membership based outside the UK, in over 40 countries around the world.

The organisation is based in Islington, North London, and has an office staff of nine, who administer the training programmes and examinations, and support the Faculty's Board and committees.

The Faculty's honorary officers are the President, Vice President, Registrar and Treasurer and other committee members are elected or appointed from the Faculty's general membership. The Faculty Board, which includes the officers and other Faculty members, has legal responsibility for the operation of the Faculty as unpaid trustees of the charity.

Faculty members have opportunities to support the development of the specialty and the Faculty by becoming trained Faculty examiners, educational supervisors, specialty advisers and appraisers for medical revalidation.

Faculty activities include: membership engagement, examinations, medical revalidation, continuing professional development, the PMST programme, qualifications in human pharmacology and experimental therapeutics; committee and working party activities; advocacy work; international liaison and collaboration; scientific meetings and events, and publications.

In 2014, the Faculty celebrated the 25th anniversary of its foundation. During the course of the year a number of special events were organised and a webpage cataloguing the history and achievements of the Faculty was created^[1].

5. Examinations and Training

The principal function of the Faculty is to set, maintain and raise standards in the specialty. Alongside PMST, the Faculty sets the syllabus for and administers the Diploma in Pharmaceutical Medicine, and training programmes and examinations in human pharmacology, outlined in [Figure 1](#).

Diploma in Pharmaceutical Medicine

An examination for physicians working in pharmaceutical medicine covering all aspects of the specialty, as part of the PMST programme or as a standalone examination.

Diploma in Human Pharmacology

A 2-year programme and examination for physicians working in pharmaceutical medicine or allied field covering the knowledge and competencies required to serve as a principal investigator for human pharmacology studies of investigational medicinal products.

Certificate in Human Pharmacology

A 1-year part-time programme and examination for physicians, scientists and clinical research managers covering all aspects of human pharmacology studies of investigational medicinal products.

Diploma in Experimental Therapeutics

An 18-month supervised workplace-based training programme and examination, intended for physicians conducting Phase I/II studies predominantly in patients within their clinical specialty, e.g. oncology, rheumatology, in a hospital clinical research facility.

Pharmaceutical Medicine Specialty Training (PMST)

A 4-year supervised workplace-centred certification programme with knowledge assessed in the Diploma in Pharmaceutical Medicine examination, and the demonstration of competencies across 7 domains of the curriculum within a framework of assessment, appraisal and annual review of competence progression. On completion pharmaceutical physicians receive a Certificate of Completion of Training (CCT) and a place on the UK GMC's specialist register in pharmaceutical medicine.

Figure 1. The examinations and training programmes of the Faculty

6. Advocacy, PR and Careers

An important part of the Faculty's work is in advocating for the highest standards of practice for the benefit of patients and the public health. The Faculty is increasingly being recognised as an authoritative voice on pharmaceutical medical issues, both in the UK and around the world. Its views are now increasingly being sought by UK and international organisations, and the media, and it is represented on many external committees and groups, which enable its voice and that of its membership to be heard widely.

Through its network of committees and shared interest groups, the Faculty responds frequently to external consultations. These are mostly issued by the UK Government and UK and European regulatory agencies, but it also comments on policy documents from organisations such as the Prescription Medicines Code of Practice Authority, European Commission, World Health Organisation and World Medical Association. Links to some of the most recent consultations can be found on the Faculty website^[2].

The Faculty undertakes a variety of activities to raise the profile of pharmaceutical medicine as a career option for doctors, such as attendance at careers fairs or invited lectures and presentations on pharmaceutical medicine.

7. Ethics and Standards

In addition to the core work of training and examinations, the Faculty also advocates and maintains rigorously the highest standard of ethical practice amongst its membership and beyond. The Faculty first produced its ethical touchstone, the "Guiding Principles for Pharmaceutical Physicians" in 1998 and this was updated and formally published in 2006^[3], with further revision in November 2010, as a result of a recommendation in the report by the Royal College of Physicians, "Innovating for health: Patients, physicians, the pharmaceutical industry and the NHS".

In 2014, the Good Pharmaceutical Medical Practice (GPMP) document was published^[4]. GPMP provides all doctors practising pharmaceutical medicine around the world with specific guidance and direction on expected standards, conduct and behaviour. GPMP complements international and national legislation and has been written to apply to all circumstances to ensure that it contains universal standards of good medical practice in pharmaceutical medicine. GPMP extends upon the principles outlined in its first publication in 2008 of GPMP, and the Guiding Principles for Pharmaceutical Physicians of 2010. GPMP encourages all pharmaceutical physicians to promote probity and adhere to the highest ethical principles and ideals, wherever they

practice, and act as an advocate for patients.

The Good Pharmaceutical Medical Practice Support Network^[4] has also been established, to provide guidance and direction to pharmaceutical physicians who face ethical or medical dilemmas in their practice. The network is free to use and is available to all registered doctors involved in the practice of pharmaceutical medicine, anywhere in the world. A panel of experienced Faculty Fellows has volunteered to give guidance to those who contact the network, whether they are a seasoned professional or a trainee. The scope of the network includes: enquiries directly related to the interpretation and adoption of the standards set out in GPMP; questions of research practice and ethics; and interpretation and implementation of global regulations, ethics and culture.

8. Medical Revalidation

Medical revalidation was introduced in the UK in December 2012. Revalidation is the process by which all licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. Revalidation aims to give extra confidence to patients that their doctor is being regularly checked by the UK GMC. Licensed doctors must revalidate every five years. During this time they maintain a portfolio of supporting information drawn from their practice, which demonstrates how they are continuing to meet the principles and values set out in Good Medical Practice (GMP)^[5]. They also have regular appraisals. The Faculty has developed specialty specific standards for revalidation and is the designated body for almost 600 of its members.

9. Specialty Training in Pharmaceutical Medicine

The purpose of PMST is to equip doctors with specialist knowledge and comprehensive skills and competencies to practise to the highest ethical and professional standards in the discovery, development, evaluation, registration, regulation and the safe use of medicines. Whilst PMST is not a mandatory programme, most companies and organisations employing pharmaceutical physicians in the UK support the programme and encourage participation. As of January 2017, over 310 pharmaceutical physicians have completed PMST, to receive their Certificate of Completion of Training (CCT) from the UK GMC. There are over 140 enrolled trainees undertaking PMST at any one time, and each year some 35 doctors join the programme, whilst around the same number complete training.

All trainees follow the same overall curriculum and structure, though the balance of in-work to course-

based training will vary depending on the role the individual is undertaking in their workplace. The PMST programme allows for considerable individual variation and flexibility in a trainee's approach to meeting the requirements of the curriculum, and an overall individual programme takes account of the trainee's experience, job description and content, and career development aspirations. The principal modules of the curriculum are: medicines regulation, clinical pharmacology, statistics and data management, clinical development, healthcare marketplace, drug safety surveillance and interpersonal, management and leadership skills.

The Faculty accepts applications for PMST from doctors from all medical specialties. The criteria that doctors must fulfil to enter are that they are registered with the UK GMC with a licence to practise, work for a UK-based pharmaceutical organisation that has been approved as a Local Education Provider (LEP) to deliver the PMST programme, and have completed approved clinical training and/or experience over a period of three or four years, depending on the year of their medical qualification.

10. Formation and Development of the Curriculum

In April 2002, the UK Parliament approved pharmaceutical medicine as a medical specialty in the UK. With the recognition of the specialty, the Faculty worked to develop the specialty training programme to provide pharmaceutical physicians with broad training, completed in the workplace, in all fields of pharmaceutical medicine, which would lead to eligibility to apply for registration on the UK GMC's specialist register in pharmaceutical medicine on successful completion of the programme.

The project involved the development of a higher medical training curriculum in pharmaceutical medicine, today known as PMST, which was achieved with the help of a Delphi exercise conducted by the University of Keele to identify the core topics for the curriculum. This higher medical training programme was approved by the Specialist Training Authority (STA) in 2002. The knowledge-based assessment of the curriculum was the Faculty's existing Diploma in Pharmaceutical Medicine examination. Recent changes to the curriculum have seen the requirement for trainees to achieve attainment levels replaced by the requirement to demonstrate achievement of competencies through the assessment of the trainee's applied knowledge, skills and behaviours.

Postgraduate medical education and specialty training in the United Kingdom continue to evolve, and it is the Faculty's aim and responsibility to ensure that its PMST programme is up-to-date and relevant to current

practice and the needs of patients. The Faculty is currently undertaking a review of the curriculum with the aim to introduce new Competencies in Practice (CiPs) for pharmaceutical medicine, which will lead ultimately to a very new-look curriculum for postgraduate training in the specialty. This is a development required by the Joint Royal Colleges of Physicians Training Board (JRCPTB) of all its specialties. The last almost 15 years of the Faculty's specialty training programme have seen major changes to postgraduate medical education in the UK, and the Faculty aims that its PMST programme will meet those changes to ensure that specialist pharmaceutical physicians meet the needs of future patients. More detail about PMST is available via the referenced link^[6].

11. Oversight and Quality Management

The management of the PMST curriculum involves a wide range of organisations and people: the trainees themselves; the pharmaceutical companies, CROs and regulatory authorities which must be approved by the UK GMC as LEPs to deliver the PMST curriculum; the approved educational supervisors who supervise and assess their trainees; the medical postgraduate dean who is responsible for the management of the PMST programme and the trainees; the members of the Annual Review of Competence Progression panels who meet trainees to formally review their progress through the PMST programme; the Faculty's team of Specialty Advisers who quality manage the delivery of the PMST programme by the LEPs, and the staff of the Pharmaceutical Medicine Virtual Deanery, together with the Lead Postgraduate Dean under whose auspices the PMST programme is delivered.

12. The Future

The Faculty continues to grow and mature as an organisation. It is growing in terms of numbers of its members and trainees, and also in terms of the less tangible, but no less important, aspects of influence and impact on practice. The next few years will be an exciting time for the organisation as it embarks on an ambitious programme of policy development. It is

hoped that the Faculty's international reputation and recognition through its membership in many countries around the world will evolve into more tangible collaborations with organisations and representative bodies in the area of pharmaceutical medicine and medicines development science. The Faculty is currently launching two major new work streams; one looking at early access to medicines and adaptive licensing, and the other examining the potential value of different types of real world data in pharmaceutical medicine. Most important of all is that the Faculty continues to acquire the recognition, the strength and the strategic vision to promote actively at home and abroad its founding mission, "*To advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public.*"

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