The pharmaceutical physician

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BMA

At a glance

A fifth of the world's most popular prescription medicines are currently developed in the UK

£4.6bn was spent on pharmaceutical research and development in the UK in 2010-11, and research costs continue to rise.

Pharmaceutical physicians are employed by pharmaceutical companies and associated organisations to lead and advise on the development of new treatments.

Pharmaceutical physicians are also responsible for ensuring that all promotional materials and communications are in line with the code of practice for the industry.

Pharmaceutical physicians involved in drug development work closely with basic scientists. Pharmaceutical physicians also design the studies and clinical trials looking into the effect of new chemical or biological entities.

Medical advisers provide the medical viewpoint in marketing strategy and promotion, lead on comparative studies and lecture in company training programmes and to external audiences.

Specialist training to CCT is through Pharmaceutical Medicine Specialty Training (PMST), a 4-year workplace training programme with assigned educational supervisors and an agreed ARCP process.

Recruitment to the sector is to a particular company and thus 'cultural fit' is an important consideration along side competences and qualifications.

There is no model contract or agreed salary scales for Pharmaceutical physicians, and pay varies according to seniority, size of company and competition in the market. A high level of UK and international travel is likely.

Appraisal and revalidation are provided through the individual's company and through the Faculty of Pharmaceutical Medicine.

Contents

Introduction

This booklet is intended to be of interest to doctors contemplating a career in pharmaceutical medicine or those already working in the specialty. Pharmaceutical medicine is a specialty focussed on the discovery, development, evaluation, registration, monitoring and medical aspects of the marketing of medicines. It is one of the fastest growing medical specialties in the UK. In 1974 there were some 260 doctors in the specialty, by 1989 this had grown to 500 and in 2013 there are an estimated 2000 pharmaceutical physicians in the UK, mainly employed within pharmaceutical companies, contract research organisations, regulatory agencies and academia, or acting as independent consultants.

This introduction to the specialty was initially written by the Pharmaceutical Physicians Group Committee of the British Medical Association and was reviewed and updated in 2006. The 2013 revision was led by the BMA's Medical Academic Staff Committee (MASC), which took over responsibility for representing pharmaceutical physicians within the BMA in 2010, and the Faculty of Pharmaceutical Medicine (FPM) – the standard setting body for the specialty. The British Association of Pharmaceutical Physicians were also asked for their views.

The BMA offers advice and counselling on all professional matters relating to medicine, including terms and conditions of service, professional training involved and working abroad. Contact: support@bma.org.uk or call 0300 123 1233; website: www.bma.org.uk The Medical Academic Staff Committee (MASC) is the lead Committee for pharmaceutical physicians and others involved in medical research. To contact the Committee and its officers e-mail info.masc@bma.org.uk

The British Association of Pharmaceutical Physicians (BrAPP) is involved in the training, education and development of pharmaceutical physicians, and published the professional journal "Pharmaceutical Physician". Contact: info@brapp.org Website: www.brapp.org

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A brief history of pharmaceutical medicine

The first full-time pharmaceutical physicians (or medical advisers as they were then known) were recruited after the Second World War to advise the growing modern pharmaceutical industry on the medical aspects of drug development, especially clinical research, as well as marketing issues.

The introduction of the 1968 Medicines Act, and the formation of the Committee on Safety of Medicines in the wake of the thalidomide tragedy, increased the need for physicians within both the pharmaceutical industry and the regulatory authorities.

An association for medical advisers in the industry had been formed as early as 1957 and this is known today as the British Association of Pharmaceutical Physicians (BrAPP). BrAPP played a major part in raising awareness of the specialty, in introducing the Diploma in Pharmaceutical Medicine in 1975 and in establishing the Faculty of Pharmaceutical Medicine in 1989. Since its formation, the Faculty, which is part of the three Royal Colleges of Physicians of the UK, has set and maintained standards in the specialty.

Pharmaceutical medicine was recognised by the UK Parliament as a medical specialty in 2002. It has a specialty training programme – Pharmaceutical Medicine Specialty Training (PMST) – which is approved by the General Medical Council (GMC), and is overseen by the Faculty of Pharmaceutical Medicine, the GMC and the Joint Royal Colleges of Physicians Training Board (JRCPTB). A Pharmaceutical physician who wants to undertake PMST must apply to become an Associate (Trainee) member of the Faculty before they can enrol onto PMST and be issued his or her National Training Number (NTN).

All pharmaceutical physicians are also eligible for membership of BrAPP, which is affiliated to the International Federation of Associations of Pharmaceutical Physicians (IFAPP).

The introduction of a number of new initiatives by the last Government directed towards ensuring clinical excellence and cost-effectiveness, notably the National Institute for Health and Care Excellence (NICE), generated the need for more evidence-based support for pharmaceutical medicines. This extended still further the contribution made by pharmaceutical physicians and their importance to the sector and the wider health community.

The pharmaceutical industry

The pharmaceutical industry strives to develop and manufacture new high quality medicines with excellent efficacy and safety profiles. Although companies operate within a commercial environment, the special nature of medicines, as distinct from general commodities, is recognised. This is reflected in the Medicines Act of 1968 and the ethical codes of practice to which the industry operates both in the development and in the eventual promotion of medicines.

The UK is the 7th largest pharmaceutical market in the world, and, as such, the sector makes a greater contribution to the UK economy than any other industrial sector – worth around £31.8bn - and generating an annual trade surplus of around £5bn. One fifth of the world's most popular prescription medicines are currently developed in the UK. The sector is particularly important in terms of its R&D contribution and the pharmaceutical sector alone accounts for more UK-based business R&D than any other manufacturing sector – around £4.6bn was spent on pharmaceutical R&D in the UK in 2010-11, over 28% of total industrial R&D spend. The pharmaceutical market is part of the overall Life Sciences sector and includes the medical technology, pharmaceutical, medical and industrial biotechnology sub-sectors and overall generates an annual turnover of £50.6bn and employs around 166,000 people in 4,500 companies.[1] Research costs continue to rise. For every marketed medicine that makes enough money to pay for its development, about 25,000 chemical compounds were tested, on average 25 of these will have gone into clinical trials and five received approval for marketing. From patent filing to product launch takes over 12 years at a total cost in excess of £1.15billion.[2]

http://www.marketresearch.com/AMA-Research-v175/Pharmaceutical-Biotechnology-Construction-Sector-UK-7161642/

http://www.abpi.org.uk/industry-info/new-medicines/Pages/default.aspx

Approval for new drugs needs to be granted by national regulatory authorities, such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, before a medicine in development can be evaluated in patients, or made available on the market. Once medicines have been approved they are subject to additional scrutiny with respect to the manner in which they are promoted through the Association of the British Pharmaceutical Industry (ABPI) Code of Practice and more recently for their cost-effectiveness for use in the health service by NICE. Pharmaceutical physicians also play a key role in conducting obligatory post-marketing surveillance involving monitoring and reviewing adverse events that may come to light as a medicine is more widely prescribed, and they advise the authorities as appropriate.

The UK pharmaceutical industry operates in a global market and, as a result, the development and registration of new treatments takes place within the context of international regulatory frameworks. The European Medicines Agency (EMA) offers centralised and mutual recognition approval procedures designed to speed up the availability of new medicines across European Union. The Medicines Act was amended to make reference to European legislation affecting the regulation of medicines and an International Conference on Harmonisation (ICH) has been striving since 1990 to bring together the procedures of European countries with those of the USA and Japan.

Much of the research work is undertaken on behalf of the industry by contract research organisations (CROs). In addition many physicians involved in medicines development are independent consultants. The roles below cover: physicians working full-time in the pharmaceutical industry; those working in CROs and independent consultants. The roles of physicians working in Medicines and Healthcare products Regulatory Agency (MHRA) are not covered below. For further information see http://www.mhra.gov.uk/Aboutus/Whoweare/index.htm

The role of the pharmaceutical physician

Pharmaceutical physicians lead and advise on the development of new treatments, established pharmaceutical products, and areas of unmet medical need. This includes advising on the medical aspects of:

- research
- development
- evaluation
- registration
- safety monitoring
- marketing of medicines in the best interests of patients.

More recently the advice provided has been extended to include the generation of additional data to support the cost-effectiveness of new medicines through clinical study programmes and pharmaco-economic studies, of which there are several recognised designs. Such studies are not part of the pivotal regulatory studies on which marketing authorisations are granted, but may inform the post-licensing considerations of e.g. NICE and matters concerning 'access to medicines'. In some cases economic variables and measures may be added to development trials (Phase III or even Phase II).

Pharmaceutical physicians are also responsible for ensuring that all promotional materials and communications are in line with the ABPI's Code of Practice for the industry. This is a voluntary code developed by the Association aimed at ensuring that the claims made regarding pharmaceutical products are evidence based. The Code covers:

- the promotion of medicines for prescribing to health professionals
- the provision of information to the public about prescription only medicines in the UK.

It is administered at 'arms-length' from the ABPI by the Prescription Medicines Code of Practice Authority (PMCPA).

Pharmaceutical physicians also play a role in reviewing and communicating data arising from complaints made about products.

The individual commitments of pharmaceutical physicians will range considerably from fundamental research and development programmes, through related policies and procedures, to the provision of professional consultation on existing products. The specific role varies from company to company, but usually requires a working relationship with practising clinicians, teaching hospitals, universities, government departments and regulatory bodies.

It is unlikely that two pharmaceutical physicians will have exactly the same combination of roles, but most physicians work within one of three main areas and these largely correspond to the well-defined phases through which a drug passes during its clinical evaluation:

- clinical pharmacology (phase I)
- clinical research (phases II and III)
- medical affairs or medical services (phase IV)

The ratio of pharmaceutical physicians in each area is approximately 1:5:10. The skills and personal attributes required by physicians working in each of these areas are rather different although some doctors, especially in smaller companies, may find their responsibilities extend across more than one area.
While not normally regarded as entry-level positions, some physicians work in drug safety/ pharmacovigilance, pharmacoeconomics, regulatory affairs, medical writing and marketing. There is some movement of doctors between the industry and regulatory authorities. Some doctors also choose to enter managerial or more commercially-orientated roles directly rather than overseeing clinical trials.

What does a pharmaceutical physician actually do?

The ***clinical pharmacologist or phase I physician*** works closely with basic research scientists, such as chemists, biochemists, pharmacologists and toxicologists who are involved with drug development including tests on healthy volunteers or patients with the disease in question. Initial studies are usually undertaken on healthy volunteers to assess safety and tolerability and to examine the drug's pharmacodynamic and pharmacokinetic profiles.

This role is a useful starting point for physicians entering the industry as it offers the opportunity to gain early exposure to the drug development process while still involving some clinical duties. Clinical research (phase I) physician positions are available in both pharmaceutical companies and clinical research organisations.

The ***clinical research physician (CRP) or phase II/III physician*** is involved in the design and monitoring of studies looking into the effects of new chemical or biological entities when they are first used in patients suffering from the target condition (phase II). When drugs go on to be studied in large multi-centre trials (phase III), CRPs also evaluate safety and efficacy. These studies form a key part of the clinical submission for international product registration. With the establishment of NICE, these studies are often augmented by additional clinical research to generate supportive data with respect to the cost-effectiveness of a new drug.

CRPs work with clinical project managers, clinical research associates (CRAs) and similar clinical operations personnel (who are usually non-medical graduates) on protocol and case record form (CRF) design and trial monitoring. They also work with regulatory affairs, statistics and pharmacoeconomics experts during the planning, implementation and reporting stages.

The CRP is responsible for ensuring an ethical and objective approach to the conduct and reporting of clinical trials. During the planning stage the CRP is usually involved in discussions with key opinion

leaders, who may also be potential investigators in the clinical trials programmes. There may also be interaction with Data Monitoring Committees (DMCs) or Data and Safety Monitoring Boards (DSMBs). These are established to oversee the safety of many large scale studies and focus on the safety:efficacy profile. All these activities can involve considerable travel both in the UK and abroad.

When studies are completed, the CRP will be involved in interpreting data and writing up the final reports along with preparing articles for journal publications or conference presentations.

The ***medical adviser (MA)*** works alongside marketing and sales colleagues in the commercial part of a company. Although essentially working with licensed products, medical advisers are still involved with clinical trials (phase IV) that are more marketing support in nature (that is, they may involve comparative studies of marketed products against local competitor products which may be different from those studied for regulatory submission); looking at new indications, modifications to formulations or routes of administration; and generating data in support of the medicine's cost-effectiveness. Safety continues to be monitored, affording clinicians an opportunity to gain experience with a new product outside the context of a clinical trial.

Working in medical services or medical affairs, the medical adviser has to recognise the commercial needs of the company, and gain the respect of colleagues by providing constructive advice on how to fulfil these needs while operating within ethical and ABPI frameworks and legal constraints.

The medical adviser provides a medical viewpoint on marketing strategy and ensures that product literature and promotional materials are factually accurate, legitimate, and in compliance with the PMCPA Code of Practice. In this context, the MA is the designated person within a company who takes responsibility for sign-off on promotional materials and is the company representative who addresses complaints should they emerge. Lecturing on company training programmes, and to external audiences, can be a significant part of the work, as can a variety of activities broadly categorised as public or professional relations.

Pharmacovigilance or ***drug safety adviser***, has evolved as a role to the point where some pharmaceutical physicians are now able to focus their careers wholly on this aspect of the safety evaluation and risk management of medicines. A solid clinical background is essential with industry experience in clinical research and/or medical affairs being helpful but not always necessary as a prerequisite.

The ***regional medical adviser*** position is a recently established discipline within the pharmaceutical environment. In many ways the role is very similar to that of the medical adviser except that it is normally field based and more marketing-support orientated. The contribution of this group of pharmaceutical physicians is becoming increasingly more important as companies require those with a medical background to assist business teams in reviewing the supporting evidence with purchasing organisations (such as Clinical Commissioning Groups (CCGs)) to facilitate the inclusion of products on to formulary lists. This is achieved through scientific and medical discussion with these purchasing and associated advisory bodies.

These positions are suitable for those who have already decided on a medico/commercial career and need to be undertaken in conjunction with a well formulated career development plan to keep the physician's options open during the early stages of their pharmaceutical industry career.

In summary, the main challenges and rewards gained in the medical affairs physician's work are in the handling and effective communication of new medical knowledge, in the appreciation of the significance of this to the company, and in the successful introduction to the community of new therapeutic agents.

Organisation of the medical department of a company

This will depend on the size of the company and the number of physicians employed by medical departments. This can be anything from one to more than 40 in the larger organisations. Similarly, job titles and their meaning can vary from company to company. A small company may have one doctor titled medical director who may or may not have a board appointment, while a physician in a larger company with the title senior medical adviser or associate medical director may be responsible for a portfolio of just some of the company's products. These, however, can be substantially larger than that of an entire small company. In the larger companies each major therapeutic area, or group of therapeutic areas, is managed by a therapeutic area head or director.

The medical department is usually led by a medical director, who is supported by a team consisting of other physicians, graduates and administrative staff. These non-medical graduates are normally pharmacists or life-scientists. In some companies they, rather than the physicians, may be responsible for provision of medical information services and staff management.

The activities of the staff of the medical department may include:

- the provision of medical information to both internal and external customers;
- setting up, monitoring and reporting of clinical trials; and
- the compilation of submissions to regulatory authorities to obtain marketing approval and the related product licence.

Why a career in pharmaceutical medicine?

Most physicians in pharmaceutical medicine would emphasise the scope, challenge, variety and career development opportunities that the work provides for them. The most frequently quoted attractions of a career in the specialty include:

- The chance to be at the forefront of medical progress combined with the intellectual interest of researching and developing new medicines
- The sense of purpose and the striving towards worthwhile medical goals
- The opportunity to develop and undertake specialty training in pharmaceutical medicine while receiving additional training and experience in business management and leadership skills
- The challenge of dealing with new and rapidly emerging areas of science (regenerative medicine, pharmacogenetics/genomics/gene therapy, personalised medicine, nanomedicine) which provide continuous intellectual challenges
- The ability to have a wider influence on the medical treatment of patients than can be achieved through individual patient contact
- The possibility of studying particular problems in depth and becoming an expert within the company and externally and possibly also internationally
- The availability of financial resources to fund clinical research programmes
- The excitement and challenge of operating at the front line commercial interface
- The stimulus of working cooperatively in a multidisciplinary team
- The international scope of the work and the possibility of travel
- The facilities and technical support provided by companies in order to keep up to date

- The opportunities for extensive personal and career development
- Potentially greater scope, on merit, for financial reward

Factors to be balanced against the attractions:

- Very limited or no clinical contact with patients, unless in clinical pharmacology
- The need to adjust to corporate life in a commercially driven environment
- Flexible working patterns which can mean long working days with some nights and weekends away from home
- Sometimes physicians can face difficulties re-integrating into a clinical position, if they decide that pharmaceutical medicine isn't for them
- Job security is less in industry than in the NHS. Companies are affected by external economic circumstances and can reduce staff, close down or be acquired by others
- Despite the recent changes to the NHS Pension Scheme it is still likely to be more generous than that offered by pharmaceutical companies

Clinical appointments

It is possible for some pharmaceutical physicians to maintain an occasional clinical appointment, usually honorary and flexible. By maintaining clinical contact the physician can keep up to date with clinical practice and developments in the health service. In addition, maintaining clinical contact gives the pharmaceutical physician more credibility when discussing clinical trials or commercially-related issues, with colleagues outside the industry.

Entry Requirements

Companies would expect a physician to start specific training once in post. Recruitment is, therefore, based on an assessment of personal attributes and competences as well as qualifications. In addition, 'cultural fit', that is personal versus company operating culture, is an important consideration.

The Faculty of Pharmaceutical Medicine strongly advises doctors that they do not embark on a career in pharmaceutical medicine with less than four years' post-qualification clinical training. Entry onto PMST is not allowed and career opportunities may be affected.

Appointments from a hospital or academic background are the most common route into the pharmaceutical industry for therapeutic-area specific roles. In these cases, recruitment is usually from the specialist registrar or research fellow level but some companies do consider SHOs (with sufficient clinical experience) or junior consultants.

With some exceptions, those with a general practice or public health background are normally better suited to join the industry in a medical affairs capacity. However, from this base it is then possible to progress into the clinical research discipline.

Surgery is another source of clinicians for the industry. Renal transplantation, prosthetic devices and ophthalmology experience are desirable attributes for particular pharmaceutical companies.

Qualifications

As the competition for places increases, the proportion of clinicians entering pharmaceutical medicine with their membership qualification has gone up. Some companies already insist on a higher medical qualification and for the individual this is advised to ensure career progress is enhanced once they have become established within the industry. Exceptions to this would be if, in addition to having a primary medical qualification, the applicant had a PhD and/or a business-related qualification such as an MBA or a marketing diploma.

In general, an applicant's chances of being selected may be enhanced by the possession of an intercalated BSc in pharmacology, biochemistry, or other evidence of scientific/research acumen (such as an MSc or PhD) and/or an MRCP, FRCA, MRCGP or equivalent. Having said that, as noted above, personal qualities and 'cultural fit' may be regarded by the company as equally important.

In certain more specialised cases it is mandatory to have a related membership (e.g. an MRCPsych, MRCPath, MRCS or MRCOG) or a research qualification in the target therapeutic area. Increasingly, commercial or business qualifications, such as an MBA or marketing diploma, are proving to be advantageous.

Pharmaceutical Medicine Specialty Training

Pharmaceutical Medicine Specialty Training (PMST) is a 4-year workplace-based training programme for pharmaceutical physicians who want to enter the GMC's specialist register for pharmaceutical medicine. The programme is overseen by the Faculty and the Joint Royal Colleges of Physicians Training Board (JRCPTB). On satisfactory completion of PMST a pharmaceutical physician will be awarded either a CCT or a Certificate of Eligibility for Specialist Registration (CESR), if the pharmaceutical physician is following the CESR (Combined Programme).

It should be noted that the PMST is currently optional but it remains advisable to participate, however, because of the comprehensive training and excellent networking opportunities provided. Please visit the link below to Faculty's website for more information about the routes to the specialist register:

http://www.fpm.org.uk/trainingexams/pmst/certification

A pharmaceutical physician must fulfil a number of criteria before he or she is eligible to enrol onto PMST. Below are listed a few of the criteria that a pharmaceutical physician must fulfil:

- Must be GMC registered and hold a licence to practise
- Must have an appointment with a pharmaceutical organisation (e.g. a pharmaceutical company, contract research organisation, regulatory agency)
- Must be an Associate (Trainee) Member of the Faculty
- Must have 4 years post-qualification clinical experience in approved training posts to the level of ST2, or equivalent, if qualified in or after 2005, or 3 years post- qualification clinical experience if qualified before 2005

Potential PMST applicants are encouraged to read the person specification for pharmaceutical medicine, which can be downloaded from the following link on the Faculty's website, for the full entry criteria:

http://www.fpm.org.uk/trainingexams/pmst/enrolment

Once a pharmaceutical physician has been enrolled onto PMST, she or he will be issued a National Training Number (NTN), a start date and an expected CCT date (i.e. date of completion of training). The trainee will follow the Specialty Training Curriculum for Pharmaceutical Medicine (August 2010), and will be required to complete workplace-based assessments, and collect evidence that demonstrate his or her competencies against the following curriculum modules:

- Module 1 – Medicines Regulation

- Module 2 – Clinical Pharmacology
- Module 3 – Statistics and Data Management
- Module 4 – Clinical Development
- Module 5 – Healthcare Marketplace
- Module 6 – Drug Safety Surveillance
- Module 7 – Interpersonal and Management Skills

Although PMST is an in-work training programme, there will be occasions where a trainee does not have exposure to one or more of the modules in his or her pharmaceutical organisation. The trainee can attend approved external module courses, which have been mapped to the August 2010 curriculum, to complete some of the modules.

Trainees are also required to sit and pass the Faculty's Diploma in Pharmaceutical Medicine (DPM) examination, which is the knowledge-based component of the August 2010 curriculum. Trainees are strongly encouraged to sit the examination in their second and third year of training.

The trainee's pharmaceutical organisation is responsible for identifying and assigning an Educational Supervisor to the trainee. The role of the Educational Supervisor is to facilitate the trainee's training; assessing the trainee's competencies, signing off modules that the trainee has completed, and identifying training opportunities within the organisation for the trainee. The Educational Supervisor will normally be the trainee's line manager or a senior doctor within the pharmaceutical organisation. Educational Supervisors must be approved and trained before they can supervise a trainee.

It is a regulatory requirement of specialty training that trainees attend an Annual Review of Competence Progression (ARCP). The ARCP is a formalised yearly review of a trainee's progress towards achieving a CCT or a CESR; it is also an opportunity for the trainee and his or her Educational Supervisor to discuss with the ARCP panel any issues or concerns about the trainee's programme of training. The members of the ARCP panel normally include the Lead Postgraduate Dean, the Faculty's Director of Education and Training, and two reviewers who are usually Senior Specialty Advisers.

The PMST programme is quality managed by the Pharmaceutical Medicine Virtual Deanery, which is an arrangement between the Faculty, the JRCPTB and the Lead Postgraduate Dean. The Senior Specialty Advisers, who are appointed by the Faculty, are responsible for quality managing the delivery of the PMST programme by pharmaceutical organisations that have been approved for training (usually known as local education providers). The external module courses are quality managed by the Faculty's PMST Courses QM Group, which sends evaluators to observe the courses to ensure that course providers have covered the relevant sections of the August 2010 curriculum in their courses.

Other training

As well as setting the curriculum for the DPM exam, the Faculty also offers three exams on different aspects of pharmaceutical medicine:

The **Diploma in Human Pharmacology** is a 2-year programme of structured training for doctors to attain and demonstrate competence to serve as a Principal Investigator (CPI) for exploratory studies of Investigational Medicinal Products (IMPs). It is anticipated that the DHP will become the primary qualification for PIs. Training for the DHP can run in parallel with Pharmaceutical Medicine Specialty Training (PMST), with workplace experience recognised for both qualifications.

The **Certificate in Human Pharmacology** is a 1-year part-time programme for doctors and scientists to attain and demonstrate a comprehensive knowledge of all aspects (design, monitoring, analysis, reporting, safety, ethics, regulation and law) of exploratory studies of IMPs.

- Enables staff to ask the right questions, anticipate and address potential issues, learning from the experience of others.
- Increases the effectiveness of individuals and strengthens the team as a whole.

In 2005, the Faculty introduced the **Certificate of Good Clinical Practice** examination, which is held once a year, usually in June. There are no specific eligibility criteria to register for the Certificate examination. It is open to all personnel involved in the conduct of clinical trials including research nurses, clinical research scientists and technicians as well as physicians. The examination will be held in the UK but candidates may be from any country. Successful candidates will be awarded the Certificate of GCP. To gain the required standard in the examination, candidates will need to prepare themselves. Other GCP-certification providers are available.

Cardiff University offers an International Postgraduate Course in Pharmaceutical Medicine which closely maps the syllabus of the DPM exam. This course was established in 1975 to provide a structured training programme in pharmaceutical medicine for doctors employed in the pharmaceutical industry, contract research organisations (CROs) and regulatory authorities. The 2 year part-time residential course provides doctors with the specialist knowledge and skills to practise as a pharmaceutical physician, to prepare them for the Royal Colleges of Physicians' Diploma in Pharmaceutical Medicine and Membership of the Royal Colleges' Faculty of Pharmaceutical Medicine, and to fulfil requirements for the first part of PMST.

King's College London (KCL) offers a programme of three Masters-level degrees in pharmaceutical medicine; these are Drug Development Sciences, Clinical Pharmacology and Translational Medicine. These are part-time modular programmes leading in-part to a diploma and in-full to an MSc in the field. A number of core modules also cover the syllabus the DPM examination, and other modules contribute to the PMST programme. In 2013 KCL will offer a 1-year full-time Masters programme in Pharmaceutical Medicine fields. This will be particularly attractive to students coming from outside Europe.

The University of Surrey offers a modular MSc in pharmaceutical medicine, the compulsory modules of which also cover the syllabus in pharmaceutical medicine and prepare doctors for the DPM examination.

For those wishing to focus their careers within the more commercial/business environment, there is the possibility of an undertaking a sponsored MBA programme. If this is supported by the company a claw-back clause is often included in the contract and is enforced in the event of the individual leaving the organisation before the end of the agreed period following achievement of the MBA or equivalent qualification.

Entry-level strategy

As the competition for entry-level positions is increasing, a physician wishing to embark on a career in pharmaceutical medicine is advised to consider strategies for getting established in their field. For example, it is often realistic to target your second job in the industry as the one that will springboard your career in the direction in which you wish to go.

The most common entry-level position is that of medical adviser, with clinical research physician being the next. However, due to the competitive nature of these assignments, alternative 'entry-level' positions can be considered such as the phase I physician or regional medical adviser roles. Along with permanent positions, a number of companies now offer fixed-term contracts, particularly in the phase I area. These may be considered as 'stepping-stone' posts to a full-time career within the pharmaceutical industry.

Career development strategy and prospects

Entry into the pharmaceutical industry is probably the most challenging stage in a physician's career development process due to the increasing competitiveness for positions requiring no previous pharmaceutical industry experience. However, once a physician has successfully adapted to the pharmaceutical industry environment, and subject to performance, future development and related career prospects are readily available and cover a diverse range of job opportunities.
Once established in the industry, there are many ways of improving long-term career prospects. These

include studying for business/commercial qualifications such as an MBA or marketing diploma along with a variety of specialist courses run within the pharmaceutical industry that aid further personal development and cover technical, inter-personal and leadership competencies.

Along with the achievement of formal qualifications, the industry offers much varied scope for continuous self-development through on-the-job activities such as special projects, secondments into non-medical departments, and international placements.

A physician entering at the clinical pharmacology (phase I), clinical research physician (phase II/III), medical adviser or regional medical adviser level can expect to advance their career within a one to three year period depending on the speed with which they adapt to the industry environment and how they perform within it. Once well-established, and having gained exposure to the wide range of career possibilities and opportunities available, a physician with one to three years' experience working in the industry can develop their career in a number of directions in line with a well-established career pathway.

Those seeking to concentrate their careers within the medico-marketing arena can do so at the local, European, or international level, including in the USA. This may involve a period gaining expanded experience in a regional office, a company headquarters, or by working in a more senior capacity in a second country operation. This development route is ideal for those wishing to advance their careers to the medical director level. However, before taking on this responsibility, it is advisable as part of your development strategy to spend a period in a clinical research role involving phase II/III study programme implementation. Additionally, many companies now prefer to appoint medical directors from among those who have had experience of working outside the UK.

Increasingly, physicians with a strong commercial/business aptitude and orientation and who have adapted well and proved themselves in the pharmaceutical industry environment, are moving into pure marketing or business unit head positions. Forward-thinking pharmaceutical companies view them as serious contenders for managing director roles. Furthermore, for those who achieve their MBA, consultancy opportunities provide an alternative career pathway.

Those wishing to focus on a career in clinical research will need to progress from an entry-level position into a clinical research physician's role involving phase II/III study design and implementation. From this position, a pharmaceutical physician can advance into a specific therapeutic area post leading to a head of a therapeutic area role and ultimately, through taking on regional responsibility, into the position of global head of a therapeutic area.

In addition to the possible career development routes referred to above, pharmaceutical physicians may also advance their career by specialising in pharmacovigilance, pharmacoeconomics, regulatory affairs, or medical writing.

Remuneration and benefits

There are no nationally agreed salary scales for medically qualified staff in the industry. They can vary widely and are related to levels of seniority, size of the company, and to some extent supply and demand at the time of appointment. Larger companies, in order to remain competitive, devise their salary scales based on surveys conducted across the industry and are therefore market dependent.

In very general terms which a doctor joining the industry would expect to receive a salary at least equivalent or in excess of that they were earning within the NHS. However, the supporting package offered by the industry could increase the total annual remuneration considerably, representing up to an additional 40 per cent. An exception to this general rule may be GPs moving from a thriving practice. Pay increments tend to be higher within the industry and often include performance-related stock or stock options combined with the scope for continuous and potentially unlimited career growth.

In addition to basic salary, annual remuneration will include some or all of the following: a company car or car allowance; participation in a performance-related bonus scheme (ranging from 5 to 25% of annual salary and in some cases greater); private health cover; a contributory or non-contributory pension scheme.

A medical director of a large research-based international company would expect a basic salary in the region of an experienced NHS consultant, although the most senior appointments in the industry can command salary packages in excess of this. The supporting package (such as company car, bonus and share option schemes etc) will help to make the industry comparatively more attractive.

Annual paid leave is usually 20 to 28 working days plus statutory public holidays.

Most companies will pay relocation expenses.

Travel

Travel, both domestic and international, may be involved in a number of pharmaceutical physician posts. The roles can include:

- arranging and coordinating clinical trials
- attending internal business strategy and project team meetings
- attending scientific/medical meetings and symposia

The requirement obviously varies from job to job but in some cases can involve up to 50 per cent or occasionally more of the working year.

Terms and conditions of service

Contracts are normally not time-limited. That is, once a physician joins a company he/she has a permanent job with the prospect, on merit, of progressing within that organisation.

The contracts of employment for pharmaceutical physicians vary between companies and there is no national model contract. All standard contracts of employment in the pharmaceutical industry incorporate clauses to cover the requirements of the relevant employment legislation, details of which are available from the personnel officer in the company. Most contracts would include a 'no-compete' clause protecting intellectual property should a physician move to a competitor company. This is in line with employment law and practice in the NHS and academic sectors and does not tend to place hurdles in the way of a pharmaceutical physician progressing their career with a new employer.

It is a legal requirement that the terms and conditions of employment of each post include job title, starting date, starting salary, holiday entitlement in the current year, notice of termination of employment, sick pay and pension entitlement, grievance and disciplinary procedures and details of the Health and Safety at Work Act. It is important that all of these items are clearly defined, understood and seen to be acceptable before any contract is signed. It is also considered to be good practice for the company to provide a job description.

Before signing any agreement pharmaceutical physicians should ensure that they understand to whom they report directly, both administratively and clinically, and that any fringe benefits proffered in advertisements beyond the negotiated basic salary are clearly itemised in writing. It is also advisable to ensure that support for PMST, along with a personal development planning process, are in place. Members of the BMA may wish to make use of the Association's contract checking service before signing any contract.

BMA

If you have an individual work-related enquiry or problem you have two routes to the information or service you need.

They are:

- On-line: www.bma.org.uk
- By phone: advisers who can discuss members' information requirements and work-related problems and assess the need for local representation

You can contact the BMA by calling 0300 123 1233 or by e-mailing support@bma.org.uk

The disciplinary and grievance procedures should be studied carefully. The disciplinary procedure should always be progressive – a verbal warning, progressing to a written warning, before dismissal. At each of these stages an appropriate appeals procedure should be available. Where the conflict exists within line management the appeals procedure should include a senior member of the company who is without direct line management. Each stage of the disciplinary procedure should include a specific period of time by which improvement is to be expected and at least one month should pass before the next stage is followed. In the case of instant dismissal for gross misconduct, an employee should be suspended on full pay until the facts are established and an appeals procedure made available.

Grievance procedures invariably exist alongside other procedures and are designed to protect individuals who feel that they have been treated unfairly or unjustly by the company. Although the majority of grievance procedures are resolved informally, it is a legal requirement for a formal grievance procedure to exist in all companies. Staff should have the right to be accompanied by any person of their choice during handling of the grievance, which could include a member of BMA regional service staff. Before formally invoking a grievance procedure, BMA members are strongly advised to contact the BMA for advice. If needs be, the query will be referred to a local BMA industrial relations officer for assistance, through members will be expected to provide the initial draft of the grievance.

Most contracts of employment are full-time, although it is possible to work part-time within the pharmaceutical industry. Although contractually a doctor may be expected to work 37 hours a week, in reality most doctors are expected to use their time flexibly in order to meet agreed objectives. This may involve working much longer hours than the contract formally stipulates. The hours may also be longer where travel is involved and some nights and weekends may be spent away from home.

Normally, but with some exceptions (non–clinical research roles and those not involving promotional materials sign-off approval), all pharmaceutical physicians are required to be fully registered with the General Medical Council.

Appraisal and revalidation

The Faculty of Pharmaceutical Medicine strongly supports the concept of revalidation and has worked collaboratively with the other member Royal Colleges and Faculties of the Academy of Medical Royal Colleges, the GMC and the Department of Health to develop the core and specialty specific standards for revalidation.

A doctor will be required to engage with the revalidation process in the following circumstances:

- If the doctor is undertaking any form of medical practice which, under UK law, currently requires the practitioner to hold a Licence to Practise
- If the terms and conditions of a doctor's employment require him/her to hold a Licence to Practise

It is anticipated that many employers for whom pharmaceutical physicians work will require them to hold a Licence to Practise; therefore, maintaining a Licence to Practise may be important to individuals in the future if they change employer. The Faculty of Pharmaceutical Medicine recommends that pharmaceutical physicians practising in the UK retain their Licence to Practise, although this is not mandatory.

Under the Medical Profession (Responsible Officers) Regulations 2010, the Faculty of Pharmaceutical Medicine was named as a designated body for revalidation; subsequently a number of pharmaceutical companies have been named as designated bodies. Faculty members employed by a company with designated body status would have a prescribed connection with that company, as this connection would take precedence, rather than the Faculty.

Where a doctor in pharmaceutical medical practice has a prescribed connection with the Faculty designated body, he/she may register with the Faculty appraisal and revalidation programme. Once registered with the programme, doctors will have access to the Faculty annual appraisal system, an interactive e-system onto which supporting information can be uploaded and the Responsible Officer service.

The requirements for revalidation of pharmaceutical physicians to a great extent mirror those for doctors who are in clinical practice in terms of the supporting information that must be produced at the annual appraisal. The exceptions are the requirement to produce evidence of patient feedback (unless the doctor undertakes occasional clinical sessions) and the option to substitute two case studies per annum instead of a full audit. In all other respects, doctors in pharmaceutical medical practice will be required to produce supporting information to the same standard as doctors working in clinical settings.

A useful set of FAQs is available here
http://www.fpm.org.uk/revalidationcpd/revalidation/revalidationfaqs

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ISBN: 0853893497

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Good Pharmaceutical Medical Practice – Version 2, Faculty of Pharmaceutical Medicine, 2008

Useful addresses and websites

British Medical Association
Tavistock Square
London WC1H 9JP
Tel: 020 7387 4499
www.bma.org.uk

Faculty of Pharmaceutical Medicine
3rd Floor, 30 Furnival Street
London EC4A 1JQ
Tel: 020 7831 7662
Email: fpm@fpm.org.uk
www.fpm.org.uk

British Association of Pharmaceutical Physicians
Email: info@brapp.org
Tel: 0118 934 1943
Email: 0118 932 0981

General Medical Council
Regent's Place
350 Euston Road
London NW1 3JN
Tel: 0845 357 3456
Email: gmc@gmc-uk.org

The Association of the British Pharmaceutical Industry (ABPI)
7th floor
Southside
105 Victoria Street
London SW1E 6QT

Medicines and Healthcare Products Regulatory Agency (MHRA)
151 Buckingham Palace Road
Victoria
London SW1W 9SZ

Prescription Medicines Code of Practice Authority (PMCPA)
7th Floor
Southside
105 Victoria Street
London
SW1E 6QT
http://pmcpa.org.uk/

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