

chapter 8

Professional registration and regulation

Overview

Upon completion of this chapter, you should be able to understand the reasons for regulation of the profession of pharmacy and be able to demonstrate knowledge of the following:

- the background and historical perspective of the profession
- restricted titles
- the role of the General Pharmaceutical Council
- the professional representative body
- professional accountability and responsibility
- fitness to practise procedures and outcomes.

Introduction

The profession of pharmacy as we currently understand it was established in 1841 when Jacob Bell and a group of fellow London practitioners set up the first Pharmaceutical Society of Great Britain. Its objectives were: to benefit the public; to introduce a scheme of education for pharmacists; and to protect the interests of practising pharmacists. Only 2 years after inception, the Pharmaceutical Society was granted a Royal Charter of Incorporation by Queen Victoria, thus giving official recognition to its role. It was to be 145 years later, in 1988, that Queen Elizabeth II conferred the title Royal to change the Society's name to the Royal Pharmaceutical Society of Great Britain (RPSGB).

The first legal register for pharmacists was set up under the Pharmacy Act 1852 and was restricted to pharmacists who had passed the Society's exams. This did not restrict the practice of pharmacy: non-registered chemists and druggists were allowed to continue in their business. Further legislation, the Pharmacy Act 1868, required registration in relation to the sale of poisons and set up the class of chemists and druggists as persons who had passed the Society's minor examination. By 1898, legislation changes allowed chemists and druggists to become full members of the Society.

Early in the 20th century, the Poisons and Pharmacy Act 1908 extended the title 'pharmacist' to all registered persons. It was also responsible for introducing the restriction on corporate bodies relating to use of the term 'chemist and druggist' only when the superintendent was a qualified pharmacist who was a member of the board of directors.

Membership of the Pharmaceutical Society remained voluntary until the Pharmacy Act 1933 introduced compulsory registration as either a 'pharmaceutical chemist' or a 'chemist and druggist' in order to practise. Later legislation, the Pharmacy Act 1954, established the single register of pharmaceutical chemists. A separate register of pharmacy premises had originally been introduced in a voluntary manner in 1936 and remains a current requirement of the Medicines Act. Regulation of company ownership of pharmacies is also covered by the Medicines Act 1968.

The 1933 Act also introduced a requirement for a mechanism to deal with removal from the register in cases of unprofessional behaviour by members. An inspectorate was set up to visit pharmacies and to investigate allegations of misbehaviour. A statutory disciplinary committee appointed to consider misconduct and criminal convictions of members considered such cases. The first case relating to an issue of being in control of a pharmacy whilst under the influence of alcohol was dealt with in 1936.

Restricted title

Titles such as 'pharmaceutical chemist' and 'pharmaceutist' were restricted by the Pharmacy Act of 1852 to persons who had passed the Society's major exam (with the title 'chemist and druggist' reserved for those who had taken the minor qualification). The Medicines Act 1968 makes it a criminal offence to use the title 'pharmacist' and others like 'pharmacy' unless legally entitled to do so under British law. The major examination followed 3 years of study and was intended for pharmacy owners, whereas the minor, more practical exam took place after 2 years' part-time study.

It is important that student pharmacists and non-pharmacist directors of bodies corporate owning pharmacies take care not to give an impression that they are registered pharmacists. To do so would be committing a crime and could result in prosecution. Only persons whose names are included on the register of pharmaceutical chemists compiled annually by the RPSGB until 2010 were entitled to use the restricted title 'pharmacist'. From 2010 the duty to compile a register of pharmacists was taken over by the General Pharmaceutical Council (GPhC: see below for details). The split of the RPSGB into a professional leadership body and a separate regulatory body has recently caused consternation amongst some pharmacists, particularly those reaching

retirement age. Registration with the GPhC is restricted to practising pharmacists whereas previously membership of the RPSGB was available to practising and non-practising pharmacists. This means that, in future, once pharmacists have retired and ceased to practise they are no longer entitled to use the restricted title or register with the regulatory body.

General Pharmaceutical Council

The RPSGB ceased to exist in relation to regulation of the profession in 2010. This was as a result of government policy – *Trust, Assurance and Safety* – regarding healthcare professional regulation, prompted by the failure of professional regulation following a series of incidents concerning various healthcare professionals. These included the activities and subsequent inquiries into Dr Harold Shipman, the Manchester general practitioner who was responsible for the murder of many of his elderly patients over a prolonged period of time (Smith 2004). Another was the findings of the Kennedy report into the actions of paediatric surgeons at Bristol Royal Infirmary, whose operations on young children had a high mortality rate (Kennedy 2001).

Legislation under section 60 of the Health Act 1999 was drafted. This Pharmacy Order 2009 set out the arrangements for the ongoing regulation of pharmacy and the establishment of the GPhC (see below).

Under the new arrangements, the GPhC takes on the registration requirements for the profession; this includes the registration of pharmacists, pharmacy technicians and pharmacy premises. The pharmacy inspectorate transferred to this new organisation which is responsible to the Department of Health. The order is also responsible for introducing a requirement for compulsory recording and monitoring continuing professional development. It is expected that a further requirement will be introduced within the next few years, that of revalidation in order to remain on the practising register. The Pharmacy Order gives the GPhC the power to enforce the fitness to practise arrangements: this includes the arrangements for conducting investigations and fitness to practise committees, as well as registration appeals committees, which take place in accordance with rules set out under the auspices of the regulations/order.

The Privy Council determines the constitution of the council. The council's duties include maintaining the register of pharmacists, pharmacy technicians and pharmacy premises. For this purpose a secretary and registrar are appointed. Other roles include determining standards for premises and registrants to protect the safety of patients and the public, to establish standards and requirements for education and training and to ensure maintenance of fitness to practise. This includes setting a code of ethics and other practice guidance or standards.

Statutory instrument 2007 no. 289, the Pharmacists and Pharmacy Technicians Order 2007, governs conditions for registration. Qualifications to apply for registration include the need to obtain a degree in pharmacy from an accredited school of pharmacy followed by a 52-week preregistration period and passing the registration examination. These procedures for registration are set out in the order and include the requirement for a signed declaration of fitness to practise, payment of a designated retention fee and an undertaking to maintain up-to-date professional knowledge and keep records of continuing professional development activities undertaken. The governing legislation for the GPhC is the Pharmacy Order 2009. It is not expected that the registration requirements will be vastly changed, although additional requirements may be added, such as the need to be a currently practising pharmacist. In order to continue to practise as a pharmacist registration with the GPhC is compulsory.

The course curriculum for accredited pharmacy degrees must meet the requirements of the relevant European directives (85/432/EEC and 85/433/EEC). One of the effects of this is that pharmacists registered in countries that are part of the European Economic Area are eligible to register and practise in Great Britain under article 44 of European directive 2005/36/EC.

Previously, reciprocal arrangements had existed that had allowed pharmacists registered in Australia, New Zealand and South Africa to complete a short period of preregistration before being eligible to apply for registration. The system worked in reverse for British pharmacists wishing to apply to register in these countries. The last of these arrangements ceased in 2006.

Pharmacists qualified in countries other than the European Economic Area may still apply for registration in Britain. They must apply under specific arrangements set up by the professional regulator. This includes completion of the Overseas Pharmacist Assessment Programme, application for which will require details of the overseas qualification and registration; this will be followed by a period of preregistration training prior to taking the preregistration examination.

For those pharmacists who have undertaken additional qualifications to become authorised prescribers the register is annotated to indicate whether they are a supplementary prescriber or an independent prescriber. In addition the register entry can indicate whether any warnings or conditions are attached to that registration as a result of fitness to practise determinations.

The draft Pharmacy Order of 2009 began its consultation phase in December 2008. This was in accordance with the requirements of section 60 of the Health Act 1999, which allows legislative amendments to statutes and devolved legislation to permit changes to be made that relate to the regulation of healthcare professionals. This is done by means of

an Order in Council. This particular draft order built on the recommendations of the White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*, which called for the establishment of the GPhC. Its intention is to modernise and strengthen the regulation of healthcare professionals, including pharmacists and pharmacy technicians, in order to ensure confidence in the regulatory bodies and to protect patients and the public.

The Pharmacy Order sets out the main objectives for the new regulatory organisation as well as the framework for governance and constitutional arrangements and how the transition from the RPSGB was to be handled. The main objective of the GPhC is to protect, promote and maintain the health, safety and well-being of members of the public, particularly those who use pharmacy services, by ensuring that these services adhere to standards that are considered necessary for safe and effective practice.

The GPhC as a professional regulator is required by the government to be seen to be independent and impartial in its actions. The Council of a regulatory body is required to focus on strategy and oversight and is similar in size and role to those of other healthcare professional regulatory organisations. It is required to have at least equal numbers of lay and professional members and these are to be independently appointed rather than elected. The arrangements for membership, term of office and other provisions relating to membership or appointment to the Council are set out in a constitution order, a statutory instrument. The Council is required to have at least one member who lives or works in each of the countries that it covers.

The registers previously maintained by the RPSGB have been taken over by the GPhC. These have been combined to form a single register of pharmacists, pharmacy technicians and pharmacy premises, although these will be set out as separate parts as determined by the Council. The requirements for the register will be subject to amendment to allow for future practice developments to be taken into account and regulated. This is similar to the addition of the provision to annotate the previous register of pharmacists to indicate that a registrant was an authorised prescriber.

The GPhC has a function in setting and enforcing standards for safe practice in registered retail pharmacies. This covers both the standards of the premises or environment as well as the individuals working there. It is anticipated that enforcement powers such as improvement notices, fines, disqualification and removal of

KeyPoints

The main functions of the GPhC include:

- the registration of competent, qualified practitioners, including arrangements for temporary registration in emergencies
- setting and securing standards of practice, education and training, continuing professional development and conduct
- setting up and maintaining fitness to practise procedures
- registration, regulation and inspection of pharmacy premises.

(Reproduced from Department of Health, 2008.)

registration will be in place to assist in these aspects of the Council's role in addition to the continued role and function of the pharmacy inspectorate. A fitness to practise mechanism exists to deal with individual registrants and representatives of bodies corporate. The procedures in place continue to be those recently established by the RPSGB, although there is provision in the Order for these to be amended if necessary (see below for details of the fitness to practise procedures).

Professional representative body

Following the removal of the regulatory aspects of its role from the charter, the RPSGB remains with a continued function in its capacity of professional leadership and support for its membership. This has required a number of changes in its constitution, many of which continue to be settled. Although a major change is that membership of the professional body is not mandatory, this means that an individual does not need to be a member to be able to practise as a pharmacist. The new professional leadership body has stated that it is committed to representing and leading its members. In addition, it speaks for its membership, aims to raise the status and profile of the profession of pharmacy and represents the interests of its members to the GPhC, government and patients. It continues to provide and is further developing its role in relation to professional development and training. This includes support for pharmacists in relation to the continuing professional development and future revalidation requirements of the professional regulator as a condition of registration. In addition the professional body continues to provide library and information and advisory services for its membership as well as guidance on good practice. Further functions are the continued publication of professional journals relevant to the practice of pharmacy and the provision of a pharmacist support service for those in difficult times.

A national assembly, drawn from representatives of each of the three national pharmacy boards by nomination, that is England, Wales and Scotland, oversees the professional body. Each national pharmacy board is made up of a number of elected members, most of whom are pharmacists, although the constitution of each board can vary. The English board has places reserved for specified sectoral representation, and all have lay representation. In addition to the nominated members from the national boards the assembly includes a pharmaceutical scientist, an academic and a lay member. The assembly members elect the president.

Professional accountability and responsibility

In addition to abiding by legislation, registration as a professional practitioner carries with it the requirement to accept professional

accountability and responsibility for practice. As a practising professional, the individual pharmacist has a legal duty of care towards his or her clients or patients. A pharmacist's training and experience mean that he or she is an expert on medicines and their use. When called upon to provide a service or advice to patients the pharmacist has a duty in law to ensure that his or her knowledge is used to ensure that so far as is possible no harm will come to the user or recipient. For example, if patients are purchasing medicines from a pharmacy they can expect safe information and advice relating to their choice, whereas a customer purchasing the same medicine from a supermarket with no pharmacy department cannot rely on a duty of care in relation to any advice provided on that medicine's use by the supermarket sales staff.

Professional responsibility and accountability are not just covered by legal requirements. Many of the standards required of individual pharmacists, whatever their actual role, are set out in the form of a code of conduct or ethics and guidance on professional practice. These are considered in detail in Chapter 9. However it is important to include mention of this here as the fitness to practise mechanisms of the regulatory body include an expectation of adherence to the code or guidance in their remit when determining unacceptable behaviour or actions by registrants.

Fitness to practise – see Health Act 2006

The current fitness to practise mechanisms were introduced by the 2007 statutory instrument number 289, also known as the Pharmacist and Pharmacy Technician Order 2007. The Pharmacy Order 2009 included provision for these procedures to continue throughout the devolution of the regulatory functions of the RPSGB to the GPhC in 2010 (see above for details of this change).

One of the key issues relating to the fitness to practise procedure is concerned with establishing whether the fitness to practise of an individual is impaired. Others require that procedures are followed in the interest of the public and that hearings are fairly conducted under common law and the requirements of the European Convention of Human Rights.

The purposes of the sanctions available under the fitness to practise procedures are to protect the public, to maintain public confidence in the profession and to maintain standards. In imposing sanctions the committees must act in a

KeyPoints

According to the Pharmacy and Pharmacy Technician's Order 2007, a person's fitness to practise may be impaired by reason of any of the following:

- misconduct
- deficient professional performance
- adverse physical or mental health
- failure to comply with reasonable requirement by assessor
- a conviction for a criminal offence – British Isles
- a police caution – British Isles
- finding impaired fitness to practise by health or social care regulatory body.

way that is fair and reasonable, consider the full range of sanctions available to them and take into account the wider public interest as well as those of the individual practitioner. This is called proportionality and ensures that the sanction imposed is appropriate to its purpose or objectives.

The procedures are operated through three committees: (1) the Investigating Committee; (2) the Disciplinary Committee; and (3) the Health Committee. Full details of the operation of the process were first set out in the statutory instrument 2007 number 442, *The Royal Pharmaceutical Society of Great Britain (Fitness to Practise and Disqualification etc. Rules) Order of Council 2007*. A brief outline of the processes and available sanctions is set out here.

Complaints received by the regulatory body are considered in relation to fitness to practise issues and if it appears that this is impaired, the case will be put to the Investigating Committee. This committee will review the documentary evidence and, if it believes that there is a real prospect of a finding of impairment, it will refer the case for consideration by either the Disciplinary or the Health Committee. It can ask for further investigations to take place or for medical reports to be obtained. This committee is supported by legal and clinical advisers who have no voting rights and any decision is made on the basis of a simple majority. Other than accepting undertakings from pharmacists, issuing a warning and giving advice, the main outcome from this committee is to refer a case to either the Health or the Disciplinary Committee. They will do this having taken into account issues such as the harm caused or potential for harm, personal health and behaviour, any attempts made to cover up or obstruct investigation of the issue, and any previous history.

The Health Committee receives evidence in writing and in person to determine whether fitness to practise is impaired and what, if any, penalty should be imposed. It operates to the civil standard of proof (see Chapter 1), which means that the decision must be made on the balance of probabilities and a simple majority is required. The committee sits in private and is assisted by non-voting legal and clinical advisers. It is up to the regulator to present the evidence to prove its case. Even when the Health Committee reaches a decision that fitness to practise is not impaired, it can still issue a warning or give advice to anybody appropriate (for example, a superintendent pharmacist about employing the individual). Where the fitness to practise is found to be impaired the sanctions include issuing a warning that can be included into the register, imposition of conditions for a period of up to 3 years or suspension from the register for up to 12 months. Conditions imposed or suspension can in certain circumstances take immediate effect; otherwise there is a 28-day period in which the individual can lodge an appeal to the High Court about the decision.

The Disciplinary Committee's role is to determine either that fitness to practise is impaired or that a corporate body has committed

misconduct and whether any sanctions should be imposed. The regulator has the task of proving its case and the standard of proof is the same as for the Health Committee, that is, on the balance of probabilities. The Disciplinary Committee takes evidence orally as well as in written form and usually sits in public. If it believes that the case relates to health issues then it can refer to the Health Committee. Only when the case has been proved and aggravating and mitigating issues have been considered will a sanction be imposed. These include: issuing a warning and including this in the register; issuing advice to appropriate persons; imposing conditions for a period of up to 3 years; suspension from the register for up to 12 months; or removal from the register. As for the Health Committee, conditions imposed or suspension can in certain circumstances take immediate effect; otherwise there is a 28-day period in which the individual can lodge an appeal to the High Court about the decision.

Once removed from the register an individual cannot apply for return to the register until a period of 5 years has elapsed and, if unsuccessful at the first attempt, a further period of 12 months must pass before a reapplication will be considered. The application will be heard by the Disciplinary Committee which will only allow it if the applicant is able to prove that he or she is entitled to register and is fit to practise. In addition conditions on practice may be imposed for up to 3 years.

One further committee exists with responsibility in relation to registration. This is the Registration Appeals Committee, which considers applications for registration that have been turned down by the secretary and registrar due to impaired fitness to practise, such as issues relating to health or character. For example, this can be a preregistration student who has disclosed a criminal conviction or health issue in his or her application which will require further investigation by the committee to determine whether to quash the decision or give a different direction. Any applicant for registration is legally obliged to provide information relating to

KeyPoints

The profession was established over 150 years ago with the purpose of representing the interests of practising pharmacists and protection of the public. Its roles evolved over time into a joint professional and regulatory organisation.

Many of the titles associated with the profession, such as pharmacist and chemist, are restricted. This means that it is illegal for the titles to be used if not legally entitled to do so.

The General Pharmaceutical Council (GPhC) replaces the regulatory functions of the Royal Pharmaceutical Society of Great Britain (RPSGB) from 2010. This change was brought about in line with government policy in relation to safety and standards of all healthcare professions.

Pharmacists' interests continue to be supported by the RPSGB as a professional representative body. It provides a voice for pharmacy, publications and opportunities for continuing professional development, amongst other services and functions.

As a professional practitioner, pharmacists and pharmacy technicians are both accountable and responsible for their working practices.

Fitness to practise procedures are the responsibility of the professional regulatory body. They operate through a number of formal committees that have various sanctions available to them. The Commission for Healthcare Regulatory Excellence (CHRE) oversees this process.

fitness to practise and, as a potential healthcare professional, is not subject to the Rehabilitation of Offenders Act 1974. This means that those criminal convictions that are more than 10 years old, which in other aspects of life might be considered to be spent, will still be considered.

The whole process is overseen by the Commission for Healthcare Regulatory Excellence (CHRE), to whom all decisions by healthcare regulatory bodies must be reported within 28 days of any hearing. The CHRE is an independent body accountable to Parliament. Its role is to review performance or monitor health profession regulators: it has the power to refer decisions that it considers to be too lenient and failing to protect the public interests to the High Court or Court of Sessions in Scotland.

In time the role in hearing fitness to practise cases will be transferred and taken over by the new Office of Health Professions adjudicator, as established by the Health and Social Care Act 2008. The GPhC will then continue to investigate alleged cases of impaired fitness to practise and will retain its prosecution functions.

Self-assessment

- 1. When was the Pharmaceutical Society established and by whom?**
 - a. 1841 by Jacob Bell
 - b. 1843 by William Allen
 - c. 1933 by Theophilus Redwood
 - d. 1954 by Joseph Ince
- 2. Which one of the following was not an aim of the newly established Pharmaceutical Society?**
 - a. To benefit the public
 - b. To introduce a scheme of pharmacy education
 - c. To protect the interests of pharmacists
 - d. To establish a register of practising pharmacists
- 3. When did it become a legal requirement for all practising pharmacists to register with the Pharmaceutical Society?**
 - a. 1853
 - b. 1868
 - c. 1933
 - d. 1954
- 4. Identify the relevant legislation that required this registration.**
 - a. The Pharmacy Act 1852
 - b. The Pharmacy Act 1868
 - c. The Pharmacy Act 1933
 - d. The Pharmacy Act 1954

5. **What year was the title 'Royal' granted to the Pharmaceutical Society?**
 - a. 1841
 - b. 1843
 - c. 1954
 - d. 1988

6. **Which of the following is not one of the roles and functions of the General Pharmaceutical Council (GPhC)?**
 - a. Registration of competent, qualified practitioners
 - b. Setting and securing standards of practice, education and training, continuing professional development and conduct
 - c. Setting up and maintaining fitness to practise procedures
 - d. Maintenance of a benevolent fund for pharmacists and their dependants

7. **Name the legislation which governs the operation of the GPhC that came into force in 2009.**
 - a. The Pharmacy and Pharmacy Technicians Order 2007
 - b. The Pharmacy Order 2007
 - c. The Pharmacy and Pharmacy Technicians Order 2009
 - d. The Pharmacy Order 2009

8. **Which one of the following is not a relevant committee under the fitness to practise mechanisms?**
 - a. Health Committee
 - b. Investigating Committee
 - c. Law and Ethics Committee
 - d. Disciplinary Committee

9. **What is the period of time that must elapse before a person removed from the register is allowed to apply for restoration?**
 - a. No time limit applies
 - b. 2 years from the date of removal
 - c. 5 years from the date of removal
 - d. 7 years from the date of removal

10. **Which of the following is not considered to be impairment in relation to fitness to practise?**
 - a. Misconduct
 - b. A police caution received in any European country
 - c. Deficient professional performance
 - d. Adverse physical or mental health

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