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Legal aspects of pharmacy business

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Introduction

Ever thought of buying a pharmacy or establishing a new one? If you have, or intend to, then a few legal hints might come in useful. Probably the first question to answer is who is going to own the business – you personally as an independent owner, a partnership, or a private limited company? All three of these legal owners can own a pharmacy business or in Medicines Act phraseology be ‘a person lawfully conducting a retail pharmacy business’. However, the only person who can individually own a pharmacy business is a pharmacist on the register in Great Britain (see also Chapter 4).

Individual ownership

An individual pharmacist may own a retail pharmacy business and as such take all the profits. However he must also accept all the liabilities that, if the business fails, could result in bankruptcy.

Partnerships

A partnership is defined in the Partnership Act 1890 as the relationship that exists between persons carrying on a business in common with a view of profit. In contrast to a company (see below), a partnership, or **firm**, is simply a number of individuals each of whom has a responsibility for the affairs and liabilities of the firm as a whole.

In England and Wales a partnership (firm) does not have a legal status of its own as does a company. This means that the private assets of each partner can be called upon to satisfy any of the firm’s debts – jointly and severally. All the partners are liable for any debts incurred by one partner acting on behalf of the firm.

In Scotland a partnership has a status similar to that of a body corporate, i.e. it is a legal person distinct from the partners of whom it is composed. It is for this reason that in a partnership owning a retail

pharmacy in England and Wales all the partners must be pharmacists, whereas in a Scottish partnership only one partner need be a pharmacist. A partnership can arise in either of two ways: by express agreement, or by implied agreement between two or more persons. A partnership can be implied if two or more persons work together in such a way as to fall within the definition as set out in the Act. Generally, if they share in the management of the business and share the profits, then the law will recognise them as partners.

When a partnership is formed to run a retail pharmacy, it is invariably a partnership of express agreement, and the conditions of the partnership should be set out in a partnership contract or articles. The articles can be altered at any time with the consent of all the partners, whether this is express or implied. The only exception is where the articles restrict the right to vary, e.g. that no change may be made for 2 years.

A partnership can be formed where one of the partners may limit their responsibility for the firm's debts, leaving the other partners to share the unlimited liability. This partner is often referred to as a **sleeping partner**, as they take no part in the management of the firm. Partnerships of this type are not common and are governed by the Limited Partnerships Act 1907. If a person wishes to limit their liability in this way today they are more likely to invest in a limited company. Once again, it is stressed that before contemplating forming a partnership pharmacists should take legal advice and have any partnership contract drawn up by a solicitor.

Companies (see also Chapter 4)

If you wish to limit your liability then you can set up a private limited company with yourself, and others, as shareholders and/or directors of the company. A company – or corporation aggregate – is a body of persons combined or incorporated for some common purpose. The most common example is a registered trading company, that is, a company that has been incorporated under the Companies Act 1985 (as amended). These Acts are a consolidation of the law relating to companies contained in a number of earlier statutes, including certain sections of the European Communities Act 1972. The notes given here can only outline the general principles of company law, with some special reference to certain aspects that particularly affect pharmacy businesses.

Incorporation as a company enables a group of people to act and to trade in the same way as an individual owner. It also enables them to trade with limited liability to the individual shareholder. Once incorporated a

company is a legal person and quite distinct from its members. It can own property, employ persons, and be a creditor or debtor just like a human being. This is the fundamental principle of company law.

The promoters of a company must file the following documents with the Register of Companies:

- Memorandum of Association.
- Articles of Association.
- List of directors and name of secretary.
- Statement of the nominal share capital.
- Notice of the address of the registered office.
- Declaration by a solicitor or a person named in the articles as a director or secretary that all the requirements of the Companies Acts in respect of registration have been complied with.

If all the documents are in order the registrar will issue a certificate of incorporation, which is conclusive evidence that the company has been registered and that the requirements of the Act have been complied with.

There are at least three types of company: a public company; a private limited company; and a private unlimited company. Most pharmacists will be concerned with the private company, whether limited or not. A **private company** needs only one director, although there may be more than one. If there is a sole director he/she cannot also be the company secretary. Shares and debentures in a private company cannot be offered to the public. An **unlimited company** is one where there is no limit on the members' liability to contribute to the assets in order to satisfy the company's debts.

A company must appoint a pharmacist as its superintendent who is responsible for the keeping, preparing, selling and dispensing of medicines and for ensuring that the business as far as it concerns the sale of medicines is under his/her control or subject to his/her directions, under the control of another pharmacist.

Memorandum of Association

The Memorandum of Association regulates the external affairs of the company and must include five clauses, namely, those relating to the name, registered office, objects, liability and capital of the company. It must be signed by each subscriber.

The name of a private limited company must end with the word 'limited'. For a public limited company the last words must be 'public limited company' or 'plc'.

There is a general freedom of choice of the company name, but a company cannot be registered under the Act by a name that includes, otherwise than at the end of its name, the words 'limited', 'unlimited' or 'public limited company' or the Welsh equivalents, e.g. 'cfyngedig'. Where 'cfyngedig' is used, the fact that the company is a limited company must also be stated in English and in legible characters on all official company stationery and publications, and in a notice conspicuously displayed in every place where the company's business is carried on.

No name may be used that the registrar considers offensive, or which, if used, would constitute a criminal offence. In the latter category would fall a retail company that is not conducting a retail pharmacy business but wishes to use the title 'chemist'. However this restriction is applied in the Medicines Act 1968.

Certain words and expressions may only be used in company or business names with the approval of the Secretary of State or other relevant body specified in regulations (SI 1981 No.1685, as amended). For the word 'chemist' the Royal Pharmaceutical Society of Great Britain is the relevant body, but, when 'chemist' or 'chemistry' is used in an industrial sense, it is the Royal Society of Chemistry. Similarly, for the word 'apothecary' the relevant body in England and Wales is the Worshipful Society of Apothecaries and in Scotland, the Royal Pharmaceutical Society of Great Britain. Some titles are totally prohibited, e.g. the word 'Royal'.

Articles of Association

The Articles of Association regulate the internal affairs of the company, i.e. the rights of shareholders and the manner in which the business of the company is conducted. A model set of articles is set out in regulations made under the Act, which may be used by a company as it is, or adapted as required. If no articles are submitted with the application for registration the statutory ones will apply. The articles of a company are freely alterable by special resolution of the company, subject to certain safeguards.

The legal effect of the Memorandum and Articles is that they bind the company and its members as if they had been signed and sealed by each individual member and contained covenants on the part of each member to observe all the provisions of the Memorandum and Articles.

Directors

The first directors of a company are usually appointed in accordance with the articles; if not they are appointed by the original subscribers to the

company. Subsequent appointments are usually governed by a procedure laid down in the articles. It must be stressed that a pharmacist becoming a director should be fully aware of the contents of the Memorandum and Articles of Association of the company he/she joins. Directors must exercise their powers as directors for the benefit of the company. A director has a duty to the company to exercise such skill and care as he/she possesses. If appointed in a specific capacity calling for a particular skill, e.g. a pharmacist who is a director of a body corporate, must exercise that skill in a reasonable manner for the benefit of the company. Directors are not bound to give continuing and unremitting attention to the company's affairs and are justified in trusting the officers of the company to perform their duties honestly.

A pharmacist who becomes superintendent chemist of a company will almost invariably be appointed a director, and a knowledge of the powers and duties of directors is essential. For example, if a company fails to make its annual return then the company and/or any of its officers or directors is liable to a default fine. A pharmacist who resigns as a superintendent chemist should ensure that they also resign as a director. Instances have occurred where a pharmacist, some years after having resigned as a superintendent chemist, has been prosecuted for failing to make an annual return because he/she had remained a director of the company.

Registration of pharmacy premises

Having made the decision to own the business and having acquired premises the next step is to register the premises with the Royal Pharmaceutical Society of Great Britain (RPSGB). The provisions for registration are laid down by the Medicines Act 1968 and a form for this purpose is available from the Society. The Society's Registrar has to inform the appropriate Minister at the Department of Health and may not register the premises before the end of two months unless the Minister consents for such registration. The registration form has to have the name of the owner, the full postal address of the premises, a brief description of the premises and two copies of a sketch plan, drawn to scale, showing where medicines are prepared, sold, dispensed, supplied or stored together with a statement that there are arrangements so as to enable supervision to be exercised by a pharmacist of any dispensing and sale of medicines at one and the same time. In the case of a company the name of the superintendent must be on the form and a declaration made by him/her as to whether or not he/she is on the

board of directors. If the superintendent is not on the board the company may only use the title 'pharmacy' in connection with its business. Before registration there will be a visit from the Society's inspector, unless it is an existing business, who will verify the particulars submitted.

In the case of new premises, the proposals submitted have to include layout of the dispensary, etc., should comply with the Society's Code of Ethics and in order to comply with the Misuse of Drugs Act 1971 there should be a controlled drugs cupboard that conforms with the legal specification and which must be bolted to the floor or wall – not a partition wall.

Employment legislation (see also Chapter 8)

Conducting a successful business, of course, depends on the employment of staff. There is a massive volume of legislation concerning the employment of staff and only a hint can be given in this chapter. Difficulties and misunderstandings frequently arise between employer and employee because the terms of the employment have not been put in writing. It is advisable to ensure that all the conditions of service are set out either in an exchange of letters or in a formal contract. More details are included in the references at the end of the chapter.

An employer is required to give an employee, not later than 8 weeks after commencement of employment, a written statement identifying the parties, specifying the date of commencement of employment and giving, among other particulars, details as to the scale or rate of remuneration; terms and conditions relating to hours of work; holiday and sickness entitlement; and the length of notice the employee is obliged to give and is entitled to receive in order to terminate their employment. Each statement must specify the person to whom an employee can apply for the purpose of seeking redress of any grievance relating to their employment and give details of any disciplinary rules which apply to them. There is no requirement to give a written statement if the employee normally works less than 16 hours per week. Note that the written statement is *not* a contract of employment.

Changes in the terms of employment have to be notified in writing by the employer to the employee within 1 month of such a change.

The amount of notice an employer must give to terminate the contract of employment of a person who has been continuously employed for 1 month or more varies with the period of continuous employment – 1 week if employment has been for less than 2 years and 1 week for each year of continuous employment after 2 years.

Statutory Sick Pay (SSP) is payable to all staff between 16 and 65 years of age who earn more than the lower earnings limit for National Insurance contributions. SSP cannot be claimed until the employee has been absent for more than 3 days. There are special detailed requirements for any pregnant employee.

There are detailed requirements regarding conditions of employment relating to working time and require employers to consult with their employees and set up procedures to monitor and record working hours. Shop workers are permitted to refuse to work on a Sunday and cannot be dismissed, made redundant or subject to any prejudicial action for so refusing.

Working conditions (see also Chapter 8)

The legislation requires that there is provision for a comprehensive system for securing the health, safety and welfare of all people at work and there is a duty placed on employers, and employees, to ensure that this is carried out. In addition, other legislation requires certain conditions to be maintained in the workplace. These include four areas – namely the working environment, safety, facilities and general house-keeping. These areas cover such matters as working room temperatures, ventilation, lighting and space; safety not only for staff but also for customers; facilities for washing and toilets; and disposal of waste materials. Special provisions are laid down for the disabled.

There are special provisions regarding the disposal of controlled waste. The Controlled Waste Regulations 1992 define clinical waste as, amongst other things, ‘waste arising from . . . pharmaceutical or similar practice . . .’ and describes clinical waste that arises from a private dwelling or residential home as household waste, as distinct from that from any other source. It is unlawful to deposit controlled waste in, or keep it on, any land, or knowingly cause or permit such waste to be deposited unless a waste management licence authorising the deposit is in force. The Water Resources Act 1991 prohibits a person from causing or knowingly permitting any noxious, poisonous or polluting matter to enter any inland waters.

Controlled waste includes household, industrial and commercial waste of any kind, whether conventionally thought of as polluting or not. A pharmacist whose actions give rise to controlled waste, including a decision to discard such material, is fully bound under the legislation as a producer of controlled waste and carries the corresponding duty of care, including where medicines are returned by patients. A clear interpretation

as to how the code of practice should be applied to medicines returned by patients is not available. It is clearly wise to contact the local office of the Environment Agency for specific guidance on compliance with the code.

There are special restrictions on the destruction of controlled drugs. Controlled drugs returned by patients are subject to the same considerations described above for other returned medicines and advice should be sought from the relevant Environment Agency. Unwanted stocks of controlled drugs are still subject to the requirement for witnessed destruction on the site of their production but disposal via the sewage system does not comply with the Water Resources Act. Accordingly, the practice has developed that the pharmacist will arrange denaturing: the resultant product and its container is then treated as a special waste.

The Special Waste Regulations 1996 provide that waste falling within certain descriptions should be designated as special waste and subject to more extensive documentation than is required for non-special waste before it may be removed from premises. Special waste means controlled waste containing substances listed in Schedule II to the regulations and that has specified hazardous properties as set out in the regulations or is a prescription-only medicinal product.

Other aspects of a pharmacy business of which owners should be aware relate to weights and measures; trade descriptions, which include advertising; and consumer protection, which includes product liability, safety of goods and price controls.

Certain activities are unlawful. The legislation renders unlawful discrimination on the grounds of sex, marriage, race or disability. It also requires that a woman shall not be treated less favourably than a man in the same employment in respect of pay and other terms of her contract where she is employed on the same or similar work as a man.

National Health Service Contracts

Most owners of retail pharmacies will want to provide pharmaceutical services, which includes the dispensing of medicines, under the provisions of the National Health Service, and will have to apply for a contract with the local health authority and comply with the chemist's terms of contract.

Sale or supply of medicines

All pharmacies are permitted to sell certain medicines over the counter. Those medicines that are on the General Sales List (GSL) may be freely sold but those that are Pharmacy-Only Medicines (P) may only be sold

from a pharmacy and even then only by, or under the supervision of a pharmacist.

A Prescription-Only Medicine (POM) may only be sold or supplied in accordance with a prescription given by a practitioner. To meet that requirement, certain conditions must be satisfied. The prescription must be signed in ink by the practitioner giving it; must be written in ink or otherwise so as to be indelible and must include the following particulars:

- the address of the practitioner giving it;
- the appropriate date;
- such particulars as whether the practitioner giving it is a doctor, a dentist, district nurse/health visitor or extended formulary nurse prescriber, or a veterinary surgeon;
- the name, address and the age, if under 12, of the person for whose treatment it is given.

Prescriptions cannot be dispensed more than 6 months after the appropriate date, unless it is a repeatable prescription.

A **repeatable prescription** means a prescription containing a direction that it may be dispensed more than once. A **health prescription** means a prescription issued by a doctor, dentist, district nurse/health visitor or extended formulary nurse prescriber under the National Health Service Act.

Records have to be kept, in a bound book or electronically, of all POMs except those written on a health prescription.

Controlled drugs are also classified as POMs but are more strictly controlled. The prescription writing particulars are similar but records must be kept in a particular way and health prescriptions for such medicines are not exempt from the record-keeping procedures.

In addition, certain controlled drugs are subject to safe keeping regulations and have to be stored in a special cupboard, secured to the floor or wall, which has to comply with the specification laid down in the regulations. The destruction of controlled drugs has to be supervised by a person who has the authority to witness such destruction.

Poisons

A pharmacy is also permitted to supply poisons that are listed in both Part I and Part II of the Poisons List. Such sales on pharmacy premises may only be sold by, or under the supervision of a pharmacist. Certain poisons may only be sold under certain conditions, e.g. Poisons in Schedule I of the Poisons Rules. In these cases the purchaser must be known to the

pharmacist to be a person to whom the poison may properly be sold, a record must be made in a special poisons register and the entry must be signed by the purchaser. A purchaser who requires a Schedule I poison for the purpose of his trade or business may give the pharmacist a signed order in lieu of a signature. The signed order must contain certain particulars including the name and address of the purchaser, his trade or business, the purpose for which the poison is required and the total quantity. Certain poisons are subject to additional restrictions. These poisons include strychnine, cyanides, thallium and zinc phosphide.

Code of conduct

In addition to the legislation, both pharmacists and persons lawfully conducting retail pharmacy businesses must comply with the RPSGB's Code of Ethics and attendant guidelines. This Code can be found in the *Medicines, Ethics and Practice* guide issued by the Society annually.

Summary

It will have been seen that opening a business is complex and surrounded by legislation, both pharmaceutical and general. This chapter has only touched on the many issues, but there are organisations and much literature available to those who wish to contemplate conducting a retail pharmacy business. Some of these are listed below.

Further reading

- Appelbe G, Wingfield J. *Pharmacy Law and Ethics*, 7th edn. London: Pharmaceutical Press, 2001. In particular Chapters 5–7 Sale of Medicines; Chapter 16 Controlled Drugs; Chapter 4 Registration; Chapter 17 Poisons; Chapter 25 General business.
- Appelbe G. Legal requirements for the sale and supply of veterinary medical products. In: Kayne S B, Jepson M, eds. *Veterinary Pharmacy*. London: Pharmaceutical Press, 2004, 159–173.
- Judge S. *Business Law*, 2nd edn. Basingstoke: Macmillan, 1999.
- MacMillan M, Lambie S. *Scottish Business Law*, 3rd edn. Harlow: Pearson Education, 1997.
- Medicines, Ethics and Practice* No. 28. London: Pharmaceutical Press, July 2004.
- Merrills J, Fisher J. *Pharmacy Law and Practice*, 3rd edn. Oxford: Blackwell, 2001.
- National Pharmaceutical Association, leaflets on employment, etc. (<http://www.npa.co.uk/>)
- Booklets from the Health and Safety Executive (<http://www.refit/hse.gov.uk>)
- Department of Trade and Industry. *Your Guide to the Working Time Regulations* (available from http://www.dti.gov.uk/er/work_time_regs/wtr0.htm (accessed 7 July 2004)).