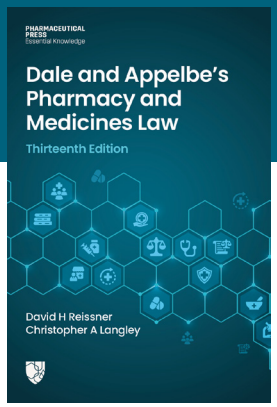
Dale & Appelbe's Pharmacy and Medicines Law

Invaluable knowledge for pharmacy professionals and students who need access to current information on British law relating to medicines, poisons and the practice of pharmacy.



Guide to law for pharmacy practice in Great Britain

Dale and Appelbe's Pharmacy and Medicines Law

Chapter 2 extract — The regulation of pharmacy and other healthcare professions

The pharmacy profession is highly regulated. In particular, pharmacists and pharmacy technicians and pharmacy premises are regulated by the General Pharmaceutical Council (GPhC), which has its own inspectorate. The GPhC and other healthcare regulators are overseen by the Professional Standards Authority.

Regulation of the pharmacy profession

The General Pharmaceutical Council (GPhC) was created by the Pharmacy Order 2010 (the Order)[1]. It is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. Prior to this, the Royal Pharmaceutical Society of Great Britain (RPSGB) was both the regulator and the professional leadership body. The creation of the GPhC resulted in the separation of the regulatory and professional leadership roles.

The Professional Standards Authority for Health and Social Care (PSA), oversees the work of the GPhC and nine other healthcare regulators and promotes the health and wellbeing of patients and the public in the regulation of health professionals (the PSA is more fully discussed below and in **Chapter 25**).

Structure of the GPhC

The GPhC has a chair and 13 other members of the Council appointed by the Public Appointments Commission. Seven members are registrants and seven are lay members. This structure was formalised by the Pharmacy Order 2010 and the General Pharmaceutical Council (Constitution) Order 2010.

There are limitations on the period for which members may serve on the Council (Art.3). The GPhC must make provision with regard to the education and training of Council members in standing orders (Art.4). Certain categories of people, for example people who have been convicted of certain types of offences, are disqualified from being members of the Council (Art.5) and once members have been appointed, there are certain circumstances in which they may be removed (Art.6) or suspended from office (Art.7).

[1] The Pharmacy Order is divided into 8 Parts and, within each Part, separate numbered provisions are referred to as Articles, abbreviated here to Art.

Provisions relating to the chair (including powers to appoint a deputy chair) of the Council can be found in Articles 8 and 9. There are also provisions relating to the proceedings of the Council including its quorum, which is eight members (Arts.11 and 12). Members of Council are appointed by the Appointments Commission to ensure a balance of qualities, skills and experience, and to reflect the diversity of the public and of the pharmacy profession.

The GPhC has a Great Britain rather than a UK jurisdiction; that is, it has regulatory powers in England, Scotland and Wales. It has appointed a director in each of Scotland and Wales, recognising the divergence in Great Britain health policy and delivery.

Role and principal functions of the GPhC

Article 6 of the Pharmacy Order 2010 stipulates that the GPhC's overarching objective in exercising its functions is the protection of the public. The role of the GPhC (also referred to as the Council) is to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy. Article 4(3) of the Pharmacy Order 2010 identifies the principle functions of the GPhC. These are set out in **Box 2.1**.

BOX 2.1: PRINCIPAL FUNCTIONS OF THE GPhC

a. to establish and maintain a register of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is, or is to be, carried on;
b. to set and promote standards for the safe and effective practice of pharmacy at registered pharmacies;
c. to set requirements by reference to which registrants must demonstrate that their practise is not impaired;
d. to promote the safe and effective practice of pharmacy by registrants (including, for example, by reference to any code of conduct for, and ethics relating to, pharmacy);
e. to set standards and requirements in respect of the education, training, acquisition of experience and CPD that it is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register or to receive an annotation in the Register and to maintain competence; and
f. to ensure the continued fitness to practise of registrants.

The GPhC has broad powers to make rules.[2]

Education and training of pharmacists

Article 42 of the Pharmacy Order requires the GPhC to produce standards for the initial education and training of pharmacists.

The standards[3] are in two parts. Part 1 comprises learning outcomes, which describe what a student

[2] Section 84A of the Medicines Act 1968

Chapter 9 extract — Hospital Pharmacy and other relevant pharmacy services

The medicinal products supplied from hospital pharmacies (and other pharmacies that are not community pharmacies) are subject to the same laws that are applicable to community pharmacies. However, there are different exemptions from the general legal requirements, and hospital pharmacies may (depending on whether they are registered with the GPhC) be subject to different regulation and enforcement.

Introduction

This chapter is concerned with the way that pharmacies in hospitals are regulated and about the manufacture and supply in hospitals of medicinal products. However, there are laws that concern the possession, administration and supply to and by midwives, who typically work from hospital settings, and ambulance services, which are closely connected to hospitals. Aspects of those laws are included in this chapter. Also, an amendment in 2022 of the Medicines Act 1968 provided relevant pharmacy services with a defence if they were prosecuted under the Act for making a dispensing error. The term relevant pharmacy services is defined in section 67F of the Medicines Act so as to refer (broadly speaking) to hospitals, care homes and prisons. It is therefore convenient to include some laws relevant to all those services in this chapter. It is also the most convenient chapter to cover the legal role of chief pharmacist, which was created when the Medicines Act was amended in 2022.

Definition of hospital

In the Human Medicines Regulations 2012 (HMR), the word hospital includes a clinic, nursing home or similar institution.[1]

In the National Health Service Act 2006, the word hospital means:

a. any institution for the reception and treatment of persons suffering from illness
b. any maternity home, and
c. any institution for the reception and treatment of persons during convalescence or persons requiring medical rehabilitation, and includes clinics, dispensaries and out-patient departments maintained in connection with any such home or institution.[2]

Which of these definitions is applicable will depend on the activity that is carried out.[3]

[1] HMR Reg.8.
[2] Section 275
[3] The Department of Health and Social Care observed in its consultation on introducing a statutory defence for prosecutions for dispensing errors: "There is no generally recognised definition of what constitutes a 'hospital'". It therefore opted to use the definition of "hospital" from the HMR when amending the Medicines Act.

NHS trusts and NHS foundation trusts

Chapter 3 of Part 2 of the National Health Service Act 2006 gives the Secretary of State for Health and Social Care power to establish NHS trusts in England. **Chapter 5** of Part 2 of the National Health Service Act gives the Secretary of State power to create NHS foundation trusts. Many hospitals are NHS trusts or NHS foundation trusts. NHS trusts and NHS foundation trusts have different governance arrangements that are outside the scope of this book.

Registration with the General Pharmaceutical Council

The Registrar of the General Pharmaceutical Council (GPhC) is required to maintain a register,[4] Part 3 of the register is for pharmacy premises. Premises are only eligible for registration if the premises are used for lawfully carrying on a retail pharmacy business. The meaning of lawfully carrying on a retail pharmacy business is considered in **Chapter 7**, but an essential ingredient of the term retail pharmacy business is that the business consists of or includes the retail sale of medicinal products that are not subject to general sale.[5]

The Medicines Act 1968 defines retail sale as referring to "selling a substance or article to a person who does not buy it for the purpose of selling or supplying it or administering it or causing it to be administered to one or more human beings in the course of a business carried on by the buyer".[6]

Historically, many NHS hospitals appear to have taken the view that they are not required to register their pharmacies with the GPhC because they do not sell medicines to patients. The GPhC does not require hospitals to register because the requirement in the HMR to sell or supply medicines that are not subject to general sale only from registered pharmacy premises[7] does not apply to a sale or supply in the course of the business of a hospital.[8] These exemptions are referred to in more detail below.

The GPhC adds on its website:

> *"Trusts/Health Boards may include several different hospitals on different sites but all the hospitals within a Trust/Health Board are viewed as being part of a single legal entity.*
>
> *The supply of medicines from one hospital to a patient in another hospital of the same Trust/Health Board is a supply within the same legal entity and would therefore be regarded as a supply in the course of the business of that hospital. As such the supplying hospital pharmacy would not be required to be registered…"*

The GPhC would require a hospital to register with it if the hospital wished to supply Pharmacy medicines or Prescription Only Medicines (POMs) to patients in a hospital belonging to a different trust or Health Board. It would also require a hospital to register with it if the hospital wished to supply POMs or Pharmacy medicines to private patients of another legal entity based in the same hospital.

[4] Article 19 of the Pharmacy Order 2010
[5] HMR Reg.8
[6] Section 121 of the Medicines Act 1968. For completeness, the section gives the expression "circumstances corresponding to retail sale" a similar meaning.
[7] HMR Reg.220
[8] https://www.pharmacyregulation.org/pharmacies/registration-and-renewal/pharmacy-owners-and-employers-FAQs (accessed 31 December 2024)

Hospitals would also be required to register with the GphC if they wished to supply a community pharmacy services to staff or to the public.

Regulation by the GPhC

If a hospital pharmacy is registered with the GPhC, it will be subject to inspection and regulation by the GPhC (see **Chapter 2**).

Regulation by the Care Quality Commission, Health Improvement Scotland and Healthcare Inspectorate Wales

If a hospital pharmacy is not registered with the GPhC, it will be subject to inspection and regulation by the Care Quality Commission (CQC) in England, Health Improvement Scotland or Healthcare Inspectorate Wales (see **Chapter 2** and Box 3.1 in **Chapter 3**).

A person who is registered with the CQC will owe a statutory duty of candour (see **Chapter 2**). This does not apply to services provides from hospitals that are registered with the GPhC.

Manufacturing medicinal products

It is not unusual for hospitals to engage in manufacturing medicinal products. Ordinarily, manufacturing is not lawful unless the manufacturer holds a manufacturer's licence that has been granted by the Medicines and Healthcare products Regulatory Agency (MHRA).[9]

However, there are exemptions for hospitals from the need for a manufacturer's licence if certain conditions are satisfied. These are dealt with below.

Exemptions for hospitals, care home services and health centres[10]

If a hospital pharmacy is registered with the GPhC, it will be able to rely on exemptions for pharmacies in section 10 of the Medicines Act 1968. These exemptions, which are described in more detail in **Chapter 5**, were considered by the Court of Appeal in Bayer PLC and Novartis Pharmaceuticals UK Ltd v NHS Darlington CCG and others[11] – see **Box 9.1**.

BOX 9.1

Darlington Clinical Commissioning Group (CCG) and some other CCGs (before Clinical Commissioning Groups were replaced by Integrated Care Boards) had adopted a policy that the NHS Trusts from which they commissioned services should use Avastin as the preferred treatment for a form of the eye disease, wet age-related macular degeneration (WAMD). Avastin had a marketing authorisation for treating colorectal cancer, but did not have a marketing authorisation for the treatment of WAMD.

Avastin is supplied in glass vials. For treating colorectal cancer, the contents of the vial are

[9] HMR Reg.17
[10] Section 10 of the Medicines Act 1968
[11] [2020] EWCA Civ 449

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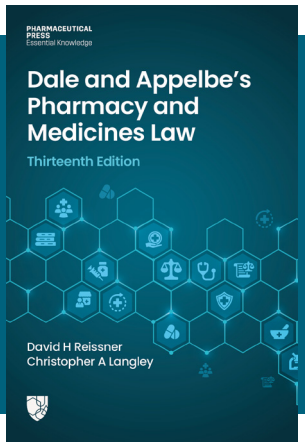

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