Chapter 7
Controls Over the Sale and Distribution of Medicines

INTRODUCTION

We have seen that strenuous efforts have been made to ensure that medicinal products are safe, efficacious and of good quality when manufactured. The benefits of all of this would be lost if there were no, or inadequate, controls over their subsequent distribution. Thus, section 61 enables the Ministers to make regulations to restrict the sale of medicines by manufacturers and wholesalers to specified classes of purchasers. These regulations have been made (1980/1923 regulation 5 and Schedule 1) and form the first step in the control of the distribution chain.

The 15th century physician Paracelsus remarked that the difference between a poison and a medicine is merely a matter of dose. While this is equally true today, we now recognise that there are additional ways in which modern medicines can be dangerous. Some react with foods and lose activity, while others react with foods and become very toxic. Many medicines, safe enough in themselves, become very dangerous when taken with other drugs, including alcohol. Not all of these interactions are necessarily lethal, but many of them are the cause of a significant degree of morbidity. Furthermore, by interrupting therapy, some interactions needlessly prolong treatment and others are responsible for 'treatment failures'. It is therefore a truism to state that in the interests of safety, the Act should confine the retail sale of medicines to pharmacies. This would enable the public to receive appropriate advice at the time of purchase and also help to ensure that medicines are used correctly and for bona fide medicinal purposes. It is also in the public interest because pharmacists are subject to a professional code which is in many ways superior to the law in the protection it provides to the public. Several pharmacists have been struck off the register for selling medicines perfectly lawfully but unprofessionally. Restriction of the number of retail outlets would also contribute to the enforcement of the Act. On the other hand, rigid adherence to this principle would cause inconvenience to the public, hence the wider availability of GSL products.

Although the majority of medicinal products are obtained by the public from shops, some are supplied directly to their patients by doctors, dentists and veterinarians. Furthermore, various other paramedical personnel such as chiropodists, opticians, nurses, and midwives need to be able to supply medicines specific to their professions to their patients (see Chapter 11 for details). Employers are often required by law to provide first aid facilities and some go further and provide occupational health schemes. Children in school may be
provided with dental treatment aimed at the prevention of caries. It is therefore necessary to make special provision for these activities and to exempt the persons involved from some or all of the restrictions that would normally operate in the sale or supply of medicines.

The framework of the restrictions over the administration, sale and sellers of medicines is contained in Part III of the Act and for these purposes medicines have been divided into THREE main classes, namely –

1. General Sale List (GSL); section 51 authorised the compilation of a list of medicines which, ‘with reasonable safety’ may be sold otherwise than under the supervision of a pharmacist. Section 53 specified the conditions which must be observed by sellers (other than pharmacists) of these medicines, and the GSL Order lists the products and contains some other conditions. GSL products may even be sold from automatic machines in accordance with section 54. While many GSL products may, perhaps, be safe, some are obsolete and their efficacy is questionable.

2. Section 52 required all other medicines to be sold by ‘persons lawfully conducting a retail pharmacy business’. Such persons may only sell these medicines from registered pharmacies and each sale must be by or under the supervision of a pharmacist. There is no list of these products, but some of them are subject to additional restrictions, mentioned in (3) below.

The requirements to be complied with in order to become a ‘person lawfully ….. business’ and the procedure involved in registering a pharmacy are described in detail in Chapter 21.

3. Section 58 authorised the preparation of a list of medicines which may only be sold or supplied to the public on the prescription of a practitioner (Prescription Only Medicines, POMs). The lists and various other matters relating to these medicines are published in the Prescription Only Medicines Orders.

**EXEMPTIONS**

The above is a summary of the general position with regard to the sale and supply of medicines to the public but there are certain exemptions to it. Section 55 exempts practitioners (i.e. doctors, dentists, and veterinarians) from the restrictions imposed by sections 52 and 53 when they sell or supply medicines to their patients. The same section exempts nurses and also midwives from such restrictions but only to the extent specified in regulations (1980/1924 as amended). Herbalists are similarly exempt from sections 52 and 53 under certain circumstances (section 56) and while many herbal substances are included in the GSL a statutory instrument (1977/2130) specifies those which may only be sold by herbalists or pharmacists. The Ministers have power to modify or extend the exemptions and have used them, e.g. Pharmacy and General Sale-Exemption Orders.

**OTHER PROVISIONS OF PART III**

Part III also contains provisions relating to new products (section 59), mainly making them POM for a period of 5 years from first licensing unless there is existing evidence of safety. It would not enable medicines to be placed on limited release, e.g. use in hospitals only for a period, but presumably the product licence could contain such a condition. Restrictions may also be imposed on the sellers, users and prescribers of other products (section 60). The Ministers have powers