

The Legal Responsibilities of Pharmacists

Misuse of Drugs Legislation

The possession, supply, administration, recording and destruction of controlled drugs is restricted by the Misuse of Drugs Act 1971 and the Regulations made thereunder, namely the Misuse of Drugs Regulations 2001 (as amended) and the Misuse of Drugs (Safe Custody) Regulations 1973 (as amended).

Misuse of Drugs Act 1971

The Misuse of Drugs Act 1971 consolidated and simplified previous legislation relating to dangerous drugs. The Act divides controlled drugs into Class A, B and C according to the perceived degree of harm. Class A drugs are those which are considered to be the most harmful when misused (e.g. morphine, diamorphine and cocaine) and as such offences in relation to Class A drugs incur the more severe punishment or penalty. Class C drugs such as anabolic steroids and benzodiazepines are considered to be less harmful and carry lower penalties for offences. Schedule 4 of the Act sets out the prosecutions and penalties for offences relating to possession, supply and other contravention of the controlled drug regulations

The Act introduced the Advisory Council on the Misuse of Drugs (ACMD). The main duty of the ACMD is to keep under review drugs that are likely to be misused or constitute a social problem in the UK and provide advice on measures to prevent misuse.

Sections 12 and 13 of the Misuse of Drugs Act permit the Secretary of State to withdraw an individual practitioner's or pharmacist's authority to handle controlled drugs. Such direction can be given as a result of conviction for certain offences or contravention of any of the requirements for prescribing, supplying, administration, storage or record keeping of controlled drugs.

The Act provides the Secretary of State with the power to make regulations for the handling of controlled drugs by authorised persons. The current Regulations are the Misuse of Drugs Regulations 2001 (as amended) and the Misuse of Drugs (Safe Custody) Regulations 1973 (as amended).

Misuse of Drugs Regulations 2001

The Misuse of Drugs Regulations 2001 divide controlled drugs into 5 Schedules. The Regulations define the restrictions on the manufacture, supply and possession of controlled drugs, as well as prescription, record keeping and destruction requirements. Schedule 1 controlled drugs are subject to the most stringent restrictions and Schedule 5 the least. The classification of a particular controlled drug may differ depending on strength, formulation and route of administration of the preparation.

Schedule 1 drugs generally have no recognised medical use and lawful production, possession and supply require a Home Office licence. For the purpose of medicinal use discussion should be restricted to Schedules 2 to 5.

Schedule 2

Schedule 2 includes the opiates (e.g. diamorphine, morphine and methadone), the major stimulants (e.g. amphetamines) and quinalbarbitone.

A licence is required to import or export schedule 2 drugs, but they may be manufactured or supplied by authorised persons including, licence holders, practitioners, and pharmacists. The drugs may be administered to a patient by a doctor or dentist, or by a person acting in accordance with the directions of a doctor or dentist. A recent amendment to the Regulations now permits a Registered Nurse, who is acting in accordance with a Patient Group Direction, to administer diamorphine for the treatment of cardiac pain, to a person admitted to a coronary care unit or accident and emergency department of a hospital.

Before supplying a Schedule 2 drug pharmacists require a valid prescription which complies with all the requirements of the Regulations, or a requisition signed by an authorised person.

Pharmacists must keep a record of all Schedule 2 drugs obtained and supplied, and safe custody requirements are applicable.

An authorised person must witness the destruction of Schedule 2 drug stock, but not patient returns.

Schedule 3

Schedule 3 drugs include temazepam, buprenorphine and other drugs that are not thought so likely to be misused.

The controls that apply to Schedule 2 drugs also apply to Schedule 3 drugs with a few exceptions. Records of Schedule 3 drugs obtained and supplied need not be kept and destruction does not need to be witnessed by an authorised person.

Safe custody requirements do apply, but most Schedule 3 drugs are exempted.

Schedule 4

Schedule 4 is split into two parts. Part I contains most of the benzodiazepines and Part II most of the anabolic and androgenic steroids.

An import or export licence is required for Schedule 4 controlled drugs other than Part II drugs that are in the form of a medicinal product, intended for administration by a person to himself. There are no restrictions on possession of any Schedule 4 Part II controlled drug when contained in a medicinal product.

Supplies can be made against a valid prescription or, for certain Part I drugs, in accordance with a Patient Group Direction (PGD). No additional prescription requirements apply except those of the Medicines Act 1968 and controlled drug registers do not need to be kept by retailers. Destruction requirements apply only to importers, exporters and manufactures.

Schedule 5

Schedule 5 contains preparations of certain controlled drugs, for example codeine, pholcodeine, morphine and cocaine that are exempt from full control when present in medicinal products of low strength.

There is no restriction on import, export, possession, administration or destruction of these preparations and safe custody requirements do not apply. Many Schedule 5 controlled drugs can be purchased over the counter from registered pharmacies, provided the sale is under the supervision of a pharmacist. Those Schedule 5 drugs that are prescription only medicines can either be supplied in accordance with a valid prescription or a PGD. No additional prescription requirements apply and records of stock obtained or supplied do not need be kept. However, invoices (or copies of them) must be kept for two years from the date of issue.

The Misuse of Drugs (Safe Custody) Regulations 1973

Retail dealers (pharmacists), private hospitals and nursing homes need to store any controlled drugs requiring safe custody in a locked safe, cabinet or room that complies with the requirements of the Misuse of Drugs (Safe Custody) Regulations 1973 or, in respect of which, a certificate of approval has been obtained from the police.

Others who are entitled to possess controlled drugs (e.g. doctors, sisters in charge of a hospital ward or department, midwives) do not have to comply with the stringent requirements stipulated in the Regulations. However, there is a requirement for them to store controlled drugs in a locked receptacle that can only be opened by them or a person acting on their authority. The term 'locked receptacle' is not defined, but the Home Office has stated that the boot of a car would not satisfy the requirements.

Safe custody requirements do not apply to patients, persons engaged in the business of a carrier, or persons engaged in the business of the Post Office.

It should also be noted that the Care Standards Act 2000 replaced the terms 'nursing home' and 'residential home' with the term 'care home', but the Safe Custody Regulations were not amended accordingly. However, current guidelines for care homes state that they should store controlled drugs to be administered by staff in a cabinet that meets the requirements of the Regulations.

The Medicines Act 1968

The Medicines Act 1968 was introduced as a result of a review of medicine legislation following the Thalidomide tragedies. It places legal restrictions on the manufacture, sale, supply and import of medicinal products.

The Act requires the manufacture and wholesale of medicines to be in accordance with the appropriate licence, unless specified exemption criteria are fulfilled. It also controls the retail sale, supply and administration of medicinal products. Medicinal products fall into one of three categories, Prescription Only, Pharmacy and General Sale List. The Medicines and Healthcare products Regulatory Agency, the Royal Pharmaceutical Society of Great Britain and local authorities have the authority to enforce specific sections of the Act.

Appendix 1

Various statutory instruments have been made under the Act, including the Prescription Only Medicines Human Use Order 1997, which details the requirements and exemptions for the prescribing, supply and administration of prescription only medicines (POM). As the majority of controlled drugs are also POM's, even if the prescribing or supply is not restricted by the Misuse of Drugs legislation, the Medicines Act requirements must still be adhered to.