21 Prescribing and administering drugs

This chapter focusses on the regulatory framework for the prescription of drugs by doctors in their daily practice. The chapter does not attempt to provide details in regard to the manufacture, approval and distribution processes for drugs or how the regulatory framework affects pharmacists, dentists, nurses and others. Through the *Therapeutic Goods Act 1989* (Cwlth), administered by the Therapeutic Goods Administration (TGA) of the Australian Government Department of Health, the federal government is responsible for the oversight of the national system that controls the safety, quality, efficacy and availability of therapeutic goods (drugs and devices), whether produced here or abroad. It is also responsible for the Pharmaceutical Benefits Scheme (PBS), which is designed to ensure community access to prescription drugs at affordable prices (see Chapter 16, which describes the PBS in some detail). The aspects of the PBS that regulate or control the prescribing by doctors of drugs included in the Scheme are covered in this chapter. The TGA provides a useful overview of this regulatory system [1].

While the registration of drugs (therapeutic goods) is a federal responsibility, controlling who has access to those drugs is constitutionally the responsibility of the states and territories. Each jurisdiction has legislation to regulate the availability and use of drugs (and poisons). The controls exist primarily to protect the public, and to a lesser extent to protect doctors from the dangers of self-administration and dependency. The legislation provides for criminal penalties for breaches; any convictions of doctors by the courts are usually examined by the Medical Board of Australia to determine whether unprofessional conduct has been involved, and whether the doctor's practice or prescribing rights should be restricted. The relevant state and territory acts are listed in Table 21.1. Telephone contact details for the drugs and poisons agency in each jurisdiction are listed in Table 21.2 and are also available, together with websites for more detailed information, on the TGA website [2].

The chapter also examines the ethical and professional issues around the important relationship that should exist between doctors and pharmacists; more information about the pharmacy profession can be found in Chapter 17. However, the clinical knowledge, skills and judgement required to prescribe drugs effectively and efficiently are beyond the scope of this book.

Table 21.1 Legislation controlling prescription and use of drugs

State	Name of legislation
New South Wales	*Poisons and Therapeutic Goods Act 1966* (amended 1996)
	Poisons and Therapeutic Goods Regulations 2008
Victoria	*Drugs, Poisons and Controlled Substances Act 1981*
	Drugs, Poisons and Controlled Substances (Commonwealth Standards) Regulations 2011
	Therapeutics Goods (Victoria) Act 2010
Queensland	*Health Act 1937*
	Health Regulation 1996
	Health (Drugs and Poisons) Regulations 1996
South Australia	*Controlled Substances Act 1984*
	Controlled Substances (Poisons) Regulations 2011
Western Australia	*Poisons Act 1964*
	Poisons Regulations 1975
Tasmania	*Poisons Act 1971*
	Poisons Regulations 2008
Northern Territory	*Poisons and Dangerous Drugs Act 1983*
	Poisons and Dangerous Drugs Regulations 2004
Australian Capital Territory	*Medicines, Poisons and Therapeutic Goods Act 2008*
	Medicines, Poisons and Therapeutic Goods Regulations 2008

21.1 Standard schedule of drugs and poisons

To ensure substantial uniformity of the approach taken by the states and territories to the regulation of drugs and poisons, the Therapeutic Goods Act provided for the establishment of the National Drugs and Poisons Schedule Committee of the Australian Health Ministers' Advisory Council. This committee of relevant state and territory representatives has a key task of maintaining the Standard for the Uniform Scheduling of Drugs and Poisons [3]. The schedules are given below, with some examples of the drugs included in each. The schedules