Poisons and Therapeutic Goods Regulation 2002

[2002-639]

New South Wales

Status Information

Currency of version

Historical version for 8 September 2006 to 30 November 2006 (accessed 15 October 2024 at 1:11)

Legislation on this site is usually updated within 3 working days after a change to the legislation.

Provisions in force

The provisions displayed in this version of the legislation have all commenced.

Notes—

- **Does not include amendments by**
  Pharmacy Practice Act 2006 No 59 (not commenced)
- **See also**
  Statute Law (Miscellaneous Provisions) Bill (No 2) 2006
  Private Health Facilities Bill 2006

Authorisation

This version of the legislation is compiled and maintained in a database of legislation by the Parliamentary Counsel's Office and published on the NSW legislation website, and is certified as the form of that legislation that is correct under section 45C of the Interpretation Act 1987.

File last modified 22 November 2006

Poisons and Therapeutic Goods Regulation 2002

New South Wales

Contents

Poisons and Therapeutic Goods Regulation 2002

New South Wales

Part 1 Preliminary

1 Name of Regulation (cf cl 1 of P&TG Reg 1994)

This Regulation is the *Poisons and Therapeutic Goods Regulation 2002*.

2 Commencement (cf cl 2 of P&TG Reg 1994)

This Regulation commences on 1 September 2002.

Note—

This Regulation replaces the *Poisons and Therapeutic Goods Regulation 1994* which is repealed on 1 September 2002 by section 10 (2) of the *Subordinate Legislation Act 1989*.

3 Definitions (cf cll 3 and 3A of P&TG Reg 1994)

(1) In this Regulation:

charitable organisation means an organisation or association that holds an authority under Part 2 of the *Charitable Fundraising Act 1991* or that is referred to in section 7 of that Act as an organisation or association to which that Act does not apply.

child-resistant closure means:

(a) in the case of a can fitted with a press-on lid, a lid of the design known as "double tight" or "triple tight", or

(b) in any other case, a closure that is resistant to opening by children and that complies with:

(i) section 2 (Requirements for Reclosable Packages) of Australian Standard AS 1928—2001, *Child-resistant packages*, or

(ii) a design approved by any order made under section 10 of the *Therapeutic Goods Act 1989* of the Commonwealth, or

(iii) a design approved for the time being by the Director-General.

Commonwealth Department of Health means the Commonwealth Department of

Health and Ageing.

current Poisons Standard has the same meaning as it has in the *Therapeutic Goods Act 1989* of the Commonwealth.

day procedure centre means premises licensed as a day procedure centre under the *Private Hospitals and Day Procedure Centres Act 1988*.

dealer, in relation to a substance, means a person who supplies the substance as a manufacturer, as an importer or exporter or as a wholesale or retail dealer, and includes a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist in his or her capacity as a supplier of the substance.

Director-General means the Director-General of the Department of Health.

function includes a power, authority and duty, ***exercise a function*** includes perform a duty, ***confer a function*** includes impose a duty.

hallucinogen means any of the following drugs of addiction:

(a) etorphine,

(b) tetrahydrocannabinol and its alkyl homologues where Schedule 8 of the Poisons List applies.

hospital means a public hospital, public institution, private hospital, nursing home, day procedure centre or residential centre for persons with disabilities.

inspector means a person authorised by the Director-General to exercise the powers conferred by section 43 of the Act.

nurse means a person who is a registered nurse within the meaning of the *Nurses Act 1991*.

nursing home has the same meaning as in the *Public Health Act 1991*.

pharmacist includes a pharmacy trainee working under the direct personal supervision of a pharmacist.

practitioner of alternative medicine means a herbalist, nutritionist, naturopath, practitioner of Chinese medicine or homoeopathic practitioner.

prescribed restricted substance means a substance listed in Appendix D.

prescription reference number means the unique reference number for the prescription recorded under clause 54 or 113.

private hospital means premises licensed as a private hospital under the *Private*

Hospitals and Day Procedure Centres Act 1988.

public hospital means a public hospital within the meaning of the *Health Services Act 1997*.

residential centre for persons with disabilities means an institution that is declared by clause 178 to be a residential centre for persons with disabilities for the purposes of this Regulation.

retail dealer, in relation to a substance, means a person who supplies the substance as a retailer, and not as a manufacturer, importer, exporter or wholesaler, and not as a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist in his or her capacity as a supplier of the substance.

retail pharmacist means a pharmacist who is employed in premises approved under section 24A of the *Pharmacy Act 1964* as suitable for carrying on the business of a pharmacist.

retail pharmacy means premises approved under section 24A of the *Pharmacy Act 1964*.

scientifically qualified person means:

(a) a medical practitioner, dentist or veterinary practitioner or pharmacist, or

(b) a person who is the holder of a degree or diploma approved for the time being by the Director-General, or

(c) a person approved for the time being by the Director-General.

seized goods means regulated goods that have been seized under section 43 of the Act.

the Act means the *Poisons and Therapeutic Goods Act 1966*.

Therapeutic Goods Order No 20 means the order of that name, as in force from time to time under Part 2 of the *Therapeutic Goods Act 1989* of the Commonwealth.

therapeutic substance means a substance that is manufactured for therapeutic use within the meaning of the current Poisons Standard.

ward of a hospital includes any theatre, laboratory or department of the hospital, other than the pharmacy department.

(2) In this Regulation:

(a) expressions that are defined in the current Poisons Standard have the meanings given to them by that Standard, and

(b) expressions that are defined in the current Poisons Standard and that are also defined in the Act or in this Regulation have the meanings given to them by the Act or this Regulation, respectively, and

(c) a reference to a Schedule 1, 2, 3, 4, 5, 6, 7 or 8 substance is a reference to a substance included in the correspondingly numbered Schedule of the Poisons List, and

(d) a reference to an Appendix B substance is a reference to a substance included in Appendix B to this Regulation.

(3) Notes in the text of this Regulation do not form part of the Regulation.

4 Authorisation of nurse practitioner or midwife practitioner under section 17A of the Act (cf cl 3B of P&TG Reg 1994)

Nothing in this Regulation authorises a nurse practitioner or midwife practitioner to possess, use, supply or prescribe any poison or restricted substance otherwise than in accordance with an authorisation in force under section 17A of the Act in respect of the nurse practitioner or midwife practitioner.

4A Authorisation of nurse practitioner or midwife practitioner to possess, use, supply or prescribe drugs of addiction

(1) Nothing in this Regulation authorises a nurse practitioner or midwife practitioner to possess, use, supply or prescribe a drug of addiction otherwise than in accordance with an authorisation of the Director-General under this clause.

(2) The Director-General may, by means of a written authorisation, authorise a nurse practitioner or midwife practitioner, or a class of nurse practitioners or midwife practitioners, to possess, use, supply or prescribe any drug of addiction for the purposes of the practice of a nurse practitioner's or midwife practitioner's profession.

(3) Such an authority is to be given only if the Director-General approves guidelines, under section 78A of the *Nurses and Midwives Act 1991*, that provide for the possession, use, supply or prescription of drugs of addiction by nurse practitioners or midwife practitioners and is to be given in accordance with those guidelines.

(4) The Director-General may amend or revoke any authorisation given under this section.

4B Authorisation of optometrist under section 17B of the Act

Nothing in this Regulation authorises an optometrist to possess, use, supply or prescribe any poison or restricted substance unless:

(a) the use of the poison or restricted substance in the practice of optometry has been approved under section 17B of the Act, and

(b) the optometrist holds a drug authority issued by the Optometrists Registration Board allowing the optometrist to possess, use, supply or prescribe that poison or restricted substance.

Note—

Section 21 (5) of the *Optometrists Act 2002* provides for a registered optometrist to possess and use certain drugs in the practice of optometry. That section is unaffected by this clause.

Part 2 Poisons (S1, S2, S3, S5, S6, S7)

Division 1 Packaging and labelling

5 Packaging and labelling generally (cf cl 4 of P&TG Reg 1994)

(1) A dealer who supplies a poison must ensure that the poison is packaged and labelled:

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a poison to which *Therapeutic Goods Order No 20* applies, in accordance with that Order.

(2) This clause does not apply to the labelling of a substance that is supplied by a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist so long as the substance is supplied in a package that is labelled in accordance with the requirements of Appendix A.

(3) A pharmacist who supplies any quantity of a Schedule 2 or 3 substance on prescription must ensure that the substance is supplied in a package that is labelled in accordance with the requirements of Appendix A instead of in accordance with the requirements of subclause (1).

Maximum penalty: 10 penalty units.

6 Misleading labelling of substances as poisons (cf cl 5 of P&TG Reg 1994)

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a poison, unless the substance is a poison.

Maximum penalty: 10 penalty units.

7 Packaging of camphor and naphthalene (cf cl 6 of P&TG Reg 1994)

A dealer must ensure that any camphor or naphthalene supplied by the dealer (being camphor or naphthalene packaged in block, disc, ball or pellet form suitable for domestic use) is packaged so that, in normal use, the contents of the package cannot be ingested or touched while the package remains unbroken.

Maximum penalty: 10 penalty units.

8 Schedule 3 substances supplied by dealers (cf cl 7 of P&TG Reg 1994)

(1) A dealer must ensure that any Schedule 3 substance supplied by the dealer is labelled with the dealer's name and address.

Maximum penalty: 2 penalty units.

(2) Subclause (1) does not apply to the supply of any Schedule 3 substance by wholesale.

9 Exemptions (cf cl 8 of P&TG Reg 1994)

(1) The Director-General may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of this Division.

(2) Such an exemption may be given unconditionally or subject to conditions.

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Director-General may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

Division 2 Storage

10 Storage generally (cf cl 9 of P&TG Reg 1994)

A dealer who has possession of any poison must keep the poison:

(a) apart from human or animal food, and

(b) in such a way that, if its container breaks or leaks, the poison cannot mix with or contaminate any human or animal food.

Maximum penalty: 10 penalty units.

11 Schedule 3 or 7 substances (cf cl 10 of P&TG Reg 1994)

A dealer who has possession of any Schedule 3 or 7 substance must keep the substance in a room or enclosure to which the public does not have access.

Maximum penalty: 10 penalty units.

12 Schedule 6 substances (cf cl 11 of P&TG Reg 1994)

(1) A dealer who has possession of any Schedule 6 substance must keep that substance:

(a) in a place to which the public does not have access, or

(b) in a place that is at least 1.2 metres above the floor and at least 1.2 metres away from any step, stairway, ramp or escalator to which the public has access.

(2) This clause does not apply to any of the following:

(a) any therapeutic substance for internal use in animals,

(b) any substance in a container that is fitted with a child-resistant closure,

(c) any substance in a pressurised spray dispenser that is fitted with a cap that can be removed only by using a levering instrument applied through a slot in the cap,

(d) any substance in a container that has a capacity of 5 litres or more or a weight (inclusive of its contents) of 5 kilograms or more,

(e) any hair dye in a container that has a capacity of 50 millilitres or less,

(f) any cockroach bait that is enclosed in a welded plastic labyrinth.

Maximum penalty: 10 penalty units.

Division 3 Prescriptions

13 Unauthorised persons not to prescribe Schedule 2 or 3 substances (cf cl 12 of P&TG Reg 1994)

(1) A person must not issue a prescription for a Schedule 2 or 3 substance unless authorised to do so by this clause.

(2) A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner may issue a prescription for a Schedule 2 or 3 substance.

Maximum penalty: 10 penalty units.

14 Certain Schedule 3 substances (cf cl 13 of P&TG Reg 1994)

(1) This clause applies to the following substances, but only in so far as they are Schedule 3 substances:

pseudoephedrine

(2) A person who issues a prescription for a substance to which this clause applies must ensure that the prescription complies with Division 3 of Part 3 as if the substance were a restricted substance.

Maximum penalty: 10 penalty units.

15 Quantity and purpose of prescriptions to be appropriate (cf cl 14 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner must not issue a prescription for a Schedule 2 or 3 substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty: 10 penalty units.

Division 4 Supply

16 Schedule 2 and 3 substances may be supplied by authorised persons (cf cl 16 of P&TG Reg 1994)

A person who is not a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist may supply a Schedule 2 or 3 substance to another person if the supplier holds a licence or authority under Part 8 to supply the substance.

17 Schedule 3 substances to be supplied personally by pharmacists (cf cl 17 of P&TG Reg 1994)

(1) A pharmacist must not supply a Schedule 3 substance to any person unless the pharmacist:

(a) personally hands the substance to the person, and

(b) gives the person an opportunity to seek advice as to the use of the substance, including advice that the person may require in respect of the dosage, frequency of administration and general toxicity of the substance.

(2) This clause does not apply to the supply of any substance:

(a) to a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner, or

(b) to any other person on the prescription of a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner.

(3) This clause does not apply to the supply of salbutamol or terbutaline in metered aerosols for first aid purposes to a person who holds a current emergency asthma management certificate issued by an organisation approved by the Director-General for the purposes of this subclause.

(4) This clause does not apply to the supply to the chief nurse of a nursing home of any substance in the manufacturer's original pack, in accordance with a written order signed by the chief nurse, if the Director-General has determined that the substance may be supplied for emergency use at the nursing home in accordance with the authorisation of a medical practitioner, nurse practitioner, dentist or optometrist who prescribes substances to the nursing home's residents.

(5) This clause does not apply to the supply of adrenaline for anaphylaxis first aid purposes if:

(a) the adrenaline is contained in single use automatic injectors that have been filled

by the manufacturer with no more than 0.3 milligrams of adrenaline each, and

(b) the supply is to a person who holds a current first aid certificate issued after completion of a first aid course approved by the WorkCover Authority as referred to in regulations made under the *Occupational Health and Safety Act 2000*, and the person has received training on the symptoms and first aid management of anaphylaxis from:

(i) a first aid training organisation approved by the WorkCover Authority, or

(ii) any other organisation approved by the Director-General for the purposes of this paragraph.

Maximum penalty: 10 penalty units.

18 Prescriptions for Schedule 2 or 3 substances to be endorsed (cf cl 19 of P&TG Reg 1994)

A pharmacist who supplies a Schedule 2 or 3 substance on prescription must endorse the prescription for the substance in accordance with clause 40 as if the substance were a restricted substance.

Maximum penalty: 10 penalty units.

19 Certain Schedule 7 substances to be supplied and used only under an authority (cf cl 20 of P&TG Reg 1994)

(1) A person must not obtain or use a Schedule 7 substance unless the person holds an authority under Part 8 to obtain or use the substance.

(2) A dealer must not supply a Schedule 7 substance to any other person unless:

(a) the dealer holds an authority under Part 8 to supply the substance, and

(b) the person being supplied holds an authority under Part 8 to obtain the substance.

(3) A person being supplied with a Schedule 7 substance must surrender to the dealer the person's authority to obtain the substance.

(4) In the case of an authority:

(a) that authorises multiple supplies of a Schedule 7 substance, or

(b) that has been issued to a class of persons (as referred to in clause 166 (3)),

it is sufficient compliance with subclause (3) if the person being supplied surrenders a copy of the authority to the dealer.

(5) The functions of the Director-General under Part 8 with respect to an authority under this clause may be exercised by the Permanent Head of the Commonwealth Department of Health.

Maximum penalty: 10 penalty units.

(6) The Director-General may, by order in writing, exempt any person or substance, or any class of persons or substances, from any or all of the requirements of this clause.

(7) Such an exemption may be given unconditionally or subject to conditions.

(8) This clause does not apply to:

(a) the supply by wholesale of any Schedule 7 substance, or

(b) the use by a person of any Schedule 7 substance that is:

(i) a pesticide (within the meaning of the *Pesticides Act 1999*), or

(ii) a stock medicine (within the meaning of the *Stock Medicines Act 1989*),

or the supply to, or obtaining by, such a person of any such substance, or

(c) the use by a person in charge of an institution or facility for scientific research, instruction, analysis or study of any Schedule 7 substance for use in that institution or facility, or the supply to, or obtaining by, such a person of any such substance for use in that institution or facility, or

(d) the use by a person of any Schedule 7 substance (other than a highly dangerous substance) for non-domestic purposes, or the supply to, or obtaining by, a person of any such substance for use for non-domestic purposes.

(9) In subclause (8) (d), ***highly dangerous substance*** means any of the following substances:

arsenic

cyanides

fluoroacetamide

fluoroacetic acid

hydrocyanic acid

strychnine

thallium

any Schedule 7 substance that is listed in Appendix C of the current Poisons Standard

20 "Particular use" poisons may only be supplied in original containers (cf cl 21 of P&TG Reg

1994)

(1) This clause applies to any Schedule 5, 6 or 7 substance that is specified in the Poisons List as being a substance that is manufactured or supplied for a particular use.

(2) A dealer (other than a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist) who supplies a substance to which this clause applies must supply the substance, unopened, in the container in which it was received by the dealer.

Maximum penalty: 10 penalty units.

21 Supply of art materials, toys, furniture etc containing poisons (cf cl 22 of P&TG Reg 1994)

(1) A person must not supply any pencil, crayon, finger colour, poster paint, school pastel or show card colour or other such article or substance if the article or substance contains a Schedule 2, 3, 5, 6 or 7 substance.

(2) Subclause (1) does not apply to the supply of artists' oil colours.

(3) A person must not supply any painted toy, furniture or other item of household goods if the paint contains a Schedule 6 or 7 substance.

Maximum penalty: 10 penalty units.

22 Quantity and purpose of supply to be appropriate (cf cl 23 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner, pharmacist or retail dealer must not supply any poison:

(a) in the case of a therapeutic substance, in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances, or

(b) in any other case, for a purpose other than that stated on its container or for a purpose other than that for which it is normally used.

Maximum penalty: 10 penalty units.

Division 5 Records of supply

23 Supply of certain Schedule 3 substances to be recorded (cf cl 25 of P&TG Reg 1994)

(1) This clause applies to the following substances, but only in so far as they are Schedule 3 substances:

pseudoephedrine

(2) A pharmacist who supplies a substance to which this clause applies, whether on prescription or otherwise, must record details of the supply in accordance with clause

54 as if the substance were a restricted substance.

Maximum penalty: 10 penalty units.

Division 6 Miscellaneous

24 Poisons to be used or disposed of safely (cf cl 26 of P&TG Reg 1994)

A person must not use or dispose of a poison in any place or in any manner likely to constitute a risk to the public.

Maximum penalty: 10 penalty units.

Part 3 Restricted substances (S4)

Division 1 Packaging and labelling

25 Packaging and labelling generally (cf cl 27 of P&TG Reg 1994)

(1) A dealer who supplies a restricted substance must ensure that the substance is packaged and labelled:

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a substance to which *Therapeutic Goods Order No 20* applies, in accordance with that Order.

(2) Despite subclause (1), a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner who supplies a restricted substance must ensure that the substance is packaged in accordance with the requirements of that subclause but labelled in accordance with the requirements of Appendix A.

(3) A pharmacist who supplies any quantity of a restricted substance on prescription, or in the circumstances referred to in clause 44 or 47, must ensure that the substance is supplied in a package that is labelled in accordance with the requirements of Appendix A instead of in accordance with the requirements of subclause (1).

Maximum penalty: 10 penalty units.

26 Misleading labelling of substances as restricted substances (cf cl 28 of P&TG Reg 1994)

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a restricted substance, unless the substance is such a substance.

Maximum penalty: 10 penalty units.

27 Exemptions (cf cl 29 of P&TG Reg 1994)

(1) The Director-General may, by order in writing, exempt any person or substance, or

any class of persons or substances, from the requirements of this Division.

(2) Such an exemption may be given unconditionally or subject to conditions.

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Director-General may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

Division 2 Storage

28 Storage generally (cf cl 30 of P&TG Reg 1994)

A dealer who has possession of any restricted substance must keep the substance:

(a) in a room or enclosure to which the public does not have access, and

(b) apart from human or animal food, and

(c) in such a way that, if its container breaks or leaks, the substance cannot mix with or contaminate any human or animal food.

Maximum penalty: 15 penalty units.

29 Storage of prescribed restricted substances in hospital wards (cf cl 32 of P&TG Reg 1994)

(1) Prescribed restricted substances that are kept in a hospital ward must be stored apart from all other goods (other than drugs of addiction) in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use.

(2) This clause does not apply to the storage of prescribed restricted substances on an emergency trolley, anaesthetic trolley or operating theatre trolley.

Maximum penalty: 20 penalty units.

30 Responsibility for storage in hospitals (cf cl 33 of P&TG Reg 1994)

(1) The chief pharmacist of a hospital is responsible for the storage of all restricted substances at the hospital other than those that have been supplied to a ward.

(2) In the case of a hospital for which there is no pharmacist, the responsibilities of a chief pharmacist under this clause are instead the responsibilities of:

(a) the chief nurse of the hospital, or

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

(3) The nurse in charge of a hospital ward is responsible for the storage of all restricted substances in the ward.

Division 3 Prescriptions

31 Unauthorised persons not to prescribe restricted substances (cf cl 34 of P&TG Reg 1994)

(1) A person must not issue a prescription for a restricted substance unless authorised to do so by this clause.

(2) A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner may issue a prescription for a restricted substance.

Maximum penalty: 15 penalty units.

32 Prescriptions may only be issued for certain purposes (cf cl 35 of P&TG Reg 1994)

(1) A medical practitioner must not issue a prescription for a restricted substance otherwise than for medical treatment.

(2) A nurse practitioner must not issue a prescription for a restricted substance otherwise than in the course of practising as a nurse practitioner.

(2A) A midwife practitioner must not issue a prescription for a restricted substance otherwise than in the course of practising as a midwife practitioner.

(3) A dentist must not issue a prescription for a restricted substance otherwise than for dental treatment, and must endorse any such prescription with the words “FOR DENTAL TREATMENT ONLY”.

(3A) An optometrist must not issue a prescription for a restricted substance otherwise than in the course of practising as an optometrist, and must endorse any such prescription with the words “FOR OPTOMETRICAL TREATMENT ONLY”.

(4) A veterinary practitioner must not issue a prescription for a restricted substance otherwise than for veterinary treatment, and must endorse any such prescription with the words “FOR ANIMAL TREATMENT ONLY”.

Maximum penalty: 15 penalty units.

33 Quantity and purpose of prescriptions to be appropriate (cf cl 36 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner must not issue a prescription for a restricted substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty: 15 penalty units.

34 Form of prescription (cf cl 37 of P&TG Reg 1994)

(1) A prescription for a restricted substance must include the following details:

(a) the date on which it is issued,

(b) the name and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner,

(c) the name, strength and quantity of the substance to be supplied,

(d) adequate directions for use,

(e) the maximum number of times the substance may be supplied on the prescription,

(f) in the case of a prescription for an Appendix B substance, the intervals at which the substance may be supplied on the prescription,

(g) if the prescription is issued at a hospital, the name and designation of the person by whom it is issued and the name, address and telephone number of the hospital,

(h) if the prescription is issued elsewhere than at a hospital, the name and designation of the person by whom it is issued and the address and telephone number of the premises at which it is issued.

(2) The details referred to in subclause (1) (a)–(f) must be made out:

(a) in the handwriting of the person by whom the prescription is issued, or

(b) in such other manner as may be approved for the time being by the Director-General,

and the prescription must be signed by the person by whom it is issued.

(3) The person by whom the prescription is issued must confirm any dose that could be regarded as being dangerous or unusual by underlining the part of the prescription that specifies the intended dose and by initialling the prescription in the margin.

(4) A person who issues a prescription for a restricted substance must ensure that the prescription complies with the requirements of this clause.

Maximum penalty: 15 penalty units.

35 Emergency prescriptions may be given by telephone or otherwise (cf cl 38 of P&TG Reg 1994)

(1) In an emergency, a medical practitioner, nurse practitioner, midwife practitioner,

dentist, optometrist or veterinary practitioner may direct the supply of a restricted substance orally, by telephone, by electronic mail or by facsimile.

(2) A person who so directs the supply of a restricted substance:

(a) must immediately make out a prescription, and

(b) must send the prescription without delay (and in any case within 24 hours) to the person to whom the direction was given.

(3) A person who issues a prescription under this clause must ensure that the prescription is endorsed with words that indicate the prescription has been issued in confirmation of a direction under this clause.

(4) This clause does not apply to a direction given under clause 57.

Maximum penalty: 15 penalty units.

36 Authority required to prescribe certain restricted substances (cf cl 39 of P&TG Reg 1994)

(1) This clause applies to the following restricted substances:

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitrophin (human follicle stimulating hormone)

(2) A person must not prescribe a restricted substance to which this clause applies unless the person holds an authority under Part 8 to prescribe the substance.

(3) This clause does not apply to the prescription of a substance:

(a) by a veterinary practitioner, or

(b) by a person who is authorised by the Permanent Head of the Commonwealth Department of Health to issue a prescription for the substance.

(4) A person who issues a prescription that authorises the supply of a substance to which this clause applies must ensure:

(a) in the case of a prescription that is issued in accordance with an authority under Part 8 that was granted to a particular person (by means of an instrument in writing given to the person), that the prescription is endorsed with the reference number shown on the authority, or

(b) in any other case, that the prescription is endorsed with the words “ISSUED UNDER CLAUSE 36 OF THE POISONS AND THERAPEUTIC GOODS REGULATION 2002” or with other words that indicate that the prescription has been issued under this clause.

Maximum penalty: 15 penalty units.

37 Records to be kept of certain prescriptions (cf cl 40 of P&TG Reg 1994)

(1) A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner who prescribes a prescribed restricted substance must make a record of the following particulars:

(a) the name, strength and quantity of the substance prescribed and the date on which it was prescribed,

(b) if the substance is intended for the treatment of a person, the name and address of the person to be treated,

(c) if the substance is intended for the treatment of an animal, the species of animal and the name and address of the animal’s owner,

(d) the maximum number of times the substance may be supplied on the prescription,

(e) in the case of a prescription for an Appendix B substance, the intervals at which the substance may be supplied on the prescription,

(f) the directions for use, as shown on the prescription.

(2) The record must be kept at the surgery, hospital or office of the person prescribing the substance.

Maximum penalty: 15 penalty units.

Division 4 Supply

Subdivision 1 Supply on prescription

38 Prescriptions may be filled only if in proper form (cf cl 41 of P&TG Reg 1994)

(1) A pharmacist must not supply a restricted substance on prescription unless the prescription is in the form required by Division 3.

(2) This clause does not prevent a pharmacist from supplying a restricted substance on prescription merely because:

(a) the prescription fails to specify the maximum number of times the substance may be supplied, or

(b) in the case of a prescription for an Appendix B substance, the prescription fails to specify the intervals at which the substance may be supplied, or

(c) the address shown on the prescription indicates that it has been issued by a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner from some other State or Territory.

(3) A pharmacist must not supply a restricted substance more than once on a prescription referred to in subclause (2) (a) or (b), regardless of how many times the prescription purports to authorise the supply of the substance.

Maximum penalty: 15 penalty units.

39 Certain prescriptions not to be filled (cf cl 42 of P&TG Reg 1994)

(1) A pharmacist must not supply a restricted substance on prescription:

(a) if the prescription is marked “CANCELLED”, or

(b) if the substance has already been supplied on the prescription the maximum number of times indicated by the prescription, or

(c) if the interval of time that has elapsed since the substance was last supplied on the prescription is less than that indicated by the prescription as the minimum interval that must elapse between successive supplies of the substance, or

(d) if the prescription is illegible or defaced, or

(e) if the prescription appears to have been forged or fraudulently obtained, or

(f) if the prescription appears to have been altered otherwise than by the medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner by whom it was issued, or

(g) if the prescription is dated more than 12 months (or, in the case of a prescription for a prescribed restricted substance, 6 months) before the date on which the supply is requested.

(2) Immediately on being requested to supply a prescribed restricted substance in either of the circumstances referred to in subclause (1) (e) or (f), a pharmacist must retain the prescription and cause notice of the request to be given to a police officer.

Maximum penalty: 15 penalty units.

40 Prescriptions to be endorsed (cf cl 43 of P&TG Reg 1994)

(1) A pharmacist who supplies a restricted substance on prescription must (on each occasion the substance is supplied) endorse the following particulars (in ink) on the prescription:

(a) the date on which the substance was supplied,

(b) the address of the place at which the substance was supplied,

(c) the prescription reference number.

(2) A person who supplies a substance on prescription must endorse (in ink) across the prescription the word “CANCELLED”:

(a) if the maximum number of times the prescription is to be dispensed is not clearly specified, or

(b) if (in the case of a prescription for an Appendix B substance) the intervals at which the substance may be supplied are not clearly specified, or

(c) if the prescription has reached the last occasion on which it can be supplied according to the maximum number of times specified on it.

Maximum penalty: 15 penalty units.

41 Prescriptions for certain substances to be kept (cf cl 44 of P&TG Reg 1994)

(1) A pharmacist who supplies an Appendix B substance on prescription must keep the prescription, whether or not the prescription authorises more than one supply of the substance.

(2) Prescriptions for Appendix B substances must be kept apart from other prescriptions (other than prescriptions for drugs of addiction).

Maximum penalty: 20 penalty units.

Subdivision 2 Supply without prescription

42 Supply by medical practitioners, nurse practitioners, midwife practitioners, dentists,

optometrists and veterinary practitioners (cf cl 45 of P&TG Reg 1994)

(1) A medical practitioner must not supply a restricted substance to any person otherwise than for medical treatment.

(2) A nurse practitioner must not supply a restricted substance to any person otherwise than in the course of practising as a nurse practitioner.

(2A) A midwife practitioner must not supply a restricted substance to any person otherwise than in the course of practising as a midwife practitioner.

(3) A dentist must not supply a restricted substance to any person otherwise than for dental treatment.

(3A) An optometrist must not supply a restricted substance to any person otherwise than in the course of practising as an optometrist.

(4) A veterinary practitioner must not supply a restricted substance to any person otherwise than for veterinary treatment.

Maximum penalty: 15 penalty units.

43 Emergency supply by pharmacists on direction of medical practitioners, nurse practitioners, midwife practitioners, dentists, optometrists or veterinary practitioners (cf cl 46 of P&TG Reg 1994)

(1) A pharmacist may supply a person with a restricted substance (including a prescribed restricted substance) in accordance with a direction given under clause 35.

(2) A prescription that is subsequently sent in confirmation of the direction must be dealt with in accordance with clauses 40 and 41, and details of the supply must be recorded in accordance with clause 54, in the same way as if the restricted substance had been supplied on prescription.

(3) If such a prescription is not received within 7 days after the substance is supplied, the pharmacist must report that fact to the Director-General.

Maximum penalty: 15 penalty units.

44 Emergency supply by pharmacists otherwise than on direction of medical practitioners, nurse practitioners, midwife practitioners, dentists or optometrists (cf cl 47 of P&TG Reg 1994)

(1) A pharmacist may supply a person with a restricted substance (other than a prescribed restricted substance) if the pharmacist is satisfied:

(a) that the person is undergoing treatment essential to the person’s well being, and

(b) that the substance has previously been prescribed for the treatment, and

(c) that the person is in immediate need of the substance for continuation of the treatment, and

(d) that, in the circumstances, it is not practicable for the person to obtain a prescription for the substance from a medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist.

(2) A restricted substance may not be supplied to any person under this clause unless:

(a) the quantity supplied is no more than that required for 3 days' treatment, or

(b) in the case of a liquid, aerosol, cream, ointment or anovulant tablet that is contained in a standard pack, the standard pack is the smallest standard pack in which that kind of liquid, aerosol, cream, ointment or anovulant tablet is generally available.

Maximum penalty: 15 penalty units.

45 Supply by pharmacists to medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner for emergency use (cf cl 48 of P&TG Reg 1994)

A pharmacist may supply a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner with a restricted substance (including a prescribed restricted substance) for emergency use, but only on a written order signed and dated by the medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner.

46 Supply by pharmacists to nursing homes of stock for emergency use (cf cl 47A of P&TG Reg 1994)

(1) A retail pharmacist may supply the chief nurse of a nursing home with a manufacturer's original pack of a relevant prescribed substance for emergency use at the nursing home in accordance with an authorisation by a medical practitioner, nurse practitioner, dentist or optometrist who prescribes substances to the nursing home's residents.

(2) A relevant prescribed substance may not be supplied under subclause (1) unless it is supplied in accordance with a written order signed by the chief nurse.

Maximum penalty: 15 penalty units.

(3) In this clause, ***relevant prescribed substance*** means a restricted substance (including a prescribed restricted substance) included in a list of substances determined for the time being by the Director-General for the purposes of this clause.

47 Supply by pharmacists of benzylpenicillin for use in animals (cf cl 67 of P&TG Reg 1994)

(1) This clause applies to benzylpenicillin, including procaine penicillin, in preparations for

use by intramuscular injection in animals.

(2) A pharmacist may supply benzylpenicillin otherwise than on prescription to a person who satisfies the pharmacist that it is needed for the urgent treatment of an animal and that, under the circumstances, it is not practicable to obtain a prescription authorising its supply.

(3) A pharmacist must not supply benzylpenicillin:

(a) to any person who is under 18 years of age, or

(b) to any person who is unknown to the pharmacist.

(4) Subclause (3) (b) does not prevent a pharmacist from supplying benzylpenicillin to a person who is unknown to the pharmacist if it is supplied in the presence of a person who is known to the pharmacist and who satisfies the pharmacist that he or she knows the person being supplied.

Subdivision 3 Supply in hospitals

48 Supply by pharmacists (cf cl 49 of P&TG Reg 1994)

A pharmacist at a hospital may supply a restricted substance:

(a) on a prescription issued in accordance with Division 3, or

(b) on the authorisation (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Director-General) of a medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist, where that authorisation is entered on a patient's medication chart, or

(c) on the requisition (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Director-General) of a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or the nurse in charge of the ward in which the substance is to be used or stored.

49 Supply in original containers: section 10 (cf cl 50 of P&TG Reg 1994)

(1) A person who supplies a restricted substance to a patient in a hospital, or to an inmate in an institution, in accordance with section 10 (4) (c) of the Act must supply the substance, unopened, in the container in which it was received by the person.

(2) This clause does not prevent the person from supplying an individual dose of the substance to the patient or inmate.

Maximum penalty: 15 penalty units.

Subdivision 4 Supply generally

50 Research drugs (cf cl 54 of P&TG Reg 1994)

(1) This clause applies to thalidomide other than as registered goods.

(2) A dealer must not supply thalidomide unless the person being supplied holds an authority under Part 8 to be supplied with thalidomide.

(3) This clause:

(a) does not prohibit a dealer from supplying thalidomide to a person who has the approval in writing of the Permanent Head of the Commonwealth Department of Health to import, buy, obtain or otherwise be supplied with thalidomide, and

(b) does not prohibit a person holding an authority under Part 8 to be supplied with thalidomide from supplying thalidomide to a person under his or her general supervision, for the purpose of enabling that other person to carry out medical diagnosis, or medical or scientific research or analysis (including the conduct of clinical trials), and

(c) does not prohibit a medical practitioner holding an authority under Part 8 to be supplied with thalidomide from supplying thalidomide to another person for the purpose of treating that other person in accordance with the authority.

(4) A person being supplied with thalidomide other than as registered goods (otherwise than as referred to in subclause (3) (c)) must surrender his or her authority to the dealer.

(5) A dealer must keep any authority surrendered to the dealer under this clause.

Maximum penalty: 15 penalty units.

51 Authority required to supply certain restricted substances (cf cl 55 of P&TG Reg 1994)

(1) This clause applies to the following substances:

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitrophin (human follicle stimulating hormone)

(2) A person must not supply a substance to which this clause applies unless the person holds an authority under Part 8 to supply the substance.

(3) This clause does not apply to the supply of a substance:

(a) by wholesale, or

(b) by a veterinary practitioner, or

(c) by a pharmacist on the prescription of:

(i) a medical practitioner holding an authority under Part 8 to prescribe the substance, or

(ii) a veterinary practitioner, or

(d) by a person who is authorised by the Permanent Head of the Commonwealth Department of Health to supply the substance.

Maximum penalty: 15 penalty units.

52 Restricted substances may be supplied by authorised persons (cf cl 56 of P&TG Reg 1994)

A person who is not a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner may supply a restricted substance to another person if the person by whom the substance is supplied holds an authority under Part 8 to supply the substance.

53 Quantity and purpose of supply to be appropriate (cf cl 57 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner or pharmacist must not supply any restricted substance in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty: 15 penalty units.

Division 5 Records of supply

54 Supply on prescription to be recorded (cf cl 58 of P&TG Reg 1994)

(1) A pharmacist who supplies a restricted substance on prescription must record the

following details in a manner approved by the Director-General:

(a) the details required by clause 34 (1) to be included in the prescription,

(b) a unique reference number for the prescription,

(c) the date on which the substance was supplied,

(d) the name of the person by whom the substance was supplied.

(2) A prescription for the supply of a restricted substance in a hospital need not be recorded so long as the chief pharmacist of the hospital keeps the prescription or a copy of the prescription.

Maximum penalty: 15 penalty units.

55 Records to be kept of supply of restricted substances by medical practitioners, nurse practitioners, midwife practitioners, dentists, optometrists and veterinary practitioners (cf cl 59 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner who supplies a restricted substance:

(a) must record the name, strength and quantity of the substance supplied and the date on which it was supplied, and

(b) must record the name and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner, and

(c) must keep the record of the supply of the substance at the hospital, surgery or office of the person supplying the substance.

Maximum penalty: 15 penalty units.

56 Certain supplies of restricted substances to be separately recorded (cf cl 60 of P&TG Reg 1994)

(1) A pharmacist who supplies a restricted substance as referred to in clause 44, or who supplies the restricted substance benzylpenicillin as referred to in clause 47, must record the following details of the supply in a manner approved by the Director-General:

(a) a unique reference number for the supply,

(b) the name and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner,

(c) the name, strength and quantity of the substance,

(d) the directions given by the pharmacist for the use of the substance,

(e) in the case of a restricted substance supplied as referred to in clause 44, the name and address of the medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist by whom it appears to the pharmacist that the substance was last prescribed,

(f) the date on which the substance was supplied,

(g) the name of the person by whom the substance was supplied.

Maximum penalty: 15 penalty units.

(2) A pharmacist who supplies a restricted substance as referred to in clause 45, or a relevant prescribed substance as referred to in clause 46, must record the following details of the supply in a manner approved by the Director-General:

(a) a unique reference number for the supply,

(b) the name and address of the person supplied,

(c) the name, strength and quantity of the substance,

(d) the date on which the substance was supplied,

(e) the name of the person by whom the substance was supplied.

Maximum penalty: 15 penalty units.

Division 6 Administration

57 Administration by persons employed at a hospital (cf cl 51 of P&TG Reg 1994)

(1) A person employed at a hospital must not administer a restricted substance to a patient in the hospital otherwise than on the direction of a medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist.

(2) Such a direction:

(a) must be given in writing (otherwise than by electronic mail or facsimile) or in any other manner approved by the Director-General for the purposes of this paragraph, or

(b) in an emergency, may be given:

(i) by electronic mail or by facsimile, or

(ii) orally, by telephone or in any other manner approved by the Director-General for the purposes of this subparagraph.

(3) A medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist who gives a direction under subclause (2) (b) (ii) must:

(a) as soon as is practicable (and in any case within the next 24 hours) either:

(i) sign an entry in the patient's medical history confirming that he or she has given the direction, or

(ii) confirm the direction by electronic mail or by facsimile, and

(b) attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

(4) If confirmation is not received within 7 days after the restricted substance is administered, the person by whom the substance was administered must report that fact to the Director-General.

(5) A medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist who, by electronic mail or by facsimile, gives or confirms a direction for the administration of a restricted substance to a patient must attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

(6) Subclauses (3), (4) and (5) do not apply to the administration of a restricted substance to an inmate of a correctional centre (within the meaning of the *Crimes (Administration of Sentences) Act 1999*) if confirmation of the direction for the administration of the substance has been given in accordance with the requirements of a protocol approved by the Director-General.

Maximum penalty: 15 penalty units.

58 Administration of prescribed restricted substances (cf cl 52 of P&TG Reg 1994)

(1) A person must not self-administer a prescribed restricted substance, or administer a prescribed restricted substance to any other person, otherwise than:

(a) for the purposes of medical treatment prescribed by a medical practitioner, or

(b) for the purposes of dental treatment prescribed by a dentist, or

(c) for the purposes of treatment prescribed by a nurse practitioner in the course of practising as a nurse practitioner, or

(d) for the purposes of treatment prescribed by a midwife practitioner in the course of practising as a midwife practitioner, or

(e) for the purposes of treatment prescribed by an optometrist in the course of practising as an optometrist.

Maximum penalty: 20 penalty units.

(2) For the purposes of subclause (1), it is sufficient if the treatment referred to in subclause (1) (a) or (b) in relation to the self-administration of a prescribed restricted

substance has been prescribed by the person by whom the substance is being self-administered.

(3) This clause has effect for the purposes of Division 1 of Part 2 of the *Drug Misuse and Trafficking Act 1985* in relation to any prescribed restricted substance that is included in Schedule 1 to that Act.

59 Authority required to administer certain restricted substances (cf cl 53 of P&TG Reg 1994)

(1) This clause applies to the following restricted substances:

acitretin

clomiphene

cyclofenil

dinoprost

dinoprostone

etretinate

follitropin beta

isotretinoin for oral use

luteinising hormone

tretinoin for oral use

urofollitrophin (human follicle stimulating hormone)

(2) A person must not administer a restricted substance to which this clause applies unless the person holds an authority under Part 8 to administer the substance.

(3) This clause does not apply to:

(a) the administration to a patient of a substance whose administration has been prescribed or directed by a medical practitioner holding an authority under Part 8 to prescribe the substance, or

(b) the administration of a substance to an animal by a veterinary practitioner or by a person acting under the general supervision of a veterinary practitioner.

Maximum penalty: 15 penalty units.

Division 7 Miscellaneous

60 Prescribed restricted substances: sections 9, 10, 11, 16, 18 and 18A (cf cl 62 of P&TG Reg

1994)

(1) For the purposes of section 16 of the Act, the substances specified in Appendix D are prescribed restricted substances.

(2) The substances specified in Appendix D are also restricted substances for the purposes of sections 9, 10, 11 and 18 of the Act, as referred to in paragraph (a) of the matter specified at the end of sections 9 (1), 10 (3), 11 (1) and 18 of the Act with respect to penalties.

(3) For the purposes of section 18A (1) of the Act, the quantities specified in Appendix D are the prescribed quantities for the corresponding restricted substances specified in that Appendix.

61 Authorised persons: section 16 (1) (e) (cf cl 63 of P&TG Reg 1994)

For the purposes of section 16 (1) (e) of the Act, the following persons are authorised to obtain possession of prescribed restricted substances for the purposes of their profession or employment:

(a) the chief nurse of a hospital that does not employ a chief pharmacist,

(b) the master of a ship, in respect of a therapeutic substance that is required by law to be carried on the ship,

(c) the holder of a licence under Part 8 to manufacture or supply drugs of addiction,

(d) an analyst,

(e) a scientifically qualified person in charge of a laboratory or department, being a person who is engaged in medical or scientific research or instruction, or in quality control or analysis,

(f) a person acting under the direct personal supervision of a person referred to in paragraph (d) or (e).

62 Disclosure of other prescribed restricted substances obtained or prescribed (cf cl 64 of P&TG Reg 1994)

(1) A person who asks a medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist:

(a) to supply the person with a prescribed restricted substance, or

(b) to give the person a prescription for a prescribed restricted substance,

must disclose to the medical practitioner, nurse practitioner, midwife practitioner, dentist or optometrist the quantity of that and any other prescribed restricted substance with which the person has been supplied, or for which the person has been

given prescriptions, within the last 2 months.

(2) If the request is made on behalf of some other person, the person making the request is obliged only to furnish such information as is within that person's knowledge.

Maximum penalty: 20 penalty units.

63 Delivery by carrier (cf cl 65 of P&TG Reg 1994)

A carrier is authorised to be in possession of a package containing a prescribed restricted substance, but for the purpose only of delivering it to the person to whom it is addressed.

64 Pentobarbitone sodium (cf cl 66 of P&TG Reg 1994)

(1) This clause applies to pentobarbitone sodium to the extent only to which it is a restricted substance, and not to the extent to which it is a drug of addiction.

(2) An authorised person who uses pentobarbitone sodium for the destruction of animals must ensure that the requirements of this clause are complied with.

(3) Pentobarbitone sodium must be kept separately from all other goods in a safe, cupboard or other receptacle:

(a) that is securely attached to a part of the premises, and

(b) that is kept securely locked except when in immediate use.

(4) An authorised person must keep a separate register of all pentobarbitone sodium that is obtained or used by the authorised person.

(5) On the day on which an authorised person obtains or uses any pentobarbitone sodium, the authorised person must enter in the register such of the following details as are relevant to the transaction:

(a) the quantity that was obtained or used,

(b) the name and address of the person from whom it was obtained,

(c) the number and species of animals for which it was used,

(d) the total quantity held by the authorised person after the entry is made.

(6) Each entry must be dated and signed by the authorised person.

(7) In this clause, ***authorised person*** means:

(a) a person nominated by the council of a local government area, or

(b) an officer of an animal welfare organisation nominated by the organisation,

being in either case a person who is authorised under section 16 (1) (d) of the Act to

obtain possession of pentobarbitone sodium for the humane destruction of animals.

Maximum penalty: 20 penalty units.

65 Restricted substances to be used or disposed of safely (cf cl 68 of P&TG Reg 1994)

A person must not use or dispose of a restricted substance in any place or in any manner likely to constitute a risk to the public.

Maximum penalty: 15 penalty units.

66 Loss or theft of prescribed restricted substances (cf cl 70 of P&TG Reg 1994)

(1) A person must immediately notify the Director-General if the person loses a prescribed restricted substance or if a prescribed restricted substance is stolen from the person.

(2) This clause does not apply to the loss of any substance by, or the theft of any substance from, a person who has been supplied with the substance by, or on the prescription of, a medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist or veterinary practitioner.

Maximum penalty: 20 penalty units.

67 Forfeiture of prescribed restricted substances (cf cl 71 of P&TG Reg 1994)

The court before which a person is convicted of the illegal possession of a prescribed restricted substance may order that the substance be forfeited to the Crown, and may further order the forfeited substance to be destroyed or otherwise disposed of as the court thinks fit.

Part 4 Drugs of addiction (S8)

Division 1 Packaging and labelling

68 Packaging and labelling generally (cf cl 72 of P&TG Reg 1994)

(1) A dealer who supplies a drug of addiction must ensure that the drug is packaged and labelled:

(a) in accordance with the relevant provisions of the current Poisons Standard, and

(b) in the case of a drug of addiction to which *Therapeutic Goods Order No 20* applies, in accordance with that Order.

(2) Despite subclause (1), a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner who supplies a drug of addiction must ensure that the drug is packaged in accordance with the requirements of that subclause but labelled in accordance with the requirements of Appendix A.

(3) A pharmacist who supplies any quantity of a drug of addiction on prescription must ensure that the drug is supplied in a package that is labelled in accordance with the requirements of Appendix A instead of in accordance with the requirements of subclause (1).

Maximum penalty: 10 penalty units.

69 Misleading labelling of substances as drugs of addiction (cf cl 73 of P&TG Reg 1994)

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a drug of addiction, unless the substance is such a drug.

Maximum penalty: 10 penalty units.

70 Packages to be sealed so that broken seal is readily distinguishable (cf cl 74 of P&TG Reg 1994)

(1) A dealer who supplies any drug of addiction must ensure that the drug is packaged in such a way that:

(a) its container is so sealed that, when the seal is broken, it is readily distinguishable from sealed containers, and

(b) if several containers are enclosed in a single primary pack, the primary pack is so sealed that, when the seal is broken, it is readily distinguishable from sealed primary packs.

(2) This clause does not apply to the supply of a drug of addiction:

(a) by a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner in the practice of his or her profession, or

(b) by a pharmacist on the prescription of a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner, or

(c) by a pharmacist employed at a hospital, on the written requisition of a medical practitioner, nurse practitioner, midwife practitioner, dentist or the nurse in charge of the ward in which the drug is to be used or stored, or

(d) by a nurse on the direction in writing of a medical practitioner, nurse practitioner, midwife practitioner or dentist.

Maximum penalty: 20 penalty units.

71 Exemptions (cf cl 75 of P&TG Reg 1994)

(1) The Director-General may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of this Division.

(2) Such an exemption may be given unconditionally or subject to conditions.

(3) Subject to subclause (4), any exemption in force under a law of the Commonwealth, or of another State or Territory, corresponding to this clause has the same effect as an exemption under this clause.

(4) The Director-General may, by order published in the Gazette, declare that subclause (3) does not have effect with respect to an exemption specified in the order.

Division 2 Storage

72 Storage generally

(1) A person who is in possession of any drug of addiction must keep the drug:

(a) in his or her possession stored apart from all other goods (other than cash or documents) in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use, or

(b) stored in any other manner approved by the Director-General for the particular person or class of persons to which the person belongs.

(2) A person who is a medical practitioner, nurse practitioner, midwife practitioner, dentist, veterinary practitioner or a person referred to in clause 101 (1) (g) is taken to comply with subclause (1) (a) if he or she keeps any drug of addiction (for use in an emergency only) in a bag that is in a room, or in a vehicle, kept locked when not occupied by the person.

Maximum penalty: 20 penalty units.

73 Responsibility for storage in hospitals (cf cl 77 of P&TG Reg 1994)

(1) The chief pharmacist of a hospital is responsible for the storage of all drugs of addiction at a hospital other than those that have been supplied to a ward.

(2) In the case of a hospital for which there is no pharmacist, the responsibilities of a chief pharmacist under this clause are instead the responsibilities of:

(a) the chief nurse of the hospital, or

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

(3) The nurse in charge of a hospital ward is responsible for the storage of all drugs of addiction in the ward.

74 Storage in hospital wards (cf cl 77A of P&TG Reg 1994)

(1) Drugs of addiction that are kept in a hospital ward must be stored apart from all other

goods (other than prescribed restricted substances) in a separate room, safe, cupboard or other receptacle securely attached to a part of the ward and kept securely locked when not in immediate use.

(2) The nurse in charge of a hospital ward must ensure that:

(a) the room, safe, cupboard or receptacle is kept securely locked when not in immediate use, and

(b) any key or other device by means of which the room, safe, cupboard or receptacle may be unlocked:

(i) is kept on the person of a nurse whenever it is in the ward, and is removed from the ward whenever there is no nurse in the ward, or

(ii) is kept in a separately locked safe to which only a nurse has access, and

(c) any code or combination that is required to unlock the room, safe, cupboard or receptacle is not divulged to any unauthorised person.

Maximum penalty: 20 penalty units.

75 Storage in pharmacies (cf cl 78 of P&TG Reg 1994)

(1) The pharmacist for the time being in charge of a pharmacy must keep any drug of addiction stored apart from other substances or goods (other than cash or documents) in a separate safe.

(2) Unless otherwise approved for the time being by the Director-General, such a safe must comply with the following requirements:

(a) it must be made of black mild steel plate at least 9 millimetres thick with continuous welding along all edges,

(b) it must be fitted with a door made of mild steel plate at least 9 millimetres thick, the door being flush fitting with a clearance around the door of not more than 1.5 millimetres,

(c) it must have a fixed locking bar, welded to the inside face of the door near the hinged edge, that engages in a rebate in the safe body when the door is closed,

(d) it must be fitted with a five lever key lock (or a locking mechanism providing at least equivalent security) securely fixed to the rear face of the door,

(e) if mounted on a brick or concrete wall or floor, it must be attached to the wall or floor by means of suitably sized expanding bolts through holes 9 millimetres in diameter drilled in the rear or bottom of the safe,

(f) if mounted on a timber framed wall or floor, it must be attached to the wall or floor

frame by means of suitably sized coachscrews through holes 9 millimetres in diameter drilled in the rear or bottom of the safe,

(g) if mounted on any other kind of wall or floor, it must be attached to the wall or floor in a manner approved for the time being by the Director-General.

(3) The pharmacist must ensure that:

(a) the safe is kept securely locked when not in immediate use, and

(b) any key or other device by means of which the safe may be unlocked:

(i) is kept on the person of a pharmacist whenever it is on the same premises as the safe, and is removed from the premises whenever there is no pharmacist at those premises, or

(ii) is kept in a separately locked safe to which only a pharmacist has access, and

(c) any code or combination that is required to unlock the safe is not divulged to any unauthorised person.

(4) This clause applies to a hospital pharmacy as well as to a retail pharmacy.

Maximum penalty: 20 penalty units.

Division 3 Prescriptions

76 Unauthorised persons not to prescribe drugs of addiction (cf cl 79 of P&TG Reg 1994)

(1) A person must not issue a prescription for a drug of addiction unless authorised to do so by this clause.

(2) A medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner may issue a prescription for a drug of addiction.

Maximum penalty: 20 penalty units.

77 Form of prescription (cf cl 82 of P&TG Reg 1994)

(1) A person who issues a prescription for a drug of addiction must ensure that the prescription includes the following details:

(a) the date on which it is issued,

(b) the name and address of the patient or (if the treatment is for an animal) the species of animal and the name and address of the animal's owner,

(c) the name, strength and quantity (expressed in both words and figures) of the drug to be supplied,

(d) adequate directions for use,

(e) the maximum number of times the drug may be supplied on the prescription,

(f) the intervals at which the drug may be supplied on the prescription,

(g) if the prescription is issued at a hospital, the name and designation of the person by whom it is issued and the name, address and telephone number of the hospital,

(h) if the prescription is issued elsewhere than at a hospital, the name and designation of the person by whom it is issued and the address and telephone number of the premises at which it is issued.

(2) The details referred to in subclause (1) (a)–(f) must be made out:

(a) in the handwriting of the person by whom the prescription is issued, or

(b) in such other manner as may be approved for the time being by the Director-General,

and the prescription must be signed by the person by whom it is issued.

(3) The person by whom the prescription is issued must confirm any dose that could be regarded as being dangerous or unusual by underlining the part of the prescription that specifies the intended dose and by initialling the prescription in the margin.

(4) A person must not issue a prescription that includes:

(a) more than one preparation containing a drug of addiction, or

(b) both a preparation containing a drug of addiction and another preparation.

Maximum penalty: 20 penalty units.

78 Prescriptions may only be issued for certain purposes (cf cl 80 of P&TG Reg 1994)

(1) A medical practitioner must not issue a prescription for a drug of addiction otherwise than for medical treatment.

(1A) A nurse practitioner must not issue a prescription for a drug of addiction otherwise than in the course of practising as a nurse practitioner.

(1B) A midwife practitioner must not issue a prescription for a drug of addiction otherwise than in the course of practising as a midwife practitioner.

(2) A dentist must not issue a prescription for a drug of addiction otherwise than for the dental treatment (for a period not exceeding one month’s continuous treatment) of a patient and must endorse any such prescription with the words “FOR DENTAL TREATMENT ONLY”.

(3) If the patient is in a hospital, the dentist may issue a prescription for any drug of addiction.

(4) If the patient is not in a hospital, the dentist may issue a prescription only:

(a) for pentazocine, or

(b) for any drug of addiction included in the list of preparations that may be prescribed by participating dental practitioners for dental treatment only set out in the *Schedule of Pharmaceutical Benefits* issued by the Commonwealth Department of Health, as that Schedule is in force from time to time.

(5) A veterinary practitioner must not issue a prescription for a drug of addiction otherwise than for veterinary treatment, and must endorse any such prescription with the words “FOR ANIMAL TREATMENT ONLY”.

Maximum penalty: 20 penalty units.

79 Quantity and purpose of prescriptions to be appropriate (cf cl 81 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner must not issue a prescription for a drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty: 20 penalty units.

80 Emergency prescriptions may be given by telephone or otherwise (cf cl 83 of P&TG Reg 1994)

(1) In an emergency, a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner may direct the supply of a drug of addiction orally, by telephone, by electronic mail or by facsimile.

(2) A person who so directs the supply of a drug of addiction:

(a) must immediately make out a prescription, and

(b) must send the prescription without delay (and in any case within 24 hours) to the person to whom the direction was given.

(3) A person who issues a prescription under this clause must ensure that the prescription is endorsed with words that indicate the prescription has been issued in confirmation of a direction under this clause.

(4) This clause does not apply to a direction given under clause 119.

Maximum penalty: 20 penalty units.

81 Records of prescriptions (cf cl 84 of P&TG Reg 1994)

(1) A medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner who prescribes a drug of addiction must make a record of the following particulars:

(a) the name, strength and quantity of the drug prescribed and the date on which it was prescribed,

(b) if the drug is intended for the treatment of a person, the name and address of the person to be treated,

(c) if the drug is intended for the treatment of an animal, the species of animal and the name and address of the animal's owner,

(d) the maximum number of times the drug may be supplied on the prescription,

(e) the intervals at which the substance may be supplied on the prescription,

(f) the directions for use, as shown on the prescription.

(2) The record must be kept at the surgery, hospital or office of the person prescribing the substance.

Maximum penalty: 20 penalty units.

82 Exceptions to section 28: prescriptions generally (cf cl 86 of P&TG Reg 1994)

(1) A medical practitioner or nurse practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if:

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the use of the drug in the course of treatment as an in-patient in a public or private hospital, and

(b) the prescription is for a course of treatment for a period of not more than 14 days following the person's admission as an in-patient.

(2) A medical practitioner or nurse practitioner is authorised to issue a prescription for a drug of addiction for a person for continuous therapeutic use by that person for a period of up to 12 months without an authority under section 29 of the Act if:

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and

(b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia, or who is approved by the Director-General for the purposes of this

paragraph, has made the diagnosis of cancer, and

(c) either the medical practitioner referred to in paragraph (a) or a medical practitioner referred to in paragraph (b) has estimated the person's life expectancy to be 12 months or less.

(3) Subclause (2) does not authorise a medical practitioner or nurse practitioner to prescribe the following drugs of addiction in the circumstances referred to in that subclause:

dextromoramide (all forms)

fentanyl (all forms, except transdermal patches)

pethidine (parenteral forms only)

(4) A medical practitioner or nurse practitioner is authorised to prescribe methadone or buprenorphine for the treatment of a person without an authority under section 29 of the Act if:

(a) in the case of a medical practitioner, the medical practitioner is approved as a prescriber of drugs of addiction under section 28A of the Act and, in the case of a nurse practitioner, the nurse practitioner is authorised by the Director-General for the purposes of this clause, and

(b) at the time the prescription is issued the person is, or at some time during the preceding 21 days was, an inmate in a correctional centre (within the meaning of the *Crimes (Administration of Sentences) Act 1999*), and

(c) the prescription is for methadone or buprenorphine in oral dosage form for use by the person as a course of treatment:

(i) while an inmate, or

(ii) during a period of not more than 21 days after release, and

(d) immediately before the person became an inmate, a medical practitioner or nurse practitioner had an authority under section 29 of the Act to prescribe methadone or buprenorphine for the person, or supply methadone or buprenorphine to the person, and

(e) the prescription is issued for the purpose of continuing the treatment that the person was receiving or was about to receive immediately before the person became an inmate.

(5) A medical practitioner or nurse practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if:

(a) the person is the subject of such an authority, and

(b) the medical practitioner or nurse practitioner is practising at the same premises as the holder of that authority, and

(c) the prescription is issued in accordance with any conditions to which that authority is subject.

83 Exceptions to section 28: prescriptions for amphetamines (cf cl 85 of P&TG Reg 1994)

(1) This clause applies to the following substances:

amphetamine

dexamphetamine

methylamphetamine

methylphenidate

phendimetrazine

phenmetrazine

(2) A medical practitioner is authorised to issue a prescription for dexamphetamine or methylphenidate for a person without an authority under section 29 of the Act:

(a) for the purpose of testing the suitability of the person to undergo a course of medical treatment involving the use of such a substance, or

(b) for the purpose of treating the person for attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD),

so long as the medical practitioner holds an authority under Part 8 to prescribe such a substance.

(3) A nurse practitioner, midwife practitioner, dentist or veterinary practitioner must not issue a prescription for a substance to which this clause applies.

Maximum penalty: 20 penalty units.

Division 4 Supply

Subdivision 1 Supply on prescription

84 Pharmacists may supply drugs of addiction on prescription (cf cl 87 of P&TG Reg 1994)

A pharmacist may supply a drug of addiction on prescription.

Maximum penalty: 20 penalty units.

85 Prescriptions may be filled only if in proper form (cf cl 88 of P&TG Reg 1994)

(1) A pharmacist must not supply a drug of addiction on prescription unless the prescription is in the form required by Division 3.

(2) This clause does not prevent a pharmacist from supplying a drug of addiction on prescription merely because the prescription fails to specify the maximum number of times, or the intervals at which, the drug may be supplied.

(3) A pharmacist must not supply a drug of addiction more than once on a prescription referred to in subclause (2), regardless of how many times the prescription purports to authorise the supply of the drug.

Maximum penalty: 20 penalty units.

86 Certain prescriptions not to be filled (cf cl 89 of P&TG Reg 1994)

(1) A pharmacist must not supply a drug of addiction on prescription:

(a) if the prescription is marked “CANCELLED”, or

(b) if the drug has already been supplied on the prescription the maximum number of times indicated by the prescription, or

(c) if the interval of time that has elapsed since the drug was last supplied on the prescription is less than that indicated by the prescription as the minimum interval that must elapse between successive supplies of the drug, or

(d) if the prescription is illegible or defaced, or

(e) if the prescription is dated more than 6 months before the date on which the supply is being requested, or

(f) if the prescription appears to have been forged or fraudulently obtained, or

(g) if the prescription appears to have been altered otherwise than by the medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner by whom it was issued, or

(h) if notice of an order prohibiting the person by whom the prescription was issued from issuing such a prescription has been published in the Gazette, unless the prescription contains a direction for the supply of the drug more than once and it appears that the drug has been supplied on the basis of the prescription at least once before the notice was published.

(2) Immediately on being requested to supply a drug of addiction in any of the circumstances referred to in subclause (1) (f), (g) or (h), a pharmacist must retain the prescription and cause notice of the request to be given to a police officer.

Maximum penalty: 15 penalty units.

(3) A pharmacist must not supply a drug of addiction on a prescription that includes:

(a) more than one preparation containing a drug of addiction, or

(b) both a preparation containing a drug of addiction and another preparation.

Maximum penalty: 20 penalty units.

87 Prescriptions require verification (cf cl 90 of P&TG Reg 1994)

(1) A pharmacist must not supply a drug of addiction on prescription unless he or she:

(a) is familiar with the handwriting of the person who issued the prescription, or

(b) knows the person for whom the drug is prescribed, or

(c) has verified that the person who is purported to have issued the prescription has actually issued the prescription.

(2) This clause does not prevent a pharmacist who is otherwise authorised to supply drugs of addiction from supplying a drug of addiction on prescription in a quantity sufficient for no more than 2 days' treatment.

Maximum penalty: 20 penalty units.

88 Prescriptions to be endorsed (cf cl 91 of P&TG Reg 1994)

(1) A person who supplies a drug of addiction on prescription must (on each occasion the drug is supplied) endorse the following particulars (in ink) on the prescription:

(a) the date on which the drug was supplied,

(b) the address of the place at which the drug was supplied,

(c) the prescription reference number.

(2) A person who supplies a drug of addiction on prescription must endorse (in ink) across the prescription the word "CANCELLED":

(a) if the maximum number of times the prescription is to be dispensed is not clearly specified, or

(b) if the intervals at which the drug may be supplied are not clearly specified, or

(c) if the prescription has reached the last occasion on which it can be supplied according to the maximum number of times specified on it.

Maximum penalty: 20 penalty units.

89 Prescriptions to be kept (cf cl 92 of P&TG Reg 1994)

(1) A pharmacist who supplies a drug of addiction on prescription must keep the prescription, whether or not the prescription authorises more than one supply of the drug.

(2) Prescriptions for drugs of addiction must be kept apart from other prescriptions (other than prescriptions for Appendix B substances).

Maximum penalty: 20 penalty units.

90 Supply by pharmacists of amphetamines (cf cl 93 of P&TG Reg 1994)

(1) This clause applies to the following substances:

amphetamine

dexamphetamine

methylamphetamine

methylphenidate

phendimetrazine

phenmetrazine

(2) A pharmacist must not supply such a substance on prescription unless the reference number of the authority to issue the prescription (whether given under section 29 of the Act or Part 8 of this Regulation) is shown on the prescription.

91 Records to be kept by pharmacists of methadone or buprenorphine prescriptions (cf cl 93A of P&TG Reg 1994)

(1) A pharmacist at a retail pharmacy who supplies any person with methadone in oral liquid form or buprenorphine tablets on a prescription for the treatment of drug dependence must keep a record of the supply in accordance with this clause.

Maximum penalty: 20 penalty units.

(2) A record under this clause must contain the following particulars:

(a) the name of the person to whom the supply was made,

(b) the number of the prescription on which the supply was made,

(c) the name of the person who gave the prescription,

(d) the amount of methadone in oral liquid form or buprenorphine tablets supplied,

(e) the date on which the supply occurred,

(f) if the whole or part of the methadone in oral liquid form or buprenorphine tablets was supplied for consumption on a different day to that on which it was supplied, the day or days on which it is to be consumed and the amount to be consumed on that day or on each of those days.

(3) Records made under this clause in relation to a particular pharmacy are to be made in writing in a book in which all such records for the pharmacy are kept.

(4) The Director-General may from time to time approve the keeping of records under this clause in any other form.

(5) A record made under this clause must be kept for at least 2 years from the date on which it is made.

92 Supply by pharmacists of methadone or buprenorphine tablets (cf cl 93B of P&TG Reg 1994)

(1) A pharmacist at a retail pharmacy must not, on any particular day, supply any person with methadone in oral liquid form or buprenorphine tablets on a prescription for the treatment of drug dependence if that supply would result in more than 50 persons having been supplied with methadone in oral liquid form or buprenorphine tablets on prescription at that pharmacy on that day.

Maximum penalty: 20 penalty units.

(2) For the purposes of subclause (1), if an amount of methadone in oral liquid form or buprenorphine tablets is or are supplied for consumption on a day other than the day on which it is supplied, the supply of that amount is taken to have occurred on the day on which the amount is to be consumed.

(3) Subclause (1) does not apply to the supply of methadone in oral liquid form or buprenorphine tablets at a pharmacy in accordance with:

(a) an exemption granted under clause 93, or

(b) a licence issued under Division 2 of Part 8.

93 Exemptions relating to methadone or buprenorphine supply at pharmacies (cf cl 93C of P&TG Reg 1994)

(1) The owner of a pharmacy may apply in writing to the Director-General for an exemption from clause 92 (1) in relation to the pharmacy.

(2) The Director-General may require the owner of the pharmacy to furnish such information as is necessary to enable the Director-General to determine the application.

(3) The Director-General may, by notice in writing served on the owner of the pharmacy, grant the exemption or refuse to grant the exemption.

(4) An exemption is subject to such conditions as may be specified in the notice referred to in subclause (3) and to such further conditions as the Director-General may from time to time notify in writing to the holder of the exemption.

(5) The Director-General may from time to time vary or revoke any condition of an exemption by notice in writing served on the holder of the exemption.

(6) An exemption remains in force until:

(a) the expiry date (if any) specified in the exemption, or

(b) it is surrendered or cancelled,

whichever occurs first.

(7) The Director-General may, if the Director-General sees fit, suspend or cancel an exemption by notice in writing served on the holder of the exemption.

(8) An exemption has no effect during any period of suspension.

(9) For the removal of doubt, an exemption is not a licence or authority for the purposes of this Regulation.

94 Exceptions to section 28: supply (cf cl 94 of P&TG Reg 1994)

(1) A medical practitioner or nurse practitioner is authorised to supply a drug of addiction for a person without an authority under section 29 of the Act if:

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the use of the drug in the course of treatment as an in-patient in a public or private hospital, and

(b) the supply is for a course of treatment for a period of not more than 14 days following the person's admission as an in-patient.

(2) A medical practitioner or nurse practitioner is authorised to supply a drug of addiction for a person, for continuous therapeutic use by that person for a period of up to 12 months, without an authority under section 29 of the Act if:

(a) the medical practitioner or nurse practitioner is of the opinion that the person requires the drug for the relief of pain associated with cancer, and

(b) a medical practitioner (whether or not the medical practitioner referred to in paragraph (a)) whose qualifications in the diagnosis and treatment of cancer are recognised by the National Specialist Qualification Advisory Committee of Australia, or who is approved by the Director-General for the purposes of this paragraph, has made the diagnosis of cancer, and

(c) either the medical practitioner referred to in paragraph (a) or a medical

practitioner referred to in paragraph (b) has estimated the person's life expectancy to be 12 months or less.

(3) Subclause (2) does not authorise a medical practitioner or nurse practitioner to supply the following drugs of addiction in the circumstances referred to in that subclause:

dextromoramide (all forms)

fentanyl (all forms, except transdermal patches)

pethidine (parenteral forms only)

(4) A medical practitioner or nurse practitioner is authorised to supply methadone or buprenorphine to a person without an authority under section 29 of the Act if:

(a) in the case of a medical practitioner, the medical practitioner is approved as a prescriber of drugs of addiction under section 28A of the Act and in the case of a nurse practitioner, the nurse practitioner is authorised by the Director-General for the purposes of this clause, and

(b) the person is an inmate in a correctional centre (within the meaning of the *Crimes (Administration of Sentences) Act 1999*), and

(c) the methadone or buprenorphine is supplied in oral dosage form for use by the person as a course of treatment while an inmate, and

(d) immediately before the person became an inmate, a medical practitioner or nurse practitioner had an authority under section 29 of the Act to prescribe methadone or buprenorphine for the person, or supply methadone or buprenorphine to the person, and

(e) the methadone or buprenorphine is supplied for the purpose of continuing the treatment that the person was receiving or was about to receive immediately before the person became an inmate.

(5) A medical practitioner or nurse practitioner is authorised to supply a drug of addiction to a person without an authority under section 29 of the Act if:

(a) the person is the subject of such an authority, and

(b) the medical practitioner or nurse practitioner is practising at the same premises as the holder of that authority, and

(c) the supply is in accordance with any conditions to which that authority is subject.

Subdivision 2 Supply without prescription

95 Supply to be on the basis of a written order (cf cl 95 of P&TG Reg 1994)

(1) A person who is authorised to supply drugs of addiction (whether by this Division or by an authority or licence under Part 8) may supply a drug of addiction:

(a) to any person who is authorised to have possession of such a drug of addiction, or

(b) to any other person if the other person is in possession of a certificate, signed by a person so authorised, to the effect that the other person is authorised to obtain the drug of addiction on behalf of the person so authorised.

(2) A supplier may supply drugs of addiction under this clause on the basis of a written order signed by a person so authorised or on the basis of an order received from such a person by telephone, electronic mail or facsimile.

(3) A person who orders a drug of addiction by telephone, electronic mail or facsimile must, within 24 hours after doing so, send written confirmation of the order to the supplier.

(4) If a supplier who supplies a drug of addiction on the basis of an order received by telephone, electronic mail or facsimile does not receive written confirmation of the order within 7 days after the drug was supplied, the supplier must report that fact to the Director-General.

(5) A person who supplies a drug of addiction in accordance with this clause must keep and cancel the relevant order and (if the drug is supplied as referred to in subclause (1) (b)) the relevant certificate.

Maximum penalty: 20 penalty units.

96 Emergency supply by pharmacists (cf cl 96 of P&TG Reg 1994)

(1) A pharmacist may supply a person with a drug of addiction in accordance with a direction given under clause 80.

(2) A pharmacist who supplies a drug of addiction in accordance with this clause:

(a) must keep and cancel the prescription that is subsequently sent in confirmation of the direction, or

(b) if such a prescription is not received within 7 days after the drug is supplied, must report that fact to the Director-General.

Maximum penalty: 20 penalty units.

97 Supply by pharmacists for emergency purposes (cf cl 97 of P&TG Reg 1994)

A pharmacist may supply a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner with a drug of addiction for emergency use, but only on a written order signed and dated by the medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner.

98 Supply of amphetamines (cf cl 98 of P&TG Reg 1994)

(1) This clause applies to the following substances:

amphetamine

dexamphetamine

methylamphetamine

methylphenidate

phendimetrazine

phenmetrazine

(2) A medical practitioner does not require an authority under section 29 of the Act to supply dexamphetamine or methylphenidate to a person for the purpose of testing the suitability of the person to undergo a course of medical treatment involving the use of such a substance so long as the medical practitioner holds an authority under Part 8 to supply such a substance.

(3) A nurse practitioner, midwife practitioner, dentist or veterinary practitioner is not authorised to supply any substance to which this clause applies.

(4) This clause does not prevent a veterinary practitioner from supplying methylphenidate in solid dosage form to a person for the treatment of an animal.

Subdivision 3 Supply in hospitals

99 Supply by pharmacists (cf cl 99 of P&TG Reg 1994)

(1) A pharmacist employed at a hospital may supply a drug of addiction from the pharmacy department of the hospital:

(a) on a prescription issued in accordance with Division 3, or

(b) on the authorisation (whether in writing, by electronic mail, by facsimile or by any other form of electronic communication approved by the Director-General) of a medical practitioner, nurse practitioner, midwife practitioner or dentist, where that authorisation is entered on a patient's medication chart, or

(c) on the requisition (whether in writing, by electronic mail, by facsimile or by any

other form of electronic communication approved by the Director-General) of a medical practitioner, nurse practitioner, midwife practitioner or dentist or of the nurse in charge of the ward in which the drug is to be used or stored.

(2) The person delivering a drug of addiction to a ward from the pharmacy department of the hospital must obtain a receipt, dated and signed, from the person to whom the drug is delivered.

Maximum penalty: 20 penalty units.

Subdivision 4 Supply generally

100 Unauthorised manufacture and supply of drugs of addiction prohibited (cf cl 102 of P&TG Reg 1994)

(1) A person must not manufacture or supply a drug of addiction unless the person is authorised to do so by this Division or by an authority or licence under Part 8.

(2) This Division does not authorise a person to manufacture or supply drugs of addiction in contravention of any prohibition or restriction to which the person is otherwise subject.

Maximum penalty: 20 penalty units.

101 Possession of drugs of addiction by medical practitioners, nurse practitioners, midwife practitioners, dentists, veterinary practitioners and hospital pharmacists (cf cl 103 of P&TG Reg 1994)

(1) The following persons are authorised to have possession of, and to supply, drugs of addiction:

(a) a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner,

(b) the chief pharmacist of, and any pharmacist employed in dispensing medicines at, any public hospital or other public institution,

(c) the chief nurse of a hospital in which a pharmacist is not employed,

(d) the nurse in charge of a ward in a public hospital,

(e) a nurse who is approved for the time being by the Director-General for the purposes of this clause, or who belongs to a class of nurses so approved,

(f) any other nurse, but for the purpose only of administering doses of such drugs to individual patients in a hospital,

(g) a person:

(i) who is employed by the Ambulance Service of New South Wales as an

ambulance officer or as an air ambulance flight nurse, and

(ii) who is approved for the time being by the Ambulance Service of New South Wales for the purposes of this clause.

(2) The following persons are authorised to have possession of (but not to supply) drugs of addiction:

(a) a person in charge of a laboratory used for the purpose of analysis, research or instruction, being a person who is approved for the time being by the Director-General for the purposes of this clause,

(b) an analyst,

(c) a person acting under the direct personal supervision of a person referred to in paragraph (a) or (b).

(3) This clause authorises a person referred to in subclause (1) or (2) to have possession of, or to supply, drugs of addiction for the purpose only of the lawful practice of the person's profession or occupation.

(4) This clause does not authorise any person to have possession of, or to supply, hallucinogens.

(5) This clause does not authorise a nurse practitioner, midwife practitioner, dentist or veterinary practitioner to have possession of, or to supply, any of the following substances:

amphetamine

dexamphetamine

methylamphetamine

methylphenidate (other than methylphenidate in solid dosage form)

phendimetrazine

phenmetrazine

102 Possession of drugs of addiction by retail pharmacists (cf cl 104 of P&TG Reg 1994)

(1) A retail pharmacist is authorised:

(a) to have possession of drugs of addiction, and

(b) to manufacture drugs of addiction and any preparation, admixture or extract of a drug of addiction, and

(c) to supply a drug of addiction:

(i) to a person who has a prescription for the drug, or

(ii) to the chief nurse of a private hospital or nursing home,

but only if he or she does so at the premises of, and in the course of carrying on the business of, the pharmacy.

(2) A retail pharmacist must not supply a drug of addiction to the chief nurse of a private hospital or nursing home unless the drug is supplied in accordance with a written order signed by the chief nurse.

(3) The chief nurse must not sign an order for any quantity of a drug of addiction if the quantity of that drug that will be in the possession of the chief nurse as a result of the order being filled will be in excess of the maximum quantity allowed by clause 103.

(4) This clause does not authorise a retail pharmacist to have possession of, or to manufacture or supply, hallucinogens.

Maximum penalty: 20 penalty units.

103 Possession of drugs of addiction by chief nurses of private hospitals (cf cl 105 of P&TG Reg 1994)

(1) The chief nurse of a private hospital or nursing home is authorised to have possession of the following drugs of addiction in the following quantities:

(a) no more than 5 ampoules, each of 1 millilitre or less, of morphine sulfate, at a concentration of 30 milligrams or less of morphine sulfate per millilitre,

(b) no more than 5 ampoules, each of 2 millilitres or less, of pethidine hydrochloride, at a concentration of 50 milligrams or less of pethidine hydrochloride per millilitre.

(2) The chief nurse must not allow any such drug of addiction to be used otherwise than for administration to a patient in accordance with the directions of a medical practitioner, nurse practitioner, midwife practitioner or dentist.

(3) This clause does not limit the power of a chief nurse to have possession of drugs of addiction, or to supply drugs of addiction to patients, in accordance with a licence under Part 8.

Maximum penalty: 20 penalty units.

104 Possession of drugs of addiction by masters of ships (cf cl 106 of P&TG Reg 1994)

(1) The master of a ship is authorised to have possession of drugs of addiction that are required by law to be carried on the ship.

(2) A pharmacist may supply drugs of addiction to the master of a ship if the pharmacist is authorised to do so by an authority under Part 8.

(3) A person must not supply a drug of addiction to the master of a ship unless the person receives:

(a) a written order for the drug (in duplicate) signed by the master of the ship, and

(b) a written statement (in duplicate) signed by the master of the ship, being a statement to the effect that the drug is required by law to be carried on the ship, and

(c) a certificate, issued by the ship's agent in New South Wales, to the effect that the signatures appearing on the order and statement are those of the master of the ship.

(4) A person who supplies a drug of addiction in accordance with this clause:

(a) must keep and cancel the relevant order and statement, and

(b) must cancel the duplicate copies of the order and statement and forward them to the Director-General, together with the certificate issued by the ship's agent, within 24 hours.

(5) This clause does not authorise the master of a ship to have possession of, or to supply, hallucinogens.

Maximum penalty: 20 penalty units.

105 Possession of hallucinogens (cf cl 107 of P&TG Reg 1994)

A person must not obtain possession of a hallucinogen unless the person is authorised to do so by an authority or licence under Part 8.

Maximum penalty: 20 penalty units.

106 Authorities to possess and administer drugs of addiction (cf cl 108 of P&TG Reg 1994)

(1) The following persons are authorised to have possession of drugs of addiction, but only if authorised to do so by an authority under Part 8:

(a) a person in an isolated locality,

(b) a person in charge of a first aid post,

(c) a person representing an organisation established for search and rescue,

(d) any other person the Minister may from time to time approve.

(2) A person who is so authorised to have possession of a drug of addiction is also authorised to administer the drug to another person in an emergency.

107 Mode of delivery (cf cl 109 of P&TG Reg 1994)

(1) A person who supplies drugs of addiction must do so personally, by registered mail or by carrier.

(2) A person who supplies a drug of addiction personally:

(a) must deliver it to the person being supplied at the premises of the supplier or at the premises of the person being supplied, and

(b) must obtain a receipt, dated and signed, from the person to whom it is delivered.

(3) A person who supplies a drug of addiction by registered mail must obtain and keep written evidence of postage of the drug.

(4) A person who supplies a drug of addiction by carrier must obtain and keep written evidence of the consignment of the drug.

(5) A person who supplies a drug of addiction must not deliver a drug of addiction by carrier otherwise than under an arrangement under which the carrier undertakes:

(a) to obtain a receipt, dated and signed, from the person to whom the drug is delivered, and

(b) to deliver the receipt to the supplier.

Maximum penalty: 20 penalty units.

108 Delivery by carrier (cf cl 110 of P&TG Reg 1994)

(1) A carrier is authorised to be in possession of a package containing a drug of addiction, but for the purpose only of delivering it to the person to whom it is addressed.

(2) A dealer (other than a medical practitioner, nurse practitioner, midwife practitioner, dentist, veterinary practitioner or pharmacist) who supplies a drug of addiction by post or by carrier must ensure that:

(a) the drug is contained in a package that has at least one opaque covering, and

(b) no other goods are contained in the package, and

(c) the package contains a document:

(i) listing the contents of the package, and

(ii) bearing the words “SCHEDULE EIGHT—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5 millimetres, and

(d) the outside of the package does not indicate that it contains a drug of addiction, and

(e) the package is properly addressed to the person to whom the drug is being supplied.

(3) This clause does not prevent a dealer from supplying a drug of addiction by means of a separately wrapped inner package within an outer package containing other goods so long as:

(a) a document listing the contents of the inner package is contained in the inner package, and

(b) the inner package is marked with the words “SCHEDULE EIGHT—CHECK CAREFULLY” in bold face sans serif capital letters with a letter height of at least 12.5 millimetres, and

(c) the outside of the outer package does not indicate that it contains a drug of addiction, and

(d) the outer package is properly addressed to the person to whom the drug is being supplied.

Maximum penalty: 20 penalty units.

109 Quantity and purpose of supply to be appropriate (cf cl 111 of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, veterinary practitioner or pharmacist must not supply any drug of addiction in a quantity, or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

Maximum penalty: 20 penalty units.

Division 5 Records of supply

Subdivision 1 Drug registers otherwise than for hospital wards

110 Application of Subdivision (cf cl 112 of P&TG Reg 1994)

This Subdivision applies to drugs of addiction that are kept at any place (including the pharmacy of a hospital) for the purposes of manufacture, supply, research or testing, but does not apply to drugs of addiction that are kept in a hospital ward or that are in the possession of a carrier for the purpose of their being delivered to the persons to whom they are addressed.

111 Drug registers to be kept (cf cl 113 of P&TG Reg 1994)

(1) A person who has possession of drugs of addiction at any place must keep a separate register (a ***drug register***) at that place.

(2) A drug register is to be in the form of a book whose pages:

(a) are consecutively numbered, and

(b) are so bound that they cannot be removed or replaced without trace, and

(c) contain provision for the inclusion of the particulars required to be entered in it.

(3) Separate pages of the register must be used for each drug of addiction, and for each form and strength of the drug.

(4) The Director-General may from time to time approve the keeping of a drug register in any other form.

Maximum penalty: 20 penalty units.

112 Entries in drug registers (cf cl 114 of P&TG Reg 1994)

(1) On the day on which a person manufactures, receives, supplies, administers or uses a drug of addiction at any place, the person must enter in the drug register for that place such of the following details as are relevant to the transaction:

(a) the quantity of the drug manufactured, received, supplied, administered or used,

(b) the name and address of the person to, from or by whom the drug was manufactured, received, supplied, administered or used,

(c) in the case of a drug that has been administered to an animal or supplied for the treatment of an animal, the species of animal and the name and address of the animal's owner,

(d) in the case of a drug that is supplied or administered on prescription:

(i) the prescription reference number, and

(ii) the name of the medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner by whom the prescription was issued,

(e) in the case of a drug that has been administered to a patient, the name of the medical practitioner, nurse practitioner, midwife practitioner or dentist by whom, or under whose direct personal supervision, the drug was administered,

(f) in the case of a drug that has been administered to an animal, the name of the veterinary practitioner by whom, or under whose direct personal supervision, the drug was administered,

(g) in the case of a drug that has been administered by a person authorised to do so by an authority under Part 8, details of the circumstances requiring administration of the drug,

(h) in the case of a drug that has been used by a person who is in charge of a

laboratory, or is an analyst, the purpose for which the drug was used,

(i) the quantity of drugs of addiction of that kind held at that place after the transaction takes place,

(j) any other details approved by the Director-General.

(2) Each entry in a drug register must be dated and signed by the person by whom it is made.

(3) The Director-General may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty: 20 penalty units.

113 Supply on prescription to be recorded (cf cl 115 of P&TG Reg 1994)

(1) A pharmacist who supplies a drug of addiction on prescription must record the following details in a manner approved by the Director-General:

(a) the details required by clause 77 (1) to be included in the prescription,

(b) a unique reference number for the prescription,

(c) the date on which the substance was supplied,

(d) the name of the person by whom the substance was supplied.

(2) A prescription for the supply of a drug of addiction in a hospital need not be recorded so long as the chief pharmacist of the hospital keeps the prescription or a copy of the prescription.

Maximum penalty: 20 penalty units.

113A Emergency supply to be recorded

A pharmacist who supplies a drug of addiction as referred to in clause 97 must record the following details of the supply in a manner approved by the Director-General:

(a) a unique reference number for the supply,

(b) the name and address of the person supplied,

(c) the name, strength and quantity of the substance,

(d) the date on which the substance was supplied,

(e) the name of the person by whom the substance was supplied.

Maximum penalty: 20 penalty units.

Subdivision 2 Drug registers for hospital wards

114 Application of Subdivision (cf cl 116 of P&TG Reg 1994)

This Subdivision applies to drugs of addiction that are kept in a hospital ward, but does not apply to drugs of addiction that are kept in a pharmacy at the hospital.

115 Ward registers to be kept (cf cl 117 of P&TG Reg 1994)

(1) The nurse in charge of a hospital ward must keep a register of drugs of addiction (a ***ward register***) in that ward.

(2) A ward register is to be in the form of a book whose pages:

(a) are consecutively numbered, and

(b) are so bound that they cannot be removed or replaced without trace, and

(c) contain provision for the inclusion of the particulars required to be entered in it.

(3) Separate pages of the register must be used for each drug of addiction, and for each form and strength of the drug.

(4) The Director-General may from time to time approve the keeping of a ward register in any other form.

Maximum penalty: 20 penalty units.

116 Entries in ward registers (cf cl 118 of P&TG Reg 1994)

(1) On the day on which a person receives, supplies or administers a drug of addiction in any ward, the person must enter in the ward register such of the following details as are relevant to the transaction:

(a) the quantity of the drug received, supplied or administered,

(b) the time of day when the drug was received, supplied or administered,

(c) in the case of a drug that is supplied or administered to a patient:

(i) the name of the patient to whom the drug was supplied or administered, and

(ii) the name of the person by whom the supply or administration of the drug was prescribed or directed,

(d) the quantity of drugs of addiction of that kind held in the ward after the transaction takes place,

(e) any other details approved by the Director-General.

(2) The entry must be dated and signed by the person by whom it is made and countersigned:

(a) in the case of an entry relating to the receipt of a drug of addiction, by a person who witnessed its receipt, or

(b) in the case of an entry relating to the supply or administration of a drug of addiction:

(i) by the person who supervised or directed its supply or administration, or

(ii) by a person who witnessed its supply or administration.

(3) The Director-General may, by order in writing, exempt any person or drug of addiction, or any class of persons or drugs of addiction, from any or all of the requirements of this clause.

(4) Such an exemption may be given unconditionally or subject to conditions.

Maximum penalty: 20 penalty units.

Subdivision 3 Records generally

117 Periodical inventory of drugs of addiction stock (cf cl 119 of P&TG Reg 1994)

(1) The person responsible for maintaining a drug register (including a ward register) at any place:

(a) must, during the prescribed periods, make an accurate inventory of all drugs of addiction at that place, and

(b) must endorse the relevant drug register, immediately under the last entry for each drug of addiction, with the quantity of each drug of addiction actually held and the date on which the inventory was made, and

(c) must sign each entry.

(2) The prescribed periods for the purposes of subclause (1) (a) are:

(a) March and September each year, or

(b) if the Director-General determines some other periods, either generally or in specified circumstances, the periods so determined.

(3) A person who assumes control for a period of one month or more over any place at which drugs of addiction are held must, immediately on assuming control, make an inventory and endorse the drug register as if the inventory were an inventory made under this clause.

Maximum penalty: 20 penalty units.

118 Loss or destruction of registers (cf cl 120 of P&TG Reg 1994)

Immediately after a drug register (including a ward register) is lost or destroyed, the person responsible for keeping the register:

(a) must give written notice to the Director-General of that fact and of the circumstances of the loss or destruction, and

(b) must make an accurate inventory of all drugs of addiction held at the premises concerned and enter, in a new drug register, the particulars of the drugs so held.

Maximum penalty: 20 penalty units.

Division 6 Administration

119 Administration by persons employed at a hospital (cf cl 100 of P&TG Reg 1994)

(1) A person employed at a hospital must not administer a drug of addiction to a patient in the hospital otherwise than on the direction of a medical practitioner, nurse practitioner, midwife practitioner or dentist.

(2) Such a direction:

(a) must be given in writing (otherwise than by electronic mail or facsimile) or in any other manner approved by the Director-General for the purposes of this paragraph, or

(b) in an emergency, may be given:

(i) by electronic mail or by facsimile, or

(ii) orally, by telephone or in any other manner approved by the Director-General for the purposes of this subparagraph.

(3) A medical practitioner, nurse practitioner, midwife practitioner or dentist who gives a direction under subclause (2) (b) (ii) must:

(a) as soon as is practicable (and in any case within the next 24 hours) either:

(i) sign an entry in the patient's medical history confirming that he or she has given the direction, or

(ii) confirm the direction by electronic mail or by facsimile, and

(b) attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

(4) If confirmation is not received within 7 days after the drug of addiction is administered, the person by whom the drug was administered must report that fact to the Director-General.

(5) A medical practitioner, nurse practitioner, midwife practitioner or dentist who, by electronic mail or by facsimile, gives or confirms a direction for the administration of a drug of addiction to a patient must also attend to review the patient as soon as he or she considers it appropriate in the circumstances of the case.

(6) Subclauses (3), (4) and (5) do not apply to the administration of a drug of addiction to an inmate of a correctional centre (within the meaning of the *Crimes (Administration of Sentences) Act 1999*) if confirmation of the direction for the administration of the substance has been given in accordance with the requirements of a protocol approved by the Director-General.

Maximum penalty: 20 penalty units.

120 Self-administration by medical practitioners and dentists (cf cl 101 of P&TG Reg 1994)

(1) For the purposes of Division 1 of Part 2 of the *Drug Misuse and Trafficking Act 1985*:

(a) a medical practitioner is authorised to self-administer a drug of addiction, but only if the medical practitioner does so for the purposes of medical treatment, and

(b) a dentist is authorised to self-administer a drug of addiction, but only if the dentist does so for the purposes of dental treatment.

(2) Subclause (1) does not authorise a medical practitioner or dentist to self-administer a drug of addiction for more than 7 days.

(3) However, a medical practitioner may self-administer a drug of addiction for more than 7 days if the medical practitioner does so in accordance with an authority issued under section 29 of the Act.

Division 7 Miscellaneous

121 Prescribed type A drugs of addiction

For the purposes of section 28 of the Act, each of the following is prescribed as a type A drug of addiction:

(a) amphetamine,

(b) dexamphetamine,

(c) methylamphetamine,

(d) methylphenidate,

(e) phendimetrazine,

(f) phenmetrazine.

121A Prescribed type B drugs of addiction

For the purposes of section 28 of the Act, each of the following is prescribed as a type B drug of addiction:

(a) a drug of addiction that is packaged and labelled in a manner that is consistent with the drug being intended for administration by injection,

(b) buprenorphine,

(c) dextromoramide,

(d) flunitrazepam,

(e) hydromorphone,

(f) methadone.

122 Loss or theft of drugs of addiction (cf cl 122 of P&TG Reg 1994)

A person who is authorised to be in possession of drugs of addiction must immediately notify the Director-General if the person loses a drug of addiction or if a drug of addiction is stolen from him or her.

Maximum penalty: 20 penalty units.

123 Drugs of addiction not to be destroyed (cf cl 123 of P&TG Reg 1994)

(1) A person who is authorised to be in possession of a drug of addiction must not wilfully destroy the drug or allow the drug to be destroyed.

(2) This clause does not apply to the destruction of a drug of addiction carried out:

(a) by or under the direct personal supervision of a police officer or an inspector or by or under the direct personal supervision of a person authorised, whether generally or in a particular case, by an authority under Part 8 held by the person, or

(b) by or under the direct personal supervision of a person who is in charge of a laboratory, or who is an analyst, but only if the destruction is carried out in accordance with an authority under Part 8 held by the person, or

(c) by a person to whom the drug has been supplied by, or in accordance with the prescription of, a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner, or

(d) in accordance with clause 124 or 125.

Maximum penalty: 20 penalty units.

124 Destruction of unusable drugs of addiction in public hospital wards (cf cl 124 of P&TG

Reg 1994)

(1) The nurse in charge of a ward in a public hospital having responsibility for a drug of addiction that becomes unusable must immediately notify the chief pharmacist of the hospital of the fact and of the circumstances under which the drug became unusable.

(2) A pharmacist employed in a public hospital:

(a) may (but only in the presence of a nurse) destroy the drug of addiction, and

(b) in that event, must record the fact of the destruction of the drug in the ward register.

(3) The entry must be dated and signed by the pharmacist and countersigned by the nurse who witnessed the destruction of the drug.

(4) In the case of a public hospital for which there is no pharmacist, the functions of a chief pharmacist or pharmacist under this clause are instead the functions of:

(a) the chief nurse of the hospital, or

(b) the medical superintendent of the hospital,

as the chief executive officer of the hospital may determine.

Maximum penalty: 20 penalty units.

125 Destruction of unwanted drugs of addiction in a private hospital, nursing home or day procedure centre (cf cl 124A of P&TG Reg 1994)

(1) A retail pharmacist who is engaged in the supply of restricted substances or drugs of addiction:

(a) to a private hospital, nursing home or day procedure centre, or

(b) to a patient in a private hospital, nursing home or day procedure centre,

is authorised to destroy any unwanted drug of addiction on the premises of that private hospital, nursing home or day procedure centre.

(2) Subclause (1) applies only where the drug is destroyed in the presence of:

(a) where the private hospital, nursing home or day procedure centre is the holder of a licence under Division 2 of Part 8, the person who is named on the licence as being responsible for the storage of drugs of addiction, or

(b) in any other case, the chief nurse of the private hospital, nursing home or day procedure centre.

(3) A pharmacist who destroys a drug of addiction in accordance with this clause:

(a) must record the fact of the destruction of the drug by an entry in the drug register maintained by the private hospital, nursing home or day procedure centre, and

(b) must ensure that the entry is dated and signed by the pharmacist, and is countersigned by a person who witnessed the destruction of the drug.

Maximum penalty: 20 penalty units.

Part 5 Supply by wholesale

126 Authorised possession for supply by wholesale (cf cl 125 of P&TG Reg 1994)

(1) For the purposes of paragraph (d) of the definition of ***supply by wholesale*** in section 4 (1) of the Act, each person who is authorised by a provision of Appendix C to be in possession of a substance or goods is authorised to be supplied with wholesale quantities of the substance or goods.

(2) If the relevant provision of Appendix C includes a maximum concentration or strength in relation to a particular substance, the authority to be supplied with wholesale quantities of the substance extends only to substances in a concentration or strength not exceeding that maximum.

127 Restrictions on supply by wholesale (cf cl 126 of P&TG Reg 1994)

A person must not supply by wholesale any Schedule 2, 3 or 4 substance that is for therapeutic use:

(a) to any person in another State or Territory, unless the person being supplied with the substance is authorised by a law of that State or Territory to obtain or supply the substance, or

(b) to any person outside Australia, unless the person supplying the substance is authorised to do so by a law of the Commonwealth.

Maximum penalty: 15 penalty units.

128 Records of supply by wholesale (cf cl 127 of P&TG Reg 1994)

(1) A person who supplies by wholesale any regulated goods must issue an invoice to the person being supplied and must keep a copy of the invoice.

(2) Each invoice must show:

(a) the date of the supply, and

(b) the name and address of the person being supplied, and

(c) the name, strength and quantity of the substance supplied.

Maximum penalty: 20 penalty units.

129 Distribution of free samples (cf cl 128 of P&TG Reg 1994)

Any person:

(a) who is engaged in the manufacture, or supply by wholesale, of any poison or restricted substance for therapeutic use, or

(b) who is acting as an agent of a person so engaged,

must not supply any such poison or restricted substance by way of distribution of free samples otherwise than in a manner approved for the time being by the Director-General.

Maximum penalty: 20 penalty units.

130 Storage of therapeutic goods for human use (cf cl 128A of P&TG Reg 1994)

(1) A person who is engaged in the supply by wholesale of therapeutic goods for human use must ensure that the recommendations and requirements of the Wholesaling Code of Practice are complied with.

Maximum penalty: 20 penalty units.

(2) In this clause, ***Wholesaling Code of Practice*** means the Code of Practice entitled *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, published by the Commonwealth Government, as in force from time to time.

Part 6 Preparation, handling, supply and labelling of therapeutic goods

Division 1 Preparation and handling of exposed substances

131 Application of Division (cf cl 136A of P&TG Reg 1994)

This Division applies to all therapeutic goods, and all substances used in the preparation of therapeutic goods, that are unpackaged or otherwise susceptible to contamination (in this Division referred to as ***exposed substances***).

132 Preparation and handling generally (cf cl 136B of P&TG Reg 1994)

A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner, pharmacist or practitioner of alternative medicine must ensure that:

(a) all exposed substances that are prepared or handled on his or her business premises are free from any contamination and from anything that is likely to render them harmful or to have an adverse effect on their efficacy, and

(b) all persons that he or she employs in the preparation or handling of exposed substances comply with the requirements of this Division.

Maximum penalty: 20 penalty units.

133 Personal cleanliness (cf cl 136C of P&TG Reg 1994)

A person who is involved in the preparation or handling of exposed substances:

(a) must be clean and must wear clean clothing, and

(b) must clean his or her hands (by means of soap or detergent and water or by some other suitable cleaning process) before starting work and before resuming work after using the toilet.

Maximum penalty: 10 penalty units.

134 Spitting and smoking etc (cf cl 136D of P&TG Reg 1994)

A person who is involved in the preparation or handling of exposed substances, or who is in a place that is used for preparing or handling exposed substances, must not:

(a) urinate, defecate or spit, or

(b) use, smoke or chew tobacco or any other similar substance, or

(c) sit, walk, stand or lie on any surface used for the purpose of preparing or handling exposed substances.

Maximum penalty: 10 penalty units.

135 Contact with hands (cf cl 136E of P&TG Reg 1994)

A person who is involved in the preparation or handling of exposed substances:

(a) must not have any unnecessary human contact with any such substance, and

(b) must not handle any such substance with his or her fingers, but must use a suitable implement to do so, and

(c) must not touch his or her mouth, eye, ear, nose or scalp while handling any such substance, and

(d) must not wipe his or her hands otherwise than with a clean towel, and

(e) must not place, so that it can come into contact with any such substance, any ticket, label or other article that is unclean or liable to contaminate any such substance or that has been in contact with the person’s mouth, and

(f) must not place in his or her pockets any implement used in preparing or handling any such substance.

Maximum penalty: 10 penalty units.

136 Contact with mouth (cf cl 136F of P&TG Reg 1994)

A person who is involved in the preparation or handling of exposed substances must not apply to his or her mouth any implement used for preparing or handling any such substance.

Maximum penalty: 10 penalty units.

137 Bandages (cf cl 136G of P&TG Reg 1994)

A person who is wearing an unclean bandage or a medicated or absorbent bandage must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances, unless the bandage is protected and covered with a waterproof covering.

Maximum penalty: 10 penalty units.

138 Persons suffering from infectious diseases (cf cl 136H of P&TG Reg 1994)

(1) A person who is suffering from an infectious disease, or who has any exposed cut, sore, wound or skin eruption, must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances.

Maximum penalty: 10 penalty units.

(2) This clause does not apply to an activity carried out by a person if the Director-General has certified in writing that the person may carry out that activity and the person complies with any conditions contained in the certificate.

139 Appliances, articles, fittings and surfaces (cf cl 136I of P&TG Reg 1994)

(1) A person who is involved in the preparation or handling of exposed substances must not use any appliance, article or fitting for preparing or handling any such substance unless the appliance, article or fitting:

(a) is designed and constructed so as to be easily cleaned, and

(b) is kept clean.

Maximum penalty: 10 penalty units.

(2) A person who is involved in the preparation or handling of exposed substances must not cause or allow any such substance to come into contact with any surface used for preparing or handling any such substance unless the surface:

(a) is designed and constructed so as to be easily cleaned, and

(b) is kept clean.

Maximum penalty: 10 penalty units.

Division 2 Supply of therapeutic goods

140 Premises to be free of vermin (cf cl 136J of P&TG Reg 1994)

A person must not use any premises for preparing, handling or supplying therapeutic goods unless the premises are clean and free from vermin.

Maximum penalty: 10 penalty units.

141 Animals not permitted on premises (cf cl 136K of P&TG Reg 1994)

(1) A person who uses any premises for preparing, handling or supplying therapeutic goods must not cause or permit any animal or bird to be in those premises.

Maximum penalty: 10 penalty units.

(2) This clause does not apply to the premises of a veterinary practitioner.

Division 3 Labelling of unscheduled therapeutic substances

142 Labelling of unscheduled therapeutic substances (cf cl 136L of P&TG Reg 1994)

(1) This clause applies to all therapeutic goods that are not therapeutic devices and are not included in a Schedule of the Poisons List (in this clause referred to as ***unscheduled therapeutic substances***).

(2) A medical practitioner, nurse practitioner, midwife practitioner, dentist, optometrist, veterinary practitioner, pharmacist or practitioner of alternative medicine must ensure that any unscheduled therapeutic substances that are supplied from his or her business premises for therapeutic use are labelled in accordance with the requirements of Appendix A.

Maximum penalty: 10 penalty units.

(3) This clause does not apply to the supply of a substance by a person referred to in subclause (2) if:

(a) the substance is supplied, unopened, in the container in which it was received by the person, and

(b) the container is labelled in accordance with the requirements of the Commonwealth therapeutic goods laws.

Part 7 Analysis and disposal of seized goods

Division 1 Analysis of seized goods

143 Samples for analysis (cf cl 136M of P&TG Reg 1994)

(1) An inspector who seizes a portion or sample of regulated goods for analysis:

(a) must immediately notify the person from whom the portion or sample was taken of the inspector's intention to submit it for analysis, and

(b) must divide the portion or sample into 3 parts and properly fasten and seal each part or (if that is impracticable) properly fasten and seal the whole portion or sample.

(2) If the portion or sample is divided into 3 parts, the inspector:

(a) must return one part to the person from whom it was taken, and

(b) must forward another part for analysis, and

(c) must retain the remaining part.

(3) If the portion or sample is not divided into 3 parts, the inspector must forward the whole of it for analysis.

(4) For the purposes of this clause, a portion or sample is properly fastened and sealed if:

(a) it is put into a container, and

(b) the container is marked with the name and address of the person from whom it was taken, and

(c) the container is fastened and sealed so as to prevent the container from being opened, or the name and address being removed, without the seal's being broken.

144 Payment for sample (cf cl 136N of P&TG Reg 1994)

Payment for a portion or sample of regulated goods that is seized for analysis is to be made by the State, at current market value:

(a) to the person from whom those goods were taken, or

(b) if the person was not the owner of those goods, to the owner.

Division 2 Disposal of seized goods

145 Release of seized goods (cf cl 136O of P&TG Reg 1994)

(1) Seized goods are to be released at the end of the period of 6 months after they were seized unless, before the end of that period, a Magistrate makes an order under this Division directing them to be forfeited to the State.

(2) This clause does not prevent seized goods from being released before the expiration of that period.

(3) Seized goods may be released:

(a) by or at the direction of the inspector who seized them or by or at the direction of the Director-General, and

(b) to the owner of the goods or the person in whose possession, care, custody or control they were at the time of the seizure.

(4) This clause does not require the release of any goods that have been damaged or destroyed in the course of analysis.

(5) A Magistrate may, in any particular case, extend the period referred to in subclause (1).

146 Order that seized goods be forfeited (cf cl 136P of P&TG Reg 1994)

(1) A Magistrate may order that seized goods specified in the order be forfeited to the State on the expiration of any period so specified.

(2) Such an order does not have effect in respect of any goods that have been released under this Division.

(3) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.

147 Order that expenses be paid (cf cl 136Q of P&TG Reg 1994)

(1) A Magistrate may order that a person from whom goods have been seized under section 43 of the Act (being a person who has been convicted of an offence in connection with those goods) must pay to the Director-General such amount (not exceeding $500) as the Magistrate considers appropriate to cover the reasonable costs of:

(a) seizing the goods, and

(b) dealing with them under this Division, and

(c) conducting any analysis for which they have been submitted.

(2) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.

(3) An order under this clause operates as an order under the *Local Courts (Civil Claims) Act 1970*, and is enforceable as such an order under the provisions of that Act.

148 Storage of and interference with seized goods (cf cl 136R of P&TG Reg 1994)

(1) Subject to any direction of the Director-General, seized goods may be kept or stored:

(a) at the premises at which they were seized, or

(b) at such other place as the inspector who seized them considers appropriate.

(2) A person must not remove, alter or interfere in any way with seized goods without the authority of an inspector or the Director-General.

Maximum penalty: 20 penalty units.

149 Forfeiture of goods with consent (cf cl 136S of P&TG Reg 1994)

If the owner of seized goods or the person in whose possession, care, custody or control they were at the time of their seizure consents in writing to their forfeiture, the goods are, by virtue of that consent, forfeited to the State.

150 Disposal of forfeited goods (cf cl 136T of P&TG Reg 1994)

Any goods forfeited under this Division may be disposed of in such manner as the Director-General may direct, either generally or in any particular case or class of cases.

Part 8 Licences and authorities

Division 1 Licences to supply Schedule 2 substances

151 Applications for licences (cf cl 137 of P&TG Reg 1994)

(1) Any person who conducts, or proposes to conduct, a retail shop may apply for a licence to supply Schedule 2 substances from the shop.

(2) The application:

(a) must be in the form approved by the Director-General, and

(b) must be accompanied by an application fee of $60, and

(c) must be lodged with the Director-General.

(3) The Director-General may require an applicant to furnish such further information as is necessary to enable the Director-General to determine the application.

152 Consideration of applications (cf cl 138 of P&TG Reg 1994)

(1) After considering an application under this Division, the Director-General may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued or renewed unless:

(a) in the case of premises the subject of an existing licence issued before 7 April 1989 that is in force, the Director-General is satisfied that the premises to which the application relates are at least 6.5 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist, or

(b) in any other case, the Director-General is satisfied that the premises to which the application relates are at least 20 kilometres (measured along the shortest practicable route) from the premises of the nearest retail pharmacist.

(4) The application fee is to be refunded if the application is refused.

153 Licences (cf cl 139 of P&TG Reg 1994)

(1) A licence is to be in the form for the time being approved by the Director-General.

(2) A licence remains in force until suspended, cancelled or surrendered.

(3) A licence is not transferable.

154 Conditions of licences (cf cl 140 of P&TG Reg 1994)

(1) A licence is subject to such conditions as the Director-General may endorse on the licence and to such further conditions as the Director-General may from time to time impose by order in writing served on the holder of the licence.

(2) The Director-General may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

155 Annual licence fees (cf cl 141 of P&TG Reg 1994)

The holder of a licence under this Division must, on or before 31 March in each year following that in which the licence was issued, pay to the Director-General an annual licence fee of $60.

Division 2 Licences to supply by wholesale poisons and restricted substances

156 Applications for licences (cf cl 141A of P&TG Reg 1994)

(1) Any person may apply to the Director-General for a licence to supply by wholesale any poisons or restricted substances.

(2) The application:

(a) must be in the form approved by the Director-General, and

(b) must be accompanied by the relevant application fee, and

(c) must be lodged with the Director-General.

(3) The relevant application fee is:

(a) $55, in the case of an application by a public institution, or

(b) $370, in any other case.

(4) The Director-General may require an applicant to furnish such further information as is necessary to enable the Director-General to determine the application.

157 Consideration of applications (cf cl 141B of P&TG Reg 1994)

(1) After considering an application under this Division, the Director-General may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued unless the Director-General is satisfied that the premises to which the application relates are appropriate for the supply of the poisons or restricted substances concerned.

(4) The application fee is to be refunded if the application is refused.

158 Licences (cf cl 141C of P&TG Reg 1994)

(1) A licence is to be in a form for the time being approved by the Director-General.

(2) A licence remains in force until suspended, cancelled or surrendered.

(3) A licence is not transferable.

159 Conditions of licences (cf cl 141D of P&TG Reg 1994)

(1) A licence is subject to such conditions as the Director-General may from time to time impose by order in writing served on the holder of the licence.

(2) The Director-General may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

160 Annual licence fees (cf cl 141E of P&TG Reg 1994)

The holder of a licence under this Division must, on or before 30 September in each year following that in which the licence was issued, pay to the Director-General an annual licence fee of:

(a) $55, if the holder is a public institution, or

(b) $370, in any other case.

Division 3 Licences to manufacture or supply drugs of addiction

161 Applications for licences (cf cl 142 of P&TG Reg 1994)

(1) Any person may apply to the Director-General for a licence to manufacture drugs of addiction at, or to supply drugs of addiction from, any premises.

(2) The application:

(a) must be in the form approved by the Director-General, and

(b) must be accompanied by the relevant application fee, and

(c) must be lodged with the Director-General.

(3) The relevant application fee for a licence to manufacture drugs of addiction is:

(a) $55, in the case of an application by a public institution, or

(b) $495, in any other case.

(4) The relevant application fee for a licence to supply drugs of addiction is:

(a) $15, in the case of an application by a charitable organisation, or

(b) $55, in the case of an application by a public institution (other than a charitable organisation), or

(c) $250, in any other case.

(5) The Director-General may require an applicant to furnish such further information as is necessary to enable the Director-General to determine the application.

162 Consideration of applications (cf cl 143 of P&TG Reg 1994)

(1) After considering an application under this Division, the Director-General may issue the licence for which the application is made or may refuse the application.

(2) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

(3) A licence may not be issued unless the Director-General is satisfied that the premises to which the application relates are appropriate for the manufacture or supply of drugs of addiction.

(3A) On and from the commencement of this subclause, the Director-General is not

empowered to issue a licence under this Division for the supply, under the program known as the New South Wales Opioid Treatment Program, of methadone or buprenorphine to drug dependent persons (as defined in section 27 of the Act) unless it is a replacement licence.

(3B) To avoid doubt:

(a) subclause (3A) does not affect the validity or operation of any licence to supply methadone or buprenorphine that was in force immediately before the commencement of that subclause, and

(b) the Director-General may, after the commencement of subclause (3A):

(i) add conditions to, or vary or revoke the conditions of, such a licence, or

(ii) vary the premises to which such a licence relates, on the application of the licensee, and

(c) the Director-General must refuse any application for the issue of a licence referred to in subclause (3A) made, but not finally determined, before the commencement of that subclause.

(4) The application fee is to be refunded if the application is refused.

(5) In this clause:

replacement licence means a licence to supply methadone or buprenorphine from premises from which a person was previously licensed under this Division to supply methadone or buprenorphine.

163 Licences (cf cl 144 of P&TG Reg 1994)

(1) A licence is to be in the form for the time being approved by the Director-General.

(2) A licence to manufacture drugs of addiction authorises the manufacturer to supply drugs that are manufactured under the licence, subject to the conditions of the licence.

(3) A licence remains in force until suspended, cancelled or surrendered.

(4) A licence is not transferable.

164 Conditions of licences (cf cl 145 of P&TG Reg 1994)

(1) A licence is subject to such conditions as the Director-General may endorse on the licence and to such further conditions as the Director-General may from time to time impose by order in writing served on the holder of the licence.

(2) The Director-General may from time to time vary or revoke any condition of a licence

by means of a further order in writing served on the holder of the licence.

(3) A licence is ineffective unless its conditions are complied with.

165 Annual licence fees (cf cl 146 of P&TG Reg 1994)

(1) The holder of a licence to manufacture drugs of addiction must, on or before 30 September in each year following that in which the licence was issued, pay to the Director-General an annual licence fee of:

(a) $55, if the holder is a public institution, or

(b) $495, in any other case.

(2) The holder of a licence to supply drugs of addiction must, on or before 30 September in each year following that in which the licence was issued, pay to the Director-General an annual licence fee of:

(a) $15, if the holder is a charitable organisation, or

(b) $55, if the holder is a public institution (other than a charitable organisation), or

(c) $250, in any other case.

Division 4 Authorities

166 Authorities (cf cl 147 of P&TG Reg 1994)

(1) The Director-General may issue authorities for the purposes of the Act and this Regulation.

(2) The Director-General may require a person seeking an authority to furnish such information as is necessary to enable the Director-General to determine the issuing of the authority.

(3) An authority may be issued to a particular person (by means of an instrument in writing given to the person) or to a specified class of persons (by means of an instrument published in a manner approved by the Director-General).

(4) In particular, the Director-General may refuse to issue an authority to a person if of the opinion that the person is not a fit and proper person to hold the authority.

(5) An authority that is issued to a particular person remains in force until it is suspended, cancelled or surrendered.

(6) An authority that is issued to a particular person is not transferable.

(7) In this Regulation, a reference to a person who holds an authority under this Part includes a reference to a person who belongs to a class of persons specified in an

instrument referred to in subclause (3).

167 Conditions of authorities (cf cl 148 of P&TG Reg 1994)

(1) The exercise of the functions conferred on a person by an authority is subject to such conditions as the Director-General may specify in the instrument by which the authority is issued and to such further conditions as the Director-General may from time to time impose by order in writing served on that person.

(2) The Director-General may from time to time vary or revoke any condition of an authority by means of a further order in writing served on the holder of the authority.

(3) An authority is ineffective unless its conditions are complied with.

Division 5 Suspension and cancellation of licences and authorities

168 Grounds for suspension or cancellation (cf cl 149 of P&TG Reg 1994)

(1) The Director-General must suspend or cancel a licence or authority in the event of one or more of the following:

(a) the holder of the licence or authority requests or agrees in writing to the suspension or cancellation of the licence or authority,

(b) the holder of the licence or authority is convicted of a serious offence against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act,

(c) the Director-General forms the opinion that the holder of the licence or authority is no longer a fit and proper person to hold the licence or authority,

(d) in the case of a licence or authority to supply methadone or buprenorphine, the Director-General forms the opinion that the supply of methadone or buprenorphine has a significant adverse effect on the amenity of the area in which the premises from which it is being supplied are situated.

(2) The Director-General may, at the Director-General's discretion, suspend or cancel a licence or authority on any one or more of the following grounds:

(a) the holder of the licence or authority contravenes any condition of the licence or authority,

(b) the holder of the licence or authority is convicted of an offence against the Act or this Regulation, or of an offence (not being a serious offence) against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act,

(c) an order is made under section 10 (1) of the *Crimes (Sentencing Procedure) Act 1999* relating to the holder of the licence or authority in respect of an offence against the Act or this Regulation, or an offence against the *Drug Misuse and*

Trafficking Act 1985 or any regulation in force under that Act,

(d) the annual fee for the licence is not duly paid.

(3) In this clause, ***serious offence*** means an offence that is punishable by imprisonment for life or for a term of 5 years or more.

169 Suspension or cancellation (cf cl 150 of P&TG Reg 1994)

(1) Before suspending or cancelling a licence or authority (otherwise than at the request of its holder), the Director-General:

(a) must cause written notice of the proposed suspension or cancellation, and of the grounds for the proposed suspension or cancellation, to be served on the holder of the licence or authority, and

(b) must give the holder of the licence or authority a reasonable opportunity to make representations with respect to the proposed suspension or cancellation, and

(c) must take any such representations into consideration.

(2) Suspension or cancellation of a licence or authority takes effect on the date on which written notice of the suspension or cancellation is served on its holder or on such later date as is specified in the notice.

(3) The Director-General may, by a further notice in writing served on the holder of a licence or authority that is suspended, revoke the suspension or vary the period of the suspension.

Division 6 Modification of applied provisions of Commonwealth therapeutic goods laws

170 Modification of applied provisions of Commonwealth therapeutic goods laws with respect to advertising: section 31 (3) (cf cl 150B of P&TG Reg 1994)

(1) This clause applies to circumstances to which the *Therapeutic Goods Act 1989* of the Commonwealth applies by reason of section 31 of the *Poisons and Therapeutic Goods Act 1966*.

(2) Part 2 of the *Therapeutic Goods Regulations* of the Commonwealth is modified in its application to circumstances to which this clause applies to the extent that the Director-General may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of that Part.

(3) Such an exemption may be given unconditionally or subject to conditions.

Part 9 Miscellaneous

171 Director-General may restrict authorisations conferred by this Regulation (cf cl 151 of P&TG Reg 1994)

(1) The Director-General may, by order in writing served on any person, prohibit or restrict the person from doing anything authorised by this Regulation.

(2) Such an order may be made on any one or more of the following grounds:

(a) the person requests or agrees in writing to the making of the order,

(b) the person is convicted of an offence against the Act or this Regulation, or of an offence against the *Drug Misuse and Trafficking Act 1985* or any regulation in force under that Act, or an order is made against the person under section 10 (1) of the *Crimes (Sentencing Procedure) Act 1999* in respect of such an offence,

(c) the person has, in the opinion of the Director-General, failed to comply with any restriction imposed on the person by an order under this clause,

(d) the person is, in the opinion of the Director-General, a person whose authorisation to do that thing should be withdrawn for the purpose of protecting the life, or the physical or mental health, of that or any other person (whether or not any other such person is identifiable).

(3) An order that restricts a person as referred to in subclause (1):

(a) may be made unconditionally or subject to conditions, and

(b) may apply generally or be limited in its application by reference to specified exceptions or factors, and

(c) may apply differently according to different factors of a specified kind.

(4) An order under this clause must specify the grounds on which it is made including, if it is made on the grounds referred to in subclause (2) (c), the reasons for its withdrawal on those grounds.

(5) An order under this clause takes effect:

(a) in the case of an order made on the grounds referred to in subclause (2) (d), when the order is served on the person against whom it is made, or

(b) in any other case, the date specified in the order in that regard.

(6) Except in the case of an order that is made on the ground referred to in subclause (2) (a), the date referred to in subclause (5) (b) must be a date occurring not less than 14 days after the date on which the order is served on the person against whom it is made.

(7) On making an order that prohibits a person from doing all of the things authorised by Part 2, 3, 4 or 5 of this Regulation, or by any two or more of those Parts, the Director-General is to cause notice of:

(a) the name of the person, and

(b) the terms of the order, and

(c) the date on which the order took effect,

to be published in the Gazette.

(8) A person must not contravene any order in force under this clause.

172 Records generally (cf cl 153 of P&TG Reg 1994)

(1) Except to the extent to which this Regulation otherwise provides, all documents required to be kept under this Regulation:

(a) must be kept in the form of legible instruments written indelibly in English, or

(b) must be kept in some other manner from which a legible instrument written indelibly in English is readily reproducible.

(2) A record required to be made of the manufacture, receipt, supply, administration or use of any substance at or from any premises must be kept at those premises.

(3) A person who is required by this Regulation to keep any document or make any record must keep it for at least 2 years, running from the latest date on which:

(a) any entry was made in the document or record, or

(b) any substance was manufactured, received, supplied, administered or used in accordance with, or on the authority of, the document or record,

and must make it available for inspection on demand by a police officer or an inspector.

Maximum penalty: 20 penalty units.

173 False or misleading entries in records and registers (cf cl 154 of P&TG Reg 1994)

(1) A person who is required by this Regulation to keep any record or register must not make any entry in the record or register that the person knows to be false or misleading in a material particular.

(2) A person must not make any alterations, obliterations or cancellations in a register required by this Regulation, but may correct any mistake in any entry by making a marginal note or footnote and by initialling and dating it.

Maximum penalty: 20 penalty units.

174 False or misleading applications (cf cl 155 of P&TG Reg 1994)

A person must not, in or in connection with an application under this Regulation, make any statement that the person knows to be false or misleading in a material particular.

Maximum penalty: 20 penalty units.

175 Service of notices (cf cl 156 of P&TG Reg 1994)

A notice referred to in this Regulation may be served on a person:

(a) by delivering it to the person personally, or

(b) by leaving it at the person's place of residence last known to the Director-General with someone who apparently resides there, or

(c) by leaving it at the person's place of business or employment last known to the Director-General with someone who is apparently employed there, or

(d) by posting it to the person in an envelope addressed to the person at the place of his or her residence, business or employment last known to the Director-General.

176 Applications for authorities under section 29 (cf cl 157 of P&TG Reg 1994)

Before determining an application referred to in section 29 (1) of the Act, the Director-General may require the applicant to furnish such further information as the Director-General may require in relation to the application.

177 Quorum for Poisons Advisory Committee (cf cl 158 of P&TG Reg 1994)

The quorum for a meeting of the Advisory Committee referred to in clause 2 of Schedule 2 to the Act is 9.

178 Residential centres for persons with disabilities

The following institutions are declared to be residential centres for persons with disabilities for the purposes of this Regulation:

The Stockton Centre, Stockton

179 Saving (cf cl 159 of P&TG Reg 1994)

Any act, matter or thing that, immediately before the repeal of the *Poisons and Therapeutic Goods Regulation 1994*, had effect under that Regulation is taken to have effect under this Regulation.

Appendix A Labelling of therapeutic substances

(Clauses 5, 25, 68 and 142)

Note—

Although this Appendix refers to labels "on" a container, the information required by this Appendix may be shown by tags, brands, marks or statements in writing on the container itself (rather than on something affixed or attached to the container). See the definition of ***Label*** in section 4 (1) of the Act.

1 General

(1) All details, words and other information that a label on a container of a therapeutic substance must carry must be in the English language (although it may also be in another language).

(2) All symbols, numbers and words on a label must be in durable characters.

(3) The label on a container of a therapeutic substance must contain the following details:

(a) the name and address of the dealer supplying the substance,

(b) the substance's approved name,

(b1) the substance's proprietary name (unless the substance is a preparation compounded in accordance with the dealer's own formula),

(c) adequate directions for use,

(d) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background,

(e) if the substance is intended for external use only, the word "POISON", or the words "FOR EXTERNAL USE ONLY", in red on a white background,

(f) if the substance is intended for the treatment of a person, the name of the person,

(g) if the substance is intended for the treatment of an animal, the species of animal and the name of the animal's owner,

(h) if the substance is supplied in the circumstances referred to in clause 44 or 47, the words "EMERGENCY SUPPLY".

2 Additional labelling requirements for certain substances

(1) The label on a container of a therapeutic substance that is supplied on prescription must also bear:

(a) the prescription reference number, and

(b) the date on which the prescription was supplied (unless that date is clear from the prescription reference number), and

(c) the directions for use set out in the prescription.

(2) The label on a container of a restricted substance that is supplied in the circumstances referred to in clause 44 or 47 must also bear:

(a) the unique reference number recorded under clause 56 with respect to the supply, and

(b) the date on which the substance was supplied, and

(c) the directions given by the pharmacist for the use of the substance.

3 Warning: therapeutic substances for internal use

The label on a container of a therapeutic substance specified in Appendix F to the current Poisons Standard (being a therapeutic substance that is intended for internal use) must bear the warning specified in that Appendix in respect of that substance.

The label on a container of a therapeutic substance specified in Appendix K to the current Poisons Standard (being a therapeutic substance that is supplied on prescription and is intended for internal use in humans) must bear Warning Statement 39, 40 or 90 specified in Part 1 of Appendix F to that Standard. The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

4 Warning: quinine

The label on a container of quinine must bear the words “WARNING—MAY BE FATAL TO CHILDREN”.

5 Warning: other substances

(1) This clause applies to the following substances:

amphetamine

chlorphentermine

dexamphetamine

diethylpropion

ephedrine

methylphenidate

phentermine

propylhexedrine

(2) The label on a container of such a substance (being a substance that is represented

as being for oral use by a person other than a child under 16) must bear the words “THIS MEDICATION (MEDICINE) MAY AFFECT MENTAL ALERTNESS OR CO-ORDINATION OR BOTH. IF AFFECTED, DO NOT DRIVE A MOTOR VEHICLE OR OPERATE MACHINERY”.

(3) The warning must be immediately preceded by a symbol in the form of an open equilateral triangle at least 4.5 millimetres high in bold print, coloured red.

Appendix B Special restricted substances

(Clauses 3, 34, 37, 38, 40, 41, 89)

Amylobarbitone when included in Schedule 4 of the Poisons List
Anabolic and androgenic steroidal agents included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix
Drostanolone
Ethyloestrenol
Fluoxymesterone
Mesterolone
Methandienone
Methandriol
Methenolone
Methylandrostanolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone in preparations for therapeutic use
Pentobarbitone when included in Schedule 4 of the Poisons List
Stanolone
Stanozolol
Testosterone except when included in Schedule 6 of the Poisons List

Appendix C Supply by wholesale

(Clause 126)

1 Medical superintendents of hospitals

The medical superintendent of a hospital is authorised to be in possession of any Schedule 2, 3 or 4 substance.

2 Persons licensed to manufacture or supply drugs of addiction

The holder of a licence under Part 8 to manufacture or supply drugs of addiction is authorised to be in possession of any Schedule 2, 3 or 4 substance.

3 Scientifically qualified persons

A scientifically qualified person in charge of a laboratory or department is authorised to be in possession of any Schedule 2, 3 or 4 substance for use in the conduct of medical or scientific research or instruction or the conduct of quality control or analysis.

4 Masters of ships

The master of a ship is authorised to be in possession of any Schedule 2, 3 or 4 substance that is required by law to be carried on the ship.

5 Miscellaneous trades and industries

A person who is engaged in any of the following activities is authorised to be in possession of any Schedule 2 or 3 substance for use in connection with that activity:

(a) jewellery manufacture,

(b) electroplating,

(c) paint manufacture,

(d) ferrous hardening,

(e) commercial pest control,

(f) mining gold or other precious metals,

(g) refining non-ferrous metals.

6 Optometrists

An optometrist is authorised to be in possession of any Schedule 2, 3 or 4 substance prescribed under the *Optometrists Act 2002* for the purposes of section 21 (5) of that Act.

7 Podiatrists

A registered podiatrist (within the meaning of the *Podiatrists Act 1989*) is authorised to be in possession of synthetic cocaine substitutes (prepared for parenteral use) for use in connection with podiatry.

8 Dental therapists

(1) A dental therapist is authorised to be in possession of the following substances for use in connection with dental therapy:

benzocaine

lignocaine

mepivacaine

prilocaine

procaine

tetracycline (in preparations for treatment of dental pulp)

triamcinolone (in preparations for treatment of dental pulp)

(2) In this clause, ***dental therapist*** means a registered dental therapist under the *Dental Practice Act 2001*.

8A Dental hygienists

(1) A dental hygienist is authorised to be in possession of the following substances for use in connection with an activity prescribed in clause 6 of the *Dental Practice Regulation 2004*:

benzocaine

lignocaine

mepivacaine

prilocaine

procaine

(2) In this clause, ***dental hygienist*** means a registered dental hygienist under the *Dental Practice Act 2001*.

9 Emergency medical treatment by ambulance officers

A person:

(a) who is employed by the Ambulance Service of New South Wales as an ambulance officer or as an air ambulance flight nurse, and

(b) who is approved for the time being by the Ambulance Service of New South Wales for the purposes of this clause,

is authorised to be in possession of such Schedule 2, 3 or 4 substances as are approved by the Ambulance Service of New South Wales for use by such persons in the carrying out of emergency medical treatment.

10 Emergency medical treatment of divers

A person:

(a) who is a dive medical technician within the Police Service, and

(b) whose duties include the carrying out (under the supervision of a medical practitioner

who is qualified in underwater medicine) of emergency medical treatment on divers,

is authorised to be in possession of any substance referred to in the Table to this clause so long as the substance complies with the requirements as to form and strength set out in that Table opposite that substance.

Table

Substance	Form	Strength
adrenaline	ampoule	not more than 0.01 per cent
amoxycillin with clavulanic acid	tablet	not more than 500 milligrams (amoxycillin) and 125 milligrams (clavulanic acid)
atropine	ampoule	not more then 600 micrograms per ampoule
dexamethasone with framycetin and gramicidin	ear drops	not more than 500 micrograms (dexamethasone), 5 milligrams (framycetin) and 50 micrograms (gramicidin)
diazepam	ampoule	not more than 10 milligrams per ampoule
diclofenac	tablet	not more than 50 milligrams
frusemide	ampoule	not more than 20 milligrams per ampoule
heparin	ampoule	not more than 25,000 units per 5 millilitres
lignocaine	ampoule	not more than 1 per cent
lignocaine with chlorhexidine	ampoule	not more than 2 per cent
metronidazole	tablet	not more than 200 milligrams
naloxone	ampoule	not more than 400 micrograms per ampoule
piroxicam	gel	not more than 0.5 per cent
prochlorperazine	ampoule	not more than 12.5 milligrams per ampoule
prochlorperazine	tablet	not more than 5 milligrams
trimethoprim with sulfamethoxazole	tablet	not more than 160 milligrams (trimethoprim) and 800 milligrams (sulfamethaxozone)

11 Industrial first aid

A person who is in control of an industrial first aid post is authorised to be in possession of any Schedule 2 substance in connection with the carrying out of industrial first aid.

12 Registered nurses involved in vaccination programs

A person who is a registered nurse and who is employed in connection with a vaccination

program carried out in a public institution or place of work is authorised to be in possession of vaccines for use in humans.

13 Ski rescue

A ski patroller who holds a valid first aid certificate issued by the Australian Ski Patrol Association for use in ski patrol duties is authorised to be in possession of methoxyflurane, nitrous oxide and trichloroethylene for use in connection with the carrying out of ski rescues.

14 Bee keeping

A person:

(a) who is registered as a beekeeper under the *Apiaries Act 1985*, and

(b) who holds a written authority (issued by the Director-General of the Department of Agriculture) recommending the use, by that person, of that substance for that purpose,

is authorised to be in possession of oxytetracycline in the form of a stock medicine registered under the *Stock Medicines Act 1989* for use in the treatment or prevention of European Foulbrood disease in bees.

15 Animal feedstuff production

(1) A person who is authorised under this Regulation to obtain a Schedule 2, 3 or 4 substance is authorised to be in possession of the substance for use in connection with the commercial production of animal feedstuffs or feedstuff premixes.

(2) In this clause, a reference to an animal feedstuff or feedstuff premix is a reference to a feedstuff or feedstuff premix containing a Schedule 2, 3 or 4 substance at such a level, or in such a form:

(a) that Schedule 6 to the Poisons List applies to the substance, or

(b) that the substance is not a poison.

16 First aid in mines

A person is authorised to be in possession of nitrous oxide for use in connection with the carrying out of first aid at a mine if:

(a) in the case of a coal or shale mine, the person is appointed in accordance with the regulations under the *Coal Mines Regulation Act 1982* to be in charge of a first aid room at the mine or as a first aid attendant at the mine, or

(b) in the case of any other mine, the person is employed in accordance with the rules under the *Mines Inspection Act 1901* to provide first aid treatment at the mine.

17 General first aid

A person who holds a current occupational first-aid certificate approved by the WorkCover Authority in accordance with the regulations under the *Occupational Health and Safety Act 2000* is authorised to be in possession of methoxyflurane and nitrous oxide in connection with the carrying out of first aid.

18 Asthma first aid

A person who holds a current emergency asthma management certificate issued by an organisation approved by the Director-General for the purposes of clause 17 (3) of this Regulation is authorised to be in possession of salbutamol or terbutaline in metered aerosols in connection with the carrying out of first aid.

19 Anaphylaxis first aid

A person is authorised to be in possession of adrenaline in connection with the carrying out of anaphylaxis first aid if:

(a) the adrenaline is contained in single use automatic injectors that have been filled by the manufacturer with no more than 0.3 milligrams of adrenaline each, and

(b) the person holds a current first aid certificate issued after completion of a first aid course approved by the WorkCover Authority as referred to in regulations made under the *Occupational Health and Safety Act 2000*, and the person has received training on the symptoms and first aid management of anaphylaxis from:

(i) a first aid training organisation approved by the WorkCover Authority, or

(ii) any other organisation approved by the Director-General for the purposes of clause 17 (5) (b).

Appendix D Prescribed restricted substances

(Clause 60)

Substance	Prescribed quantity
Alprazolam	0.25 gram
Amylobarbitone when included in Schedule 4 of the Poisons List	50.0 grams
Anabolic and androgenic steroidal agents included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix	5.0 grams
Androisoxazole	5.0 grams
Barbiturates included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix	50.0 grams

Benzodiazepine derivatives included in Schedule 4 of the Poisons List, except when referred to elsewhere in this Appendix	0.5 gram
Benzphetamine	5.0 grams
Bolandiol	5.0 grams
Bolasterone	5.0 grams
Boldenone	2.5 grams
Bolmantalate	5.0 grams
Bromazepam	5.0 grams
Calusterone	30.0 grams
Cathine	5.0 grams
Chlorandrostenolone	5.0 grams
Chlordiazepoxide	5.0 grams
Chloroxydienone	5.0 grams
Chloroxymesterone	5.0 grams
Clobazam	2.5 grams
Clonazepam	0.5 gram
Clorazepate	3.0 grams
Clostebol	2.0 grams
Dextropropoxyphene when included in Schedule 4 of the Poisons List	15.0 grams
Diazepam	2.5 grams
Diethylpropion	5.0 grams
Dihydrolone	5.0 grams
Dimethandrostanolone	5.0 grams
Dimethazine	5.0 grams
Doxapram	2.0 grams
Drostanolone	2.0 grams
Ephedrine	5.0 grams
Ethchlorvynol	50.0 grams
Ethinamate	50.0 grams
Ethyldienolone	5.0 grams
Ethyloestrenol	1.0 gram

Fencamfamin	1.0 gram
Fenproporex	1.0 gram
Fluoxymesterone	2.0 grams
Flurazepam	10.0 grams
Formebolone	1.0 gram
Formyldienolone	1.0 gram
Furazabol	0.5 gram
Glutethimide	50.0 grams
Hydroxystenozol	5.0 grams
Ketamine	2.0 grams
Lorazepam	1.0 gram
Mazindol	0.5 gram
Medazepam	2.5 grams
Mefenorex	5.0 grams
Meprobamate	100.0 grams
Mesabolone	5.0 grams
Mestanolone	5.0 grams
Mesterolone	10.0 grams
Methandienone	1.0 gram
Methandriol	20.0 grams
Methenolone	2.0 grams
Methylandrostanolone	5.0 grams
Methylclostebol	5.0 grams
Methylphenobarbitone	50.0 grams
Methyltestosterone	20.0 grams
Methyltrienolone	5.0 grams
Methyprylone	40.0 grams
Mibolerone	0.01 gram
Midazolam	0.5 gram
Nalbuphine	0.5 gram
Nandrolone	1.0 gram

Nitrazepam	1.0 gram
Norandrostenolone	1.0 gram
Norbolethone	5.0 grams
Norethandrolone	4.0 grams
Normethandrone	0.5 gram
Oxabolone	0.5 gram
Oxandrolone	1.0 gram
Oxazepam	10.0 grams
Oxymesterone	4.0 grams
Oxymetholone	40.0 grams
Paraldehyde	250 millilitres
Pentobarbitone when included in Schedule 4 of the Poisons List	50.0 grams
Phenobarbitone	50.0 grams
Phentermine	10.0 grams
Pipradrol except in compounded preparations containing 0.01 per cent or less of pipradrol	1.0 gram
Prasterone	1.0 gram
Prazepam	2.5 grams
Propylhexedrine	5.0 grams
Pseudoephedrine when included in Schedule 4 of the Poisons List	20.0 grams
Pyrovalerone	1.0 gram
Quinbolone	3.0 grams
Silandrone	5.0 grams
Stanolone	10.0 grams
Stanozolol	2.0 grams
Stenbolone	5.0 grams
Temazepam	5.0 grams
Testolactone	100.0 grams
Testosterone except when included in Schedule 6 of the Poisons List	20.0 grams
Thiomesterone	5.0 grams
Trenbolone except when included in Schedule 6 of the Poisons List	5.0 grams

Trestolone	5.0 grams
Triazolam	0.05 gram
Zolazepam	2.5 grams