SOUTH AUSTRALIA

CONTROLLED SUBSTANCES (POISONS) REGULATIONS 1996

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REGULATIONS UNDER THE CONTROLLED SUBSTANCES ACT 1984

Controlled Substances (Poisons) Regulations 1996

being

No. 4 of 1996: *Gaz*. 4 January 1996, p. 36[1]

as varied by

No. 9 of 1997: *Gaz*. 30 January 1997, p. 728[2]
No. 94 of 1997: *Gaz*. 13 May 1997, p. 1895[3]

[1] Came into operation 4 January 1996: reg. 2.
[2] Came into operation 30 January 1997: reg. 2.
[3] Came into operation 1 July 1997: reg. 2.

PART 1
PRELIMINARY

Citation

1. These regulations may be cited as the *Controlled Substances (Poisons) Regulations 1996*.

Commencement

2. These regulations will come into operation on 4 January 1996.

Revocation

3. (1) The *Controlled Substances (Poisons) Regulations 1991* (see *Gazette* 24 January 1991 p. 238), as varied, are revoked.

(2) The *Controlled Substances (Possession of Poisons) Regulations 1988* (see *Gazette* 19 May 1988 p. 1265), as varied, are revoked.

(3) The *Controlled Substances (Declared Prescription Drugs) Regulations 1992* (see *Gazette* 14 May 1992 p. 1400) are revoked.

Interpretation

4. (1) In these regulations, unless the contrary intention appears—

"**the Act**" means the *Controlled Substances Act 1984*;

"**chiropodist**" means a person registered as a chiropodist under the *Chiropodists Act 1950*;

"**dental therapist**" has the same meaning as in section 85 of the *Dentists Act 1984*;

"**to dispense**" means to supply a drug in accordance with a prescription for that drug;

"**health service**" means a health service provided for the public or any section of the public for the purpose of curing, alleviating, diagnosing or preventing the spread of any mental or physical illness, disease, abnormality or disability, and includes a hospital and a nursing home;

"**optometrist**" means a person registered as an optometrist under the *Optometrists Act 1920*;

"**poison**" means a substance declared by these regulations to be a poison;

"**prescriber**" means a medical practitioner, dentist, veterinary surgeon or surgical podiatrist;

"**record**" means—

(a) a documentary record; or

(b) a record made by an electronic, electromagnetic, photographic or optical process; or

(c) any other kind of record,

and "**to record**" has a corresponding meaning;

"**S4 drug**" means a schedule 4 poison;

"**schedule F poison**" means a poison that is listed in schedule F of these regulations;

"**surgical podiatrist**" means a person registered as a chiropodist under the *Chiropodists Act 1950* who—

(a) is a member of the Australian College of Surgical Podiatrists Inc.; or

(b) has successfully completed the course of instruction required to qualify for membership of the Australian College of Surgical Podiatrists Inc.;

"**Uniform Poisons Standard**" means the "*Standard for the Uniform Scheduling of Drugs and Poisons*" published by the Australian Health Ministers Advisory Council, as amended from time to time by that Council.

(2) In these regulations—

(a) a reference to "**schedule 1**", "**schedule 2**", "**schedule 3**", "**schedule 4**", "**schedule 5**", "**schedule 6**", "**schedule 7**", or "**schedule 8**" is a reference to the corresponding schedule in the Uniform Poisons Standard (as incorporated into these regulations); and

(b) a reference to a "**schedule 1 poison**" is a reference to a poison listed in schedule 1, a reference to a "**schedule 2 poison**" is a reference to a poison listed in schedule 2, and so on.

Incorporation of the Uniform Poisons Standard

5. The *Uniform Poisons Standard*, as modified by schedule A of these regulations, is incorporated into these regulations.

Declaration of poisons (s. 12(1))

6. (1) Pursuant to section 12(1) of the Act, the following substances (whether in a pure form, or contained in a preparation or admixture) are declared to be poisons:

primary substances:

(a) the substances listed in schedules 1 to 8 of the *Uniform Poisons Standard*, as modified by schedule A of these regulations; and

(b) the substances listed in appendix C of the *Uniform Poisons Standard*; and

(c) the substances listed in schedules B and C of these regulations; and

related substances:

(d) the following substances, but subject to any express exclusion contained in the Standard:

(i) the artificial form of a primary substance;

(ii) where a primary substance is a plant (other than a plant included in schedule 8)—that plant, or any part of that plant, when packed or prepared for therapeutic use;

(iii) every salt, active principle or derivative (including an ester or ether) of a primary substance and every salt of such an active principle or derivative;

(iv) every alkaloid of a primary substance and every salt of such an alkaloid;

(v) except in the case of levomethorphan or levorphanol, every stereoisomer of a primary substance and every salt of such a stereoisomer.

(2) A related substance will be taken to be included in the schedule, or schedules, of the *Uniform Poisons Standard* in which the primary substance to which it is related is included.

(3) A reference in these regulations to a particular primary poison will be taken to include a reference to its related substances.

Declaration of prescription drugs (s. 12(2))

7. Pursuant to section 12(2) of the Act, the poisons listed in schedule 4 and schedule 8 are declared to be prescription drugs.

Certain new substances to be taken to be schedule 4 poisons

8. On a substance designed for human or animal therapeutic use being approved by—

(a) the Therapeutic Goods Administration of the Commonwealth for inclusion in the *Australian Register of Therapeutic Goods*; or

(b) the National Registration Authority of the Commonwealth for inclusion in the *Australian Register of Agricultural and Veterinary Chemical Products*,

the substance will be taken to be a schedule 4 poison until—

(c) it is listed in some other schedule to the *Uniform Poisons Standard*; or

(d) it is exempted from listing in the *Uniform Poisons Standard*.

Application of these regulations

9. These regulations do not apply in relation to—

(a) a poison when contained in a product that is listed in appendix A of the *Uniform Poisons Standard*; or

(b) a poison listed in appendix G of the *Uniform Poisons Standard* when contained in a preparation in a concentration not exceeding the concentration specified in appendix G for that poison; or

(c) a poison that is listed in any of the schedules 1 to 6 (but is not listed in schedule 7 or 8) of the *Uniform Poisons Standard* when contained in a preparation in a concentration not exceeding 10 milligrams per litre or 10 milligrams per kilogram.

PART 2
LICENCES

Licences

10. (1) Licences under the Act will be of the following classes:

(a) manufacturers licence (s. 13);

(b) wholesale dealers licence (s. 14);

(c) retail sellers licence (s. 15);

(d) medicine sellers licence (s. 15);

(e) licence to supply and administer an S4 drug (s. 18);

(f) licence to possess schedule F poisons (s. 22).

(2) An application for a licence must be made to the Health Commission on a form approved by the Commission, completed and signed by the applicant in accordance with the instructions contained in the form, and must be accompanied by the appropriate fee set out in schedule D of these regulations.

(3) Where a licence is to be granted or renewed for a term of less than 12 months, the fee payable is a proportion of the appropriate fee, being the proportion that the number of whole months in the term of the licence bears to 12 months.

(4) Licences expire as follows:

(a) manufacturers licence or wholesale dealers licence—on 28 February next following the date on which the licence was granted or last renewed;

(b) retail sellers licence or medicine sellers licence—on 30 November next following the date on which the licence was granted or last renewed;

(c) licence to supply or administer an S4 drug or licence to possess schedule F poisons—on 31 May next following the date on which the licence was granted or last renewed.

Note: Section 55 of the Act provides that the Health Commission may grant a licence subject to such conditions as it thinks fit and specifies in the licence and may at any time, by notice in writing given personally or by post to the holder, vary or revoke a condition, or attach a further condition, to the licence.

Restrictions on medicine sellers licences

11. (1) A person is not eligible to be granted a medicine sellers licence unless he or she is carrying on the business of selling goods by retail in premises that are open for business for not less than 38 hours per week and—

(a) the premises are at least 25 kilometres (by the shortest practical route) from the nearest pharmacy that is open for not less than 3 hours per day (excluding Saturdays, Sundays and public holidays); or

(b) he or she satisfies the Health Commission that the local community is in particular need of a licensed medicine seller.

(2) A medicine sellers licence will be subject to a condition that the holder of the licence must not sell a schedule 2 poison other than one that is listed in schedule E of these regulations.

PART 3
APPLICATION OF GENERAL OFFENCES (PART 4) OF THE ACT

Manufacture, production and packing (s. 13)

12. (1) Section 13 of the Act applies to all poisons listed in schedules 1 to 7.

(2) *Exemption*—A person who holds a licence under the *Therapeutic Goods Act 1989* of the Commonwealth to manufacture goods that are poisons listed in schedules 1 to 7 is exempt from the requirement to hold a licence under section 13 of the Act in respect of the manufacture of those goods.

(3) *Exemption*—A person who packs for retail sale a liquid hydrocarbon listed in schedule 5 is exempt from the requirement to hold a licence under section 13 of the Act to the extent that he or she packs the substance at the place at which the sale takes place.

Sale by wholesale (s. 14)

13. Section 14 of the Act applies to all poisons listed in schedules 1 to 7.

Sale or supply to end user (s. 15)

14. (1) Section 15 of the Act applies to all poisons listed in schedules 1 to 3 and schedule 7.

(2) A person who sells by retail or supplies to a person a schedule 3 poison—

(a) must personally (that is to say, not through an assistant) give oral directions, supplemented wherever practicable with written directions, for the safe and proper use of the poison to the person purchasing or being supplied with the poison; and

(b) in respect of a schedule 3 poison that is listed in schedule G of these regulations, must (unless he or she is a medical practitioner, dentist or veterinary surgeon)—

(i) record—

(A) the name and address of the person for whom the poison is purchased or supplied; and

(B) the date of sale or supply; and

(C) the directions given for the safe and proper use of the poison; and

(D) the trade name or the approved name of the poison sold or supplied, or, if it does not have either a trade or approved name, its ingredients and the form, strength and quantity sold or supplied; and

(E) a unique identifier enabling those records to be linked with the poison sold or supplied; and

(ii) lodge with the Health Commission within 15 days of the end of each month a copy of the records kept under this subregulation in respect of the poisons sold or supplied during that month.

Penalty: $3 000.

(3) Despite subregulation (2)*(a)*, an interpreter may be used to assist in the giving of oral directions to a person who is not sufficiently familiar with the English language.

Sale of certain poisons (s. 16)

15. (1) Section 16 of the Act applies to all poisons listed in schedule 7.

(2) For the purposes of section 16(4)*(c)* of the Act, the additional matters that a person who sells a schedule 7 poison must record are as follows:

(a) the date of purchase; and

(b) the address and usual occupation of the purchaser; and

(c) the trade name or the approved name of the poison purchased; and

(d) the form and strength of the poison purchased; and

(e) the quantity of the poison purchased.

Possession (s. 22)

16. (1) Section 22 of the Act applies to all schedule F poisons.

(2) *Exemption*—A person is exempt from section 22 of the Act in respect of possession of—

(a) 7 litres or less of chloropicrin; or

(b) any quantity of a preparation containing chloropicrin, provided that the concentration of chloropicrin in the preparation does not exceed five per cent; or

(c) a quantity of baits containing sodium fluoroacetate if—

(i) the concentration of sodium fluoroacetate in each bait does not exceed 0.03 per cent; and

(ii) the total amount of sodium fluoroacetate present in that particular quantity does not exceed 10 grams; and

(iii) the person—

(A) has the written approval of the Animal and Plant Control Commission ("**the APCC**") to acquire and possess those baits; and

(B) acquires the baits from a supplier approved by the APCC; and

(C) complies with any conditions imposed by the APCC on granting the approval to acquire and possess baits.

(3) The APCC may, on granting an approval under subregulation (2)*(c)*(iii), impose such conditions as it thinks fit.

(4) A person who does not comply with a condition imposed under subregulation (3) is guilty of an offence.

Penalty: $3 000.

(5) The APCC may, for such reasons as it thinks fit, vary or revoke an approval given under this regulation.

(6) In this regulation—

"**bait**" means a preparation used for the purposes of poisoning dingoes and foxes.

Exemption from s. 22 may be granted to certain pest controllers

17. (1) The Health Commission may exempt a person who is licensed under the *Controlled Substances (Pesticide) Regulations 1988* from the requirement to hold a licence under section 22 of the Act in respect of the use of a pesticide that is a schedule F poison.

(2) The Health Commission may, by notice in writing to an exempted person, vary or revoke the exemption.

Packaging of poisons (s. 24)

18. (1) For the purposes of section 24*(b)* of the Act, the requirements as to packaging with which the seller or supplier of a poison must comply are—

(a) the requirements set out in the *Uniform Poisons Standards* (as incorporated into these regulations); and

(b) the additional requirements set out in subregulation (3) in the case of a poison referred to in that subregulation.

(2) The Health Commission may grant an exemption from subregulation (1) to a seller or supplier in respect of a particular product if the Commission is satisfied that the product is otherwise adequately packaged.

(3) Subject to subregulation (4)—

(a) a poison listed in clause 1 of schedule H of these regulations that is in the form of a tablet, capsule, lozenge, pastille, suppository or similar discrete solid dosage unit must be enclosed in a child-resistant package or container approved by the Health Commission; and

(b) a poison in liquid form listed in clause 2 of schedule H of these regulations must be packed in a child-resistant package or container approved by the Health Commission.

(4) Subregulation (3) does not apply to a poison that is listed in schedule H of these regulations if the poison—

(a) is packed as an individually wrapped powder; or

(b) is packed in a package or container containing not less than 500 solid dosage units; or

(c) is sold to a person who is likely to suffer undue hardship through difficulty in opening a package or container that complies with subregulation (3)*(a)*; or

(d) is sold to a health service for administration to an inpatient of the health service.

Labelling of poisons (s. 24)

19. (1) For the purposes of section 24*(c)* of the Act, the requirements as to labelling with which the seller or supplier of a poison must comply are as follows:

(a) in the case of the supply in the course of professional practice or the sale by retail (other than pursuant to dispensing a prescription) of a poison designed for human or animal therapeutic use (not being a schedule 3 poison that is listed in schedule G of these regulations), the package or container in which the poison is supplied or sold must have affixed to it—

(i) the manufacturer's label, if that label conforms with the requirements of the *Uniform Poisons Standard* (as incorporated into these regulations); or

(ii) a label that conforms with subregulation (2);

(b) in the case of the supply or sale by retail of a schedule 3 poison that is listed in schedule G of these regulations, the package or container in which the poison is supplied or sold must have affixed to it a label that conforms with subregulation (2);

(c) in the case of the sale of a poison designed for human or animal therapeutic use pursuant to dispensing a prescription for the poison, the package or container in which the poison is sold must have affixed to it a label that conforms with subregulation (2);

(d) in any other case, the package or container in which the poison is sold (whether by wholesale or retail) must have affixed to it a label that conforms with the requirements of the *Uniform Poisons Standard* (as incorporated into these regulations).

(2) For the purposes of paragraphs *(a)*(ii), *(b)* and *(c)* of subregulation (1), the label must have the following information clearly printed on it:

(a) the name (or business name), business address and telephone number of the person by whom the poison is sold or supplied; and

(b) —

(i) the name of the person for whose use the poison is sold or supplied; or

(ii) where the poison is intended for an animal—the species of animal for which it is intended and the name of the owner of the animal and the name (if any) of the animal; and

(c) the trade name or the approved name of the poison or, if it does not have either a trade or approved name, its ingredients; and

(d) if the poison is part of a preparation or admixture—the strength or proportion of poison contained in the preparation or admixture; and

(e) directions for the safe and proper use of the poison, including (where relevant) the route of administration; and

(f) the date on which the poison is sold or supplied; and

(g) in the case of a poison sold pursuant to dispensing a prescription for the poison—a unique identifier that enables the poison to be linked with the prescription; and

(h) in the case of a schedule 3 poison that is listed in schedule G of these regulations—a unique identifier enabling that poison to be linked with the records required to be kept under regulation 14(2)*(b)*; and

(i) in the case of a preparation for internal use by humans (other than infants)—

(i) that contains a poison listed in appendix K of the Uniform Poisons Standard—one of the following statements:

"This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol."; or

"This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery."; or

(ii) that contains levocabastine—the following statement:

"Do not use if pregnant."; or

(iii) that contains misoprostol—the following statement:

"CAUTION—Misoprostol should not be used by pregnant women.".

(3) The Health Commission may grant an exemption from this regulation, or any provision of this regulation, to a seller or supplier in respect of a particular product if the Commission is satisfied that the product is otherwise adequately labelled.

Storage of poisons (s. 25)

20. (1) For the purposes of section 25 of the Act, a person must not store—

(a) any poison in a container that—

(i) is normally used for containing food or beverages; or

(ii) is similar to a container that is normally used for containing food or beverages; or

(b) a schedule 3, 4 or 7 poison in retail premises unless it is stored in a part of the premises to which the public is not permitted access; or

(c) a schedule 2, 5 or 6 poison (other than a schedule 6 poison that is a hair colouring preparation) in retail premises unless—

(i) it is stored in a part of the premises to which the public is not permitted access; or

(ii) if it is stored in a part of the premises to which the public is permitted access, it—

(A) is stored not less than 1.2 metres above floor level; or

(B) is enclosed in a child-resistant package or container approved by the Health Commission; or

(C) is enclosed in a blister pack; or

(D) is stored in a container that has a capacity of not less than five litres; or

(E) is stored in a container that has a gross weight of not less than five kilograms.

Transport of poisons (s. 26)

21. For the purposes of section 26 of the Act, a person must not—

(a) consign a poison for transport unless it is packed in such a way as to avoid leakage arising from the ordinary risks of handling and transport; or

(b) transport a poison in a vehicle in which any food, or component of food, for human or animal consumption is being transported unless the poison is carried in a part of the vehicle effectively separated from that part of the vehicle containing the food.

Prohibition on use of certain poisons for certain purposes (s. 27)

22. (1) For the purposes of section 27 of the Act, a person must not—

(a) sell, supply, purchase or use a schedule 7 poison for a domestic, or domestic gardening, purpose; or

(b) prescribe, sell, supply, purchase or use a poison that is listed in appendix C of the *Uniform Poisons Standard* for the purpose or purposes indicated in relation to that poison in appendix C; or

(c) in the case of a poison produced for the treatment of animals—

(i) prescribe, sell, supply or purchase such a poison if he or she knows, or if there are reasonable grounds for suspecting, that the poison is intended for human use; or

(ii) administer to any person (including himself or herself) such a poison; or

(d) use chloramphenicol for the treatment of stock bred, raised or used for the purpose of providing a product for human consumption.

(2) In this regulation—

"**stock**" means any animal or bird and any bee of the genus *Apis* or *Megachile*.

Restriction on advertising (s. 28)

23. (1) Section 28 of the Act applies to all poisons listed in schedules 3, 4 and 8, except where the advertisement of such a poison appears in a journal that is circulated predominantly among medical professionals.

(2) In this regulation—

"**journal**" means a newsletter, magazine or other periodical, whether published for sale or for distribution without charge;

"**medical professionals**" includes medical practitioners, dentists, veterinary surgeons, nurses, pharmacists, chiropodists, optometrists, dental therapists, medical administrators, physiotherapists registered under the *Physiotherapists Act 1945*, scientists working in medical laboratories and those who hold a wholesale dealers licence.

PART 4
PRESCRIPTIONS AND DISPENSING

Interpretation

24. In this Part—

"**drug**" means a poison designed for human or animal therapeutic use.

Prescription to be given in writing or by telephone or fax, etc.

25. (1) Subject to subregulation (2), a prescriber must give a prescription for a drug in writing, and must give it to the person for whom the drug is to be supplied, or to a person acting on behalf of that person.

Penalty: $5 000.

(2) A prescriber may, if of the opinion that good reason exists for doing so, give a prescription for a drug to a pharmacist by telephone, facsimile transmission or some other form of electronic transmission.

(3) If a prescription is given by telephone or by some form of electronic transmission (other than facsimile), the prescriber—

(a) must give the pharmacist the following information:

(i) his or her name and full address; and

(ii) the name and address of the person to whom the drug is to be supplied; and

(iii) the name, dose form and (if relevant) the route of administration of the drug to be dispensed; and

(iv) where applicable—the strength of the drug to be dispensed; and

(v) the dose of the drug to be administered to the person for whom the drug is prescribed or to the animal in relation to which the drug is prescribed; and

(vi) the total amount of the drug to be dispensed; and

(vii) the frequency at which the drug is to be administered; and

(b) must, immediately after giving the prescription by that method—

(i) complete a written prescription that clearly states that it is given in confirmation of the prescription given by telephone or by electronic transmission (as the case may be) and that otherwise complies with these regulations; and

(ii) forward the written prescription to the pharmacist as soon as practicable.

Penalty: $3 000.

(4) If a prescription is given to a pharmacist by facsimile transmission, the prescriber must forward the original prescription to the pharmacist as soon as practicable.

Penalty: $3 000.

Written prescriptions

26. (1) A prescriber who writes a prescription for the supply of a drug must—

(a) write it legibly in ink; and

(b) date and personally sign the prescription; and

(c) include on the prescription—

(i) his or her professional name, address and telephone number; and

(ii) —

(A) the name and address of the person for whom the prescription is intended; or

(B) where the prescription is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal; and

(iii) where the prescriber is a dentist—the words "For dental treatment only"; and

(iv) where the prescriber is a veterinary surgeon—the words "For animal treatment only"; and

(v) where the prescriber is a surgical podiatrist—the words "For podiatric treatment only"; and

(d) specify—

(i) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(ii) where applicable—the strength of the drug; and

(iii) the dose of the drug to be administered to the person for whom, or the animal for which, it is prescribed; and

(iv) the frequency at which the drug is to be administered; and

(v) the total amount of the drug to be supplied each time the prescription is dispensed; and

(vi) the total number of times the drug may be dispensed.

(2) If the prescriber is prescribing an above average strength or potentially dangerous dose of the drug, he or she must—

(a) underline the statement of the dose of the drug in the prescription; and

(b) sign his or her initials alongside the underlined portion of the prescription referred to in paragraph *(a)*.

(3) A person who contravenes or fails to comply with this regulation is guilty of an offence.

Penalty: $3 000.

Dispensing prescriptions for drugs

27. (1) A pharmacist or medical practitioner who dispenses a prescription for a drug—

(a) must write in ink on the face or back of the prescription—

(i) his or her name, business name and business address; and

(ii) the date on which the drug is dispensed; and

(iii) the unique identifier applicable to the drug; and

(b) must, on the day on which the drug is dispensed, record—

(i) the unique identifier applicable to the drug dispensed on the prescription; and

(ii) his or her name as the dispenser; and

(iii) the date; and

(iv) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, its ingredients; and

(v) —

(A) the name and address of the person for whose use the drug is dispensed; or

(B) where the drug is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal; and

(vi) the form, strength and quantity of the dispensed drug; and

(vii) the directions given for the safe and proper use of the dispensed drug; and

(viii) the name, address and business telephone number of the person who prescribed the drug; and

(ix) the number of times the prescription may be dispensed and (where the prescription so specifies) the intervals at which the drug may be dispensed; and

(c) if the prescription is for a schedule 4 poison and does not specify the number of times the drug is to be dispensed, must—

(i) dispense it once only pursuant to that prescription; and

(ii) write "CANCELLED" on the prescription; and

(iii) unless it is for any reason forwarded to the Health Commission, retain the original or duplicate prescription (as the case may be) for at least one year and have it readily available for inspection during that period; and

(d) if the prescription specifies the number of times and the intervals at which the drug may be dispensed—must not dispense the drug more times than the number specified or at intervals less than those specified; and

(e) where a prescription is dispensed more than once, must—

(i) when the drug is dispensed for the last time specified in the prescription—write "CANCELLED" on the prescription; and

(ii) unless it is for any reason forwarded to the Health Commission, retain the original or duplicate prescription (as the case may be), for at least two years and have it readily available for inspection during that period.

Penalty: $5 000.

(2) If a prescription has been issued in duplicate and the original is retained by the pharmacist or medical practitioner, it is sufficient compliance with this regulation if the required information is marked on the duplicate prescription.

(3) Despite subregulation (1)*(d)*, if a pharmacist or medical practitioner is satisfied that a person—

(a) has lost a previously dispensed supply of a drug; or

(b) will, through absence from the State or otherwise, find it unduly difficult to have future supplies of a drug dispensed as needed,

he or she may (but is not obliged to) dispense a prescription for the person at an interval earlier than that specified on the prescription.

(4) A pharmacist or medical practitioner must not dispense a prescription for a drug if the prescription—

(a) is presented more than 12 months after the date of its issue; or

(b) has been cancelled; or

(c) has, in the pharmacist's or medical practitioner's opinion, been altered, forged or obtained by false pretences.

Penalty: $5 000.

PART 5
SPECIAL PROVISIONS RELATING TO S4 DRUGS

Prescribed professions (s. 18(1)*(b)*)

28. (1) Subject to the limitations set out in this regulation, the following professions are prescribed professions for the purposes of section 18(1)*(b)* of the Act:

Chiropody;
Dental therapy;
Optometry.

(2) Subject to subregulation (3), a chiropodist or dental therapist may only administer an S4 drug listed in clause 1 of Schedule I of these regulations.

(3) A chiropodist who is a surgical podiatrist may, for the purpose of podiatric treatment, prescribe, supply or administer an S4 drug that is listed in schedule J of these regulations in a form and quantity that complies with that schedule.

(4) An optometrist may only administer an S4 drug listed in clause 2 of schedule I of these regulations.

Additional requirements for S4 drugs listed in schedule K (s. 18(2))

29. (1) For the purposes of section 18(2) of the Act—

(a) the S4 drugs listed in schedule K of these regulations are prescribed prescription drugs; and

(b) the qualifications and authorisations referred to in subregulations (2), (3) and (4) are prescribed qualifications.

(2) A person must not prescribe for human use an S4 drug that is listed in clause 1 of schedule K of these regulations unless he or she is a medical practitioner who—

(a) is a specialist in endocrinology; or

(b) is a specialist in obstetrics and gynaecology; or

(c) provides services to an endocrinology unit or obstetrics and gynaecology unit of a teaching hospital in South Australia.

(3) A person must not prescribe for human internal use an S4 drug that is listed in clause 2 of schedule K of these regulations unless he or she is a medical practitioner who—

(a) is a specialist in dermatology; or

(b) is a specialist in another field and is authorised to prescribe such drugs by the Health Commission.

(4) A person must not prescribe for human use an S4 drug that is listed in clause 3 of schedule K of these regulations unless he or she is a medical practitioner who is authorised by the Health Commission to prescribe that drug for a specified patient.

(5) Where a medical practitioner prescribes an S4 drug that is listed in clause 2 or 3 of schedule K of these regulations, he or she must—

(a) inform the patient of the name of the drug and that the drug may cause birth defects; and

(b) provide the patient with written information about the drug and its potential side effects; and

(c) inform the patient of the dangers should the patient unlawfully supply the drug to another person; and

(d) where the patient is a female of child-bearing age—

(i) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and

(ii) inform her that she must not become pregnant during treatment or within the prescribed period after completion of treatment; and

(e) obtain written consent for the treatment from the patient.

Penalty: $5 000.

(6) A person who sells or supplies for human internal use an S4 drug that is listed in clause 2 or 3 of schedule K of these regulations must include (in prominent print) on the label to be affixed to the package or container in which the drug is sold or supplied the following statement:

"WARNING—Causes birth defects. Do not use if pregnant. Do not become pregnant during use or within [*insert prescribed period*] of stopping treatment.".

Penalty: $5 000.

(7) In this regulation—

"**prescribed period**" means—

(a) in the case of treatment with etretinate or acitretin—24 months;

(b) in the case of treatment with isotretinoin, thalidomide or tretinoin—one month.

Additional requirements for Nalbuphine

30. (1) In relation to the S4 drug Nalbuphine—

(a) a medical practitioner must not—

(i) prescribe Nalbuphine for use by a person for a period of more than two consecutive months without reporting details of the person’s case and treatment to the Health Commission; or

(ii) prescribe a further dose of the drug for that person without an authority to do so from the Health Commission;

(b) when a pharmacist cancels a prescription for Nalbuphine after dispensing the prescription for the drug for the last time, he or she must forward the cancelled prescription to the Health Commission at the end of the month in which the drug was dispensed;

(c) a medical practitioner, veterinary surgeon or pharmacist who sells or supplies Nalbuphine must record—

(i) the amount of Nalbuphine obtained by him or her and the name and address of the person from whom the drug was obtained; and

(ii) the quantity of any of the drug sold or supplied by him or her and the quantity remaining in his or her possession; and

(iii) in the case of sale by a pharmacist, the name of the prescriber and the identification number of the prescription.

Penalty: $5 000.

(2) The holder of a wholesale dealers licence who sells Nalbuphine must record—

(a) the quantities of Nalbuphine obtained by him or her; and

(b) the quantities of Nalbuphine sold by him or her; and

(c) the order numbers of the orders for any Nalbuphine.

Penalty: $3 000.

Exemptions from s. 18 of the Act

31. (1) Section 18 of the Act does not apply to the supply of an S4 drug by a council or a health service to a person where the drug is provided pursuant to a community immunisation program run by the council or health service.

(2) Section 18 of the Act does not apply to a pharmacist in relation to the supply of an S4 drug (without dispensing a prescription) provided that—

(a) the drug is supplied to a council or a health service for use in a community immunisation program and the pharmacist has received a written order for the drug from the council or health service; or

(b) the drug is for use by a person who holds a licence to supply or administer an S4 drug and the pharmacist has received a written order for the drug from the licensee; or

(c) the drug is supplied for the mass treatment of certain animals to the owner of the animals and—

(i) the pharmacist has received a written order for the drug from a veterinary surgeon; or

(ii) —

(A) the drug is an antibiotic; and

(B) the pharmacist has received a written order for the drug from an inspector appointed under the *Stock Act 1990*; and

(C) the written order is on a form approved by the Chief Inspector of Stock under that Act and has been countersigned by the Chief Inspector; or

(d) the drug is supplied to a member of a profession authorised by the Act or these regulations to supply or administer S4 drugs and the pharmacist has received a written order for the drug from that person; or

(e) the drug is needed to complete the quantity of drugs required to be carried on a ship in port in South Australia in compliance with—

(i) the *Scale of Medicines and Medical Stores* prescribed under section 125 of the *Navigation Act 1912* of the Commonwealth; or

(ii) the *Scale of Medicines and Medical Stores* prescribed by the Navigation Authority of any State in Australia; or

(iii) the *Scale of Medicines and Medical Stores* prescribed by law for ships in the country in which the ship is registered or the *United Nations World Health Organization Ships Captains Medical Guide*; or

(iv) appendix L (Medicine and Medical Stores) of the *Uniform Shipping Laws Code* (section 13; Miscellaneous Equipment), being the Code of that name adopted by the Australian Transport Advisory Council, as in force from time to time,

and the pharmacist has received a written order for the drug from the master or medical officer of such a ship; or

(f) the drug is not one that is listed in schedule K of these regulations and the pharmacist—

(i) is satisfied that—

(A) the person for whom it is to be supplied is being medically treated with the drug; and

(B) the continued supply of that drug is essential to the health of that person; and

(C) there is good reason for the person's inability to produce a prescription for the drug; and

(ii) supplies—

(A) in the case of a drug that is a cream, ointment or liquid or one that is packaged in such a manner as to promote the safe and proper use of the drug—the smallest standard package or container made by the manufacturer; or

(B) in any other case—no more than three days' dosage of the drug; and

(iii) on the day on which the drug is supplied, records—

(A) his or her name as the supplier of the drug; and

(B) the date; and

(C) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, its ingredients; and

(D) the name and address of the person for whom the drug is supplied; and

(E) the form, strength and quantity of the drug; and

(F) the directions given for the safe and proper use of the drug, including (where appropriate) the route of administration of the drug.

(3) In this regulation—

"**council**" means a council constituted under the *Local Government Act 1934*.

PART 6
SPECIAL PROVISIONS RELATING TO PRECURSOR CHEMICALS

Prohibition of manufacture, sale, possession, etc., of certain precursor chemicals

32. A person must not, unless he or she holds a permit from the Health Commission to do so, manufacture, sell, supply or be in possession of a poison listed in schedule B of these regulations.

Penalty: $5 000.

Strict regulation of storage and sale of certain precursor chemicals

33. (1) This regulation applies to the following poisons:

Acetic anhydride
Bromobenzene
Cathine (nor-pseudoephedrine)
Ephedrine
Ethyl phenylacetate
Hydriodic acid
Hypophosphorous acid
Isosafrole
Methyl phenylacetate
N-methylephedrine
N-methylpseudoephedrine
Phenyl-2-propanone
Phenylacetamide
Phenylacetic acid
Phenylacetonitrile
Phenylacetyl chloride
Phenylpropanolamine
Phosphorus, red
Piperonal
Pseudoephedrine
Safrole.

(2) A person must not sell a poison to which this regulation applies to another person unless—

(a) the purchaser holds an account with the seller; and

(b) the sale is transacted as a sale on account pursuant to a duly completed order form supplied by the purchaser; and

(c) the order form is accompanied by a duly completed end user statement in the form set out in schedule L of these regulations; and

(d) the seller is satisfied, on the production of a driver's licence, passport or other sufficient evidence, as to the identity of the person collecting the poison and that the person is the purchaser or is acting on behalf of the purchaser; and

(e) the seller duly completes the seller's section of the end user statement.

Penalty: $5 000.

(3) A seller of poisons to which this regulation applies—

(a) must, in relation to each sale of such a poison, keep a record of—

(i) the name and address of the purchaser; and

(ii) the name of the poison and the quantity sold; and

(iii) the date of the sale; and

(b) must retain an end user statement for at least five years after the date of the sale to which it relates; and

(c) must make the record referred to in paragraph *(a)* and the end user statements available for inspection at any time by an authorised officer under the Act; and

(d) must, if at any time he or she forms a suspicion that an order or enquiry for the purchase of such a poison may be connected to an unlawful use of the poison, inform the Commissioner of Police of the suspicion.

Penalty: 3 000.

(4) A seller of poisons to which this regulation applies—

(a) must keep those poisons in storage that is secure from access by any person other than a person who is authorised in writing by the seller to have such access; and

(b) must retain such a written authorisation while it is current and for at least five years after it ceases to have effect and make it available for inspection at any time by an authorised officer under the Act; and

(c) must cause the stock of those poisons to be checked, after each sale, by some person other than the person who directly handled the sale.

Penalty: $3 000.

(5) This regulation does not apply in relation to the sale of a poison to which this regulation applies if the sale—

(a) is of a poison contained in a preparation designed, packaged and labelled for human or animal therapeutic use; and

(b) is made to, or by, a medical practitioner, dentist, veterinary surgeon, nurse, optometrist or pharmacist acting in the ordinary course of his or her profession.

Regulation of sale of other precursor chemicals

34. (1) This regulation applies to the following poisons:

N-acetylanthranilic acid
Anthranilic acid
Benzaldehyde
Benzyl chloride
Boron tribromide
Ethylamine
N-ethylephedrine
N-ethylpseudoephedrine
Formamide
Methylamine
Nitroethane
3-Phenyl-1-propene
Piperidine
Propionic anhydride
Pyridine.

(2) A person must not sell a poison to which this regulation applies to another person unless—

(a) the purchaser provides the seller with a duly completed end user statement in the form set out in schedule L of these regulations; and

(b) the seller is satisfied, on the production of a driver's licence, passport or other sufficient evidence, as to the identity of the purchaser; and

(c) the seller duly completes the seller's section of the end user statement.

Penalty: $3 000.

(3) A seller of poisons to which this regulation applies must, if at any time he or she forms a suspicion that an order or enquiry for the purchase of such a poison may be connected to an unlawful use of the poison, inform the Commissioner of Police of the suspicion.

Penalty: $3 000.

(4) This regulation does not apply in relation to the sale of a poison to which this regulation applies if the sale—

(a) is of a poison contained in a preparation designed, packaged and labelled for human or animal therapeutic use; and

(b) is made to, or by, a medical practitioner, dentist, veterinary surgeon, nurse, optometrist or pharmacist acting in the ordinary course of his or her profession.

PART 7
OTHER OFFENCES

Restriction on giving samples of poisons

35. (1) Subject to this regulation, a person must not promote a poison for human, or animal, therapeutic use by supplying samples of the poison.

Penalty: $5 000.

(2) The holder of a manufacturers licence or wholesale dealers licence may give a sample of a poison for human, or animal, therapeutic use to a medical practitioner, dentist, veterinary surgeon, podiatrist, optometrist, dental therapist or pharmacist.

(3) A medical practitioner, dentist, veterinary surgeon, podiatrist, optometrist or dental therapist acting in the ordinary course of his or her profession may give to a person a sample of a poison for human, or animal, therapeutic use.

(4) A pharmacist acting in the ordinary course of his or her profession may give to a person a sample of a poison (other than an S4 drug) for human, or animal, therapeutic use.

(5) On each occasion that the holder of a manufacturers licence or wholesale dealers licence gives a sample of a poison, he or she must record—

(a) the date on which the sample of poison was supplied; and

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

(c) the trade name or the approved name of the poison supplied, or if it has neither a trade nor an approved name, its ingredients; and

(d) the quantity of the poison supplied.

Penalty: $3 000.

(6) Nothing in this regulation empowers any person to give a sample of a schedule 8 poison.

Offences relating to sale or supply of poisons

36. (1) A person must not sell or supply a poison in any residential premises, or from door to door, or in a public place.

(2) A person must not sell or supply a poison in a container that—

(a) is normally used for containing food or beverages; or

(b) is similar to a container that is normally used for containing food or beverages.

(3) A person must not sell camphor or naphthalene in block, ball, disc or pellet form for domestic use unless the blocks, balls, discs or pellets are enclosed in a device that restricts removal or ingestion of its contents.

(4) A person must not sell any liquid preparation or admixture containing paraquat unless it is coloured blue or green and contains a stenching agent in sufficient quantity to produce an offensive odour.

(5) A person who contravenes or fails to comply with this regulation is guilty of an offence.

Penalty: $5 000.

(6) In this regulation—

"**public place**" includes—

(a) a place to which free access is permitted to the public, with the express or tacit consent of the owner or occupier of that place; and

(b) a place to which the public are admitted on payment of money, the test of admittance being the payment of money only; and

(c) a road, street, footway, court, alley or thoroughfare that the public are allowed to use, notwithstanding that the road, street, footway, court, alley or thoroughfare is on private property.

Offence to dispose of poison

37. A person must not dispose of or use, or cause to be disposed of or used, a poison in any place or manner that constitutes, or is likely to constitute, a risk to public health or safety.

Penalty: $5 000.

Keeping of records

38. (1) A person who is required by these regulations to keep certain records must—

(a) in respect of any entry in the records, retain the records at the registered address of the business in this State for a period of two years from the day on which the entry was made; and

(b) have the records readily available for inspection at all reasonable times.

Penalty: $3 000.

(2) Where the information contained in the records is available only after the record is subjected to an electronic or other process, it is sufficient for the purposes of subregulation (1)*(b)* for the person to produce for inspection a reproduction or computerised record of any entry in the records.

False information

39. A person who, in providing any information required under these regulations, furnishes any information that is false or misleading in a material particular is guilty of an offence.

Penalty: $5 000.

Vicarious liability

40. For the purposes of these regulations, an act or omission of an employee or agent will be taken to be the act or omission of the employer or principal unless it is proved that the act or omission did not occur in the course of the employment or agency.

PART 8
MISCELLANEOUS

Analysis of substance (s. 53)

41. (1) A person who initiates an analysis pursuant to section 53(2) of the Act, must do so by notice in writing that—

(a) is signed by him or her; and

(b) is addressed to a person appointed as an analyst under the Act; and

(c) describes the substance to be analysed; and

(d) is accompanied by the appropriate fee set out in schedule D of these regulations.

(2) A Certificate of Analysis must be given in the form set out in schedule M of these regulations.

Research permit

42. An application for a research permit under section 56 of the Act must be made in writing to the Health Commission and be signed by the applicant.

Copies of codes, etc., to be kept at Health Commission's principal office

43. For the purposes of section 63(5a) of the Act, the office of the Health Commission at 11-13 Hindmarsh Square, Adelaide is the place at which copies of codes, standards, etc., must be kept and made available for inspection by members of the public.

Transitional provision—licences

44. A hospital or nursing home is exempted until 1 June 1996 from the requirement to hold a licence under section 18 of the Act in respect of supplying or administering an S4 drug to a patient in the hospital or nursing home.

SCHEDULE A

Modification of the Uniform Poisons Standard
(Regulation 5)

The *Uniform Poisons Standard* is to be read as if—

1. Part 3 were struck out.

2. Part 4 were varied—

(a) by the following items being struck out from schedule 8:

ACETYLMORPHINES
COCA LEAF
CONCENTRATE OF POPPY STRAW
4-CYANO-2-DIMETHYLAMINO-4,4-DIPHENYLBUTANE
4-CYANO-1-METHYL-4-PHENYLPIPERIDINE
ECGONINE
2-METHYL-3-MORPHOLINO-1,1-DIPHENYLPROPANE CARBOXYLIC ACID
1-METHYL-4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID
4-PHENYLPIPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER; and

(b) by the following item being inserted alphabetically in schedule 8:

MORAMIDE;

(c) by schedule 9 being struck out.

3. Part 5 were varied by the following Appendices being struck out:
B, D, and J.

SCHEDULE B

Precursor chemicals declared as Poisons (Possession and Sale Prohibited)
(Regulations 6 and 32)

Ephedrone
2-Chloro-1-phenylpropane
2-Nitro-1-phenyl-1-propene
2-Amino-1-chloro-1-phenylpropane
2-Bromo-1-phenylpropane
2-Iodo-1-phenylpropane
2-(N-methylamino)-1-chloro-1-phenylpropane
3,4-Methylenedioxyphenylpropan-2-one.

SCHEDULE C

Precursor Chemicals declared as Poisons (Sale Regulated)
(Regulations 6, 33 and 34)

N-acetylanthranilic acid
Anthranilic acid
Benzaldehyde
Benzyl chloride
Boron tribromide
Bromobenzene
Ethyl phenylacetate
Ethylamine
N-ethylephedrine
N-ethylpseudoephedrine
Formamide
Hydriodic acid
Hypophosphorous acid
Isosafrole
Methylamine
Methyl phenylacetate
N-methylpseudoephedrine
Nitroethane
Phenyl-2-propanone
Phenylacetamide
Phenylacetic acid
Phenylacetonitrile
Phenylacetyl chloride
3-Phenyl-1-propene
Phosphorus, red
Piperidine
Piperonal
Propionic anhydride
Pyridine.

SCHEDULE D

Fees

(Regulations 10 and 40)

$

1. Annual fee for manufacturers licence—

(a) for a manufacturer who manufactures only schedule 1 poisons 0
(b) for a manufacturer who manufactures schedule 2 poisons 152
(c) for a manufacturer who manufactures schedule 3 poisons 152
(d) for a manufacturer who manufactures schedule 4 poisons 152
(e) for a manufacturer who manufactures schedule 5 poisons 101
(f) for a manufacturer who manufactures schedule 6 poisons 152
(g) for a manufacturer who manufactures schedule 7 poisons 152

(**NB** The maximum cumulative annual fee for a manufacturer is $506)

2. Annual fee for wholesale dealers licence

(a) for a wholesaler who sells only schedule 1 poisons 0
(b) for a wholesaler who sells schedule 2 poisons 51
(c) for a wholesaler who sells schedule 3 poisons 51
(d) for a wholesaler who sells schedule 4 poisons 101
(e) for a wholesaler who sells schedule 5 poisons 51
(f) for a wholesaler who sells schedule 6 poisons 51
(g) for a wholesaler who sells schedule 7 poisons 101

(**NB** The maximum cumulative annual fee for a wholesaler is $253)

3. Annual fee for retail sellers licence 101

4. Annual fee for medicine sellers licence 25

5. Annual fee for a licence to supply or administer an S4 drug 51

6. Annual fee for licence to possess schedule F poisons 76

7. Application fee for analysis of substance 152

SCHEDULE E

Schedule 2 Poisons Authorised to be Sold by Holder of a Medicine Sellers Licence
(Regulation 11(2))

The following poisons are authorised to be sold by the holder of a medicine sellers licence:

Antazoline
Aspirin (excluding packs of more than 50 dosage units)
Atropine
Belladonna
Benzamine
Benzocaine
Benzoyl peroxide
Benzydamine
Bromhexine
Brompheniramine
Buclizine
Butylaminobenzoate
Carbaryl
Carbenoxolone
Carbetapentane
Chloroform
Chlorpheniramine
Clotrimazole
Codeine
Creosote
Dexchlorpheniramine
Dextromethorphan
Dicyclomine (excluding preparations for infants)
Dihydrocodeine
Dimenhydrinate
Diphemanil methylsulphate
Diphenhydramine
Diphenylpyraline
Doxylamine
Ether
Ethylmorphine
Fluorides
Gelsemium
Glutaraldehyde
Guaiphenesin
Hexachlorophane
Homatropine
Hydroquinone
8-Hydroxyquinoline
Hyoscine
Hyoscyamine
Hyoscyamus
Iodine
Iron compounds
Lignocaine
Lindane
Lobeline
Lobelia
Mebendazole
Mefenamic acid
Mercuric oxide
Mercury organic compounds
Methoxamine
Miconazole
Naphazoline
Naproxen
Niclosamide
Oxethazaine
Oxymetazoline
Papaverine
Paracetamol (excluding packs of more than 50 dosage units)
Phenazone
Pheniramine
Phenol
Phenylenediamines and alkylated phenylenediamines
Phenylephephrine
Pholcodine
Prilocaine
Promethazine
Propantheline
Pseudoephedrine (excluding packs of more than 30 dosage units)
Pyrantel
Salicylamide
Silver salts
Sodium cromoglycate
Staphisagria
Stramonium
Tetrahydrozoline
Thenyldiamine
Trimeprazine
Triprolidine
Tymazoline
Xylometazoline.

SCHEDULE F

Prescribed Poisons for the Purposes of s. 22 of the Act
(Regulation 16)

Section 22 of the Act applies to the following poisons:

Acrolein
Arsenic when included in schedule 7
Chloropicrin
Cyanides when included in schedule 7
DDT
Fluoroacetamide
Fluoroacetic acid
Hydrocyanic acid when included in schedule 7
Methyl bromide
Mirex
Sodium fluoroacetate
Strychnine when included in schedule 7
Thallium.

SCHEDULE G

Schedule 3 Poisons to which Regulation 14(2) applies

Adrenaline (in metered aerosols)
Dihydrocodeine (in cough preparations)
Doxylamine (in preparations also containing codeine)
Promethazine (in preparations also containing codeine).

SCHEDULE H

Poisons that must be Packed in Child-resistant Containers
(Regulation 18)

1. Poisons in the form of tablets, capsules, etc.—

ANTIHISTAMINES—

Antazoline
Astemizole
Azatadine
Bamipine
Brompheniramine
Bromodiphenhydramine
Buclizine
Carbinoxamine
Cetoxime
Chlorocyclizine
Chloropyrilene
Chlorpheniramine
Chlorphenoxamine
Cinnarizine
Clemastine
Clemizole
Cycliramine
Cyclizine
Cyproheptadine
Deproprine
Dexbrompheniramine
Dexchlorpheniramine
Dimenhydrinate
Dimethindene
Dimethothiazine
Diphenhydramine
Diphenidol
Diphenylpyraline
Doxylamine
Embramine
Halopyramine
Histapyrrodine
Homochlorcyclizine
Hydroxyzine
Isothipendyl
Loratadine
Mebhydrolin
Meclozine
Mepyramine
Methaphenilene
Methdilazine
Phenindamine
Pheniramine
Phenyltoloxamine
Promethazine
Prothipendyl
Pyrathiazine
Pyroxamine
Pyrrobutamine
Rotoxamine
Terfenadine
Thenalidine
Thenyldiamine
Thiazinamium
Thonzylamine
Tolpropamine
Trimeprazine
Trimethobenzamid
Tripelennamine
Triprolidine

TRICYCLIC ANTIDEPRESSANTS—

Amitriptyline
Amoxapine
Butriptyline
Cidoxepin
Clomipramine
Desipramine
Dibenzepin
Dothiepin
Doxepin
Fantridone
Imipramine
Intriptyline
Iprindole
Ketipramine
Lofepramine
Loxapine
Maprotiline
Melitracen
Mezepine
Mianserin
Monometacrine
Nortriptyline
Noxiptyline
Octriptyline
Opipramol
Pirandamine
Prazepine
Protriptyline
Tandamine
Trimipramine

MONOAMINE OXIDASE INHIBITORS—

Iproniazid
Isocarboxazid
Phenelzine
Tranylcypromine

ANTIARRHYTHMICS—

Amiodarone
Bretylium
Flecainide
Mexiletine
Procainamide
Quinidine
Verapamil

ANTICONVULSANTS—

Carbemazepine
Phenytoin

OTHER—

Aspirin
Chloroquine
Digitalis glycosides
Diphenoxylate hydrochloride with atropine sulphate
Fluoride salts in packs containing the equivalent of more than 100 milligrams of elemental fluorine
Glutethimide
Iron compounds (in substances containing more than the equivalent of 5mg of elemental iron in each solid dosage form)
Lithium carbonate
Orphenadrine
Paracetamol
Quinine
Salicylamide

2. Poisons in liquid form—

Digitalis glycosides
Iron compounds (in preparations containing the equivalent of more than 250 mg of elemental iron in the total content of the container)
Paracetamol (in preparations where paracetamol is the only therapeutically active substance *except* in paediatric drops in packs containing not more than 2 gm of paracetamol).

SCHEDULE I

S4 Drugs that may be Administered by Prescribed Professionals
(Regulation 28)

1. The following S4 drugs may be administered by chiropodists or dental therapists:

Amethocaine
Amylocaine
Benzocaine
Bupivacaine
Butacaine
Butylaminobenzoate
Cinchocaine
Diperodon
Etidocaine
Lignocaine
Mepivacaine
Oxybuprocaine
Prilocaine
Procaine
Proxymetacaine.

2. The following S4 drugs may be administered (as eye drops only) by optometrists:

Cyclopentolate
Oxybuprocaine
Phenylephrine
Physostigmine
Pilocarpine
Proxymetacaine
Tropicamide.

SCHEDULE J

S4 drugs that may be Supplied or Prescribed by a Surgical Podiatrist
(Regulation 28)

1. The following S4 drugs may be supplied or prescribed by a surgical podiatrist:

(a) as an oral preparation only—

Amoxycillin
Amoxycillin and clavulanic acid
Cephalexin
Ciprofloxacin (when microbiological tests indicate it is the only effective drug)
Codeine phosphate 30mg (in combination with paracetemol 500mg only)
Diazepam
Diclofenac
Doxycycline
Erythromycin
Flucloxacillin
Loratidine
Phenoxymethyl penicillin
Promethazine
Roxithromycin
Sulindac
Temazepam;

(b) as an oral preparation or as a suppository—

Metronidazole
Naproxen;

(c) as a cream—

Hydrocortisone cream 0.5 - 1%;

(d) as an ointment—

Mupiricin.

2. The maximum quantity of an S4 drug listed in clause 1 that may be provided by a surgical podiatrist to any person, whether by direct supply or prescription or both, in the course of treating that person for a particular condition, is that usually required for 10 days' treatment of the condition with that drug.

SCHEDULE K

Restrictions on Prescribing Certain S4 Drugs
(Regulation 29)

1. S4 drugs to be prescribed for human use only by registered endocrinologists, obstetricians and gynaecologists—

Clomiphene
Cyclofenil
Dinoprost
Dinoprostone
Luteinising hormone
Urofollitrophin (follicle stimulating hormone).

2. S4 drugs to be prescribed only by registered dermatologists or other authorised specialist medical practitioners—

Acitretin
Etretinate
Isotretinoin
Tretinoin.

3. S4 drugs to be prescribed only by medical practitioners authorised to prescribe the drug for a specified patient—

Thalidomide.

SCHEDULE L
Controlled Substances Act 1984
END USER STATEMENT
(Regulations 33 and 34)

CLIENT NOTE

The chemical product for which this statement is required may be used in the manufacture of illicit drugs. This statement, with section A filled in, must be provided to the seller. Cash sale transactions will not be accepted for certain chemicals.

A. (this section to be completed by purchaser)

PRODUCT/CHEMICAL

Product Name: Supplier Catalogue No:

Quantity: Pack Size:

INTENDED USE (tick appropriate box)

[ ] Analytical

[ ] Manufacturing

[ ] Resale

[ ] Research and Development

[ ] Other (please specify)

PURCHASER

Business/Company/Institution Name:

Address:

Licence Type and No (if relevant): Account No (if relevant):

Name of person authorising purchase:

SIGNED . . . . . Date:. . . . . .
(person authorising purchase)

B. (this section to be completed by seller)

COLLECTION AGENT
Name: Date of Birth:

Home Address: Vehicle Reg. No. (vehicle used in collection):

Status (tick appropriate box):

[ ] Purchaser

[ ] Employee of purchaser

[ ] Contractor

[ ] Employee of contractor

VERIFICATION

I sighted the following proof of identity produced by the above COLLECTION AGENT (tick appropriate box):

[ ] Current Driver's Licence No:

[ ] Current Passport No: issued at:

[ ] Other ID (please specify):

Name of person handling sale:

SIGNED . . . . . Date:
(person handling sale)

SCHEDULE M

Certificate of Analysis
(Regulation 41)

Pursuant to section 53 of the *Controlled Substances Act 1984*,

I . . . . . .
(Print name in full)

an Analyst appointed under the *Controlled Substances Act 1984*, certify that . . . . . .

. . . . . .

. . . . . .

. . . . . .

. . . . . .

. . . . . .
(insert results of analysis)

Signature of Analyst . . . . . .

Date . . . . . .

APPENDIX

LEGISLATIVE HISTORY

Regulation 10(2):	varied by 9, 1997, reg. 3
Regulation 19(2):	varied by 9, 1997, reg. 4
Regulation 28(2):	substituted by 9, 1997, reg. 5(a)
Regulation 28(4):	substituted by 9, 1997, reg. 5(b)
Regulation 29(3):	varied by 9, 1997, reg. 6(a)
Regulation 29(5):	varied by 9, 1997, reg. 6(b)
Regulation 29(6):	substituted by 9, 1997, reg. 6(c)
Regulation 29(7):	inserted by 9, 1997, reg. 6(c)
Regulation 33(1):	varied by 9, 1997, reg. 7
Regulation 36(5):	varied by 9, 1997, reg. 8
Schedule B heading:	varied by 9, 1997, reg. 9
Schedule C heading:	varied by 9, 1997, reg. 10
Schedule C:	varied by 9, 1997, reg. 11
Schedule D:	substituted by 94, 1997, reg. 3
Schedule I	
Clause 2:	substituted by 9, 1997, reg. 12
Schedule K	
Clause 2:	varied by 9, 1997, reg. 13
Schedule L heading:	varied by 9, 1997, reg. 14