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South Australia

Controlled Substances (Poisons) Variation Regulations 2016

under the *Controlled Substances Act 1984*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Controlled Substances (Poisons) Variation Regulations 2016*.

2—Commencement

These regulations come into operation on the day on which they are made.

3—Variation provisions

In these regulations, a provision under a heading referring to the variation of specified regulations varies the regulations so specified.

Part 2—Variation of *Controlled Substances (Poisons) Regulations 2011*

4—Variation of regulation 3—Interpretation

Regulation 3, definitions of ***National Health (Residential Medication Chart) Determination*** and ***prescribed (residential medication chart) pharmaceutical benefit***—delete the definitions

5—Variation of regulation 5—Declaration of poisons (section 12(1) of Act)

Regulation 5(1)(a)—delete "Appendix C" and substitute:

Schedule 10

6—Variation of regulation 14—Special provisions relating to sale or supply of pseudoephedrine

Regulation 14(3)(b)—delete paragraph (b) and substitute:

(b) the sale or supply of pseudoephedrine in the course of professional practice by—

(a) a pharmacist in a hospital; or

(b) a registered health practitioner other than a pharmacist; or

(c) a veterinary surgeon.

7—Variation of regulation 19—Regulation of prescription drugs—prescription of certain S4 drugs by medical practitioners (section 18(2) of Act)

(1) Regulation 19(1), table—delete the table and substitute:

	Prescription drug	Use	Qualifications and requirements
1	Clomiphene Cyclofenil Follitropin alpha (recombinant human follicle stimulating hormone) Follitropin beta (recombinant human follicle stimulating hormone) Luteinising hormone Urofollitrophin (follicle stimulating hormone)	Human use	Medical practitioner who— (a) is registered in the specialty of endocrinology or obstetrics and gynaecology; or (b) provides services to a fertility unit, an endocrinology unit or obstetrics and gynaecology unit of a teaching hospital in South Australia.
2	Acitretin Bexarotene Etretinate	Human use	Medical practitioner who— (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other specialty and is authorised by the Minister to prescribe such drugs.
3	Isotretinoin	Human internal use	Medical practitioner who— (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.

	Prescription drug	Use	Qualifications and requirements
4	Tretinoin	Human internal use	Medical practitioner who— (a) is registered in the specialty of oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.
5	Lenalidomide Pomalidomide Thalidomide	Human use	A medical practitioner who— (a) is registered in the specialty of oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
6	Ambrisentan Bosentan Macitentan Sitaxentan	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
7	Enzalutamide	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.

	Prescription drug	Use	Qualifications and requirements
8	Riociguat	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.

(2) Regulation 19(3)(b)—delete "or 5" and substitute:

, 5 or 8

(3) Regulation 19(3)(c)—after "item 6" insert:

or 7

8—Variation of regulation 25—Possession of poisons (section 22 of Act)

(1) Regulation 25(1)—before "Acrolein" insert:

4-aminopropiophenone

(2) Regulation 25(2)—delete subregulation (2) and substitute:

(2) A person is exempt from section 22 of the Act in respect of the possession of 4-aminopropiophenone if—

(a) the 4-aminopropiophenone is a constituent of baits designed for destroying vertebrate animals; and

(b) the concentration of 4-aminopropiophenone in each bait does not exceed 2%; and

(c) the total amount of 4-aminopropiophenone in the particular quantity of baits for destroying vertebrate animals does not exceed 5 kilograms; and

(d) the person—

(i) has the written approval of the Minister to acquire and possess those baits; and

(ii) acquires the baits from a supplier approved by the Minister.

(3) A person is exempt from section 22 of the Act in respect of the possession of sodium fluoroacetate if—

(a) —

(i) in the case of sodium fluoroacetate that is contained in a capsule for use with a Pest Canid Ejector designed for destroying foxes or wild dogs—the concentration of sodium fluoroacetate in each capsule does not exceed 0.8%; or

(ii) in the case of sodium fluoroacetate that is a constituent of baits designed for destroying vertebrate animals—the concentration of sodium fluoroacetate in each bait does not exceed 0.04%; and

(b) the total amount of sodium fluoroacetate present in the particular quantity of capsules or baits does not exceed 50 grams; and

(c) the person—

(i) has the written approval of the Minister to acquire and possess those capsules or baits; and

(ii) acquires the capsules or baits from a supplier approved by the Minister.

(3) Regulation 25(7) and (8)—delete subregulations (7) and (8)

9—Variation of regulation 26—Packaging and labelling of poisons (section 24 of Act)

Regulation 26(8)—delete subregulation (8) and substitute:

(8) The Minister may grant a seller or supplier, or a class of sellers or suppliers, an exemption from subregulation (1)(b)(iv) in relation to specified packaging requirements of Therapeutic Goods Order No 80 for a specified prescribed medicine.

(9) In this regulation—

prescribed medicine means—

(a) a medicine that contains a substance listed in Schedule 1 to Therapeutic Goods Order No 80 or a salt, ester or other derivative of such a substance; or

(b) a product that—

(i) contains a substance listed in Schedule 1 to Therapeutic Goods Order No 80 or a salt, ester or other derivative of such a substance; and

(ii) is intended solely for use in animals;

prescribed S3 poison means any of the following S3 poisons:

(a) dihydrocodeine in cough preparations;

(b) doxylamine in preparations also containing codeine;

(c) promethazine in preparations also containing codeine;

(d) pseudoephedrine;

Therapeutic Goods Order No 80 means Therapeutic Goods Order No 80 entitled *Child-Resistant Packaging Requirements for Medicines* made under the Commonwealth Act on 27 August 2008, as in force from time to time.

10—Variation of regulation 30—Prohibition on use of certain poisons for certain purposes (section 27 of Act)

(1) Regulation 30(2)—delete "Appendix C" and substitute:

Schedule 10

(2) Regulation 30(2)—delete "that Appendix" and substitute:

that Schedule

11—Variation of regulation 32—Restrictions on advertising (section 28 of Act)

Regulation 32(1)(a)—delete "Appendix C" and substitute:

Schedule 10

12—Variation of regulation 33—How prescription to be given

Regulation 33(6) and (7)—delete subregulations (6) and (7) and substitute:

(6) This regulation does not apply to a prescriber who gives a prescription for a drug if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the *National Health (Pharmaceutical Benefits) Regulations 1960* of the Commonwealth applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription for the drug (whether or not the drug is a pharmaceutical benefit).

13—Variation of regulation 34—Written prescriptions

Regulation 34(4)—delete subregulation (4) and substitute:

(4) This regulation does not apply to a person who writes a prescription for a drug if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the *National Health (Pharmaceutical Benefits) Regulations 1960* of the Commonwealth applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription for the drug (whether or not the drug is a pharmaceutical benefit).

14—Variation of regulation 35—Dispensing prescriptions

(1) Regulation 35(1)(b)(v)(A)—delete subsubparagraph (A) and substitute:

(A) if the drug is dispensed for a person—

- the full name and address of the person; and

- in the case of a drug of dependence—the person's date of birth; or

(2) Regulation 35(1)(b)—after subparagraph (ix) insert:

(x) any instructions the prescriber has included on the prescription in relation to a specialised supply of the drug; and

(xi) if the prescription is endorsed for dispensing at a single pharmacy—the name and address of that pharmacy; and

(3) Regulation 35(1)(f) and (g)—delete paragraphs (f) and (g) and substitute:

(f) in the case of prescription for a drug of dependence—

(i) must, each time the drug is dispensed, make a record in electronic form that complies with paragraph (b); and

(ii) must transmit that record electronically to the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was dispensed or such later date as the Chief Executive may, on application by the pharmacist or medical practitioner, authorise; and

(g) if a drug is fully dispensed, must—

(i) on the day on which the prescription is fully dispensed, endorse the word "CANCELLED" on the prescription or, in the case of a prescription given by fax that is endorsed with the name and address of a single pharmacy at which the prescription may be dispensed, on the faxed copy of the prescription; and

(ii) retain the original or duplicate prescription or in the case of a prescription given by fax that is endorsed with the name and address of a single pharmacy at which the prescription may be dispensed, the faxed copy of the prescription for at least 2 years and have it readily available for inspection during that period; and

(4) Regulation 35—after subregulation (1) insert:

(1a) Subregulation (1)(f) does not apply to a medical practitioner who dispenses a drug of dependence on a prescription.

(1b) A pharmacist or medical practitioner who dispenses a drug of dependence on a prescription must—

(a) retain the original prescription or a copy of the prescription for a period of at least 2 years; and

(b) keep it readily available for inspection by an authorised officer; and

(c) on request by an authorised officer—send a copy of the prescription to the authorised officer.

(5) Regulation 35(10)—delete subregulation (10)

(6) Regulation 35(12)—delete subregulation (12) and substitute:

(12) This regulation (other than subregulations (1)(b), (1b) and (7)(a) and (b)) does not apply to a pharmacist or medical practitioner who dispenses a drug on a prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the *National Health (Pharmaceutical Benefits) Regulations 1960* of the Commonwealth applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit).

15—Variation of regulation 40—Records to be kept by sellers and suppliers of drugs of dependence

(1) Regulation 40(1)—delete subregulation (1) and substitute:

(1) A supplier who sells or supplies a drug of dependence must comply with the following provisions:

(a) the supplier must, immediately after selling or supplying the drug—

(i) make a record in electronic form of—

(A) his or her name and business address; and

(B) the name and address of the person to whom the drug was sold or supplied; and

(C) the date on which the drug was sold or supplied; and

(D) the trade or approved name of the drug or, if the drug does not have either a trade or approved name, the ingredients in the drug; and

(E) the amount and, if applicable, the strength of the drug; and

(F) if the drug was sold or supplied on order—the invoice number (if any) for the sale or supply of the drug;

(ii) make a record of the total amount of the drug now in stock on the premises from which the drug was sold or supplied and sign the record;

(b) if the drug is sold or supplied in accordance with an order, the supplier must, as soon as practicable after selling or supplying the drug, cancel the order by writing "CANCELLED" on the order or, if the order was given by fax endorsed with the name and address of a single pharmacy that may sell or supply the drug, on the faxed copy of the order;

(c) the supplier must transmit the record referred to in paragraph (a)(i) electronically to the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was sold or supplied or such later date as the Chief Executive may, on application by the supplier, authorise.

Maximum penalty: $5 000.

(1a) A supplier who sells or supplies a drug of dependence on an order must—

(a) retain the original order or a copy of the order for a period of at least 2 years; and

(b) keep it readily available for inspection by an authorised officer; and

(c) on request by an authorised officer—send a copy of the order to the authorised officer.

(2) Regulation 40(2)—delete "The requirement to forward an order or notice to the Chief Executive under subregulation (1)(b) does not apply to—" and substitute:

Subregulation (1)(c) does not apply to—

(3) Regulation 40—after subregulation (5) insert:

(6) The Minister may exempt a supplier, or a class of suppliers, from this regulation, or specified provisions of this regulation, if satisfied that the supplier, or class of suppliers, has adequate arrangements for the keeping of records.

16—Variation of regulation 41—Records to be kept by suppliers of drugs of dependence who receive such drugs

Regulation 41—after subregulation (2) insert:

(3) The Minister may exempt a person, or class of persons, from this regulation, or specified provisions of this regulation, if satisfied that the person, or class of persons, has adequate arrangements for the keeping of records and the security of drugs of dependence.

17—Variation of regulation 42—Supply or administration of drugs of dependence by registered health practitioner

Regulation 42—after subregulation (3) insert:

(4) The Minister may exempt a registered health practitioner, or class of registered health practitioners, from this regulation, or specified provisions of this regulation, if satisfied that the registered health practitioner, or class of registered health practitioners, has adequate arrangements for the keeping of records.

18—Variation of regulation 44—Additional requirements for administration of drugs of dependence in health service facility

Regulation 44—after subregulation (5) insert:

(5a) The Minister may exempt a health service facility, or class of health service facilities, from this regulation, or specified provisions of this regulation, if satisfied that the health service facility, or class of health service facilities, has adequate arrangements for the administration of drugs of dependence.

19—Variation of regulation 49—Keeping of records etc

Regulation 49(3)—delete subregulation (3) and substitute:

(3) Details that are required to be recorded under these regulations in respect of drugs of dependence must, unless otherwise specified, be recorded in a register of drugs of dependence (and any electronic register of drugs of dependence must be in a form approved by the Minister).

20—Substitution of regulation 53

Regulation 53—delete the regulation and substitute:

53—Prescribed professional associations (section 58(1a) of Act)

For the purposes of section 58(1a) of the Act, the following professional associations are prescribed:

(a) in the case of publishing information to medical practitioners—

(i) the Australian Medical Association; and

(ii) the Royal Australian College of General Practitioners;

(b) in the case of publishing information to pharmacists—

(i) the Friendly Society Medical Association; and

(ii) the Pharmaceutical Society of Australia; and

(iii) the Pharmacy Guild of Australia; and

(iv) the Society of Hospital Pharmacists of Australia.

21—Substitution of regulation 56

Regulation 56—delete the regulation and substitute:

56—Approvals, determinations and exemptions

(1) The Minister may, at any time, by notice in writing—

(a) impose such conditions as the Minister thinks fit on an approval or exemption granted by the Minister, or on a determination made by the Minister, under these regulations; or

(b) vary or revoke the conditions of such an approval, determination or exemption as the Minister thinks fit; or

(c) revoke, as the Minister thinks fit, an approval or exemption granted by the Minister, or a determination made by the Minister, under these regulations.

(2) A person must not contravene or fail to comply with a condition of an approval or exemption granted by the Minister, or a determination made by the Minister, under these regulations.

Maximum penalty: $3 000.

Note—

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

Made by the Governor

after consultation by the Minister with the Controlled Substances Advisory Council and with the advice and consent of the Executive Council
on 3 March 2016

No 17 of 2016

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