No 38 of 2010 published in *Gazette 3.6.2010 p 2145*

South Australia

Controlled Substances (Poisons) Variation Regulations 2010

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 2010*.

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 1996*

4—Variation of regulation 4—Interpretation

(1) Regulation 4(1)—after the definition of ***address*** insert:

APVMA means the Australian Pesticides and Veterinary Medicines Authority of the Commonwealth;

(2) Regulation 4(1), definition of ***dental therapist***—delete the definition and substitute:

dental hygienist means a person registered as a dental hygienist under the law of this State;

dental therapist means a person registered as a dental therapist under the law of this State;

(3) Regulation 4(1), definitions of ***midwife***, ***National Drugs and Poisons Schedule Committee***, ***optometrist***, ***podiatric surgeon*** and ***podiatrist***—delete the definitions and substitute:

midwife means a person registered as a midwife under the law of this State;

optometrist means a person registered as an optometrist under the law of this State;

podiatric surgeon means a person registered under the law of this State in the specialty of podiatric surgery;

podiatrist means a person registered as a podiatrist under the law of this State;

(4) Regulation 4(1), definitions of ***surgical podiatrist*** and ***Uniform Poisons Standard***—delete the definitions and substitute:

Uniform Poisons Standard means the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth.

5—Variation of regulation 8—Certain new substances to be taken to be schedule 4 poisons

Regulation 8(b)—delete paragraph (b) and substitute:

(b) APVMA for inclusion in the Public Chemical Registration Information System (PUBCRIS),

6—Variation of regulation 10—Licences

Regulation 10(3) and (4)—delete subregulations (3) and (4) and substitute:

(3) The term of a licence is 1 year or 3 years at the option of the applicant.

(4) If a licence is to be granted or renewed for a period of 3 years, the fee payable is the appropriate fee set out in Schedule D of these regulations multiplied by 3.

7—Variation of regulation 12—Manufacture, production and packing (section 13)

(1) Regulation 12(1)—delete "schedules 1 to 7" and substitute:

schedules 1, 2, 3, 4 and 7

(2) Regulation 12(2)—delete "schedules 1 to 7" and substitute:

schedules 1, 2, 3, 4 and 7

(3) Regulation 12(3)—delete subregulation (3)

8—Variation of regulation 13—Sale by wholesale (section 14)

Regulation 13—delete "schedules 1 to 7" and substitute:

schedules 1, 2, 3, 4 and 7

9—Regulation 14—Sale or supply to end user (section 15)

(1) Regulation 14(2)(b)—delete "a schedule 3 poison that is listed in Schedule G of these regulations" and substitute:

pseudoephedrine

(2) Regulation 14(2)(b)(i)—delete "poison" wherever occurring and substitute in each case:

pseudoephedrine

(3) Regulation 14(2)(b)(ii)—delete "the poisons" and substitute:

pseudoephedrine

10—Variation of regulation 15D—Exemptions from section 18A of Act

(1) Regulation 15D(1)(a)—delete ", hydromorphone"

(2) Regulation 15D(1)(b)(i)—delete ", hydromorphone"

(3) Regulation 15D(1)(c) to (e) inclusive—delete paragraphs (c) to (e) and substitute:

(c) a person in respect of whom a section 18A authority exists, provided that—

(i) in the case of a person who is receiving treatment in a hospital or correctional institution—

(A) the medical practitioner notifies the authorised prescriber that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; and

(B) the drug is only administered to the person while in the hospital or correctional institution; and

(C) if the drug is solely for the treatment of drug dependence—the dose administered does not exceed the dose authorised; or

(ii) in the case of a person who is being discharged from a hospital following treatment in the hospital—

(A) the medical practitioner notifies the authorised prescriber that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; and

(B) if the drug is solely for the treatment of drug dependence—the dose prescribed does not exceed the dose authorised; or

(iii) in the case of a person not referred to in subparagraph (i) or (ii)—

(A) the medical practitioner prescribing or supplying the drug—

- notifies the authorised prescriber that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; or
- is a medical practitioner (including a locum for the time being substituting for such a practitioner) in the same practice as the authorised prescriber; and

(B) the medical practitioner prescribing or supplying the drug does so with the approval of the authorised prescriber; and

(C) the medical practitioner prescribing or supplying the drug complies with the section 18A authority relating to the person for whom the drug is prescribed or to whom the drug is supplied; or

(d) a person in respect of whom a section 18A authority does not exist, provided that—

(i) in the case of a person who is receiving treatment in a hospital or correctional institution—the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(ii) in the case of a person who is being discharged from a hospital following treatment in the hospital—the duration of treatment of the person with the drug after discharge does not exceed 14 days.

(4) Regulation 15D(3)—after the definition of ***authorised prescriber*** insert:

correctional institution has the same meaning as in the *Correctional Services Act 1982*;

11—Variation of regulation 16—Possession (section 22)

(1) Regulation 16(2)(c)(i)—delete "wild rabbits, dingoes or foxes" and substitute:

vertebrate animals

(2) Regulation 16(2)(c)(iii)—delete "wild rabbits, dingoes or foxes" and substitute:

vertebrate animals

12—Variation of regulation 17—Exemption from section 22 may be granted to certain pest controllers

Regulation 17(1)—delete "*Controlled Substances (Pesticide) Regulations 1988*" and substitute:

Controlled Substances (Pesticides) Regulations 2003

13—Variation of regulation 19—Labelling of poisons (section 24)

Regulation 19(2)(i)—delete paragraph (i) and substitute:

(i) in the case of a preparation for internal use by humans (other than infants) that contains a poison listed in appendix K of the Uniform Poisons Standard—1 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

(j) in the case of—

(i) adapalene, dienestrol, leflunomide, levocabastine or misoprostol; or

(ii) a poison that is listed in the table in Schedule K of these regulations (other than in item 1),

the warning statements prescribed for that poison in Appendix F, Part 1 of the Uniform Poisons Standard.

14—Variation of regulation 20—Storage of poisons (section 25)

Regulation 20(d)—delete "dated 31 July 2000 and published in the Gazette on 24 August 2000" and substitute:

as in force from time to time

15—Variation of regulation 21—Transport of poisons (section 26)

Regulation 21(c)—delete "dated 31 July 2000 and published in the Gazette on 24 August 2000" and substitute:

as in force from time to time

16—Substitution of regulation 22

Regulation 22—delete the regulation and substitute:

22—Prohibition on use of certain poisons for certain purposes (section 27)

(1) For the purposes of section 27 of the Act, a person must not sell, supply, purchase or use a schedule 7 poison for a domestic purpose or domestic gardening purpose.

(2) For the purposes of section 27 of the Act, a person must not prescribe, sell, supply or use a poison listed in appendix C of the Uniform Poisons Standard for the purpose or purposes indicated in relation to that poison in appendix C (other than amygdalin for human therapeutic use).

(3) For the purposes of section 27 of the Act, a person must not prescribe, sell, supply or use amygdalin for human therapeutic use unless—

(a) special access to amygdalin has been authorised in accordance with the requirements of sections 18 and 31A of the *Therapeutic Goods Act 1989* of the Commonwealth and regulation 12A of the *Therapeutic Goods Regulations 1990* of the Commonwealth; and

(b) permission for the importation of amygdalin (subject to special access authorisation) has been granted under regulation 5H and Schedule 8 item 12AA of the *Customs (Prohibited Imports) Regulations 1956* of the Commonwealth.

(4) For the purposes of section 27 of the Act, a person must not—

(a) prescribe, sell, supply or purchase a poison produced for the treatment of animals if the person knows, or if there are reasonable grounds for suspecting, that the poison is intended for human use; or

(b) administer to any person (including himself or herself) a poison produced for the treatment of animals; or

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

(5) In this regulation—

stock means—

(a) any bird or other animal; and

(b) any bee of the genus *Apis* or *Megachile*.

17—Variation of regulation 23—Restriction on advertising (section 28)

(1) Regulation 23(1)—delete "medical professionals" and substitute:

health practitioners, scientists working in medical laboratories or persons who hold a wholesale dealers licence.

(2) Regulation 23(2)—before the definition of ***journal*** insert:

health practitioner means—

(a) a person who is registered under the law of this State as a chiropractor, dentist, dental hygienist, dental prosthetist, dental technician, dental therapist, medical practitioner, midwife, nurse, optometrist, osteopath, pharmacist, podiatrist, podiatric surgeon, physiotherapist, psychologist or veterinary surgeon; or

(b) a medical administrator;

(3) Regulation 23(2), definition of ***medical professionals***—delete the definition

18—Variation of regulation 25—How prescription to be given

(1) Regulation 25(2)—delete "facsimile" and substitute:

fax

(2) Regulation 25(3)—delete "facsimile" and substitute:

fax

(3) Regulation 25(4)—delete subregulation (4) and substitute:

(4) If, in accordance with subregulation (2), a prescription is given to a pharmacist by fax the prescriber must—

(a) in the case of a prescription for a drug of dependence—forward the original prescription to the pharmacist within 24 hours of giving the prescription by fax; or

(b) in any other case—forward the original prescription to the pharmacist as soon as practicable after giving the prescription by that method,

unless the prescriber has endorsed the prescription given by fax with the name and address of a single pharmacy at which the prescription may be dispensed.

Maximum penalty: $3 000.

19—Variation of regulation 26—Written prescriptions

Regulation 26(1)(c)(v)—delete "surgical podiatrist" and substitute:

podiatric surgeon

20—Variation of regulation 27—Dispensing prescriptions

(1) Regulation 27(1)(a)—after "prescription" insert:

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

(2) Regulation 27(1)(c)(ii) and (iii)—delete subparagraphs (ii) and (iii) and substitute:

(ii) 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

(iii) unless the prescription is for any reason forwarded to the Department or the Minister—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 (as the case may be) for at least 1 year and have it readily available for inspection during that period; and

(3) Regulation 27(1)(f)—delete paragraph (f) and substitute:

(f) if a prescription 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) —

(A) in the case of a prescription for a drug of dependence—forward to the CEO 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, the faxed copy of the prescription, not later than the 7th day of the month following the month in which the drug was so dispensed (or such later date as the CEO may, on the application by the pharmacist or medical practitioner, authorise); or

(B) in any other case—retain the original or duplicate prescription and, 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 (as the case may be), for at least 2 years and have it readily available for inspection during that period.

(4) Regulation 27—after subregulation (4) insert:

(4a) If a prescription given by fax is endorsed with the name and address of a single pharmacy at which the prescription may be dispensed, a pharmacist must not dispense the prescription unless he or she is on duty at that pharmacy.

Maximum penalty: $5 000.

(5) Regulation 27(5)(c)(i)—delete subparagraph (i) and substitute:

(i) in the case of prescription that is to be dispensed for the first or only time—

(A) an original prescription is presented; or

(B) the prescription is given by fax and is endorsed with the name and address of a single pharmacy at which the prescription may be dispensed; or

(6) Regulation 27(6)(b)—delete paragraph (b) and substitute:

(b) hand over the dispensed drug until—

(i) the person for whose use the drug is dispensed has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription and unless the person is known to the pharmacist or practitioner, has produced satisfactory evidence of his or her identity; or

(ii) an agent acting on behalf of the person for whose use the drug is intended has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription and, unless the agent is known to the pharmacist or practitioner, has produced satisfactory evidence of his or her identity.

21—Variation of regulation 28—Prescribed professions and limitations (section 18(1))

(1) Regulation 28(1)—before paragraph (a) insert:

(aa) dental hygiene;

(2) Regulation 28—after subregulation (1) insert:

(2) A dental hygienist may only administer an S4 drug listed in clause 1 of Schedule I of these regulations if he or she holds a written authorisation granted by the Dental Board of South Australia under regulation 9(2)(n) of the *Dental Practice (General) Regulations 2007*.

22—Substitution of regulations 29 and 30

Regulations 29 and 30—delete the regulations and substitute:

29—Additional requirements for S4 drugs listed in Schedule K (section 18)

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

(a) each of the S4 drugs listed in the table in Schedule K of these regulations is a prescribed prescription drug; and

(b) the qualifications and authorisations specified in that table alongside a drug are prescribed qualifications.

(2) A person must not prescribe an S4 drug listed in the table in Schedule K of these regulations for a use specified in that Schedule alongside that drug unless the person has the qualifications or authorisations specified in that Schedule alongside that drug and that use of the drug.

Maximum penalty: $5 000.

(3) A medical practitioner who prescribes an S4 drug listed in the table in Schedule K of these regulations (other than in item 1) 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) if 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.

Maximum penalty: $5 000.

(4) In this regulation—

prescribed period means—

(a) in the case of treatment with a drug listed in item 2 of Schedule K of these regulations (other than bexarotene)—24 months;

(b) in the case of treatment with bexarotene or a drug listed in item 3, 4 or 5 of Schedule K of these regulations—1 month;

(c) in the case of treatment with a drug listed in item 6 of Schedule K of these regulations—3 months.

23—Variation of regulation 31—Exemptions from section 18 of Act

(1) Regulation 31(2)(c)(ii)(B)—delete "*Stock Act 1990*" and substitute:

Livestock Act 1997

(2) Regulation 31(3), definition of ***council***—delete the definition and substitute:

council has the same meaning as in the *Local Government Act 1999*.

24—Variation of regulation 31E—Supply of drugs of dependence

(1) Regulation 31E(1)—delete subregulation (1) and substitute:

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

(a) he or she must, immediately after supplying the drug, record the following details and sign the record:

(i) his or her name and business address;

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

(iii) the date on which the drug was supplied;

(iv) 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;

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

(vi) if the drug was supplied on order—the invoice number (if any) for the supply of the drug;

(vii) the total amount of the drug now in stock on the premises from which the drug was supplied;

(b) he or she must, if he or she supplies the drug in accordance with an order—

(i) as soon as practicable after 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 supply the drug, on the faxed copy of the order; and

(ii) unless exempted under subregulation (2), forward the cancelled order or a copy of the cancelled faxed order (as the case may require) to the CEO, no later than the 7th day of the month following the month in which the drug was supplied or such later date as the CEO may, on application by the supplier, authorise.

(2) Regulation 31E—after subregulation (4) insert:

(5) A person who makes a record under subregulation (1) must ensure that the record is kept at all times on the premises from which the drug was supplied.

25—Substitution of regulation 31F

Regulation 31F—delete the regulation and substitute:

31F—Receipt of drugs of dependence

(1) If a supplier of drugs of dependence receives such a drug, or a person receives a drug of dependence from a supplier on order, the person receiving the drug must—

(a) give to the person who provided the drug a signed and dated receipt for the drug; and

(b) record the following details and sign the record:

(i) the name and address of the person who provided the drug;

(ii) the name and address of the person who took delivery of the drug;

(iii) the date on which the drug was received;

(iv) 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;

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

(vi) if the drug was provided on order—the invoice number (if any) for the supply of the drug;

(vii) the total amount of the drug now in stock on the premises at which the drug was received.

(2) A person who makes a record under this regulation must ensure that the record is kept at all times on the premises at which the drug was received.

26—Variation of regulation 31I—Additional requirements for administration of drugs of dependence in health service

Regulation 31I(1)(c)—delete paragraph (c) and substitute:

(c) the drug must not be administered to the person unless the administration is witnessed by a nurse or midwife, or, where a nurse or midwife is not reasonably available, by some other responsible person;

27—Revocation of regulation 44

Regulation 44—delete the regulation

28—Variation of Schedule A—Modification of Uniform Poisons Standard

Schedule A(b)—delete paragraph (b)

29—Variation of Schedule D—Fees

(1) Schedule D, clause 1, paragraphs (e) and (f)—delete paragraphs (e) and (f)

(2) Schedule D, clause 2, paragraphs (e) and (f)—delete paragraphs (e) and (f)

30—Variation of Schedule F—Prescribed poisons for the purposes of section 22 of Act

Schedule F—insert in alphabetical order:

Cyanogen

31—Variation of heading to Schedule G

Heading to Schedule G—delete "**regulation 14(2)**" and substitute:

regulation 19

32—Variation of Schedule I—S4 drugs that prescribed professionals may administer

Schedule I, clause 1—before "dental therapists" insert:

dental hygienists,

33—Substitution of Schedule K

Schedule K—delete the Schedule and substitute:

Schedule K—Restrictions on prescribing certain S4 drugs

(Regulation 29)

	Prescription Drug	Use	Qualifications and authorisations
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.

	Prescription Drug	Use	Qualifications and authorisations
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 speciality 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.
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.

	Prescription Drug	Use	Qualifications and authorisations
5	Lenalidomide Thalidomide	Human use	A medical practitioner who— (a) is a specialist in 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 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.

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 June 2010

No 38 of 2010

HEAC09/019CS