Queensland

Health Act 1937

Health Regulation 1996

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Queensland

Health Regulation 1996

Contents

Health Regulation 1996

Part 1 Preliminary

1 Short title

This regulation may be cited as the *Health Regulation 1996*.

Part 4 Dispensary

Division 1 Preliminary

22 Definitions

In this part—

AS 2252.6 means AS 2252.6—2011 (Controlled environments, Part 6: Clean workstations—Design, installation and use).

AS/NZS means a standard published jointly by Standards Australia and Standards New Zealand.

AS/NZS ISO means a standard adopted from the International Organisation for Standardisation and published jointly by Standards Australia and Standards New Zealand.

AS/NZS ISO 14644 means each of the following standards—

(a) AS ISO 14644.1:2017 (Cleanrooms and associated controlled environments, Part 1: Classification of air cleanliness by particle concentration);

(b) AS/NZS 14644.3:2009 (Cleanrooms and associated controlled environments, Part 3: Test methods);

(c) AS/NZS ISO 14644.4:2002 (Cleanrooms and associated controlled environments, Part 4: Design, construction and start-up);

(d) AS/NZS ISO 14644.5:2006 (Cleanrooms and associated controlled environments, Part 5: Operations).

dispensary means a place used by a pharmacist to dispense a drug or poison.

dispense includes compound.

equipment includes apparatus and utensils.

extemporaneous preparation means a medicine made from 2 or more weighed or measured ingredients (other than a medicine obtained by merely reconstituting an existing medicine).

therapeutic use means use for or in—

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or

(b) influencing, inhibiting or modifying a physiological process; or

(c) testing the susceptibility of a person or animal to a disease or ailment.

Division 2 General requirements

23 Restriction on use of place as dispensary

(1) The occupier of a dispensary must ensure the dispensary—

(a) is adequately enclosed, ventilated, painted and lit; and

(b) has lined walls and ceilings; and

(c) has a floor covering that may be easily cleaned; and

(d) has a stainless steel sink supplied with—

(i) cold running water; and

(ii) hot running water of at least 60ºC; and

(e) has a separate dispensing bench with a smooth, impervious surface.

(2) The occupier of a dispensary must ensure the dispensary is only used for a purpose associated with dispensing a drug or poison.

Maximum penalty—20 penalty units.

24 Standards to be maintained

The occupier of a dispensary must ensure—

(a) the dispensary is kept clean, and free from anything able to contaminate a drug or poison; and

(b) benches, shelves, drawers, and other places used in association with the dispensary, where drugs or poisons are placed or stored, are kept clean, and free from anything able to contaminate a drug or poison; and

(c) equipment used to dispense a drug or poison is—

(i) free from cracks and chips; and

(ii) regularly serviced, kept in an efficient state of operation, and repaired as necessary; and

(iii) kept clean, and free from anything able to contaminate a drug or poison; and

(d) containers used to hold drugs and poisons are always kept clean, and free from—

(i) cracks and chips; and

(ii) anything able to contaminate a drug or poison; and

(e) drugs and poisons are stored at appropriate temperatures.

Maximum penalty—20 penalty units.

25 Items to be available at dispensary

(1) The occupier of a dispensary must ensure the items in schedule 4 are available at the dispensary.

Maximum penalty—20 penalty units.

(2) If a dispensary is used to dispense an extemporaneous preparation, the occupier of the dispensary must ensure the additional items in schedule 5 are available at the dispensary.

Maximum penalty—20 penalty units.

(3) If an item mentioned in schedule 4 or 5 is a document, the document may be a printed, microfiche or electronic copy of the document.

Division 3 Sterile dispensing

26 Application of division

(1) This division applies to the dispensing of drugs or poisons for therapeutic use, using—

(a) an aseptic technique; or

(b) a process in which sterilisation happens as the last stage of dispensing the drugs or poisons.

(2) However, this division does not apply to the dispensing of—

(a) proprietary eye drops that are merely reconstituted; or

(b) antineoplastic drugs.

27 General requirements

The occupier of a dispensary used for drug or poison dispensing to which this division applies must ensure the dispensing happens—

(a) in a separate part of the dispensary; and

(b) under a system that controls particulate and microbial contaminants in a way appropriate to the class of drugs or poisons being dispensed; and

(c) under a high standard of hygiene; and

(d) with special care and attention to detail; and

(e) in the way specified under procedures established and validated by the pharmacist managing or supervising the dispensary; and

(f) using a properly maintained laminar flow cabinet in an area complying with—

(i) AS 2252.6; and

(ii) AS/NZS ISO 14644.

Maximum penalty—20 penalty units.

28 Standard operating procedures to be applied

(1) An occupier mentioned in section 27 must ensure—

(a) written policies and standard operating procedures are prepared—

(i) for the drug or poison dispensing; and

(ii) complying with subsection (2); and

(b) the policies and procedures are available in the dispensary; and

(c) the drug or poison dispensing complies with the policies and procedures; and

(d) the policies and procedures are reviewed at intervals of not more than 1 year.

Maximum penalty—20 penalty units.

(2) The policies and procedures mentioned in subsection (1) must provide for—

(a) the training and monitoring of staff involved in a technique or process mentioned in section 26(1); and

(b) the operation and cleaning of the part of the dispensary mentioned in section 27(a); and

(c) spillage, storage and disposal of waste; and

(d) servicing of equipment used in drug or poison dispensing; and

(e) quality assurance; and

(f) packing, labelling, handling and storage of drugs and poisons.

29 Maintenance

(1) An occupier mentioned in section 27 must ensure equipment used for sterile drug or poison dispensing, and air handling facilities for the part of the dispensary mentioned in section 27(a), are regularly maintained under a planned maintenance schedule.

(2) The occupier must also ensure the equipment and facilities mentioned in subsection (1) are maintained and tested in a way complying with—

(a) AS 2252.6; and

(b) AS/NZS ISO 14644.

Maximum penalty—20 penalty units.

Division 4 Dispensing of antineoplastic drugs

30 Application of division

This division applies to the dispensing of antineoplastic drugs.

31 General requirements

(1) The occupier of a dispensary used for dispensing to which this division applies must ensure the dispensing happens—

(a) in a separate part of the dispensary; and

(b) under a system that controls particulate and microbial contaminants in a way appropriate to the class of drugs being dispensed; and

(c) under a high standard of hygiene; and

(d) with special care and attention to detail; and

(e) in the way specified under procedures established and validated by the pharmacist managing or supervising the dispensary.

(2) If it is necessary to store an antineoplastic agent within a particular temperature range to ensure that the agent will be effective when it is used, an occupier mentioned in subsection (1) who has any of the agent must ensure it is stored—

(a) in a refrigerator at the appropriate temperature; and

(b) in an enclosed container preventing the agent from contaminating other items in the refrigerator.

Maximum penalty—20 penalty units.

32 Dispensing

(1) An occupier mentioned in section 31(1) must ensure, for the purpose of the dispensing, that—

(a) AS 2252.5 is complied with; and

(b) vertical laminar flow cabinets complying with AS 2252.5 are used; and

(c) persons directly involved in the dispensing wear impervious clothing and gloves; and

(d) the compounding room and an adjoining anteroom have an air supply and extraction system separate from the air supply and extraction for any other part of the premises in which the rooms are situated; and

(e) air exhausts are sited so as not to cause pollution or toxicity outside the area where the dispensing happens.

Maximum penalty—20 penalty units.

(2) This section does not apply to the dispensing of an antineoplastic drug if it is a pre-packed product not needing further preparation.

(3) In this section—

AS 2252.5 means AS 2252.5:2017 (Controlled environments, Part 5: Cytotoxic drug safety cabinets (CDSC)—Design, construction, installation, testing and use).

33 Standard operating procedures to be applied

(1) An occupier mentioned in section 31(1) must ensure—

(a) written policies and standard operating procedures are prepared—

(i) for the dispensing; and

(ii) complying with subsection (2); and

(b) the policies and procedures are available in the dispensary; and

(c) the way the drugs are dispensed complies with the policies and procedures; and

(d) the policies and procedures are reviewed at intervals of not more than 1 year.

Maximum penalty—20 penalty units.

(2) The policies and procedures mentioned in subsection (1) must provide for—

(a) the training and monitoring of staff involved in the dispensing; and

(b) the operation and cleaning of the part of the dispensary mentioned in section 31(1)(a); and

(c) spillage, storage and disposal of waste; and

(d) servicing of equipment used in the dispensing; and

(e) quality assurance; and

(f) packing, labelling, handling and storage of antineoplastic drugs.

34 Maintenance

An occupier mentioned in section 31(1) must ensure equipment used to dispense antineoplastic drugs, and air handling facilities for the part of the dispensary mentioned in section 31(1)(a), are regularly maintained under a planned maintenance schedule.

Maximum penalty—20 penalty units.

Part 16 Therapeutic goods and other drugs

153 Definitions

In this part—

APF means the latest edition for the time being of the Australian Pharmaceutical Formulary and Handbook published by the Pharmaceutical Society of Australia.

batch number means any combination of letters or figures or both given by a manufacturer of therapeutic goods or other drugs to a batch thereof manufactured by the manufacturer by which that batch can be traced in manufacture and identified in distribution.

expiry date, when used in relation to therapeutic goods or other drugs, means the date—

(a) after which they may be expected to cease to comply with standards applicable thereto; or

(b) where there are no such standards, signifying the end of their minimum durable life.

main label means the face of a label on or attached to a package containing therapeutic goods or other drugs on which face the name of such goods or drugs is most prominently shown and where such name is equally prominent on 2 or more faces each such face shall be taken to be a main label.

other drugs means cosmetics, deodorants, dusting powders, soaps, tobaccos, unguents, other toilet articles and any other drugs prescribed to be drugs to which this part applies.

soap means the product called 'soap' that complies with the standard for soap prescribed by this part.

Standard for the Uniform Scheduling of Medicines and Poisons means the Standard for the Uniform Scheduling of Medicines and Poisons published by the Commonwealth.

therapeutic device means any of the following—

(a) a device that—

(i) is included in a class of devices the sole or principal use of which is, or ordinarily is, a therapeutic use; or

(ii) is represented to be, or might reasonably be taken to be, for therapeutic use;

(b) a device that—

(i) is included in a class of devices the sole or principal use of which is, or ordinarily is, a use for the purpose of or in connection with measuring or weighing therapeutic goods by the person using or administering those goods; or

(ii) is represented to be, or might reasonably be taken to be, for a use of the kind referred to in subparagraph (i);

but does not include goods for animal use only.

therapeutic goods means a therapeutic substance or therapeutic device and includes a package thereof.

therapeutic substance means any of the following—

(a) a substance that—

(i) is included in a class of substances the sole or principal use of which is, or ordinarily is, a therapeutic use; or

(ii) is represented to be, or might reasonably be taken to be, for therapeutic use;

(b) a substance that—

(i) is represented to be, or might reasonably be taken to be, for use as an ingredient or the sole ingredient in the manufacture of a substance referred to in paragraph (a), whether or not the substance that is so represented or might reasonably be so taken is to be itself the subject of manufacture or of further manufacture; or

(ii) is included in a class of substances the sole or principal use of which is, or ordinarily is, a use of the kind referred to in subparagraph (i);

(c) any gelatine capsule or other substance enclosing a substance referred to in paragraph (a) or (b), if that capsule or other substance is intended to be consumed or otherwise administered together with the substance referred to;

but does not include—

(d) food within the meaning of the *Food Act 2006*; or

(e) goods for animal use only; or

(f) a substance consisting of a vaccine prepared from microscopic organisms from the body of a person for use only in the treatment of that person.

therapeutic use means a use for the purpose of or in connection with—

(a) preventing, diagnosing, curing or alleviating any disease, ailment, defect or injury in any person; or

(b) influencing, inhibiting or modifying a physiological process in any person; or

(c) testing the susceptibility of any person to a disease or ailment.

154 References to prescribed standard

A reference in this part to the nature, substance, composition, strength, weight, quantity, purity or quality of any therapeutic goods or other drugs or any article or any ingredient or component thereof, shall be the prescribed standard with respect to those goods or other drugs or that article, ingredient or component.

155 Application of Statutory Instruments Act 1992, s 23

The *Statutory Instruments Act 1992*, section 23, applies to this part as if it were made on the commencement of this section.

Editor's note—

The *Statutory Instruments Act 1992*, section 23, allows a statutory instrument to provide for a matter by applying another document. Section 23(2) provides—

(2) If a statutory instrument made after 1 January 1992 applies, adopts or incorporates the provisions of a document, the provisions applied, adopted or incorporated are the provisions as in force from time to time unless the statutory instrument expressly provides otherwise.

This part contains provisions relocated from a regulation made in 1982. Section 155 clarifies how the *Statutory Instruments Act 1992*, section 23, applies by providing that this part was made on the commencement of this section, not in 1982.

156 Labelling requirements generally

(1) A package containing therapeutic goods or other drugs shall bear on or attached to it a label on which shall be written such particulars or statements as are prescribed by this part.

Maximum penalty—20 penalty units.

(2) Particulars or statements referred to in subsection (1)—

(a) shall be written—

(i) in the English language;

(ii) on the face of the main label;

(iii) in durable, conspicuous and legible characters of not less than 1.5mm face depth;

(iv) in such colour or colours as will ensure a distinct contrast to the background colour;

(b) shall include—

(i) the name, trade name or description of the therapeutic goods or other drugs contained in the package;

(ii) the name and business address of the manufacturer or importer or the vendor or packer, not being a post office address;

(iii) the net weight or number or true measure or, as the case requires, volume of the contents of the package;

(iv) in the case of a package containing therapeutic goods, the batch number immediately preceded by the words, or the symbol for the words, 'Batch No.';

(v) in a case where the chief executive considers that the therapeutic goods or other drugs contained in the package may have a limited durable life, the expiry date of the contents of the package immediately preceded by words clearly indicating that the date is the expiry date;

(vi) in the case of a package containing a therapeutic substance, except a substance specified in schedule 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons, the precise dose and frequency of the dose required;

(c) shall not include—

(i) a reference to the Act;

(ii) any comment on, reference to or explanation of a particular or statement required by the Act or this part to be included in the label that directly or by

implication contradicts, qualifies or modifies that particular or statement;

(iii) in the case of a package containing a therapeutic substance any comment or statement likely to induce or encourage the consumption of the substance except in accordance with the prescribed dose.

(3) A person who packs for sale or labels for sale therapeutic goods or other drugs in a manner contrary to or otherwise than in compliance with this part commits an offence against this part.

Maximum penalty—20 penalty units.

(4) A person shall not sell therapeutic goods or other drugs, the label on or attached to which contravenes this part.

Maximum penalty—20 penalty units.

157 Advertising and further labelling requirements

(1) The label on or attached to a package containing therapeutic goods or other drugs for sale or any advertisement relating to such goods or drugs shall not contain a statement, claim or representation, pictorial or otherwise, in relation to such goods or drugs that directly or by implication indicates or suggests any matter or thing—

(a) with respect to the use of such goods or drugs for the purpose of or in connection with—

- abortifacient action
- acidity of the stomach, other than temporary relief
- alcoholism
- anaemia
- arthritis (all forms including rheumatoid arthritis), other than temporary relief of pain
- asthma, other than relief of mild spasms
- baldness

- blindness
- boils, other than treatment by local application
- bronchitis, other than relief of cough
- bust development
- carbuncles
- cardiovascular system diseases, ailments or defects (including high or low blood pressure), other than temporary relief of varicose veins by use of elastic hosiery
- cataract
- catarrh, other than temporary relief
- chilblains, other than temporary relief of symptoms
- colds, other than temporary relief of symptoms
- coughs, other than temporary relief
- croup
- deafness, other than relief by an appliance
- diphtheria
- eczema, other than temporary relief of symptoms
- endocrine system diseases, ailments, defects or injuries (including diabetes and goitre)
- erysipelas
- fungus infections, other than treatment of tinea (athlete's foot)
- gall bladder diseases, ailments, defects or injuries
- gastric or duodenal ulcer
- genito-urinary system diseases, ailments, defects or injuries
- glandular diseases, ailments, defects or injuries (including glandular enlargement)

- glaucoma
- gout
- haemorrhoids, other than the temporary relief of discomfort by local application
- headaches, other than temporary relief
- height increase
- immune system diseases, ailments, defects or injuries including acquired immune deficiency syndrome (AIDS), other than reduction of the risk of transmission of acquired immune deficiency syndrome by the use of condoms
- impetigo
- impotence
- indigestion, other than temporary relief
- infertility
- influenza, other than temporary relief of symptoms
- liver diseases, ailments, defects or injuries
- lupus
- menopausal diseases, ailments or defects
- menstrual diseases, ailments, defects or injuries, other than temporary relief of pain
- mouth ulcers, other than temporary relief of recurrent ulcers
- muscular aches and pains, other than temporary relief
- neoplastic diseases (including cancer and leukaemia), other than the use of sunscreening preparations as an aid in the prevention of skin cancer, being a use that is approved in writing by the chief executive

- nervous system diseases, ailments, defects or injuries (including convulsions, epilepsy, fits, mental illness or paralysis)
- overweight, other than suppression of appetite in conjunction with a medically sound diet
- phlebitis
- prostate gland diseases, ailments, defects or injuries
- psoriasis
- purpura
- pyorrhoea
- rheumatism, other than temporary relief of pain
- rupture or hernia
- scabies
- sexual intercourse and diseases arising therefrom, other than reduction in the possibility of conception or the risk of transmission of venereal disease
- sexual potency or virility
- sinus infection, other than temporary relief of sinusitis
- sleeplessness, other than temporary relief
- thrombosis
- tuberculosis
- varicose ulcers or varicose veins, other than temporary relief of symptoms by use of elastic hosiery
- whooping cough;

(b) with respect to the use or consumption of such goods or drugs, that—

(i) depicts excessive pain or suffering;

(ii) induces or is likely to induce persons to believe that they are suffering from a serious ailment;

(iii) induces or is likely to induce persons to believe that harmful consequences will result if such goods or drugs are not used or consumed;

(iv) disparages any physical or mental affliction or deformity;

(v) claims or implies or induces or is likely to induce persons to infer that such goods or drugs or their sales are recommended or used generally by medical practitioners, pharmacists, dentists, nurses or physiotherapists or by persons having or purporting to have a qualification in a health care field;

(c) with respect to the use or consumption of such goods or drugs, that such goods or drugs—

(i) are a universal panacea;

(ii) possess infallible, unfailing, sure, magical or miraculous curing properties;

(iii) possess unique or absolute properties, except where that statement, claim or representation is approved in writing by the chief executive;

(iv) are immediately or rapidly acting;

(v) are a natural remedy or nature's remedy;

(vi) possess stimulant properties;

(vii) promote vitality;

(viii) must be used for the relief of symptoms of any disease, ailment, defect or injury.

Maximum penalty—20 penalty units.

(2) A fictitious testimonial or the name of a fictitious person shall not be included in the label on or attached to or in an advertisement relating to therapeutic goods or other drugs.

Maximum penalty—20 penalty units.

(3) A person shall not publish or display in any manner or cause to be published or displayed in any manner an advertisement that contravenes this part.

Maximum penalty—20 penalty units.

(4) A person shall not attach to or permit to be attached to or allow to remain upon an automatic vending machine or similar mechanical device used for the sale or supply of condoms any advertisement, statement, claim, representation or pictorial design other than—

(a) the name and address of the manufacturer or vendor; or

(b) directions for use of the machine; or

(c) a description of the contents of the machine expressed as a brand or trade name in conjunction with the word 'condom'; or

(d) any other advertisement, statement, claim, representation or pictorial design approved by the chief executive.

Maximum penalty—20 penalty units.

(5) This section shall not be construed so as to prohibit the publication of advertisements relating to therapeutic goods or other drugs in medical journals, bona fide trade journals or price lists for the use of the retail trade.

158 Further labelling where claims as to presence of vitamins made

Where a claim is made as to the presence of vitamins in therapeutic goods or other drugs, there shall be written in the label on or attached to the package containing such goods or drugs a statement setting out separately in respect of each vitamin claimed to be so present the amount thereof in international units or milligrams in a stated quantity of such goods or drugs and a claim so made shall not be extended by the use in the label of the word 'enriched' or 'fortified' or any word or words having the same or a similar effect.

Maximum penalty—20 penalty units.

159 Further labelling where alcohol present

(1) Subject to subsection (2), there shall be written in the label on or attached to a package containing therapeutic goods or other drugs for sale for internal use by man that are compounded with ethyl alcohol in a proportion greater than 50 millilitres per litre, in boldface sans serif capital letters, the proportion of alcohol contained in such goods or drugs expressed in the form—

'ALCOHOL

THIS MIXTURE CONTAINS NOT

MORE THAN (here insert the number of

parts per centum present,

volume in volume) of ALCOHOL'.

Maximum penalty—20 penalty units.

(2) This section does not apply to therapeutic goods or other drugs dispensed and supplied on any prescription or order signed by a medical practitioner or dentist.

160 Further labelling where methylated spirits present

There shall be written in the label on or attached to a package containing therapeutic goods or other drugs for external use that are mixed or prepared with methylated spirits, in boldface sans serif capital letters, a statement declaring the presence of those spirits and the proportion thereof contained in that substance in the form—

'THIS PREPARATION CONTAINS

(here insert the number of parts

per centum present,

volume in volume) OF ALCOHOL

IN THE FORM OF METHYLATED SPIRITS'.

Maximum penalty—20 penalty units.

161 Further labelling for analgesics

(1) Subject to subsection (2), there shall be written in the label on or attached to a package containing a preparation for internal use by man that consists of or contains any of the substances—

(a) aspirin (acetylsalicylic acid) and its salts;

(b) paracetamol;

(c) salicylic acid, its salts, derivatives and their salts other than aspirin;

a statement in 1 of the forms—

'WARNING—This medication may

be dangerous when used in

large amounts or for a long period'

or

'CAUTION—This preparation is for

the relief of minor and temporary

ailments and should be used

strictly as directed. Prolonged

use without medical supervision

could be harmful'.

Maximum penalty—20 penalty units.

(2) This section does not apply to a preparation dispensed by a medical practitioner or dentist or by a pharmaceutical chemist upon the prescription of a medical practitioner or dentist.

162 Further labelling requirements for tobacco

(1) This section applies to a retail package only as far as the Commonwealth regulation does not apply to the package.

Editor's note—

The Commonwealth regulation applies to a corporation, in trade or commerce, supplying goods that are intended to be used, or are of a kind likely to be used, by a consumer. See the *Competition and Consumer Act 2010* (Cwlth).

This section provides for the same labelling requirements to apply to a package of tobacco under this regulation as apply to a package under the Commonwealth regulation.

(2) A retail package must be labelled in the way specified in the Commonwealth regulation, as if it were a package to which the Commonwealth regulation applied.

(3) In this section—

Commonwealth regulation means the *Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004* (Cwlth).

retail package has the meaning given by the Commonwealth regulation.

163 Soap and soap mixtures

(1) Soap is a product prepared from the action of a solution of alkali on fats, oils or resins or a mixture of any 2 or all of them.

(2) Soap—

(a) shall contain—

(i) not less than 590 grams of fatty acids and resin acids or both per kilogram;

(ii) not more than—

(A) 1 gram of free caustic alkali;

(B) 30 grams of sodium carbonate;

per kilogram;

(b) shall not contain any other substances save water, perfume and harmless colouring matter.

Maximum penalty—20 penalty units.

(3) Soap mixture is soap mixed with mineral substances or vegetable substances or both in such proportion as to ensure that the total content of any such substance or a mixture of them does not exceed 100 grams per kilogram.

(3A) Soap mixture shall contain not less than 530 grams of fatty acids or resin acids or both per kilogram.

Maximum penalty—20 penalty units.

(3B) There shall be stamped or embossed on all bars and cakes of soap mixture for sale in that form, in boldface sans serif capital letters with a minimum letter height of 8mm, the words—

'SOAP MIXTURE'.

Maximum penalty—20 penalty units.

(3C) Where soap mixture is for sale enclosed in a package, there shall be written in the label on or attached to that package, in boldface sans serif capital letters with a minimum letter height of 8mm, a statement in the form—

'SOAP MIXTURE

SOAP MIXED WITH (here insert

in letters with a minimum letter

height of 2 millimetres the

name or names of the admixed

substance or substances)'.

Maximum penalty—20 penalty units.

(4) Abrasive soap is a preparation of soap and any abrasive substance or substances for sale as being suitable for abrasive purposes.

(4A) There shall be written in the label on or attached to a package containing abrasive soap, in boldface sans serif capital letters with a minimum letter height of 4.5mm, the words—

'ABRASIVE SOAP'

or

'PUMICE SOAP'

or words having the same or a similar effect.

Maximum penalty—20 penalty units.

(4B) Where abrasive soap is for sale in unwrapped bars or cakes, the words specified shall be stamped or embossed on each such bar and cake in accordance with subsection (4A).

Maximum penalty—20 penalty units.

(5) Medicated soap is soap mixed with a drug of recognised therapeutic properties.

(5A) There shall be written in the label on or attached to a package containing medicated soap, in boldface sans serif capital letters with a minimum letter height of 4.5mm, the word—

'MEDICINAL', 'MEDICATED',

or 'MEDICAL' followed

by the word 'SOAP'.

Maximum penalty—20 penalty units.

(5B) Where medicated soap is for sale in unwrapped bars or cakes, those words shall be stamped or embossed on each such bar and cake in accordance with subsection (5A).

Maximum penalty—20 penalty units.

(6) Borax soap is soap mixed with a quantity of not less than 20 grams of borax per kilogram.

(7) Castile soap is soap prepared by the action of sodium hydroxide on olive oil.

(7A) It shall comply with the general standard for soap prescribed by this part.

(7B) The word 'castile' or any word or words resembling or having the same or a similar effect as 'castile' shall not be used on a bar or cake of or package containing soap other than soap that complies with the standard prescribed by this part for castile soap.

Maximum penalty—20 penalty units.

(8) Soft soap is a product prepared from the action of a solution of potassium hydroxide, with or without sodium hydroxide, on fats, oils or resin.

(8A) Soft soap—

(i) shall contain not less than 400 grams of fatty acids or resin acids or both per kilogram;

(ii) may contain not more than 30 grams of potassium silicate per kilogram.

Maximum penalty—20 penalty units.

(9) Shaving soap in the form of shaving sticks, shaving cakes or other solids purporting to be suitable for use in shaving shall comply with the general standard for soap prescribed by this part.

Maximum penalty—20 penalty units.

(9A) Unwrapped cakes or sticks of shaving soap for sale in that form shall be stamped or embossed with the name of the product.

Maximum penalty—20 penalty units.

(9B) The general labelling requirements prescribed by this part apply to shaving soap in any form for sale in packages.

(10) Liquid soap is a product that contains not less than 100 grams per kilogram of fatty acids or resin acids or both, combined as soap.

(10A) Liquid soap need not comply with the general standard for soap prescribed by this part.

(13) The general standard for soap prescribed by this section does not apply to the product called washing powder.

(14) For the purposes of this section, a declaration of the presence of a colouring substance in any variety of soap is not required.

164 Requirements as to packages

(1) A person engaged in or in connection with the manufacture, preparation, production or packing for sale of therapeutic goods or other drugs shall ensure that—

(a) every package intended to be used by the person to hold such goods or drugs or in which they are to be packed—

(i) is scrupulously clean and free from foreign matter;

(ii) has been and is being kept stored until such time as it is used, in such manner as to protect it from contamination from any source;

(iii) is free from every ingredient capable of imparting to it any unwholesome property or poisonous or injurious matter or thing;

(iv) is free from cracks and chips;

(b) every second-hand package, intended to be used by the person, pursuant to paragraph (a), in addition to being subject to the requirements specified in that paragraph, has been properly cleaned and washed in accordance with this part;

(c) every cork, crown seal, wad or appliance intended to be used by the person in the closing or sealing of such goods or drugs is new and clean and has been and is being kept stored until it is so used, in such manner as to protect it from contamination from any source.

Maximum penalty—20 penalty units.

(2) A person shall not use for the purpose of holding any substance or thing a package intended to be used by the person for holding therapeutic goods or other drugs, if such use were such as to result in the likelihood of contaminating or affecting the quality or taste of such goods or other drugs if they were subsequently packed in that package.

Maximum penalty—20 penalty units.

(3) A person shall not use a package intended to be used by the person for holding therapeutic goods or other drugs as a

receptacle for urine or sputum or for the purpose of holding, storing or preserving a pathological specimen or any objectionable matter or thing.

Maximum penalty—20 penalty units.

165 Restrictions on use of certain second-hand packages

A person shall not pack therapeutic goods or other drugs for sale in a package that has been previously used where that package is made wholly or partly of paper, cardboard or the like absorbent material.

Maximum penalty—20 penalty units.

166 Requirements as to conduct of business of preparing second-hand or used packages for sale

(1) A person shall not conduct the business of preparing second-hand bottles or used bottles, cans or other packages for sale as packages of therapeutic goods or other drugs unless and until—

(a) the place in or at which those packages are and are to be stored;

(b) the plant to be used, methods of treatment (whether by washing, cleaning or other process) and storage of those packages;

have been approved by the chief executive.

Maximum penalty—20 penalty units.

(2) Packages that have been treated in accordance with subsection (1) shall be stored and kept stored in such place and manner as to ensure that those packages are protected from re-contamination by dust or other means.

Maximum penalty—20 penalty units.

(3) A person shall not convey a package that has been treated and stored in accordance with subsections (1) and (2) through a street or other open place by such method and in such manner

as to render that package likely to be contaminated by dust or other means.

Maximum penalty—20 penalty units.

(4) A person shall not sell as fit for use as a package for therapeutic goods or other drugs a second-hand package or used package that has not been treated, stored and kept stored in accordance with subsections (1) and (2).

Maximum penalty—20 penalty units.

(5) The chief executive may at any time furnish to a person engaged in the packing of therapeutic goods or other drugs a list of persons and their business addresses whose premises and plant have been approved by the chief executive under subsection (1).

167 Packaging of certain therapeutic and other substances

(1) A person must not sell a prescribed substance unless it is packed—

(a) in a reclosable container that has directions for opening and closing the container conspicuously marked or written on it or on a label securely attached to it; or

(b) in a non-reclosable container.

Maximum penalty—8 penalty units.

(2) Subsection (1) does not apply to a prescribed substance—

(a) in a container holding 500 solid dosage units or more; or

(b) supplied to a person whom the doctor, dentist, veterinary surgeon or pharmacist prescribing or supplying the substance believes would suffer undue hardship if the person were required to open a container complying with this section; or

(c) to be used by, or administered to, a patient in a hospital or nursing home.

(3) In this section—

non-reclosable container means a container that—

(a) is in the form of a blister package or other sealed unit; and

(b) is made from paper, film, plastic material, metal foil or another sheet or strip material, other than cellulose film or unlaminated paper; and

(c) contains a single dosage unit, whether or not as part of a continuous series forming a strip or sheet of the same material.

prescribed substance means—

(a) a capsule, lozenge, pastille, suppository, tablet or similar discrete solid dosage unit, other than individually wrapped powders, containing—

(i) a therapeutic or animal use substance mentioned in schedule 14, part 1; or

(ii) an ester, salt or other derivative of a therapeutic or animal use substance mentioned in schedule 14, part 1; or

(b) a liquid preparation containing a therapeutic or animal use substance mentioned in schedule 14, part 2.

reclosable container means—

(a) a container fitted with a closure mentioned in schedule 13, part 1; or

(b) a container mentioned in schedule 13, part 2.

therapeutic or animal use substance means—

(a) a therapeutic substance; or

(b) a substance for animal use that would be a therapeutic substance if it were for human use.

168 Biological preparations

(1) In this section—

biological preparation means—

(a) a product prepared from animal tissue (including blood, lymph or glandular secretion) or by the agency of microscopic or ultramicroscopic organisms or ferment of any kind, used for or in relation to therapeutic use;

(b) a synthetic compound identical with or closely related to the products specified in paragraph (a) and in respect of which a claim is made that it has comparable therapeutic use.

(2) A person shall not sell a package containing a biological preparation unless the label on or attached to that package—

(a) complies with the general labelling requirements prescribed by this part;

(b) bears thereon or therein—

(i) the nature and proportion of antiseptic (if any) that has been added;

(ii) the precautions necessary for preserving the properties of the contents during the period to and including the expiry date;

(iii) in the case of diphtheria or tetanus antitoxic sera—

(A) the number of immunising units contained in any stated volume expressed in terms of the units prescribed by the Therapeutic Substances Regulations made under the *Therapeutic Substances Act 1925* (UK) or the Therapeutic Goods Regulations made under the *Therapeutic Goods Act 1989* (Cwlth), or adopted by the National Institute of Health, Washington, D.C., United States of America;

(B) whether or not the contents are free from organisms natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins;

(iv) in the case of bacterial vaccines—

(A) the identity and number of organisms per millilitre and the maximal doses for administration;

(B) whether or not the contents are free from organisms other than those peculiar to the preparation;

(v) in the case of antitoxin, whether or not the contents are sterile or contain free toxin.

Maximum penalty—20 penalty units.

(3) A biological preparation in which the growth of pathological organisms is possible shall not be packed in a rubbercapped package for repeated use unless there is present in the preparation a sufficient concentration of antiseptic to inhibit bacterial growth.

Maximum penalty—20 penalty units.

(4) Where no antiseptic is present in a biological preparation, there shall be written in the label on or attached to a package containing the preparation, in boldface sans serif capital letters, the words—

'NO ANTISEPTIC IS PRESENT IN THE CONTENTS OF THIS PACKAGE. THEY SHOULD BE USED FORTHWITH ON OPENING AND THE UNUSED PORTION SHOULD BE DISCARDED'.

Maximum penalty—20 penalty units.

(5) A person shall not sell a biological preparation unless it is packed in a package prescribed by the Therapeutic Goods Regulations made under the *Therapeutic Goods Act 1989* (Cwlth) or in a clear glass container.

Maximum penalty—20 penalty units.

169 Duties of manufacturer

(1) A person who manufactures for sale a therapeutic substance shall assign to each batch of that substance manufactured by

the person a batch number and shall make and maintain records in accordance with subsection (2) indicating—

(a) the substances used in the manufacture of each batch;

(b) the analyses performed on those substances referred to in paragraph (a) and the results of those analyses;

(c) the quantities of each substance used in the manufacture of each batch;

(d) the procedures and controls applied in the course of manufacture to each batch being manufactured and the results of any measurements made on the batch or a sample from the batch taken during its manufacture;

(e) the analyses performed on each batch and the results of those analyses.

Maximum penalty—20 penalty units.

(2) The records prescribed by subsection (1) shall be maintained for—

(a) at least 1 year after the expiry date shown with respect to the therapeutic substance in question;

(b) where no expiry date is shown, at least 6 years after the date of completion of manufacture of the therapeutic substance in question.

(2A) A copy of any record made and maintained under this section, certified as correct by the manufacturer, shall be sent to the chief executive when and as often as the chief executive makes a request in that behalf.

Maximum penalty—20 penalty units.

(3) A person who manufactures for sale a therapeutic substance—

(a) shall take a sample of each substance used in the manufacture of each batch so manufactured of at least twice the quantity necessary for the tests required to establish its identity and purity;

(b) shall retain each sample taken in accordance with paragraph (a) for at least 2 years after the date of the use of the substance in such manufacture;

(c) shall take a sample of each therapeutic substance so manufactured of such quantity as is adequate to permit examination of the substance at suitable intervals of time and the investigation of possible complaints;

(d) shall store the sample taken in accordance with paragraph (c) under the conditions of storage (if any) recommended on the label otherwise under such conditions as will ensure preservation of the sample;

(e) shall retain the sample taken in accordance with paragraph (c)—

(i) for at least 1 year after the expiry date shown with respect to the therapeutic substance in question;

(ii) where no expiry date is shown, for at least 6 years after the date of completion of the manufacture of the therapeutic substance in question.

Maximum penalty—20 penalty units.

(4) Where the chief executive considers that it is necessary in the interests of public health to do so, a sample taken and retained in accordance with subsection (3)—

(a) shall be subjected to such analyses and examinations as the chief executive directs; or

(b) shall, at the direction of the chief executive, be furnished wholly or in part to an inspector for submission by the inspector to a laboratory of the Department of Health.

(5) A person shall not use or cause to be used in the manufacture, preparation or production of a therapeutic substance for sale water other than potable water.

Maximum penalty—20 penalty units.

(6) For the purposes of this section, potable water is water—

(a) that has been obtained from an approved source; or

(b) that has been distilled, boiled, filtered or otherwise rendered sterile by an approved process.

(7) Potable water—

(a) shall contain not more than 100 micro-organisms in 1ml;

(b) shall be colourless;

(c) shall not contain—

(i) micro-organisms of intestinal origin;

(ii) objectionable chemical constituents;

(iii) sediment;

(d) shall not be used for any purpose specified in this part requiring the use of potable water unless it has been stored and kept during the period between its collection or sterilisation and its manufacture or sale in such place and such manner as to protect and preserve it from contamination.

Maximum penalty—20 penalty units.

170 Specifications for places

(1) A person shall not establish or conduct or suffer or cause to be established or conducted a business with respect to or connected with the manufacture, preparation, production, storage, handling, packing, displaying, serving, selling or other dealing with any therapeutic substance or other drug in or at a place other than a place that complies in all respects with this part.

Maximum penalty—20 penalty units.

(2) The occupier of a place in or at which any therapeutic substance or other drug for sale or a substance used or intended to be used in the manufacture or preparation of any therapeutic substance or other drug for sale is manufactured, prepared, produced, stored, handled, packed, displayed,

served, sold or otherwise dealt with, shall ensure that the place—

(a) is constructed and maintained in accordance with the *Public Health Regulation 2018*, part 2, division 3; and

(b) is provided with sewerage and drainage in compliance with the requirements of the local government, in accordance with the *Plumbing and Drainage Act 2018* or any other enactment relating to sewerage or drainage, maintained at all times in good and efficient working order; and

(c) complies with the *Work Health and Safety Regulation 2011*, part 3.2, division 2.

Maximum penalty—20 penalty units.

171 Prohibition of use of certain places

A person shall not manufacture, prepare, produce, store, handle, pack, display, serve or sell any therapeutic substance or other drug for sale or a substance used or intended to be used in the manufacture, preparation or production of any therapeutic substance or other drug for sale in or at a place or part of a place—

(a) that is at any time—

(i) used as a sleeping apartment or in which there is a bed or bedding or in direct communication by means of any door, window or other opening with a sleeping apartment or place in which there is a bed or bedding;

(ii) used as a sanitary convenience or in direct communication by means of any door, window or other opening with a sanitary convenience or place in which any animal or bird is allowed to be at large;

(iii) used as a change room;

(b) in or at which—

(i) work is being performed that would be likely to contaminate that substance or drug or injuriously affect its wholesomeness, quality or cleanliness;

(ii) there is an opening in direct communication with a sewer or drain;

(iii) any animal or bird is stabled, kept or allowed to be at large;

(c) that is in such an insanitary condition or so located or maintained as to be unfit for use in or in connection with a process or procedure specified in this section;

(d) that is a cellar, basement, underground room or place, save with the written consent of the chief executive.

Maximum penalty—20 penalty units.

172 Power of chief executive to require cessation of use of or alterations to places or equipment

(1) The chief executive may give a written notice requiring the owner or occupier of a place used for the manufacture, preparation, production, storing, handling, packing, displaying, serving or selling therapeutic goods or other drugs for sale, which place the chief executive has reason to believe by reason of its situation, condition, construction or disrepair is such as to render possible contamination of those goods or drugs, to cease to use in or in connection with a process or procedure specified in this subsection or to reconstruct, alter, clean, repair or otherwise deal with, that place or any part thereof as directed and within the time specified in the notice.

(2) The chief executive, by notice in writing directed to the owner or occupier of a place used for the manufacture, preparation or production of therapeutic goods or other drugs for sale, may prohibit the use in the manufacture, preparation or production of such goods or drugs of any appliance, apparatus or equipment that the chief executive has reason to believe is unsuitable for the purpose for which it is being so used.

(3) The chief executive, by notice in writing directed to the occupier of a place used for the manufacture, preparation or production of therapeutic goods or other drugs for sale, may require the occupier to restrict, in the manner and to the extent specified in the notice or to cease within the time specified such manufacture, preparation or production.

173 Maintenance of places and equipment

(1) The occupier of a place where therapeutic goods or other drugs for sale or a substance used or intended for use in the manufacture of therapeutic goods or other drugs for sale are manufactured, prepared, produced, stored, handled, packed, displayed, served or sold, at all times, shall—

(a) maintain in a clean, serviceable and sanitary condition and a state of good repair—

(i) such place and all vehicles used in or in connection with the conveyance of such goods or other drugs;

(ii) all apparatus, appliances, implements, fittings, machinery and utensils used in or at such place in or in connection with a process or procedure specified in this section;

(b) provide adequate facilities, including hot water, for cleaning such place and all apparatus, appliances, implements, fittings or machinery used in or in connection with a process or procedure specified in this section carried out or performed in or at such place;

(c) keep or cause to be kept—

(i) such place free from rats, mice, cockroaches, flies or other vermin or insects;

(ii) for the purpose specified in subparagraph (i)—

(A) all materials used in or in connection with such place so stored, stacked and arranged as to preclude harbourage for rats, mice, cockroaches, flies or other vermin or insects;

(B) all land adjoining and every shed and outbuilding appurtenant to such place clean and free from lumber, rubbish, garbage and deleterious substances;

(iii) the interior surfaces of every wall and ceiling of every room or compartment of such place thoroughly treated with paint or other durable material;

(d) for the purpose of compliance with paragraph (c)(i), protect, so far as is practicable, all doors, windows and other openings in or at such place, by means of self-closing wire gauze doors or, as the case requires, wire gauze screens constructed from suitable mesh and materials;

(e) when required so to do by the chief executive, cause any floor of such place to be covered with impervious material;

(f) not conduct in such place, save with the consent of the chief executive, any other trade or business.

Maximum penalty—20 penalty units.

(2) A person engaged in the manufacture, preparation, production, storage, handling, packing, conveyance or delivery for sale of therapeutic goods and other drugs shall at all times take all steps and do all such acts and things as are necessary to protect such goods and drugs and every ingredient used in the manufacture thereof from rats, mice, cockroaches, flies or other vermin or insects and any contaminating or unwholesome matter, odour or thing.

Maximum penalty—20 penalty units.

174 Prohibition as to poisonous preparations

A person shall not keep, use or spread or cause or suffer to be kept, used or spread a preparation containing any poison or other objectionable, injurious or deleterious matter on, in or from any place in such manner and to such extent as to expose

therapeutic goods or other drugs for sale to the risk of contamination.

Maximum penalty—20 penalty units.

175 Requirements as to personal cleanliness

(1) Subject to this subsection, a person engaged in the manufacture, preparation, production, storage, handling, packing, serving, selling, conveyance or delivery of therapeutic goods or other drugs for sale, whilst so engaged shall—

(a) not expectorate or smoke;

(b) be clean in his or her habits, body and attire;

(c) be free from any contagious or infectious disease or communicable skin infection or infected wound;

(d) not wear a bandage or dressing that may come into contact with or contaminate such goods or drugs;

(e) immediately before commencing work and upon every occasion after visiting a sanitary convenience before resuming work, wash his or her hands and brush his or her fingernails thoroughly with soap and clean water;

(f) for the purpose of the prevention of the risk of contamination to or by such goods or drugs and when so directed in writing by the chief executive so to do, wear such clothing as the person is directed to wear.

Maximum penalty—20 penalty units.

(1A) Subsection (1)(a), so far as it relates to smoking, does not apply with respect to a person engaged in or in connection with the storage, handling, conveyance or delivery of therapeutic goods or other drugs for sale in cases where such goods are enclosed in hermetically sealed packages.

(2) Subject to subsection (3), a person shall not expectorate or smoke in or at any place used in the manufacture, preparation, production, storage, handling, packing, serving, selling, conveyance or delivery of therapeutic goods or other drugs for

sale or whilst on or in a vehicle engaged in the conveyance for sale of such goods or drugs.

Maximum penalty—20 penalty units.

(3) The prohibition with respect to smoking specified in subsection (2) does not apply in cases where therapeutic goods or other drugs for sale contained in hermetically sealed packages are stored, handled, conveyed or delivered.

176 Prohibition as to certain persons

(1) A person who—

(a) is suffering from—

(i) any contagious or infectious disease;

(ii) any communicable skin infection or acute respiratory infection;

(iii) any open sore or infected wound;

(b) is wearing a bandage or dressing that may come into contact with or contaminate therapeutic goods or other drugs;

shall not be engaged in or in connection with the manufacture, preparation, production, storage, handling, packing, serving, selling, conveyance or delivery of therapeutic goods or other drugs for sale.

Maximum penalty—20 penalty units.

(2) A person who is a carrier of disease shall not be engaged in, or be employed in any capacity in, a business connected with the manufacture, preparation, production, storage, handling, packing, serving, selling, conveyance or delivery of therapeutic goods or other drugs for sale or handle any instrument, package, receptacle, utensil or vessel or other thing used in or in connection with the processes or procedures specified in this subsection.

Maximum penalty—20 penalty units.

(3) The chief executive, by order in writing directed to the chief executive, may require a person who is employed in or in connection with—

(a) manufacturing, preparing, producing, storing, handling, packing, displaying, serving, selling, conveying or delivering or otherwise dealing with therapeutic goods or other drugs for sale;

(b) handling any receptacle, utensil, vessel or other thing in, on or from which such goods or drugs are kept or served;

to submit himself or herself to any process of clinical or bacteriological examination specified in the order for the purpose of ascertaining whether such person is capable of conveying the germs of disease to a consumer of those goods or drugs and for the purpose of such examination to present himself or herself to the medical officer in charge of the hospital nearest to the place in question or some other duly qualified medical practitioner specified in the order.

(4) Where the chief executive is satisfied that a person is capable of conveying the causal agent of disease to a consumer of therapeutic goods or other drugs, the chief executive, by order in writing addressed to that person, may direct that person to forthwith cease work in or in connection with—

(a) the manufacture, preparation, production, storage, handling, serving, selling, conveying, delivering or other dealing with such goods or drugs for sale;

(b) the handling or other dealing with any receptacle, utensil, vessel or other thing in, on or from which such goods or drugs are kept or served;

and refrain from resuming such work until after the production by the person to the chief executive of satisfactory evidence that the person is fit to do so and the receipt by the person of permission in writing signed by the chief executive that the person may resume such work.

177 Offence as to therapeutic substance to which certain colouring substance added

A person shall not manufacture, prepare, produce or sell a therapeutic substance that contains a colouring substance other than a permitted colouring substance stated in Standard A5 of the Food Standards Code.

Maximum penalty—20 penalty units.

178 Compliance of therapeutic goods or other drugs with certain description or standard

(1) Therapeutic goods and other drugs that are included in the APF shall comply with the descriptions therein specified for them.

(1A) However—

(a) wherever therapeutic goods or other drugs are included in the British pharmacopoeia, APF and the British pharmaceutical codex, the standard of the British pharmacopoeia shall prevail;

(b) wherever therapeutic goods and other drugs are included in the APF and the British pharmaceutical codex but not in the British pharmacopoeia, the standard of the APF shall prevail;

(c) where olive oil, cottonseed oil, sesame oil or arachis oil is indicated in the British pharmacopoeia or British pharmaceutical codex as a constituent of therapeutic goods or other drugs, maize oil may be used in the stead of any of those oils.

Maximum penalty—20 penalty units.

(2) Sunscreening preparations shall comply with AS/NZS 2604:2012 (Sunscreen products—Evaluation and Classification).

(3) A person shall not sell a sunscreening preparation which does not comply with the above standard.

Maximum penalty—20 penalty units.

Part 18 Miscellaneous

204 Automatic machines—Act, s 106

For section 106 of the Act, the sale or supply of condoms, by means of an automatic machine or similar mechanical device, is prohibited in—

- a State school within the meaning of the *Education (General Provisions) Act 2006*, schedule 4
- an accredited school under the *Education (Accreditation of Non-State Schools) Act 2017*
- a grammar school, within the meaning of the *Grammar Schools Act 1975*.

209 Inspector may serve notice to comply

(1) If an inspector believes, on reasonable grounds, that a person is committing an offence against this regulation, the inspector may give the person a written notice (***notice to comply***) under this section.

(2) A notice to comply must state—

(a) the act or omission comprising the alleged offence; and

(b) the action the person must take to rectify the alleged offence; and

(c) the day or time by which the person must take the action (the ***due date***).

(3) The time between when the notice to comply is given to the person and the due date must be reasonable, having regard to the action the person must take.

(4) A person who receives a notice to comply may not be prosecuted for the alleged offence unless the person does not comply with the notice by the due date.

(5) A person may be prosecuted for an offence against this regulation even though the person has not received a notice to comply.

210 Fees

The fees payable under the Act are in schedule 3.

211 Additional payment if GST applies

(1) This section applies if GST is payable in relation to a supply under this regulation.

(2) A person liable to pay a fee under this regulation for the supply must, in addition to the fee and at the same time as the fee is paid, pay an amount equal to 10% of the fee.

Part 19 Repeals

Division 1 Repeals for Subordinate Legislation 1996 No. 121

424 Repeals

(1) The following regulations made under the Act are repealed—

- Camping Ground Regulation 1987
- Cancer Registration Regulation 1981
- Hairdressers Regulation 1989
- Hazardous Substances (Placarding) Regulation 1988
- Health (Analysis Fees) Regulation 1981
- Health (Analyst's Certificate) Regulation 1993
- Health (Dispensary) Regulation 1993
- Health (Pest Control Operators) Regulation 1977

- Health (Poisons—Fumigation) Regulation 1973
- Health (Radioactive Substances) Regulation 1994
- Health (Scientific Research and Studies) Regulation 1993
- Hyperbaric Chamber Therapy Regulation 1989
- Maltreatment of Children Regulation 1980
- Mosquito Prevention and Destruction Regulation 1982
- Perinatal Statistics Regulation 1986
- Prescribed Substances Standards and Methods Regulation 1987
- Skin Penetration Regulation 1987
- Therapeutic Goods and Other Drugs Regulation 1982
- Vermin Control Regulation 1991.

(2) The instruments made under the Act as notifications and published in the gazette on the dates and at the pages stated below are repealed—

(a) 26 June 1982 at page 1643; and

(b) 22 October 1988 at page 881; and

(c) 16 June 1990 at page 962; and

(d) 4 June 1993 at page 777.

(3) The instruments made under the Act as orders in council and published in the gazette on the dates and at the pages stated below are repealed—

(a) 8 May 1971 at page 183; and

(b) 30 July 1977 at page 1695; and

(c) 1 September 1979 at page 75; and

(d) 13 August 1988 at page 3393; and

(e) 22 October 1988 at page 881; and

(f) 1 September 1990 at page 84.

Division 2 Transitional provisions for Health Amendment Regulation (No. 4) 1999

425 Transitional provisions for offences against repealed part

(1) Proceedings for an offence against the repealed part may be started or continued, and the provisions of the repealed part and the *Health Act 1937* that are necessary or convenient to be used in relation to the proceedings continue to apply, as if the *Health Amendment Regulation (No. 4) 1999* had not commenced.

(2) For subsection (1), the *Acts Interpretation Act 1954*, section 20 applies, but does not limit the subsection.

(3) In this section—

repealed part means the *Health Regulation 1996*, part 2, as in force from time to time before its repeal by the *Health Amendment Regulation (No. 4) 1999*.

Schedule 3 Fees

section 210

	$
Analysis of a drug or article by a State analyst by any of the following methods—	
(a) chemical	367.50
(b) physical	367.50
(c) chemical and physical	367.50
(d) microbiological	367.50

Schedule 4 Items to be provided

section 25(1)

1 a refrigerator, fitted with a device capable of registering the minimum and maximum temperature, for use for storing therapeutic products at appropriate temperatures

2 three metric certified dispensing measures

3 a funnel

4 two spatulas

5 a tablet counting tray

6 a current copy of each of the following—

(a) the *Health (Drugs and Poisons) Regulation 1996*;

(b) the Standard for the Uniform Scheduling of Medicines and Poisons published by the Commonwealth;

(c) the Register of Dental Practitioners kept under the Health Practitioner Regulation National Law;

(d) the Register of Medical Practitioners kept under the Health Practitioner Regulation National Law;

(e) the register of veterinary surgeons kept under the *Veterinary Surgeons Act 1936*, section 16(1)(a)

Schedule 5 Additional items

section 25(2)

1 a set of mechanical or electronic counter scales, capable of weighing up to 1kg with an appropriate set of metric weights (if necessary)

2 a dispensing balance capable of weighing up to 50g that is either—

(a) an electronic balance; or

(b) a mechanical balance with an appropriate set of metric weights (if necessary)

3 a certified 10ml, 20ml, 50ml, 100ml, 200ml and 1L dispensing measure

4 a mortar and pestle

5 a stirring rod

6 an ointment slab

7 an electric or gas heating appliance for use in dispensing a drug or poison

Schedule 13 Closures and containers

section 167(3), definition *reclosable container*

Part 1 Closure

Name of closure	Australian registered trade mark	Australian patent number	Approved sizes	Australian distributor	Australian manufacturer
Argus-Loc	yes	none	28 33 38mm	ACI Plastics Kingsway MOORABBIN 3189	imported
Clic-Loc	no	477954	22 24 28 33 38mm	ACI Plastics Kingsway MOORABBIN 3189	imported
Clic-Loc	no	477954	24 28 33 38mm	GLASS-PAK (Aust) Pty Ltd 349 Darebin Road THORNBURY 3071	imported
Easy Lok	yes	467825	28 and 38mm	RTTA Plastics Marketing & Development Pty Ltd PO Box 443 CARINGBAH 2229	imported
Kerr CR-1	yes	none	20 22 24 28 30 33 38mm	O R Cormack Pty Ltd 13 Leeds Street RHODES 2138	20 24 28 30 33 38mm manufactured by O R Cormack Pty Ltd 13 Leeds Street RHODES 2138 22mm imported

Name of closure	Australian registered trade mark	Australian patent number	Approved sizes	Australian distributor	Australian manufacturer
Key	no	60320/80 applied for	28mm only	Van Leer Australia Pty Ltd Plastics Division cnr Ferndell Street & Boundary Road CHESTER HILL 2162	Van Leer Australia Pty Ltd Plastics Division cnr Ferndell Street & Boundary Road CHESTER HILL 2162
Ring guard	yes	449374	20 22 24 28 33 38mm	O R Cormack Pty Ltd 13 Leeds Street RHODES 2138	28mm only manufactured by O R Cormack Pty Ltd 13 Leeds Street RHODES 2138 other sizes imported
Spotlock	yes	none	28mm only	Madrega Pty Ltd 139 Green's Road DANDENONG 3175	imported
Sunbeam FG	no	80696/82 applied for	28mm only	RTTA Plastics Marketing & Development Pty Ltd PO Box 443 CARINGBAH 2229	imported
Willsafe	yes	550878	24 28 33 38mm	Williamson Ltd & Co Pty Ltd 27 Anzac Street GREENACRE 2190	Williamson & Co Pty Ltd 27 Anzac Street GREENACRE 2190

Part 2 Reclosable container

Name of container	Australian registered trade mark	Australian patent number	Approved sizes	Australian distributor	Australian manufacturer
Loxon	yes	438899	28mm only	Loxon Products 30 Albert Parade ASHFIELD 2131	J W S Plastics Pty Ltd 15 Stanton Road SEVEN HILLS 2147
Snap-safe	yes	PA33918/71	24 28 38mm	OR Cormack Pty Ltd 13 Leeds Street RHODES 2138	closure–imported container manufactured by OR Cormack Pty Ltd 13 Leeds Street RHODES 2138
Snap-safe Closure with Neta vial	yes	462620	20mm only	closure–OR Cormack Pty Ltd 13 Leeds Street RHODES 2138 vial–Neta Moulders 181 Burwood Road HAWTHORN 3122	closure–imported vial–manufactured by Neta Moulders 181 Burwood Road HAWTHORN 3122

Schedule 14 Prescribed substances

section 167(3), definition *prescribed substance*

Part 1 Solid dosage unit

1 Antihistamines, that is all substances the principal action of which is to antagonise the effects of histamine on H1 receptors, in preparations where the antihistamine is the only therapeutically active substance, including—

antazoline	dexbrompheniramine	phenindamine
astemizole	dexchlorpheniramine	pheniramine
azatadine	dimenhydrinate	phenyltoloxamine
bamipine	dimethindene	promethazine
bromodiphenhydramine	dimethothiazine	prothipendyl
brompheniramine	diphenhydramine	pyrathiazine
buclizine	diphenidol	pyroxamine
carbinoxamine	diphenylpyraline	pyrrobutamine
cetoxime	doxylamine	rotoxamine
chlorcyclizine	embramine	thenalidine
chloropyrilene	halopyramine	thenyldiamine
chlorpheniramine	histapyrrodine	thiazinamium
chlorphenoxamine	homochlorcyclizine	thonzylamine
cinnarizine	hydroxyzine	tolpropamine
clemastine	isothipendyl	trimeprazine
clemizole	mebhydrolin	trimethobenzamide
cycliramine	meclozine	tripelennamine

	cyclizine	mepyramine	triprolidine
	cyproheptadine	methaphenilene	
	deproprine	methdilazine	

2 Tricyclic antidepressants including—

amitriptyline	imipramine	monometacrine
amoxapine	intriptyline	nortriptyline
butriptyline	iprindole	noxiptyline
cidoxepin	ketipramine	octriptyline
clomipramine	lofepramine	opipramol
desipramine	loxapine	pirandamine
dibenzepin	maprotiline	prazepine
dothiepin	melitracen	protriptyline
doxepin	mezepine	tandamine
fantridone	mianserin	trimipramine

3 Aspirin

4 Paracetamol

5 Salicylamide

6 Iron compounds, other than in preparations containing the equivalent of 5mg or less of elemental iron in each solid dosage form

7 Digitalis glycosides

8 Quinine

9 Chloroquine

10 Monoamine oxidase inhibitors including—

iproniazid	phenelzine
isocarboxazid	tranylcypromine

11 Antiarrhythmics including—

amiodarone	mexiletine
bretylium	procainamide
disopyramide	quinidine
flecainide	verapamil

12 Anticonvulsants including—

carbamazepine	phenytoin

13 Glutethimide

14 Orphenadrine

15 Lithium carbonate

16 Diphenoxylate hydrochloride with atropine sulphate

17 Fluoride salts, in packs containing the equivalent of more than 100mg of elemental fluorine

Part 2 Liquid preparations

18 Paracetamol, in preparations where paracetamol is the only therapeutically active substance, except in paediatric drops in packs containing not more than 2g of paracetamol

19 Methyl salicylate, in preparations containing more than 50% volume in volume of methyl salicylate, in a volume of 200ml or less

20 Eucalyptus oil, in preparations containing more than 50% volume in volume of eucalyptus oil, in a volume of 200ml or less

21 Digitalis glycosides

22 Iron, in preparations containing the equivalent of more than 250mg of elemental iron in the total contents of the container

23 Melaleuca oil, in preparations containing more than 25% of cineole and in packs of 200ml or less