



Queensland

*Health Act 1937*

# Health Regulation 1996

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## Queensland

# Health Regulation 1996

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# Health Regulation 1996

[as amended by all amendments that commenced on or before 1 August 2006]

## 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 1386* means Australian Standard 1386—Cleanrooms and Clean Work Stations.

*AS 2639* means Australian Standard 2639—Cytotoxic Drug Safety Cabinets—Installation and Use.

*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 60°C; 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 parts 1 to 6 of AS 1386.

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 AS 1386.

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 2639 is complied with; and
  - (b) vertical laminar flow cabinets complying with AS 2639 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.

### **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 7 Maltreatment of children****65 Order for detention of child in hospital—Act, s 76L(2)(c) or (d)**

An order for the admission of a child to hospital, or for a child to be taken into custody and brought to a hospital, must be in the approved form.

**Part 8 Mosquito prevention and destruction****Division 1 Preliminary****66 Definitions**

In this part—

*approved* means approved in writing by the chief executive.

*occupier*, of premises, includes, if there is no person in actual occupation of the premises, a person entitled to possession of the premises.



*water or other liquid* means water or other liquid—

- (a) in which mosquitoes are likely to breed; or
- (b) that is likely to provide harbourage for mosquitoes.

**67 All mosquitoes noxious**

Mosquitoes of all species are hereby declared to be noxious.

**68 Local governments to superintend**

The local government shall superintend and see to the execution of this part and shall do and provide all such acts, matters, and things as may be necessary for superintending or aiding in the execution of this part.

**Division 2 Measures to be adopted by  
manufacturers, owners and  
occupiers**

**69 Tanks to be protected**

- (1) A person must not construct any tank or other receptacle that is used or intended to be used for the holding or storing of water or other liquid unless the tank or other receptacle complies with subsections (3) and (4).
- (2) The owner of any premises must not—
  - (a) install or place on the premises, whether above or below ground, any tank or other receptacle that is used or intended to be used for the holding or storing of water or other liquid; or
  - (b) permit or allow any such tank or other receptacle to remain on the premises;

unless the tank or other receptacle complies with subsections (3) and (4).

- (3) A tank or other receptacle used or intended to be used for the holding or storing of water or other liquid must be provided with—
- (a) mosquito-proof screens of brass, copper, aluminium or stainless steel gauze not coarser than 1mm aperture mesh of substantial construction and installed in such a manner as not to cause or accelerate corrosion; or
  - (b) flap valves at every opening of the tank or other receptacle; or
  - (c) other approved means for preventing the ingress or egress of mosquitoes.
- (4) Where a tank or other receptacle is provided with a manhole, the manhole must have a diameter of no more than 40cm.

Maximum penalty—40 penalty units.

## **70 Ponds and pools to be covered or treated**

The occupier of any premises shall at all times ensure that any pond, pool, trough, fountain, barrel, trench, or other like place or receptacle which ordinarily or occasionally contains water or other liquid is prevented from serving as a breeding place or harbourage for mosquitoes by 1 or more of the following methods, namely—

- (a) by keeping the water or other liquid therein covered or treated with kerosene, other suitable oil, or other suitable substance;
- (b) by keeping the water or other liquid stocked with mosquito-larvae-destroying fish;
- (c) by covering all openings in the manner prescribed by section 69;
- (d) by completely drawing off or emptying all water or other liquids from the receptacle and allowing the interior to dry, or thoroughly scrubbing all parts of the interior of the receptacle after emptying, at least once in every 7 days.

Maximum penalty—40 penalty units.

**71 Certain ponds and pools to be drained or filled**

- (1) Where there is on any premises any pond, pool, swamp, or other accumulation of water or other liquid, whether permanent or not, which is likely to serve as a breeding place or harbourage for mosquitoes if it is not drained or filled in, the owner of the premises shall effectively drain or fully fill in such pond, pool, swamp or other accumulation of water or other liquid.
- (2) The owner of the premises shall—
  - (a) ensure that all drains are at all times properly maintained and kept free from obstruction;
  - (b) maintain the surface of the land at appropriate levels so that at all times the water or other liquid does not remain on any portion of the premises and flows into the drains without obstruction.

Maximum penalty—40 penalty units.

**72 Other measures to be taken by occupiers**

- (1) The occupier of any premises shall at least once in every 7 days completely empty all water from every can, bowl, bottle, tub, bucket, pot, barrel, jug, vase, flowerpot, safe dish, or other like receptacle kept on the premises, and shall thoroughly dry and cleanse such receptacle before again filling it, so as to prevent it from serving as a breeding place or harbourage for mosquitoes.
- (2) The occupier of any premises shall not permit or allow to remain on the premises any tin, bottle, can, container, or other thing which by collecting rain water or other water or other liquid is likely to serve as a breeding place or harbourage for mosquitoes.
- (3) The occupier of any premises shall ensure that all open drains and channels on the premises are kept free from obstruction to prevent them holding water or other liquid that is likely to serve as a breeding place or harbourage for mosquitoes.

Maximum penalty—40 penalty units.

**73 Other measures to be taken by owners**

- (1) The owner of any premises shall—
- (a) ensure that every gutter, drain, roof, spouting, roof gutter, and other like channel is properly maintained and kept free from obstruction, so as to prevent water or other liquid remaining in it and serving as a breeding place or harbourage for mosquitoes;
  - (b) cut down and remove any vegetation or undergrowth that is likely to serve as a breeding place or harbourage for mosquitoes or to obstruct any gutter, drain or watercourse.

Maximum penalty—40 penalty units.

- (2) The owner of any premises shall, when so directed by a notice in writing given to the owner by an inspector—
- (a) cut back and trim to the extent specified in the notice any overhanging branches of trees, so as to prevent leaves or debris being deposited in any roof gutter, tank top or other place where the free flow of water or other liquid may be obstructed, whether upon the owner's own or any adjoining premises;
  - (b) take such other measures that are reasonably practicable and are specified in the notice, to prevent the premises or any part thereof serving as a breeding place or harbourage for mosquitoes.

**74 Local government premises**

The local government shall—

- (a) in respect of premises owned or occupied by it or under its management and control, take the measures prescribed by this division for owners and occupiers of premises;
- (b) in respect of roads, drains and sewers, including disused drains and sewers, take such measures that are reasonably practicable and are specified in a notice given to it by the chief executive, to prevent any road, drain or sewer or any part thereof serving as a breeding place or harbourage for mosquitoes.

## **Division 3                      Miscellaneous**

### **75            House-to-house visitation**

- (1) The local government may and when required by the chief executive by notice in writing shall undertake a house-to-house visitation within its area or part thereof and inspect all the premises therein.
- (2) The local government shall in respect of every such visitation and inspection which has been required by the chief executive furnish to the chief executive within the time specified by the chief executive a full report in writing—
  - (a) whether the provisions of this part are being complied with by the owners and occupiers of premises; and
  - (b) upon the action taken or proposed to be taken by the local government with respect to any premises which were ascertained to be or to be likely to be a breeding place or harbourage for mosquitoes.

### **76            Damaging drains, screens or covers**

A person who—

- (a) destroys, damages or obstructs any drain that has been constructed or installed on any premises for any purpose of this part;
- (b) destroys, damages or removes any screen or other protective covering affixed to any tank or other receptacle for any purpose of this part;

commits an offence.

Maximum penalty—40 penalty units.

### **77            Failing to fill in excavation**

A person who cuts turfs or removes soil or other material from any premises and who does not forthwith fill in the excavation with clean, sound material, finishing off level with the surface of the surrounding ground, commits an offence, unless written

permission to the contrary has been obtained from the local government.

Maximum penalty—40 penalty units.

## **78 Default of owner or occupier**

- (1) If the owner or occupier of any premises to whom a notice has been given under section 73(2) or 209 neglects to comply with such notice, or fails to comply therewith within the time specified therein, the chief executive or the local government may, whether or not that person has been proceeded against for an offence against this part, by the chief executive or local government or by the chief executive's or local government's contractor enter the premises to which the notice relates and do or cause to be done all such acts and things and perform or cause to be performed all such work as is necessary to comply with the requirements of the notice.
- (2) Any expenses incurred in so doing shall be paid to the chief executive or, as the case may be, to the local government by the owner or occupier concerned within the time specified by the chief executive or local government (being not less than 30 days) after the giving to that person of a notice in writing specifying the amount of such expenses incurred and giving reasonable particulars thereof.

## **Part 13 Prescribed substances standards and methods**

### **130 Definitions**

In this part—

*BS* means a British Standard published by the British Standards Institution.

*flat ware* means any plate (including soup or dessert plate), saucer, similar food receptacle or cooking utensil.

*hollow ware* means any cup, mug, jar, teapot, coffeepot or cooking utensil.

*metal* includes a compound of metal.

*prescribed substance* means a metal specified in section 132.

### **131 Adoption of Australian, British and other standards**

- (1) Prescribed methods of analysis of cooking utensils, food receptacles, toys, wallpaper or other decorative paper, paper serviettes, or paper used in the packaging, of food, hair and scalp preparations, articles and substances, for the presence of a prescribed substance shall be in accordance with and not inferior to the requirements of the relevant standard specification of the Standards Association of Australia.
- (1A) In the event of a relevant standard specification of the Standards Association of Australia not existing, the relevant standard specification of the British Standards Institution shall apply.
- (2) In the event of no relevant standard specification of the Standards Association of Australia or the British Standards Institution existing, the chief executive may determine a relevant standard specification which shall apply in subsection (1).
- (3) However, if a relevant standard specification is subsequently determined by either of the above 2 bodies the standards specification determined by the chief executive shall lapse.

### **132 Prescribed substances**

For part 4, division 3 of the Act, the following substances are prescribed substances—

- antimony
- arsenic
- barium
- cadmium
- chromium
- lead

- mercury
- selenium.

**133 Prescribed proportions**

For part 4, division 3 of the Act, the prescribed proportions of prescribed substances are specified in schedule 11.

**134 Prescribed methods of analysis**

For part 4, division 3 of the Act, the prescribed methods of analysis are specified in schedule 11.

**Part 15 Skin penetration****Division 1 Application, interpretation and administration of part****136 Application**

This part shall not apply in the case of—

- (a) medical practitioners in the conduct of their profession;
- (b) persons acting under the direction of medical practitioners given in the conduct of their profession;
- (c) dentists in the conduct of their profession;
- (d) persons acting under the direction of dentists given in the conduct of their profession;
- (e) podiatrists in the conduct of their profession;
- (f) physiotherapists in the conduct of their profession;
- (g) registered nurses in the conduct of their profession;
- (h) administering injections of a substance required as a treatment for a medical condition.



**137 Definitions**

(1) In this part—

**customer** means a person receiving or seeking or awaiting the provision of some skin penetration service at an establishment.

**dentist** means a person registered under the *Dental Practitioners Registration Act 2001*, other than a person registered as a dental auxiliary registrant.

**establishment** means a place or room within which skin penetration is or may be carried out commercially or for remuneration or for the public.

**operator** means a person who carries out skin penetration.

**physiotherapist** means a person registered under the *Physiotherapists Registration Act 2001*.

**podiatrist** means a person registered under the *Podiatrists Registration Act 2001*.

**proprietor** in relation to an establishment means the owner, occupier or other person who has the control or management of the carrying out of skin penetration at that establishment.

**skin penetration** means any process by which a person's skin is penetrated, including by acupuncture, but does not include skin penetration that is a personal appearance service to which the *Public Health (Infection Control for Personal Appearance Services) Act 2003* applies.

**waste receptacle** means a waste container within the meaning of the *Environmental Protection (Interim Waste) Regulation 1996*.

(2) For the purpose of this part, an appliance, implement, tool or thing used for skin penetration shall be deemed to be sterilised if it has been—

(a) cleansed of all visible matter by washing in cold water and then subjected to saturated steam under pressure in a steam steriliser at 134°C for not less than 3 minutes; or

(b) cleansed of all visible matter by washing in cold water and then heated in a hot air oven at a temperature of not less than 160°C for not less than 60 minutes; or

- (c) taken directly from a sealed container which bears a label affixed by the manufacturer stating that the contents thereof are sterile; or
- (d) subjected to another process that has been approved in writing by the chief executive.

### **138 Superintendence by local governments**

- (1) This part shall be in force within the areas of all local governments.
- (2) Each local government shall superintend and see to the execution of divisions 3 and 4 within its area and shall do and provide all such acts, matters and things as may be necessary for superintending or aiding in the execution thereof.

## **Division 3 Premises**

### **142 Use or conduct of premises**

A person shall not use an establishment or permit or cause an establishment to be used for the carrying out of skin penetration unless—

- (a) at least 1 basin for each 5 operator positions or part thereof is fitted within that establishment in accordance with the *Standard Plumbing and Drainage Regulation 2003*, so located as to be readily accessible to such operators, the water supply to each basin being controlled by arm or foot operated cocks; and
- (b) there is an adequate supply of hot and cold water to that establishment to carry out the particular process of skin penetration involved hygienically; and
- (c) there is at all times available in that establishment for the exclusive personal use of the operators an adequate supply of—
  - (i) soap or antibacterial cleansing agent of a type specified in schedule 12, part 1; and
  - (ii) nailbrushes; and

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- (iii) clean paper; and
- (iv) clean towels or other hand drying equipment which has been approved in writing by the chief executive;  
for the operators to remain clean; and
- (d) all walls, floors, ceilings, floor coverings, shelves, fittings, furniture, appliances, implements, tools and things that are situated or used in that establishment are maintained in good order and in a clean condition so that the particular process of skin penetration involved may be carried out hygienically; and
- (e) all surfaces within that establishment on which appliances, implements, tools or things are or may be placed are of a durable, smooth and impervious material free from cracks or crevices; and
- (f) there are within that establishment adequate vermin-proof cupboards, cabinets or similar fittings for the storage of all the clean towels, linen or other materials that may be required to carry out the particular process of skin penetration involved hygienically; and
- (g) there are within that establishment adequate waste receptacles for the storage of waste matter generated in the process of skin penetration carried out therein; and
- (h) there are within that establishment adequate receptacles—
  - (i) constructed of smooth, impervious material with close fitting lids; and
  - (ii) having painted thereon or affixed thereto in letters of not less than 100mm in height the words ‘SOILED LINEN’;for the reception of all soiled towels, cloths, linen and similar material; and
- (i) the contents of all receptacles for the reception of soiled linen are removed from the establishment daily and are not brought back into the establishment unless and until properly cleaned.

Maximum penalty—10 penalty units.

## **Division 4                      Sanitary provisions**

### **143      Operator to remain clean**

An operator whilst at an establishment shall—

- (a) at all times keep his or her clothing, hands, fingernails and body clean; and
- (b) thoroughly cleanse his or her hands by washing and brushing with soap or antibacterial cleansing agent of a type specified in schedule 12, part 1 and water and drying them with a clean towel or other hand drying equipment of a type approved in writing by the chief executive—
  - (i) immediately before commencing and immediately after completing a process of skin penetration;
  - (ii) immediately after visiting or using a sanitary convenience;
  - (iii) immediately after smoking;
  - (iv) immediately after using a handkerchief or nasal tissue;
  - (v) immediately after handling or touching soiled towels, linen or similar materials, biological matter or waste materials used or produced in connection with a process of skin penetration; and
- (c) at all times wear a clean coat over any other garment.

Maximum penalty—10 penalty units.

### **146      Cleansing surfaces etc.**

- (1) An operator shall immediately following service to a customer cause every bench, table or other article of equipment used in the carrying out of a process of skin penetration to be washed down with a solution specified in schedule 12, part 2.
- (2) An operator shall, before service to a customer, cause every bench, table or other article likely to be contaminated with biological matter or waste materials that may be generated in

the carrying out of skin penetration to be covered with a clean towel, clean cloth or a clean, unused paper towel or paper cover.

- (3) Whenever a paper towel or paper cover is used for the purposes of subsection (2), an operator shall cause such paper towel or paper cover to be disposed of in a waste receptacle immediately following the service to a customer and shall not use such paper towel or paper cover in the service of another customer.

Maximum penalty—10 penalty units.

#### **147 Disposal of soiled linen etc.**

An operator shall, immediately following service to a customer, cause—

- (a) all soiled towels, cloths, linen and similar materials generated in the carrying out of skin penetration on that customer to be placed in a receptacle for soiled linen; and
- (b) all biological matter or waste materials generated in the carrying out of skin penetration on that customer to be disposed of in a waste receptacle.

Maximum penalty—10 penalty units.

#### **148 Cleansing of skin, appliances etc.**

- (1) Before commencing to carry out skin penetration on a customer an operator shall cleanse the whole of the area of the skin to be treated with a sterile swab impregnated with a solution specified in schedule 12, part 3, which solution has been taken directly from the container in which it was supplied.
- (2) An operator shall cause every appliance, implement, tool and thing which is used or which comes into contact with the skin of a customer while a process of skin penetration is being carried out to be cleansed and sterilised and maintained free from contamination before—
- (a) any subsequent application to the customer if it has been touched by another person; or

(b) its first application to another customer.

Maximum penalty—10 penalty units.

#### **149 Sterilisation of electrical actuating appliances**

Where an electrical actuating appliance or instrument for projecting a needle or thing into the skin of a customer is used in the carrying out of a process of skin penetration the handpiece thereof shall be deemed to be sterilised if it is wiped with a clean paper towel or clean cloth soaked in methylated spirits or in 95% ethyl alcohol.

#### **151 Expectorating, keeping animals**

- (1) A person shall not expectorate in an establishment.
- (2) A person shall not keep or allow an animal to be in an establishment.

Maximum penalty—10 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 Association of Australia and New Zealand.

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

***therapeutic device*** means—

- (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;
  - (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;
  - (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—

- (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;
  - (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;
  - (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 1981*;
- (e) goods for animal use only;
- (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;
- (b) influencing, inhibiting or modifying a physiological process in any person;



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

*workplace amenity* see the *Workplace Health and Safety (Miscellaneous) Regulation 1995*, section 52.

## 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.<sup>1</sup>

## 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;

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1 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.

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- (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 Drugs 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 suncreening 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

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- 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

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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, unailing, 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.<sup>2</sup>
- (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 (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—

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<sup>2</sup> 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 *Trade Practices Act 1974* (Cwlth), section 65D.

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.

- (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.

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- (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.

- (11) Toilet soap is soap that complies with the Australian Standard Specification for Toilet Soap published by the Standards Association of Australia (AS 1877–1976).

- (12) Laundry soap or bar soap is soap that complies with the Australian Standard Specification for Laundry Tablet or Bar Soap published by the Standards Association of Australia (AS 1878–1976).
- (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;

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- (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 part 17; and
  - (b) is provided with sewerage and drainage in compliance with the requirements of the local government, in accordance with the *Sewerage and Water Supply Act 1949* or any other enactment relating to sewerage or drainage, maintained at all times in good and efficient working order; and
  - (c) if the occupier is an entity to whom section 53(1) of the *Workplace Health and Safety (Miscellaneous)*

*Regulation 1995* does not apply—has each workplace amenity stated in schedule 7 of that regulation.

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;

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- (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 the Australian Standard for Sunscreen Products—Evaluation and Classification (AS 2604–1993) as published by the Standards Association of Australia.
- (3) A person shall not sell a sunscreening preparation which does not comply with the above standard.

Maximum penalty—20 penalty units.

### **179 Sale, supply and use of certain therapeutic goods restricted**

- (1) A person must not sell, supply or use a reagent for testing for antibodies to the human immunodeficiency virus unless permitted under this section.

Maximum penalty—20 penalty units.

- (2) The reagent may be sold or supplied to a person who has the management and control of an approved hospital or laboratory.
- (3) The reagent may be used by a person in the course of the person's professional duties at an approved hospital or laboratory.
- (4) The chief executive may approve a hospital or laboratory in writing for the purposes of this section if the chief executive is satisfied the reagent will be used in a safe and correct manner.
- (5) The chief executive may impose conditions on the approval that the chief executive considers appropriate.

## Part 17 Vermin control

### Division 1 Preliminary

#### 180 Definitions

In this part—

***assembly place*** means a place designed, constructed, adapted or used for the assembly of persons for civic, political, educational, transit, religious, social, recreational, sporting, entertainment or amusement purposes or any purpose associated with those purposes.

***occupier***, of a place, includes, if there is no person in actual occupation of the place, a person entitled to possession of the place.

***permit*** means a permit issued under section 194E.

***refuse*** includes any thing which could be a source of food for vermin or encourage vermin to visit or frequent any place or afford or form or be likely to afford or form shelter or attraction for vermin.

***vermin*** means rats, mice, guinea pigs and other rodents capable of carrying or transmitting a notifiable disease, but does not include a protected animal within the meaning of the *Nature Conservation Act 1992*.

***vermin-proof material*** means any material that effectively prevents access by vermin.

#### 181 All vermin noxious

Vermin of all species are declared to be noxious.

#### 182 Local governments to superintend

- (1) This part is in force within the areas of all local governments.
- (2) Each local government must enforce this part and do and provide all acts, matters and things necessary for the enforcement of this part.

## **Division 2                    Measures to be adopted by owners and occupiers**

### **183    Buildings etc. to be vermin proofed**

The owner of any place must cause—

- (a) every floor, wall, partition, ceiling, roof and every ancillary fitting thereto of every building or other structure on such place to be so construed and maintained as to prevent the entry of vermin into such place; and
- (b) every hole or opening in every floor, wall, partition, ceiling or roof and in every ancillary fitting thereto of every building or other structure on such place, to be securely covered with a suitable vermin-proof material; and
- (c) every retaining wall, embankment, improvement or work of any kind or any formation, whether natural or artificial on such place, to be so constructed and maintained as not to afford or form or be likely to afford or form shelter or attraction for vermin.

Maximum penalty—40 penalty units.

### **184    Vegetation and other things not to provide shelter**

(1) The occupier of any place must not—

- (a) have or suffer or permit to remain on such place any vegetation which is growing in such a way as to afford or form or be likely to afford or form shelter or attraction for vermin; and
- (b) have or suffer or permit to remain on such place any thing which is in such condition or is kept or stored in such a way as to afford or form or be likely to afford or form shelter or attraction for vermin.

Maximum penalty—40 penalty units.

(2) A reference to vermin in this section does not include vermin permitted to be kept under division 3A.



**185 Drains etc. to be vermin proofed**

- (1) Every covered drain, sewer, pipe, covered conduit or covered channel within any place must be so trapped or otherwise protected by the owner as to prevent the ingress or egress of vermin.
- (2) Every disused covered drain, disused sewer, disused pipe, disused covered conduit or disused covered channel must be removed or blocked or otherwise dealt with by the owner so as to prevent the ingress or egress of vermin.

Maximum penalty—40 penalty units.

**186 Wharves to be vermin proofed**

The owner of any wharf, dock or slip, must cause such place and any retaining wall thereon to be constructed and maintained so as to prevent vermin from sheltering on or in the wharf, dock, slip or wall.

Maximum penalty—40 penalty units.

**187 Food and water not to be accessible to vermin**

- (1) The occupier of any place must cause—
  - (a) every thing on such place which is or may be a source of food for vermin, to be protected so as to effectively prevent access by vermin to such thing; and
  - (b) every supply or collection of water on such place to be protected as far as is practicable so as to effectively prevent access by vermin to such water.

Maximum penalty—40 penalty units.

- (2) A reference to vermin in this section does not include vermin permitted to be kept under division 3A.

**188 Storage of refuse, keeping of animals**

The occupier of any place must not—

- (a) have or suffer or permit to remain on such place any refuse unless such refuse is stored in accordance with the *Environmental Protection (Interim Waste)*

*Regulation 1996*, and in the case of an assembly place all refuse must be collected and so stored immediately at the conclusion of every assembly of persons at that place; or

- (b) have or keep or suffer or permit to remain or to keep on such place any bird or animal in such a way as to afford or form or be likely to afford or form shelter or attraction for vermin.

Maximum penalty—40 penalty units.

### **189 Notification of presence of vermin**

- (1) The occupier of any place must—
  - (a) notify in writing the relevant local government of the presence of vermin on such place immediately on becoming aware of its presence; and
  - (b) cause every thing which is infested with vermin to be treated in the manner directed by the local government.

Maximum penalty—40 penalty units.

- (2) A reference to vermin in this section does not include vermin permitted to be kept under division 3A.

### **190 Local government premises**

The local government must—

- (a) in respect of premises owned or occupied by it or under its management or control take the measures prescribed by this division for owners and occupiers of places; and
- (b) in respect of roads, drains and sewers, including disused drains and sewers within its area, take such measures as are reasonably practicable or as are required by notice given to it by the chief executive, to prevent any road, drain or sewer from serving as a shelter or attraction for vermin.

## **Division 3                      Destruction of vermin by local governments**

### **191      Local government to destroy vermin in the area**

- (1) The local government must—
  - (a) do all such acts, matters and things or cause to be done all such acts, matters and things as are necessary to destroy vermin in its area; and
  - (b) immediately investigate any notification that any place is infested with vermin, and do all such acts, matters and things or cause to be done all such acts, matters and things as are necessary to destroy any vermin at such place.
- (2) A reference to vermin in this section does not include vermin permitted to be kept under division 3A.

### **192      Vermin infested areas**

- (1) The chief executive may, if satisfied on the evidence available, that any place is infested with vermin, by notice in writing require the local government to do or cause to be done such acts, matters and things designed to destroy vermin in that place as are specified in that notice.
- (2) A reference to vermin in this section does not include vermin permitted to be kept under division 3A.

### **193      Unusual sickness or mortality in vermin**

If any unusual or suspicious sickness or any abnormal mortality rate occurs in vermin in any part of its area, the local government must immediately notify the medical officer of health, or if there is no medical officer of health, the chief executive, of the circumstances, and at the same time provide the fullest information available relating thereto.

**194 Local government to examine vermin specimens**

The local government must, when required by the chief executive by notice in writing—

- (a) cause such examinations as may be specified in the notice, to be made of all vermin destroyed by it or obtained by it and must provide within the time specified in the notice a full report in writing containing the results of such examinations; and
- (b) obtain and submit to the Centre for Public Health Sciences or such other laboratory as may be approved by the chief executive, such vermin specimens or specimens from vermin cadavers as may be specified in the notice, and mark those specimens with the particulars specified in the notice.

**Division 3A Keeping vermin****194A Prohibition from keeping vermin**

- (1) A person must not keep vermin other than under this division.  
Maximum penalty—40 penalty units.
- (2) A person may keep vermin, without a permit, under section 194D.
- (3) A person may keep rats, mice or guinea pigs—
  - (a) without a permit, under section 194C; or
  - (b) under a permit.

**194B Conditions under which vermin must be kept**

A person permitted to keep vermin under this division must keep them—

- (a) under hygienic conditions; and
- (b) in an enclosure from which they can not escape.

Maximum penalty—40 penalty units.

**194C Keeping up to 100 rats, mice or guinea pigs**

- (1) A person may keep up to 100 rats, mice or guinea pigs at a place.
- (2) However, if someone else also keeps rats, mice or guinea pigs at the place, the total number kept at the place must not be more than 100.
- (3) In this section—

*place* means a dwelling, shop or other separate premises.

**194D Keeping vermin at a laboratory**

A person may keep any number of vermin at a laboratory or a place ancillary to a laboratory for medical, research, scientific or teaching purposes pursued at the laboratory.

**Division 3B Permits****194E Keeping rats, mice or guinea pigs under a permit**

- (1) A person may keep rats, mice or guinea pigs at a place under a permit given under this section.
- (2) An application for a permit, or the renewal of a permit, must be made, in the approved form, to the local government in whose area the place is situated.
- (3) The local government must promptly consider the application and either grant or refuse to grant the application.
- (4) If the local government decides to grant the application, it must promptly issue a permit to the applicant.
- (5) A permit may be issued on reasonable conditions imposed by the local government.
- (6) If the local government refuses to grant the application or issues a permit on conditions, it must give the applicant written notice of its decision within 14 days after making it.
- (7) The notice must state—
  - (a) the decision; and

- (b) the reasons for the decision; and
  - (c) that the applicant may appeal against the decision to a Magistrates Court within 28 days after the applicant receives the notice.
- (8) If the local government fails to decide the application within 60 days after its receipt, the failure is taken to be a decision by the local government to refuse to grant the application.

### **194F Criteria for decisions about applications**

In deciding the application, the local government must consider the following criteria—

- (a) the security of the place where the rats, mice or guinea pigs are kept or intended to be kept;
- (b) the conditions under which the rats, mice or guinea pigs are kept or intended to be kept;
- (c) the design and construction of the enclosure in which the rats, mice or guinea pigs are kept or intended to be kept;
- (d) the existence of a management plan, addressing the following issues—
  - (i) identification and minimisation of potential risks to public health;
  - (ii) odour and noise;
  - (iii) security;
  - (iv) escape of rats, mice or guinea pigs;
  - (v) sanitation;
  - (vi) waste disposal;
  - (vii) pest control;
  - (viii) provision of food and water;
  - (ix) dealing with diseased rats, mice or guinea pigs;
  - (x) ventilation;
  - (xi) training of staff in disease management;
- (e) any other relevant issue.

## **Division 3C                      Suspension or cancellation of permits**

### **194G    Grounds for suspension or cancellation**

Each of the following is a ground for the suspension or cancellation of a permit—

- (a) the permit was obtained because of incorrect or misleading information;
- (b) the holder of the permit has contravened a condition of the permit;
- (c) the holder of the permit has been found guilty of an offence against this part.

### **194H    Procedure for suspension or cancellation**

- (1) If a local government believes a ground exists to suspend or cancel a permit (the *proposed action*), the local government must give the holder of the permit written notice—
  - (a) stating the proposed action; and
  - (b) stating the grounds for the proposed action; and
  - (c) outlining the facts and circumstances forming the basis for the local government's belief; and
  - (d) if the proposed action is suspension of the permit—
    - (i) stating the proposed suspension period; and
    - (ii) explaining the effect of suspension under this division; and
  - (e) inviting the holder to show in writing, within a stated reasonable time of at least 28 days, why the proposed action should not be taken.
- (2) If, after considering all written representations made within the stated time, the local government still considers a ground for the proposed action exists, the local government may—
  - (a) if the proposed action was to suspend the permit for a stated period—suspend the permit for no longer than the proposed suspension period; or

- (b) if the proposed action was to cancel the permit—either cancel the permit or suspend it for a period.
- (3) The local government must inform the holder of its decision by written notice.
- (4) The notice must be given within 10 days after the local government makes its decision.
- (5) If the local government decides to suspend or cancel the permit, the notice must state—
  - (a) the decision; and
  - (b) the reasons for the decision; and
  - (c) that the holder may appeal against the decision to a Magistrates Court within 28 days after the holder receives the notice.
- (6) The decision takes effect on the later of the following days—
  - (a) the day when the notice is given to the holder;
  - (b) the day of effect stated in the notice.
- (7) However, if the ground for the suspension or cancellation of the permit is that the holder has been found guilty of an offence against this part, the suspension or cancellation has no effect if the finding is quashed on appeal.
- (8) Also, subsections (1) to (7) do not apply if the holder agrees to the local government cancelling the permit.
- (9) The local government may cancel a permit under subsection (8) by written notice given to the holder.

#### **194I Procedure for immediate suspension**

- (1) This section applies if—
  - (a) the local government believes a ground exists to cancel or suspend a permit; and
  - (b) the local government considers the health of members of the public may be adversely affected if urgent action to suspend the permit is not taken.
- (2) The local government may immediately suspend the permit by written notice given to the holder of the permit.



- (3) The suspension takes effect immediately the notice is given to the holder.
- (4) The notice must state—
  - (a) that the permit is suspended; and
  - (b) the reasons for the suspension; and
  - (c) that the holder may appeal against the suspension to a Magistrates Court within 28 days after the holder receives the notice.
- (5) The local government must at the same time give the holder a notice under section 194H(1).
- (6) The suspension of the permit continues until the first to happen of the following—
  - (a) the local government cancels the suspension;
  - (b) the local government gives the holder notice of its decision under section 194H(3);
  - (c) the end of 60 days after the notice under subsection (2) was given to the holder.

## **Division 3D                      Amendment of permits**

### **194J Procedure for amendment**

- (1) The local government may amend a permit if—
  - (a) the holder of the permit agrees to the amendment; or
  - (b) the local government is reasonably satisfied the permit should be amended.
- (2) If the local government is reasonably satisfied the permit should be amended under subsection (1)(b), the local government must give the holder a written notice that—
  - (a) states the proposed amendment and the reasons for the amendment; and
  - (b) outlines the facts and circumstances forming the basis for the reasons; and

- (c) invites the holder to make written representations to the local government, within a stated reasonable time of at least 28 days, to show why the amendment should not be made.
- (3) If, after considering the representations properly made by the holder, the local government is still reasonably satisfied the permit should be amended in the way mentioned in the notice, or in another way having regard to the representations, the local government must—
- (a) issue a new permit to the holder; and
  - (b) give the holder a written notice that states—
    - (i) that the old permit has been cancelled; and
    - (ii) the way in which the new permit is different from the old permit; and
    - (iii) the reasons for the amendment; and
    - (iv) that the holder may appeal to a Magistrates Court against its decision within 28 days after the person receives the notice.
- (4) The new permit takes effect on the later of the following days—
- (a) the day when the notice is given to the holder;
  - (b) the day of effect stated in the notice.
- (5) In this section—
- amend*, a permit, means—
- (a) impose conditions on the permit; or
  - (b) vary any conditions of the permit.

## Division 3E Appeals

### 194K Decisions open to appeal

- (1) An applicant for a permit may appeal against a decision of a local government to—
- (a) refuse to grant the application; or

- (b) impose a condition on the permit under section 194E(5).
- (2) The holder of a permit may appeal against a decision of a local government to—
  - (a) cancel or suspend the permit; or
  - (b) amend the permit under section 194J(1)(b).

### **194L Starting an appeal**

- (1) A person starts an appeal by—
  - (a) filing a written notice of appeal with a Magistrates Court; and
  - (b) serving a copy of the notice on the local government.
- (2) The appeal may be made to a Magistrates Court nearest the place—
  - (a) where the person lives; or
  - (b) where the place the subject of the application or permit is situated.
- (3) However, subsection (2) does not limit the jurisdiction of another Magistrates Court to hear the appeal.
- (4) The notice of appeal must state fully the grounds of the appeal and the facts relied on.

### **194M Time for starting an appeal**

- (1) An appeal may be started at any time.
- (2) However, if written notice is given of a decision, and reasons for the decision are included in the notice, an appeal against the decision by a person to whom the notice was given must be started within 28 days after the person receives the notice.
- (3) A Magistrates Court may at any time extend the period for filing a notice of appeal.

### **194N Stay of operation of decisions**

- (1) The Magistrates Court may grant a stay of the operation of the decision to secure the effectiveness of the appeal.

- (2) A stay—
  - (a) may be granted on the conditions the court considers appropriate; and
  - (b) applies for the period the court states, but must not extend past the time when the court makes a decision on the appeal; and
  - (c) may be cancelled or amended by the court.

**194O Hearing procedures**

- (1) In deciding the appeal, the Magistrates Court—
  - (a) has the powers of the local government in relation to permits; and
  - (b) is not bound by the rules of evidence; and
  - (c) must comply with natural justice; and
  - (d) may hear the appeal in court or in chambers.
- (2) The appeal is by way of rehearing.

**194P Powers of court on appeal**

- (1) In deciding the appeal, the Magistrates Court may—
  - (a) confirm the decision; or
  - (b) set aside the decision and substitute another decision; or
  - (c) set aside the decision and return the issue to the local government with the directions the court considers appropriate.
- (2) If the Magistrates Court substitutes another decision, the substituted decision is, for this part (other than this division), taken to be that of the local government.

**194Q Appeal to District Court**

An appeal to the District Court may be made from a decision of a Magistrates Court under this division, but only on a question of law.

**Division 4                      Miscellaneous****195      House-to-house visits**

- (1) The local government may, and when required by the chief executive by notice in writing must, undertake house-to-house visits within its area or that part of its area specified in the notice, and inspect every place therein.
- (2) The local government must in respect of every such visitation and inspection which has been required by the chief executive, furnish to the chief executive within the time specified a full report in writing—
  - (a) as to whether the provisions of this part are being complied with by the owners and occupiers of such places; and
  - (b) upon action taken or proposed to be taken by the local government with respect to any places which were ascertained to afford or form or to be likely to afford or form shelter or attraction for vermin.

**196      Damaging vermin-proofing measures**

A person must not, without lawful reason, interfere with or damage or destroy any thing which has been constructed or installed or placed on any place for the purposes of this part.

Maximum penalty—40 penalty units.

**197      Local government to employ persons for purpose of this part**

The local government must, when required by the chief executive by notice in writing, employ at its expense such number of persons and provide such equipment, appliances and animals as may be specified in the notice for the purpose of this part.

**198 Food not to be thrown on roads**

A person must not throw, place, leave or have any thing in or upon any road or place so as to provide a potential source of food or sustenance for vermin.

Maximum penalty—40 penalty units.

**200 Default of owner or occupier**

- (1) If the owner or occupier of any place to whom a notice has been given under section 209 neglects to comply with such notice, or fails to comply within the time specified, the chief executive or the local government, whether or not that person has been proceeded against for an offence against this part and without prejudice to the commencement of such proceedings, may enter the place to which the notice relates and do or cause to be done all acts and things and perform or cause to be performed all work necessary to comply with the requirements of the notice.
- (2) Any expenses incurred under subsection (1) must be paid to the chief executive or, as the case may be, to the local government by the owner or occupier concerned within the time specified (being not less than 30 days) after the giving to that person of a notice in writing specifying the amount of such expenses incurred and giving reasonable particulars thereof.

**201 Default of local government**

If the local government makes default in carrying out or fails to do anything which by this part it is required to do, the chief executive may carry out and do such things, and in such case may recover all expenses so incurred from the local government in the manner provided by section 200.

## 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 1989*, section 2(1)
- a school that is provisionally accredited, or accredited, under the *Education (Accreditation of Non-State Schools) Act 2001*
- a grammar school, within the meaning of the *Grammar Schools Act 1975*.

### 205      **Institutions—Act, s 130B**

For section 130B of the Act, the following are institutions—

- Cairns Base Hospital
- Mackay Base Hospital
- Mental Health Building, Royal Brisbane Hospital
- Townsville General Hospital
- Wacol Rehabilitation Clinics, Wacol
- Wolston Park Hospital, Wacol.

### 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.

## **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 Regulation 1996*

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- 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<sup>3</sup> applies, but does not limit the subsection.
- (3) In this section—

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

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3      *Acts Interpretation Act 1954*, section 20 (Saving of operation of repealed Act etc.)

4      Part 2 (Camping grounds)

**Schedule 3      Fees**

section 210

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Analysis of a drug or article by an analyst by any of the following methods—

(a) chemical . . . . .	242.50
(b) physical . . . . .	242.50
(c) chemical and physical . . . . .	242.50
(d) microbiological . . . . .	242.50

## **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 Drugs and Poisons published by the Commonwealth;
  - (c) the register of medical practitioners, Queensland;
  - (d) the register kept under the *Dental Practitioners Registration Act 2001*, section 215;
  - (e) the roll of veterinary surgeons of Queensland.

**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 11 Prescribed methods of analysis and permissible levels of metal release

sections 133 and 134

**Table 1**

Column 1	Column 2	Column 3	Column 4	
Description of article	Liquid capacity	Method of analysis	cadmium mg/l	lead mg/l
cooking utensils (glazed ceramic ware)	—	method specified and described in paragraph 4 (other than subparagraph 4.1) of part 2 of BS 4860:1972	0.7	7.0
cooking utensils (other)	—	method specified and described in paragraph 4 (other than subparagraph 4.1) of part 2 of BS 4860:1972	0.7	7.0
food receptacle (glazed ceramic ware)				
(a) hollow ware	1100ml and above	method specified and described in paragraph 4 (other than subparagraph 4.1) of part 1 of BS 4860:1972	0.2	2.0
(b) hollow ware	below 1100ml		0.7	7.0
(c) flat ware	any		2.0	20.0
food receptacle (other)	—	method specified and described in paragraph 4 (other than subparagraph 4.1) of part 1 of BS 4860:1972	2.0	20.0

**Table 2**

Column 1	Column 2	Column 3
Description of article	Method of analysis	lead mg/kg
hair and scalp preparations	—	500
buildings (structural purposes)	—	10000
buildings (water conservation)	—	10000

## Schedule 11 (continued)

Table 3

Column 1	Column 2	Column 3							
Description of article	Method of analysis	antimony mg/kg	arsenic mg/kg	barium mg/kg	cadmium mg/kg	chromium mg/kg	lead mg/kg	mercury mg/kg	selenium mg/kg
toys:									
(a) consisting wholly or in part of a prescribed substance;		—	—	—	—	—	—	—	—
(b) consisting wholly or in part of any material containing more than a prescribed proportion or a prescribed substance;		—	—	—	—	—	2500	—	—
(c) consisting wholly or in part of any material yielding more than a prescribed amount of a prescribed substance	method specified and described in appendix A to AS 1647, part 3–1982	250	100	500	100	250	250	100	100

Table 4

Column 1	Column 2	Column 3		
Description of article	Method of analysis	arsenic mg/kg	lead mg/kg	cadmium mg/kg
serviettes, paper used in the enclosure of food	as described in appendix A to AS 1647	10	500	50
wallpaper and other decorative paper	—	1000	5000	1000

## Schedule 11 (continued)

**Table 5**

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	
<b>Description of article</b>	<b>Method of analysis</b>	<b>arsenic mg/kg</b>	<b>lead mg/kg</b>
wearing apparel (textile)	—	10	500



## **Schedule 12      Cleansers**

sections 142(c), 143(b), 145(5), 146(1), 148(1), 150(1) and 152

### **Part 1                      Antibacterial cleansing agents**

chlorhexidine gluconate 4%, foaming detergent

chlorhexidine gluconate 0.5%, aqueous

chlorhexidine gluconate 0.5%, in ethyl alcohol 95%, with glycerol 1%

chlorhexidine gluconate 0.5%, in isopropyl alcohol 70%

hexachlorophane 3%, antibacterial cleansing agent

### **Part 2                      Disinfecting solutions for surfaces etc.**

alcohol, ethyl 70%

alcohol, isopropyl 70%

hospital grade disinfectant

sodium hypochlorite 1%

### **Part 3                      Disinfecting solutions for tattooing equipment etc.**

alcohol, ethyl 70%

alcohol, isopropyl 70%

cetrimide and chlorhexidine paint APF

**Schedule 12 (continued)**

chlorhexidine gluconate 0.5%, in ethyl alcohol 70%

chlorhexidine gluconate 0.5%, in isopropyl alcohol 70%

povidone-iodine 10%, in ethyl alcohol 70%

## 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

## Schedule 13 (continued)

<b>Name of closure</b>	<b>Australian registered trade mark</b>	<b>Australian patent number</b>	<b>Approved sizes</b>	<b>Australian distributor</b>	<b>Australian manufacturer</b>
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

## Schedule 13 (continued)

**Part 2****Reclosable container**

<b>Name of container</b>	<b>Australian registered trade mark</b>	<b>Australian patent number</b>	<b>Approved sizes</b>	<b>Australian distributor</b>	<b>Australian manufacturer</b>
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
bucizine	diphenidol	pyroxamine
carbinoxamine	diphenylpyraline	pyrrobutamine
cetoxime	doxylamine	rotoxamine
chlorcyclizine	embramine	thalidine
chloropyrilene	halopyramine	thenyldiamine
chlorpheniramine	histapyrrodine	thiazinamium
chlorphenoxamine	homochlorcyclizine	thonzylamine
cinnarizine	hydroxyzine	tolpropamine
clemastine	isothipendyl	trimeprazine
clemizole	mebhydrolin	trimethobenzamide
cycliramine	meclozine	tripeleppamine
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

## Schedule 14 (continued)

- |  |            |             |               |
|--|------------|-------------|---------------|
|  | 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   |
| bretylum     | 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

## Schedule 14 (continued)

**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



## Endnotes

### 1 Index to endnotes

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### 2 Date to which amendments incorporated

This is the reprint date mentioned in the Reprints Act 1992, section 5(c). Accordingly, this reprint includes all amendments that commenced operation on or before 1 August 2006. Future amendments of the Health Regulation 1996 may be made in accordance with this reprint under the Reprints Act 1992, section 49.

**Note—This new regulation includes provisions relocated from several older regulations (see list of legislation). The list of annotations does not include information about the history of any provision before its relocation to the Health Regulation 1996.**

### 3 Key

#### Key to abbreviations in list of legislation and annotations

Key	Explanation	Key	Explanation
AIA	= Acts Interpretation Act 1954	(prev)	= previously
amd	= amended	proc	= proclamation
amdt	= amendment	prov	= provision
ch	= chapter	pt	= part
def	= definition	pubd	= published
div	= division	R[X]	= Reprint No.[X]
exp	= expires/expired	RA	= Reprints Act 1992
gaz	= gazette	reloc	= relocated
hdg	= heading	renum	= renumbered
ins	= inserted	rep	= repealed
lap	= lapsed	(retro)	= retrospectively
notfd	= notified	rv	= revised edition
o in c	= order in council	s	= section
om	= omitted	sch	= schedule
orig	= original	sdiv	= subdivision
p	= page	SIA	= Statutory Instruments Act 1992
para	= paragraph	SIR	= Statutory Instruments Regulation 2002
prec	= preceding	SL	= subordinate legislation
pres	= present	sub	= substituted
prev	= previous	unnum	= unnumbered

### 4 Table of reprints

Reprints are issued for both future and past effective dates. For the most up-to-date table of reprints, see the reprint with the latest effective date.

If a reprint number includes a letter of the alphabet, the reprint was released in unauthorised, electronic form only.

Reprint No.	Amendments to	Effective	Reprint date
1	1996 SL No. 121	7 June 1996	8 July 1996
1A	1996 SL No. 415	20 December 1996	9 April 1997
2	1998 SL No. 74	9 April 1998	1 May 1998
2A	1998 SL No. 246	4 September 1998	7 September 1998
2B	1998 SL No. 343	21 December 1998	12 January 1999
2C	1999 SL No. 4	8 February 1999	8 February 1999
2D	1999 SL No. 13	5 March 1999	9 March 1999
2E	1999 SL No. 174	30 July 1999	2 November 1999
2F	1999 SL No. 257	30 July 1999	29 November 1999
2G	1999 SL No. 330	1 January 2000	11 January 2000
3	1999 SL No. 330	1 January 2000	2 March 2000
3A	2000 SL No. 80	5 May 2000	19 May 2000
3B	2000 SL No. 148	1 July 2000	25 July 2000
3C	2000 SL No. 295	30 November 2000	14 December 2000
3D	2001 SL No. 67	8 June 2001	22 June 2001
3E	2001 Act No. 103	1 January 2002	15 January 2002
3F	2001 Act No. 103	1 February 2002	8 February 2002

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Reprint No.	Amendments to	Effective	Reprint date
3G	2002 SL No. 20	15 February 2002	22 February 2002
3H	2002 SL No. 80	1 May 2002	6 May 2002
3I	2002 SL No. 80	1 May 2002	17 May 2002
3J	2002 SL No. 156	28 June 2002	28 June 2002

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Reprint No.	Amendments included	Effective	Notes
3K	2002 SL No. 156	1 July 2002	
3L	2002 SL No. 195	9 August 2002	R3L withdrawn, see R4
4	—	9 August 2002	
4A	2003 SL No. 79	1 May 2003	
4B	2003 SL No. 130	1 July 2003	
4C	2001 Act No. 103	20 September 2003	
4D	2004 SL No. 34	8 April 2004	
4E	2003 Act No. 81 2004 SL No. 27	1 July 2004	
4F	2004 SL No. 154	18 August 2004	
4G	2005 SL No. 170	29 July 2005	
5	2005 SL No. 192	31 August 2005	
5A	2005 SL No. 247	7 October 2005	
5B	2005 SL No. 281	1 December 2005	
5C	2006 SL No. 190	1 August 2006	

## 5 Tables in earlier reprints

Name of table	Reprint No.
Changed citations and remade laws	1
Changed names and titles	1
Corrected minor errors	1, 2, 3, 5
Renumbered provisions	1

## 6 List of legislation

### Health Regulation 1996 SL No. 121

made by the Governor in Council on 6 June 1996

notfd gaz 7 June 1996 pp 902–5

commenced on date of notification

exp 1 September 2006 (see SIA s 54)

Note—The expiry date may have changed since this reprint was published. See the latest reprint of the SIR for any change.

**list of legislation to Camping Ground Regulation 1987—before relocation of ss 4–17 to Health Regulation 1996 SL No. 121 as pt 2 ss 2–15 (see 1996 SL No. 121 s 226)**

**Camping Ground Regulation 1987**

pubd gaz 6 June 1987 pp 921–30  
commenced on date of publication

amending legislation—

**regulation published gazette (pre SL series)—**

18 May 1991 pp 275–6  
commenced on date of publication

**Health Regulation 1996 SL No. 121 pts 1, 19 div 1, sch 15**

notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Health (Dispensary) Regulation 1993—before relocation of divs 1–4, schs 1–2 to Health Regulation 1996 SL No. 121 as pt 4 divs 1–4, schs 4, 5 (see 1996 SL No. 121 s 246)**

**Health (Dispensary) Regulation 1993 SL No. 509**

notfd gaz 17 December 1993 pp 1812–21  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 January 1994 (see s 2)

amending legislation—

**Health Regulation 1996 SL No. 121 pts 1, 19 div 2**

notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Hairdressers Regulation 1989—before relocation of divs 1–6, sch 2 to Health Regulation 1996 SL No. 121 as pt 5 divs 1–6, sch 6 (see 1996 SL No. 121 s 278)**

**Hairdressers Regulation 1989**

pubd gaz 28 January 1989 pp 537–54  
commenced on date of publication

amending legislation—

**Health Regulation 1996 SL No. 121 pts 1, 19 div 3**

notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Hyperbaric Chamber Therapy Regulation 1989—before relocation of ss 3–5 to Health Regulation 1996 SL No. 121 as pt 6 ss 60–62 (see 1996 SL No. 121 s 283)**

**Hyperbaric Chamber Therapy Regulation 1989**

pubd gaz 14 October 1989 pp 1169–70  
commenced on date of publication (see s 2)

amending legislation—

**Health Regulation 1996 SL No. 121 pts 1, 19 div 4**

notfd gaz 7 June 1996 pp 902–5  
 commenced on date of notification

**list of legislation to Mosquito Prevention and Destruction Regulation 1982—before relocation of divs 1–3 to Health Regulation 1996 SL No. 121 as pt 8 divs 1–3 (see 1996 SL No. 121 s 303)**

**Mosquito Prevention and Destruction Regulation 1982**

pubd gaz 2 October 1982 pp 487–9  
 commenced on date of publication  
 exempted from application of Regulatory Reform Act 1986 by o in c pubd gaz 6 May 1989 pp 208–9

amending legislation—

**regulation published gazette (pre SL series)—**

20 April 1991 pp 2570–1  
 commenced on date of publication

**Health Regulation 1996 SL No. 121 pts 1, 19 div 5**

notfd gaz 7 June 1996 pp 902–5  
 commenced on date of notification

**list of legislation to Health (Pest Control Operators) Regulation 1977—before relocation of ss 3–12 to Health Regulation 1996 SL No. 121 as pt 10 ss 82–90 (see 1996 SL No. 121 s 308)**

**Health (Pest Control Operators) Regulation 1977 (prev Pest Control Operators Regulation 1977 (see 1994 SL No. 213 s 21))**

pubd gaz 16 July 1977 p 1544  
 commenced 1 October 1977 (see s 1)  
 exempted from application of Regulatory Reform Act 1986 by o in c pubd gaz 6 May 1989 pp 108–9

amending legislation—

**regulations published gazette (pre SL series)—**

23 December 1978 p 1990  
 commenced on date of publication

25 August 1979 p 2187  
 commenced on date of publication

10 November 1979 p 1097  
 commenced on date of publication

1 November 1980 p 1056  
 commenced on date of publication

3 October 1981 p 472  
 commenced on date of publication

27 November 1982 p 1560  
 commenced on date of publication

19 November 1983 p 1245  
commenced on date of publication

22 September 1984 p 417  
commenced on date of publication

9 November 1985 p 1316  
commenced on date of publication

9 August 1986 p 2507  
commenced on date of publication

26 September 1987 p 337  
commenced on date of publication

22 October 1988 p 853  
commenced on date of publication

23 September 1989 p 750  
commenced on date of publication

15 September 1990 p 281  
commenced on date of publication

**Department of Health (Variation of Fees) Regulation (No. 2) 1991 SL No. 147 pts 1, 4**  
pubd gaz 30 November 1991 pp 1644–55  
commenced on date of publication

**Pest Control Operators Amendment Regulation (No. 1) 1994 SL No. 106**  
notfd gaz 25 March 1994 pp 1228–32  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 1994 SL No. 213 pts 1, 6**  
notfd gaz 24 June 1994 pp 1058–61  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 July 1994 (see s 2(1))

**Health Regulation 1996 SL No. 121 pts 1, 19 div 6, sch 16**  
notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Hazardous Substances (Placarding) Regulation 1988—before relocation of divs 1–5, schs 1–4 to Health Regulation 1996 SL No. 121 as pt 11 divs 1–5, schs 7–10 (see 1996 SL No. 121 s 328)**

**Hazardous Substances (Placarding) Regulation 1988**  
pubd gaz 13 August 1988 pp 3381–90  
commenced on date of publication  
amending legislation—

**regulation published gazette (pre SL series)—**  
21 January 1989 pp 318–19  
commenced on date of publication

**Health Regulation 1996 SL No. 121 pts 1, 19 div 7**

notfd gaz 7 June 1996 pp 902–5  
 commenced on date of notification

**list of legislation to Health (Poisons—Fumigation) Regulation 1973—before relocation of ss 3–33 to Health Regulation 1996 SL No. 121 as pt 12 ss 99–129 (see 1996 SL No. 121 s 339)**

**Health (Poisons—Fumigation) Regulation 1973 (prev Poisons Fumigation Regulation 1973 (see 1994 SL No. 213 s 37))**

pubd gaz 1 September 1973 pp 19–26  
 commenced on date of publication (see s 1)  
 exempted from application of Regulatory Reform Act 1986 by o in c pubd gaz 18 June 1988 p 1433

amending legislation—

**regulations published gazette (pre SL series)—**

12 January 1974 p 133  
 commenced on date of publication

10 August 1974 p 2029  
 commenced on date of publication

3 September 1977 p 56  
 commenced on date of publication

8 July 1978 p 1209  
 commenced on date of publication

10 November 1979 p 1097  
 commenced on date of publication

1 November 1980 p 1056  
 commenced on date of publication

25 July 1981 pp 2089–90  
 commenced on date of publication

31 October 1981 p 961  
 commenced on date of publication

19 November 1983 p 1246  
 commenced on date of publication

7 July 1984 p 1630  
 commenced on date of publication

22 September 1984 p 416  
 commenced on date of publication

9 November 1985 p 1313  
 commenced on date of publication

9 August 1986 p 2503  
 commenced on date of publication

26 September 1987 p 335  
commenced on date of publication

22 October 1988 p 850  
commenced on date of publication

23 September 1989 p 751  
commenced on date of publication

15 September 1990 p 284  
commenced on date of publication

**Department of Health (Variation of Fees) Regulation (No. 2) 1991 SL No. 147 pts 1, 5**  
pubd gaz 30 November 1991 pp 1644–55  
commenced on date of publication

**Poisons (Fumigation) Amendment Regulation (No. 1) 1994 SL No. 108**  
notfd gaz 25 March 1994 pp 1228–32  
commenced on date of notification

**Poisons (Fumigation) Amendment Regulation (No. 2) 1994 SL No. 197**  
notfd gaz 10 June 1994 pp 896–8  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 1994 SL No. 213 pts 1, 8**  
notfd gaz 24 June 1994 pp 1058–61  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 July 1994 (see s 2(1))

**Health Regulation 1996 SL No. 121 pts 1, 19 div 8, sch 17**  
notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Prescribed Substances Standards and Methods Regulation 1987—before relocation of ss 2–6, sch 2 to Health Regulation 1996 SL No. 121 as pt 13 ss 130–134, sch 11 (see 1996 SL No. 121 s 346)**

**Prescribed Substances Standards and Methods Regulation 1987**  
pubd gaz 19 December 1987 pp 1716–19  
commenced on date of publication  
amending legislation—

**Health Regulation 1996 SL No. 121 pts 1, 19 div 9**  
notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Skin Penetration Regulation 1987—before relocation of divs 1–5, sch 3 to Health Regulation 1996 SL No. 121 as pt 15 divs 1–5, sch 12 (see 1996 SL No. 121 s 372)**

**Skin Penetration Regulation 1987**  
pubd gaz 24 January 1987 pp 269–81  
commenced on date of publication  
amending legislation—



**regulation published gazette (pre SL series)—**

4 July 1987 pp 2574–5  
commenced on date of publication

**Skin Penetration Amendment Regulation 1992 SL No. 50**

pubd gaz 13 March 1992 pp 1491–3  
commenced on date of publication

**Health Regulation 1996 SL No. 121 pts 1, 19 div 10**

notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Therapeutic Goods and Other Drugs Regulation 1982—before relocation of ss 2–25A, schs 1–2 to Health Regulation 1996 SL No. 121 as pt 16 ss 153–179, schs 13, 14 (see 1996 SL No. 121 s 391)**

**Therapeutic Goods and Other Drugs Regulation 1982**

pubd gaz 26 June 1982 pp 1645–66  
commenced 1 July 1982 (see s 1)

amending legislation—

**regulations published gazette (pre SL series)—**

1 February 1986 pp 404–5  
commenced on date of publication

6 December 1986 pp 2020–1  
commenced 1 July 1987 and 1 September 1987 (see s 2)

6 June 1987 p 997  
commenced on date of publication

2 April 1988 p 2012  
commenced on date of publication

21 May 1988 p 576  
commenced on date of publication

8 October 1988 p 684  
commenced on date of publication

**Therapeutic Goods and Other Drugs (Amendment) Regulation 1991 SL No. 24**

pubd gaz 13 July 1991 pp 1584–5  
commenced on date of notification

**Therapeutic Goods and other Drugs Amendment Regulation (No. 1) 1994 SL No. 15**

notfd gaz 28 January 1994 pp 229–31  
commenced on date of notification

**Therapeutic Goods and Other Drugs Amendment Regulation (No. 1) 1995 SL No. 266**

notfd gaz 15 September 1995 pp 317–18  
commenced on date of notification

**Health Regulation 1996 SL No. 121 pts 1, 19 div 11**

notfd gaz 7 June 1996 pp 902–5  
commenced on date of notification

**list of legislation to Vermin Control Regulation 1991—before relocation of divs 1–4 to Health Regulation 1996 SL No. 121 as pt 17 divs 1–4 (see 1996 SL No. 121 s 419)**

**Vermin Control Regulation 1991**

pubd gaz 2 February 1991 pp 413–19

commenced on date of publication

amending legislation—

**Health Regulation 1996 SL No. 121 pts 1, 19 div 12**

notfd gaz 7 June 1996 pp 902–5

commenced on date of notification

**amending legislation to Health Regulation 1996 SL No. 121—after relocation of Camping Ground Regulation 1987 ss 4–17, Health (Dispensary) Regulation 1993 SL No. 509 divs 1–4, sch 1–2, Hairdressers Regulation 1989 divs 1–6, sch 2, Hazardous Substances (Placarding) Regulation 1988 divs 1–5, schs 1–4, Health (Pest Control Operators) Regulation 1977 ss 3–12, Health (Poisons—Fumigation) Regulation 1973 ss 3–33, Hyperbaric Chamber Therapy Regulation 1989 ss 3–5, Mosquito Prevention and Destruction Regulation 1982 divs 1–3, Prescribed Substances Standards and Methods Regulation 1987 ss 2–6, sch 2, Skin Penetration Regulation 1987 divs 1–5, sch 3, Therapeutic Goods and Other Drugs Regulation 1982 ss 2–25A, schs 1–2, Vermin Control Regulation 1991 divs 1–4**

**Health Amendment Regulation (No. 1) 1996 SL No. 415**

notfd gaz 20 December 1996 pp 1588–98

commenced on date of notification

**Health Amendment Regulation (No. 1) 1998 SL No. 48**

notfd gaz 27 March 1998 pp 1310–12

commenced on date of publication

**Health Amendment Regulation (No. 2) 1998 SL No. 74**

notfd gaz 9 April 1998 pp 1530–2

commenced on date of notification

**Health Amendment Regulation (No. 3) 1998 SL No. 246**

notfd gaz 4 September 1998 pp 68–9

commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 1998 SL No. 343 pts 1, 6**

notfd gaz 18 December 1998 pp 1551–7

ss 1–2 commenced on date of notification

remaining provisions commenced 21 December 1998 (see s 2)

**Health Amendment Regulation (No. 1) 1999 SL No. 4**

notfd gaz 5 February 1999 pp 393–4

ss 1, 3 commenced on date of notification

remaining provisions commenced 8 February 1999 (see s 3)

**Health Amendment Regulation (No. 2) 1999 SL No. 13**

notfd gaz 5 March 1999 pp 950–3

commenced on date of notification

**Health Amendment Regulation (No. 3) 1999 SL No. 154**

notfd gaz 2 July 1999 pp 1223–4  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 1999 SL No. 174 pts 1, 3**

notfd gaz 30 July 1999 pp 1905–6  
commenced on date of notification

**Health Amendment Regulation (No. 4) 1999 SL No. 257**

notfd gaz 5 November 1999 pp 918–21  
ss 1–2 commenced on date of notification  
remaining provisions commenced 31 December 1999 (see s 2)

**Radiation Safety Regulation 1999 SL No. 330 ss 1–2, pt 11**

notfd gaz 17 December 1999 pp 1586–9  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 January 2000 (see s 2)  
Note—A regulatory impact statement and explanatory note were prepared

**Health Amendment Regulation (No. 1) 2000 SL No. 80**

notfd gaz 5 May 2000 pp 65–66  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 2000 SL No. 148 pts 1, 3**

notfd gaz 30 June 2000 pp 736–48  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 July 2000 (see s 2)

**Private Health Facilities Regulation 2000 SL No. 295 ss 1–2, 11**

notfd gaz 24 November 2000 pp 1188–9  
ss 1–2 commenced on date of notification  
remaining provisions commenced 30 November 2000 (see s 2)  
Note—A regulatory impact statement and explanatory note were prepared

**Dangerous Goods Safety Management Act 2001 No. 28 ss 1–2, 189(1) sch 1**

date of assent 25 May 2001  
ss 1–2 commenced on date of assent  
remaining provisions commenced 7 May 2002 (2002 SL No. 86)

**Health Amendment Regulation (No. 1) 2001 SL No. 67**

notfd gaz 8 June 2001 pp 516–17  
commenced on date of notification

**Education (Accreditation of Non-State Schools) Regulation 2001 SL No. 211 ss 1–2, 23**

notfd gaz 23 November 2001 pp 1088–91  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 January 2002 (see s 2)

**Dental Practitioners Registration Regulation 2001 SL No. 264 ss 1–2, 17 sch 5**

notfd gaz 14 December 2001 pp 1351–4  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 January 2002 (see s 2)

**Pharmacists Registration Regulation 2001 SL No. 267 ss 1–2, 14 sch 4**

notfd gaz 14 December 2001 pp 1351–4  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 February 2002 (see s 2)

**Physiotherapists Registration Regulation 2001 SL No. 268 ss 1–2, 10 sch 3**

notfd gaz 14 December 2001 pp 1351–4  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 February 2002 (see s 2)

**Pest Management Act 2001 No. 103 ss 1–2, 145 sch 2**

date of assent 19 December 2001  
ss 1–2 commenced on date of assent  
remaining provisions commenced 20 September 2003 (automatic commencement under AIA s 15DA(2) (2002 SL No. 345 s 2))

**Health Legislation Amendment Regulation (No. 1) 2002 SL No. 20 pts 1, 4**

notfd gaz 15 February 2002 pp 618–19  
commenced on date of notification

**Podiatrists Registration Regulation 2002 SL No. 80 ss 1–2, 10 sch 3**

notfd gaz 26 April 2002 pp 1540–3  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 May 2002 (see s 2)

**Health Legislation Amendment Regulation (No. 2) 2002 SL No. 156 pts 1, 4**

notfd gaz 28 June 2002 pp 876–83  
s 19 commenced 1 July 2002 (see s 2)  
remaining provisions commenced on date of notification

**Health Amendment Regulation (No. 1) 2002 SL No. 195**

notfd gaz 9 August 2002 pp 1362–3  
commenced on date of notification

**Health Amendment Regulation (No. 1) 2003 SL No. 79**

notfd gaz 1 May 2003 pp 1–2  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 1) 2003 SL No. 130 pts 1, 4**

notfd gaz 27 June 2003 pp 749–56  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 July 2003 (see s 2)

**Public Health (Infection Control for Personal Appearance Services) Act 2003 No. 81 ss 1–2, 162 sch 1**

date of assent 6 November 2003  
ss 1–2 commenced on date of assent  
remaining provisions commenced 1 July 2004 (2003 SL No. 351)

**Dental Practitioners Registration and Other Legislation Amendment Regulation (No. 1) 2004 SL No. 27 ss 1–2, 3(2), sch**

notfd gaz 2 April 2004 pp 1315–16  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 July 2004 (see s 2)

**Health Legislation Amendment Regulation (No. 1) 2004 SL No. 34 pts 1, 5**

notfd gaz 8 April 2004 pp 1391–3  
commenced on date of notification

**Health Legislation Amendment Regulation (No. 3) 2004 SL No. 154 ss 1–2(1), pt 4**

notfd gaz 13 August 2004 pp 1165–7  
ss 1–2 commenced on date of notification  
remaining provisions commenced 18 August 2004 (see s 2(1))

**Health Legislation Amendment Regulation (No. 4) 2005 SL No. 170 s 1, pt 4**

notfd gaz 29 July 2005 pp 1146–8  
commenced on date of notification

**Health Amendment Regulation (No. 1) 2005 SL No. 192**

notfd gaz 12 August 2005 pp 1297–1303  
ss 1–2 commenced on date of notification  
remaining provisions commenced 31 August 2005 (see s 2, 2004 No. 36 s 66 and 2005 SL No. 62)

**Health Legislation Amendment Regulation (No. 6) 2005 SL No. 247 pts 1, 4**

notfd gaz 7 October 2005 pp 507–9  
commenced on date of notification

**Public Health Regulation 2005 SL No. 281 ss 1–2(1), pt 8**

notfd gaz 25 November 2005 pp 1132–3  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 December 2005 (see s 2(1))

**Health Legislation Amendment Regulation (No. 6) 2006 SL No. 190 ss 1, 2(1), pt 4**

notfd gaz 28 July 2006 pp 1480–2  
ss 1–2 commenced on date of notification  
remaining provisions commenced 1 August 2006 (see s 2(1))

## **7 List of annotations**

**PART 2—CAMPING GROUNDS**

**pt 2 (ss 2–15)** om 1999 SL No. 257 s 4

**PART 3—CANCER REGISTRATION**

**pt hdg** om 2005 SL No. 281 s 21

**Definition for part**

**s 16** om 2000 SL No. 295 s 11(2)

**Class of patient or resident—Act, s 100C(1)**

**s 17** sub 1998 SL No. 343 s 16  
amd 2000 SL No. 295 s 11(3)  
om 2005 SL No. 281 s 21

**Time for giving return—Act, s 100C(1)**

**s 18** amd 1998 SL No. 343 s 17; 2000 SL No. 295 ss 11(3)–(4)  
om 2005 SL No. 281 s 21

**Person required to complete return—Act, s 100C(1)**

**s 19** amd 1998 SL No. 343 s 18; 2000 SL No. 295 ss 11(4)  
om 2005 SL No. 281 s 21

**Classes of cancer—Act, s 100C(2)**

**s 20** om 2005 SL No. 281 s 21

**Time for giving return—Act, s 100C(2) and (3)**

**s 21** amd 2002 SL No. 156 s 10  
om 2005 SL No. 281 s 21

**Person prescribed as contractor—Act, s 100DA(1)**

**s 21A** ins 1998 SL No. 343 s 19  
om 2005 SL No. 281 s 21

**Time for giving further information—Act, s 100DC(3)(a)**

**s 21B** ins 1998 SL No. 343 s 19  
om 2005 SL No. 281 s 21

**Disclosure of information from register—Act, s 100E(3)(e)**

**s 21BA** ins 1999 SL No. 174 s 5  
om 2005 SL No. 281 s 21

**PART 3A—PAP SMEAR REGISTER**

**pt 3A (s 21C)** ins 1999 SL No. 4 s 4  
om 2005 SL No. 281 s 21

**Definitions**

**s 22** def “**Australian Standard**” om 2002 SL No. 156 s 11  
def “**Standard for the Uniform Scheduling of Drugs and Poisons**” om  
2002 SL No. 156 s 11

**PART 5—HAIRDRESSERS**

**pt hdg** om 2003 No. 81 s 162 sch 1

**Division 1—Administration of part and interpretation**

**div 1 (ss 35–36)** om 2003 No. 81 s 162 sch 1

**Division 2—Licences**

**div 2 (ss 37–46)** om 2003 No. 81 s 162 sch 1

**Division 3—Licensed premises**

**div 3 (ss 47–48)** om 2003 No. 81 s 162 sch 1

**Division 4—Sanitary provisions**

**div 4 (ss 49–57)** om 2003 No. 81 s 162 sch 1

**Division 5—Disinfection of appliances etc.**

**div 5 (s 58)** om 2003 No. 81 s 162 sch 1

**Division 6—Miscellaneous**

**div 6 (s 59)** om 2003 No. 81 s 162 sch 1

**PART 6—HYPERBARIC CHAMBER THERAPY**

**pt hdg** om 2001 SL No. 67 s 3

**Definitions**

s 60 om 2001 SL No. 67 s 3

**Application**

s 61 amd 1998 SL No. 343 s 20  
om 2001 SL No. 67 s 3

**Hyperbaric oxygen therapy prohibited**

s 62 om 2001 SL No. 67 s 3

**Authorised persons—Act, s 76K(1)**

s 63 om 2005 SL No. 192 s 4

**Further notification of maltreatment—Act, s 76K(3)**

s 64 om 2002 SL No. 156 s 12

**Definitions**

s 66 def “approved” amd 1998 SL No. 343 s 20

**Other measures to be taken by owners**

s 73 amd 1998 SL No. 246 s 3

**Local government premises**

s 74 amd 1998 SL No. 343 s 20

**House-to-house visitation**

s 75 amd 1998 SL No. 343 s 20

**Default of owner or occupier**

s 78 amd 1998 SL No. 246 s 4; 1998 SL No. 343 ss 20, 22

**PART 9—PERINATAL STATISTICS**

pt hdg om 2005 SL No. 281 s 21

**Prescribed class of child**

s 79 om 2005 SL No. 281 s 21

**Returns**

s 80 amd 1998 SL No. 343 ss 20, 21  
om 2005 SL No. 281 s 21

**Inadequate returns**

s 81 amd 1998 SL No. 343 s 20  
om 2005 SL No. 281 s 21

**PART 10—PEST CONTROL OPERATORS**

pt hdg om 2001 Act No. 103 s 145 sch 2

**Application for a licence**

s 82 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Application for renewal of a licence**

s 83 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Production of licence**

s 84 om 2001 Act No. 103 s 145 sch 2

**Storage of pesticide**

s 85 om 2001 Act No. 103 s 145 sch 2

**Key to pesticide storage place**

s 86 om 2001 Act No. 103 s 145 sch 2

**Pesticide in vehicle**

s 87 om 2001 Act No. 103 s 145 sch 2

**Pesticide in container**

s 88 om 2001 Act No. 103 s 145 sch 2

**Disposal of pesticide**

s 89 om 2001 Act No. 103 s 145 sch 2

**Disposal of pesticide container**

s 90 om 2001 Act No. 103 s 145 sch 2

**PART 11—PLACARDING FOR HAZARDOUS SUBSTANCES**

pt hdg om 2001 Act No. 28 s 189(1) sch 1

**Division 1—Interpretation**

div hdg om 2001 Act No. 28 s 189(1) sch 1

**Definitions**

s 91 om 2001 Act No. 28 s 189(1) sch 1

**Adoption of ADG code**

s 92 om 2001 Act No. 28 s 189(1) sch 1

**Division 2—Application**

div hdg om 2001 Act No. 28 s 189(1) sch 1

**Application**

s 93 amd 1998 SL No. 343 s 20  
om 2001 Act No. 28 s 189(1) sch 1

**Division 3—Warning signs**

div hdg om 2001 Act No. 28 s 189(1) sch 1

**Warning signs to be displayed**

s 94 om 2001 Act No. 28 s 189(1) sch 1

**Warning signs**

s 95 om 2001 Act No. 28 s 189(1) sch 1

**Location of warning signs**

s 96 om 2001 Act No. 28 s 189(1) sch 1

**Division 4—Class labels**

div hdg om 2001 Act No. 28 s 189(1) sch 1

**Requirements**

s 97 om 2001 Act No. 28 s 189(1) sch 1

**Division 5—Hazchem code**

div hdg om 2001 Act No. 28 s 189(1) sch 1



**Hazchem code**

s 98 om 2001 Act No. 28 s 189(1) sch 1

**PART 12—POISONS (FUMIGATION)**

**pt hdg** om 2001 Act No. 103 s 145 sch 2

**Definitions**

s 99 def “**fumigant**” amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Use of fumigant**

s 100 om 2001 Act No. 103 s 145 sch 2

**Application for licence**

s 101 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Time licence expires**

s 102 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Application for renewal of licence**

s 103 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Applicant**

s 104 amd 1998 SL No. 343 ss 20, 22  
om 2001 Act No. 103 s 145 sch 2

**Medical examinations and tests**

s 105 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Suspension of licence**

s 106 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Notice to show cause**

s 107 amd 1998 SL No. 343 ss 20, 22  
om 2001 Act No. 103 s 145 sch 2

**Accident**

s 108 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Exhaust System**

s 109 om 2001 Act No. 103 s 145 sch 2

**Mask or respirator**

s 110 om 2001 Act No. 103 s 145 sch 2

**Smoking**

s 111 om 2001 Act No. 103 s 145 sch 2

**Doors and entrances**

s 112 om 2001 Act No. 103 s 145 sch 2

**No doors and entrances**

s 113 om 2001 Act No. 103 s 145 sch 2

**Re-entry into building**

s 114 om 2001 Act No. 103 s 145 sch 2

**Instructions by an officer**

s 115 om 2001 Act No. 103 s 145 sch 2

**Procedures before fumigation**

s 116 om 2001 Act No. 103 s 145 sch 2

**Procedures after fumigation**

s 117 om 2001 Act No. 103 s 145 sch 2

**Concentration of fumigant**

s 118 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Mask**

s 119 om 2001 Act No. 103 s 145 sch 2

**Canisters**

s 120 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Fumigator using certain poisons must have halide detector**

s 121 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Respiratory apparatus**

s 122 om 2001 Act No. 103 s 145 sch 2

**Period of use of canister**

s 123 om 2001 Act No. 103 s 145 sch 2

**Storage and transportation of fumigant**

s 124 om 2001 Act No. 103 s 145 sch 2

**First aid and resuscitation equipment**

s 125 amd 1998 SL No. 343 s 20  
om 2001 Act No. 103 s 145 sch 2

**Carbon disulphide**

s 126 om 2001 Act No. 103 s 145 sch 2

**Record of each fumigation procedure**

s 127 om 2001 Act No. 103 s 145 sch 2

**Non-application of part**

s 128 om 2001 Act No. 103 s 145 sch 2

**Fumigant used for agricultural or horticultural purposes**

s 129 om 2001 Act No. 103 s 145 sch 2

**Definitions**

s 130 def "AS" om 2002 SL No. 156 s 13

**Adoption of Australian, British and other standards**

s 131      amd 1998 SL No. 343 s 20

**PART 14—RADIOACTIVE SUBSTANCES**

pt 14 (s 135) om 1999 SL No. 330 s 59(2)

**PART 15—SKIN PENETRATION****Application**

s 136      amd 2002 SL No. 156 s 14; 2003 No. 81 s 162 sch 1

**Definitions**

s 137      amd 1998 SL No. 343 s 20  
def “**closed ear piercing**” om 2003 No. 81 s 162 sch 1  
def “**dentist**” sub 2001 SL No. 264 s 17 sch 5  
    amd 2004 SL No. 27 s 3(2) sch  
def “**physiotherapist**” sub 2001 SL No. 268 s 10 sch 3  
def “**podiatrist**” sub 2002 SL No. 80 s 10 sch 3  
def “**skin penetration**” sub 2003 No. 81 s 162 sch 1

**Superintendence by local governments**

s 138      amd 2003 No. 81 s 162 sch 1

**Division 2—Registration**

div hdg    om 2003 No. 81 s 162 sch 1

**Registration of establishments**

s 139      om 2003 No. 81 s 162 sch 1

**Form of application etc.**

s 140      om 2003 No. 81 s 162 sch 1

**Suspension etc. of registration**

s 141      amd 2002 SL No. 156 s 15  
    om 2003 No. 81 s 162 sch 1

**Use or conduct of premises**

s 142      amd 1998 SL No. 343 s 20; 2005 SL No. 247 s 7

**Operator to remain clean**

s 143      amd 1998 SL No. 343 s 20

**Smoking**

s 144      om 2003 No. 81 s 162 sch 1

**Notifiable diseases**

s 145      om 2003 No. 81 s 162 sch 1

**Cleansing of skin, appliances etc.**

s 148      amd 2003 No. 81 s 162 sch 1

**Tattooing**

s 150      om 2003 No. 81 s 162 sch 1

**Division 5—Closed ear piercing**

div hdg    om 2003 No. 81 s 162 sch 1



**Food and water not to be accessible to vermin**

s 187      amd 1998 SL No. 48 s 5

**Notification of presence of vermin**

s 189      amd 1998 SL No. 48 s 6

**Local government premises**

s 190      amd 1998 SL No. 343 s 20

**Local government to destroy vermin in the area**

s 191      amd 1998 SL No. 48 s 7

**Vermin infested areas**

s 192      amd 1998 SL No. 48 s 8; 1998 SL No. 343 s 20

**Unusual sickness or mortality in vermin**

s 193      amd 1998 SL No. 343 s 20

**Local government to examine vermin specimens**

s 194      amd 1998 SL No. 343 s 20

**Division 3A—Keeping vermin**

div 3A (ss 194A–194D) ins 1998 SL No. 48 s 9

**Division 3B—Permits**

div 3B (ss 194E–194F) ins 1998 SL No. 48 s 9

**Division 3C—Suspension or cancellation of permits**

div 3C (ss 194G–194I) ins 1998 SL No. 48 s 9

**Division 3D—Amendment of permits**

div 3D (s 194J) ins 1998 SL No. 48 s 9

**Division 3E—Appeals**

div hdg    ins 1998 SL No. 48 s 9

**Decisions open to appeal**

s 194K    ins 1998 SL No. 48 s 9

**Starting an appeal**

s 194L    ins 1998 SL No. 48 s 9

**Time for starting an appeal**

s 194M    ins 1998 SL No. 48 s 9

**Stay of operation of decisions**

s 194N    ins 1998 SL No. 48 s 9

**Hearing procedures**

s 194O    ins 1998 SL No. 48 s 9

**Powers of court on appeal**

s 194P    ins 1998 SL No. 48 s 9

**Appeal to District Court**

s 194Q    ins 1998 SL No. 48 s 9  
          amd 1999 SL No. 174 s 6

**House-to-house visits**

s 195 amd 1998 SL No. 343 s 20

**Local government to employ persons for purpose of this part**

prov hdg amd 1996 SL No. 415 s 4

s 197 amd 1998 SL No. 343 s 20

**Vermin not to be kept**

s 199 om 1998 SL No. 48 s 10

**Default of owner or occupier**

s 200 amd 1998 SL No. 343 s 20

**Default of local government**

s 201 amd 1998 SL No. 343 s 20

**Notifiable diseases—Act, s 32(1)**

s 202 om 2005 SL No. 281 s 22

**Controlled notifiable diseases—Act, s 48(1)**

s 203 om 2005 SL No. 281 s 22

**Automatic machines—Act, s 106**

s 204 amd 2001 SL No. 211 s 23

**Hazardous substances—Act, s 131WE**

s 206 om 2001 Act No. 28 s 189(1) sch 1

**Articles and drugs—Act, s 134A**

prov hdg amd 2001 SL No. 67 s 4(1)

s 207 amd 2001 SL No. 67 s 4(2)–(3)

om 2005 SL No. 247 s 9

**Analyst's certificate—Act, s 136**

s 208 om 2005 SL No. 247 s 9

**Expiry of regulation**

s 211 sub 1998 SL No. 74 s 3

amd 1999 SL No. 13 s 3; 2000 SL No. 80 s 3; 2002 SL No. 156 s 18

om 2004 SL No. 34 s 31

**PART 19—REPEALS**

pt hdg amd R1 (see RA s 7(1)(k))

sub 1999 SL No. 174 s 7

divs 1–12 (ss 212–419) om R1 (see RA s 40)

**Division 13—Repeals, transitional and expiry provisions**

div hdg exp 7 June 1996 (see prev s 425)

**Definitions**

s 420 exp 7 June 1996 (see prev s 425)

**Reference to relocated provisions and regulation**

s 421 exp 7 June 1996 (see prev s 425)

(1)–(2) AIA s 20A applies (see s 421(3))

**Authorities etc. under relocated regulation**

s 422 exp 7 June 1996 (see prev s 425)

**Legal proceedings**

s 423 exp 7 June 1996 (see prev s 425)  
(1) AIA s 20A applies (see s 423(2))

**Division 1—Repeals for Subordinate Legislation 1996 No. 121**

div hdg prev div 1 hdg prec s 212 om R1 (see RA s 40)  
pres div 1 hdg ins 1999 SL No. 257 s 5

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

div hdg prev div 2 hdg prec s 227 om R1 (see RA s 40)  
pres div 2 hdg ins 1999 SL No. 257 s 6

**Transitional provisions for offences against repealed part**

s 425 prev s 425 exp 7 June 1996 (see prev s 425)  
pres s 425 ins 1999 SL No. 257 s 6  
(1) AIA s 20 applies (see s 425(2))

**SCHEDULE 1—AUTHORISED PERSONS**

om 2005 SL No. 192 s 5

**SCHEDULE 2—NOTIFIABLE AND CONTROLLED NOTIFIABLE DISEASES**

amd 1999 SL No. 154 s 3; 2001 SL No. 67 s 5; 2002 SL No. 195 s 5; 2003 SL  
No. 79 s 3; 2005 SL No. 247 s 10  
om 2005 SL No. 281 s 23

**SCHEDULE 3—FEES**

amd 2000 SL No. 148 s 6  
sub 2002 SL No. 20 s 7; 2002 SL No. 156 s 19  
amd 2003 SL No. 130 s 8  
sub 2004 SL No. 34 s 32; 2004 SL No. 154 s 9; 2005 SL No. 170 s 8; 2006 SL  
No. 190 s 8

**SCHEDULE 4—ITEMS TO BE PROVIDED**

amd 2001 SL No. 264 s 17 sch 5; 2001 SL No. 267 s 14 sch 4; 2002 SL No.  
156 s 20

**SCHEDULE 6—CLEANSERS AND DISINFECTANTS**

om 2003 No. 81 s 162 sch 1

**SCHEDULE 7—ALTERATIONS, AMENDMENTS, MODIFICATIONS AND VARIATIONS OF THE ADG CODE**

om 2001 Act No. 28 s 189(1) sch 1

**SCHEDULE 8—FACTOR CALCULATION FOR THE PURPOSES OF SECTION 93**

om 2001 Act No. 28 s 189(1) sch 1

**SCHEDULE 9—EXEMPTION LIMITS FOR CLASS 2—GASES**

om 2001 Act No. 28 s 189(1) sch 1

**SCHEDULE 10—REQUIREMENTS FOR WARNING SIGNS**

om 2001 Act No. 28 s 189(1) sch 1

**SCHEDULE 11—PRESCRIBED METHODS OF ANALYSIS AND PERMISSIBLE  
LEVELS OF METAL RELEASE**

amd 1996 SL No. 415 s 5