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Statutory Rules 1995 No. L[1] 208

Therapeutic Goods Regulations[2] (Amendment)

I, THE GOVERNOR-GENERAL of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated L 1995. 4 July

L BILL HAYDEN
Governor-General

By His Excellency's Command,

L ROSEMARY CROWLEY
Minister for Family Services

1. Commencement

1.1 These Regulations, other than regulations 6 and 8 and subregulations 9.2, 9.3, 10.6, 10.7, 11.7, 13.2 and 14.4, commence on 4 July 1995.

1.2 Regulation 6 and subregulation 9.3 commence on 1 October 1995.

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1.3 Regulation 8 and subregulations 9.2, 10.6 and 11.7 commence on 1 January 1996.

1.4 Subregulation 10.7 commences on 1 October 1996.

1.5 Subregulations 13.2 and 14.4 commence on 1 January 1997.

2. Amendment

2.1 The Therapeutic Goods Regulations are amended as set out in these Regulations.

3. Regulation 2 (Interpretation)

3.1 Definition of "antiseptic":

Omit the definition, substitute:

" **'antiseptic'** means a substance:

(a) that is recommended by its manufacturer for:

(i) dermal application: or

(ii) application to the mucous membranes of a person or an animal:

(A) to kill micro organisms; or

(B) to prevent the growth of micro organisms to a level that causes or may cause clinical infection; and

(b) that is not represented to be suitable for internal use;".

3.2 Definition of "disinfectant":

Omit the definition, substitute:

" **'disinfectant'** means a substance:

(a) that is recommended by its manufacturer for application to an inanimate object to kill micro organisms; and

(b) that is not represented by the manufacturer to be suitable for internal use;".

3.3 Insert the following definitions:

" **'active implantable therapeutic device'** means a therapeutic device that is designed to be totally or partially introduced:

(a) surgically into the human body; or

(b) by medical intervention into a natural orifice of the human body;

and to remain there after introduction;

'active therapeutic device' means a device that relies for its functioning on a source of electrical energy or any other source of power that is not generated directly by the human body or by gravity;

'critical medical device' means a device that, when used as recommended by its manufacturer, is in a sterile condition on introduction into the human body;

'fungicide' means a chemical agent that kills a fungus or spores of a fungus;

'high level disinfectant' means a disinfectant that:

(a) kills all microbial pathogens, except bacterial endospores, when used as recommended by its manufacturer; and

(b) is the minimum treatment recommended by the manufacturer of a semi critical medical device for the reprocessing of the device;

'hospital grade disinfectant' means a disinfectant that is represented to be suitable for therapeutic use:

(a) in premises used for:

(i) the investigation or treatment of a disease, ailment or injury; or

(ii) procedures that are carried out involving the penetration of the human skin; or

(b) in connection with:

(i) the business of beauty therapy or hairdressing; or

(ii) the practice of podiatry;

but does not include:

(c) an antibacterial clothes preparation; or
(d) a sanitary fluid; or
(e) a sanitary powder; or
(f) a sanitiser;

'household grade disinfectant' means a disinfectant that is not:

(a) an antibacterial clothes preparation; or
(b) a hospital grade disinfectant; or
(c) a sanitary fluid; or
(d) a sanitary powder; or
(e) a sanitiser;

'instrument grade disinfectant' means:

(a) a high level disinfectant; or
(b) a sterilant;

that is used to reprocess reusable semi critical or critical medical devices;

'non critical medical device' means a device that, when used as recommended by its manufacturer:

(a) does not ordinarily contact the human body; or
(b) if contact with the human body is made—contacts only healthy intact skin;

'semi critical medical device' means a device that, when used as recommended by its manufacturer:

(a) makes contact with healthy intact mucous membranes of the human body; and
(b) does not ordinarily enter normally sterile areas of the body;

'sporicide' means a chemical agent that:

(a) kills bacterial spores; and
(b) has the potential to act as a sterilising agent after prolonged contact with an inanimate object;

'sterilant' means a chemical agent that kills microbes with the result that the sterility assurance level of a microbial survivor is less than 10^{-6};

'tuberculocide' means a chemical agent that kills *Mycobacterium tuberculosis* and related acid-fast bacteria;

'virucide' means a chemical agent that renders a virus non-infective.".

4. New regulation 6A

4.1 After regulation 6, insert:

Unacceptable presentations

"6A. For the purposes of paragraph 3 (5) (e) of the Act, any labelling, packaging or presentation of therapeutic goods (including novelty dosage forms in the shape of animals, robots, cartoon characters or other similar objects) that is likely to result in those goods being mistaken for or confused with confectionery or toys is an unacceptable presentation of the goods.".

5. Regulation 9A (Information about certain therapeutic goods to be supplied)

5.1 Paragraph 9A (1) (a):

After "Schedule 10", insert "except a drug that is specified in Schedule 3 of the Poisons Standard".

5.2 After subregulation 9A (1), insert:

"(1A) The sponsor of therapeutic goods that are:

(a) specified in Schedule 3 of the Poisons Standard; and

(b) are approved for registration on or after 4 July 1995;

must not supply the goods unless the sponsor supplies with the goods written information about the goods that meets the requirements for a patient information document set out in Schedule 13.

Penalty: 10 penalty units.".

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5.3 Subregulation 9A (2):
After "subregulation (1)", insert "or (1A)".

6. Regulation 34 (Therapeutic Goods Committee)

6.1 Subregulations 34 (2), (3) and (4):
Omit the subregulations, substitute:

"(2) The Committee's functions are:

(a) to consider:

(i) the adoption of standards for therapeutic goods;

(ii) matters relating to standards for therapeutic goods; and

(iii) requirements for labelling and packaging of therapeutic goods; and

(iv) principles to be observed in the manufacture of therapeutic goods for human use;

and advise the Minister of the results of its consideration; and

(b) to advise the Minister on the likely impact that adoption of a proposed standard would have on Australian domestic and international trade; and

(c) to consider a matter that is referred to the Committee by the Minister and to advise the Minister of the results of its consideration.

"(3) The Committee must:

(a) give to the Minister the reasons for any advice of the Committee; and

(b) when considering a matter to which paragraph (2) (a) applies, have regard to:

(i) the desirability of adopting standards of the British Pharmacopoeia and other recognised international standards for therapeutic goods in the interests of international harmonisation of therapeutic goods standards; and

(ii) whether the application of those standards to Australian conditions is appropriate.

"(4) The Minister must appoint in writing 11 persons to the Committee in accordance with subregulations (4A), (4B) and (4C).

"(4A) The Committee must comprise the following persons:

(a) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of prescription drug products;

(b) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of non-prescription drug products;

(c) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of alternative medicines;

(d) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of Australian manufacturers of therapeutic devices;

(e) a person who is nominated to the Minister in writing by a body that represents, or a combination of bodies that together represent, the interests of consumers of health services;

(f) a person with expertise in microbiology and virology;

(g) a person with expertise in biomedical engineering;

(h) a person with expertise in the biological safety of biomaterials;

(i) a person with expertise in biotechnology;

(j) a person with expertise in pharmaceutical sciences;

(k) a member of the Health and Food Standards Advisory Committee of Standards Australia.

"(4B) At least 1 of the persons appointed to the Committee must be a medical practitioner.

"(4C) At least 1 of the persons to whom paragraphs (4A) (f), (g), (h), (i), (j) and (k) refer must be able to represent the interests of consumers of health services.

"(4D) The chairperson of the Committee may invite a person who is nominated in writing by the National Registration Authority for Agricultural and Veterinary Chemicals to attend a meeting at which a matter that is relevant to the function of the Authority is to be discussed.".

7. Schedule 1 (Part 2 does not apply to members of an Australian branch of one of these bodies)

7.1 After item 11, insert:

"11A Australian Society of Homeopaths Inc".

7.2 Item 19A:

Omit the item.

8. Schedule 2 (Prohibited and required representations for the purposes of paragraphs 6 (1) (a) and (b))

8.1 Part 1, item 6 (column 2):

Add at the end:

"; or

(d) contradicting or conflicting with the common name; or

(e) that is not more specific than the common name as a description or measure of activity against micro organisms; or

(f) containing a reference to an effect against viruses, except a representation that is approved in writing by the Secretary; or

(g) containing a reference to an effect against *Mycobacterium tuberculosis* and related acid fast bacteria, except a representation that is approved in writing by the Secretary; or

(h) containing a reference to the disinfection of inaccessible parts of drains".

8.2 Part 1:
After item 6, insert:

"6A	a representation that: (a) anaesthetic apparatus; or (b) respiratory apparatus; or (c) surgical instruments; may be stored in the disinfectant after disinfection	instrument disinfectants".

9. Schedule 3 (Therapeutic goods required to be included in the part of the Register for registered goods)

9.1 Part 1:
Add at the end:

"4 active implantable medical devices, other than:
(a) auditory nerve stimulators; or
(b) bone growth stimulators; or
(c) incontinence control stimulators; or
(d) peripheral nerve stimulators; or
(e) spinal cord stimulators;
that were being supplied on 3 July 1995".

9.2 Part 2:
Add at the end:

"5	instrument grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides that are intended by the manufacturer to be used on: (a) a critical medical device; or (b) a semi critical medical device
6	hospital grade or household grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides".

9.3 Part 2:
Add at the end:

"7	diagnostic goods for *in vitro* use that are: (a) goods for use in the diagnosis of Human Immunodeficiency Virus; or (b) goods for use in the diagnosis of hepatitis C virus".

10. Schedule 4 (Therapeutic goods required to be included in the part of the Register for listed goods)

10.1 Part 1, item 2, paragraph (a):
Omit the paragraph, substitute:

"(a) item 3 or 4 of Part 1 of Schedule 3 applies; or".

10.2 Part 1, item 3, paragraph (d):
Omit the paragraph, substitute:

"(d) the herbal substances are not included in Part 4 of this Schedule; and".

10.3 Part 1, item 7:
Omit the item, substitute:

"7	sunscreen preparations for dermal application (other than preparations for the treatment of a condition referred to clause 4 of the Therapeutic Goods Advertising Code), if: (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1993, as in force from time to time; and (b) the performance statements and markings on the label comply with that Standard; and (c) the sun protection factor stated on the label is: (i) 4 or greater; or

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(ii) less than 4 and the preparations include an ingredient of human origin, or animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:

(A) adrenal;
(B) brain;
(C) cerebro-spinal fluid;
(D) dura mater;
(E) eye;
(F) ileum;
(G) lymph nodes;
(H) pineal gland;
(I) pituitary;
(J) placenta;
(K) proximal colon;
(L) spinal cord;
(M) spleen;
(N) tonsil;".

10.4 Part 1, item 13, paragraph (a):
Omit the paragraph, substitute:

"(a) made of poly(methyl methacrylate); and".

10.5 Part 1:
Add at the end:

"15	non-powered endoscopes and endoscopic accessories".

10.6 Part 1:
Add at the end:

"16	hospital grade disinfectants when used as recommended by the manufacturer on non critical surfaces if no claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides".

10.7 Part 2:
Omit "Ascorbyl palmitate", substitute:

"Ascorbyl palmitate in oral preparations, if the goods are labelled with a recommended daily dose that is equivalent to 100mg or less of ascorbyl palmitate".

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10.8 Part 4:
Omit the Part, substitute:

"PART 4

HERBAL SUBSTANCES TO WHICH PARAGRAPH (d) OF ITEM 3 OF PART 1 OF THIS SCHEDULE APPLIES

1. Herbal substances that may not be included in listed therapeutic goods

Herbal substances derived from the following plant material:

Name	Common name
Abrus precatorius seed and root	Jequirity
Acorus calamus	Sweet flag
Amanita (all or any species)	
Anadenanthera peregrina	
Argyreia nervosa	Morning glory
Aristolochia (all or any species)	Snakeroot, Birthwort
Aspergillus fumigatus	Fungus
Aspergillus nidulans	Fungus
Aspergillus niger	Fungus
Aspergillus sydowi	Fungus
Aspergillus terreus	Fungus
Banisteriopsis caapi	Banisteria
Candida albicans	Thrush fungus, Tinea fungus
Cannabis	
Catha edulis	Khat
Conocybe (all or any species)	
Crotalaria (all or any species)	
Cynoglossum officinale	Hounds tongue
Epidermophyton floccosum	Tinea fungus
Erythroxylum coca	Coca leaf
Geotrichum candidum	Thrush fungus
Gymnopilus (all or any species)	
Haemadictyon (all or any species)	
Heliotropium (all or any species)	Heliotrope

Ipomoea burmanni (Rivea corymbosa)	
Ipomoea hederacea	
Ipomoea violacea (Ipomoea tricolor)	
Lophophora (all or any species)	
Microsporum audouinni	Ringworm fungus
Microsporum canis	Ringworm fungus, Tinea fungus
Opuntia cylindrica	San Pedro cactus
Papaver bracteatum	
Papaver somniferum	Opium poppy
Peganum harmala	Wild rue
Petasites (all or any species)	Butterbur
Piptadenia macrocarpa	
Piptadenia peregrina	Cohoba
Psylocybe (all or any species)	
Pteridium aquilinum	Bracken fern
Rhizopus oligosporus	Fungus
Senecio (all or any species)	
Sophora secundiflora	Mescal bean
Stropharia cubensis	
Strychnos gaulthieriana	
Strychnos ignatii (Ignatia amara)	Ignatious bean
Symphytum (all or any species)	Comfrey
Trichophyton (all or any species)	Fungus
Tussilago farfara	Coltsfoot
Virola sebifera	Cuajo negro, Camaticaro

[NOTE: As to preparations containing a herbal substance derived from a herb not approved in Australia for therapeutic use in humans, *see* Schedule 3, item 2.]

2. Herbal substances that may only be included in listed therapeutic goods in minute doses or if other specified conditions are met

Herbal substances derived from the following plant material, except if the recommended daily dose is equivalent to 1mg or less of the dry herbal material or is subject to a qualification set out in column 1:

Column 1 Name	Column 2 Common name
Abrus cantoniensis seed	
Arisaema (all or any species), other than preparations containing no cardiac glycosides	Arum
Armoracia rusticana (Cochlearia armoracia), other than preparations the recommended daily dose of which contain 20mg or less of volatile oil	Horseradish oil
Arnica (all or any species), other than for external use	Arnica
Arum maculatum	Cuckoopint, Lords-and-ladies
Brachyglottis (all or any species)	
Brassica (all or any species) seed, other than preparations the recommended daily dose of which contain 20mg or less of allyl isothiocyanate (volatile oil component)	Mustard seed oil
Brunfelsia uniflora	Manaca, Mercury
Chenopodium ambrosioides, other than preparations the recommended daily dose of which contain 10mg or less of volatile oil	Wormseed oil
Cicuta virosa	Cowbane
Croton (all or any species)	Cascarilla, Croton
Daphne mezereum, except if the recommended daily external dose is equivalent to 10mg or less of the dry herbal material and the labels on the goods include directions only for external use on unbroken skin	Mezereum

Dryopteris filix-mas	Male fern
Echium vulgare	Viper's bugloss
Euonymus europaeus	European spindle tree
Helleborus (all or any species)	Hellebore
Hydnocarpus anthelmintica seed and seed oil preparations for internal use	Chaulmoogra seed
Lantana camara	Lantana
Lathyrus sativus, other than the cooked seed	Grass pea
Lithospermum (all or any species)	
Menispermum canadense	Yellow parilla
Mentha pulegium, other than preparations the recommended internal daily dose of which contain 50mg or less of volatile oil and the recommended external daily dose of which contain 150mg or less of volatile oil	Pennyroyal oil
Monstera deliciosa leaf	Monstera leaf
Oenanthe (all or any species)	Chervin, Dropwort
Peumus boldus , other than preparations the recommended daily dose of which contain 100mg or less of volatile oil	Boldo oil
Phytolacca decandra (americana)	Pokeroot, Pokeweed
Prunus dulcis (P. amygdalus) var. *amara* seed, other than preparations containing no cyanogenic glycosides	Bitter almond oil
Pseudolarix kaempferi, other than stem bark and root preparations for external use	Golden larch
Rhododendron molle	Chinese azalea
Ricinus communis, other than the fixed oil of the seed	Castor tree
Robinia pseudoacacia, other than the leaf and flower	False acacia
Rohdea japonica	
Schoenocaulon officinale (Sabadilla officinarum, Veratrum officinale)	Sabadilla
Semecarpus anacardium (Anacardium orientale), other than the seed	Marking nut tree

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Solanum (all or any species) preparations for internal use, except if the recommended daily dose contains 10mg or less of total steroidal alkaloids including solanine, solaneine and solanidine	
Spigelia marilandica	Pink root, Worm grass
Tamus communis fruit and root	Black bryony fruit and root
Teucrium (all or any species)	Germander
Toxicodendron radicans (Rhus toxicodendron)	Poison ivy".

11. Schedule 5 (Therapeutic goods exempt from the operation of Part 3 of the Act)

11.1 Item 7, subparagraph (b) (iv):

After "Virus", insert ", or goods for use in the diagnosis of hepatitis C virus".

11.2 Item 7, paragraph (d):

Omit the paragraph, substitute:

"(d) non-powered medical or dental instruments that:

(i) depend on manual dexterity for their use; and

(ii) are not supplied in whole or in part in a sterile state;

except endoscopes and endoscopic accessories, flexible tubes, catheters, cannulae, fluid and gas lines and other instruments that introduce fluids or gases to, or remove them from, the body; or".

11.3 Item 7, paragraph (g):

Omit the paragraph, substitute:

"(g) non-powered devices used in general patient care, being devices that do not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition; or".

11.4 Item 7, subparagraph (l) (ii):

Omit the subparagraph, substitute:

"(ii) single use containers designed for the collection, storage and transfer of blood for diagnostic testing (other than single use containers recommended by the manufacturer to be used only in equipment measuring the physical properties of blood); or".

11.5 Item 8, paragraph (a):

Add at the end:

"and which do not include an ingredient of:

(i) human origin; or

(ii) animal origin, if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:

(A) adrenal;

(B) brain;

(C) cerebrospinal fluid;

(D) dura mater;

(E) eye;

(F) ileum;

(G) lymph nodes;

(H) pineal gland;

(I) pituitary;

(J) placenta;

(K) proximal colon;

(L) spinal cord;

(M) spleen;

(N) tonsil;".

11.6 Item 8, paragraph (d):

After "use", insert "if the medication consists solely of an antiseptic having a secondary role in the formulation,".

11.7 Item 8, paragraph (f):

Omit the paragraph, substitute:

"(f) disinfectants, except:

(i) disinfectants included in items 5 and 6 of Part 2 of Schedule 3; or

(ii) disinfectants included in item 16 of Part 1 of Schedule 4; or

(iii) disinfectants for use with contact lenses;".

11.8 Item 8, paragraph (g):

Omit the paragraph, substitute:

"(g) sunscreen preparations for dermal application, if:

(i) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1993, as in force from time to time; and

(ii) the performance statements and markings on the label comply with that Standard; and

(iii) the sun protection factor stated on the label is less than 4, unless the preparations include ingredients of human origin, or of animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:

(A) adrenal;

(B) brain;

(C) cerebrospinal fluid;

(D) dura mater;

(E) eye;

(F) ileum;

(G) lymph nodes;

(H) pineal gland;

(I) pituitary;

(J) placenta;

(K) proximal colon;

(L) spinal cord;

(M) spleen;

(N) tonsil;".

12. Schedule 5A (Therapeutic goods exempt from the operation of Part 3 of the Act subject to conditions)

12.1 Item 1:

Omit the item, substitute:

"1	Therapeutic goods imported into Australia that are held under the direct control of the sponsor, until the goods are: (a) the subject of a notification under item 3; or (b) approved for importation into Australia under subsection 19 (1) of the Act	(a) the sponsor must: (i) keep records relating to the source and supply of the goods; and (ii) if requested by the Secretary—supply the records to the Secretary; and (b) if the goods are the subject of a notification under item 3 or an approval under subsection 19 (1) of the Act—the supply of the goods must be in accordance with the notification or approval; and (c) if the goods are the subject of a notification under item 3 or an approval under subsection 19 (1) of the Act and are kept in a warehouse in accordance with the notification or approval for a period of up to 12 months: (i) in the case of therapeutic goods other than therapeutic devices—the goods must be destroyed within 1 month of the end of that period; and

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		(ii) in the case of therapeutic devices—the devices must be destroyed or returned to the consignor of the devices within 1 month of the end of that period
1A	Therapeutic goods imported into Australia and held under the direct control of the sponsor, until a decision is made under section 25 or 26 of the Act in relation to the goods	(a) the sponsor must: (i) keep records relating to the source of the goods; and (ii) if requested by the Secretary—supply the records to the Secretary; and (iii) have lodged an application under section 23 of the Act in relation to the goods before their importation; and (b) if the goods are not registered or listed: (i) the goods must be destroyed; or (ii) in the case of therapeutic devices—the devices must be destroyed or returned to the consignor of the devices within 1 month of the decision not to register or list the devices".

12.2 Add at the end:

"7 Therapeutic goods, or parts of therapeutic goods, that form part of one of the following device kits:

(a) orthopaedic fixation systems;

(b) diagnostic goods for *in vitro* use that are reagents, reagent products or a combination of those products;

(c) drug delivery systems in which the drug is supplied in a device that acts as a container;

(d) dental restorative systems

(a) none of the goods, or any part of the goods are separately supplied in Australia; and

(b) if the component and kit manufacturer are the same manufacturer and the components are not separately supplied outside the kit by the kit sponsor; and

(c) if the kit sponsor or the manufacturer obtains components from other manufacturers and the kit manufacturer's licence covers quality control of those components".

13. Schedule 6 (Therapeutic devices prescribed for the purposes of paragraph 26 (1) (g) of the Act)

13.1 Item 3, paragraph (f):

Add at the end:

"(iv) goods for use in the diagnosis of hepatitis C virus; or".

13.2 Add at the end:

"5 hospital grade disinfectants when used as recommended by the manufacturer on non critical surfaces if no claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides".

14. Schedule 7 (Therapeutic goods exempt from the operation of Part 4 of the Act unless supplied as pharmaceutical benefits)

14.1 Item 4, paragraph (g):

Add at the end:

"(iv) goods for use in the diagnosis of hepatitis C virus; or".

14.2 Item 5, paragraph (b):

Omit the paragraph, substitute:

"(b) single use containers designed for the collection, storage and transfer of blood for diagnostic testing (other than single use containers recommended by the manufacturer to be used only in equipment measuring the physical properties of blood)".

14.3 Item 10:

Add at the end ", if the medication consists solely of an antiseptic having a secondary role in the formulation".

14.4 Add at the end:

"20 instrument grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides when used as recommended by the manufacturers on:

(a) a critical medical device; or

(b) a semi critical medical device

21	hospital grade or household grade disinfectants that are claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides
22	hospital grade disinfectants when used as indicated by the manufacturer on non critical surfaces, if no claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides".

15. Schedule 9 (Fees)

15.1 Item 4:

After "Drug", insert "Safety and".

16. Schedule 10 (Drugs evaluated by the Drug Evaluation Branch of the Department)

16.1 Heading:

After "DRUG", insert "SAFETY AND".

16.2 Item 8:

Add at the end ", other than barium sulphate preparations for radiological use".

17. Schedule 12 (Patient information documents)

17.1 Omit *Note 1*, substitute:

"*Note 1*: 'Common name' is the name approved under the Australian Approved Names published by the Therapeutic Goods Administration from time to time.".

18. New Schedule 13

18.1 After Schedule 12, insert:

SCHEDULE 13 Subregulation 9A (1A)

PATIENT INFORMATION DOCUMENTS

A patient information document about a medicinal product must be:

- written in English
- clearly legible
- written in language that will easily be understood by patients
- consistent with product information (within the meaning of section 32 of the Act) about the product.

A patient information document must include the following:

1. *Identification*

The name of the medicinal product, which is the name given to the product by the sponsor.

A statement of the active ingredients expressed quantitatively and excipients expressed qualitatively, using their common names, in the case of each presentation of the product.

The pharmaceutical form and the contents by weight, volume or number of doses of the product, in the case of each presentation of the product, together with its identifying Australian Register number.

2. *What the product is used for and how it works*

The therapeutic indications, unless a competent authority determines that dissemination of such information may have serious disadvantages for the patient.

The pharmaco-therapeutic group, or type of activity, if there is a term that is easily comprehensible for the patient. If not, a simple description of what the medicinal product is for and how it works, in 1 or 2 sentences.

SCHEDULE 13—continued

3. *Advice before using the medicinal product*

A list of factors that are useful to consider before taking the medicinal product, including, if appropriate:

- contraindications, including consideration of whether the patient has experienced previous allergic reactions
- precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions
- potential effects of the medicinal product on the ability to drive vehicles or to operate machinery
- interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product
- special warnings, such as effects on sensitivity to sun exposure.

4. *How to use the medicinal product properly*

The necessary and usual instructions for proper use of the medicinal product, in particular:

- the dosage, together with an indication that this may not always apply and may be modified by the prescriber
- the method and, if necessary, route of administration
- the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product should or must be used

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SCHEDULE 13—continued

In addition, depending upon the nature of the therapeutic goods:

- the duration of treatment, if it should be limited
- the expected effect of using the medicinal product
- what to do if 1 or more doses have not been taken
- the way the treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects.

5. *Further information*

For example, habit forming potential.

6. *Unwanted effects*

A description of the undesirable effects that can occur under normal use of the medicinal product and, if necessary, the action to be taken if experienced.

The patient should be expressly invited to communicate any undesirable effect, especially if it is not mentioned in the patient information document, to his or her health care practitioner or pharmacist.

7. *In case of overdose*

The action to be undertaken in the case of overdose (for example, symptoms and emergency procedures).

8. *Storage conditions*

An indication of the appropriate storage conditions; a reference to the expiry date indicated on the label, with a warning against using the medicinal product after this date; if appropriate, a warning against visible signs of deterioration.

SCHEDULE 13—continued

9. *Where to go for further information*

A direction to patients to discuss any aspect with the health care practitioner or pharmacist and, if appropriate, where further information may be obtained.

10. *Sponsor*

The name and address of the Australian sponsor of the medicinal product.

11. *Date of information*

The date on which the patient information document was last revised.

Note 1: 'Common name' is the name approved under the Australian Approved Names published by the Therapeutic Goods Administration from time to time.

Note 2: The information need not appear in the order outlined above. For example, the subsidiary information under *"Identification"* could appear at the end of the patient information document.".

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19. Transitional provisions

19.1 If:

(a) an application is made under section 23 of the Act in relation to therapeutic goods to which paragraph (d) or subparagraph (l) (ii) of item 7 in Schedule 5 to the Therapeutic Goods Regulations, as in force immediately before 4 July 1995; and

(b) the application is made in the period from the beginning of 4 July 1995 to the end of 31 December 1995;

Part 3 of the Act applies to those goods as if subregulations 10.5, 11.2 and 11.4 of these Regulations had not commenced until the application is decided.

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19.2 If:

(a) an application is made under section 23 of the Act in relation to therapeutic goods to which paragraphs (a) and (g) of item 8 in Schedule 5 to the Therapeutic Goods Regulations, as in force immediately before 4 July 1995; and

(b) the application is made in the period from the beginning of 4 July 1995 to the end of 30 September 1995;

Part 3 of the Act applies to those goods as if subregulations 10.3, 11.5 and 11.8 of these Regulations had not commenced until the application is decided.

NOTES

1. Notified in the *Commonwealth of Australia Gazette* on 4 1995. 4 July

2. Statutory Rules 1990 No. 394 as amended by 1991 Nos. 84 and 485; 1992 Nos. 19, 89, 109, 332, 370 and 430; 1993 No. 141; 1994 Nos. 150, 222 and 364; 1995 Nos. 33, 111 and 192.