

# **Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006**

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The Ministerial Council established under the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products, done at Wellington on 10 December 2003, makes the following Rule.

Dated 2006

**[DRAFT ONLY – NOT FOR SIGNATURE]**

Minister for Health and Ageing  
Australia

Minister of Health  
New Zealand

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**CONSULTATION DRAFT ONLY**

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## Part 1 Preliminary

### 1.01 Name of Rule

This Rule is the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006*.

### 1.02 Commencement

This Rule commences on [^date^].

### 1.03 Definitions

#### *General*

(1) In this Rule:

***annual charge***, in relation to a product licence, means such a charge imposed in relation to the licence under Part 11.

***anthroposophic medicine*** means a medicine that:

- (a) contains one or more anthroposophic preparations; and
- (b) may contain excipients necessary for presentation of the medicine in the final dosage form.

***anthroposophic preparation*** means a preparation prepared:

- (a) from a mother substance specified, for the purpose of this definition, in an Order; and
- (b) in accordance with:
  - (i) an anthroposophic manufacturing procedure described by an approved anthroposophic reference; or
  - (ii) a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia.

***antiseptic*** means a substance:

- (a) that is recommended for dermal application or for application to mucous membranes; and
- (b) the purpose of which is to kill micro organisms, or to prevent the growth of micro organisms to a level that causes, or may cause, clinical infection; and
- (c) that is not represented to be suitable for internal use.

***approved anthroposophic reference*** means an anthroposophic reference specified, for the purpose of this definition, in an Order.

***approved essence manufacturing procedure*** means a procedure specified, for the purpose of this definition, in an Order.

***approved homoeopathic pharmacopoeia*** means a homoeopathic pharmacopoeia specified, for the purpose of this definition, in an Order.

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**batch**, in relation to a medicine, means a quantity of the medicine that is:

- (a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and
- (b) made in one cycle of manufacture and, in the case of a medicine that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

**bioburden**, in relation to a medicine, means the quantity and characteristics of microorganisms present in the medicine or to which the medicine may be exposed in a manufacturing environment.

**Class 1 medicine** has the meaning given by section 3.12

**Class 2 medicine** has the meaning given by section 3.17.

**Class 1 permitted ingredient** has the meaning given by section 3.13.

**complementary healthcare practitioner** means a herbalist, nutritionist, naturopath, practitioner of traditional medicine or homeopathic practitioner.

**consumer medicine information** has the meaning given by section 7.04.

**default standard** means a default standard mentioned in section 2.04.

**destination country**, in relation to an export-only medicine, means a country, other than Australia and New Zealand, to which the medicine is, or is to be, exported.

**essence** means a preparation that:

- (a) is prepared in accordance with an approved essence manufacturing procedure; and
- (b) is derived from:
  - (i) plant material; or
  - (ii) a mineral; or
  - (iii) non-human animal material; and
- (c) is not derived from a substance that:
  - (i) is included in the Scheduling Standard; or
  - (ii) has the characteristics of a substance that could be included in the Scheduling Standard; and
- (d) may contain excipients necessary for presentation of the preparation in the final dosage form.

**excipient**, in relation to a medicine, means an ingredient of the medicine other than the active ingredient.

**export-only medicine** has the meaning given by section 3.18.

**export-only (Class 1) medicine** has the meaning given by section 3.18.

**export-only (Class 2) medicine** has the meaning given by section 3.18.

**evaluation fee** means a fee payable under section 3.27.

**Good Manufacturing Practice contract** means [to be completed]

**homoeopathic medicine** means a medicine that:

- (a) contains one or more homoeopathic preparations; and

- 
- (b) may contain excipients necessary for presentation of the medicine in the final dosage form.

**homoeopathic preparation** means a preparation prepared:

- (a) from a mother substance specified, for the purpose of this definition, in an Order; and
- (b) in accordance with a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia.

**indications**, in relation to a medicine that is the subject of a product licence or of an application for a product licence, means the specific therapeutic uses intended for the medicine by the holder of, or applicant for, the product licence.

**licensed**, in relation to a person and a medicine, means the person who is the holder of a licence of the relevant kind, in relation to the medicine, that is in force.

**manufacturing licence** means a licence granted to the manufacturer of a medicine under Part 4.

**Manufacturing Principles** has the meaning given by section 4.02.

**mother substance** means a homoeopathic, anthroposophic or essence starting material derived from a plant or a plant material, an alga, a fungus, a micro-organism, an animal material or a chemical, and may include a composition of such starting materials.

**product information**, in relation to a medicine, has the meaning given by section 7.03.

**product licence**, in relation to a medicine, means a product licence granted in respect of the medicine under Part 3.

**protected information**, in relation to a medicine, has the meaning given by section 3.33.

**provisional product licence** means a provisional product licence granted under section 3.09.

**quality**, in relation to a medicine, includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the medicine.

**standard**, in relation to a medicine, means:

- (a) a standard determined by an Order under section 2.02; or
- (b) a default standard.

**Standard AS/NZS** means a joint Australian and New Zealand Standard published by:

- (a) for Australia — Standards Australia Limited; and
- (b) for New Zealand — the body known as Standards New Zealand.

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***traditional preparation***, in relation to a complementary medicine, means a preparation obtained from a plant, plant material, mineral or a non-human animal material, for therapeutic application in humans:

- (a) using a method that is based on health theories, beliefs or experiences of a traditional healing paradigm; and
- (b) having a documented methodology established over at least 3 generations.

***unique identifier*** has the meaning given by section 3.07.

### *Glossary relating to complementary medicines*

- (2) The Authority may, by Order, define or delimit any term or expression that appears in Schedule 1 (not being a term or expression otherwise defined in these Rules) in relation to all complementary medicines or a particular kind of complementary medicines.

*Note* Other terms and expressions used in this Rule are defined, for the purposes of the Rules generally, in the Administration and Interpretation Rule. The Administration and Interpretation Rule also indicates terms that are defined in the Agreement, or that are defined by reference to their definition in other Rules. A term defined in the Agreement has the same meaning when used in a Rule: see subsection 1.01 (2) of Part 1 of Schedule 1 to the Administration and Interpretation Rule.

Terms and expressions defined or referred to in the Administration and Interpretation Rule include:

|                                |                              |
|--------------------------------|------------------------------|
| active ingredient              | medical practitioner         |
| advertisement                  | Mutual Recognition Agreement |
| Advertising Code               | Practice Guidelines          |
| Agreement                      | premises                     |
| appropriate ethics committee   | presentation                 |
| approved form                  | primary pack                 |
| authorised person              | principal investigator       |
| container                      | prohibited export            |
| dental practitioner            | prohibited import            |
| directions for use             | quality                      |
| expert advisory committee      | record                       |
| expiry date                    | Scheduling Standard          |
| life-threatening (disease etc) | serious (disease etc)        |
| gene therapy                   | specialist                   |
|                                | substance                    |
|                                | working day                  |

Terms defined in the Agreement and used in this Rule include:

|             |                     |
|-------------|---------------------|
| Authority   | Rule                |
| manufacture | supply              |
| Order       | therapeutic product |
| promotion   | therapeutic use.    |

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#### 1.04 What is a medicine?

- (1) For the purposes of this Rule, a therapeutic product is a *medicine* if it is a substance or combination of substances that:
  - (a) is presented as having properties for treating or preventing a disease, ailment, defect or injury in human beings; or
  - (b) may be used in human beings with a view to making a medical diagnosis or to restoring, correcting, maintaining or modifying physiological functions; or
  - (c) is declared to be a medicine by an order under paragraph (3) (a).
- (2) However, a therapeutic product is not a medicine for the purposes of this Rule if it is so declared by an Order under paragraph (3) (b).
- (3) The Authority may by Order declare that, for the purposes of the Rules, a therapeutic product:
  - (a) is a medicine; or
  - (b) is not a medicine.

*Note 1* For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Act; and
- (b) in New Zealand — [Part 2] of the Act.

*Note 2* A declaration under this section does not stop an article from being a therapeutic product. However, the Authority may, under paragraph 2 of Article 10 of the Agreement, by Order declare that particular products or classes of products are not, or are not when used, promoted or presented in a particular way, therapeutic products.

#### 1.05 What is a complementary medicine?

For this Rule, a *complementary medicine* is:

- (a) a medicine that:
  - (i) does not contain an active ingredient other than a substance:
    - (A) specified in Part 1 of Schedule 1; or
    - (B) declared in writing by the Authority to be a complementary medicine substance for the purpose of this definition; and
  - (ii) does not contain a substance:
    - (A) specified in Part 2 of Schedule 1; or
    - (B) declared in writing by the Authority not to be a complementary medicine substance for the purposes of this definition; or
- (b) a homoeopathic medicine; or
- (c) an anthroposophic medicine; or
- (d) an essence.

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## 1.06 Presentation that is not acceptable

- (1) For this Rule, the presentation of a medicine is *not acceptable* if it is capable of being misleading or confusing as to the content or proper use or identification of the medicine.
- (2) Without limiting subsection (1), the presentation of a medicine is not acceptable:
  - (a) if it states or suggests that the medicine has an ingredient, component or characteristic that it does not have; or
  - (b) if the product name is the same as the product name applied to another medicine that:
    - (i) is supplied in Australia or New Zealand; and
    - (ii) contains an additional or different therapeutically active ingredient; or
  - (c) if the label of the medicine does not declare the presence of an active ingredient; or
  - (d) if a form of presentation of the medicine could lead to unsafe use of the medicine or suggests a purpose that is not in accordance with a condition applicable to the supply of the medicine; or
  - (e) if the label of the medicine includes any information that would, if the label were an advertisement, be contrary to the following requirements of Part B1 of the Advertising Code:
    - (i) Requirement 3;
    - (ii) sections R4.1 and R4.2 of Requirement 4;
    - (iii) Requirement 5; or
  - (f) in a case (if any) specified, for the purposes of this paragraph, in an Order.
- (3) In paragraph (2) (b), *product name* has the same meaning as in subsection 3.10 (8).

*Note* For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Act; and
- (b) in New Zealand — [Part 2] of the Act.

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## Part 2 Standards

### 2.01 Overview of this Part

This Part provides for the application of standards to medicines. Standards may relate to any matter relevant to the quality, safety or efficacy of a medicine. Standards may be determined by the Authority or may be adopted. Generally, a medicine must not be imported, exported or supplied if it does not conform to an applicable standard.

### 2.02 Determination of standards

- (1) The Authority may, from time to time, by Order, determine that matters specified in the Order constitute a standard for a medicine, or for medicines of a particular kind, identified in the Order.
- (2) The Authority may, by Order, determine that a standard constituted by the Order does not apply to a medicine, or to medicines of a particular kind, identified in the Order.
- (3) Subject to subsection (4), the Authority must not determine a standard, or amend or revoke an Order determining a standard, unless the Authority has consulted with respect to the proposed action with the appropriate expert advisory committee.
- (4) In exceptional circumstances in the nature of an urgent public health need or other emergency, the Authority may determine a standard, or amend an Order determining a standard, without first consulting with the appropriate expert advisory committee, but must submit the determination or amendment to the committee within 6 months for its advice on the determination or amendment.

*Note 1* A standard that applies to a medicine may also apply to an ingredient or component in the manufacture of the medicine, and to a container or part of a container for the medicine, ingredient or component: see the definition of *therapeutic product* in Article 1 of the Agreement.

*Note 2* For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Act; and
- (b) in New Zealand — [Part 2] of the Act.

### 2.03 Content of standards

- (1) Without limiting the scope of section 2.02, an Order determining a standard for a medicine, or for medicines of a particular kind, may:
  - (a) specify matters by reference to:
    - (i) the quality of the medicine, or of medicines of that kind; or

- 
- (ii) the quantity of the medicine, or of medicines of that kind, when contained in specified containers; or
  - (iii) procedures to be carried out in the manufacture of the medicine, or of medicines of that kind; or
  - (iv) a default standard; or
  - (v) a monograph in another publication approved in writing by the Authority for the purposes of this subsection; or
  - (vi) such a monograph as modified in a manner specified in the Order; or
  - (vii) a standard published by a standards organisation; or
  - (viii) such other matters as the Authority thinks fit; or
- (b) require that a matter relating to the standard be determined in accordance with a particular test; or
  - (c) require that the medicine, or kind of medicines, identified in the Order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the Order.
- (2) For the purposes of subparagraph (1) (a) (vii), these are *standards organisations*:
- (a) Standards Australia Limited;
  - (b) Standards New Zealand;
  - (c) the International Organisation for Standardization;
  - (d) the European Committee for Standardization;
  - (e) any other organisation declared by the Authority by notice published in the Authority Gazette.
- (3) Without limiting the generality of paragraph (1) (c), the Authority, in an Order determining a standard, may direct that there be set out, in a specified manner, on:
- (a) a medicine, or medicines of a particular kind, identified in the Order; or
  - (b) a container or package containing a medicine, or medicines of a particular kind, identified in the Order; or
  - (c) a label of a medicine, or medicines of a particular kind, identified in the Order;
- such particulars as are specified in the Order.

## **2.04 Application of standards**

- (1) If a standard is determined for a medicine, or for medicines of a particular kind, by an Order under section 2.02, and is in force, that standard applies to the medicine, or to medicines of that kind.
- (2) If there is no standard determined for a medicine, or for medicines of a particular kind, by an Order under section 2.02, or no such standard is in force, the appropriate default standard (if any) applies to the medicine, or to medicines of that kind.

- 
- (3) In subsection (2):

***default standard***, for a medicine, means a monograph relating to the medicine in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary, as interpreted by the General Notices section of the particular pharmacopoeia.

## 2.05 Special provisions relating to standards

### *Statements in default standards*

- (1) For the purposes of this Part, if a statement in a default standard (the ***first statement***) refers to a statement in a monograph in another publication (the ***second statement***), the first statement is taken to include the second statement.
- (2) Subsection (1) does not apply if the first statement is a statement in a monograph in the United States Pharmacopoeia-National Formulary that refers to conformance with a regulation made by the Food and Drug Administration of the United States of America.

### *Labelling and packaging requirements*

- (3) Subject to subsection (4), if:
- (a) a standard applicable to a kind of medicine is a default standard; and
  - (b) a requirement applicable to the labelling or packaging of medicines of that kind is specified in the default standard; and
  - (c) a medicine of that kind is not labelled or packaged in accordance with the requirement;
- the medicine is taken not to conform to the applicable standard.

### *Inconsistency between standards*

- (4) If:
- (a) a standard determined by an Order under section 2.02 applies to a medicine; and
  - (b) a requirement applicable to the medicine is specified in a default standard; and
  - (c) the requirement mentioned in paragraph (b) is inconsistent with a requirement specified in the standard mentioned in paragraph (a);
- the requirement mentioned in paragraph (b) is, so far as it is inconsistent, disregarded for the purposes of this Rule.
- (5) If:
- (a) a standard applies to a particular kind of medicines; and
  - (b) another standard applies to some only of the medicines of that kind; and

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- (c) those standards are inconsistent;  
the standard mentioned in paragraph (a) is, to the extent of the inconsistency, of no effect in relation to the medicines mentioned in paragraph (b).

*Medicines consisting of mixtures of ingredients or combinations of component parts*

- (6) If:
- (a) a medicine consists, or is represented to consist, of a mixture of ingredients or of a combination of component parts; and
  - (b) a standard is applicable to the mixture or the combination;  
that standard takes precedence over any standard that is applicable to the individual ingredients or component parts.
- (7) If:
- (a) a medicine consists, or is represented to consist, of a mixture of ingredients or of a combination of component parts; and
  - (b) there is no standard applicable to the medicine, but a standard is applicable to at least one of the ingredients or component parts; and
  - (c) the Authority has, by Order, determined that the standard does not apply to the medicine;
- the standard is of no effect in so far as it would otherwise apply to the medicine.

## **2.06 Import or supply of non-conforming medicine**

- (1) A person must not:
- (a) import a medicine; or
  - (b) supply a medicine;
- if the medicine does not conform to a standard applicable to the medicine.
- (2) Paragraph (1) (a) does not apply to a medicine if its failure to comply is by reason only of matters relating to packaging or labelling.
- (3) Subsection (1) does not apply to a medicine that is imported or supplied in accordance with an approval granted by the Authority under section 5.02.
- (4) In relation to a failure to comply with subsection (1):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

## **2.07 Export of non-conforming medicine**

- (1) A person must not export a medicine if the medicine does not conform to a standard applicable to the medicine.

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- (2) Subsection (1) does not apply to a medicine that is exported in accordance with an approval granted by the Authority under section 5.02.
  - (3) Subsection (1) does not apply to a medicine that is exported, or to medicine that is exempt from product licensing under section 5.03, if its failure to comply is by reason only of matters relating to labelling of the medicine.
  - (4) In relation to a failure to comply with subsection (1):
    - (a) for Australia — sections [ ] of the Act apply; and
    - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

## **2.08 Treating non-conforming medicines as prohibited imports or exports**

If:

- (a) the importation or export of a kind of medicine is prohibited under section 2.06 or 2.07; and
- (b) the Authority gives written notice to:
  - (i) for Australia — the Chief Executive Officer of the Australian Customs Service; and
  - (ii) for New Zealand — the Chief Executive Officer of the New Zealand Customs Service;

that the Authority wishes the forfeiture provisions of the Customs Act to apply to medicines of that kind;

that Act has effect, for the purposes of those provisions, as if a medicine of that kind were, within the meaning of that Act, a prohibited import or prohibited export.

*Note* See:

- (a) for Australia — [Division 1 of Part XIII of the *Customs Act 1901*]; or
- (b) for New Zealand —[ ].

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## **Part 3                    Product licences for medicines**

### **Division 3.1            General**

#### **3.01            Overview of this Part**

The object of this Part is to prevent (with certain exceptions) the import, export supply and manufacture of a medicine that is not a medicine in respect of which an appropriate product licence is in force. A product licence can be granted in respect of a medicine if the requirements under this Part applying to the medicine are complied with. To be the holder of a product licence a person must reside, or carry on business, in Australia or New Zealand.

A product licence has effect subject to certain conditions that apply automatically under this Rule and, in many cases, further conditions that the Authority may impose at its discretion.

*Note* [Re provision of civil and criminal penalties in principal legislation]

#### **3.02            Need for a product licence**

- (1) Except as otherwise provided in this Rule, a person must not:
  - (a) import a medicine; or
  - (b) export a medicine; or
  - (c) supply a medicine;unless the person is the holder of a product licence that:
  - (d) is in force; and
  - (e) authorises that importation, export or supply of the medicine, as the case may be.
- (2) Except as otherwise provided in this Rule, a person must not manufacture a medicine in Australia or New Zealand, unless the person is the holder of a product licence that:
  - (a) is in force; and
  - (b) authorises:
    - (i) the export of the medicine by the licence holder; or
    - (ii) the supply of the medicine by the licence holder.
- (3) Subsections (1) and (2) do not apply to a person who was not the sponsor of the medicine at the time of the importation, export, supply or manufacture, as the case may be.

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*Note for subsection (3)* In Part 1 of Schedule 1 to the Administration and Interpretation Rule, *sponsor* is defined as follows:

‘*sponsor*, in relation to a therapeutic product, means:

- (a) a person who imports, or arranges the import of, the product; or
- (b) a person who exports, or arranges the export of, the product; or
- (c) a person who, in Australia or New Zealand, manufactures the product, or arranges for another person to manufacture the product, for supply (whether in Australia, New Zealand or elsewhere);

but does not include a person who:

- (d) imports, exports or manufactures the product; or
- (e) arranges the importation, export or manufacture of the product;

on behalf of another person who, at the time of the importation, export, manufacture or arrangements, is a resident of, or is carrying on business in, Australia or New Zealand.’

- (4) Nothing in this section affects the obligation of a manufacturer of a medicine to hold a manufacturing licence under Part 4.
- (5) In relation to a failure to comply with subsection (1) or (2):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* Certain medicines are exempt from licensing, either unconditionally or subject to specified conditions. Medicines may also be exempt from licensing if they are the subject of an approval granted by the Authority for special or experimental use, for authorised prescribers, or in cases of shortage or public health emergency: see, generally, Division 5.3.

*Note 2* [Re criminal and civil penalties, and infringement notices]

### **3.03 Licence holder to reside or carry on business in Australia or New Zealand**

A person may not be the holder of a product licence in respect of a medicine unless the person is a resident of, or carries on business in, Australia or New Zealand.

### **3.04 Activities authorised by a product licence**

- (1) Subject to this section and to sections 3.05 and 3.09, the activities authorised by a product licence in respect of a medicine are the importation, export and supply of the medicine.
- (2) A product licence in respect of an export-only medicine:
  - (a) authorises the export of the medicine (including the importation of the medicine for that purpose); and
  - (b) does not authorise the supply of the medicine (or the importation of the medicine for that purpose).
- (3) A product licence does not authorise the manufacture of a medicine.

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- (4) The activities authorised by a product licence may be limited by the terms and conditions of the licence.

*Note* This section sets out the activities that are authorised by a product licence. The issue of who is required to hold a licence for the conduct of these activities is dealt with in section 3.02. As to manufacturing licences, see Part 4.

### **3.05 Countries in which product licence has effect**

- (1) Subject to the laws of Australia and New Zealand (including a law made in either country for the purpose of Article 12 of the Agreement), a product licence has effect:
- (a) in Australia and New Zealand; or
  - (b) if expressed to have effect in one of those countries only — in that country only.
- (2) A licence that has effect in both countries may be expressed to apply in different ways in each country if:
- (a) the Authority considers that it is desirable for the kind of medicine concerned to be supplied in a different manner or subject to different requirements in the territory of each country, having regard to the differences in public health, safety, environmental or cultural circumstances; or
  - (b) this Rule so provides.

### **3.06 Notification of decision on application for product licence**

- (1) Within 20 working days after making its decision in respect of an application for a product licence for a medicine, the Authority must give the applicant written notice of the Authority's decision and, if the decision is to not grant a licence, or is to grant a licence subject to a condition (other than a condition mentioned in section 3.42), set out in the notice the reasons for the decision.

*Note 1* For the licence application process, see Divisions 3.3, 3.4 and 3.5.

*Note 2* A decision to not grant a licence, or a decision that includes a decision to attach a condition (other than a general condition) to a licence, is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

- (2) If the Authority decides to grant a product licence, it must:
- (a) issue the licence within the period mentioned in subsection (1); and
  - (b) notify the decision in the Authority Gazette as soon as is practicable after the decision is made.

### **3.07 Medicine to have unique identifier**

- (1) On the grant of a product licence in respect of a medicine the Authority must assign a unique identifier to the medicine.
- (2) For subsection (1), a *unique identifier* means a set of numbers, or letters and numbers, that is unique to a medicine.

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### 3.08 Content and period of product licence

- (1) A product licence in respect of a medicine must specify:
  - (a) the date of its commencement; and
  - (b) the unique identifier for the medicine; and
  - (c) particulars about:
    - (i) the medicine; and
    - (ii) the licence holder; and
    - (iii) the manufacture of the medicine, and the manufacturer or manufacturers; and
    - (iv) the indications or intended use of the medicine; and
  - (d) the country, or countries, in which the licence has effect; and
  - (e) the conditions subject to which the licence is granted; and
  - (f) other information, if any, that the Authority regards as significantly relevant to the issuing of the licence.
- (2) A product licence (other than a provisional product licence) in respect of a medicine commences on the day specified in the licence and remains in force unless suspended or revoked.

*Note* Section 3.09 deals with the grant of provisional product licences.

### 3.09 Provisional product licence

- (1) If the Authority decides to not grant a product licence to an applicant in respect of a medicine, on the grounds that there is insufficient information about the safety or efficacy of the medicine available to justify the grant of a licence that is not provisional, but considers that:
  - (a) there is clinical need for a medicine of that kind for the prevention or treatment of a life-threatening disease, disorder or condition; and
  - (b) the medicine offers a likely superior therapeutic benefit over existing treatments (if any);the Authority may grant to the applicant a provisional product licence in respect of the medicine.
- (2) A provisional product licence does not authorise the export of the medicine (or the importation of the medicine for that purpose).
- (3) Subject to this Rule, a provisional product licence has effect for:
  - (a) a period of 2 years from the date of its commencement, or a shorter period specified in the licence; or
  - (b) if the period mentioned in paragraph (a) is extended under subsection (4), that period as so extended.
- (4) On the application in writing of the licence holder, the Authority may extend the period mentioned in paragraph (3) (a) (the **original period**) for a further period not exceeding 2 years from the expiry of the original period.

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- (5) A provisional licence that has been extended under subsection (4) cannot be further extended.
  - (6) A provisional product licence is subject to any conditions that are applicable to the licence under Division 3.7 and, in addition, to the following conditions:
    - (a) the licence holder must continue to test and study the safety and efficacy of the medicine, and, at least annually, report to the Authority the results of the tests and studies;
    - (b) the licence holder must comply with any restriction imposed by the Authority regarding the person, persons or classes of persons to whom the medicine may be supplied;
    - (c) the licence holder must comply with any restriction imposed by the Authority regarding the person, persons or classes of persons in respect of whom the medicine may be used;
    - (d) the licence holder must comply with any restriction imposed by the Authority regarding the person, persons or classes of persons by whom the medicine may be administered;
    - (e) the licence holder must ensure that any advertising or promotion of the medicine must, in addition to complying with this Rule and the Advertising Rule, comply with the written approval of the Authority.

### 3.10 When is a medicine separate and distinct?

#### *Class 1 Medicines*

- (1) For the purposes of this Rule, a Class 1 medicine is taken to be separate and distinct from other therapeutic products if, in relation to those products, it is different in respect of its:
  - (a) product name; or
  - (b) dosage form; or
  - (c) active ingredient; or
  - (d) quantity of active ingredient; or
  - (e) excipient ingredient; or
  - (f) quantity of a restricted ingredient that is an excipient; or
  - (g) concentration of a restricted ingredient, if the restriction on the ingredient relates to its concentration; or
  - (h) recommended single or daily dose set out in the directions for use, if, in respect of a restricted ingredient, the restriction relates to its quantity in the recommended single or daily dose; or
  - (i) indications.

*Note* For the classification of Class 1 medicines, see Division 3.2.
- (2) For subsection (1), a substance is a ***restricted ingredient*** if:
  - (a) it is an ingredient in a Class 1 medicine; and

- 
- (b) for that medicine to be, or to remain, eligible as a Class 1 medicine, the permissible quantity or concentration of the substance in the medicine is restricted by operation of any of the following:
- (i) an Order made for the purposes of section 3.13;
  - (ii) the Scheduling Standard;
  - (iii) a condition of a product licence;
  - (iv) a standard;
  - (v) any other provision of an Order relating to Class 1 medicines.

### *Class 2 Medicines*

- (3) For the purposes of this Rule, a Class 2 medicine is taken to be separate and distinct from other therapeutic products if, in relation to those products, it is different in respect of its:
- (a) product name; or
  - (b) dosage form; or
  - (c) formulation or composition; or
  - (d) strength, or size (disregarding packaging size); or
  - (e) indications; or
  - (f) directions for use; or
  - (g) type of container.

*Note* For the classification of Class 2 medicines, see Division 3.2.

### *Export-only (Class 1) Medicines*

- (4) For the purposes of this Rule, an export-only (Class 1) medicine is taken to be separate and distinct from other therapeutic products if, in relation to those products, it is different in respect of its:
- (a) dosage form; or
  - (b) formulation or composition; or
  - (c) strength, or size (disregarding packaging size); or
  - (d) indications.

*Note* For the classification of export-only (Class 1) medicines, see Division 3.2.

### *Export-only (Class 2) Medicines*

- (5) For the purposes of this Rule, an export-only (Class 2) medicine is taken to be separate and distinct from other therapeutic products if, in relation to those products, it is different in respect of its:
- (a) dosage form; or
  - (b) formulation or composition; or
  - (c) strength, or size (disregarding packaging size); or
  - (d) indications.
  - (e) directions for use; or

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(f) type of container.

*Note* For the classification of export-only (Class 2) medicines, see Division 3.2.

- (6) for the purpose of paragraphs (3) (g) and (5) (f), a difference in the size of a container is not a difference in the type of container.
- (7) For the purposes of this Rule, if:
- (a) a person applies for a product licence in respect of a medicine that is not, under subsection (1), (3), (4) or (5), separate and distinct from another therapeutic product in respect of which:
    - (i) an application for a product licence has been made and has not yet been determined; or
    - (ii) a product licence is in force; and
  - (b) the person is not:
    - (i) the applicant in respect of the application mentioned in subparagraph (a) (i); or
    - (ii) the holder of the product licence mentioned in subparagraph (b) (ii);

the medicine is taken to be separate and distinct.

(8) In this section:

***product name***, of a therapeutic product, means the name assigned to the product by an applicant or licence holder, including any trade name or trade mark, together with other information (such as statements or logos) appearing on the label that, in combination, uniquely distinguish therapeutic products supplied, or to be supplied, by the applicant or licence holder:

- (a) from each other; or
- (b) from therapeutic products supplied by other persons.

***[Drafter's note: Provision will be made in this Part, and by an Order, to enable the replacement and concurrent grouping of medicines under a single product licence in certain circumstances.]***

## **Division 3.2      Classification of medicines**

### **3.11      Purpose of classification**

For the purposes of this Rule, a medicine is taken to be:

- (a) a Class 1 medicine; or
- (b) a Class 2 medicine; or
- (c) an export-only (Class 1) medicine; or
- (d) an export-only (Class 2) medicine.

*Note* A Class 1 medicine is regarded as constituting a lower level of risk to a person using or administering it than does a Class 2 medicine.

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### 3.12 What is a Class 1 medicine?

A medicine is a Class 1 medicine if it:

- (a) contains only Class 1 permitted ingredients; and
- (b) is any of the following:
  - (i) a medicine that complies with the criteria specified in section 1.01 of Schedule 2;
  - (ii) a homoeopathic medicine or anthroposophic medicine that complies with the criteria specified in section 1.02 of Schedule 2;
  - (iii) a sunscreen preparation that complies with the criteria specified in section 1.03 of Schedule 2;
  - (iv) a medicine of a kind mentioned in section 1.04 of Schedule 2 that complies with the criteria specified for that medicine;
  - (v) a medicine kit that complies with the criterion specified in section 1.05 of Schedule 2; and
- (c) is not an export-only medicine.

### 3.13 Class 1 permitted ingredients

- (1) For this Rule, a substance is a *Class 1 permitted ingredient* if:
  - (a) it is a substance included in a list of ingredients set out in the Orders that are specified as ingredients permitted in a Class 1 medicine; and
  - (b) its use as an ingredient is in accordance with any conditions or qualifications applying to the inclusion of the substance in that list.
- (2) For the purposes of subsection (1), the Orders may provide for separate lists of ingredients for substances of different kinds.
- (3) A substance that is a herbal material is not permitted as a Class 1 permitted ingredient unless it is a Class 1 herbal ingredient.
- (4) In this section:
  - approved herbal material* means a herbal material approved by the Authority, in writing, for use in a Class 1 medicine;
  - Class 1 herbal ingredient* means:
    - (a) a traditional preparation of an approved herbal material, obtained by methods traditionally used to prepare that herbal material for therapeutic application; or
    - (b) a non-traditional preparation of an approved herbal material that:
      - (i) is not obtained by using a chemical transformation process; and
      - (ii) either:
        - (A) is not significantly different from a traditional preparation of that approved herbal material that is an active ingredient in a licensed Class 1 medicine; or
        - (B) is otherwise assessed by the Authority as safe for use as an ingredient in a Class 1 medicine.

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**herbal material** means a plant or part of a plant (defined by its botanical scientific name according to the binominal nomenclature system, including author, and by the plant part), whether whole, fragmented, cut or ground, and in an unprocessed state (whether fresh or dried).

- (5) The Authority may, by Order, set out:
  - (a) a process for determining the matter mentioned in sub-subparagraph (b) (ii) (A) of the definition of ‘Class 1 herbal ingredient’ in subsection (4); and
  - (b) a process for assessment of the matter mentioned in sub-subparagraph (b) (ii) (B) of that definition.

### **3.14 Class 1 permitted ingredients list — applications for inclusion**

- (1) A person may apply to the Authority for inclusion of a substance in a list of Class 1 permitted ingredients.
- (2) An application must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (3) An application is not effective unless:
  - (a) the application complies with subsection (2); and
  - (b) the prescribed application fee under Part 11 has been paid; and
  - (c) the application contains no information that is false or misleading in a material particular.

*Note* [Re penalties for false or misleading statements].

### **3.15 Class 1 permitted ingredients list — decision on an application**

- (1) The Authority must consider and determine an effective application under section 3.14.
- (2) The Authority, in making its decision, must have regard to:
  - (a) whether the applicant has given to the Authority all information requested by the Authority in relation to the application; and
  - (b) whether the substance:
    - (i) meets the applicable requirements for not being included in the Scheduling Standard; or
    - (ii) in the case of a substance permitted, for the purposes of paragraph (b) of item 1.02 of Schedule 2, in an Order — complies with the criteria specified in the Order.
- (3) In subparagraph (2) (b) (i):

**applicable requirements** means the factors for the classification of medicines set out in policy guidelines issued by an appropriate committee of the Australian Health Ministers’ Advisory Council recognised for this purpose by the Ministerial Council.

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- (4) Before including a substance in the list of Class 1 permitted ingredients, the Authority must have assessed the substance to be safe as an ingredient for use in a Class 1 medicine, and, for that purpose, may:
    - (a) consider any matter relevant to the assessment; and
    - (b) consider the advice of an expert advisory committee; and
    - (c) consider the advice of any other person the Authority believes has relevant expertise.
  - (5) In including a substance in the list of Class 1 permitted ingredients, the Authority may attach conditions or qualifications to its use as an ingredient.

### **3.16 Class 1 permitted ingredients list — notice to applicant**

Within 20 working days after making a decision in respect of an application under section 3.14, the Authority must give the applicant written notification of the decision and, if the decision is to not include a substance in the list of Class 1 permitted ingredients, or is to include the substance subject to a condition or qualification, set out in the notice the reasons for the decision.

### **3.17 What is a Class 2 medicine?**

A medicine is a Class 2 medicine if it is not:

- (a) a Class 1 medicine; or
- (b) an export-only medicine; or
- (c) a medicine in respect of which an exemption or approval under Division 5.3 is in force.

*Note* Division 5.3 relates to exemptions from the requirements of product licensing.

### **3.18 What is an export-only medicine?**

- (1) A medicine is an *export-only medicine* if it is intended to be exported to a country that is not Australia or New Zealand, and will not be supplied in Australia or New Zealand.
- (2) An export-only medicine is:
  - (a) an *export-only (Class 1) medicine*, if it has the composition and character of a Class 1 medicine; or
  - (b) an *export-only (Class 2) medicine*, if it has the composition and character of a Class 2 medicine.
- (3) For the purposes of paragraph (2) (a), an export-only medicine does not cease to have the composition and character of a Class 1 medicine by reason only that the medicine contains an ingredient mentioned in paragraph 3.13 (1) (a) that, in respect of its use, does not comply with a condition or qualification mentioned in paragraph 3.13 (1) (b) relating to labelling.

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## Division 3.3      Licensing of Class 1 Medicines

### 3.19      Application for a product licence — Class 1 medicine

- (1) An application for a product licence in respect of a Class 1 medicine must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (2) An application is not effective unless:
  - (a) it complies with subsection (1); and
  - (b) the prescribed application fee under Part 11 has been paid; and
  - (c) the application is supported by sufficient information, in a form acceptable to the Authority, to enable its assessment; and
  - (d) it is supported by the certification mentioned in section 3.20; and
  - (e) if section 3.21 applies in relation to the medicine — it is accompanied by a certificate mentioned in that section; and
  - (f) if section 3.22 applies in relation to the medicine — it is accompanied by a certificate mentioned in that section; and
  - (g) the application includes no information that is false or misleading in a material particular.

*Note* [Re penalties for making false or misleading statement]

### 3.20      Applicant certification — Class 1 medicine

The applicant for a product licence in respect of a Class 1 medicine must certify that:

- (a) the medicine is a Class 1 medicine; and
- (b) the medicine is safe for the purpose or purposes for which it is designed to be used; and
- (c) the medicine conforms to every standard (if any) applicable to it; and
- (d) advertising of the medicine complies with the requirements (if any) applicable to it under this Rule or the Advertising Rule, relating to advertising; and
- (e) the medicine complies with the requirements (if any) applicable to it under this Rule, and under the Orders, relating to quality and safety; and
- (f) for a medicine manufactured in Australia or New Zealand — each step in the manufacture has been carried out by a person who:
  - (i) is the holder of a manufacturing licence to carry out that step; or
  - (ii) is exempt, under this Rule, from the requirement to hold a manufacturing licence to carry out that step; and
- (g) the medicine contains no substance that is a prohibited import; and

- 
- (h) the applicant holds information or other evidence that:
    - (i) supports any claim made by the applicant in relation to the medicine; and
    - (ii) complies with the requirements (if any) specified in the Orders; and
  - (i) the applicant holds product specifications and labels (draft or actual) for the medicine; and
  - (j) the applicant holds data that demonstrates that the specifications attributed to the product by the manufacturer will continue to be met for the duration of the shelf life nominated by the manufacturer under the storage conditions nominated by the manufacturer; and
  - (k) all of the manufacturers of the medicine are nominated as manufacturers in the application; and
  - (l) the presentation of the medicine is acceptable; and
  - (m) the applicant is a resident of, or carries on business in, Australia or New Zealand; and
  - (n) the application contains no information that is false or misleading in a material particular.

*Note 1* For paragraph (l), section 1.06 sets out the kinds of presentation that are not acceptable.

*Note 2* [Re penalties for making false or misleading statement]

### **3.21 Foreign manufacture — Class 1 medicine**

If a step in the manufacture of a Class 1 medicine has been carried out outside Australia and New Zealand, the applicant for a product licence in respect of the medicine must have obtained from the Authority, before the application is lodged, a certificate stating that the manufacturing and quality control procedures used in the step are acceptable to the Authority.

### **3.22 Class 1 medicine containing ingredient of animal origin**

If a Class 1 medicine contains any ingredient of animal origin in respect of which the Authority considers that there is a safety risk associated with its use, the applicant must have obtained from the Authority, before the application is lodged, a certificate that the ingredient is acceptable to the Authority (subject to any specified condition) for use in the medicine.

### **3.23 Grant of licence — Class 1 medicine**

If:

- (a) an application under section 3.19 for a product licence in respect of a medicine is an effective application; and
- (b) the medicine is separate and distinct from other therapeutic products; and
- (c) the Authority has validated the key data in the application; and

- 
- (d) in the case of a medicine in respect of which a product licence has previously been granted — that product licence has not been suspended or revoked;

the Authority must grant to the applicant a licence in respect of the medicine.

*Note 1* For information about what constitutes a separate and distinct medicine, see section 3.10.

*Note 2* For notification of decisions on an application see section 3.06.

*Note 3* For conditions of a licence see Division 3.7.

## **Division 3.4          Licensing of Class 2 medicines**

### **3.24          Calculation of periods for this Division**

The following periods are to be disregarded in calculating, for the purposes of a provision in this Division, the number of working days taken to perform the action that the provision requires to be performed:

- (a) the period commencing on the day on which the Authority sends a query, or a request for information, to an applicant and ending at the end of the day on which the Authority receives from the applicant a complete response to the query or request;
- (b) the period commencing on the day of lodgement of an appeal concerning the application for which the action is required to be performed and ending at the end of the day on which the appeal is finally disposed of;
- (c) any other period to which the Authority and the applicant agree in writing for the purposes of this section.

*Note* The term *working day* is defined in the Administration and Interpretation Rule.

### **3.25          Application for a product licence — Class 2 medicine**

- (1) An application for a product licence in respect of a Class 2 medicine must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (2) An application is not effective unless:
  - (a) the application complies with subsection (1); and
  - (b) the prescribed application fee under Part 11 has been paid; and
  - (c) the application is supported by sufficient information, in a form acceptable to the Authority, to enable evaluation of the medicine and assessment of the application under this Division; and
  - (d) the application includes no information that is false or misleading in a material particular.

*Note* [Re penalties for a false or misleading statement].

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### 3.26 Evaluation of Class 2 medicine

- (1) Before a product licence can be granted by the Authority in respect of a Class 2 medicine, the Authority must evaluate the medicine in respect of its quality, efficacy and safety.
- (2) On receipt of an application for such a product licence, the Authority must send written notice to the applicant stating whether the application has been accepted or rejected for evaluation.
- (3) The notice must be sent:
  - (a) if section 3.30 applies in relation to the evaluation — within 20 working days; or
  - (b) in any other case — within 40 working days; after the day of receipt of the application.
- (4) An application lapses if:
  - (a) any part of the evaluation fee payable under Part 11 in respect of the application remains unpaid at the end of the period of 40 working days after the day on which the amount became due and payable; or
  - (b) the application contains information that is inaccurate or misleading in a material particular; or
  - (c) information given to the Authority by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 8.02, is inaccurate or misleading in a material particular; or
  - (d) the applicant fails to comply with a requirement under section 8.02 to give information consisting of individual patient data in relation to the products.
- (5) In this section, *individual patient data*, in relation to a medicine, means information, derived from clinical trials, relating to individuals before, during and after the administration of the medicine to those individuals, including, but not limited to, demographic, biochemical and haematological information.

### 3.27 Evaluation fee

- (1) An evaluation fee in accordance with Part 11 is payable for the evaluation of a Class 2 medicine.
- (2) The evaluation fee is due and payable on the day on which the application is made.

### 3.28 Reduction of evaluation fee where evaluation period exceeded

- (1) If the evaluation of a Class 2 medicine (other than an evaluation to which section 3.30 applies) is not completed within 255 working days after notification under paragraph 3.26 (3) (b), the applicable total evaluation fee under section 3.27 is reduced by one quarter.

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- (2) For the purpose of this section, the evaluation is to be taken to be completed:
- (a) when the applicant is notified, under section 3.06, of the Authority's decision on the application for a product licence; or
  - (b) if:
    - (i) the Authority has given the applicant all evaluation reports relating to the medicine; and
    - (ii) the Authority has given those reports, or proposes to give those reports, to an appropriate expert advisory committee for advice; and
    - (iii) the applicant withdraws the application after being given the reports, and before the end of the period mentioned in subsection (1);at the time of the withdrawal.
- (3) If, in respect of an application, the fee is reduced under subsection (1), the Authority must repay to the applicant the amount by which the fee is reduced.

### **3.29 Deemed refusal to grant licence**

- (1) If, at the end of 255 working days after notification under paragraph 3.26 (3) (b), evaluation in respect of an application for a product licence has not been completed, the applicant may give the Authority, at any time before the evaluation is completed, written notice that the applicant wishes to treat the application as having been refused.
- (2) If a notice has been given under this section, this Rule has effect as if:
- (a) the Authority had decided to not grant the licence; and
  - (b) that decision had been made on the day on which notice was given under this section.

### **3.30 Shorter evaluation period in certain cases**

- (1) Subject to subsection (2), this section applies to the evaluation of a Class 2 medicine in relation to an application for a product licence if:
- (a) it is a medicine of a kind mentioned in Part 1 of Schedule 3; and
  - (b) the applicant holds a product licence for a medicine that contains the same active ingredient or active ingredients, in the same dosage form and strength, as the medicine that is the subject of the application.
- (2) This section does not apply to an application that, in the opinion of the Authority, needs to be supported by clinical, non-clinical or bio-equivalence data.
- (3) In the case of an application to which this section applies, the Authority must:
- (a) decide the application and notify the applicant of the decision; or

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- (b) raise an objection concerning the application;  
within 45 working days after the day on which the application is lodged and the evaluation fee payable under Part 11 is paid or, if lodgement and payment occur on different days, after the later of those days.
- (4) If the Authority raises an objection concerning the application, the Authority must decide the application and notify the applicant of the decision within 30 working days after the day on which the Authority receives the applicant's response to the objection.
- (5) If the Authority does not comply with subsection (3) and, if applicable, subsection (4) in the case of an application to which this section applies, the Authority is taken to have approved the application.

### **3.31 Priority evaluation**

- (1) The Authority may give priority to the evaluation of a Class 2 medicine if:
- (a) the active ingredient is a new chemical entity; and
  - (b) the medicine is indicated for the treatment or diagnosis of a disease, disorder or condition that is life-threatening or otherwise severely debilitating; and
  - (c) there are grounds for believing that the medicine may provide an important therapeutic gain; and
  - (d) the Authority considers that it is in the interests of public health for the evaluation to be given priority; and
  - (e) the applicant agrees to, and does, give timely and adequate information to the Authority in response to any reasonable request by the Authority for information relating to the evaluation.
- (2) A decision to give priority to an evaluation:
- (a) does not require the Authority to complete the evaluation within a shorter period than if priority was not given to the evaluation; and
  - (b) may be revoked at any time if:
    - (i) the applicant does not comply with paragraph (1) (e); or
    - (ii) it appears to the Authority that any information provided by the applicant for the purposes of this section was false or misleading.

### **3.32 Evaluation process — general**

- (1) In evaluating a Class 2 medicine, the Authority must determine:
- (a) whether the quality, safety and efficacy of the medicine for the purpose for which it is to be used have been satisfactorily established; and
  - (b) whether the presentation of the medicine is acceptable; and
  - (c) whether the medicine conforms to any applicable standard; and
  - (d) if the medicine has been manufactured in Australia or New Zealand — whether it has been manufactured in accordance with Part 4; and

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- (e) if a step in the manufacture of the medicine has been carried out outside Australia and New Zealand — whether the manufacturing and quality control procedures used in the step are acceptable; and
  - (f) whether all manufacturers of the medicine are nominated in the application as its manufacturers; and
  - (g) if Part 7 applies in relation to the medicine — whether the product information document for the medicine complies with the requirements under that Part;
  - (h) such other matters (if any) as the Authority considers relevant.

*Note* The Authority must not use protected information to support the evaluation of a medicine for a product licence (see section 3.33).

- (2) For paragraph (1) (a), the evaluation process includes having regard to the principle that the concepts of safety and efficacy must be judged in relation to each other and in accordance with the state of relevant scientific knowledge at the time of the evaluation.
- (3) If an exemption from the operation of Part 4 is in force in respect of the manufacture of the medicine, subsection (1) has effect, in relation to the medicine, as if paragraph (d) were omitted.
- (4) If an exemption from the operation of Part 4 is in force in respect of a step in the manufacture of the medicine, subsection (1) has effect, in respect of the medicine, as if the reference in paragraph (d) to Part 4 were a reference to that Part to the extent that it does apply to a person in relation to the manufacture of the medicine.
- (5) If:
  - (a) the medicine was manufactured outside Australia or New Zealand; and
  - (b) had the medicine been manufactured in Australia or New Zealand, an exemption from the operation of Part 4 would have been force in respect of the medicine;subsection (1) has effect, in relation to the medicine, as if paragraph (e) were omitted.
- (6) In making a decision for the purpose of paragraph (1) (e), the matters that may be taken into account include:
  - (a) whether the applicant has provided an acceptable form of evidence from an overseas authority that is acceptable to the Authority, establishing that the manufacture of the medicine is of a standard at least equivalent to the standard required for an equivalent licensed manufacturer in Australia or New Zealand; and
  - (b) whether the applicant has agreed to provide, in the event that the Authority considers an audit of the manufacturing procedures used in the manufacture of the medicine to be necessary:
    - (i) funds for the carrying out of that audit by the Authority; and
    - (ii) evidence that the manufacturer has agreed to such an audit.

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- (7) A decision for the purpose of paragraph (1) (e) may also take into account any information provided to the Authority by a health authority of a country that is a party to a Mutual Recognition Agreement.
  - (8) Information referred to in subsection (7), and provided in accordance with a Mutual Recognition Agreement, is taken to be equivalent to information obtained as a result of an audit under Part 4.
  - (9) In evaluating a medicine, the Authority may:
    - (a) seek the advice of an appropriate expert advisory committee; and
    - (b) take any such advice into account.

### **3.33 Authority not to use protected information**

- (1) When evaluating a Class 2 medicine in relation to an application for the grant of a product licence, the Authority must not use information about another medicine that is protected information.
- (2) Subsection (1) does not apply if the information is about a medicine in respect of which the applicant for the product licence already holds a product licence.
- (3) For subsection (1), information is *protected information* if:
  - (a) the information was given to the Authority in connection with an application for a product licence in respect of a medicine (the *new medicine*); and
  - (b) the information is about the active moiety of an active ingredient that the new medicine consists of, or contains, and is not available to the public; and
  - (c) when the application was lodged, no other licence was, or had previously been, in force in respect of a medicine containing that active moiety; and
  - (d) 5 years have not elapsed since the day on which the licence in respect of the new medicine was granted; and
  - (e) the licence holder has not given the Authority permission, in writing, to use the information for any other purpose.

- (4) In this section:

*active moiety*, of an active ingredient, means a part or portion of a molecule, generally complex, having a characteristic chemical or pharmacological property, being the portion of the active ingredient that is responsible for the effect of the active ingredient.

*[Drafter's Note 1 A transitional provision will be necessary in respect of products registered before the commencement of the Trans-Tasman Scheme]*

*[Drafter's Note 2 Indemnity provisions relating to the Authority will appear in the implementing legislation for each country]*

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### **3.34 Grant of licence — Class 2 medicine**

- (1) The Authority must consider and determine an application under section 3.25 for a product licence in respect of a medicine on the basis of the matters set out in subsection (2).
- (2) If:
  - (a) the application is effective in accordance with this Rule; and
  - (b) the medicine is separate and distinct from other therapeutic products; and
  - (c) the Authority is satisfied, upon the evaluation of the medicine, that all the criteria set out in section 3.32 for the grant of a licence in respect of the medicine are met; and
  - (d) the applicant is a resident of, or carries on business in, Australia or New Zealand;the Authority must grant to the applicant a licence in respect of the medicine.

*Note 1* For information about what constitutes a separate and distinct medicine, see section 3.10.

*Note 2* For conditions of a licence see Division 3.7.

## **Division 3.5 Licensing of export-only medicines**

### **3.35 Application for a product licence — export-only medicine**

- (1) An application for a product licence in respect of an export-only medicine must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (2) An application is not effective unless:
  - (a) it complies with subsection (1); and
  - (b) the prescribed application fee under Part 11 has been paid; and
  - (c) the application is supported by sufficient information, in a form acceptable to the Authority, to enable its assessment; and
  - (d) it is supported by the certification mentioned in section 3.36; and
  - (e) if section 3.37 applies in relation to the medicine — it is accompanied by a certificate mentioned in that section; and
  - (f) if section 3.38 applies in relation to the medicine — it is accompanied by a certificate mentioned in that section; and
  - (g) the application includes no information that is false or misleading in a material particular.

*Note* [Re penalties for making a false or misleading statement]

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### 3.36 Applicant certification — export-only medicine

- (1) The applicant for a product licence in respect of an export-only (Class 1) medicine or an export-only (Class 2) medicine must certify that:
  - (a) the medicine is intended to be exported to a country that is not Australia or New Zealand, and will not be supplied in Australia or New Zealand; and
  - (b) the medicine is safe for the purpose or purposes for which it is designed to be used; and
  - (c) the medicine conforms to every standard (if any) applicable to it; and
  - (d) the medicine complies with any requirements (if any) relating to quality or safety prescribed by this Rule, or the Orders, and applicable to the medicine; and
  - (e) for a medicine manufactured in Australia or New Zealand — each step in the manufacture has been carried out by a person who:
    - (i) is the holder of a manufacturing licence to carry out that step; or
    - (ii) is exempt, under this Rule, from the requirement to hold a manufacturing licence to carry out that step; and
  - (f) the medicine contains no substance that is a prohibited export for the country from which it is to be exported; and
  - (g) the applicant:
    - (i) holds information or other evidence in support of any claim made by the applicant in relation to the medicine; or
    - (ii) can demonstrate that, under a written agreement between the applicant and the importer of the medicine into the destination country, the importer is wholly responsible for substantiation of claims made in relation to the medicine; and
  - (h) the applicant holds product specifications and labels (draft or actual) for the medicine; and
  - (i) the applicant:
    - (i) holds data that demonstrates that the specifications attributed to the product by the manufacturer will continue to be accurate for the duration of the shelf life nominated by the manufacturer under the storage conditions nominated by the manufacturer; or
    - (ii) can demonstrate that, under a written agreement between the applicant and the importer of the medicine into the destination country, the importer is wholly responsible for determining the shelf life that is nominated for the medicine; and
  - (j) for:
    - (i) an export-only Class 1 medicine — the medicine does not contravene any requirement, known to the applicant, of the destination country, or countries, that affects its eligibility for importation into that country or those countries; or
    - (ii) an export-only Class 2 medicine — the medicine complies with all regulatory requirements of the destination country, or

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- countries, that affect its eligibility for importation into that country or those countries; and
- (k) the applicant is a resident of, or carries on business in, Australia or New Zealand; and
  - (l) the application contains no information that is false or misleading in a material particular.

*Note* [Re penalties for making false or misleading statement]

- (2) If the application is in respect of an export-only (Class 1) medicine, the applicant must also certify that the medicine is an export-only (Class 1) medicine.

### **3.37 Foreign manufacture of export-only medicine**

If a step in the manufacture of an export-only medicine has been carried out outside Australia and New Zealand, the applicant for a product licence in respect of the medicine must have obtained from the Authority, before the application is lodged, a certificate stating that the manufacturing and quality control procedures used in the step are acceptable to the Authority.

### **3.38 Export-only medicine containing ingredient of human or animal origin**

If an export-only medicine contains any ingredient of human or animal origin in respect of which the Authority considers that there is a safety risk associated with its use, the applicant must have obtained from the Authority, before the application is lodged, a certificate that the ingredient is acceptable to the Authority (subject to any specified condition) for use in the medicine.

### **3.39 Pre-licence audit**

- (1) For an application in respect of an export-only (Class 1) medicine, the assessment process must include an initial audit by the Authority if the application discloses that, in respect of the medicine:
  - (a) a product licence has previously been sought that would enable the medicine to be supplied in Australia or New Zealand, and has been refused; or
  - (b) a product licence has previously been suspended or revoked.
- (2) For an application in respect of an export-only (Class 2) medicine, the assessment process must include an initial audit by the Authority if:
  - (a) the medicine contains a substance that is not a substance contained in any other medicine in respect of which a product licence has been granted; or

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- (b) the application discloses that, in respect of the medicine:
    - (i) a product licence has previously been sought that would enable the medicine to be supplied in Australia or New Zealand, and has been refused; or
    - (ii) a product licence has previously been suspended or revoked.
  - (3) An application in respect of an export-only (Class 2) medicine (other than an application to which subsection (2) applies) may be subjected to an initial audit by the Authority if the Authority considers an audit to be appropriate.
  - (4) An audit of an application under subsection (1), (2) or (3) may be conducted on any or all aspects of the application.
  - (5) If the Authority selects an application for audit, the Authority must give the applicant a written notice, within 10 working days after the application is made:
    - (a) informing the applicant of the selection; and
    - (b) requesting the applicant to provide any further information necessary for the auditing.
  - (6) An application that has been selected for auditing lapses if:
    - (a) the applicant does not deliver to the Authority (in the country in which the application was made) such information (in a form approved in writing by the Authority) as will allow the audit of the application; or
    - (b) the applicant does not comply with a requirement by the Authority to deliver to the Authority (in the country in which the application was made) a reasonable number of samples of the kind of medicine to which the application relates; or
    - (c) the applicant fails to comply with the requirements of a notice under section 8.02 to give information in relation to the medicine; or
    - (d) information given to the Authority by, or on behalf of, the applicant in connection with the application, including information given in response to a requirement of a notice under section 8.02, is false or misleading in a material particular.

### **3.40 Grant of licence — export only medicine**

- (1) Subject to subsection (2), if:
  - (a) an application under section 3.35 for a product licence in respect of an export-only medicine is effective in accordance with this Rule; and
  - (b) the medicine is separate and distinct from other therapeutic products; and
  - (c) the Authority has validated the key data in the application;the Authority must grant to the applicant a licence in respect of the medicine.

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- (2) If an application is audited under section 3.39, the Authority, before granting a licence, must be satisfied as to all aspects of the application considered in the audit.
  - (3) The Authority, in considering, for the purposes of an audit, whether it can be satisfied as to the safety of an export-only medicine, may have regard to:
    - (a) whether a relevant authority of the country to which the medicine is to be exported has confirmed that it has no objection to the medicine being imported; and
    - (b) whether a product licence for supply of the medicine has been refused, suspended or revoked.

*Note 1* For information about what constitutes a separate and distinct medicine, see section 3.10.

*Note 2* For conditions of a licence see Division 3.7.

## **Division 3.6            Post-licence audits — Class 1 and export-only medicines**

### **3.41            Post-licence audit — Class 1 and export-only medicines**

- (1) The Authority may audit an application for a product licence in respect of a Class 1 medicine or an export-only medicine at any time after the grant of a product licence in respect of the medicine.
- (2) The purposes of an audit under this section are to:
  - (a) assess or review the quality, safety and efficacy of the medicine for the purpose for which it is designed to be used; and
  - (b) conduct a risk assessment of the medicine; and
  - (c) determine the validity of the applicant's certification under:
    - (i) for a Class 1 medicine — section 3.20; or
    - (ii) for an export-only medicine — section 3.36.

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## Division 3.7      Product licence — conditions

### 3.42      Conditions applicable to all product licences

#### *New manufacturer*

- (1) A product licence in respect of a medicine is subject to the following conditions:
- (a) if a person who was not nominated as a manufacturer of the medicine in the application for the licence is to become a manufacturer (the ***new manufacturer***) in relation to any step in the manufacture, the licence holder will inform the Authority, in writing, of the name and address of the new manufacturer:
    - (i) if the licence is in respect of a Class 2 medicine — before the new manufacturer begins to carry out that step in the manufacture; or
    - (ii) in any other case — before, or as soon as practicable after, the new manufacturer begins to carry out that step in the manufacture;
  - (b) if premises that were not nominated in the application as premises to be used in the manufacture of the medicine are to become premises (the ***new premises***) used in relation to any step in the manufacture, the licence holder will inform the Authority, in writing, of the name and address of the new premises:
    - (i) if the licence is in respect of a Class 2 medicine — before the new premises are used in the manufacture; or
    - (ii) in any other case — before, or as soon as practicable after, the new premises are used in the manufacture;
  - (c) if the person mentioned in paragraph (a) is, or the new premises mentioned in paragraph (b) are, in Australia or New Zealand — the person who is the manufacturer:
    - (i) is the holder of a manufacturing licence in respect of that step in the manufacture of the medicine at those premises; or
    - (ii) is exempt, under this Rule, from the requirement to hold a manufacturing licence in respect of that step in the manufacture of the medicine at those premises;
  - (d) if the person mentioned in paragraph (a) is, or the premises mentioned in paragraph (b) are, outside Australia and New Zealand — the licence holder has obtained certification from the Authority that the manufacturing and quality control procedures used in each step of the manufacture of the medicine, or of medicines of that kind, by the manufacturer at those premises, are acceptable.

*Note* An additional condition is imposed in respect of a change of manufacturer or premises in the case of a class 2 medicine — see section 3.44.

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### *Entry and inspection*

- (2) A product licence in respect of a medicine is subject to the conditions that the licence holder:
- (a) allow an authorised person:
    - (i) to enter, at any reasonable time and whether or not with prior notice, any premises (including premises outside Australia and New Zealand) at which the licence holder, or any other person on behalf of the licence holder, deals with the medicine; and
    - (ii) while on those premises:
      - (A) to inspect the premises, the medicine and any substance or material used in the manufacture of the medicine, at any of its stages of manufacture, at the premises; and
      - (B) to take samples of the medicine and of any substance or material used in the manufacturing processes at no cost to the Authority; and
      - (C) to take visual records of those premises, medicines or processes; and
      - (D) to carry out related duties; and
  - (b) if requested to do so by an authorised person:
    - (i) produce to the authorised person such documents relating to the medicine (or an ingredient or other component) as the person requires; and
    - (ii) allow the authorised person to copy the documents.

### *Compliance with Customs laws*

- (3) A product licence in respect of a medicine is subject to the condition that:
- (a) in respect of any substance imported for the purpose of the manufacture of the medicine, the importation does not contravene:
    - (i) for importation into Australia — regulation 5 of the *Customs (Prohibited Imports) Regulations 1956*; or
    - (ii) for importation into New Zealand — section 54 of the Customs Act; and
  - (b) in respect any export of the medicine, the export does not contravene:
    - (i) for export from Australia — regulation 10 of the *Customs (Prohibited Exports) Regulations 1958*; or
    - (ii) for export from New Zealand — section 56 of the Customs Act.

### *Delivery of samples*

- (4) A product licence in respect of a medicine is subject to the condition that the licence holder will deliver to the Authority a reasonable number of samples of the medicine, if, at any time, the Authority so requests:
- (a) within the period specified in the request (being a period of at least 10 working days); and

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- (b) in a form suitable for the purposes specified in the request; and
  - (c) in accordance with any other requirements specified in the request (for example, including other materials necessary to enable successful testing); and
  - (d) at no cost to the Authority.

*Time-expired medicine*

- (5) A product licence in respect of a medicine is subject to the condition that no batch of the medicine is supplied or exported after the date specified by the manufacturer as the expiry date applying to that batch.

*Display of identifier*

- (6) A product licence in respect of a medicine that is to be supplied in Australia or New Zealand is subject to the condition that the medicine must be supplied with labelling that:
  - (a) clearly displays the unique identifier for the medicine; and
  - (b) otherwise conforms to any requirements specified in this Rule or in the Orders.

*Adverse overseas information*

- (7) A product licence in respect of a medicine that is to be supplied in Australia or New Zealand is subject to the condition that if at any time while the licence is not revoked, the licence holder becomes aware of any information about any product recall or other regulatory action taken by the relevant authority in a country other than Australia or New Zealand where the medicine is distributed, being information that may be relevant to the quality, safety or efficacy of the medicine as supplied, the licence holder will immediately give that information to the Authority.

*Adverse information from third parties*

- (8) A product licence in respect of a medicine is subject to the condition that, at any time while the licence is not revoked, the licence holder will:
  - (a) keep details of information relating to the medicine that:
    - (i) is required, under section 9.02, to be given to the Authority by the licence holder; and
    - (ii) has been given to the licence holder by a person other than the licence holder; and
  - (b) if the Authority so requests, provide those details to the Authority, together with details of that other person, within the period (being a period of at least 10 working days) specified in the request.

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### *Advertising material*

- (9) A product licence in respect of a medicine is subject to the condition that advertising material relating to the medicine:
- (a) is consistent with the intended purpose specified in the licence; and
  - (b) does not, intentionally or recklessly, represent the medicine as effective for indications not specified in the licence; and
  - (c) complies with the Advertising Code.

### *Record-keeping*

- (10) A product licence in respect of a medicine is subject to the condition that, at any time while the licence is in force, the licence holder will maintain records, in a form that will enable, in respect of any batch of the medicine:
- (a) identification of the countries in which medicine from the batch was supplied, or to which it was exported; and
  - (b) identification of every manufacturer involved in the manufacture of medicine from the batch; and
  - (c) identification of the site or sites of manufacture of medicine from the batch; and
  - (d) prompt recall of medicine from the batch.
- (11) A product licence in respect of a medicine is subject to the condition that, at any time while the licence is in force, the licence holder will:
- (a) retain records of the distribution (including export) of the medicine for at least 5 years; and
  - (b) retain records relating to the manufacture of a batch of the medicine for at least 12 months after the expiry date for the batch; and
  - (c) provide the records, or copies of the records, mentioned in paragraph (a) and (b) to the Authority, if requested by the Authority to do so.

### *Subcontracted manufacturing*

- (12) A product licence in respect of a medicine is subject to the condition that, if any step in the manufacture of the medicine is carried out (whether in, or outside, Australia or New Zealand) by a person who is not the licence holder, the licence holder will:
- (a) for so long as that part of the process is performed by that person — retain a copy of its Good Manufacturing Practice contract with that person; and
  - (b) on request by an authorised person, make the contract available for convenient examination by the authorised person.

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### *Offshore manufacturing*

- (13) A product licence in respect of a medicine is subject to the condition that, if any step in the manufacture of the medicine is carried out outside Australia and New Zealand and is a step that, if carried out in Australia or New Zealand, would be required by this Rule to be carried out by the holder of a manufacturing licence in respect of the medicine and on premises to which the manufacturing licence relates, the holder of the product licence:
- (a) will:
    - (i) maintain current evidence, in a form acceptable to the Authority, that the manufacture of the medicine meets the standards required, under this Rule, of an Australian or New Zealand manufacturer; and
    - (ii) on request at any time, deliver a copy of that evidence to the Authority; and
    - (iii) if evidence delivered to the Authority under subparagraph (ii) ceases to be current — deliver to the Authority, within 20 working days after the evidence ceases to be current, a copy of the evidence that is updated and current; or
  - (b) will, if acceptable evidence mentioned in paragraph (a) is not available, meet necessary costs incurred by the Authority in making any reasonable audit and inspection of the manufacturing process and premises.

### *Change necessitating licence variation*

- (14) A product licence in respect of a medicine is subject to the condition that the licence holder must apply promptly for a variation of the licence in respect of a change in:
- (a) the particulars included on a product licence; or
  - (b) information contained in the application for the licence, or in a subsequent application for variation of licence, being information of a kind specified for the purposes of this paragraph in an Order, if the information becomes incorrect or becomes known to be incorrect; or
  - (c) if the medicine is of a kind for which product information is required — the product information; or
  - (d) if the medicine is a Class 2 medicine — the label.
- (15) A change of a kind mentioned in paragraph (14) (c) or (d):
- (a) must not occur until after the requested variation of the licence has been granted; and
  - (b) must comply strictly with the terms of the variation.
- (16) In relation to a failure to comply with a condition mentioned in this section:
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

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*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

### **3.43 Additional conditions — Class 1 medicine**

- (1) If:
  - (a) in, or in connection with, an application for a product licence in respect of a Class 1 medicine, a claim is made by the applicant in relation to the medicine concerned; and
  - (b) the claim is mentioned in the licence issued in respect of the medicine; the product licence is subject to the following conditions:
  - (c) the applicant had, at the time when the claim was made, information or other evidence supporting the claim and complying with the requirements (if any) specified in the Orders;
  - (d) at all times while the licence is in force, the licence holder retains the information or evidence;
  - (e) at any time while the licence is in force, the licence holder will, if asked to do so by the Authority, give the information or evidence to the Authority.
- (2) If a step in the manufacture of a Class 1 medicine is carried out by a manufacturer in a country outside Australia and New Zealand, the product licence is subject to a condition that the licence holder will, if the manufacturer is found to be unacceptable by an authority of that country that is equivalent to the Authority, notify the Authority of that event as soon as the licence holder becomes aware of its occurrence.
- (3) In relation to a failure to comply with a condition mentioned in subsection (1) or (2):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

### **3.44 Additional conditions — Class 2 medicine**

- (1) A product licence in respect of a Class 2 medicine is subject to the following conditions:
  - (a) the licence holder will give notice to the Authority of the date when supply of the medicine begins;
  - (b) the licence holder will give the Authority, in a form acceptable to the Authority, a copy of the label, or labels, with which the medicine is supplied to consumers:
    - (i) when the supply of the medicine begins; and
    - (ii) at any other time, if so requested by the Authority;

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- (c) the licence holder will notify the Authority if an application relating to any form of approval affecting the supply of the medicine (or of the active ingredient in the medicine) in Canada, the European Union or the United States of America is unsuccessful, including details of the application and the reasons for its failure.
- (2) Without limiting paragraph (1) (c), applications to which that paragraph applies include an application relating to:
    - (a) an extension of indications for which the medicine is useful; or
    - (b) a new dosage form or strength; or
    - (c) a new method of administration.
  - (3) If a step in the manufacture of a Class 2 medicine is carried out by a manufacturer in a country outside Australia and New Zealand, the product licence is subject to a condition that the licence holder will, if the manufacturer is found to be unacceptable by an authority of that country that is equivalent to the Authority, notify the Authority of that event as soon as the licence holder becomes aware of its occurrence.
  - (4) A product licence in respect of a Class 2 medicine to which Part 7 applies is subject to a condition that the licence holder will make the product information document publicly available in accordance with the requirements (if any) of an Order under section 7.03.
  - (5) In relation to a failure to comply with a condition mentioned in subsection (1), (3) or (4):
    - (a) for Australia — sections [ ] of the Act apply; and
    - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

### **3.45 Additional conditions — export-only medicine**

- (1) A product licence in respect of an export-only medicine is subject to the following conditions:
  - (a) if the licence holder relies on an agreement between the licence holder and the foreign importer, under which the foreign importer is wholly responsible for substantiation of claims made in relation to the medicine — the licence holder will, on request, give a copy of the agreement to the Authority;
  - (b) if the licence holder relies on an agreement between the licence holder and the foreign importer, under which the foreign importer is wholly responsible for determining the shelf life that is nominated for the medicine — the licence holder will, on request, give a copy of the agreement to the Authority.
- (2) In subsection (1), *foreign importer*, in relation to a medicine, means an importer of the medicine into one or more destination countries.

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- (3) If a step in the manufacture of an export-only medicine is carried out by a manufacturer in a country outside Australia and New Zealand, the product licence is subject to a condition that the licence holder will, if the manufacturer is found to be unacceptable by an authority of that country that is equivalent to the Authority, notify the Authority of that event as soon as the licence holder becomes aware of its occurrence.
- (4) In relation to a failure to comply with a condition mentioned in subsection (1) or (3):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

### **3.46 Discretionary conditions**

- (1) The Authority may impose conditions on a product licence, in addition to the conditions mentioned in other provisions of this Division, relating to any of the following matters:
- (a) the manufacture of the medicine;
  - (b) the custody, use, supply, disposal or destruction of the medicine;
  - (c) testing of the medicine;
  - (d) presentation of the medicine;
  - (e) advertising or promotion of the medicine;
  - (f) the keeping of records relating to the medicine (including post-market records on the use of the medicine in Australia, New Zealand and other countries);
  - (g) matters mentioned in standards applicable to the medicine, or additional matters relevant to applicable standards;
  - (h) such other matters relating to the medicine as the Authority considers appropriate.
- (2) In addition to conditions imposed on the grant of a product licence, the Authority may at any time, by notice in writing given to the licence holder:
- (a) impose new conditions on the licence; or
  - (b) vary or remove existing conditions;
- and may do so at the request of the licence holder, or of the Authority's own motion.
- (3) Without limiting subsection (2), the Authority may impose a condition in respect of a variation to which subsection 3.49 (3) applies, that, if so requested by the Authority, the licence holder will provide to the Authority the evidence used to validate the variation, within such period (being a period of not less than 20 working days after the request is made) as is specified in the request.

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- (4) The imposition or variation of a condition under this section takes effect:
- (a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury — on the day on which the notice is given to the licence holder; or
  - (b) if the notice states that the action is taken because of a perceived risk of death, serious illness or serious injury — on the day on which the notice is given to the licence holder; or
  - (c) in any other case — on the day specified in the notice, being a day not earlier than 20 working days after the notice is given to the licence holder.
- (5) Unless a condition under this section is expressed to apply in respect of a specific batch, or specific batches, of the medicine concerned, the condition is taken to apply in respect of all batches of the medicine.
- (6) In relation to a failure to comply with a condition of a product licence imposed or varied under this section:
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

*Note 3* A decision to impose a condition on a product licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

## **Division 3.8          Product licence — variation**

### **3.47          Variation — General**

- (1) The Authority may vary a product licence in respect of a medicine:
- (a) upon a request in writing to the Authority by the holder of the product licence; or
  - (b) on the Authority's own initiative;  
to correct or complete particulars on a licence that are incorrect or incomplete.
- (2) Nothing in subsection (1) obliges the Authority to comply with a request mentioned in paragraph (1) (a) if the Authority:
- (a) considers that an application for a variation of the licence should be made under this Division; and
  - (b) so notifies the licence holder.
- (3) The holder of a product licence in respect of a medicine must apply for variation of the licence immediately upon the holder becoming aware that:
- (a) information relied on in the application for the licence, or in a subsequent application resulting in variation of the licence, is significantly incorrect or incomplete; or

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- (b) information relating to the safe and effective use of the medicine (including the usefulness and any limitation of the medicine) that appears on the packaging, or in the product information, for the medicine, is incorrect or incomplete.
  - (4) For subsection (3), information is *significantly* incorrect or incomplete if the difference between that information and the information that is correct or complete could have been relevant to the Authority's decision:
    - (a) to grant or vary the product licence; or
    - (b) to grant or vary the licence in the form in which it was issued or varied.
  - (5) The holder of a product licence in respect of a Class 2 medicine must apply for variation of the licence if:
    - (a) the medicine is of a kind to which Part 7 applies; and
    - (b) there is a change to the product information.
  - (6) The holder of a product licence in respect of a Class 2 medicine must apply for variation of the licence if there is a change to the label for the medicine.

### **3.48 Variation — Class 1 medicine**

- (1) An application for variation of a product licence in respect of a Class 1 medicine is not effective unless:
  - (a) it is in a form acceptable to the Authority; and
  - (b) it sets out, in detail, the variation sought; and
  - (c) it is accompanied by certification complying with section 3.20, as if the application were for the grant of a licence; and
  - (d) if appropriate, it is accompanied by a copy of a relevant certificate mentioned in section 3.21 or 3.22; and
  - (e) it is accompanied by the prescribed fee under Part 11 in respect of the variation.
- (2) The Authority must vary the licence in the manner sought if, and only if, it is satisfied that:
  - (a) the application is effective; and
  - (b) if the proposed variation reflects a change in a component, or an attribute, of the medicine, the medicine so changed:
    - (i) remains a Class 1 medicine; and
    - (ii) is not a separate and distinct product in respect of which a separate product licence should be sought; and
  - (c) the variation does not otherwise result in the medicine becoming a separate and distinct product in respect of which a separate product licence should be sought; and
  - (d) all key data included in the application have been validated.

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### 3.49 Variation — Class 2 medicine

- (1) An application for variation of a product licence in respect of a Class 2 medicine is not effective unless:
  - (a) it is in a form acceptable to the Authority; and
  - (b) it sets out, in detail, the variation sought; and
  - (c) in the case of an application to which subsection (3) applies, it is accompanied by the certification mentioned in paragraph (c) of that subsection; and
  - (d) it is accompanied by the prescribed fee under Part 11 in respect of the variation.
  
- (2) If:
  - (a) the application is effective; and
  - (b) the Authority is satisfied that:
    - (i) the only effect of the variation would be:
      - (A) to reduce the class of persons for whom the medicine is suitable; or
      - (B) to add a precaution that does not include any comparison of the medicine with any other medicine by reference to quality, safety or efficacy; and
    - (ii) all parts of the variation are necessary to produce that effect; and
  - (c) the Authority is satisfied as to the matters set out in subsection (7);  
the Authority must vary the licence in the manner sought.
  
- (3) If:
  - (a) the application is effective; and
  - (b) the medicine and the variation are of a kind specified, for the purposes of this subsection, in an Order; and
  - (c) the applicant has certified that:
    - (i) the application contains no information that is false or misleading in a material particular; and
    - (ii) the applicant holds sufficient evidence to validate each proposed variation; and
    - (iii) no proposed variation has been implemented at the time of submission of the application; and
  - (d) the Authority is satisfied as to the matters set out in subsection (7);  
the Authority must vary the licence in the manner sought.

*Note* The Authority may impose an additional condition on a product licence in respect of a variation under this subsection: see subsection 3.43 (3).
  
- (4) If an application for a variation is not one to which subsection (2) or (3) applies, the Authority must evaluate the medicine in respect of its quality, safety and efficacy, having regard to the effect of the variation.

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- (5) The provisions of Division 3.4 (other than section 3.30), apply to the evaluation of a medicine for the purposes of this section as if:
- (a) a reference in those provisions to an application for a product licence were a reference to an application for variation; and
  - (b) a reference in those provisions to section 3.30 were a reference to section 3.50.
- (6) If, in respect of an application to which subsection (4) applies:
- (a) the application is effective; and
  - (b) the Authority is satisfied, on the basis of the evaluation, that the variation does not indicate any reduction in the quality, safety or efficacy of the medicine for a purpose for which it is intended to be used; and
  - (c) the Authority is satisfied as to the matters set out in subsection (7);  
the Authority must vary the licence in the manner sought.
- (7) For the purposes of subsections (2), (3) and (6), the matters in respect of which the Authority must be satisfied are:
- (a) if the proposed variation reflects a change in a component, or an attribute, of the medicine — the medicine so changed is not a separate and distinct product in respect of which a separate product licence should be sought; and
  - (b) the variation does not otherwise result in the medicine becoming a separate and distinct product in respect of which a separate product licence should be sought; and
  - (c) the variation does not result in a presentation that is not acceptable.

### **3.50 Variation — shorter evaluation period in certain cases**

- (1) This section applies to an application for variation of a product licence in respect of a Class 2 medicine:
- (a) that is not an application that the Authority considers needs to be supported by clinical, non-clinical or bio-equivalence data; and
  - (b) that is in relation to:
    - (i) the specifications for the active ingredient, finished product or excipients; or
    - (ii) the manufacturing procedure for the active ingredient; or
    - (iii) the manufacturing procedure for the finished product; or
    - (iv) the site of manufacture of the active ingredient or the finished product; or
    - (v) the specified shelf life; or
    - (vi) the specified storage conditions; or
    - (vii) the labelling of the product; or
    - (viii) any consequential change to the product information or consumer medicine information.

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- (2) The Authority must:
    - (a) decide the application and notify the applicant of the decision; or
    - (b) raise an objection concerning the application;  
within 45 working days after the day on which the application is lodged and the prescribed fee under Part 11 is paid or, if lodgement and payment occur on different days, after the later of those days.
  - (3) If the Authority raises an objection concerning the application, it must decide the application and notify the applicant of the decision within 30 working days after the day on which the Authority receives the applicant's response to the objection.
  - (4) If the Authority does not comply with subsection (2) (and, if applicable, subsection (3)), the Authority is taken to have approved the application.

### **3.51 Variation — export-only medicine**

- (1) An application for variation of a product licence issued in respect of an export-only medicine is not effective unless:
  - (a) it is in a form acceptable to the Authority; and
  - (b) it sets out, in detail, the variation sought; and
  - (c) it is accompanied by certification complying with section 3.36, as if the application were for grant of a licence; and
  - (d) if appropriate, it is accompanied by a copy of a relevant certificate mentioned in section 3.37 or 3.38; and
  - (e) it is accompanied by the prescribed fee under Part 11 in respect of the application.
- (2) The Authority must vary the licence in the manner sought if, and only if, it is satisfied that:
  - (a) the application is effective; and
  - (b) if the proposed variation reflects a change in a component, or an attribute, of the medicine, the medicine so changed:
    - (i) remains an export-only medicine; and
    - (ii) is not a separate and distinct product in respect of which a separate licence should be sought; and
  - (c) the variation does not otherwise result in the medicine becoming a separate and distinct product in respect of which a separate licence should be sought; and
  - (d) all key data included in the application has been validated.

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## **Division 3.9      Product licence — suspension and revocation**

### **Subdivision 3.9.1      Suspension of licence**

#### **3.52      Suspension — reasons and notice**

- (1) The Authority may, by written notice given to the holder of a product licence in respect of a medicine, suspend the licence if:
  - (a) the Authority is satisfied that:
    - (i) there is a risk of death, serious illness or serious injury if the medicine continues to be available for supply or export; and
    - (ii) it is likely that the licence holder will, within the period of the suspension, be able to take the action necessary to ensure that the medicine does not cause a risk of death, serious illness or serious injury if it were to continue to be available for supply or export;  
or
  - (b) the Authority is satisfied that it is likely that there are grounds for revoking the licence under Subdivision 3.9.2 (other than under subsection 3.57 (2), paragraph 3.57 (3) (a) or (e), paragraph 3.58 (1) (e), subsection 3.58 (2) or subsection 3.59 (2)).
- (2) The notice:
  - (a) must give the reason for the suspension; and
  - (b) must specify the period of the suspension, being a period not longer than 6 months; and
  - (c) may include conditions to be complied with by the licence holder as prerequisite to a decision whether to withdraw the suspension.

*Note* The period of a suspension may be extended under subsection 3.54 (3).

- (3) As soon as practicable after the suspension, the Authority must publish in the Authority Gazette a notice setting out particulars of the suspension.

*Note* A decision to suspend a product licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

#### **3.53      Proposed suspension — opportunity to make submissions**

- (1) Before suspending a licence in respect of a medicine for the reason given in paragraph 3.52 (1) (b), the Authority must, if the matter of concern is a matter mentioned in subsection 3.60 (1), by notice in writing to the licence holder, give the licence holder a reasonable opportunity to make submissions to the Authority in relation to the proposed suspension.
- (2) The Authority must not make a decision relating to the proposed suspension until it has had regard to any submissions made by the licence holder within the time allowed for submissions.

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- (3) This section does not apply if the notice under section 3.52 states that the suspension is necessary to prevent a risk of death, serious illness or serious injury.

### **3.54 Duration of suspension**

- (1) Suspension of a product licence in respect of a medicine takes effect:
- (a) if the notice under subsection 3.52 (1) states that the suspension is necessary to prevent a risk of death, serious illness or serious injury — on the day on which the notice is given to the licence holder; or
  - (b) in any other case — on the day specified by the notice, being a day not earlier than 20 working days after the notice is given to the licence holder.
- (2) A suspension has effect until:
- (a) the Authority withdraws it under section 3.55; or
  - (b) the end of:
    - (i) the period specified by the notice, under subsection 3.52 (2); or
    - (ii) if the period is extended under subsection (3) of this section, the period as so extended.

*Note* Unless a suspension of a licence has been withdrawn, the licence is automatically revoked at the end of the period mentioned in paragraph (b): see section 3.57.

- (3) If, in relation to a suspended licence, the licence holder demonstrates that steps have been taken to eliminate grounds for revoking the licence under Subdivision 3.9.2, the Authority may, by written notice given to the licence holder, extend the period of suspension by a further specified period not exceeding 6 months.
- (4) As soon as practicable after the extension, the Authority must publish in the Authority Gazette a notice setting out particulars of the extension.

### **3.55 Withdrawal of suspension**

- (1) The Authority must withdraw the suspension of a product licence in respect of a medicine if it is satisfied that:
- (a) the ground for the suspension no longer applies; and
  - (b) there are no other grounds for suspension.
- (2) The Authority's power to withdraw may be exercised:
- (a) on request in writing by the licence holder; or
  - (b) on the Authority's own initiative.
- (3) If the Authority decides to withdraw the suspension, the Authority must:
- (a) within 20 working days after the decision is made, give written notice of the withdrawal to the licence holder; and
  - (b) as soon as practicable, publish notice of the withdrawal in the Authority Gazette.

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- (4) If, following a request under paragraph (2) (a), the Authority decides to not withdraw the suspension, the Authority must:
- (a) within 20 working days after the decision is made, give written notification of the decision to the licence holder; and
  - (b) state in the notice the reasons for the decision.

*Note* A decision to not withdraw a suspension of a product licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

### **3.56 Revocation power unaffected**

This Division does not affect the Authority's power under Subdivision 3.9.2 to revoke a licence.

## **Subdivision 3.9.2 Revocation of licence**

### **3.57 Immediate revocation — reasons and notice generally**

- (1) The Authority must, by written notice given to the holder of a product licence that has been suspended, revoke the licence if the period of suspension specified under subsection 3.52 (2), and any extension of that period, has expired and the suspension has not been withdrawn under section 3.55.
- (2) The Authority must, by written notice given to the holder of a product licence that has resulted from an evaluation in which protected information (other than protected information to which subsection 3.33 (2) applies) was used, revoke the licence.
- (3) The Authority may, by written notice given to the holder of a product licence in respect of a medicine, revoke the licence if:
  - (a) the Authority is satisfied that there is an imminent risk of death, serious illness or serious injury if the medicine continues to be available for supply or export; or
  - (b) the medicine is no longer a therapeutic product; or
  - (c) the product is no longer a medicine; or
  - (d) the medicine becomes an exempt medicine under section 5.03; or
  - (e) the licence holder has requested, in writing, that the licence be revoked; or
  - (f) the licence holder has failed to comply with a direction given, or a requirement made, by a relevant authority constituted under the Advertising Rule, in relation to advertising the medicine; or
  - (g) the medicine contains a substance that is a prohibited import; or
  - (h) the licence holder has failed to comply with a condition mentioned:
    - (i) in subsection 3.42 (2) or (4); or

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- (ii) in subsection 3.42 (11):
    - (A) if requested to make the record concerned available at or before a particular time — before the end of 24 hours after that time; or
    - (B) if requested to make the record concerned available immediately — within 24 hours after the request was made; or
  - (i) the annual charge payable to the Authority in respect of the licence has not been paid within 20 working days after it becomes payable.
- (4) Revocation under this section takes effect immediately when the licence holder is notified of the decision.

*Note* A decision to revoke a product licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

### **3.58 Immediate revocation — additional reasons — Class 1 medicine**

- (1) The Authority may, by written notice given to the holder of a product licence in respect of a Class 1 medicine, revoke the licence for any of the following reasons, whether or not a reason set out in section 3.57 exists:
- (a) the medicine is not a Class 1 medicine;
  - (b) the medicine is an exempt medicine under section 5.03;
  - (c) it appears to the Authority that the certification under paragraph 3.20 (a), (f) or (g) is incorrect;
  - (d) it appears to the Authority that a certificate required under section 3.21 or 3.22 has not been obtained;
  - (e) it appears to the Authority that:
    - (i) a requirement under this Rule or the Advertising Rule, relating to advertising, has been significantly contravened in relation to the medicine; and
    - (ii) as a result of the contravention, the presentation of the medicine is misleading to a significant extent.
- (2) The Authority may, by written notice given to the holder of a product licence in respect of a Class 1 medicine, revoke the licence if:
- (a) the Authority, under section 8.02, gives to the person a notice requiring the person to give to the Authority information or documents relating to the medicine or to medicines of that kind; and
  - (b) the notice under section 8.02 is given for the purpose of ascertaining whether a product licence should have been granted in respect of the medicine, or in respect of medicines of that kind; and
  - (c) the person fails to comply with the notice under section 8.02 within a further 10 working days after the day specified in that notice.
- (3) Revocation under this section takes effect immediately when the licence holder is notified of the decision.

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### **3.59 Immediate revocation — additional reasons — export-only medicine**

- (1) The Authority may, by written notice given to the holder of a product licence in respect of an export-only medicine, revoke the licence for any of the following reasons, whether or not a reason set out in section 3.57 exists:
  - (a) the medicine is not an export-only medicine;
  - (b) it appears to the Authority that the certification under paragraph 3.36 (1) (a), (e) or (f), or under subsection 3.36 (2), is incorrect;
  - (c) it appears to the Authority that a certificate required under section 3.37 or 3.38 has not been obtained.
- (2) The Authority may, by written notice given to the holder of a product licence in respect of an export-only medicine, revoke the licence if:
  - (a) the Authority, under section 8.02, gives to the person a notice requiring the person to give to the Authority information or documents relating to the medicine or to medicines of that kind; and
  - (b) the notice under section 8.02 is given for the purpose of ascertaining whether a product licence should have been granted in respect of the medicine, or in respect of medicines of that kind; and
  - (c) the person fails to comply with the notice under section 8.02 within a further 10 working days after the day specified in that notice.
- (3) Revocation under this section takes effect immediately when the licence holder is notified of the decision.

### **3.60 Revocation following warning notice**

#### *General*

- (1) The Authority may, in accordance with the procedures set out in this section, revoke a product licence in respect of a medicine for any of the following reasons:
  - (a) the medicine, as a product, has so changed since the licence was issued that, in comparison to the product at that time, it has become a separate and distinct product;
  - (b) the licence holder has failed to comply with a condition of the licence (other than a condition mentioned in paragraph 3.57 (3) (h));
  - (c) the Authority is satisfied that the quality, safety or efficacy of the medicine is unacceptable;
  - (d) the medicine does not conform to a standard applicable to it;
  - (e) a step carried out in the manufacture of the medicine is an unauthorised step;
  - (f) the medicine, as a product, does not conform to an applicable requirement under this Rule or the Advertising Rule relating to advertising;

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- (g) the Authority is satisfied that the presentation of the medicine is not acceptable;
  - (h) the classification under which the medicine was assessed or evaluated for the purpose of the issue of the product licence is not the appropriate classification under this Rule;
  - (i) the licence holder has contravened section 9.02 in relation to the medicine;
  - (j) a change of ownership of the licence, being a change of a kind mentioned in section 3.62, has occurred, and notice under that section has not been given to the Authority;
  - (k) the licence holder has ceased to be a resident of, or to carry on business in, Australia or New Zealand.
- (2) Without limiting paragraph (1) (c), the quality, safety or efficacy of a medicine is taken to be unacceptable if the benefit of the medicine is no longer commensurate with the risk to public safety.
- (3) For paragraph (1) (e), a step is an *unauthorised step* if:
- (a) for a step in the manufacture that was performed in Australia or New Zealand:
    - (i) the step was performed by a person who is not the holder of a manufacturing licence in respect of the medicine and the step; and
    - (ii) no relevant exemption or approval is in operation under this Rule in respect of the medicine or the step; or
  - (b) for a step in the manufacture that was performed outside Australia and New Zealand, being a step that, if performed in Australia or New Zealand, would, under this Rule, be required to be performed in accordance with a manufacturing licence:
    - (i) the licence holder has not given the Authority adequate evidence demonstrating that the standard of manufacture is, in respect of that step, acceptable to the Authority; or
    - (ii) the person performing the step refuses to allow an inspection of the person's premises by the Authority; or
    - (iii) the Authority considers that an inspection should not be made because of health or safety concerns;
- and no relevant exemption or approval is in operation under this Rule in respect of the medicine or the step.

### *Class 1 medicines*

- (4) Whether or not a reason set out in subsection (1) exists, the Authority may, in accordance with this section, revoke a product licence in respect of a Class 1 medicine if it appears to the Authority that a certification under section 3.20 (other than a certification of a matter mentioned in paragraph 3.20 (a), (f) or (g)) is incorrect.

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### *Export-only medicines*

- (5) Whether or not a reason set out in subsection (1) exists, the Authority may, in accordance with this section, revoke a product licence in respect of an export-only medicine if it appears to the Authority that a certification under section 3.36 (other than a certification of a matter mentioned in paragraph 3.36 (1) (a), (e) or (f)), or in subsection 3.36 (2), is incorrect.

### *Procedure*

- (6) Before a licence is revoked under this section, the Authority must:
- (a) give the licence holder written notice that the Authority is considering revoking the licence, setting out the reasons for the proposed action; and
  - (b) give the licence holder a reasonable opportunity to respond to the notice, including making written submissions to the Authority; and
  - (c) give appropriate consideration to the responses made by the licence holder.
- (7) A decision to revoke a licence, after the procedure under subsection (5) has been complied with, takes effect immediately when the holder receives the notice of the decision.

*Note* A decision to revoke a product licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

## **3.61 Publication of revocation**

As soon as practicable after revoking a product licence in respect of a medicine, the Authority must publish, in the Authority Gazette, a notification of the revocation.

## **Division 3.10 Product licence — change in ownership**

### **3.62 Change and deemed change in ownership**

- (1) If a person who is the holder of a product licence dies, the legal personal representative of the person:
- (a) is taken to be the licence holder; and
  - (b) within 3 months after the death, must give the Authority written notice of the death.
- (2) If a person who is the holder of a product licence becomes bankrupt, the trustee of the estate of the bankrupt:
- (a) is taken to be the licence holder; and
  - (b) within 3 months after the bankruptcy, must give the Authority written notice of the bankruptcy.

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- (3) If a body corporate that is the holder of a product licence is being wound up, the liquidator of the body corporate:
- (a) is taken to be the licence holder; and
  - (b) within 3 months after the winding up commencing, must give the Authority written notice of the winding up.
- (4) If a person who is the holder of a product licence assigns to another person (*the transferee*), in whole or in part:
- (a) the business to which the licence relates; or
  - (b) the licence holder's interest in the licence;
- the transferee:
- (c) is taken, to the extent of the interest assigned, to be the licence holder; and
  - (d) must, not later than 3 months after the assignment, notify the Authority that the transferee has, because of the assignment, become an applicant in relation to the transfer of the licence.
- (5) If a person who is the holder of a product licence:
- (a) changes his, her or its name; or
  - (b) being a corporation that amalgamates with another corporation, assumes a changed name;
- and gives written notice of the change to the Authority, and the circumstance giving rise to it, within 3 months after the occurrence of the circumstance, the licence then has effect as if it had been granted to the holder in the holder's new name.
- (6) A notice given under subsection (1), (2), (3), (4) or (5) must be accompanied by documentary evidence that verifies the event asserted in the notice.
- (7) If a person gives notice under subsection (1), (2), (3) or (4), the Authority:
- (a) may treat that person as an applicant for the transfer of the licence; and
  - (b) may deal with the notice as if it were an application for the transfer of the licence.
- (8) Despite subsection (7), a person who is treated as an applicant for the transfer of a licence because of the operation of that subsection may continue to conduct the activity to which the original licence relates until the application is finally determined.

*Note* Failure to give notice under this section may result in the licence concerned being revoked (see section 3.60).

- (9) The Authority may, by Order, make further provision for procedures relating to the transfer of a product licence.

***[Drafter's note: Additional provision will be made for the return of a product licence after transfer or revocation.]***

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## Part 4 Medicines — Manufacturing

### Division 4.1 General

#### 4.01 Overview of this Part

The object of this Part is to ensure that the standard of manufacture of medicines in Australia and New Zealand is acceptable. A manufacturing licence can be issued in respect of a medicine if the requirements under this Part applying to the medicine are complied with.

A manufacturing licence has effect subject to certain conditions that apply automatically under this Rule and, in many cases, further conditions that the Authority may impose at its discretion.

#### 4.02 Determination of Manufacturing Principles

- (1) The Authority may, from time to time, by Order, determine principles (*Manufacturing Principles*) to be observed in the manufacture of medicines in Australia and New Zealand, in relation to the following matters:
  - (a) the standards to be maintained in the manufacture;
  - (b) the premises and equipment to be used;
  - (c) procedures for quality assurance and quality control to be employed;
  - (d) the qualifications and experience required of employees;
  - (e) the manufacturing practices to be employed;
  - (f) other matters relevant to the quality, safety and efficacy of the medicine.
- (2) The Manufacturing Principles may be in the form of codes of good manufacturing practice.
- (3) The Authority may, before determining, amending or revoking a Manufacturing Principle, consult with respect to the proposed action with an appropriate expert advisory committee.

*Note 1* For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Act; and
- (b) in New Zealand — [Part 2] of the Act.

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#### **4.03 Need for manufacturing licence**

- (1) Except as otherwise provided in this Rule, a person must not carry out any step in the manufacture of a medicine, or a kind of medicines, at premises in Australia or New Zealand, unless the person is the holder of a manufacturing licence in respect of that medicine, or kind of medicines, that:
  - (a) is in force; and
  - (b) authorises the carrying out of that step at those premises.
- (2) In relation to a failure to comply with subsection (1):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

### **Division 4.2 Manufacturing licence — application and grant**

#### **4.04 Application for a manufacturing licence**

- (1) An application for a manufacturing licence in respect of a medicine, or kind of medicines, must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (2) An application is not effective unless:
  - (a) the application complies with subsection (1); and
  - (b) the prescribed application fee under Part 11 has been paid; and
  - (c) the application is supported by sufficient information, in a form acceptable to the Authority, to enable assessment of the application; and
  - (d) the application includes no information that is false or misleading in a material particular.

*Note* [Re penalties for making false or misleading statement]

- (3) An application must include the following information:
  - (a) identification of the medicine, or kind of medicines, that the applicant proposes to manufacture;
  - (b) identification of the premises proposed to be used in the manufacture of the medicine or medicines;
  - (c) identification of the manufacturing steps proposed to be carried out by the applicant;
  - (d) a document to provide specific, factual information about the production and control of manufacturing operations, commonly known as a Site Master File;

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- (e) identification of the persons (including details of the qualifications and experience of those persons) who are intended to be responsible for:
    - (i) production of the medicine or medicines; and
    - (ii) quality control measures, including the release of the medicine or medicines;
  - (f) any other information specified in the application form that is relevant to the applicant.

#### **4.05 Additional information for application**

The Authority may give an applicant for a manufacturing licence written notice requiring the applicant:

- (a) within such reasonable time as is specified in the notice — to give to the Authority further specified information in relation to the application; or
- (b) to allow an authorised person, at any reasonable time specified in the notice, to enter the manufacturing premises and carry out an audit of the premises, equipment, processes, documentation and other facilities intended to be used in the manufacture of:
  - (i) the medicine or medicines; or
  - (ii) other products on those premises.

#### **4.06 Grant of manufacturing licence**

- (1) If:
  - (a) an application is effective, under subsection 4.04 (2); and
  - (b) any prescribed assessment and audit fees under Part 11 have been paid; and
  - (c) the applicant has complied with any requirements notified by the Authority under section 4.05 in relation to the application;the Authority must grant the applicant a licence to manufacture the medicine or medicines, or to carry out the steps, to which the application relates, at the premises to which the application relates, unless the Authority is satisfied that:
  - (d) the applicant will be unable to comply with the Manufacturing Principles; or
  - (e) the premises are not satisfactory for the proposed manufacture; or
  - (f) the applicant is not a fit and proper person to hold a licence; or
  - (g) a person who is participating in, or is likely to participate in, managing the applicant's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence; or
  - (h) a person who has, or is likely to have, effective control over the applicant is not a fit and proper person to have effective control over a holder of a licence.

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- (2) In considering whether the applicant or other person is, for the purpose of subsection (1), a fit and proper person, the Authority must have regard to:
- (a) any suspension or revocation of a manufacturing licence granted to:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time of the suspension or revocation; or
  - (b) any conviction, for an offence against a law of Australia (including a law of a State or Territory) or New Zealand, against:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time the offence was committed or the time of the conviction; or
  - (c) any failure to comply with a condition of a manufacturing licence by:
    - (i) the applicant or person; or
    - (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities); or
    - (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time of the failure;

and may have regard to any other matter that the Authority considers to be relevant.

- (3) The Authority may grant a licence to an applicant who, apart from this subsection, it considers could not be granted a licence because of paragraph (1) (f), (g) or (h) if the Authority considers that the particular circumstances make it appropriate to do so.

- (4) In subsection (2):

***manufacturing licence*** includes a licence issued under any law of Australia (including a law of a State or Territory) or New Zealand relating to the manufacture of therapeutic products.

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#### **4.07 Notification of decision**

- (1) The Authority must, within 20 working days after the occurrence of the later of the following events in respect of an application:
  - (a) the completion of the assessment of the application;
  - (b) the payment of all fees payable under Part 11 in respect of the application and assessment;

give the applicant written notification of the Authority's decision and, if the decision is to not grant a licence, or is to grant a licence subject to a condition, set out in the notice the reasons for the decision.

*Note* A decision to not issue a licence, or a decision that includes a decision to attach a condition to a licence, is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

- (2) If the Authority decides to grant a licence, it must:
  - (a) issue the licence within the period mentioned in subsection (1); and
  - (b) notify the decision in the Authority Gazette as soon as is practicable after the decision is made.

#### **4.08 Term of manufacturing licence**

A manufacturing licence commences on the day specified in the licence and, subject to this Part, remains in force for 3 years.

*Note* A licence may be renewed under Division 4.3.

### **Division 4.3 Manufacturing licence — renewal and variation**

#### **4.09 Application to renew manufacturing licence**

- (1) The holder of a manufacturing licence may, not earlier than 3 months and not later than 1 month before the licence is due to expire, apply to the Authority for the renewal of the licence.
- (2) The Authority may extend the period within which an application for renewal may be made, whether or not the period has ended or the licence has expired.
- (3) An application for renewal must be:
  - (a) made in accordance with the approved form; and
  - (b) delivered to an office of the Authority.
- (4) An application is not effective unless:
  - (a) the application complies with subsection (3); and
  - (b) the prescribed application fee under Part 11 has been paid; and

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- (c) the application is supported by sufficient information, in a form acceptable to the Authority, to enable assessment of the application; and
  - (d) the application includes no information that is false or misleading in a material particular.

*Note* [Re penalties for making false or misleading statement]

- (5) An application for renewal must include the following:
  - (a) confirmation by the licence holder that the information included in the licence is correct;
  - (b) if relevant, details of any changes to be made to the licence;
  - (c) a declaration by the licence holder that:
    - (i) the licence holder is a fit and proper person to hold a licence; and
    - (ii) any person who is participating in, or is likely to participate in, managing the licence holder's affairs is a fit and proper person to participate in the management of the affairs of a licence holder; and
    - (iii) any person who has, or is likely to have, effective control over the licence holder is a fit and proper person to have effective control over a licence holder;
  - (d) any other information specified in the application form that is relevant to the manufacture of the medicine or medicines.
- (6) Section 4.05 applies to an application for renewal of a licence under this section as it applies to an application for a licence under section 4.04.

*Note* Under section 4.05, the Authority may require additional information or an audit.

- (7) Subject to this Division, if an application for renewal is made within the period mentioned in subsection (1), or the period as extended under subsection (2), but before the licence is due, apart from this subsection, to expire, the licence remains in force until the application for renewal is finally determined.

#### **4.10 Renewal of licence**

- (1) If:
  - (a) an application is effective, under subsection 4.09 (4); and
  - (b) any prescribed assessment and audit fees applicable under Part 11 have been paid; and
  - (c) the licence holder has complied with any requirements notified by the Authority under section 4.05 in relation to the application;the Authority must renew the licence, unless the Authority is satisfied that, if the licence were renewed, the Authority would have grounds for revoking the licence under section 4.20.

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- (2) The Authority must, within 20 working days after the occurrence of the later of the following events in respect of an application:

- (a) the completion of the assessment of the application;
- (b) the payment of all fees payable under Part 11 in respect of the application;

give the applicant written notification of the Authority's decision, and if the decision is to not renew a licence, or is to renew a licence subject to a variation in the conditions of the licence, set out in the notice the reasons for the decision.

*Note* A decision to not renew a licence, or a decision to renew that includes a decision to vary the licence conditions, is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

- (3) If the Authority decides to renew a licence, it must notify the decision in the Authority Gazette as soon as is practicable after the decision is made.

#### **4.11 Term of renewed licence**

- (1) Subject to this Division, a manufacturing licence that has been renewed:
- (a) remains in force for a period of 3 years from the date on which the licence would have expired apart from the renewal; and
  - (b) may be further renewed.
- (2) A manufacturing licence that is suspended under this Division may be renewed under this section, but the renewal does not take effect until the suspension ends.
- (3) A renewal of a licence does not take effect if, on or before the date on which the licence would, apart from the renewal, expire, the licence is revoked.

#### **4.12 Variation of licence**

- (1) The Authority may vary a manufacturing licence in respect of a medicine:
- (a) upon a request in writing to the Authority by the holder of the licence;  
or
  - (b) on the Authority's own initiative;
- to correct or complete particulars on a licence that are incorrect or incomplete.
- (2) Nothing in subsection (1) obliges the Authority to comply with a request mentioned in paragraph (1) (a) if the Authority:
- (a) considers that a new application for a licence should be made under this Part; and
  - (b) so notifies the licence holder.

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- (3) The Authority may vary a manufacturing licence upon a request in writing to the Authority by the holder of the licence:
- (a) to add a medicine, or a step in the manufacture of a medicine, not covered by the licence; or
  - (b) to remove a medicine, or a step in the manufacture of a medicine, covered by the licence.

*Note* Discretionary conditions of a licence may be varied under section 4.14.

## **Division 4.4            Manufacturing licence — conditions**

### **4.13        Conditions applicable to all manufacturing licences**

#### *Conditions relating to production*

- (1) A manufacturing licence in respect of a medicine is subject to the following conditions (unless the licence expressly states otherwise):
- (a) the licence holder must:
    - (i) ensure that the medicine conforms to any applicable standard; and
    - (ii) comply with the Manufacturing Principles in carrying out any steps in the manufacture of the medicine;
  - (b) the licence holder must comply with any reasonable request by the Authority to provide specified information relating to the manufacture of the medicine;
  - (c) the licence holder must give written notice to the Authority of any information that indicates that the quality, safety or efficacy of the medicine is unacceptable, as soon as the licence holder becomes aware of the information;
  - (d) the licence holder must allow an authorised person:
    - (i) to enter, at any reasonable time and whether or not with prior notice, the manufacturing premises to which the licence relates; and
    - (ii) while on those premises:
      - (A) to inspect those premises, any therapeutic products on the premises including any medicines manufactured at those premises, and the processes and documentation relating to that manufacture, and to carry out an audit; and
      - (B) to take samples of starting materials, intermediate products, finished products and retention samples relating to the medicines manufactured; and
      - (C) to take visual records of those premises, medicines or processes;

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- (e) the licence holder must ensure that questions asked by an authorised person in relation to an inspection or audit under subparagraph (d) (ii) are adequately answered by the licence holder or an employee at those premises;
  - (f) if requested to do so by an authorised person, the licence holder must:
    - (i) produce such documents as the authorised person requires relating to the manufacture of medicines at the premises, and allow the person to copy the documents; or
    - (ii) produce to the authorised person, for examination, any batch samples or samples of retained materials used in the manufacture of medicines and kept by the licence holder;
  - (g) the licence holder must ensure that the persons nominated as being responsible for the production of the medicine, and for quality control measures (including release of the medicine), maintain that responsibility.

*Conditions relating to records, etc*

- (2) A manufacturing licence in respect of a medicine is subject to the following conditions:
  - (a) the licence holder must keep, at the premises to which the licence relates, a copy of the licence and of any document issued by the Authority that imposes, or varies, a condition attaching to the licence;
  - (b) unless the contrary intention appears in the licence or in a document issued by the Authority that imposes, or varies, a condition attaching to the licence, the licence holder must, as far as applicable:
    - (i) keep records showing details of:
      - (A) the materials used in the manufacture of the medicine, the suppliers and the quantities; and
      - (B) tests performed on those materials and the results of those tests; and
      - (C) the procedures and controls employed in the manufacture of the medicine, including the results of tests carried out during manufacture; and
      - (D) tests performed on the medicine and the results of those tests; and
      - (E) the stability studies (if any) that validate the recommended shelf life and appropriate storage conditions of the medicine; and
    - (ii) retain those records at the premises to which the licence relates for at least 12 months after the expiry date of the medicine to which they relate; and
    - (iii) for medicine produced in identifiable batches:
      - (A) assign a batch number to each batch of the medicine; and

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- (B) if it is not unreasonable in the circumstances — retain at the premises, for not less than 12 months after the date specified by the manufacturer as the expiry date applying to the medicine, a sample of each batch of the medicine; and
  - (iv) ensure, if there is a transfer of the licence of a kind mentioned in subsection 4.23 (1), (2), (3) or (4), that those records and samples, to the extent that they are required to be retained, are made available to the transferee.

#### *Requests for production details*

- (3) It is a condition of a manufacturing licence that, if at any time the Authority, in writing, so requests, the licence holder will provide to the Authority, in writing and within the period specified in the request (being a period of at least 10 working days):
  - (a) details of medicines manufactured by, or on behalf of, the licence holder during the period of 12 months immediately preceding the request; and
  - (b) details (including the names, qualifications and relevant experience) of the persons responsible for:
    - (A) production of the medicines to which the licence relates; and
    - (B) the quality control measures that are to be used in relation to the manufacture.

#### *Change of responsible person*

- (4) It is a condition of a manufacturing licence that, if the manufacturer proposes to replace the person nominated to the Authority as:
  - (a) the person responsible for the production of the medicine; or
  - (b) the person responsible for quality control procedures in relation to the manufacture;the licence holder must inform the Authority, in writing and as soon as is practicable, of the name, qualifications and relevant experience of the new person responsible.

#### *Annual declaration*

- (5) It is a condition of a manufacturing licence that the licence holder must provide to the Authority, at least once a year, a declaration in the approved form, stating that:
  - (a) the licence holder's data profile is current and correct; and
  - (b) the statement on fit and proper persons is current and accurate; and
  - (c) the licence holder complies with the requirements of good manufacturing practice.

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- (6) In relation to a failure to comply with a condition mentioned in this section:
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

#### **4.14 Discretionary conditions**

- (1) The Authority may impose conditions on a manufacturing licence, in addition to the conditions mentioned in section 4.13, relating to the manufacture of the medicine, as the Authority, on the grant of the licence, considers appropriate.
- (2) In addition to conditions imposed on the grant of a manufacturing licence, the Authority may, at any time, by notice in writing given to the licence holder:
  - (a) impose new conditions on the licence; or
  - (b) vary or remove existing conditions;and may do so at the request of the licence holder, or of the Authority's own motion.
- (3) The imposition or variation of a condition under subsection (2) takes effect:
  - (a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the licence holder; or
  - (b) if the notice states that the action is taken because of a perceived risk of death, serious illness or serious injury—on the day on which the notice is given to the licence holder; or
  - (c) in any other case — on the day specified in the notice, being a day not earlier than 20 working days after the notice is given.

*Note* A decision to impose, or vary, a condition on a manufacturing licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

- (4) In relation to a failure to comply with a condition mentioned in subsection (1) or (2):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* Failure to comply with a condition may result in suspension or revocation of a licence (see Division 3.9).

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## **Division 4.5      Manufacturing licence — suspension and revocation**

### **Subdivision 4.5.1      Suspension of licence**

#### **4.15      Suspension — reasons and notice**

- (1) The Authority may, by written notice given to the holder of a manufacturing licence in respect of a medicine, suspend the licence if the Authority is satisfied that:
  - (a) the holder has been convicted of an offence against the Act; or
  - (b) the holder controls another person (whether directly, or indirectly through one or more interposed entities) who has been convicted of an offence against the Act (or, in Australia, against a law of a State or Territory relating to therapeutic products); or
  - (c) the holder controlled another person (whether directly, or indirectly through one or more interposed entities) when the other person committed an offence against the Act (or, in Australia, against a law of a State or Territory relating to therapeutic products), and the other person has been convicted of that offence; or
  - (d) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against the Act (or, in Australia, against a law of a State or Territory relating to therapeutic products); or
  - (e) the holder has failed to comply with a condition of the licence; or
  - (f) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has failed a duty to comply with a condition of a licence granted under this Rule; or
  - (g) the holder controls another person (whether directly, or indirectly through one or more interposed entities) and that other person has, while controlled by the holder, failed a duty to comply with a condition of a licence issued under this Rule; or
  - (h) the holder is not a fit and proper person to hold a licence; or
  - (i) a person who is participating in managing the holder's affairs is not a fit and proper person to participate in the management of the affairs of a holder of a licence issued under this Rule; or
  - (j) a person who has effective control over the holder is not a fit and proper person to have effective control over a holder of a licence issued under this Rule; or
  - (k) the holder requests in writing that the licence be suspended; or
  - (l) the holder ceases to carry on the business of manufacturing the medicine, or kind of medicines, to which the licence relates; or

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- (m) an inspection or audit fee payable under Part 11 in respect of the licence has not been paid within 20 working days after it has become payable;
  - (n) an approval applies in respect of the medicine under section 5.10 and the licence holder has contravened a condition of the approval.
- (2) In considering whether the licence holder or other person is, for the purpose of subsection (1), a fit and proper person, the Authority:
- (a) must have regard to the matters set out in paragraphs 4.06 (2) (a), (b) and (c); and
  - (b) may have regard to any other matter that the Authority considers to be relevant.
- (3) The notice:
- (a) must give the reason for the suspension; and
  - (b) must specify the period of the suspension, being a period not longer than 6 months; and
  - (c) may include conditions to be complied with by the manufacturer as prerequisite to a decision whether to withdraw the suspension.

*Note* The period of a suspension may be extended under subsection 4.17 (3).

- (4) As soon as practicable after the suspension, the Authority must publish in the Authority Gazette a notice setting out particulars of the suspension.
- (5) During the period of suspension, the manufacturing steps to which the licence applies must not be performed by the manufacturer.

*Note* A decision to suspend a manufacturing licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

#### **4.16 Proposed suspension — opportunity to make submissions**

- (1) Before suspending a manufacturing licence (otherwise than at the request of the licence holder), the Authority must, unless the Authority considers that failure to suspend immediately would create an imminent risk of death, serious illness or serious injury:
- (a) give the licence holder written notice of the proposed suspension, and the reasons for the proposed action; and
  - (b) give the licence holder a reasonable opportunity to make submissions to the Authority in relation to the proposed suspension (unless the reason for the proposed action is the reason set out in paragraph 4.15 (1) (m)).
- (2) The Authority must not make a decision relating to the proposed suspension until it has had regard to any submissions made by the licence holder, as permitted under subsection (1).

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#### **4.17 Duration of suspension**

- (1) Suspension of a manufacturing licence in respect of a medicine takes effect:
  - (a) if the notice under subsection 4.15 (1) states that the suspension is necessary to prevent a risk of death, serious illness or serious injury — on the day on which the notice is given to the licence holder; or
  - (b) in any other case — on the day specified by the notice, being:
    - (i) a day not earlier than 20 working days after the notice is given to the licence holder; or
    - (ii) if a day is requested by the licence holder that is earlier than 20 working days after the notice is given — that day.
- (2) A suspension has effect until:
  - (a) the Authority withdraws it under section 4.18; or
  - (b) the end of:
    - (i) the period specified by the notice, under subsection 4.15 (3); or
    - (ii) if the period is extended under subsection (3) of this section, the period as so extended.
- (3) If, in relation to a suspended licence, the licence holder demonstrates that steps have been taken to eliminate grounds for revoking the licence under section 4.20, the Authority may, by written notice given to the licence holder, extend the period of suspension by a further specified period not exceeding 6 months.
- (4) As soon as practicable after the extension, the Authority must publish in the Authority Gazette a notice setting out particulars of the extension.

#### **4.18 Withdrawal of suspension**

- (1) The Authority must withdraw suspension of a manufacturing licence in respect of a medicine if it is satisfied that:
  - (a) the ground for the suspension no longer applies; and
  - (b) there are no other grounds for suspension.
- (2) The Authority's power to withdraw may be exercised:
  - (a) on request in writing by the licence holder; or
  - (b) on the Authority's own initiative.
- (3) If the Authority decides to withdraw the suspension, the Authority must:
  - (a) within 20 working days after the decision is made, give written notice of the withdrawal to the licence holder; and
  - (b) as soon as practicable, publish notice of the withdrawal in the Authority Gazette.

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- (4) If, following a request under paragraph (2) (a), the Authority decides to not withdraw the suspension, the Authority must:
- (a) within 20 working days after the decision is made, notify the applicant, in writing, of the decision; and
  - (b) state in the notice the reasons for the decision.

*Note* A decision to not withdraw a suspension of a manufacturing licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

#### **4.19 Revocation power unaffected**

This Subdivision does not affect the Authority's power under Subdivision 4.5.2 to revoke a licence.

#### **Subdivision 4.5.2 Revocation of licence**

#### **4.20 Revocation — reasons and notice generally**

- (1) The Authority, by written notice given to the holder of a manufacturing licence that has been suspended, must revoke the licence if the period of suspension specified under subsection 4.15 (3), and any extension of that period, has expired and the suspension has not been withdrawn under section 4.18.
- (2) The Authority may, by written notice given to the holder of a manufacturing licence in respect of a medicine, revoke the licence if the Authority is satisfied that:
  - (a) any of the circumstances mentioned in subsection 4.15 (1) (except the circumstance mentioned in paragraph 4.15 (1) (k)) apply in relation to the licence, and that suspension of the licence is an insufficient action; or
  - (b) a change of ownership of the licence, being a change of a kind mentioned in section 4.23, has occurred, and notice under that section has not been given to the Authority.

*Note* For the interim arrangement applying to a transferred licence, see Division 4.6.

- (3) Before revoking a manufacturing licence (otherwise than at the request of the licence holder), the Authority must, unless the Authority considers that failure to suspend immediately would create an imminent risk of death, serious illness or serious injury:
  - (a) give the licence holder written notice of the proposed revocation, and the reasons for the proposed action; and
  - (b) give the licence holder a reasonable opportunity to make submissions to the Authority in relation to the proposed revocation (unless the reason for the proposed action is the reason set out in paragraph 4.15 (1) (m) or in paragraph (2) (b) of this section; and

- 
- (c) give appropriate consideration to the responses made by the licence holder.

*Note* A decision to revoke a manufacturing licence is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

#### **4.21 Taking effect of revocation**

Revocation of a manufacturing licence takes effect:

- (a) if the notice of revocation states that the revocation is necessary to prevent a risk of death, serious illness or serious injury — on the day on which the notice is given to the licence holder; or
- (b) in any other case — on the day specified by the notice, being a day not earlier than 20 working days after the notice is given to the licence holder.

#### **4.22 Publication of revocation**

As soon as practicable after revoking a manufacturing licence in respect of a medicine, the Authority must publish in the Authority Gazette a notification of the revocation.

### **Division 4.6 Manufacturing licence — Change in ownership**

#### **4.23 Change and deemed change in ownership**

- (1) If a person who is the holder of a manufacturing licence dies, the legal personal representative of the person:
  - (a) is taken to be the licence holder; and
  - (b) within 3 months of the death, must give the Authority written notice of the death.
- (2) If a person who is the holder of a manufacturing licence becomes bankrupt, the trustee of the estate of the bankrupt:
  - (a) is taken to be the licence holder; and
  - (b) within 3 months of the bankruptcy, must give the Authority written notice of the bankruptcy.
- (3) If a body corporate that is the holder of a manufacturing licence is being wound up, the liquidator of the body corporate:
  - (a) is taken to be the licence holder; and
  - (b) within 3 months of the winding up commencing, must give the Authority written notice of the winding up.
- (4) If a person who is the holder of a manufacturing licence assigns to another person (*the transferee*), in whole or in part:
  - (a) the business to which the licence relates; and

- 
- (b) the licence holder's interest in the licence;  
the transferee:
- (c) is taken, to the extent of the interest assigned, to be the licence holder;  
and
- (d) must, not later than 3 months after the assignment, notify the Authority that the transferee has, because of the assignment, become an applicant in relation to the transfer of the licence.
- (5) If a person who is the holder of a manufacturing licence:
- (a) changes his, her or its name; or
- (b) being a corporation that amalgamates with another corporation, assumes a changed name;
- and gives written notice of the change to the Authority, and the circumstance giving rise to it, within 3 months after the occurrence of the circumstance, the licence then has effect as if it had been granted to the holder in the holder's new name.
- (6) A notice given under subsection (1), (2), (3), (4) or (5) must be accompanied by documentary evidence that verifies the event asserted in the notice.
- (7) If a person gives notice under subsection (1), (2), (3) or (4), the Authority:
- (a) may treat that person as an applicant for the transfer of the licence; and
- (b) may deal with the notice as if it were an application for the transfer of the licence.
- (8) Despite subsection (7), a person who is treated as an applicant for the transfer of a licence because of the operation of that subsection may continue to conduct the activity to which the original licence relates until the application is finally determined.
- (9) The Authority may, by Order, make further provision for procedures relating to the transfer of a manufacturing licence.

*Note* Failure to give notice under this section may result in the licence concerned being revoked (see section 4.20).

***[Drafter's note: Additional provision may be required for the return of a licence after transfer or revocation.]***

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## **Part 5 Exemption from standards and licensing**

### **Division 5.1 General**

#### **5.01 Overview of this Part**

This Part provides for exemptions from the provisions of this Rule relating to standards, product licensing and manufacturer licensing, either directly or upon obtaining the approval of the Authority. Exemptions and approvals may be subject to conditions.

### **Division 5.2 Standards — approval for non-conforming medicines**

#### **5.02 Approval to import etc non-conforming medicines**

- (1) In relation to the supply, importation or export of a medicine otherwise in compliance with the provisions of this Rule, the Authority may grant an approval for that activity to occur although the medicine does not conform to an applicable standard.
- (2) An approval under this section may be granted:
  - (a) unconditionally or subject to conditions; or
  - (b) in respect of a particular medicine or kind of medicines.
- (3) As soon as practicable after granting an approval under this section, the Authority must publish particulars of the approval in the Authority Gazette.
- (4) Within 20 working days after making a decision to refuse to grant an approval under this section, the Authority must give the applicant written notice of the decision and the reasons for the decision.
- (5) In relation to a failure to comply with a condition mentioned in subsection (2):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

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## Division 5.3 Exemptions etc — product licensing

### 5.03 Exempt medicines generally

- (1) Part 3 of this Rule has no application in relation to a medicine, or to medicines of a particular kind, specified in Part 1 of Schedule 4.
- (2) Part 3 of this Rule has no application in relation to a medicine, or to medicines of a particular kind, specified in Part 2 of Schedule 4 if, in relation to the medicine or kind of medicine, the specified conditions are met.
- (3) If:
  - (a) a medicine, or medicines of a particular kind, mentioned in subsection (1) or (2) cease to be exempt from the application of Part 3; and
  - (b) an application has been made for a product licence in respect of the medicine, or medicines of that kind, before the exemption ceased;the medicine, or medicines of that kind, are taken to be exempt from the operation of Part 3 until the application is determined.

### 5.04 Medicine used urgently for life-threatening or seriously debilitating condition

- (1) Part 3 of this Rule has no application in relation to a medicine that is administered by a medical practitioner to a Category A patient as a therapeutic treatment in the following circumstances:
  - (a) the medicine is not included:
    - (i) in Schedule 9 to the Scheduling Standard; or
    - (ii) if the medicine is to be administered in New Zealand — in Schedule 1 (Class A controlled drugs) to the Misuse of Drugs Act 1975 of New Zealand
  - (b) the therapeutic treatment is necessitated by the state of the disease, disorder or condition;
  - (c) the patient (or the patient's guardian) has given informed consent to the therapeutic treatment;
  - (d) the administration of the medicine is in accordance with the prescription of a medical practitioner given, in relation to the patient, in accordance with good medical practice.
- (2) In subsection (1):

**Category A patient** means a person who:

  - (a) is seriously ill with a condition that is reasonably likely to lead to the death of the person within a matter of months; or
  - (b) has a medical condition that, in the absence of immediate treatment, is likely to lead to the imminent loss of:
    - (i) an arm, leg, hand or foot of the person; or
    - (ii) an organ of the person; or

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(iii) the person's sight.

***informed consent***, in relation to a therapeutic treatment or proposed therapeutic treatment for a person, means consent to the treatment freely given by the person on the basis of information given to the person about the potential risks and benefits of the treatment that is sufficient to allow the person to make an informed decision whether to consent to the treatment.

- (3) Within 20 working days after prescribing the medicine, the medical practitioner must give to the Authority a signed statement (or a copy of the signed statement):
- (a) in relation to the patient and the treatment; and
  - (b) in the approved form.
- (4) Treatment with the medicine must not exceed a period of 12 months unless, before the end of that period, the medical practitioner gives to the Authority a further signed statement (or a copy of the signed statement) of the kind mentioned in subsection (3).
- (5) In relation to a failure to comply with subsection (3) or (4):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* This section gives effect to the Special Access Scheme as it applies to Category A patients. For information and guidelines relating to the Scheme, see the Authority website.

*Note 2* Medicines imported for supply under this section may be exempt from licensing while held by the importer: see item 1 of Part 2 of Schedule 3.

*Note 3* [Re criminal and civil penalties, and infringement notices]

## **5.05 Medicine used for a special purpose**

- (1) Part 3 of this Rule has no application in relation to a medicine that is supplied in accordance with an approval granted by the Authority for the purpose solely of use in the medical treatment of a specified person.
- (2) An application for an approval under this section must:
- (a) be made in a form acceptable to the Authority; and
  - (b) be supported by such information as is required by the Authority.
- (3) The Authority must not grant an approval under this section to a person unless the person:
- (a) is a medical practitioner or dental practitioner; and
  - (b) is a resident of, or carries on business in, Australia or New Zealand.
- (4) An approval is subject to the conditions (if any) specified in the approval.
- (5) In relation to a failure to comply with a condition mentioned in subsection (4):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

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*Note 1* This section gives effect to the Special Access Scheme as it applies principally to category B patients. For information and guidelines relating to the Scheme, see the Authority website.

*Note 2* Medicines imported pending the grant of an approval under this section may be exempt from licensing while held by the importer: see item 1 of Part 2 of Schedule 3.

*Note 3* [Re criminal and civil penalties, and infringement notices]

***[Drafter's Note: Indemnity provisions relating to the Authority will appear in the implementing legislation for each country]***

## **5.06 Medicine used for an experimental purpose (Clinical Trial Assessment Scheme)**

- (1) Part 3 of this Rule has no application in relation to a medicine that is supplied in accordance with an approval granted by the Authority under this section for the purpose solely of use for experimental purposes in humans in accordance with a procedural protocol agreed with an appropriate ethics committee.
- (2) An approval under this section is required if the medicine or the proposed experimental use (or both the medicine and the proposed experimental use, as the case may be) meet the criteria specified, for the purposes of this subsection, in an Order.
- (3) Subject to this section, an application may be made for an approval under this section even if an approval is not required under subsection (2).
- (4) An application for an approval under this section is not effective unless:
  - (a) it is in a form acceptable to the Authority; and
  - (b) is accompanied by:
    - (i) a procedural protocol relating to the experimental use; and
    - (ii) the information specified in subsection (5) and such additional information as is required by the Authority; and
    - (iii) the prescribed evaluation fee payable under Part 11.
- (5) For subparagraph (4) (b) (ii), the following information is specified:
  - (a) the name of, and the contact details for, the principal investigator for each clinical trial involving the medicine;
  - (b) the location of each trial site;
  - (c) the name of the person who will be in charge of the trial site (or each trial site, if the trial is to be conducted at more than 1 site);
  - (d) information about whether or not any conditions specified by the ethics committee have been met.
- (6) The Authority must not grant an approval under this section to an applicant unless:
  - (a) the application is effective; and

- 
- (b) the applicant is a resident of, or carries on business in, Australia or New Zealand; and
  - (c) the Authority is satisfied that the information (including any data) accompanying the application is sufficient to demonstrate that the procedural protocol is adequate to protect both the welfare of participants and the public interest.
- (7) An approval under this section is subject to:
- (a) the conditions (if any) specified in the approval; and
  - (b) the conditions specified in subsection (8).
- (8) For subsection (7), the following conditions are specified:
- (a) before any trial begins, the Authority must have received from the holder of the approval:
    - (i) evidence that the procedural protocol has been agreed with an appropriate ethics committee; and
    - (ii) the name of the ethics committee and of its accrediting body;
  - (b) the holder of the approval must have received the advice of the ethics committee, and have determined to conduct the clinical trials having regard to that advice;
  - (c) the ethics committee must have undertaken to assume responsibility for monitoring the conduct of each trial;
  - (d) the terms of the proposed trials determined by holder of the approval, must be no less restrictive than the terms advised by the ethics committee;
  - (e) before any trial begins, the Authority must have received from the holder of the approval, and the principal investigator for each trial site, written undertakings:
    - (i) to conduct the trials in accordance with the principles set out in the Practice Guidelines; and
    - (ii) to comply with requests by an authorised person, whether made before or after the start of the trial, to give information about the conduct of the trial; and
    - (iii) to allow an authorised person to do the things mentioned in section 9.04 of the Administration and Interpretation Rule;
  - (f) the trials must comply with the agreed procedural protocol;
  - (g) the trials must be conducted in accordance with the principles set out in the Practice Guidelines;
  - (h) the trials must not be conducted, or continue, if the ethics committee or the Authority informs the holder of the approval that the use is inconsistent with:
    - (i) the procedural protocol; or
    - (ii) any condition of the approval.

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- (i) the trials must not be conducted, or continue, if the Authority:
    - (i) becomes aware that to conduct or continue the trials would be contrary to the public interest; and
    - (ii) for that reason, gives a direction to the holder of the approval that the trials not be conducted, or not be continued.
  - (9) In relation to a failure to comply with a condition mentioned in subsection (7) or (8):
    - (a) for Australia — sections [ ] of the Act apply; and
    - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

### **5.07 Medicine used for an experimental purpose (Clinical Trial Certification Scheme)**

- (1) Part 3 of this Rule has no application in relation to a medicine that is supplied in accordance with an approval granted by the Authority under this section for the purpose solely of use for experimental purposes in humans in accordance with a procedural protocol agreed with an appropriate ethics committee, not being a use for experimental purposes for which an approval is required under section 5.06:
- (2) An application for an approval under this section is not effective unless:
  - (a) it is in a form acceptable to the Authority; and
  - (b) is accompanied by:
    - (i) the information specified in subsection (3) and such additional information as is required by the Authority; and
    - (ii) the certification mentioned in subsection (4); and
    - (iii) the prescribed application fee payable under Part 11.
- (3) For subparagraph (2) (b) (i), the following information is specified:
  - (a) the name of the ethics committee and of its accrediting body;
  - (b) the name of, and the contact details for, the principal investigator for each clinical trial involving the medicine;
  - (c) the location of each trial site;
  - (d) the name of the person who will be in charge of the trial site (or each trial site, if the trial is to be conducted at more than 1 site);
  - (e) information about whether or not any conditions specified by the ethics committee have been met.
- (4) For subparagraph (2) (b) (ii), the applicant must certify that:
  - (a) the applicant is a resident of, or carries on business in, Australia or New Zealand; and
  - (b) an approval under section 5.06 in respect of the use for experimental purposes is not required; and

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- (c) a procedural protocol has been agreed with an appropriate ethics committee; and
  - (d) the application contains no information that is false or misleading in a material particular.
- (5) The Authority must grant an approval under this section to an applicant if:
- (a) the application is effective; and
  - (b) the Authority is satisfied as to all aspects of the certification.
- (6) An approval under this section is subject to:
- (a) the conditions (if any) specified in the approval; and
  - (b) the conditions specified in subsection (7).
- (7) For subsection (6), the following conditions are specified:
- (a) the holder of the approval must have received the advice of the ethics committee, and have determined to conduct the clinical trials having regard to that advice;
  - (b) the ethics committee must have undertaken to assume responsibility for monitoring the conduct of each trial;
  - (c) the terms of the proposed trials determined by the holder of the approval, must be no less restrictive than the terms advised by the ethics committee;
  - (d) before any trial begins, the Authority must have received from the holder of the approval, and the principal investigator for each trial site, written undertakings:
    - (i) to conduct the trials in accordance with the principles set out in the Practice Guidelines; and
    - (ii) to comply with requests by an authorised person, whether made before or after the start of the trial, to give information about the conduct of the trial; and
    - (iii) to allow an authorised person to do the things mentioned in section 9.04 of the Administration and Interpretation Rule;
  - (e) the trials must comply with the agreed procedural protocol;
  - (f) the trials must be conducted in accordance with the principles set out in the Practice Guidelines;
  - (g) the trials must not be conducted, or continue, if the ethics committee or the Authority informs the holder of the approval that the use is inconsistent with:
    - (i) the procedural protocol; or
    - (ii) any condition of the approval;
  - (h) the trials must not be conducted, or continue, if the Authority:
    - (i) becomes aware that to conduct or continue the trials would be contrary to the public interest; and
    - (ii) for that reason, gives a direction to the holder of the approval that the trials not be conducted, or not be continued.

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(8) In relation to a failure to comply with a condition mentioned in subsection (6) or (7):

- (a) for Australia — sections [ ] of the Act apply; and
- (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

## **5.08 Exemption for authorised prescribers**

(1) Part 3 of this Rule has no application in relation to a medicine that is supplied in accordance with an approval granted by the Authority to a specified medical practitioner for the purpose solely of treatment of a person suffering a life-threatening, or otherwise serious, disease, disorder or condition.

(2) An approval under this section may authorise the practitioner to supply to the person, or a class of persons, specified in the approval:

- (a) a specified medicine; or
- (b) medicines of a specified kind;

and may be granted subject to specified conditions (including a condition requiring compliance with any direction by the Authority regarding use of the medicine, or medicines, in the treatment of a patient).

(3) An approval may only be given to:

- (a) a medical practitioner engaged in clinical practice in a hospital who has the approval of an appropriate ethics committee to supply the medicine or kind of medicines; or
- (b) a medical practitioner engaged in clinical practice outside a hospital who:
  - (i) has the approval of an appropriate ethics committee to supply the medicine or kind of medicines; or
  - (ii) having no reasonable access to an appropriate ethics committee that could approve the supply of the medicine or kind of medicines, has an endorsement to so supply from a specialist college with expertise relevant to the use of the medicine or medicines of that kind.

(4) The Authority may, by written notice, impose conditions, or further conditions, on an approval.

(5) In relation to a failure to comply with a condition mentioned in subsection (2) or (4):

- (a) for Australia — sections [ ] of the Act apply; and
- (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* Medicines imported pending the grant of an approval under this section may be exempt from licensing while held by the importer: see item 1 of Part 2 of Schedule 4.

*Note 2* For information and guidelines relating to access to unlicensed medicines by authorised prescribers under this section, see the Authority website.

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*Note 3* [Re criminal and civil penalties, and infringement notices]

## **5.09 Medicine substituting for unavailable licensed medicine**

- (1) Part 3 of this Rule has no application in relation to a medicine that is imported or supplied in accordance with an approval granted to a person by the Authority:
  - (a) for the purpose of substituting for a medicine in respect of which a product licence is in force but which is unavailable or is available in insufficient quantity; or
  - (b) because there is no medicine in respect of which a product licence is in force that could be used as a substitute.
- (2) An approval may be granted in respect of a medicine for the purpose mentioned in paragraph (1) (a) only if:
  - (a) either:
    - (i) an effective application has been made under this Rule for a product licence in respect of the medicine; or
    - (ii) the medicine is registered or otherwise approved for general marketing in at least one country other than Australia and New Zealand that is specified for the purposes of this subparagraph in an Order; and
  - (b) the medicine is of a kind:
    - (i) mentioned in Schedule 3; or
    - (ii) specified for the purposes of this subparagraph in an Order; and
  - (c) the Authority considers the approval to be necessary in the interests of public health.

*Note* For the publication, operation and disallowance of Orders, see:
  - (a) in Australia — [Division 2 of Part 2] of the Act; and
  - (b) in New Zealand — [Part 2] of the Act.
- (3) An approval may be granted in respect of a medicine for the reason mentioned in paragraph (1) (b) only if:
  - (a) an effective application has been made under this Rule for a product licence in respect of the medicine; and
  - (b) the medicine is of a kind:
    - (i) mentioned in Schedule 3; or
    - (ii) specified for the purposes of this subparagraph in an Order; and
  - (c) the Authority considers the approval to be necessary in the interests of public health.
- (4) An approval under this section may be granted subject to specified conditions and for a specified period.
- (5) An approval lapses if:
  - (a) the period specified in the approval expires; or

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- (b) the Authority is satisfied that:
- (i) the circumstances mentioned in paragraph (1) (a) or (b), as the case requires, no longer exist; or
  - (ii) paragraph (2) (a), (b) or (c), or paragraph (3) (a), (b), or (c), as the case requires, no longer applies; or
  - (iii) a condition of the approval has been contravened;
- and has given written notice to the approval holder that it is so satisfied.
- (6) Subsection (5) does not prevent a further approval being granted before an approval lapses because of expiry, to take effect immediately after that lapsing.
- (7) In relation to a failure to comply with a condition mentioned in subsection (4):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.
- Note* [Re criminal and civil penalties, and infringement notices]

## **5.10 Medicine required for public health emergency**

- (1) Part 3 of this Rule has no application in relation to a medicine, or kind of medicines, that is imported or supplied in accordance with an approval granted by the Authority in accordance with this section.
- (2) An approval may be granted to a person or a class of persons specified in the approval.
- (3) An approval must be granted if, and only if, the Minister gives the Authority written notification that he or she is satisfied that either of the following circumstances exists:
- (a) the medicine, or kind of medicines, needs to be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possibly impending emergency;
  - (b) the medicine, or kind of medicines, needs to be made available urgently in order to deal with an actual threat to public health caused by an emergency that has occurred or is occurring.
- (4) An approval is subject to conditions specified in the approval about any of the following:
- (a) the quantity of a medicine to which the approval applies;
  - (b) the source of the medicine;
  - (c) the importation, manufacture or export of the medicine;
  - (d) the supply of the medicine (including the persons or class of persons to whom the medicine may be supplied for use and the circumstances under which a stockpile of the medicine may be supplied for use);
  - (e) the storage and security of the medicine;

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- (f) the keeping and disclosure of, and access to, records about the medicine;
  - (g) the disposal of unused medicine;
  - (h) the manner in which the medicine is to be dealt with if an approval condition is contravened;
  - (i) any other matter that the Authority considers appropriate.
- (5) An approval:
- (a) has effect only in the country whose Government the Minister represents; and
  - (b) takes effect on the day on which it is made or, if a later day is specified, on that day.
- (6) An approval ceases to have effect in relation to a medicine on the earliest of the following dates:
- (a) the day specified in the approval as the end of the period of effect of the approval;
  - (b) the date of effect of revocation of the approval, on the Minister's written request;
  - (c) the date of commencement of a product licence issued in respect of the medicine;
  - (d) in the case of an approval relating to a kind of medicines that includes that medicine — the date of a variation of the approval, on the Minister's written request, that removes from it the medicine concerned.
- (7) If an approval is revoked, or varied, the revocation or variation takes effect:
- (a) if the revocation or variation states that the revocation or variation is necessary to prevent imminent risk of death, serious illness or serious injury — on the day on which the revocation or variation is made; or
  - (b) in any other case — on the day specified by the revocation or variation, being a day not earlier than 20 working days after the day on which the revocation or variation is made.
- (8) An approval does not cease to have effect by reason only of a contravention of a condition.
- (9) If so requested by the Minister, in writing, the Authority must, in writing, revoke or vary a condition of an approval (including, by addition of a new condition).
- (10) If a condition is revoked, or varied, the revocation or variation takes effect:
- (a) if the revocation or variation states that the revocation or variation is necessary to prevent imminent risk of death, serious illness or serious injury — on the day on which the revocation or variation is made; or
  - (b) in any other case — on the day specified by the revocation or variation, being a day not earlier than 20 working days after the day on which the revocation or variation is made.

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- (11) In relation to a failure to comply with a condition of an approval:
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

***[Drafter’s note The placement and application of this provision (and the provision of appropriate indemnities) is still under consideration]***

## **Division 5.4 Exemptions — manufacturing**

### **5.11 Exempt manufacturers**

A manufacturer mentioned in column 2 of an item in Part 1 of Schedule 5 is exempt from the operation of Part 4 of this Rule in respect of the manufacture, or steps in the manufacture, of a kind of medicine mentioned in column 3 of that item.

### **5.12 Exemption in respect of certain medicines**

- (1) A manufacturer is exempt from the operation of Part 4 of this Rule in respect of the manufacture, or steps in the manufacture, of a kind of medicine mentioned in column 2 of an item in Part 2 of Schedule 5.
- (2) Subsection (1) does not apply to the manufacture, or a step in the manufacture, of a medicine to the extent that the medicine is for supply:
  - (a) in Australia, as a Commonwealth pharmaceutical benefit under the *National Health Act 1953* or the *Veteran’s Entitlement Act 1986*; or
  - (b) in New Zealand, and is listed on the New Zealand Pharmaceutical Schedule.
- (3) If:
  - (a) a kind of medicine mentioned in Part 2 of Schedule 5 ceases to be a medicine in respect of which a manufacturer is exempt from the operation of Part 4 of this Rule; and
  - (b) before the day on which the cessation begins, each person who carries out a step in the manufacture of the medicine applies for a manufacturing licence authorising the person to carry out the step on premises identified in the application;

the medicine produced by those persons carrying out the steps on those premises is taken, until each application is determined, to be a medicine in respect of which those persons are exempt from the operation of that Part.

### **5.13 Revocation of exemption**

If the exemption of a manufacturer from the operation of Part 4 of this Rule ceases because of an amendment of this Rule, the cessation takes effect 20 working days after the amendment takes effect.

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## Part 6 Recall of deficient and unused medicines

### 6.01 Overview of this Part

This Part enables the Authority to issue notices for the recall of a medicine that is defective or is supplied in contravention of this Rule. Product licence holders and others to whom a notice is addressed must comply with the requirements of a notice. The Authority may also issue notices informing the public about the recall.

### 6.02 Recall of medicines

- (1) In a circumstance mentioned in relation to a medicine in an item in the following table, the Authority may, in writing, impose requirements on the person mentioned in the item.

#### Circumstances in which requirements may be imposed

| Item | Circumstance relating to a medicine  | Person subject to requirements   |
|------|--|--|
| 1    | A medicine is supplied in accordance with a product licence, but:<br>(a) the medicine does not conform to an applicable standard; or<br>(b) the Manufacturing Principles have not been observed in its manufacture; or<br>(c) the Authority is satisfied that the quality, safety or efficacy of the medicine is unacceptable, or that the presentation of the medicine is not acceptable; or<br>(d) a step in its manufacture has been carried out by a manufacturer not licensed to carry out the step | The holder of the product licence  |
| 2    | The product licence in respect of a medicine has been suspended under this Rule  | The holder of the product licence  |
| 3    | The product licence in respect of a medicine has been revoked under this Rule  | The person who was the holder of the product licence immediately before the revocation |

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**Circumstances in which requirements may be imposed**

| <b>Item</b> | <b>Circumstance relating to a medicine</b>  | <b>Person subject to requirements</b>   |
|-------------|---|---|
| 4           | <p>A medicine is supplied while exempt under section 5.03, but:</p> <ul style="list-style-type: none"><li>(a) the medicine does not conform to an applicable standard; or</li><li>(b) the Manufacturing Principles have not been observed in its manufacture; or</li><li>(c) the Authority is satisfied that the quality, safety or efficacy of the medicine is unacceptable</li></ul>  | The person supplying the medicine   |
| 5           | <p>A medicine is supplied in accordance with an approval granted under section 5.05, 5.06, 5.07, 5.08, 5.09 or 5.10 but:</p> <ul style="list-style-type: none"><li>(a) the medicine does not conform to an applicable standard; or</li><li>(b) the Manufacturing Principles have not been observed in its manufacture; or</li><li>(c) the Authority is satisfied that the quality, safety or efficacy of the medicine is unacceptable; or</li><li>(d) in the case of a medicine supplied in accordance with an approval granted under section 5.08 — the medicine is not fit for its intended use</li></ul> | The holder of the approval or, in the case of an approval under section 5.10 any person authorised by the approval to supply the medicine |
| 6           | <p>A medicine is supplied, but none of the following paragraphs apply in relation to the medicine:</p> <ul style="list-style-type: none"><li>(a) the medicine is supplied in accordance with a product licence that:<ul style="list-style-type: none"><li>(i) is in force; and</li><li>(ii) authorises that supply;</li></ul></li><li>(b) the medicine is exempt under section 5.03 or 5.04;</li><li>(c) the medicine supplied in accordance with an approval under section 5.05, 5.06, 5.07, 5.08, 5.09 or 5.10</li></ul>  | The person supplying the medicine   |
| 7           | <p>A medicine:</p> <ul style="list-style-type: none"><li>(a) is imported or supplied; and</li><li>(b) is counterfeit</li></ul>  | The person importing or supplying the medicine  |

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**Circumstances in which requirements may be imposed**

| <b>Item</b> | <b>Circumstance relating to a medicine</b>  | <b>Person subject to requirements</b> |
|-------------|---|---------------------------------------|
| 8           | A medicine is, or has been, supplied, and the Authority is satisfied that the medicine is, has been, or could possibly be, subject to actual or potential tampering | The person supplying the medicine     |

- (2) The requirements may be one or more of the following:
- (a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover the medicine that has been imported or supplied;
  - (b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstance mentioned in subsection (1) has occurred in relation to the medicine;
  - (c) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, that is relevant to this section relating to the importation or supply of the medicine.
- (3) A requirement under this section does not apply to medicine that cannot be recovered because it has been administered to, or applied in the treatment of, a person.
- (4) If the circumstance mentioned in subsection (1) applies only to a batch of the medicine, the Authority may limit the imposition of the requirements to medicine included in that batch.
- (5) If:
- (a) A requirement under this section has been, or is about to be, imposed on the holder of a product licence in respect of the medicine concerned, in a circumstance mentioned in that subsection; and
  - (b) an event of a kind mentioned in subsection 4.23 (1), (2), (3) or (4) occurs in relation to the licence holder; and
  - (c) it is not possible or practicable, in the circumstances, for the licence holder, or the person who, under section 4.23, is taken to be the licence holder as a consequence of the event, to comply with the requirement;
- the Authority may impose the requirement on any other person who was the holder of a product licence in respect of the medicine at any time when the medicine was supplied in the circumstance mentioned.
- (6) As soon as practicable after imposing a requirement under this section, the Authority must publish in the Authority Gazette a notice setting out particulars of the requirement.

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(7) In relation to a failure to comply with a requirement imposed under this section:

- (a) for Australia — sections [ ] of the Act apply; and
- (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

*Note* [Re right of each country to take recall action and recover costs]

### **6.03 Powers of suspension and revocation unaffected**

Imposition of a requirement under section 6.02 does not affect the Authority's power:

- (a) to suspend or revoke a product licence in respect of the medicine concerned; or
- (b) in the case of medicine in respect of which an approval has been granted under Part 5 — to revoke the approval.

### **6.04 Recall of medicine approved for public health emergency**

(1) This section applies to a medicine that is the subject of an approval under subsection 5.10 (1) if:

- (a) a person supplies a batch of the medicine; and
- (b) the Authority is satisfied that medicine included in that batch:
  - (i) does not conform to a standard applicable to medicine of that kind; or
  - (ii) is otherwise not fit to be used for its intended purpose.

(2) The Authority may, by written notice given to the person, require the person to take steps to recover medicine included in the batch (other than medicine that cannot be recovered because it has been used).

(3) The notice may specify one or more of the following requirements:

- (a) the steps to be taken to recover the medicine;
- (b) the manner in which the steps are to be taken;
- (c) a reasonable period within which the steps are to be taken.

(4) As soon as practicable after giving the notice, the Authority must publish it in the Authority Gazette.

(5) In relation to a failure to comply with the requirements of a notice given under subsection (2):

- (a) for Australia — sections [ ] of the Act apply; and
- (b) for New Zealand — section [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

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**6.05 Disposal of unused medicine exempted for a public health emergency**

- (1) This section applies to a medicine that is the subject of an approval under subsection 5.10 (1) if:
  - (a) the approval ceases to have effect otherwise than because a product licence has been issued in respect of the medicine; and
  - (b) the medicine has not been used before the approval so ceases to have effect.
- (2) The Authority may arrange for the disposal of any of the medicine in accordance with the Orders.
- (3) Orders made for the purpose of subsection (2) may set out the methods by which the medicine is to be stored, supplied, destroyed, exported or otherwise disposed of.
- (4) A method set out for subsection (3) must not enable or permit any benefit to be conferred on a person (including the Government of Australia or of New Zealand) other than the owner of the medicine.

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## Part 7                      Product and consumer information documents

### 7.01      Overview of this Part

This Part enables the Authority to impose requirements with respect to the information to be provided in product information documents and consumer information documents for certain medicines.

### 7.02      Application of this Part

This Part applies to a Class 2 medicine, or a kind of class 2 medicines:

- (a) mentioned in Part 1 of Schedule 3; or
- (b) included in Schedule 3, 4, 8 or 9 of the Scheduling Standard.

### 7.03      Product information

- (1) In this section:

*product information*, in relation to a medicine, means information relating to the safe and effective use of the medicine, including information regarding the usefulness and limitations of the medicine.

*product information document* means a document that includes product information.

- (2) The Authority may, by Order, specify, for a medicine or a kind of medicines to which this Part applies, either or both of the following:
- (a) the requirements of a product information document, including:
    - (i) the form of the document; and
    - (ii) the written information to be included in the document;
  - (b) the manner in which, and the extent to which, the product information document must be made publicly available.

*Note 1* It is a requirement for the grant of a product licence in respect of a medicine to which this Part applies that a product information document for the medicine comply with the requirements of this Part: see sections 3.32 and 3.34.

*Note 2* For the publication, operation and disallowance of Orders, see:

- (a) in Australia — [Division 2 of Part 2] of the Act; and
- (b) in New Zealand — [Part 2] of the Act.

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## 7.04 Consumer medicine information

- (1) In this section:
- consumer medicine information*, in relation to a medicine, means information for consumers relating to the safe and effective use of the medicine, including information regarding the usefulness and limitations of the medicine.
- consumer medicine information document* means a document that includes consumer medicine information.
- (2) The holder of a product licence in respect of a medicine or a kind of medicines to which this Part applies, must not supply the medicine, or a medicine of that kind, if the licence holder does not provide, with the medicine, a consumer medicine information document that meets the requirements specified, for the medicine, or for medicines of that kind, in an Order under subsection (4).
- (3) For the purposes of subsection (2), the consumer medicine information document must be provided:
- (a) in the primary pack in which the medicine is supplied; or
  - (b) in another manner that will enable the information to be given to the person to whom the medicine is administered or otherwise dispensed.
- (4) The Authority may, by Order, specify, for a medicine or a kind of medicines to which this Part applies, the requirements of a consumer medicine information document, including:
- (a) the form of the document; and
  - (b) the information to be included in the document.
- Note* For the publication, operation and disallowance of Orders, see:
- (a) in Australia — [Division 2 of Part 2] of the Act; and
  - (b) in New Zealand — [Part 2] of the Act.
- (5) In relation to a failure to comply with subsection (2):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.
- Note* [Re criminal and civil penalties, and infringement notices]

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## Part 8 Obtaining information

### 8.01 Overview of this Part

The purpose of this Part is to provide that the Authority may obtain information about medicines from applicants for, and holders of, product licences, and from persons importing, manufacturing or supplying medicines that are exempted from product licensing. The Authority may also obtain information about medicines under other provisions of this Rule, or, generally, about products that may be therapeutic products, under Division 11.3 of the Administration and Interpretation Rule.

*Note* [Re provision of civil and criminal penalties in principal legislation]

### 8.02 Authority may require information from product licence holders and applicants

- (1) The Authority may, by written notice given to a person who is an applicant for, or the holder of, a product licence in respect of a medicine, require the person to give to the Authority:
  - (a) within such reasonable time as is specified in the notice, being not less than 10 working days; and
  - (b) in such form as is specified in the notice;information or documents relating to one or more of the following:
  - (c) the formulation of the medicine;
  - (d) the composition of the medicine;
  - (e) the design specifications of the medicine;
  - (f) the quality of the medicine;
  - (g) the method and place of manufacture or preparation of the medicine and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the medicine;
  - (h) the presentation of the medicine;
  - (i) the safety and efficacy of the medicine;
  - (j) the conformity of the medicine to a requirement applicable under this Rule or the Advertising Rule relating to advertising;
  - (k) if the medicine is a Class 2 medicine or an export-only (Class 2) medicine — the regulatory history of the medicine in a country other than Australia or New Zealand.
- (2) A notice under subsection (1) may require or permit information to be given in accordance with specified software requirements:
  - (a) on a specified kind of data processing device; or
  - (b) by way of a specified kind of electronic transmission.

- 
- (3) In relation to a failure to comply with the requirements of a notice given under subsection (1):
- (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

***[Drafter’s note: The implementing legislation will include offence provisions relating to the giving of false or misleading information or documents.]***

### **8.03 Information about certain medicines**

#### *Medicine to be used urgently for life-threatening etc condition*

- (1) The Authority may by written notice given to a medical practitioner who administers, or is to administer, a medicine mentioned in section 5.04, require the medical practitioner to give to the Authority information or documents relating to one or more of the matters specified in subsection (6) in relation to the medicine.

#### *Medicine to be used for special or experimental purposes*

- (2) The Authority may, by written notice given to a person who is an applicant for, or the holder of, an approval under section 5.05, 5.06 or 5.07 in respect of a medicine, require the person to give to the Authority information or documents relating to one or more of the matters specified in subsection (6) in relation to the medicine.

#### *Medicine to be used by authorised prescribers*

- (3) The Authority may, by written notice given to a medical practitioner who is an applicant for, or the holder of, an approval under section 5.08 in respect of a medicine, require the medical practitioner to give to the Authority information or documents relating to one or more of the matters specified in subsection (6) in relation to the medicine.

#### *Medicine substituting for unavailable licensed medicine*

- (4) The Authority may, by written notice given to a person who is an applicant for, or the holder of, an approval under section 5.09 in respect of a medicine, require the person to give to the Authority information or documents relating to one or more of the matters specified in subsection (6) in relation to the medicine.

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*Medicine to be used in a public health emergency*

- (5) The Authority may, by written notice given to a person who is an applicant for, or the holder of, an approval under section 5.10 in respect of a medicine, require the person to give to the Authority information or documents relating to one or more of the matters specified in subsection (6) in relation to the medicine.
- (6) For subsections (1), (2), (3), (4), and (5), the following matters are specified in relation to a medicine:
  - (a) the supply of the medicine;
  - (b) the handling of the medicine;
  - (c) the monitoring of the supply of the medicine;
  - (d) the results of the supply of the medicine;
  - (e) in the case of a medicine mentioned in subsection (1) — the condition of the person to whom the medicine is, or is to be, administered.
- (7) A notice under subsection (1), (2), (3), (4) or (5):
  - (a) must specify a reasonable period, of at least 10 working days, for compliance by the person to whom the notice is given; and
  - (b) may require information to be given in accordance with specified software requirements:
    - (i) on a specified kind of data processing device; or
    - (ii) by way of a specified kind of electronic transmission.
- (8) In relation to a failure to comply with the requirements of a notice given under subsection (1), (2), (3), (4) or (5):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

***[Drafter's note: The implementing legislation will include offence provisions relating to the giving of false or misleading information or documents.]***

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## Part 9 Adverse event reporting

### 9.01 Overview of this Part

This part imposes requirements on the holder of a product licence in respect of a medicine to notify the Authority of any adverse event relating to the medicine. The Authority may also require information about an adverse event from an applicant where a licence application lapses or is withdrawn. Other obligations of a licence holder relating to adverse events are included in licence conditions.

*Note* [Re provision of civil and criminal penalties in principal legislation]

### 9.02 Notification of adverse effects etc of medicines

- (1) If the holder of a product licence in respect of a medicine becomes aware of information of a kind mentioned in subsection (2) relating to the medicine, the person must give the information to the Authority, in writing, in accordance with the pharmacovigilance requirements.
- (2) For subsection (1), the kinds of information are as follows:
  - (a) information that contradicts information already furnished by the licence holder under the Rules;
  - (b) information that indicates that the use of the medicine in accordance with the recommendations for its use may have an unintended harmful effect;
  - (c) information that indicates that the medicine, when used in accordance with the recommendations for its use, may not be as effective as the application for the licence, or information already furnished by the licence holder under the Rules, suggests;
  - (d) information that indicates that the quality, safety or efficacy of the medicine is unacceptable.
- (3) In subsection (1), *pharmacovigilance requirements* means the pharmacovigilance requirements specified, for the purposes of this section, in an Order.
- (4) In relation to a failure to comply with the requirement of subsection (1):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note 1* [Re criminal and civil penalties, and infringement notices]

*Note 2* A contravention of this section by a licence holder in relation to a medicine may lead to the suspension or revocation of the product licence: see subsections 3.52 (1) and 3.60 (1).

*Note 3* For further obligations of a licence holder relating to notifying the Authority of adverse information about a medicine, see subsections 3.42 (7) and (8).

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*Note 4* For the audit and inspection powers of the Authority in relation to the pharmacovigilance obligations of licence holders, see Part 9 of the Administration and Interpretation Rule.

### **9.03 Notification of adverse effects etc where product licence application lapses or is withdrawn**

- (1) If an application for a product licence in respect of a medicine lapses or is withdrawn, the Authority may give the applicant written notice requiring the applicant:
  - (a) to inform the Authority in writing whether the applicant is aware of any information of a kind mentioned in subsection 9.02 (2) relating to the medicine; and
  - (b) if the applicant is aware of such information, to give the information to the Authority in writing.
- (2) A notice under subsection (1) may be given within 10 working days after an application lapses or is withdrawn.
- (3) In relation to a failure to comply with the requirements of a notice under subsection (1):
  - (a) for Australia — sections [ ] of the Act apply; and
  - (b) for New Zealand — sections [ ] of the Act apply.

*Note* [Re criminal and civil penalties, and infringement notices]

***[Drafter's note: Details of the adverse event/pharmacovigilance framework are yet to be finalised and will be the subject of a future discussion paper and consultation.]***

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## Part 10 Orphan medicines

### 10.01 Meaning of orphan medicine

- (1) Subject to subsections (3), (4) and (5), a medicine is an *orphan medicine* if:
  - (a) the medicine is intended to treat, prevent or diagnose a rare disease or condition; or
  - (b) it is not commercially viable to supply the medicine for the treatment, prevention or diagnosis of another disease or condition.
- (2) For subsection (1), a disease or condition is *rare* if it is likely to affect not more than a total of 2,400 people in Australia and New Zealand at any one time.
- (3) A medicine is not an orphan medicine if any of the following persons or bodies has, whether before or after the commencement of this Division, refused to approve the medicine for use for the disease or condition mentioned in paragraph (1) (a) for a reason related to the medicine's safety:
  - (a) the Authority;
  - (b) the Food and Drug Administration of the United States of America;
  - (c) the Medicines and Healthcare Products Regulatory Agency of the United Kingdom;
  - (d) the Health Products and Food Branch of Health Canada;
  - (e) the Medical Products Agency of Sweden;
  - (f) the Medicines Evaluation Board of the Netherlands;
  - (g) the European Agency for the Evaluation of Medicines;
  - (h) Medsafe;
  - (i) the Therapeutic Goods Administration.
- (4) It is not an orphan medicine if it has been approved for use for the disease or condition mentioned in paragraph (1) (a) by Medsafe or the Therapeutic Goods Administration before the commencement of this Rule.
- (5) However, it is not prevented from being an orphan medicine solely because it has been approved for another use or indication by Medsafe or the Therapeutic Goods Administration before the commencement of this Rule.

### 10.02 Application for orphan medicine designation

- (1) An applicant for a product licence in respect of a medicine may apply to the Authority for the medicine to be designated as an orphan medicine.
- (2) An application must be made in accordance with the approved form.
- (3) The application must show why the medicine is an orphan medicine.

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- (4) If the medicine is a vaccine or *in vivo* diagnostic agent, the application must also state that the medicine will be administered to not more than a total of 2,400 people in Australia and New Zealand in each year after a product licence is granted in respect of the medicine for use for the disease or condition.

*Note* There is no fee for making the application: see section [ ] of Part 11.

### **10.03 Orphan medicine designation**

- (1) The Authority must consider an application made in accordance with section 10.02.
- (2) The Authority must designate the medicine, in writing, as an orphan medicine if the Authority is satisfied that the statements made in the application are correct.
- (3) The Authority must refuse to designate the medicine as an orphan medicine if the Authority is not satisfied that all of the statements made in the application are correct.

- (4) The Authority must notify the applicant in writing, as soon as practicable after making the decision, whether the medicine has been designated.

*Note* There is no fee for making the Authority's decision: see section [ ] of Part 11.

- (5) If the Authority decides to not designate the medicine, the Authority must give reasons for the decision in the notice to the applicant.

*Note* A decision to not designate a medicine is a reviewable decision: see Division 11.2 of the Administration and Interpretation Rule.

- (6) If the Authority designates the medicine, the Authority must publish a notice in the Authority Gazette, as soon as practicable after making the decision, giving the following information:
  - (a) the applicant's name;
  - (b) the dose form and indication of the medicine;
  - (c) a statement that the medicine is a designated orphan medicine.

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## **Part 11                      Fees and charges**

*[Drafter's Note   This Part is yet to be drafted]*

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## Part 12                      **Miscellaneous**

*[Drafter's Note Provisions (if any required) yet to be drafted]*

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## Schedule 1 Complementary medicines

(section 1.05)

### Part 1 Complementary medicines substances

| Item | Substance   |
|------|---|
| 1    | A plant or a plant material, an alga, a fungus, a mineral or a non-human animal material  |
| 2    | A substance or mixture of substances:<br>(a) obtained by expression, extraction, distillation, purification or a traditional preparation of a material described in item 1; and<br>(b) not subject to any other process involving chemical transformation other than hydrolysis for preparation of the substance or mixture of substances in an active medicinal form |
| 3    | A vitamin or provitamin, including salts and other compounds of the following types:<br>vitamin A<br>vitamin B1<br>vitamin B2<br>vitamin B3<br>vitamin B5<br>vitamin B6<br>vitamin B12<br>vitamin C<br>vitamin D<br>vitamin E<br>vitamin K<br>biotin<br>choline<br>folic acid   |
| 4    | An amino acid listed in Part 3  |
| 5    | A synthetic equivalent of any substance specified in item 2, 3 or 4   |
| 6    | A mineral compound  |
| 7    | A microorganism, whole or extracted, except a vaccine   |

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## Part 2 Substances ineligible for regulation as complementary medicines

| Item | Substance  |
|------|--|
| 1    | A single chemical entity obtained from a material specified in item 1 of Part 1, if: <ul style="list-style-type: none"><li>(a) there is no history of human use of the material so specified; or</li><li>(b) the intrinsic risk of the single chemical entity fulfils the criteria of a substance:<ul style="list-style-type: none"><li>(i) that should only be available on prescription; or</li><li>(ii) that requires the restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence; or</li><li>(iii) the manufacture, possession, sale or use of which should be prohibited to avoid abuse or misuse</li></ul></li></ul> |
| 2    | A medicine mentioned in Part 1 of Schedule 3   |

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## Part 3 Acceptable Amino Acids

| Item | Substance     |
|------|---------------|
| 1    | Alanine       |
| 2    | Arginine      |
| 3    | Asparagine    |
| 4    | Aspartic acid |
| 5    | Cysteine      |
| 6    | Glutamine     |
| 7    | Glutamic acid |
| 8    | Glycine       |
| 9    | Histidine     |
| 10   | Isoleucine    |
| 11   | Leucine       |
| 12   | Lysine        |
| 13   | Methionine    |
| 14   | Phenylalanine |
| 15   | Proline       |
| 16   | Serine        |
| 17   | Threonine     |
| 18   | Tryptophan    |

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| <b>Item</b> | <b>Substance</b> |
|-------------|------------------|
| 19          | Tyrosine         |
| 20          | Valine           |

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## Schedule 2      Class 1 medicines — specified criteria

(section 3.12)

### 1.01      Low risk medicines generally

For the purposes of subparagraph 3.12 (b) (i), the criteria are that the medicine:

- (a) contains no ingredient that:
  - (i) is a substance included in the Scheduling Standard; or
  - (ii) is a substance listed in Appendix C to the Scheduling Standard; or
  - (iii) has the characteristics of a substance that could be a substance to which subparagraph (i) or (ii) applies; and
- (b) if the medicine contains a homoeopathic or anthroposophic preparation — the homoeopathic or anthroposophic preparation is of a mother substance specified, for the purposes of this paragraph, in an Order; and
- (c) contains no ingredient that is a prohibited import; and
- (d) is not required, by a standard, to be sterile; and
- (e) is supplied, imported or exported with no representations expressly or impliedly referring to a serious disease, disorder or condition, other than representations permitted by the Authority; and
- (f) is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease, disorder or condition, other than, in the case of a sunscreen, a representation that is permitted under section 1.03.

### 1.02      Homoeopathic and anthroposophic medicines generally

For the purposes of subparagraph 3.12 (b) (ii), the criteria are that the homoeopathic medicine or anthroposophic medicine:

- (a) contains no active ingredient other than a homoeopathic or anthroposophic preparation of a mother substance specified, for the purposes of this paragraph, in an Order; and
- (b) contains no ingredient that:
  - (i) is a substance included in the Scheduling Standard; or
  - (ii) has the characteristics of a substance that could be included in the Scheduling Standard;unless otherwise permitted, in relation to the substance and for the purposes of this paragraph, in an Order; and
- (c) contains no ingredient that is a prohibited import; and
- (d) is not required, by a standard, to be sterile; and

- 
- (e) is supplied, imported or exported with no representations expressly or impliedly referring to a serious disease, disorder or condition, other than representations permitted by the Authority; and
  - (f) is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease, disorder or condition.

### **1.03 Sunscreen preparations**

- (1) For the purposes of subparagraph 3.12 (b) (iii), the criteria in respect of a sunscreen preparation are set out in subsections (2) to (4).
- (2) The sunscreen preparation must be a preparation for dermal application.
- (3) The sunscreen preparation must be a preparation that is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease disorder or condition, other than a representation that:
  - (a) it assists in the prevention of sunburn; or
  - (b) if the claimed sun protection factor is 30 or more, that it assists in the prevention of sunburn, skin cancer or premature skin ageing;
- (4) The sunscreen preparation must be one in relation to which:
  - (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and
  - (b) the performance statements and markings on the label are restricted to those specified in that Standard.

### **1.04 Other medicines**

#### *Medicated throat lozenges*

- (1) For the purposes of subparagraph 3.12 (b) (iv), the criteria in respect of a medicated throat lozenge are that the medicine:
  - (a) consists only of volatile oils and their constituents alone or in combination with ascorbic acid (or its salts); and
  - (b) is supplied, imported or exported with no representations expressly or impliedly referring to a serious disease, disorder or condition; and
  - (c) is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease, disorder or condition.

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*Uncompounded medical substances for retail sale*

- (2) For the purposes of subparagraph 3.12 (b) (iv), the criteria in respect of an uncompounded medicine substance packed for retail sale are that the substance:
- (a) complies with a monograph for that substance in a default standard; and
  - (b) is not included in a Schedule of the Scheduling Standard; and
  - (c) is supplied, imported or exported with no representations expressly or impliedly referring to a serious disease, disorder or condition; and
  - (d) is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease, disorder or condition.

*Medicated space sprays*

- (3) For the purposes of subparagraph 3.12 (b) (iv), the criterion in respect of a medicated space spray is that it consists only of volatile oils and their constituents.

**1.05 Medicine kits**

- (1) For the purposes of subparagraph 3.12 (b) (v), the criteria are that the medicine kit:
- (a) is not a composite pack; and
  - (b) consists solely of medicines, if any of the individual medicines contained in the kit is a Class 1 medicine or a Class 2 medicine.
- (2) For paragraph (1) (a), a package and medicines in the package together constitute a ***composite pack*** if:
- (a) there are 2 or more medicines in the package; and
  - (b) the medicines are for administration as a single treatment or as a single course of treatment; and
  - (c) it is necessary that the medicines be combined before administration or that they be administered in a particular sequence.

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## Schedule 3 Medicines for evaluation

(sections 3.30, 5.09, 7.02)

### Part 1 Evaluation by the Office of Prescription Medicines of the Authority

| Column 1<br>Item | Column 2<br>Medicine   |
|------------------|--|
| 1                | a medicine (except a complementary medicine or a medicine specified in another Part of this Schedule), that: <ul style="list-style-type: none"><li>(a) contains a substance included in Schedule 4, 8 or 9 to the Scheduling Standard; or</li><li>(b) contains a substance not included in any of those Schedules but which meets the criteria for inclusion in any of those Schedules</li></ul> |
| 2                | a medical gas  |
| 3                | a vaccine  |
| 4                | an allergen, except an allergen for skin patch testing on unbroken skin  |
| 5                | a biotechnology medicine   |
| 6                | a radio contrast agent, except barium sulphate preparation for radiological use  |
| 7                | a radiopharmaceutical  |
| 8                | a dialysis solution, except a haemodialysis solution   |
| 9                | a special dosage form, such as a transdermal system or osmotic pump  |
| 10               | an injectable medicine dosage form   |
| 11               | a medicine referred for evaluation to the Office of Prescription Medicines of the Authority  |
| 12               | an excipient in a medicine mentioned in this Part  |
| 13               | a medical device that depends upon the release of a substance for some or all of its action  |

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## **Part 2 Evaluation by the Office of Complementary Medicines of the Authority**

A medicine of any of the following kinds:

| <b>Column 1<br/>Item</b> | <b>Column 2<br/>Medicine</b>   |
|--------------------------|--|
| 1                        | a complementary medicine   |
| 2                        | an excipient in a complementary medicine   |
| 3                        | a medicine referred for evaluation to the Office of Complementary Medicines of the Authority |

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## **Part 3 Evaluation by the Office of OTC Medicines of the Authority**

A medicine of any of the following kinds, if the applicant or licence holder has satisfied the Authority that the medicine does not meet the criteria for inclusion in Schedule 4, 8 or 9 of the Scheduling Standard:

| <b>Column 1<br/>Item</b> | <b>Column 2<br/>Medicine</b>   |
|--------------------------|--|
| 1                        | an antiseptic  |
| 2                        | a sunscreen preparation  |
| 3                        | all other medicines not specified in another Part of this Schedule                 |
| 4                        | an excipient in a medicine specified in this Part                                  |
| 5                        | a medicine referred for evaluation to the Office of OTC Medicines of the Authority |

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## Schedule 4 Product Licensing exemptions

(subsections 5.03 (1) and (2))

### Part 1 Unconditional exemptions

| Item | Medicine   |
|------|--|
| 1    | <p>a medicine that is imported for use in the treatment of the importer or a member of the importer's immediate family, if:</p> <ul style="list-style-type: none"><li>(a) the medicine does not contain a substance that is a prohibited import; and</li><li>(b) in the case of an injectable medicine that contains material of human or animal origin — the medicine is an insulin preparation or a product of recombinant technology; and</li><li>(c) in the case of any other medicine:<ul style="list-style-type: none"><li>(i) either:<ul style="list-style-type: none"><li>(A) the quantity imported in one importation is not more than 3 months' supply at the maximum dose recommended by the manufacturer; and</li><li>(B) the total quantity of the medicine imported in the period of 12 months ending on the day on which the latest importation occurs does not exceed 15 months' supply at the maximum dose recommended by the manufacturer; or</li></ul></li><li>(ii) the medicine has been approved, or is a medicine of a particular kind that has been approved, for importation:<ul style="list-style-type: none"><li>(A) for Australia — under regulation 5 of the <i>Customs (Prohibited Imports) Regulations</i>; or</li><li>(B) for New Zealand — under section 54 of the <i>Customs Act</i>; and</li></ul></li></ul></li><li>(d) if the medicine is included in Schedule 4 or Schedule 8 to the Scheduling Standard:<ul style="list-style-type: none"><li>(i) a medical practitioner has given a written authority for its use in that treatment; or</li><li>(ii) the goods are carried by the importer as a passenger on a ship or aircraft</li></ul></li></ul> |
| 2    | <p>a medicine imported, exported or supplied, or manufactured in Australia or New Zealand, not for therapeutic use, but as a sample for:</p> <ul style="list-style-type: none"><li>(a) submission to a regulatory authority; or</li><li>(b) subjection to developmental or quality control procedures; or</li><li>(c) examination, demonstration or display; or</li><li>(d) subjection to analysis or laboratory testing procedures</li></ul>  |

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| Item | Medicine   |
|------|--|
| 3    | a medicine imported solely for the purpose of export, that: <ul style="list-style-type: none"> <li>(a) remains subject to the control of Customs; and</li> <li>(b) is not subject to manufacture in Australia or New Zealand</li> </ul>  |
| 4    | a medicine (other than a medicine used for gene therapy, xenotransplantation or somatic cell therapy) that is extemporaneously compounded, by a medical practitioner, pharmacist or complementary healthcare practitioner for one particular person for therapeutic application to that person   |
| 5    | a homoeopathic medicine or anthroposophic medicine that: <ul style="list-style-type: none"> <li>(a) contains only one homeopathic preparation or anthroposophic preparation; and</li> <li>(b) contains a concentration of the mother substance of not more than 10mg/kg; and</li> <li>(c) includes on the label a statement to the effect that the medicine is only to be used in accordance with homoeopathic or anthroposophic principles (as the case requires); and</li> <li>(d) includes the manufacturer's manufacturing licence number on the label and otherwise complies with the requirements as to labelling specified in the Orders; and</li> <li>(e) is not promoted for therapeutic use; and</li> <li>(f) is not required to be sterile; and</li> <li>(g) does not contain a substance that:               <ul style="list-style-type: none"> <li>(i) is included in the Scheduling Standard; or</li> <li>(ii) has the characteristics of a substance that could be included in the Scheduling Standard;                   <br/>unless otherwise permitted, in relation to the substance and for the purposes of this item, in an Order; and</li> </ul> </li> <li>(h) is not derived from a mother substance specified, for the purposes of this item, in an Order.</li> </ul> |
| 6    | a homoeopathic preparation or anthroposophic preparation that is supplied as a starting material to a licensed manufacturer.   |
| 7    | a medicine of any of the following kinds: <ul style="list-style-type: none"> <li>(a) a medicated insect repellent for dermal application, if the medication consists solely of an antiseptic that has a secondary role in the formulation and is not included in a Schedule of the Scheduling Standard;</li> <li>(b) a lotion, shampoo or hairdressing for the prevention or treatment of dandruff, if no ingredient of the product is included in a Schedule of the Scheduling Standard;</li> </ul> <p>other than a medicine in respect of which the therapeutic indications offer a treatment or cure for, or prevention or management of, a serious disease, disorder or condition, or a medicine containing an ingredient that is not an ingredient in another medicine in respect of which a product licence is in force</p>  |

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| <b>Item</b> | <b>Medicine</b>   |
|-------------|---|
| 8           | a starting material used in the manufacture of a medicine, unless it is: <ul style="list-style-type: none"> <li>(a) prepackaged for supply for another therapeutic purpose; or</li> <li>(b) formulated as a dosage form</li> </ul>  |
| 9           | an allergen for skin patch testing on unbroken skin   |
| 10          | a radiopharmaceutical cold kit that is: <ul style="list-style-type: none"> <li>(a) a container of sterile reagents to which radioisotope is added immediately before injection into a patient; and</li> <li>(b) manufactured by a radiochemist, or a pharmacist in a public or private hospital, for subsequent extemporaneous compounding and dispensing for use by, or in connection with:               <ul style="list-style-type: none"> <li>(i) in New Zealand — a patient of the hospital or of another public or private hospital; or</li> <li>(ii) in Australia — a patient of the hospital or of another public or private hospital in the same State or Territory</li> </ul> </li> </ul> |

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## **Part 2      Conditional exemptions**

| <b>Item</b> | <b>Medicine and applicable conditions</b>  |
|-------------|--|
| 1           | a medicine imported and held under the direct control of the importer or applicant for approval — until the medicine: <ul style="list-style-type: none"> <li>(a) is the subject of an approval under section 5.05, 5.06, 5.07 or 5.08; or</li> <li>(b) is supplied to a hospital for dispensing as a medicine prescribed for patients with a life-threatening disease, disorder or condition (whether or not there are such patients at the time of supply)</li> </ul> |

### *Conditions*

the following conditions apply:

- (a) the medicine must have been imported for the purpose to which it is subsequently applied under this item;
- (b) the medicine must not be supplied other than for the purpose indicated by the applicable notification, approval or prescription;
- (c) the medicine must be kept in a warehouse, or other properly secured area, under the control of the importer or applicant for approval;
- (d) if the medicine is not used within 12 months of importation, the medicine must be destroyed within 1 month after the end of that period;
- (e) the importer or applicant for approval must:
  - (i) keep written records relating to the source and supply of the medicine; and
  - (ii) if the medicine is destroyed, under paragraph (d), keep records relating to the destruction; and
  - (iii) if requested, give a copy of the records to the Authority

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**Item    Medicine and applicable conditions**

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- 2    a medicine imported and held under the direct control of the importer or applicant for a product licence, until a decision is made in relation to the grant of a product licence in respect of the medicine

*Conditions*

the following conditions apply:

- (a) the applicant must:
  - (i) have lodged an application for a product licence in relation to the medicine before its importation; and
  - (ii) keep written records relating to the source of the medicine; and
  - (iii) if requested, give a copy of the records to the Authority;
- (b) if a product licence is not granted in respect of the medicine, the medicine must be destroyed

- 3    a medicine that is:

- (a) manufactured:
  - (i) under a contract between the manufacturer and a private hospital; and
  - (ii) in accordance with a formulation specified by the hospital; and
  - (iii) for use by, or in connection with, a patient of the hospital; or
- (b) manufactured:
  - (i) under a contract between the manufacturer and a public hospital; and
  - (ii) in accordance with a formulation specified by the hospital; and
  - (iii) for use by, or in connection with, a patient of the hospital or:
    - (A) in Australia —a patient of another public hospital in the same State or Territory; or
    - (B) in New Zealand —a patient of another public hospital;or
- (c) manufactured:
  - (i) under a contract between the manufacturer and a public institution that gives medical treatment to persons suffering a disease, disorder or condition; and
  - (ii) in accordance with a formulation specified by the institution; and
  - (iii) for use by, or in connection with, a patient of the institution

*Conditions*

the following conditions apply:

- (a) there is not available another medicine in respect of which a product licence is in force that, in all relevant respects, is substantially similar to the medicine concerned;

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| Item | Medicine and applicable conditions |
|------|------------------------------------|
|------|------------------------------------|

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- (b) the manufacturer:
    - (i) manufactures the medicine at premises in Australia or New Zealand; and
    - (ii) holds a manufacturing licence in relation to the medicine and the premises;
  - (c) the manufacturer notifies the Authority, in the approved form and within 20 working days of the end of a quarter during which the medicine is manufactured, of:
    - (i) the quantity of the medicine manufactured under the contract during that quarter; and
    - (ii) the name of the private hospital, public hospital or public institution with which the manufacturer entered the contract
- 4 a medicine imported by a member of a group of persons:
- (a) visiting Australia or New Zealand to participate, as a group, in a national or international sporting event; or
  - (b) that includes the Head of State or Head of Government of a country other than Australia or New Zealand, and senior officials of that country, who are visiting Australia or New Zealand on official business; or
  - (c) visiting Australia or New Zealand for any other purpose recognised by the Authority for the purpose of this item

*Conditions*

the following conditions apply:

- (a) the medicine must not be a prohibited import;
- (b) the medicine must be for use in the treatment of a member or members of the visiting group;
- (c) the medicine must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group;
- (d) a member of the group must be responsible for the control and custody of the medicine while the group is in Australia or New Zealand;
- (e) the responsible person must:
  - (i) keep a list, written in English, of the quantity and nature of medicines imported by the group; and
  - (ii) include in the list the generic name and strength of the active ingredient of each medicine; and
  - (iii) keep a record of the use of the medicines while the group is in Australia or New Zealand;
  - (iv) produce the list or the record for inspection at the request of a customs officer or authorised person under [Part ? (examination, testing and analysis of samples) of the Administration and Interpretation Rule];
- (f) any portion of the medicine that is unused at the end of the visit must be destroyed, or removed from Australia and New Zealand

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**Item    Medicine and applicable conditions**

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- 5    a medicine imported by a member of a group of persons who are members of a military force of the government of a country other than Australia or New Zealand and who are visiting Australia or New Zealand, as a group, for military training

*Conditions*

the following conditions apply:

- (a) the medicine must be for use in the treatment of a member or members of the visiting group;
  - (b) the medicine must not be supplied to, or used in the treatment of, a person other than a member of:
    - (i) the visiting group; or
    - (ii) the Australian Defence Force or the New Zealand Defence Force;
  - (c) a member of the group must be responsible for the control and custody of the medicine while the group is in Australia or New Zealand;
  - (d) the responsible person must:
    - (i) keep a list, written in English, of the quantity and nature of medicines imported by the group; and
    - (ii) include in the list the generic name and strength of the active ingredient of each medicine; and
    - (iii) keep a record of the use of the medicines while the group is in Australia or New Zealand;
    - (iv) produce the list or the record for inspection at the request of a customs officer or authorised person;
  - (e) any portion of the medicine that is unused at the end of the visit must be destroyed, or removed from Australia and New Zealand
- 6    a medicine that is exported otherwise than for commercial supply

*Conditions*

the following conditions apply:

- (a) the medicine must not contain a substance that is a prohibited export;
- (b) if the medicine is exported for use in clinical trials on humans — the exporter must comply promptly with any request by the Authority for information about the medicine or its use;
- (c) if the medicine is exported for humanitarian donation — the exporter must keep detailed records of the medicine so exported and, on request, make the records available to the Authority

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**Item    Medicine and applicable conditions**

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- 7    an unused emergency medicine, directed by the Authority, under an Order made for the purposes of section 6.05, to be exported from Australia or New Zealand

*Conditions*

the following condition applies:

the person who is directed to export the medicine comply with the requirements of the Order relating to the export of the medicine

- 8    a medicine that is imported by a medical practitioner or a member of a medical team (being 1 or more persons under the professional supervision of a medical practitioner)

*Conditions*

the following conditions apply:

- (a) the medical practitioner or medical team must be accompanying a person to Australia or New Zealand who:
  - (i) has a life-threatening disease, disorder or condition; and
  - (ii) is under the direct care and supervision of the practitioner or team;
- (b) the medicine must be for use in the treatment of the person who has the disease, disorder or condition;
- (c) the medicine must not contain a substance that is a prohibited import;
- (d) the quantity of the medicine must be consistent with the quantity required for the treatment of the person mentioned in paragraph (b);
- (e) the medicine must not be supplied to, or used in the treatment of, a person other than the person mentioned in paragraph (b);
- (f) any portion of the medicine that is unused at the end of the visit must be destroyed or removed from Australia or New Zealand;
- (g) the medical practitioner, or a member of the medical team, must be responsible for the control and custody of the medicine while the practitioner or team is in Australia or New Zealand;
- (h) the responsible person must:
  - (i) keep a list, written in English, of the quantity and nature of the medicines imported; and
  - (ii) include in the list the generic name and strength of the active ingredient of each medicine; and
  - (iii) keep a record of the use of the medicines while the medical practitioner or team is in Australia or New Zealand;
  - (iv) produce the list or the record for inspection at the request of a customs officer or authorised person

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**Item    Medicine and applicable conditions**

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9    a medicine on a ship or aircraft visiting Australia or New Zealand

*Conditions*

the following conditions apply:

- (a) the medicine must be part of the medical supplies of the ship or aircraft;
- (b) the medicine must be for use in the treatment of a passenger or member of the crew travelling on the ship or aircraft;
- (c) the medicine must not contain a substance that is a prohibited import;
- (d) the quantity of the medicine must be consistent with the quantity required for the treatment of passengers and members of the crew travelling on the ship or aircraft;
- (e) the medicine must not be supplied to, or used in the treatment of, a person other than a passenger or member of the crew travelling on the ship or aircraft;
- (f) the medicine must not be removed from the ship or aircraft while the ship or aircraft is in Australia or New Zealand;
- (g) the master of the ship or pilot of the aircraft must be responsible for the control and custody of the medicine while the ship or aircraft is in Australia or New Zealand;
- (h) the responsible person must:
  - (i) keep a list, written in English, of the quantity and nature of the medicines imported; and
  - (ii) include in the list the generic name and strength of the active ingredient of each medicine; and
  - (iii) keep a record of the use of the medicines while the ship or aircraft is in Australia or New Zealand;
  - (iv) produce the list or the record for inspection at the request of a customs officer or authorised person

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## Schedule 5      Manufacturing Licensing exemptions

(section 5.11 and subsection 5.12 (1))

### Part 1      Exempt manufacturers

| Item | Manufacturer  | Kind of medicine in respect of which exemption applies  |
|------|---|---|
| 1    | medical practitioner or dental practitioner   | a medicine manufactured specifically for a patient under the care of the medical practitioner or dental practitioner  |
| 2    | pharmacist  | a medicine manufactured for supply (other than by wholesale) from any of the following premises: <ul style="list-style-type: none"><li>(a) a pharmacy in which the pharmacist practices and which is open to the public;</li><li>(b) a dispensary conducted by a Friendly Society;</li><li>(c) a private hospital</li></ul>   |
| 3    | radiochemist or pharmacist, in a public hospital or other public institution                            | a medicine manufactured by the person, as an employee of the public hospital or public institution, for supply in the same hospital or institution  |
| 4    | a complementary healthcare practitioner who is engaged in the manufacture of any complementary medicine | a preparation to be supplied in the course of the practitioner's business, if: <ul style="list-style-type: none"><li>(a) it is manufactured on premises that the practitioner occupies and that he or she is able to close so as to exclude the public; and</li><li>(b) the practitioner:<ul style="list-style-type: none"><li>(i) supplies the preparation for administration to a particular person after consulting with that person; and</li><li>(ii) uses his or her own judgment as to the treatment required</li></ul></li></ul> |

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| <b>Item</b> | <b>Manufacturer</b>  | <b>Kind of medicine in respect of which exemption applies</b>   |
|-------------|--|---|
| 5           | a person who applies supplementary labelling to a manufactured medicine  | a supplementary label that contains only a name and address or the product licence number of the medicine concerned |
| 6           | a person who re-labels a medicine in order to comply with the signal heading labelling requirements of the Scheduling Standard | the new label   |

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## **Part 2 Exempt manufacture — kinds of medicines**

| <b>Item</b> | <b>Kind of Medicine</b>  |
|-------------|--|
| 1           | a medicine prepared for the initial experimental studies in human volunteers at the preliminary stages of development of the medicine  |
| 2           | an ingredient (other than water) used in the manufacture of a medicine if the ingredient: <ul style="list-style-type: none"> <li>(a) does not have a therapeutic action; or</li> <li>(b) is a herbal material, or an oil extracted from a herbal material, the sole therapeutic use of which is as starting material for use by a licensed manufacturer</li> </ul> |
| 3           | a dentifrice that contains no therapeutically active substance other than not more than 1000 milligrams per kilogram of fluoride   |
| 4           | a medicated insect repellent for dermal use, if the medication consists solely of an antiseptic having a secondary role in the formulation   |
| 5           | a lotion, shampoo or hairdressing for the prevention or treatment of dandruff  |
| 6           | a medicated soap   |
| 7           | a medicated throat lozenge, if the medication consists only of volatile oils and their constituents, either alone or in combination with ascorbic acid or its salts  |
| 8           | a medicated space spray, if the medication consists only of volatile oils and their constituents   |
| 9           | a bulk, liquefied medical gas  |
| 10          | an allergen for skin patch testing on unbroken skin  |
| 11          | a medicinal oxygen cylinder that has been decant-filled, transfilled or cascade-filled by: <ul style="list-style-type: none"> <li>(a) a hospital; or</li> <li>(b) an ambulance, fire or rescue service</li> </ul>  |

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## Additional Requirements

The current Australian regulatory scheme for therapeutic goods includes the following requirements and it is expected that they will continue.

### 1. Patent Certification

Extract from Therapeutic Goods Act 1989

#### 26B Certificates required in relation to patents

- (1A) A certificate is required under subsection (1) in relation to an application for registration or listing of therapeutic goods only if:
- (a) the applicant is required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing; and
  - (b) in order to satisfy that requirement, the applicant relies (in whole or in part) on evidence or information that another person submitted to the Secretary:
    - (i) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and
    - (ii) as part of the process of applying for the registration or listing of those other goods.
- (1) The certificate required under this subsection is either:
- (a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or
  - (b) a certificate to the effect that:
    - (i) a patent has been granted in relation to the therapeutic goods; and
    - (ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and
    - (iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

- (2) A person is guilty of an offence if:
- (a) the person gives a certificate required under subsection (1); and
  - (b) the certificate is false or misleading in a material particular.

Maximum penalty: 1,000 penalty units.

- (3) For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent.
- (4) In this section:

*patent* has the same meaning as in the *Patents Act 1990*.

## 26BA Approved form for notices

An approval of a form for a notice for the purposes of subsection 25(4), 26(1) or 26A(1) may require or permit the notice to be given in accordance with specified software requirements:

- (a) on a specified kind of data processing device; or
- (b) by way of a specified kind of electronic transmission.

## 26C Certificates required in relation to patent infringement proceedings

- (1) This section applies if:
  - (a) a person gives a certificate required under subsection 26B(1) in relation to therapeutic goods; and
  - (b) another person (the *second person*) intends to commence proceedings under the *Patents Act 1990* against the person referred to in paragraph (1)(a) for infringement of a patent that has been granted in relation to the therapeutic goods (the *proceedings*).
- (2) The second person, before the date upon which the proceedings are commenced, must give to the Secretary and to the person referred to in paragraph (1)(a) the certificate required by subsection (3).
- (3) The certificate required by this subsection is a certificate to the effect that the proceedings:
  - (a) are to be commenced in good faith; and
  - (b) have reasonable prospects of success; and
  - (c) will be conducted without unreasonable delay.The certificate must be signed by, or on behalf of, the second person and must be in a form approved by the Secretary.
- (4) For the purpose of paragraph (3)(b), proceedings have reasonable prospects of success if:
  - (a) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in addition to the fact of grant of the patent), for believing that he or she would be entitled to be granted final relief by the court against the person referred to in paragraph (1)(a) for infringement by that person of the patent; and
  - (b) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged, is valid; and
  - (c) the proceedings are not otherwise vexatious or unreasonably pursued.
- (5) The person referred to in paragraph (1)(a), with leave of the court, or the Attorney-General, may apply to a prescribed court for an order that the second person pay to the Commonwealth a pecuniary penalty if the second person gives a certificate required under subsection (3) and:
  - (a) the certificate is false or misleading in a material particular; or
  - (b) the second person breaches an undertaking given in the certificate.

Maximum penalty: \$10,000,000.

- (6) When determining the extent of a pecuniary penalty to be ordered pursuant to subsection (5), the court must take into account:
  - (a) any profit obtained by the second person; and

- (b) any loss or damage suffered by any person;  
by reason of the second person exploiting the patent during the proceedings.
- (7) For the avoidance of doubt, subsection (6) does not limit the matters the court may take into account when determining a pecuniary penalty ordered pursuant to subsection (5).
- (8) If:
  - (a) the second person has sought and obtained in the proceedings an interlocutory injunction restraining the person referred to in paragraph (1)(a) from infringing a patent; and
  - (b) section 26D does not apply; and
  - (c) a prescribed court declares that the second person has given a certificate required under subsection (3); and
  - (d) a prescribed court declares that:
    - (i) the certificate is false or misleading in a material particular; or
    - (ii) the second person has breached an undertaking given in the certificate;the prescribed court may, pursuant to this section, order that the second person pay to the Commonwealth, a State or a Territory compensation for any damages sustained or costs incurred by the Commonwealth, a State or a Territory as a result of the grant of the interlocutory injunction.
- (9) In this section:

*prescribed court* has the same meaning as in the *Patents Act 1990*.

## **26D Requirements for interlocutory injunction**

- (1) This section applies where:
  - (a) an applicant gives notice to a patentee in accordance with subparagraph 26B(1)(b)(iii); and
  - (b) the patentee and/or its exclusive licensee (in this section the party or parties is or are referred to as the *patentee*) applies to a prescribed court for an interlocutory injunction to restrain the applicant from marketing the therapeutic goods the subject of the application on the ground that such conduct will constitute an infringement of its patent.
- (2) An application for interlocutory relief in accordance with subsection (1) may not be instituted unless the patentee has first notified the Attorney-General of the Commonwealth, or of a State or of a Territory, in writing of the application.
- (3) The Attorney-General of the Commonwealth shall be deemed to be a party to any proceedings commenced in accordance with subsection (1) unless the Attorney-General gives written notice to the prescribed court that he or she does not desire to be a party.
- (4) If an interlocutory injunction is granted pursuant to an application made as described in subsection (1) and:
  - (a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties thereto; or
  - (b) the principal proceedings are dismissed; and
  - (c) in either case, the prescribed court declares that:
    - (i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee or which ought reasonably have been known to the patentee:

- (A) to believe that it would be granted final relief by the prescribed court against the applicant referred to in paragraph (1)(a) for infringement by that person of the patent; or
  - (B) (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged in the proceedings, would have a reasonable prospect of being held to be valid if challenged by the applicant referred to in paragraph (1)(a); or
  - (ii) the application for the interlocutory injunction was otherwise vexatious or not reasonably made or pursued;
- the prescribed court may, in addition to any other relief which it believes should be granted to any person, make any of the orders described in subsection (5).
- (5) If the prescribed court makes a declaration pursuant to paragraph (4)(c), the prescribed court may, pursuant to the usual undertaking as to damages given by the patentee to the prescribed court to obtain the interlocutory injunction:
- (a) assess and award compensation to the applicant referred to in paragraph (1)(a) against whom the interlocutory injunction was made:
    - (i) on the basis of an account of the gross profits of the patentee arising from the sale by it in Australia of the therapeutic goods the subject of the interlocutory injunction, during the period of the interlocutory injunction, without requiring the said applicant to establish or quantify its actual loss; or
    - (ii) on such other basis as the court determines to be appropriate; and
  - (b) award to the Commonwealth compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction; and
  - (c) award to a State or a Territory compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction.
- (6) In this section:

*prescribed court* has the same meaning as in the *Patents Act 1990*.

Under the joint scheme the same obligations will be imposed on all applicants for a product licence for these types of product by including the certification requirements in the Medicines Rule.

## 2. Use of Human Embryos

Extract from Therapeutic Goods Regulations 1990

### 9B Information about therapeutic goods manufactured using human embryos

- (1) A sponsor of therapeutic goods (other than medical devices) commits an offence if:
- (a) the sponsor supplies the goods on or after 1 July 2004; and
  - (b) the sponsor knows the goods were manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell; and
  - (c) the goods are of a kind specified in Part 1 of Schedule 10; and
  - (d) on or after 1 July 2004, the goods are included in the part of the Register for goods known as registered goods; and

- (e) the goods are supplied without written information stating that the goods were manufactured using a human embryo or human embryonic stem cell, or other material sourced from a human embryo or human embryonic stem cell.

Penalty: 10 penalty units.

- (2) Strict liability applies to the physical elements mentioned in paragraphs (1) (c), (d) and (e).
- (3) The information in relation to the therapeutic goods must be included in:
  - (a) the patient information document required under regulation 9A; and
  - (b) the product information in relation to the goods.

- (4) In this regulation:

*human embryo* means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

*human embryonic stem cell* means undifferentiated cells derived from a human embryo that have the potential to become a wide variety of specialised cell types.

*product information*, in relation to therapeutic goods, has the meaning given by subsection 9D (5) of the Act.

- (5) For the purposes of the definition of *human embryo* in subregulation (4), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

Under the joint scheme, this requirement will remain. All applicants for a product licence for a medicine described in Part 1 of Schedule 3 to the Medicines Rule must notify the Authority if the medicine has been manufactured using a human embryo or human embryonic stem cell or any other material sourced from a human embryo or human embryonic stem cell. If the medicine has been manufactured using these materials, medicine must not be supplied unless the licence holder supplies with the medicine a written statement that human embryos or human embryonic stem cells or any other material sourced from a human embryo or human embryonic stem cell were used in the manufacture of the medicine. This statement, if applicable, will need to be included in the product information and consumer information documents described in Part 7 of the Medicines Rule.

### **3. Consultation with the Gene Technology Regulator**

Extract from the Therapeutic Goods Act 1989

#### **30C Consultation with Gene Technology Regulator**

- (1) This section applies to an application for listing or registration of a therapeutic good under section 23 if the therapeutic good is, or contains, a GM product.
- (2) Subject to subsection (5), the Secretary must give written notice to the Gene Technology Regulator:
  - (a) stating that the application has been made; and
  - (b) requesting the Gene Technology Regulator to give advice about the application.

- (3) If the Secretary gives the Gene Technology Regulator a notice under subsection (2), the Gene Technology Regulator may give written advice to the Secretary about the application.
- (4) The advice is to be given within the period specified in the notice.
- (5) If an advice from the Gene Technology Regulator is in force under section 30D in relation to a class of therapeutic goods, the Secretary is not required to notify the Regulator under this section in relation to an application for listing or registration of a therapeutic good belonging to that class.

### **30D Secretary may seek advice about classes of GM products**

- (1) The Secretary may request advice from the Gene Technology Regulator in relation to therapeutic goods that consist of, or that contain, a GM product belonging to a class of GM products specified in the request.
- (2) A request for advice under subsection (1) must specify the matters to which the advice is to relate.
- (3) If the Secretary requests advice from the Gene Technology Regulator under subsection (1), the Gene Technology Regulator may provide written advice in relation to the matters specified in the request.
- (4) If the Gene Technology Regulator gives advice to the Secretary under subsection (3), the advice remains in force until it is withdrawn by the Gene Technology Regulator by written notice given to the Secretary.

### **30E Secretary to take advice into account**

If the Secretary receives advice from the Gene Technology Regulator:

- (a) in response to a notice under section 30C within the period specified in the notice;  
or
- (b) under section 30D;

the Secretary must:

- (c) ensure that the advice is taken into account in making a decision on the application to which the notice relates, or on an application to which the advice under section 30D relates, as the case requires; and
- (d) inform the Gene Technology Regulator of the decision on the application.

The Ministerial Council Rules will include a provision that will require the Authority to advise the Australian Gene Technology Regulator when the Authority receives an application for a product licence for a product containing any genetically modified ingredient. If advice is provided by the Gene Technology Regulator, the Authority must take this advice into account when making a decision on the application.