

# **Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) 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 (Administration and Interpretation) Rule 2006*.

*[Drafter's note: Consideration is being given to replacing this Rule with separate Rules for the administration and interpretation provisions respectively.]*

### 1.02 Commencement

This Rule commences on [^date^].

### 1.03 Interpretation of Rules and Orders

- (1) Certain words and expressions used in the Rules are affected by definitions and rules of interpretation set out in Schedule 1.
- (2) Unless the contrary intention appears:
  - (a) a definition in Schedule 1 applies to each use of the word or expression in the Rules; and
  - (b) a rule of interpretation in Schedule 1 applies to each provision of the Rules, and to each word or expression used in the Rules, to which it can be given application.
- (3) Any Order or other instrument (except a contract) made, granted or issued by the Authority under a power conferred by a provision in the Agreement or the Rules is to be read and construed subject to the Agreement or the Rules, and so as not to exceed the power conferred.
- (4) If an Order or instrument would, but for subsection (3), be construed as exceeding the power conferred, it is nevertheless taken to be a valid Order or instrument to the extent to which it is not in excess of that power.
- (5) Subsection (2) applies in relation to an Order, or an instrument mentioned in subsection (3), as it applies in relation to the Rules.

*Note 1* A Rule is a rule made by the Ministerial Council under Article 9 of the Agreement — see Article 1 of the Agreement.

*Note 2* The rules of interpretation set out in this Rule are based on similar provisions of the *Acts Interpretation Act 1901* of Australia and the *Interpretation Act 1999* of New Zealand. Those enactments have not been applied to Ministerial Council Rules.

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## Part 2

## Governance and accountability of Authority

*[Drafter's note: This Part may contain matters to be provided for under subparagraph (a) of paragraph 1 of Article 9 of the Agreement. However, a separate Rule for governance and related matters is under consideration.]*

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## Part 3                      Financial matters

*[Drafter's note: This Part may contain matters to be provided for under subparagraphs (b) and (f) of paragraph 1 of Article 9 of the Agreement]*

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## Part 4

## Administrative procedural matters

*[Drafter's note: This Part may contain matters to be provided for under subparagraph (d) of paragraph 1 of Article 9 of the Agreement]*

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## Part 5                      Orders

*[Drafter's note: This Part may contain matters to be provided for under subparagraph (h) of paragraph 1 of Article 9 of the Agreement]*

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## Part 6

## The Board

*[Drafter's note: This Part may contain matters to be provided for under subparagraphs (k), (l), m) and (n) of paragraph 1 of Article 9 of the Agreement]*

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## Part 7

## Authority staff

*[Drafter's note: This Part may contain matters to be provided for under subparagraph (c) of paragraph 1 of Article 9 of the Agreement]*

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## Part 8 Committees

### Division 8.1 General

#### 8.01 Overview of this Part

This Part provides for the establishment of a number of expert advisory committees to provide the Authority with scientific and regulatory advice. The Part also provides for other committees to be appointed by the Ministerial Council. The functions, membership and procedural aspects of the committees are set out in this Part.

### Division 8.2 Expert Advisory Committee on Prescription Medicines

#### Subdivision 8.2.1 Interpretation

#### 8.02 Definitions

In this Division:

*Committee* means the Expert Advisory Committee on Prescription Medicines.

*medicine* means a medicine of a kind mentioned in Part 1 of Schedule 3 to the Medicines Rule.

#### Subdivision 8.2.2 Establishment, functions and constitution of Committee

#### 8.03 Establishment

There is established a committee to be known as the Expert Advisory Committee on Prescription Medicines.

#### 8.04 Functions of Committee

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following aspects of medicines:
  - (a) quality, safety and efficacy;
  - (b) evaluation;
  - (c) bioequivalence and bioavailability;
  - (d) scheduling;

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- (e) standards;
  - (f) labelling and other information requirements;
  - (g) product licensing and any variations of product licences;
  - (h) manufacture, import or export, promotion, distribution, supply and use.
- (2) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to medicines).
  - (3) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
  - (4) Recommendations by the Committee are to be made public.

#### **8.05 Committee consists of core and associate members**

The Committee consists of core and associate members.

#### **8.06 Requirements for core members**

- (1) There must be at least 6, and not more than 7, core members.
- (2) The core members must include:
  - (a) three medical practitioners eminent in the medical profession; and
  - (b) one pharmacologist, or a person who holds a university degree in science or a branch of science and has specialised in pharmaceutical science.
- (3) However, at least 2 of the medical practitioners must be specialists in clinical medicine.

#### **8.07 Requirements for associate members**

- (1) There must be at least 10, and not more than 20, associate members.
- (2) The associate members must include:
  - (a) a pharmaceutical chemist with expertise in the manufacturing of therapeutic products; and
  - (b) a toxicologist; and
  - (c) a medical practitioner currently engaged in general practice; and
  - (d) a person with expertise in consumer issues.
- (3) Each of the remaining associate members must be:
  - (a) qualified as mentioned in one of the paragraphs in subsection (2); or
  - (b) a medical practitioner with specialist qualifications and experience in a field of medicine that complements the expertise of the core members mentioned in paragraph 8.06 (2) (a).

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### **Subdivision 8.2.3 Other provisions applicable to Committee**

#### **8.08 Application of Division 8.9**

Division 8.9 applies in relation to the Committee.

### **Division 8.3 Expert Advisory Committee on OTC Medicines**

#### **Subdivision 8.3.1 Interpretation**

##### **8.09 Definitions**

In this Division:

*Committee* means the Expert Advisory Committee on OTC Medicines.

*ingredient* means an ingredient for a medicine.

*medicine* means a medicine of a kind mentioned in Part 3 of Schedule 3 to the Medicines Rule.

#### **Subdivision 8.3.2 Establishment, functions and constitution of Committee**

##### **8.10 Establishment**

There is established a committee to be known as the Expert Advisory Committee on OTC Medicines.

##### **8.11 Functions of Committee**

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following:
  - (a) quality, safety and efficacy of medicines;
  - (b) quality and safety of ingredients;
  - (c) evaluation of medicines;
  - (d) evaluation of ingredients;
  - (e) scheduling;
  - (f) standards;
  - (g) labelling and other information requirements;
  - (h) product licensing and any variations of product licences;
  - (i) the manufacture, import or export, promotion, distribution, supply and use of medicines or ingredients.

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- (2) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to medicines or ingredients).
  - (3) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
  - (4) Recommendations by the Committee are to be made public.

## **8.12 Constitution**

- (1) There must be at least 8, and not more than 12, members of the Committee.
- (2) A member must have expertise in at least one of the following fields:
  - (a) general medical practice;
  - (b) specialist medical practice of a kind relevant to the Committee's functions;
  - (c) pharmaceutical chemistry;
  - (d) pharmacology;
  - (e) toxicology;
  - (f) microbiology;
  - (g) community pharmacy;
  - (h) manufacture of medicines;
  - (i) consumer issues.
- (3) It is intended, as far as reasonably practicable, that membership of the Committee should represent the widest possible range of the fields mentioned in subsection (2).

### **Subdivision 8.3.3 Other provisions applicable to Committee**

## **8.13 Application of Division 8.9**

Division 8.9 applies in relation to the Committee.

## **Division 8.4 Expert Advisory Committee on Complementary Medicines**

### **Subdivision 8.4.1 Interpretation**

## **8.14 Definitions**

In this Division:

*Committee* means the Expert Advisory Committee on Complementary Medicines.

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*ingredient* means an ingredient for a complementary medicine.

#### **Subdivision 8.4.2 Establishment, functions and constitution of Committee**

##### **8.15 Establishment**

There is established a committee to be known as the Expert Advisory Committee on Complementary Medicines.

##### **8.16 Functions of Committee**

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following:
  - (a) quality, safety and efficacy of complementary medicines;
  - (b) quality and safety of ingredients;
  - (c) evaluation of complementary medicines and any variations of complementary medicines;
  - (d) evaluation of ingredients;
  - (e) scheduling;
  - (f) standards;
  - (g) labelling and other information requirements;
  - (h) licensing of complementary medicines;
  - (i) the manufacture, import or export, promotion, distribution, supply and use of complementary medicines or ingredients.
- (2) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to complementary medicines or ingredients).
- (3) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
- (4) Recommendations by the Committee are to be made public.

##### **8.17 Constitution**

- (1) There must be at least 8, and not more than 12, members of the Committee.
- (2) A member must have expertise in at least one of the following fields:
  - (a) complementary medical practice;
  - (b) manufacture of medicines;
  - (c) consumer issues;
  - (d) medical practice;
  - (e) herbal medicine;

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- (f) naturopathy;
  - (g) nutrition and nutritional medicine;
  - (h) pharmacognosy;
  - (i) pharmacology;
  - (j) toxicology;
  - (k) epidemiology.
- (3) At least 4 members must have professional clinical experience in one of those fields.
- (4) It is intended, as far as reasonably practicable, that membership of the Committee should represent the widest possible range of the fields mentioned in subsection (2).

### **Subdivision 8.4.3 Other provisions applicable to Committee**

#### **8.18 Application of Division 8.9**

Division 8.9 applies in relation to the Committee.

## **Division 8.5 Expert Advisory Committee on Medical Devices**

### **Subdivision 8.5.1 Interpretation**

#### **8.19 Definition**

In this Division:

*Committee* means the Expert Advisory Committee on Medical Devices.

### **Subdivision 8.5.2 Establishment, functions and constitution of Committee**

#### **8.20 Establishment**

There is established a committee to be known as the Expert Advisory Committee on Medical Devices.

#### **8.21 Functions of Committee**

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following aspects of medical devices:
- (a) quality, safety and performance;
  - (b) evaluation and assessment and any variations;
  - (c) essential principles;

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*Note* As to the meaning of *essential principles*, see section 2.02 of the Medical Devices Rule.

- (d) conformity assessment procedures;
  - (e) scheduling;
  - (f) standards;
  - (g) labelling and other information requirements;
  - (h) product licensing;
  - (i) manufacture, import or export, promotion, distribution, supply and use.
- (2) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to medical devices).
  - (3) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
  - (4) Recommendations by the Committee are to be made public.

## **8.22 Committee consists of core and associate members**

The Committee consists of core and associate members.

## **8.23 Requirements for core members**

- (1) There must be at least 8, and not more than 12, core members.
- (2) The core members must include:
  - (a) three medical practitioners eminent in the medical profession; and
  - (b) one person with expertise in consumer issues; and
  - (c) one person with expertise in the manufacture of medical devices; and
  - (d) one biomedical engineer, or a person who holds a university degree in biomedical engineering; and
  - (e) one person with expertise in biomaterials, or who holds a university degree in biomaterial science.
- (3) However, at least 2 of the medical practitioners must be specialists in clinical medicine.

## **8.24 Requirements for associate members**

- (1) There must be at least 8, and not more than 20, associate members.
- (2) The associate members must include:
  - (a) a medical practitioner eminent in the medical profession; and
  - (b) a biomedical engineer, or a person who holds a university degree in biomedical engineering; and
  - (c) a person with expertise in biomaterials, or who holds a university degree in biomaterial science.

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### **Subdivision 8.5.3 Other provisions applicable to Committee**

#### **8.25 Application of Division 8.9**

Division 8.9 applies in relation to the Committee.

### **Division 8.6 Expert Advisory Committee on Adverse Reactions to Medicines**

#### **Subdivision 8.6.1 Interpretation**

##### **8.26 Definition**

In this Division:

*Committee* means the Expert Advisory Committee on Adverse Reactions to Medicines.

#### **Subdivision 8.6.2 Establishment, functions and constitution of Committee**

##### **8.27 Establishment**

There is established a committee to be known as the Expert Advisory Committee on Adverse Reactions to Medicines.

##### **8.28 Functions of Committee**

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following:
  - (a) safety, quality and efficacy of medicines;
  - (b) risk-benefit profiles of marketed medicines;
  - (c) surveillance issues;
  - (d) recall activities;
  - (e) general policy matters related to pharmacovigilance.
- (2) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to medicines).
- (3) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
- (4) Recommendations by the Committee are to be made public.

*[Drafter's note: The functions of the Committee are yet to be finalised and will be the subject of further consultation.]*

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## 8.29 Constitution

- (1) There must be at least 8, and not more than 12, members of the Committee.
- (2) The Committee must include the following:
  - (a) a gastroenterologist;
  - (b) a clinical epidemiologist;
  - (c) a paediatrician;
  - (d) a clinical pharmacologist;
  - (e) a medical practitioner currently engaged in general practice in Australia;
  - (f) a medical practitioner currently engaged in general practice in New Zealand;
  - (g) a person with expertise in OTC and complementary medicines.
- (3) Other members must have expertise in at least one of the following fields:
  - (a) endocrinology;
  - (b) infectious diseases;
  - (c) neurology;
  - (d) dermatology;
  - (e) psychiatry;
  - (f) renal medicine;
  - (g) haematology;
  - (h) hospital pharmacy.
- (4) It is intended, as far as reasonably practicable, that membership of the Committee should include the widest possible range of the fields mentioned in subsection (3).

*[Drafter's note: The constitution of the Committee is still under review and will be the subject of further consultation.]*

### Subdivision 8.6.3 Other provisions applicable to Committee

## 8.30 Application of Division 8.9

Division 8.9 applies in relation to the Committee.

## Division 8.7 Medicines Scheduling Committee

*[Drafter's note: Provisions relating to the Committee are to be included at a later date.]*

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## **Division 8.8      Expert Advisory Committee on Standards**

### **Subdivision 8.8.1      Interpretation**

#### **8.31      Definition**

In this Division:

*Committee* means the Expert Advisory Committee on Standards.

### **Subdivision 8.8.2      Establishment, functions and constitution of Committee**

#### **8.32      Establishment**

There is established a committee to be known as the Expert Advisory Committee on Standards.

#### **8.33      Functions of Committee**

- (1) The Committee has the functions of giving advice, and making recommendations, to the Authority in relation to the following aspects of therapeutic products:
  - (a) the adoption of standards; and
  - (b) matters relating to standards; and
  - (c) requirements for labelling and packaging; and
  - (d) standards for manufacture.
- (2) The Committee has the function of giving advice to the Authority on the likely impact that adoption of a proposed standard would have on Australian and New Zealand domestic and international trade.
- (3) The Committee also has the function of giving advice and making recommendations to the Authority in relation to any other matter referred to the Committee by the Authority (whether or not related to therapeutic products).
- (4) The Ministerial Council may require the Committee to pass on its advice to other persons or bodies.
- (5) Recommendations by the Committee are to be made public.

#### **8.34      Committee consists of core and associate members**

- (1) The Committee consists of core and associate members.
- (2) The members must include the following persons (qualified to be a core member or an associate member):
  - (a) a medical practitioner with expertise in general practice;

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- (b) a medical practitioner with expertise in clinical medicine;
  - (c) a dentist;
  - (d) a practising hospital or community pharmacist.
- (3) It is intended, as far as reasonably practicable, that membership of the Committee should represent the widest possible range of the fields mentioned in subsections 8.35 (2) and 8.36 (2).

### **8.35 Requirements for core members**

- (1) There must be at least 7, and not more than 8, core members.
- (2) A core member must have expertise in one or more of the following areas:
  - (a) chemistry;
  - (b) pharmaceutical science;
  - (c) biomedical engineering;
  - (d) blood, tissues and cellular therapies;
  - (e) microbiology or sterility, and virology;
  - (f) good manufacturing practices or quality systems;
  - (g) consumer issues.

### **8.36 Requirements for associate members**

- (1) There must be at least 8, and not more than 20, associate members.
- (2) An associate member must have expertise in one or more of the following areas:
  - (a) manufacture of medicines;
  - (b) manufacture of medical devices;
  - (c) manufacture of biologicals;
  - (d) manufacture of tissues and cellular therapies;
  - (e) natural products chemistry or complementary medicines chemistry;
  - (f) statistics;
  - (g) pharmacokinetics or bioavailability;
  - (h) development and testing of in-vitro diagnostic devices;
  - (i) biomaterials;
  - (j) toxicology of biomaterials.

### **Subdivision 8.8.3 Other provisions applicable to Committee**

#### **8.37 Application of Division 8.10**

Division 8.10 applies in relation to the Committee.

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## **Division 8.9      General provisions**

### **Subdivision 8.9.1      Interpretation**

#### **8.38      Definitions**

In this Division:

*Chair* means Chair of the Committee.

*Committee* means a committee in relation to which this Division applies.

*member* means a member of the Committee.

### **Subdivision 8.9.2      Membership of Committee**

#### **8.39      Appointment of members**

- (1) Members are to be appointed in writing by the Ministerial Council on the recommendation of the Authority.
- (2) The Ministerial Council is entitled to appoint to be a member whoever it believes in its discretion to be appropriately qualified, but it is intended that members should be appointed on the basis of expertise rather than to represent a particular jurisdiction or interest unless required by this Part for the office.
- (3) A member is appointed for the term stated in the member's appointment.
- (4) The term stated in the appointment must not be longer than 3 years.
- (5) However, a member may be reappointed for further terms of up to 3 years each, but may not serve more than 3 consecutive terms.

#### **8.40      Appointment of Chair**

- (1) The Ministerial Council must appoint to be Chair of the Committee a member nominated for that office by the Authority.
- (2) The Chair holds that office for the term stated in the appointment.
- (3) The Chair may be reappointed for further terms.
- (4) An appointment under this section must be in writing.

#### **8.41      Resignation or vacancy**

- (1) A member may resign as member by signed notice of resignation given to the Ministerial Council.
- (2) The Chair may resign from that office by signed notice of resignation given to the Ministerial Council.

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- (3) If the Chair ceases to be a member, his or her office as Chair is taken also to be vacant.

#### **8.42 Termination of appointment**

- (1) The Ministerial Council may terminate a member's appointment on the grounds of:
  - (a) physical or mental incapacity; or
  - (b) misbehaviour; or
  - (c) incompetence; or
  - (d) inefficiency; or
  - (e) bankruptcy; or
  - (f) failing to comply, either recklessly or intentionally, with section 8.52.
- (2) The Ministerial Council must terminate the member's appointment if the member:
  - (a) is convicted of an offence punishable by imprisonment for 1 year or longer; or
  - (b) is absent without leave of absence from 3 consecutive meetings of the Committee.

#### **8.43 Leave of absence**

- (1) The Ministerial Council may grant leave of absence to the Chair.
- (2) The Chair may grant leave of absence to another Committee member.

#### **8.44 Acting members**

- (1) The Ministerial Council may appoint a person to act as a member:
  - (a) during a vacancy in the office, whether or not an appointment has previously been made to the office; or
  - (b) during any period, or during all periods, when the holder of the office is absent from duty or is, for any reason, unable to perform the duties of the office.
- (2) A person appointed to act in an office need not have any qualification required for the substantive holder of the office, but it is intended, as far as reasonably practicable, that:
  - (a) if a particular qualification is required for the substantive holder—the person to act would ordinarily have that qualification; or
  - (b) where paragraph (a) does not apply, but differing qualifications are required for all members of the committee—the person to act would ordinarily have one of those qualifications.
- (3) A person appointed to act during a vacancy in the office of a member must not continue to act for more than 12 months.

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*Note* This section needs to be read in conjunction with subsection 2.20 (2) of Schedule 1 which makes further provision in relation to acting appointments.

### **Subdivision 8.9.3 Committee procedures**

#### **8.45 Committee procedures generally**

- (1) In performing its functions, the Committee:
  - (a) must act according to this Division; and
  - (b) must act with as little formality and as quickly as the requirements of this Division, and a proper consideration of the issues before the Committee, allow; and
  - (c) is not bound by rules of evidence; and
  - (d) may, subject to section 8.55, obtain information about an issue in any way it considers appropriate; and
  - (e) may receive information or submissions orally or in writing.
- (2) In addition, the Committee must comply with any directions given, in writing, to the Committee by the Ministerial Council or the Authority about the Committee's performance of its functions.
- (3) However, a direction may not be given about any advice given or proposed to be given by the Committee.

#### **8.46 Meetings**

- (1) The Chair may, by written notice to the Committee, direct the Committee to hold meetings at the times and places, and to deal with matters in the manner, stated in the notice.

*Note* Section 2.23 of Schedule 1 enables the Committee, if it so desires, to permit its members to participate in a meeting, or all meetings, although physically absent from the place of meeting.

- (2) Subject to this Division, the procedure of a meeting is as decided by the Committee.

#### **8.47 Meetings of Committees with associate members**

- (1) This section only applies to a Committee that has core members and associate members.
- (2) An associate member may only attend a meeting of the Committee at the invitation of the Chair.
- (3) The Chair need not invite every associate member.
- (4) A meeting is not invalidated by:
  - (a) the failure to invite an associate member to the meeting; or
  - (b) the absence of an invited member from the meeting; or
  - (c) the presence of an associate member who was not invited.

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- (5) However, it is intended that an associate member whose expertise or experience is relevant to the matter to be considered at the meeting would ordinarily be present.
  - (6) Section 8.46 also applies to a Committee to which this section applies.

#### **8.48 Presiding member**

- (1) The Chair must:
  - (a) preside at a Committee meeting; or
  - (b) nominate a member of the Committee to preside at the meeting.
- (2) If the Chair is temporarily absent from a meeting, the member chosen by the members present must preside.
- (3) A member chosen to preside may exercise the powers and functions of the Chair.

#### **8.49 Quorum**

- (1) At a Committee meeting, a quorum exists when at least half of the members invited to the meeting are present or, if an odd number of invited members attend, a majority of those members.
- (2) However, if a Committee has core members and associate members, a quorum exists when at least half of the core members are present or, if the Committee has an odd number of core members, a majority of those members.

#### **8.50 Voting**

- (1) A decision made at a Committee meeting by a majority of the votes of the members present and voting is a decision of the Committee.
- (2) The member presiding at a Committee meeting has a deliberative vote and, in the event of an equality of votes, also has a casting vote.

#### **Subdivision 8.9.4 Miscellaneous**

##### **8.51 Sitting fees and travel entitlements**

A member is entitled to sitting fees and travel entitlements as determined by the Ministerial Council by instrument in writing.

##### **8.52 Disclosure of interests**

- (1) A member who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the Committee must, without delay, disclose the nature of the interest at, or before, the meeting of the Committee.

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- (2) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines:
    - (a) be present during any deliberation of the Committee about the matter; or
    - (b) take part in any decision of the Committee about that matter.
  - (3) When the Committee is making a determination under subsection (2) about a member who has made a disclosure, the member, and any other member who has a direct or indirect pecuniary interest in the matter to which the disclosure relates, must not:
    - (a) be present during any deliberation of the Committee; or
    - (b) take part in making the determination.
  - (4) A member of a subcommittee under section 8.53, who is aware that he or she has a direct or indirect pecuniary interest in a matter being considered, or about to be considered, at a meeting of the subcommittee must, without delay, disclose the nature of the interest at, or before, the meeting of the subcommittee.

#### **8.53 Committee may establish subcommittees**

- (1) The Committee, with the approval of the Authority, may appoint subcommittees, consisting of members and other persons.
- (2) The function of a subcommittee is to inquire into, and report to the Committee on, any specified matter that is within the functions of the Committee.

#### **8.54 Authority may seek further advice**

Advice given by the Committee to the Authority may be passed to another expert advisory committee for the advice of that committee.

#### **8.55 Committee may seek advice and assistance**

- (1) The Committee, in performing its functions under this Division, may seek advice from other persons.
- (2) However, the Committee must first seek the approval of the Authority.

#### **8.56 Validity of acts of members etc**

- (1) Anything done by a person purporting to be or act as a member is not invalid merely because:
  - (a) the occasion for the person's appointment had not arisen; or
  - (b) there is a defect or irregularity in connection with the person's appointment; or
  - (c) the appointment had ceased to have effect.

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- (2) In this section:  
*member* includes Chair.

**8.57 Records and reports**

- (1) The Committee must keep a record of its proceedings.
- (2) The Committee must prepare any other report about its activities that is requested by the Ministerial Council or the Authority.

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## Part 9                      Inspection of premises and    examination, analysis etc of    therapeutic products

### Division 9.1              Authorised persons

#### 9.01              Authorised persons

The Authority may, in writing, authorise any of the following persons to exercise powers under a specified provision of a Rule:

- (a) an employee of, or a person on secondment to, the Authority;
- (b) an officer of the department of state of Australia that deals primarily with health matters;
- (c) an officer of the department of state of New Zealand that deals primarily with health matters;
- (d) an officer of an Australian or New Zealand authority that has one or more functions in relation to therapeutic products;
- (e) an APS employee in an Authority (within the meaning of the *Public Service Act 1999* of Australia) that has functions in relation to therapeutic products.
- (f) an officer or employee of:
  - (i) a department of state of a State of Australia; or
  - (ii) a department or administrative unit of the public service of a Territory of Australia; or
  - (iii) an authority of such a State or Territory;  
being a department, unit or authority that has functions relating to health matters.

*[Drafter's note: Provisions relating to New Zealand authorities are still to be finalised for this section.]*

#### 9.02              Identity cards

- (1) The Authority must ensure that each authorised person is issued with an identity card that incorporates a recent photograph of the person.
- (2) If an authorised person enters premises in the course of exercising his or her powers or performing his or her functions under the Rules, the authorised person must, if requested by any person to do so at those premises, produce his or her identity card for inspection by that person.
- (3) A person:
  - (a) to whom an identity card is issued under this section; and
  - (b) who ceases to be an authorised person;

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must, as soon as practicable after so ceasing, return the identity card to the Authority.

- (4) Subsection (3) does not apply if the identity card has been lost or destroyed.
- (5) In relation to a failure to comply with subsection (3):
  - (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].

### **9.03 Entry and inspection under licence conditions etc**

- (1) Subject to subsection (2), an authorised person may, for the purpose of exercising his or her powers and performing his or her functions as an authorised person:
  - (a) during normal business hours, enter the premises of:
    - (i) an applicant for a product licence, manufacturing licence or conformity assessment certificate; or
    - (ii) the holder of a product licence, manufacturing licence or conformity assessment certificate; or
    - (iii) any other person whose premises are, under the conditions of a product licence, manufacturing licence or conformity assessment certificate, to be made available for entry and inspection by an authorised person; or
    - (iv) a wholesaler of therapeutic products;  
being premises connected with the importation, export, manufacture, supply or testing of therapeutic goods, or for the keeping of records relating to any such activity; and
  - (b) while on those premises:
    - (i) inspect the premises and any therapeutic products on the premises; and
    - (ii) conduct an audit; and
    - (iii) carry out tests, or require tests to be carried out, on the therapeutic products; and
    - (iv) take visual records of the premises, therapeutic products or processes; and
    - (v) take samples of the therapeutic products; and
    - (vi) ask the appropriate person mentioned in paragraph (a), or the person apparently in charge of the premises or therapeutic products, for information relevant to the importation, export, manufacture, supply or testing of the therapeutic products; and
    - (vii) carry out related functions.

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- (2) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:
- (a) the occupier of the premises requires the authorised person to produce his or her identity card for inspection by the occupier; and
  - (b) the authorised person fails to comply with the requirement.

*Note 1* A reference to a therapeutic product includes a reference to an ingredient or component in the manufacture of the product, and a container for the product, ingredient or component: see the definition of *therapeutic product* in Article 1 of the Agreement.

*Note 2* For additional powers of authorised persons relating to entry etc of premises, see:

- (a) for Australia — [Division 3 of Part 3 of the Act]; and
- (b) for New Zealand — [ ] of the Act.

#### **9.04 Clinical trials and investigations — powers of entry, inspection etc**

- (1) In this section:
- clinical trial* means a clinical trial mentioned in section 5.06 or 5.07 of the Medicines Rule.
- clinical investigation* means a clinical investigation mentioned in section 6.06 or 6.07 of the Medical Devices Rule.
- (2) An authorised person may, in relation to a clinical trial or clinical investigation:
- (a) enter any site of the trial or investigation; and
  - (b) search the site and any part of the site; and
  - (c) inspect, examine, take measurements of, or conduct tests on (including by the taking of samples), any thing on the site that relates to the trial or investigation; and
  - (d) take visual records of the site or any thing on the site; and
  - (e) inspect any book, record or document on the site that relates to the trial or investigation; and
  - (f) request the principal investigator to:
    - (i) answer any questions asked by the authorised person; and
    - (ii) produce any book, record or document requested by the authorised person.
- (3) Despite subsection (2), an authorised person is not entitled to do a thing mentioned in that subsection if:
- (a) the principal investigator, or any other person present at the site concerned and in apparent control of the site, or of the trial or investigation, requests the authorised person to produce his or her identity card for inspection; and
  - (b) the authorised person fails to comply with the request.

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- (4) The principal investigator, or any other person present at the site and in apparent control of the site, or of the trial or investigation, is entitled to observe a search conducted under paragraph (2) (b), but must not impede the search.
  - (5) Subsection (4) does not prevent 2 or more areas of the site being searched at the same time.

*[Drafter's note: Audit powers in relation to the pharmacovigilance obligations of licence holders for medicines will be added at a later date.]*

## **Division 9.2 Examination, testing and analysis of therapeutic products**

### **9.05 Interpretation for this Division**

- (1) In this Division, unless the contrary intention appears:  
*Authority laboratory* means a laboratory operated by the Authority.  
*relevant test*:
  - (a) for the analysis of a medicine, means a relevant test mentioned in subsection 9.11 (1); and
  - (b) for the analysis of a medical device, means a relevant test mentioned in subsection 9.11 (2).
- (2) For this Division, a sample of a therapeutic product is *appropriately packaged, fastened and sealed* if the sample is fastened and sealed:
  - (a) in a vessel or package that is marked with the name and address of:
    - (i) the person from whom the sample was taken; or
    - (ii) for a sample delivered to the Authority in accordance with a requirement under the Rules or a condition of a product licence, manufacturing licence or conformity assessment certificate— the person who is required to comply with the requirement or condition; and
  - (b) so as to prevent the opening of the vessel or package, and the removal of the name and address, without breaking the seal.

### **9.06 Official analysts**

- (1) The Authority may appoint, in writing, a person who has appropriate qualifications and experience to be an official analyst for the purposes of the Rules.
- (2) The Authority must:
  - (a) maintain a register of the names of official analysts; and
  - (b) publish the names in the Authority Gazette from time to time.

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- (3) In addition to the other powers and functions of an official analyst, an official analyst may:
    - (a) ask an authorised person to take samples of therapeutic products; and
    - (b) determine the tests that are to be performed on a sample:
      - (i) taken by an authorised person; or
      - (ii) delivered to the Authority in accordance with a requirement under the Rules or a condition of a product licence, manufacturing licence or conformity assessment certificate; and
    - (c) nominate an official analyst to be responsible for the examination, testing or analysis of a sample so taken or delivered.

### **9.07 Samples taken for examination, testing or analysis**

- (1) An authorised person who takes a sample of a therapeutic product in accordance with paragraph 9.03 (1) (b) or 9.04 (2) (c), (other than a further sample taken under the circumstances described in subsection 9.13 (6)) must:
  - (a) give to the person from whom the sample was taken a written notice:
    - (i) that the sample is to be sent to an Authority laboratory for examination, testing or analysis; and
    - (ii) setting out details of the product; and
  - (b) send the sample to the Authority laboratory.
- (2) The authorised person must ensure that any sample of a product taken (including a further sample taken under the circumstances described in subsection 9.13 (6)) is:
  - (a) appropriately packaged, fastened and sealed; and
  - (b) stored and transported in accordance with the instructions (if any) specified on the label of the product.

### **9.08 Samples delivered for examination, testing or analysis**

- (1) When a sample of a therapeutic product is delivered to the Authority in accordance with a requirement under the Rules or a condition of a product licence, manufacturing licence or conformity assessment certificate, the Authority must, as soon as practicable, determine whether the sample is appropriately packaged, fastened and sealed, and:
  - (a) if the sample is appropriately packaged, fastened and sealed — send the sample, in the form in which it was received, to an Authority laboratory for examination, testing or analysis; or
  - (b) if the sample is not appropriately packaged, fastened or sealed — so inform, in writing, the person who is required to deliver the sample, explaining in what way the sample is not appropriately packaged, fastened or sealed.

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- (2) While dealing with the sample, the Authority must ensure that the sample is stored and transported in accordance with the instructions (if any) specified on the label of the product.

### **9.09 Samples received by Authority laboratory**

When a sample of a therapeutic product is received at an Authority laboratory for examination, testing or analysis, the Authority:

- (a) must determine whether the sample is appropriately packaged, fastened and sealed; and
- (b) if appropriately packaged, fastened and sealed — must store the sample under secure conditions that are appropriate to therapeutic products of that kind.

### **9.10 Examination, testing and analysis of samples**

- (1) An official analyst must, as soon as practicable, commence the examination, testing or analysis of a sample held by the Authority laboratory.
- (2) The examination, testing or analysis must include relevant tests to the extent the analyst considers necessary to establish:
  - (a) the quantity and quality of the product comprising the sample; and
  - (b) any other matter relevant to determining whether:
    - (i) for a medicine — the product from which the sample comes conforms to any standard applicable to a medicine of that kind and any relevant conditions of a product licence relating to such a standard; or
    - (ii) for a medical device — the product from which the sample comes conforms with the applicable provisions of the essential principles and any relevant conditions of a product licence relating to those provisions.
- (3) If multiple samples of a product are received, nothing in this section requires the analysis of every sample.

### **9.11 Relevant tests**

#### *Medicines*

- (1) Each of the following is a relevant test for determining whether a medicine conforms to a standard applicable to medicines of that kind:
  - (a) a test specified by the Authority for medicines of that kind in relation to that standard;
  - (b) if the Authority has not specified a test under paragraph (a) — a test specified in a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary for medicines of that kind in relation to that standard;

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- (c) a test acceptable to the Authority for the purposes of granting a product licence in respect of a medicine of that kind;
  - (d) any other appropriate test that the Authority requires to be carried out for medicines of that kind in relation to that standard.

#### *Medical devices*

- (2) Each of the following is a relevant test for determining whether a kind of medical device conforms with the applicable provisions of the essential principles:
  - (a) a test specified in a Medical Device Standards Order or Conformity Assessment Standards Order for the kind of device;
  - (b) a test acceptable to the Authority for the purpose of issuing a conformity assessment certificate in respect of the device;
  - (c) a test required as a condition of a product licence in respect of the kind of medical device;
  - (d) any other appropriate test that the Authority requires to be carried out in respect of the kind of device for the purpose of demonstrating conformity with the applicable provisions of the essential principles.

### **9.12 Certificate of official analyst**

- (1) Within a reasonable time after completion of the examination, testing or analysis of a sample, the Authority must send a certificate, signed by the official analyst and setting out the results of the examination, testing or analysis:
  - (a) if the sample was taken by an authorised person — to the person from whom the sample was taken; or
  - (b) if the sample was delivered in accordance with a requirement under the Rules or a condition of a product licence, manufacturing licence or conformity assessment certificate — to the person who was required to comply with the requirement or condition.
- (2) If the official analyst's certificate states:
  - (a) for a medicine — that the product represented by the sample does not conform to a standard applicable to products of that kind or to a relevant condition mentioned in subparagraph 9.10 (2) (b) (i); or
  - (b) for a medical device — that the product represented by the sample does not comply with the applicable provisions of the essential principles or to a relevant condition mentioned in subparagraph 9.10 (2) (b) (ii);the certificate must be accompanied by a notice that complies with subsection (3).
- (3) For subsection (2), the notice must:
  - (a) state that the person to whom the certificate is sent may ask for the findings of the official analyst to be reviewed in accordance with section 9.13; and

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- (b) specify the time within which a request for a review may be made; and
  - (c) state that the person may ask for an extension of that time if it is not reasonable to expect the person to comply with section 9.13 within the specified time.
- (4) In any proceedings under the Act, a certificate of an official analyst issued under subsection (1), or a certified copy of that certificate, is, in the absence of evidence to the contrary, conclusive proof of the matters set out or stated in it.
- (5) A document purporting to be:
- (a) a certificate of an official analyst issued under subsection (1); or
  - (b) a certified copy of that certificate;
- and purporting to be signed by an official analyst is, in the absence of evidence to the contrary, to be taken to be the certificate or a copy of the certificate and to have been issued under subsection (1).

*[Drafter's note: The evidentiary provisions (subsections (4) and (5)) may appear in a general evidentiary provision in the implementing legislation for each country.]*

### **9.13 Review of findings of official analyst**

- (1) A person:
- (a) to whom a certificate setting out the results of the examination, testing or analysis of a sample is sent under subsection 9.12 (1); and
  - (b) who sends to the Authority evidence in writing establishing:
    - (i) for a medicine — that the product represented by the sample conforms to the applicable standard or relevant condition; or
    - (ii) for a medical device — that the product represented by the sample conforms with the applicable provisions of the essential principles or relevant condition;
- may ask for the findings of the official analyst to be reviewed.
- (2) A request for review must:
- (a) set out the reasons for the review; and
  - (b) be made not later than 21 days after the person receives the certificate.
- (3) The Authority must extend the period of 21 days if it is not reasonable to expect the person to provide the evidence within 21 days.
- (4) A person is not to be regarded as having sent the Authority the evidence mentioned in paragraph (1) (b) unless the person has sent to the Authority a certificate of an analyst who has appropriate qualifications and experience:
- (a) stating that the analyst has examined, tested or analysed a part of the same sample, or a similar sample from the same batch (if any), of the product; and
  - (b) setting out

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- (i) the results of that examination, testing or analysis; and
    - (ii) details of the tests used in the examination, testing or analysis.
  - (5) If a certificate under subsection (4) shows that an examination, test or analysis for the purpose of establishing conformity or compliance asserted under paragraph (1) (b) was carried out in accordance with the relevant tests in relation to the products, subsection (6) applies.
  - (6) For subsection (5), unless the results of an examination, testing or analysis under subsection (4), or other information available to the Authority in relation to the product, show lack of homogeneity in the sample, the Authority, if so requested by the person who requested the review, must direct:
    - (a) if part of the sample remains unimpaired — the official analyst to send so much of the sample as remains unimpaired; or
    - (b) if no part of the sample remains unimpaired — that a further sample taken by an authorised person from the same batch as the original sample be sent;to an analyst agreed upon by the person who requested the review and the official analyst, or, in the absence of agreement, to an analyst nominated by the Authority.
  - (7) If a sample is sent to an analyst under subsection (6), the analyst must:
    - (a) examine, test or analyse the sample in accordance with any relevant tests;
    - (b) send to the Authority a certificate, signed by the analyst, setting out the results of the examination, testing or analysis; and
    - (c) send a copy of that certificate, signed by the analyst, to the person who requested the review.
  - (8) A certificate under section 9.12 setting out the results of the examination, testing or analysis of a sample of a product ceases to have effect when the Authority receives the certificate in relation to that product under subsection (7).
  - (9) If the findings of the official analyst are upheld by the certificate under subsection (7), the person who requested the review must pay any charges payable to the analyst whose certificate it is.
  - (10) In any proceedings under the Act, a certificate of an analyst issued under subsection (7) or a certified copy of that certificate is, in the absence of evidence to the contrary, conclusive proof of the matters stated in it.
  - (11) A document purporting to be:
    - (a) a certificate of an analyst issued under subsection (7); or
    - (b) a certified copy of that certificate;and purporting to be signed by the analyst, is, in the absence of evidence to the contrary, to be regarded as the certificate, or a copy of the certificate, and to have been issued under that subsection.

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*[Drafter's note: The evidentiary provisions (subsections (10) and (11)) may appear in a general evidentiary provision in the implementing legislation for each country.]*

#### **9.14 Application of Division to samples taken under the Act**

- (1) Subject to any contrary provision of the Act, this Division applies in relation to a sample of a therapeutic product taken under a relevant provision of the Act as it applies to a sample of a therapeutic product taken under a provision of this Part.
- (2) For the purposes of subsection (1), a reference in this Division to an authorised person is taken to be a reference to a person who is authorised to take samples under the relevant provision of the Act.
- (3) In this section, *relevant provision* of the Act means:
  - (a) for Australia — a provision of [Division 5 of Part 3] of the Act; or
  - (b) for New Zealand — a provision of [ ] of the Act.

### **Division 9.3 Conduct relating to authorised persons etc**

#### **9.15 Conduct relating to authorised persons etc**

- (1) A person must not:
  - (a) molest, obstruct or try to intimidate or influence an authorised person in the execution of his or her powers or the performance of his or her functions mentioned in section 9.03 or 9.04; or
  - (b) on being asked by an authorised person, fail:
    - (i) to show the authorised person the place where a therapeutic product is kept; or
    - (ii) to admit the authorised person to a place where a therapeutic product is kept; or
    - (iii) to show the authorised person, or let the authorised person inspect, therapeutic products kept by the person; or
    - (iv) to allow a sample of a therapeutic product to be taken in accordance with the Rules; or
    - (v) to give an authorised person information requested by the authorised person, being information relevant to the manufacture or testing of a therapeutic product, that the person is reasonably able to provide; or
    - (vi) to assist the authorised person in the execution of his or her powers or the performance of his or her functions; or
  - (c) on being asked by an official analyst, fail to give any information requested by the official analyst, being information relevant to the examination, testing or analysis of a therapeutic product, that the person is reasonably able to provide.

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- (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].

***[Drafter's note: Part or all of this provision may appear in the implementing legislation of each country.]***

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## Part 10

## Scheduling of substances

*[Drafter's note: Provisions relating to scheduling are to be included at a later date.]*

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## Part 11 Miscellaneous

### Division 11.1 Delegations

*Note* For general interpretation provisions relating to delegations, see Division 2.3 of Schedule 1.

*[Drafter's note 1: Delegation provisions may be revised when the staffing arrangements for the Authority in the implementing legislation are finalised.]*

*[Drafter's note 2: Delegation provisions relating to the Advertising Rule will be added when that Rule is drafted.]*

#### 11.01 Delegation by Board

- (1) The Board may, by instrument in writing, delegate all or any of its powers or functions to:
  - (a) a member of the Board (including the Managing Director); or
  - (b) an employee of the Authority.
- (2) In exercising or performing a delegated power or function, the delegate must comply with any written directions of the Board.
- (3) A delegation by the Board continues in force despite a change in membership of the Board.
- (4) A delegation by the Board may be varied or revoked by instrument in writing (whether or not there has been a change in membership of the Board).
- (5) Subject to subsection 11.02 ( ), a power or function delegated by the Board under this section cannot be further delegated.

*Note* As to the powers and functions of the Board, see [ ] of the Australian Act.

*[Drafter's note: Delegations by the Board are still under consideration. A provision may be included as part of a separate Rule relating to governance of the Authority.]*

#### 11.02 Delegation by Managing Director — general

- (1) Except as otherwise provided in these Rules, the Managing Director, by instrument in writing, may delegate all or any of the Managing Director's powers or functions (including regulatory functions that the Managing Director exercises on behalf of and in the name of the Authority) to an employee of, or a person on secondment to, the Authority.
- (2) Subsection (1) does not apply to the power of delegation under this section.

- 
- (3) If the Board delegates to the Managing Director a power or function relating to:
- (a) the engagement of staff of the Authority; or
  - (b) determining the terms and conditions of employment by the Authority; the Managing Director may delegate that power or function only to an employee of the Authority.
- (4) Subject to subsection (5), in exercising a delegated power or performing a delegated function under these Rules a delegate must comply with any directions of the Managing Director.
- (5) If:
- (a) the Board has given written directions with respect to the exercise or performance of a power or function delegated to the Managing Director under subsection (3); and
  - (b) the Managing Director delegates that power or function to another person;
- the Managing Director must give corresponding directions to the person to whom the power or function is delegated, and the person must comply with those directions.

*[Drafter's note: The classes of persons to whom powers and functions may be delegated under this section and subsequent sections of this Division are still under consideration.]*

### **11.03 Delegation — exemption for special purpose**

- (1) In this section:
- delegation** means a delegation of the powers of the Authority to grant an approval:
- (a) under section 5.05 of the Medicines Rule for the supply of a medicine for the purpose solely of use in the medical treatment of a specified person; or
  - (b) under section 6.05 of the Medical Devices Rule for the supply of a medical device for the purpose solely of use in the medical treatment of a specified person.
- Note* Sections 5.05 of the Medicines Rule and 6.05 of the Medical Devices Rule give effect to the Special Access Scheme as it applies principally to Category B patients.
- (2) The Managing Director may make a delegation only to:
- (a) a person who is a medical practitioner, dental practitioner or pharmacist, or is eligible for registration, in Australia or New Zealand, as a medical practitioner, dental practitioner or pharmacist, and who:
    - (i) is an employee of, or a person on secondment to, the Authority;or

- 
- (ii) is a person:
- (A) holding, occupying or performing the functions of an office; or
  - (B) holding an appointment (whether under a contract or otherwise);
- being an office or appointment specified, for the purposes of this subparagraph, in an Order; or
- (b) is a person who:
- (i) is a medical practitioner or dental practitioner; and
  - (ii) is employed by an institution that has an ethics committee; and
  - (iii) is proposed as a delegate for the purposes of this section by the medical superintendent or, if there is no medical superintendent, by the person occupying an office comparable to that of medical superintendent, of the institution.
- (3) If:
- (a) under subparagraph (2) (b) (iii), a person proposes another person to be a delegate; and
  - (b) that other person becomes a delegate;
- the first-mentioned person must supervise each approval that the delegate grants under the delegation.
- (4) An instrument of delegation to a person mentioned in paragraph (2) (b) must describe the person or class of persons to be treated with the medicine, or kind of medical device, to which the delegation relates.
- (5) A delegation to a person mentioned in paragraph (2) (b) may be made for the purpose of allowing the delegate to grant an approval in relation to:
- (a) a particular medicine or medical device; or
  - (b) a particular kind of medicines or medical devices; or
  - (c) a particular class of medical devices;
- for treating a specific illness or condition.
- (6) A person mentioned in paragraph (2) (b) to whom a delegation is made may grant an approval only if:
- (a) another medical practitioner has stated in writing that the person who is to be treated with the medicine or medical device to which the approval relates has an illness or condition that requires treatment with a medicine or medical device of that kind; and
  - (b) an ethics committee has agreed to the grant of an approval under section 5.05 of the Medicines Rule or section 6.05 of the Medical Devices Rule (as the case requires) for the use, in the circumstances in which the delegate grants the approval, of the kind of medicine or medical device to which the delegation relates.

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- (7) A person mentioned in paragraph (2) (b) to whom a delegation is made is, in the exercise of a delegated power, subject to the directions of:
- (a) the Managing Director; or
  - (b) an employee of, or a person on secondment to, the Authority.

#### **11.04 Delegation — exemption for authorised prescribers**

- (1) In this section:

*delegation* means a delegation of the powers of the Authority to grant an approval to a specified medical practitioner:

- (a) under section 5.08 of the Medicines Rule, for the supply of a medicine for the purpose solely of treatment of a person suffering a life-threatening or otherwise serious disease, disorder or condition; or
- (b) under section 6.08 of the Medical Devices Rule, for the supply of a medical device for the purpose solely of treatment of a person suffering a life-threatening or otherwise serious disease, disorder or condition.

*Note* Sections 5.08 of the Medicines Rule and 6.08 of the Medical Devices Rule relate to access to unlicensed medicines and medical devices by authorised prescribers for limited purposes.

- (2) The Managing Director may make a delegation only to a person who is a medical practitioner or dental practitioner, or is eligible for registration, in Australia or New Zealand, as a medical practitioner or dental practitioner, and who:
- (a) is an employee of, or a person on secondment to, the Authority; or
  - (b) is a person:
    - (i) holding, occupying or performing the functions of an office; or
    - (ii) holding an appointment (whether under a contract or otherwise);being an office or appointment specified, for the purposes of this paragraph, in an Order.

#### **11.05 Delegation — exemption where medicine or medical device is unavailable**

- (1) In this section:

*delegation* means a delegation of the powers of the Authority to grant an approval:

- (a) under section 5.09 of the Medicines Rule, for the importation or supply of a medicine for a purpose set out in that section; or
- (b) under section 6.10 of the Medical Devices Rule, for the supply of a medical device for a purpose set out in that section.

- (2) The Managing Director may make a delegation only to a person who is an employee of the Authority.

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## 11.06 Delegation — exemption for public health emergency

- (1) In this section:  
*delegation* means a delegation of the powers of the Authority to grant an approval:
  - (a) under section 5.10 of the Medicines Rule, for the importation or supply of a medicine for a purpose set out in that section; or
  - (b) under section 6.11 of the Medical Devices Rule, for the importation or supply of a medical device for a purpose set out in that section.
- (2) The Managing Director may make a delegation only to a person who is an employee of, or a person on secondment to, the Authority.
- (3) The Minister may, by instrument in writing, delegate his or her power to give notification under:
  - (a) paragraph 5.10 (3) (a) or (b) of the Medicines Rule; or
  - (b) paragraph 6.11 (3) (a) or (b) of the Medical Devices Rule;to the Managing Director.

*[Drafter's note: This section will be reviewed when the application and placement of provisions in the Medicines and Medical Devices Rules relating to the exemption of medicines/medical devices for public health emergencies is settled.]*

## Division 11.2 Internal review of decisions under the Medicines and Medical Devices Rules

*Note 1* For the internal review of decisions relating to scheduling of medicines, see Division 10.5 of the Administration and Interpretation Rule.

*Note 2* For the internal review of decisions relating to advertisements for therapeutic products, see Part [ ] of the Advertising Rule.

## 11.07 What is an initial regulatory decision?

- (1) For the purposes of this Division, an *initial regulatory decision* is a decision by the Authority of a kind mentioned in subsection (2), other than a decision made on review under section 11.09.
- (2) For subsection (1), the kinds of decisions are:
  - (a) a decision in relation to an application for a product licence under Part 3 of the Medicines Rule or Part 4 of the Medical Devices Rule, other than:
    - (i) a decision in relation to the selection of product licence applications for auditing under Subdivision 4.2.2 of the Medical Devices Rule; or
    - (ii) a decision about which aspects of the matters mentioned in paragraphs 4.14 (1) (a) or (b) of the Medical Devices Rule to consider in auditing an application under Subdivision 4.2.2 of the Medical Devices Rule;

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- (b) a decision in relation to the imposition of conditions on, or the variation, suspension or revocation of, a product licence mentioned in paragraph (a);
  - (c) a decision in relation to an application for a manufacturing licence under Part 4 of the Medicines Rule;
  - (d) a decision in relation to the imposition of conditions on, or the renewal, variation, suspension or revocation of, a manufacturing licence mentioned in paragraph (c);
  - (e) a decision in relation to an application for a conformity assessment certificate under Part 5 of the Medical Devices Rule;
  - (f) a decision in relation to the imposition of conditions on, or the suspension or revocation of, a conformity assessment certificate mentioned in paragraph (e);
  - (g) a decision in relation to an application for an approval under Part 5 of the Medicines Rule or Part 6 of the Medical Devices Rule;
  - (h) a decision in relation to the imposition of conditions on, or the variation, suspension or revocation of, an approval mentioned in paragraph (g);
  - (i) a decision in relation to the imposition of a requirement under Part 6 of the Medicines Rule or Part 7 of the Medical Devices Rule;
  - (j) a decision in relation to a requirement to provide information or documents under Part 8 of the Medicines Rule;
  - (k) a decision in relation to a requirement to provide information under Part 9 of the Medicines Rule or Part 9 of the Medical Devices Rule ;
  - (l) a decision in relation to an application for designation of a medicine as an orphan medicine under Part 10 of the Medicines Rule.
- (3) For the avoidance of doubt, the following are not initial regulatory decisions for the purposes of this Division:
- (a) a proposal to suspend a conformity assessment certificate under section 5.15 of the Medical Devices Rule;
  - (b) a proposal to revoke a conformity assessment certificate under section 5.21 of the Medical Devices Rule;
  - (c) a proposal to suspend a product licence under section 3.52 of the Medicines Rule or section 4.21 of the Medical Devices Rule;
  - (d) a proposal to revoke a product licence under section 3.60 of the Medicines Rule or section 4.32 of the Medical Devices Rule.

*[Drafter's note: This provision will be reviewed for completeness when drafting of the Scheme is completed.]*

## **11.08 Application to review initial regulatory decision**

- (1) A person whose interests are affected by an initial regulatory decision (other than a decision made personally by the Managing Director) may apply in writing to the Authority for a review of the decision.

- 
- (2) An application under subsection (1) must be made:
    - (a) if particulars of the decision are required to be notified in the Authority Gazette or on the Authority website — within 90 days after the notification; or
    - (b) in any other case — within 90 days after the decision first comes to the person's notice.

*Note* Initial regulatory decisions made by the Managing Director personally are subject to review by a Review Tribunal, see:

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

### **11.09 Review of initial regulatory decision**

- (1) Subject to this section, the Managing Director must, as soon as practicable after receiving an application under section 11.08:
  - (a) personally review the initial regulatory decision; or
  - (b) cause the decision to be reviewed by a delegate of the Managing Director who:
    - (i) was not involved in the initial regulatory decision; and
    - (ii) if the delegate is a member of the staff of the Authority — holds a more senior office than the delegate who made the initial regulatory decision.
- (2) Subsection (1) does not apply if the Managing Director remits the decision to a delegate under section 11.10.
- (3) On a review, the Managing Director or delegate may:
  - (a) confirm the initial regulatory decision; or
  - (b) revoke the initial regulatory decision, or revoke that decision and make a decision in substitution for the revoked decision.
- (4) If, within 60 days after an application is made under section 11.08, the applicant does not receive:
  - (a) notice of the decision of the Authority on review of the initial regulatory decision; or
  - (b) if applicable, notice that the matter has been remitted under section 11.10 to a delegate;the Authority is to be taken to have confirmed the initial regulatory decision.
- (5) The person reviewing the initial regulatory decision must give the applicant a notice in writing stating the result of the review.
- (6) A notice under subsection (5) must include a statement to the effect that, subject to the applicable legislation of Australia or New Zealand (as the case requires), the applicant may:
  - (a) apply to the Authority for a statement setting out the reasons for the decision on review; and

- 
- (b) apply to a Review Tribunal for a review of that decision.
  - (7) A failure to comply with the requirements of subsection (5) or (6) does not affect the validity of the decision on review.

#### **11.10 New information on review — discretion to remit**

- (1) This section applies only if a person whose interests are affected by an initial regulatory decision:
  - (a) applies under section 11.08 for a review of an initial regulatory decision made:
    - (i) under section 3.07 or 3.37 of the Medicines Rule, in relation to an application for a product licence in respect of a medicine; or
    - (ii) under section 5.09 of the Medical Devices Rule, in relation to an application for a conformity assessment certificate; and
  - (b) gives to the Authority new information in support of the application.
- (2) If the decision is reviewed by the Managing Director personally, or by a delegate mentioned in paragraph 11.09 (1) (b), the Managing Director or delegate must take the new information into account in the review.
- (3) However, the Managing Director, or the delegate mentioned in paragraph 11.09 (1) (b), may remit the matter to a delegate of the Managing Director who, as the case requires, is authorised:
  - (a) for the purpose of exercising a power in relation to the grant of a product licence under Part 3 of the Medicines Rule; or
  - (b) for the purpose of exercising a power in relation to the issue of a conformity assessment certificate under Part 5 of the Medical Devices Rule;to make a fresh decision.
- (4) If:
  - (a) the matter relates to a decision of a kind mentioned in subparagraph (1) (a) (i); and
  - (b) the matter is remitted to a delegate under subsection (3); and
  - (c) the applicant has paid, as a further evaluation fee, the evaluation fee that the person would have to pay under the applicable provision of the Medicines Rule on making a new application for a product licence in respect of the medicine;the delegate must make a decision under the applicable provision of the Medicines Rule as if a fresh application for a product licence had been made.
- (5) If:
  - (a) the matter relates to a decision of a kind mentioned in subparagraph (1) (a) (ii); and
  - (b) the matter is remitted to a delegate under subsection (3); and

- 
- (c) the applicant has paid, as a further conformity assessment fee, the conformity assessment fee that the person would have to pay under the applicable provision of the Medical Devices Rule on making a new application for a conformity assessment certificate;
- the delegate must make a decision under section 5.09 of the Medical Devices Rule as if a fresh application for a conformity assessment certificate had been made.
- (6) To remove any doubt, the delegate's fresh decision is to be treated, for the purposes of any subsequent application of the provisions of this Division, as a decision under paragraph 11.07 (2) (a) or (e).
- (7) In this section:
- new information*** means information that:
- (a) was in existence at the time the initial regulatory decision mentioned in subsection (1) was made; and
- (b) was not made available to the delegate of the Managing Director for the purpose of making the decision; and
- (c) is relevant to the decision;
- and includes any opinions that are wholly or substantially based on such information (whether or not the opinions were formed before or after the decision was made).

#### **11.11 Notice of initial regulatory decision to include statement about review**

- (1) If the Authority gives written notice of the making of an initial regulatory decision (other than a decision made personally by the Managing Director) to a person whose interests are affected by the decision, the notice must include a statement to the effect that a person whose interests are affected by the decision may:
- (a) under this Division, apply for a review of the decision; and
- (b) if the person is dissatisfied with the decision on review, and subject to the applicable legislation of Australia or New Zealand (as the case requires), apply to a Review Tribunal for a review of that decision.
- (2) If the Authority gives written notice of the making, by the Managing Director personally, of an initial regulatory decision to a person whose interests are affected by the decision, the notice must include a statement to the effect that a person whose interests are affected by the decision may, subject to the applicable legislation of Australia or New Zealand (as the case requires), apply to a Review Tribunal for a review of that decision.
- (3) A failure to comply with the requirements of subsection (1) or (2) does not affect the validity of the initial regulatory decision.

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## 11.12 Internal review a regulatory function

For paragraph (b) of the definition of *regulatory function* in Article 1 of the Agreement, the function of the Authority in reviewing decisions by the Authority, as provided under this Division, is declared to be a regulatory function.

## Division 11.3 Review by Review Tribunal

### 11.13 Definitions

In this Division:

*Australian Act* means the *Therapeutic Products Act 2006* of Australia.

*country*, in relation to a Law Minister, means the country in relation to which the person is the Law Minister.

*Crown* means:

- (a) for Australia — the Crown in right of the Commonwealth;
- (b) for New Zealand — the Crown in right of New Zealand.

*Law Minister* means:

- (a) for Australia — the Minister administering the *Legislative Instruments Act 2003*;
- (b) for New Zealand — [instructions required]

*New Zealand Act* means the *Therapeutic Products Act 2006* of New Zealand.

*request* means a request for a statement under subsection 11.16 (1).

*reviewable decision* means a decision in relation to which an application may be made:

- (a) under section 412 of the Australian Act; or
- (b) under section 410 of the New Zealand Act.

*Tribunal* means:

- (a) the Australian Review Tribunal provided for under section 410 of the Australian Act; or
- (b) the Review Tribunal established under section 414 of the New Zealand Act.

### 11.14 Matters specified for and open to merits review

A matter (other than a matter relating to an approval) that is the subject of a decision of a kind mentioned in subsection 11.07 (2):

- (a) is specified for paragraph 412 (1) (c) of the Australian Act; and
- (b) is open to merits review for paragraph (c) of the definition of *reviewable decision* in section 401 of the New Zealand Act.

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*Note* Subsection 412 (1) of the Australian Act provides:

- (1) An application may be made to the Australian Review Tribunal for the review of the following decisions:
  - (a) a decision by the Authority in relation to an application for an approval;
  - (b) a decision by the Authority in relation to the amendment, suspension or revocation of an approval;
  - (c) a decision by the Authority in relation to any other matter specified in the Rules.

This subsection has effect subject to subsections (3) and (4) and to section ^414.

*Note* Section 410 of the New Zealand Act provides that a person whose interests are affected by a ‘reviewable decision’ may apply to the Review Tribunal for a review of that decision. Section 401 defines ‘reviewable decision’ as follows:

**reviewable decision** means a decision of the [Authority] in relation to—

- (a) an application for an Approval;
- (b) the amendment, suspension or revocation of an Approval;
- (c) any other matter specified in the Rules as being open to merits review.

### **11.15 Notice of decision and review rights to be given [AAT s 27A]**

A person who makes a reviewable decision must take such steps as are reasonable in the circumstances to give to any person whose interests are affected by the decision notice, in writing or otherwise:

- (a) of the making of the decision; and
- (b) of the right of the person to have the decision reviewed; and
- (c) of the reasons for the decision.

### **11.16 Person affected by decision may request statement of reasons [AAT s 28 (1)]**

- (1) If a person (the **decision maker**) makes a reviewable decision, any person (the **applicant**) entitled to apply to the Tribunal for a review of the decision may, by notice in writing given to the decision maker, request the decision maker to give to the applicant a statement.
- (2) The statement must:
  - (a) be in writing; and
  - (b) set out the findings on material questions of fact, referring to the evidence or other material on which those findings were based; and
  - (c) give the reasons for the decision.
- (3) Subject to section 11.20, the decision maker must, as soon as practicable but in any case within 28 days after receiving the request, prepare, and give to the applicant, the statement.

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**11.17 Applicant not entitled to request statement of reasons  
[AAT s 28 (4)]**

The applicant is not entitled to make a request if:

- (a) the decision sets out the findings on material questions of fact, refers to the evidence or other material on which those findings were based and gives the reasons for the decision, and a document setting out the terms of the decision has been given to the applicant; or
- (b) a statement in writing setting out the findings on material questions of fact, referring to the evidence or other material on which those findings were based and giving the reasons for the decision has already been given to the applicant.

**11.18 Refusal to give statement of reasons — request made too late  
[AAT s 28 (1A) & (1B)]**

- (1) The decision maker may refuse a request if:
  - (a) in the case of a decision the terms of which were recorded in writing and set out in a document that was given to the applicant—the request was not made on or before the twenty-eighth day after the day on which that document was given to the applicant; or
  - (b) in any other case—the request was not made within a reasonable time after the decision was made.
- (2) For paragraph (1)(b), a request is taken to have been made within a reasonable time if the Tribunal, on application by the person who made the request, declares that the request was made within a reasonable time after the decision was made.
- (3) If the decision maker refuses the request the decision maker must give to the applicant, as soon as practicable but in any case within 28 days after receiving the request, notice in writing stating:
  - (a) that the statement will not be given to the applicant; and
  - (b) the reason why the statement will not be given.

**11.19 Refusal to give statement of reasons — public interest  
certificate [AAT s 28 (2), (3) & (3A)]**

- (1) This section applies if the Law Minister gives a signed certificate to the effect that the disclosure of any matter in a statement under section 11.16 would be contrary to the public interest:
  - (a) by reason that it would prejudice the security, defence or international relations of the country; or
  - (b) by reason that it would involve the disclosure of deliberations of the Cabinet or of a Committee of the Cabinet; or
  - (c) for any other reason specified in the certificate that could form the basis for a claim by the Crown in a judicial proceeding that the matter should not be disclosed.

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- (2) The decision maker:
    - (a) is not required to include in the statement any matter in relation to which the Law Minister has given a certificate; and
    - (b) where the statement would be false or misleading if it did not include that matter—is not required by section 11.16 to give the statement to the applicant.
  - (3) Where a certificate is given in relation to a matter that relates to a decision, the decision maker must notify the applicant in writing to the effect:
    - (a) in a case where the matter is not included in the statement—that the matter is not so included and give the reason for not including the matter; or
    - (b) in a case where the statement is not given—that the statement will not be given and give the reason for not giving the statement.

*Note* Subsection 420 (7) of the Australian Act provides that the *Administrative Appeals Tribunal Act 1975* applies with such other modifications as are specified in the regulations. Regulation [ ] of the *Therapeutic Products Regulations 2006* made under the Australian Act modifies subsections 36(2), (3), (3A) and (4) and 36D(1) to (6) of the *Administrative Appeals Tribunal Act 1975*.

#### **11.20 Decision maker believes applicant not entitled to statement [AAT s 28 (1AA) & (1AB)]**

- (1) If the decision maker believes that the applicant is not entitled to a statement under section 11.16, the decision maker must, as soon as practicable but in any case within 28 days after receiving the applicant's request, give the applicant written notice of the decision maker's belief.
- (2) Subject to subsection (3), the decision maker is not required to comply with the request if the decision maker gives notice of his or her belief.
- (3) If the Tribunal, on application under section 11.21, decides that the applicant was entitled to be given the statement, the decision maker must prepare the statement and give it to the applicant within 28 days after the decision of the Tribunal is given.

#### **11.21 Application to Tribunal for statement of reasons [AAT s 28 (1AC)]**

The Tribunal, on application by the applicant, must decide whether the applicant was, or was not, entitled to be given the statement.

*[Drafter's note: Consideration is being given to including this provision in the implementing Bills.]*

#### **11.22 Inadequate statement of reasons [AAT s 28 (5)]**

- (1) An applicant given a statement under section 11.16 may apply to the Tribunal for a declaration under subsection (2).

- 
- (2) After considering the statement, the Tribunal may declare that the statement does not contain 1 or more of the following:
    - (a) adequate particulars of findings on material questions of fact;
    - (b) an adequate reference to the evidence or other material on which those findings were based;
    - (c) adequate particulars of the reasons for the decision.
  - (3) If a declaration is made, the decision maker must, as soon as practicable but in any case within 28 days after the Tribunal makes the declaration, give to the applicant an additional statement or additional statements containing further and better particulars in relation to matters specified in the declaration with respect to those findings, that evidence or other material or those reasons.

*[Drafter's note: Consideration is being given to including this provision in the implementing Bills.]*

## **Division 11.4      Other matters**

### **11.23      Authority may require information about therapeutic products imported or supplied**

- (1) The Authority may, by written notice given to a person who has imported or supplied:
  - (a) a therapeutic product; or
  - (b) a product or class of products in respect of which the Authority is considering making an order under paragraph 2 of Article 10 of the Agreement;request the person to give to an employee of the Authority identified in the notice, within such reasonable period as is specified in the notice, information required by the notice concerning the composition, indications, directions for use or labelling of the product or concerning advertising material relating to the product.
- (2) A notice under subsection (1) may require the information to be given:
  - (a) in writing; or
  - (b) 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.
- (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].

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

**11.24 Approved forms**

- (1) The Authority may approve forms for the purposes of these Rules.
- (2) An approval of a form may require or permit an application or 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.

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## Schedule 1 Interpretation of Ministerial Council Rules and Orders

(rule 3)

*[Drafter's note 1: The list of definitions will require further revision as drafting of the Rules is completed.]*

*[Drafter's note 2: The final placement of definitions will depend on their usage in the Rules and will be settled when the drafting of the Rules is completed.]*

### Part 1 Definitions

*Note 1* A definition in this Part applies to the use of a word or expression in a Rule subject to a contrary intention — see subsection 1.03 (2) in Part 1 (Preliminary) of this Rule.

*Note 2* A definition in this Part applies to the use of a word or expression in an Order or other instrument made under a Rule, as it applies to use in a Rule — see subsection 1.03 (5) in Part 1 (Preliminary) of this Rule

#### 1.01 Definitions and related meanings of defined terms

(1) In a Rule:

**accessory**, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**Act** means:

- (a) for Australia — the *Therapeutic Products Act 2006*; and
- (b) for New Zealand — the *Therapeutic Products and Medicines Act 2006*.

**active ingredient** means:

- (a) in relation to a medicine, a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the product as a medicine; and
- (b) in relation to a medical device, a substance that is, or one of the substances that together are, primarily responsible for achieving the effect identifying the product as a medical device.

**active medical device** has the meaning given by section 1.03 of the Medical Devices Rule.

**active medical device for diagnosis** has the meaning given by section 1.03 of the Medical Devices Rule.

**active medical device for therapy** has the meaning given by section 1.03 of the Medical Devices Rule.

**active moiety**, in relation to an active ingredient, means the portion of the active ingredient that is responsible for the effect of the active ingredient.

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**actual or potential tampering**, in relation to a medicine, has the meaning given by [to be completed].

**[Drafter’s note: Definition will be adopted from criminal offence provisions in the implementing legislation.]**

**Administration and Interpretation Rule** means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006*.

**Advertising Code** has the meaning given by section 1.03 of the Advertising Rule.

**Advertising Rule** means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Advertising) Rule 2006*.

**advertisement**, in relation to a therapeutic product, has the meaning given by section 1.03 of the Advertising Code.

**Authority** means the Australia New Zealand Therapeutic Products Authority established by section [ ] of the *Therapeutic Products Act 2006* of Australia.

**Authority Gazette** means the publication of that name on the Authority website.

**Authority website** means the Internet website maintained by or on behalf of the Authority.

*Note* The Authority website is at [link].

**Agreement:**

- (a) means 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; and
- (b) includes that Agreement as amended from time to time.

**analysis** includes examination and testing.

**appropriate ethics committee** means:

- (a) for Australia — a committee:
  - (i) constituted and operating as an ethics committee in accordance with guidelines issued by the National Health and Medical Research Council established under the *National Health and Medical Research Council Act 1992*; and
  - (b) that has notified its existence to the Australian Health Ethics Committee established under that Act; or
- (b) for New Zealand — a committee accredited by the Health Research Council of New Zealand.

**approved form** means a form approved under section 11.24.

**approved type**, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**ASMI** means Australian Self-Medication Industry Incorporated (ABN 55 082 798 952).

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**Australia** or **the Commonwealth** means the Commonwealth of Australia, and when used in a geographical sense, includes the Territory of Christmas Island and the Territory of Cocos (Keeling) Islands, but does not include any other external territory of Australia within the meaning of section 17 of the *Acts Interpretation Act 1901* of Australia.

**[Drafter’s note: Definition to be reviewed when the implementing legislation is settled.]**

**Australian Customs Service** means the service established by section 4 of the *Customs Administration Act 1985*.

**Australian Minister** means the Minister of the Government of Australia who is responsible for the health portfolio or any other Minister acting for or on behalf of such Minister.

**authorised person**, in relation to any provision of a Rule, means a person authorised under section 9.01 to exercise powers or perform functions under that provision.

**batch**, in relation to a medicine, has the meaning given by section 1.03 of the Medicines Rule.

**bioburden**, in relation to a medicine, has the meaning given by section 1.03 of the Medicines Rule.

**body orifice:**

- (a) means a natural opening, or a permanent artificial opening, in a person’s body; and
- (b) includes the external surface of a person’s eyeball.

**British Pharmacopoeia** means the edition of the publication of that name, including any amendments, that was in effect for the purposes of the *Therapeutic Goods Act 1989* of the Commonwealth of Australia immediately before the commencement of this Rule, and thereafter each new edition, or amendment, from the effective date published by the British Pharmacopoeia Commission.

**calendar year** means a period of 12 months commencing on 1 January.

**central circulatory system** means the blood-flow system comprising the following vessels:

- (a) arteriae pulmonales;
- (b) aorta ascendens;
- (c) arteriae coronariae;
- (d) arteria carotis communis;
- (e) arteria carotis externa;
- (f) arteria carotis interna;
- (g) arteriae cerebrales;
- (h) truncus brachicephalicus;
- (i) venae cordis;
- (j) venae pulmonales;
- (k) venae cava superior;

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- (l) venae cava inferior;
  - (m) arcus aorta;
  - (n) thoracica aorta;
  - (o) abdominalis aorta;
  - (p) ilica communis.

**central nervous system** means the system in a human being comprising the brain, meninges and spinal cord.

**CHCA** means the Complementary Healthcare Council of Australia [ABN 34 874 859 470].

**classification**, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**classification rules**, in relation to a medical device, means the rules for classifying the device set out in Part 1 of Schedule 2 to the Medical Devices Rule.

**Class 1 medicine**, has the meaning given by section 3.12 of the Medicines Rule.

**Class 2 medicine**, has the meaning given by section 3.17 of the Medicines Rule.

**Class I medical device** means a medical device that, under Schedule 2 to the Medical Devices Rule, is classified as Class I.

**Class IIa medical device** means a medical device that, under Schedule 2 to the Medical Devices Rule, is classified as Class IIa.

**Class IIb medical device** means a medical device that, under Schedule 2 to the Medical Devices Rule, is classified as Class IIb.

**Class III medical device** means a medical device that, under Schedule 2 to the Medical Devices Rule, is classified as Class III.

**Class AIMD medical device** means an active implantable medical device that, under Schedule 2 to the Medical Devices Rule, is classified as Class AIMD.

**clinical assessment procedures** means the conformity assessment procedures set out in Part 9 of Schedule 3 to the Medical Devices Rule.

**commencement:**

- (a) in relation to a Rule or a provision of a Rule, means the time at which the Rule or provision starts to have effect; and
- (b) in relation to a licence, means the time at which the licence comes into force.

**complementary healthcare practitioner** has the meaning given by section 1.03 of the Medicines Rule.

**complementary medicine** has the meaning given by section 1.05 of the Medicines Rule.

**conformity assessment certificate** means a certificate issued under Part 5 of the Medical Devices Rule to a manufacturer of medical devices.

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**conformity assessment fee** means a conformity assessment fee payable under Part 10 of the Medical Devices Rule.

**conformity assessment procedures** has the meaning given by section 3.03 of the Medical Devices Rule.

**Conformity Assessment Standards Order** has the meaning given by section 1.03 of the Medical Devices Rule.

**consumer medicine information** has the meaning given by section 1.03 of the Medicines Rule.

**container**, in relation to a therapeutic product, means an article that immediately covers the product, and includes an ampoule, blister pack, bottle, box, dial dispenser pack, jar, packet, sachet, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include an article intended for ingestion.

**contravene** includes fail to comply with.

**counterfeit** has the meaning given by [to be completed].

*[Drafter's note: Definition to be completed when implementing legislation is settled.]*

**custom-made medical device** has the meaning given by section 1.03 of the Medical Devices Rule.

**Customs** means:

- (a) for Australia — the Australian Customs Service; and
- (b) for New Zealand — the New Zealand Customs Service.

**Customs Act** means:

- (a) for Australia — the *Customs Act 1901*; and
- (b) for New Zealand — the Customs and Excise Act 1996.

**Customs employee** means an employee of Customs, within the meaning of:

- (a) for Australia — the *Customs Act 1901*; and
- (b) for New Zealand — [to be completed].

**data processing device** means any article or material (for example, a disc) from which information is capable of being reproduced with or without the aid of any other article or device.

**default standard**, in relation to a medicine, has the meaning given by section 1.03 of the Medicines Rule.

**dental practitioner** means a person registered as a dental practitioner under:

- (a) for Australia — a law of a State or Territory that provides for the registration of dental practitioners; or
- (b) for New Zealand — a law of New Zealand that provides for the registration of dental practitioners.

**designated orphan medicine** means an orphan medicine designated under section 10.03 of the Medicines Rule.

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***directions for use***, in relation to a therapeutic product, includes information on:

- (a) appropriate doses of the product; and
- (b) the method of administration or use of the product; and
- (c) the frequency and duration of treatment for each indication of the product; and
- (d) the use of the product by persons of a particular age or by persons having a particular medical condition.

***document*** includes:

- (a) any paper or other material on which there is writing;
- (b) any paper or other material on which there are marks, figures, symbols or perforations having a meaning for persons qualified to interpret them; and
- (c) any data processing device in or on which there is information.

***essential principles***, in relation to a medical device, has the meaning given by section 2.02 of the Medical Devices Rule.

***European Pharmacopoeia*** means the English edition of the publication of that name, including Supplements, that was stated to be the current edition by the Council of Europe immediately before the commencement of this Rule, and thereafter each new edition, including Supplements, from the effective date published by the Council of Europe.

***expert advisory committee*** means any of the following:

- (a) the Expert Advisory Committee on Adverse Reactions to Medicines;
- (b) the Expert Advisory Committee on Complementary Medicines;
- (c) the Expert Advisory Committee on Medical Devices;
- (d) the Expert Advisory Committee on OTC Medicines;
- (e) the Expert Advisory Committee on Prescription Medicines;
- (f) the Expert Advisory Committee on Standards.

***Expert Advisory Committee on Adverse Reactions to Medicines*** means the committee of that name established by Division 8.6 of the Administration and Interpretation Rule.

***Expert Advisory Committee on Complementary Medicines*** means the committee of that name established by Division 8.4 of the Administration and Interpretation Rule.

***Expert Advisory Committee on Medical Devices*** means the committee of that name established by Division 8.5 of the Administration and Interpretation Rule.

***Expert Advisory Committee on OTC Medicines*** means the committee of that name established by Division 8.3 of the Administration and Interpretation Rule.

***Expert Advisory Committee on Prescription Medicines*** means the committee of that name established by Division 8.2 of the Administration and Interpretation Rule.

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**Expert Advisory Committee on Standards** means the committee of that name established by Division 8.8 of the Administration and Interpretation Rule.

**expiry date**, for a therapeutic product, means the date (expressed as a month and year, or as a day, month and year) after which the product should not be used, being a date that is not more than 5 years after:

- (a) if the particular batch of the product is released less than 30 days after the date of production — the date of release of the batch; or
- (b) if the particular batch of the product is released 30 days or more after the date of production — the date of production of the batch.

**export-only medicine** has the meaning given by section 1.03 of the Medicines Rule.

**financial year** means a period of 12 months beginning on 1 July.

**function** includes a duty.

**gene therapy** means the *in vivo* transfer of DNA or RNA into the cells of a human recipient.

**guardian**, in relation to a person (**the subject person**), means a person who has formal responsibility for the long-term welfare of the subject person.

**health professional** includes the following:

- (a) a medical practitioner, dental practitioner or pharmacist;
- (b) a health care worker of any kind registered under:
  - (i) for Australia — a law of a State or Territory that provides for the registration of health care workers of that kind; or
  - (ii) for New Zealand — a law of New Zealand that provides for the registration of health care workers of that kind;
- (c) a biomedical engineer, chiropractor, optometrist, orthodontist, osteopath, physiotherapist, podiatrist, prosthetist or rehabilitation engineer.

**individual** means a natural person.

**in vitro diagnostic device** or **IVD** has the meaning given by section 1.03 of the Medical Devices Rule.

**kind**, in relation to a medical device, has the meaning given by section 1.07 of the Medical Devices Rule.

**label**, in relation to a therapeutic product, means a display of printed information about the product:

- (a) on, or attached to, the product; or
- (b) on, or attached to, a container or primary pack in which the product is supplied; or
- (c) otherwise intended to be supplied to consumers with such a container or pack.

**licence** means a licence granted under the Rules, and constitutes an approval within the meaning of the Agreement.

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**manufacturer** means the manufacturer of a therapeutic product and, in the case of a manufacturer of a therapeutic product that is a medical device, has the meaning given by section 1.08 of the Medical Devices Rule.

**manufacturing licence**, in relation to a medicine, means a licence granted the manufacturer of the medicine under Part 4 of the Medicines Rule

**manufacturing premises** means premises at one location employed for the manufacture of a particular kind of therapeutic product.

**Manufacturing Principles** has the meaning given by section 1.03 of the Medicines Rule.

**medical device** has the meaning given by section 1.04 of the Medical Devices Rule.

**medical device classification** means a classification specified under Division 3.2 of the Medical Device Rule.

**Medical Device Standards Order** has the meaning given by section 1.03 of the Medical Devices Rule.

**medical device used for a special purpose** means a medical device to which section 2.07 of Part 2 of Schedule 2 to the Medical Devices Rule applies.

**Medical Devices Rule** means the *Australia New Zealand Therapeutic Products Regulatory Scheme (Medical Devices) Rule 2006*.

**medical practitioner** means a person registered as a medical practitioner under:

- (a) for Australia — a law of a State or Territory that provides for the registration of medical practitioners; or
- (b) for New Zealand — a law of New Zealand that provides for the registration of medical practitioners.

**medicine** has the meaning given by section 1.04 of the Medicines Rule.

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

**Medsafe** means the former New Zealand Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health.

**Minister** means, in relation to an action mentioned in the Rules that is taken, or that may or must be taken:

- (a) in Australia — the Australian Minister; and
- (b) in New Zealand — the New Zealand Minister.

**month** means a calendar month, that is, a period commencing at the beginning of a day of one of the 12 months of the year and ending immediately before the beginning of the corresponding day of the next month or, if there is no such corresponding day, ending at the expiration of the next month.

**Mutual Recognition Agreement** means [*to be completed*]

**New Zealand**, when used as a territorial description, means the islands and territories within the Realm of New Zealand, but does not include the

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self-governing state of the Cook Islands, the self-governing State of Niue, Tokelau, or the Ross Dependency.

*[Drafter's note: Definition to be kept under review.]*

***New Zealand Customs Service*** means the department of State of that name referred to in section 5 of the Customs and Excise Act 1996 of New Zealand.

***New Zealand Minister*** means the Minister of the Government of New Zealand who is responsible for the health portfolio or any other Minister acting for or on behalf of such Minister.

***office*** includes position.

***officer***, in relation to Australia, includes an employee in the Australian Public Service.

***official analyst*** means a person appointed by the Authority under section 9.06 of the Administration and Interpretation Rule.

***open shelf life***, for a therapeutic product, means the time, after the container holding the product is opened, after which the product should not be used.

***orphan medicine*** has the meaning given by section 10.01 of the Medicines Rule.

***OTC medicine*** means a therapeutic product mentioned in Part 3 of Schedule 3 to the Medicines Rule.

***person*** (and any expression used to denote persons generally such as 'someone', 'anyone', 'no-one', 'one', 'another' and 'whoever') includes an individual, a corporation sole, a body corporate or an unincorporated body.

***pharmacist*** means a person registered as a pharmacist under:

- (a) for Australia — a law of a State or Territory that provides for the registration of pharmacists; or
- (b) for New Zealand — a law of New Zealand that provides for the registration of pharmacists.

***post-production phase***, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

***Practice Guidelines*** means the document entitled 'Guidelines for Good Clinical Practice', as in force from time to time, published jointly by the International Conference on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Committee for Medicinal Products for Human Use of the European Medicines Authority (EMA).

***premises*** includes:

- (a) a structure, building, aircraft, vehicle or vessel; and
- (b) a place (whether enclosed or built-upon or not); and
- (c) a part of a thing referred to in paragraph (a) or (b).

***prescribed*** means prescribed by a Rule or an Order.

***presentation***, in relation to a therapeutic product, means the way in which the product is presented for supply, and includes matters relating to the

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name of the product, the labelling and packaging of the product and any advertising or other informational material associated with the product.

**primary pack**, in relation to a therapeutic product, means the complete pack in which the product is, or the product and its container are, to be supplied to consumers.

**principal investigator**, in relation to a clinical trial of a therapeutic product, means the person who is in charge of the conduct of the trial.

**procedures for medical devices used for a special purpose** means the conformity assessment procedures set out in Part 8 of Schedule 3 to the Medical Devices Rule.

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

**product licence** means:

- (a) in respect of a medicine — a product licence under Part 3 of the Medicines Rule; or
- (b) in respect of a medical device — a product licence under Part 4 of the Medical Devices Rule.

**production quality assurance procedures** means the conformity assessment procedures set out in Part 5 of Schedule 3 to the Medical Devices Rule.

**product quality control procedures** means the conformity assessment procedures set out in Part 6 of Schedule 3 to the Medical Devices Rule.

**prohibited export** means:

- (a) for Australia — a prohibited export within the meaning of the *Customs Act 1901*; and
- (b) for New Zealand — a prohibited export within the meaning of [*to be completed*]

**prohibited import** means:

- (a) for Australia — a prohibited import within the meaning of the *Customs Act 1901*; and
- (b) for New Zealand — a prohibited import within the meaning of [*to be completed*]

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

**quarter**, as a measurement of time, means a period of 3 months commencing on 1 January, 1 April, 1 July or 1 October in a calendar year.

**record** includes information stored or recorded by means of a data processing device.

**refurbishment**, in relation to a medical device, has the meaning given by section 1.10 of the Medical Devices Rule.

**Regulations** means Regulations under the Act.

**reusable surgical instrument** has the meaning given by section 1.03 of the Medical Devices Rule.

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**Rules of Court**, in relation to a court in Australia or New Zealand, means rules made by the authority having for the time being power to make rules or orders regulating the practice and procedure of the court.

**sample** includes part of a sample.

**scheduling**, in relation to a substance, means the classification of the substance to enable the application of a system of access controls to the substance.

**[Drafter's note: Scheduling would be effected under Part 10 of this Rule.]**

**ship** includes a yacht or other marine vessel.

**specialist** has the same meaning as:

- (a) for Australia — it has in the *Health Insurance Act 1973*; and
- (b) for New Zealand — [ ].

**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.

**standard** (other than a standard determined by a Conformity Assessment Standards Order), in relation to a therapeutic product, means:

- (a) for a medicine — a standard that applies to the medicine under section 2.04 of the Medicines Rule; or
- (b) for a medical device — a Medical Device Standards Order.

**substance** means any matter of chemical, biological, human, animal or non-animal origin.

**surgically invasive medical device** has the meaning given by section 1.03 of the Medical Devices Rule.

**tampering**, in relation to a therapeutic product, has the meaning given by [*to be completed*].

**[Drafter's note: Definition to be derived from offence provisions of the implementing legislation.]**

**Therapeutic Goods Administration** means the former administrative Division of that name in the Department of Health and Ageing of the Commonwealth of Australia.

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**the Rules** means the Rules made by the Ministerial Council under article 9 of the Agreement.

**type**, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**type examination procedures** means the conformity assessment procedures set out in Part 3 of Schedule 3 to the Medical Devices Rule.

**unique identifier**, in relation to a medicine, has the meaning given by section 3.06 of the Medicines Rule.

**unique licence number**, in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**United States Pharmacopoeia-National Formulary** means the English edition of the publication of that name, including Supplements, that was stated to be the current edition by the United States Pharmacopoeial Convention Inc. immediately before the commencement of this Rule, and thereafter each new edition, including Supplements, from the effective date published by the United States Pharmacopoeial Convention Inc.

**variant** in relation to a medical device, has the meaning given by section 1.03 of the Medical Devices Rule.

**verification procedures** means the conformity assessment procedures set out in Part 4 of Schedule 3 to the Medical Devices Rule.

**visual record** includes a video recording, a photograph and a sketch.

**working day** means any day of a week except the following:

- (a) Saturday;
- (b) Sunday;
- (c) a day that is a public holiday in both Canberra (Australia) and Wellington (New Zealand);
- (d) a day between 25 December and 1 January inclusive.

**writing** includes representing or reproducing words, figures, drawings or symbols:

- (a) in a visible and tangible form by any means and in any medium; or
- (b) in a visible form in any medium by electronic means that enables them to be stored in permanent form and to be retrieved and read.

#### *Use of terms defined in the Agreement*

- (2) An expression used in a Rule that is defined in the Agreement has the same meaning in the Rule as it has in the Agreement.

*Note* The following expressions are used in both the Agreement and in the Rules:

Authority	promotion
Board	Review Tribunal
Managing Director	Rule
manufacture	supply
Ministerial Council	therapeutic product
Order	therapeutic use.

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*Parts of speech and grammatical forms*

- (3) Parts of speech and grammatical forms of a word that is defined in a Rule have corresponding meanings in the same Rule.

**1.02 Meaning of serious disease etc**

For the Rules, a disease, disorder, condition, ailment or defect is *serious* if the disease, disorder, condition, ailment or defect (or any symptom of the disease, disorder, condition, ailment or defect) is generally accepted as not suitable for at least one of the following:

- (a) self-diagnosis;
- (b) self-management.

**1.03 Meaning of life-threatening disease etc**

For the Rules, a disease, disorder, condition, ailment or defect is *life-threatening* if the affected person is, as a result of the disease, disorder, condition, ailment or defect likely to die, in the absence of effective treatment:

- (a) within a few months; or
- (b) otherwise prematurely.

**Part 2 Rules of interpretation**

*Note 1* The rules of interpretation in this Part apply to a provision of a Rule subject to a contrary intention — see subsection 1.03 (2) in Part 1 (Preliminary) of the Administration and Interpretation Rule.

*Note 2* The rules of interpretation in this Part apply to a provision in an Order or other related instrument, as they apply to a provision of a Rule — see subsection 1.03 (5) in Part 1 (Preliminary) of the Administration and Interpretation Rule.

**Division 2.1 General**

**2.01 Time of commencement**

A Rule that is provided to have effect on a particular day starts to have effect at the beginning of that day.

*Note 1* As to the date of commencement of Rules, see:

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

*Note 2* As to expressions of time generally, see section 2.11 in this Part.

**2.02 Regard to be had to the objectives of the Agreement**

In the interpretation of a provision of a Rule, a construction that would promote the objectives set out in Article 2 of the Agreement is to be preferred to a construction that would not promote those objectives.

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### **2.03 Amending Rules**

- (1) An amending Rule is to be interpreted with, and as part of, the Rule that it amends.
- (2) If an amending Rule inserts:
  - (a) a definition in a list of definitions; or
  - (b) a name in a list of names;in the provision it amends, but does not specify the position in that provision where the definition or name is to be inserted, it is taken to be inserted in the appropriate alphabetical position, determined on a letter-by-letter basis.

### **2.04 Examples**

- (1) If a Rule includes an example of the operation of a provision, the example is not to be taken as exhaustive.
- (2) If the example is inconsistent with the provision, the provision prevails.

### **2.05 Headings and notes**

- (1) A heading to a Part, Division, Schedule, section or any other provision of a Rule is part of the Rule.
- (2) A note in a Rule is explanatory and is not part of the Rule.

### **2.06 Use of singular and plural words**

In a Rule, words in the singular include the plural and words in the plural include the singular.

### **2.07 References to nil amounts**

In any Rule:

- (a) a reference to an amount in general terms includes a nil amount; and
- (b) zero is taken to be a number.

### **2.08 References to amended or re-enacted laws of Australia or New Zealand**

- (1) This section applies if a Rule contains a reference to a short title or other citation that is or was provided by the law of Australia, a State or Territory of Australia, or New Zealand, for the citation of a law (the *cited law*) of Australia, a State or Territory of Australia, or New Zealand, respectively, as originally made or as amended.
- (2) The reference is taken to be a reference to the cited law as originally enacted or made and as amended from time to time.

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- (3) If the cited law has been repealed and re-enacted or re-made, with or without modification:
    - (a) the reference is taken to include a reference to the re-enacted or re-made law as originally enacted or made and as amended from time to time; and
    - (b) if, in connection with that reference, particular provisions of the cited law are referred to, being provisions to which provisions of the re-enacted or re-made law correspond, the reference to those particular provisions is taken to include a reference to those corresponding provisions.

## **2.09 Change in name of a body or office**

- (1) This section applies if:
  - (a) in a Rule a reference is made to a body (whether or not incorporated) or office by name; and
  - (b) a law of Australia or New Zealand, or a law of a State or Territory of Australia, changes the name of the body or office.
- (2) The reference to the body or office under the former name is, except in relation to any matter that occurred before the change took effect, to be taken as a reference to the body or office under the new name.

## **2.10 Mention of office holder in general terms**

If in a Rule any person holding or occupying a particular office is mentioned or referred to in general terms, the reference is to be taken to include all persons who at any time occupy for the time being, or perform for the time being the functions of, that office.

## **2.11 Time**

- (1) In any Rule:
  - (a) a period of time described as beginning at, on, or with a specified day, act or event includes that day or the day of the act or event; and
  - (b) a period of time described as beginning from or after a specified day, act or event does not include that day or the day of the act or event; and
  - (c) a period of time described as ending by, on, at, or with, or as continuing to or until, a specified day, act or event includes that day or the day of the act or event; and
  - (d) a period of time described as ending before a specified day, act or event does not include that day or the day of the act or event; and
  - (e) a reference to a number of days between 2 events does not include the days on which the events happened; and
  - (f) a thing that, under the Rule, must or may be done on a particular day or within a limited period of time may, if that day or the last day of that period is not a working day, be done on the next working day.

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- (2) A reference to a time in any Rule is to be taken in each part of Australia or New Zealand to mean the standard or legal time in that part of Australia or New Zealand.

### **2.12 Provision for matters by reference to other instruments**

- (1) This section applies if the Agreement authorises or requires provision to be made in relation to any matter in a Rule.
- (2) A Rule may make provision in relation to the matter by applying, adopting or incorporating, with or without modification, any matter contained in any other instrument or writing:
- (a) if expressly so stated in the Rule — as in force or existing at a particular time or as in force or existing from time to time; or
  - (b) if the Rule makes no express statement mentioned in paragraph (a) — as in force or existing at the time when the Rule starts to have effect.

### **2.13 Distance**

In any Rule a reference to a distance means a distance measured in a straight line on a horizontal plane.

### **2.14 Production of records kept in computers etc**

- (1) This section applies in relation to a person (the *record-keeper*) who:
- (a) keeps a record of information by means of a mechanical, electronic or other device; and
  - (b) is required, by or under a Rule, to:
    - (i) produce the information, or a document containing the information, to a court, tribunal or person; or
    - (ii) make a document containing the information available for inspection by a court, tribunal or person.
- (2) Unless the court, tribunal or person otherwise directs:
- (a) a requirement mentioned in paragraph (1) (b) is to be taken to oblige the record-keeper to produce, or make available for inspection, as the case may be, a writing that reproduces the information in a form capable of being understood by the court, tribunal or person; and
  - (b) the production or making available of such a writing to the court, tribunal or person constitutes compliance with the requirement.

### **2.15 Compliance with prescribed forms**

If a Rule prescribes a form, strict compliance with the form is not required and substantial compliance is sufficient.

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## 2.16 Service of documents

- (1) This section applies if a Rule requires or permits a document to be served on a person, whether the expression ‘serve’, ‘give’ or ‘send’ or any other expression is used.
- (2) The document may be served:
  - (a) on a natural person:
    - (i) by delivering it to the person personally; or
    - (ii) by leaving it at, or by sending it by prepaid post to, the address of the place of residence or business of the person last known to the person serving the document; or
  - (b) on a body corporate — by leaving it at, or sending it by prepaid post to, the head office, a registered office or a principal office of the body corporate.
- (3) Nothing in subsection (2):
  - (a) affects the operation of any law of:
    - (i) Australia, or a State or Territory of Australia; or
    - (ii) New Zealand;that authorises the service of a document otherwise than as provided in that subsection; or
  - (b) affects the power of a court or tribunal to authorise service of a document otherwise than as provided in that subsection.
- (4) Service by post is taken to be effected by properly addressing, prepaying and posting the document as a letter.
- (5) Unless the contrary is proved, service by post is taken to have been effected at the time at which the letter would be delivered in the ordinary course of post.

*[Drafter’s note: Further provisions relating to service and other notification are under consideration.]*

## Division 2.2 Powers and functions

### 2.17 References to Authority in relation to powers and functions

In any Rule, a reference to the Authority in relation to the exercise of a power or the performance of a function includes a reference to the Managing Director.

### 2.18 Exercise of powers between making and having effect of Rule

- (1) A power conferred by a Rule may be exercised before the Rule starts to have effect, to:
  - (a) make an Order or other instrument; or

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- (b) serve a notice or document; or
  - (c) appoint a person to an office; or
  - (d) establish a body of persons; or
  - (e) do any other act or thing for the purposes of a Rule.
- (2) The power may be exercised only if the exercise of the power is necessary or desirable to bring, or in connection with bringing, a Rule into operation.
  - (3) The power may not be exercised if anything that results from exercising the power has effect before the Rule itself has effect unless the exercise of the power is necessary or desirable to bring, or in connection with bringing, the Rule into operation.
  - (4) Subsection (1) applies as if the Rule under which the power is exercised and any other Rule that does not have effect when the power is exercised did have effect when the power is exercised.

### **2.19 Power to appoint to an office**

If a Rule confers a power to appoint a person to an office, that power includes the power to do each of the following:

- (a) remove or suspend a person from the office;
- (b) reappoint or reinstate a person to the office;
- (c) appoint another person in place of a person who:
  - (i) has vacated the office; or
  - (ii) has died; or
  - (iii) is absent; or
  - (iv) is incapacitated in a way that affects the exercise or performance of that person's powers or functions.

### **2.20 Acting appointments**

- (1) This section applies if:
  - (a) a provision of a Rule confers power to appoint a person (the *appointee*) to act in a particular office; and
  - (b) an appointment is made under the provision.
- (2) While the appointee is acting in the office:
  - (a) the appointee has and may exercise all the powers, and is to perform all the functions, of the holder of the office; and
  - (b) the Rule or any other Rule applies in relation to the appointee as if the appointee were the holder of the office.

### **2.21 Exercise of powers and functions — general**

- (1) If a Rule confers a power or function, the power may be exercised and the function is to be performed from time to time as the circumstances require.

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- (2) If a Rule confers a power or function on the holder of an office as such, the power may be exercised and the function is to be performed by the holder for the time being of the office.
  - (3) If a Rule confers a power or function on a body (whether or not the body is incorporated), the exercise of the power or the performance of the function is not affected merely because of a vacancy or vacancies in the membership of the body.

## **2.22 Powers relating to instruments and other writings**

- (1) This section applies if a Rule confers a power to make, grant or issue an instrument.
- (2) The power is to be taken as including a power exercisable in the same manner and subject to the same conditions (if any) to revoke, amend or vary the instrument.
- (3) If the power is expressed to be exercisable in respect of particular matters (however the matters are described), the power is to be taken as including a power:
  - (a) to make, grant or issue the instrument:
    - (i) with respect to some only of those matters; or
    - (ii) with respect to a particular class or particular classes of those matters; and
  - (b) to provide differently for different matters or different classes of matters.
- (4) The power is not to be taken, by implication, not to include the power to provide for or in relation to a particular aspect of a matter merely because the Rule provides in relation to another aspect of that matter or in relation to another matter.
- (5) In this section, a reference to an instrument includes a writing.

## **2.23 Participation in meetings by telephone etc**

- (1) This section applies to a committee or other body established by a Rule if the Rule requires or permits meetings of the members of the body to be held.
- (2) The body may permit its members to participate in a meeting, or all meetings, by:
  - (a) telephone; or
  - (b) closed-circuit television; or
  - (c) any other means of communication.
- (3) A member who participates in a meeting as permitted by the body under subsection (2) is taken to be present at the meeting.

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## **Division 2.3 Delegations**

### **2.24 Delegation to office holders for time being**

- (1) This section applies if a Rule confers power to delegate a power or function.
- (2) The power of delegation is taken to include the power to delegate the power or function:
  - (a) to a specified person; or
  - (b) to any person from time to time holding, occupying or performing the functions of, a specified office.
- (3) Paragraph (2) (b) applies even if the specified office does not come into existence until after the delegation is made.

### **2.25 Effect of delegation**

If a Rule confers power on a person or body (the *authority*) to delegate a power or function:

- (a) the delegation may be made either generally or as otherwise provided by the instrument of delegation; and
- (b) the powers that may be delegated do not include that power to delegate; and
- (c) a power or function so delegated, when exercised or performed by the delegate is, for the purposes of the Rule, taken to have been exercised or performed by the authority; and
- (d) a delegation by the authority does not prevent the exercise or performance of a power or function by the authority; and
- (e) if the authority is not a person, section 2.26 applies as if it were.

### **2.26 Exercise of certain powers or functions by a delegate**

If:

- (a) under a Rule, the exercise of a power, or the performance of a function, by a person is dependent upon the opinion, belief or state of mind of that person in relation to a matter; and
- (b) that power or function has been delegated under that or any other Rule; the power may be exercised, or the function may be performed, by the delegate upon the opinion, belief or state of mind of the delegate in relation to the matter.

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## Division 2.4 Consequences of Rules ceasing to have effect

### 2.27 Definitions

In this Division:

*disallowance provision of the Act* means:

- (a) subsection 210 (2), 214 (1) or (2) of the *Therapeutic Products Act 2006* of Australia; or
- (b) subsection 210 (2) or 224 (2) of the *Therapeutic Products Act 2006* of New Zealand.

*part of a Rule* includes a reference to any provision of the Rule, or any words, figures, drawings or symbols in the Rule.

*Rule* includes part of a Rule.

### 2.28 Consequences of Rule ceasing to have effect

- (1) This section applies if a Rule ceases to have effect under the Act.
- (2) The cessation of effect of a Rule does not:
  - (a) revive anything not in force or existing when the cessation takes effect; or
  - (b) affect the previous operation of the Rule or anything done, begun or suffered under the Rule; or
  - (c) affect any right, privilege, obligation or liability acquired, accrued or incurred under the Rule; or
  - (d) affect any penalty, forfeiture or punishment incurred in respect of any offence committed in relation to the Rule.
- (3) An investigation, proceeding or remedy concerning anything to which paragraphs (c) or (d) apply is not affected by the cessation.
- (4) Without limiting subsection (3), and as if the cessation had not occurred:
  - (a) the investigation or proceeding may be started, continued or completed; and
  - (b) the remedy may be exercised; and
  - (c) the right, privilege, obligation or liability may be enforced; and
  - (d) the penalty, forfeiture or punishment may be imposed.

### 2.29 Revocation of revoking Rule

If a Rule (the *first Rule*) is revoked by another Rule, the first Rule is not revived only because the other Rule is revoked.

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### 2.30 Revival of Rule where revoking Rule disallowed

- (1) This section applies if:
  - (a) a Rule (the *former Rule*) ceases at a particular time (the *disallowance time*) to have effect under a disallowance provision of the Act; and
  - (b) the former Rule revoked another Rule or Order that was in force immediately before the time when the former Rule commenced.

*Note* As a result of the definition of *Rule* in section 2.27, paragraph (b) also applies where the former Rule revoked *part* of another Rule or Order.

- (2) The cessation of effect of the former Rule has the effect of reviving the other Rule or Order from the disallowance time, as if the former Rule had not been made.