

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

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## EXTRACTS RELATING TO THE SCHEDULING OF THERAPEUTIC SUBSTANCES

(Draft of 6 October 2006)

### Division 8.7 Medicines Scheduling Committee

#### Subdivision 8.7.1 Interpretation

##### 8.31 Definitions

In this Division:

*Committee* means the Medicines Scheduling Committee.

*relevant policy guidelines* has the meaning given by section 10.02.

*substance* has the meaning given by section 10.02.

#### Subdivision 8.7.2 Establishment, functions and constitution of Committee

##### 8.32 Establishment

There is established a committee to be known as the Medicines Scheduling Committee.

##### 8.33 Functions of Committee

- (1) The functions of the Committee are:
  - (a) to give advice and make recommendations to the Authority in relation to the following matters referred to the Committee under Part 10:
    - (i) scheduling or rescheduling of substances; and
    - (ii) reconsiderations of decisions of the Authority relating to the scheduling or rescheduling of substances; and
  - (b) to advise the Authority on:
    - (i) technical aspects in implementing the relevant policy guidelines that should be applied by the Authority in relation to the scheduling or rescheduling of substances; and
    - (ii) any other matter relating to scheduling or rescheduling referred to the Committee by the Authority; and
  - (c) any other related function:

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- (i) prescribed in the Orders; or
  - (ii) conferred by the Act.
- (2) In performing its functions under paragraphs (1) (a) and (b), the Committee must have regard to:
  - (a) the matters mentioned in subsection 10.09 (1) in relation to substances generally; and
  - (b) any relevant policy guidelines.
- (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.

**8.34 Constitution**

- (1) There must be at least 12, and not more than 16, members of the Committee.
- (2) Subject to subsection (3), the following are each entitled to nominate a person for appointment as a member:
  - (a) the Authority;
  - (b) the department of state of New Zealand that deals primarily with health matters;
  - (c) a department, unit or authority that has functions relating to health matters being:
    - (i) a department of state of a State of Australia; or
    - (ii) a department or administrative unit of the public service of the Australian Capital Territory or of the Northern Territory; or
    - (iii) an authority of such a State or Territory.
- (3) A person who is nominated must be qualified in 1 or more of the following ways:
  - (a) expertise in the regulation of substances in Australia or New Zealand;
  - (b) toxicology;
  - (c) currently engaged in community pharmacy practice;
  - (d) currently engaged in general medical practice;
  - (e) clinical pharmacology.
- (4) If a person is nominated, the Authority in its discretion may recommend the person's appointment under section 8.44.
- (5) Other members of the Committee (apart from those mentioned in subsection (6)) must be qualified in 1 or more of the ways indicated in subsection (3).

- (6) The Committee must include 2 other members, one of whom must have expertise in the issues mentioned in paragraph (a) and the other as mentioned in paragraph (b):
  - (a) therapeutic product industry issues;
  - (b) consumer issues.
- (7) Apart from the members mentioned in subsection (6), it is intended, as far as reasonably practicable, that membership of the Committee should include the widest possible range of the qualifications mentioned in subsection (3).

### **Subdivision 8.7.3 Other provisions applicable to Committee**

#### **8.35 Application of Division 8.9**

Division 8.9 applies in relation to the Committee.

## **Division 8.9 General provisions**

### **Subdivision 8.9.1 Interpretation**

#### **8.43 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**

#### **8.44 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.

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**8.45      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.

**8.46      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.
- (3) If the Chair ceases to be a member, his or her office as Chair is taken also to be vacant.

**8.47      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 8.57.
- (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.

**8.48      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.

**8.49      Acting members**

- (1) The Ministerial Council may appoint a person to act as a member:

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- (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.

*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****8.50 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 8.60, 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.

**8.51 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.

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*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.

**8.52 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.
- (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 8.51 also applies to a Committee to which this section applies.

**8.53 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.

**8.54 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.

**8.55 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****8.56 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.

**8.57 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.
- (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 8.58, 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.

**8.58 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.

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**8.59 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.

**8.60 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.

**8.61 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.
- (2) In this section:  
*member* includes Chair.

**8.62 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.

## Part 10 Scheduling of substances

### Division 10.1 General

#### 10.01 Overview of this Part

This Part provides for the establishment and maintenance by the Authority of a register to be known as the Standard for the Uniform Scheduling of Medicines and Poisons (or Scheduling Standard). Under this Part, decisions of the Authority in relation to the scheduling of substances will be recorded in the register. The scheduling framework is to provide the basis for a uniform system of access controls for therapeutic products in Australia and New Zealand.

#### 10.02 Definitions etc. for this Part

- (1) In this Part, unless the contrary intention appears:

***amend***, in relation to the Scheduling Standard, includes:

- (a) alter any provision (including a reference to a substance) in the Scheduling Standard; or
- (b) omit any provision (including a reference to a substance) from the Scheduling Standard; or
- (c) insert any provision (including a reference to a substance) in the Scheduling Standard.

***new substance*** means a substance that:

- (a) is not included in the Scheduling Standard; and
- (b) is not included as an active ingredient in any other therapeutic product in respect of which a product licence has been granted; and
- (c) is not classified as a Class 1 permitted ingredient in an Order made under section 3.13 of the Medicines Rule.

***public submission*** means a submission to the Authority, or to an expert advisory committee, other than a submission prepared by:

- (a) the Authority; or
- (b) a member of an expert advisory committee.

***relevant policy guidelines***, in relation to a matter, means policy guidelines about the matter issued by an appropriate committee of the Australian Health Ministers' Advisory Council recognised for the purpose by the Ministerial Council.

***scheduling***, in relation to a substance, means determining, for the purpose of facilitating the application to the substance of a system of access controls:

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- (a) the schedule or schedules in the Scheduling Standard in which the name or a description of the substance, or the kind of substance, is to be included; and
- (b) the application of other parts of the Scheduling Standard to the substance or kind of substance.

**scheduling decision** means a decision by the Authority under this Part relating to the scheduling or rescheduling of a substance.

**Scheduling Standard** means the register maintained under section 10.04, as amended from time to time under this Part.

**substance** means an ingredient, compound, material or preparation that is present in a therapeutic product.

- (2) A reference in this Part to a substance includes a reference to substances of a particular kind.

**10.03 Commercial-in-confidence information**

Nothing in this Part requires the Authority to make available to any person any information in, or in support of, a proposal or submission to the Authority under this Part if the Authority is satisfied that the information is commercial-in-confidence.

**Division 10.2 The Scheduling Standard**

**10.04 The Scheduling Standard**

- (1) The Authority is to maintain a register, to be known as the *Standard for the Uniform Scheduling of Medicines and Poisons* (the **Scheduling Standard**).
- (2) The Scheduling Standard is to include a record of the scheduling decisions of the Authority under this Part.
- (3) The Scheduling Standard is to be maintained by electronic means.
- (4) The authoritative version of the Scheduling Standard is the version in electronic form.
- (5) Decisions made in relation to the classification and scheduling of substances under the *Therapeutic Goods Act 1989* of Australia by the National Drugs and Poisons Schedule Committee established under section 52B of that Act, that were in effect immediately before the commencement of this Part, are, on and after the commencement of this Part, taken to be:
  - (a) decisions of the Authority under this Part in respect of the scheduling of those substances in the Scheduling Standard; and
  - (b) included in the Scheduling Standard accordingly.
- (6) For the avoidance of doubt, Division 10.5 does not apply to decisions of the Authority mentioned in subsection (5).

- (7) Nothing in this section is intended to prevent the inclusion of other matters in the Scheduling Standard under the Rules, or Australian or New Zealand legislation.

*Example*

Separate Australian legislation may provide for classification in the Scheduling Standard of substances (including poisons) that are not therapeutic products.

### **10.05 Inspection and copies of Scheduling Standard**

- (1) The Scheduling Standard is to be made available for inspection on the Authority's website.

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

- (2) The Authority must take reasonable steps to ensure that the Scheduling Standard is made available for inspection and purchase in hard copy form.

*Note* The authoritative version of the Scheduling Standard is the electronic version: see section 10.04.

- (3) The Authority may provide a document that is a certified printout of the Scheduling Standard, or of an extract from it, on payment of the prescribed fee (if any).

### **10.06 Amendments to the Scheduling Standard**

- (1) The Authority may, on its own initiative, amend the Scheduling Standard to complete or correct any provision that is incomplete or incorrect.

- (2) The power of the Authority to amend the Scheduling Standard under subsection (1) is in addition to any power of the Authority to amend the Scheduling Standard as the result of a scheduling decision under this Part.

- (3) Before amending the Scheduling Standard under this Part, the Authority must publish, in the Authority Gazette, a notice stating:

- (a) that an amendment is to be made to the Scheduling Standard; and
- (b) the date on which the amendment is to be made.

- (4) An amendment to the Scheduling Standard under this Part comes into effect on the day on which it is made.

## **Division 10.3 Scheduling of new substances**

### **10.07 Proposals for scheduling**

- (1) A proposal for the scheduling of a new substance may be made, in writing, to the Authority by any person.

- (2) Subject to subsections (3), (4) and (5), the Authority must consider a proposal and:

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- (a) determine whether to include the new substance in the Scheduling Standard; and
- (b) if the new substance is to be included, determine:
  - (i) the schedule or schedules in the Scheduling Standard in which the name or a description of the substance is to be included; and
  - (ii) the application of other parts of the Scheduling Standard to the substance.
- (3) If the proposal is made by a member of the Medicines Scheduling Committee, the proposal must comply with the relevant policy guidelines (if any) relating to the making of proposals by a member.
- (4) If the proposal is made by a person who is not a member of the Medicines Scheduling Committee, the Authority is not required to consider the proposal unless:
  - (a) the Authority is satisfied that consideration of the proposal is necessary for reasons of public health and safety; or
  - (b) the proposal relates to an effective application for a product licence under the Rules;  
and the prescribed fee (if any) payable in respect of the proposal has been paid.
- (5) A proposal must be supported by sufficient information, in a form acceptable to the Authority, to enable the application to be considered.

**10.08 Scheduling on the Authority's initiative**

If:

- (a) an effective application is made for a product licence in respect of:
  - (i) a Class 2 medicine that contains a new substance; or
  - (ii) a medical device that incorporates a new substance; or
- (b) the Authority is satisfied that a new substance presents public health and safety concerns;  
the Authority, on its own initiative, may:
- (c) determine whether to include the new substance in the Scheduling Standard; and
- (d) if the new substance is to be included, determine:
  - (i) the schedule or schedules in the Scheduling Standard in which the name or a description of the substance is to be included; and
  - (ii) the application of other parts of the Scheduling Standard to the substance.

**10.09 Scheduling — matters to be taken into account**

- (1) In making a decision under section 10.07 or 10.08 in relation to a substance, the Authority must take the following matters into account (if relevant):

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- (a) the toxicity and safety of the substance;
  - (b) the risks and benefits associated with the use of the substance;
  - (c) the potential hazards associated with the use of the substance;
  - (d) the extent and patterns of use of the substance;
  - (e) the dosage and formulation of the substance;
  - (f) the need for access to the substance, taking into account its toxicity compared with other substances available for a similar purpose;
  - (g) the potential for abuse of the substance;
  - (h) the purposes for which the substance is to be used;
  - (i) any other matters that the Authority considers necessary to protect public health and safety, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use;
- and may take into account the labelling, packaging and presentation of the substance.
- (2) In taking into account the matters mentioned in subsection (1), the Authority must comply with the relevant policy guidelines (if any).
  - (3) The Authority must also take into account:
    - (a) any advice or recommendation of the Medicines Scheduling Committee, or another expert advisory committee to which the Authority has referred the proposed scheduling under section 10.10; and
    - (b) any public submissions made in accordance with section 10.11 relating to the proposed scheduling.

**10.10 Referral of proposed scheduling**

- (1) The Authority may refer the proposed scheduling of a new substance to the Medicines Scheduling Committee or another expert advisory committee for the advice or recommendation of that committee on the proposed scheduling.
- (2) If the Authority decides, under section 10.11, to consult on a proposed scheduling, it must refer the proposed scheduling, and all public submissions on the proposed scheduling that the Authority is required under that section to consider, to the Medicines Scheduling Committee for the advice or recommendation of that committee on the proposed scheduling.
- (3) The Authority, or a member of an expert advisory committee, may prepare a submission relating to the proposed scheduling for the consideration of the Medicines Scheduling Committee or another expert advisory committee.

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**10.11 Proposed scheduling — public consultation**

- (1) Before making a decision under section 10.07 or 10.08, the Authority must consider whether, having regard to the nature of the new substance concerned and its use, it would be in the public interest to consult on the proposed scheduling.
- (2) If the Authority decides to consult on a proposed scheduling, the Authority must publish in the Authority Gazette, before a meeting of the Medicines Scheduling Committee at which the proposed scheduling is to be considered, a notice:
  - (a) stating:
    - (i) the proposed date of the meeting (the *meeting date*); and
    - (ii) the name or a description of the new substance; and
    - (iii) subject to section 10.03, full details of the proposed scheduling; and
  - (b) inviting public submissions in relation to the proposed scheduling to be made to the Authority by a date mentioned in the notice as the closing date for public submissions (the *closing date*).
- (3) The closing date must be at least 4 weeks after publication of the notice.
- (4) The meeting date must be at least 2 weeks after the closing date.
- (5) The Authority must consider all public submissions that:
  - (a) address a matter mentioned in subsection 10.09 (1) or (2) that is relevant to the application; and
  - (b) are made by the closing date.
- (6) The Authority need not consider a public submission made after the closing date.
- (7) Subject to section 10.03, the Authority must publish on the Authority's website, or make available in such other manner as the Authority considers appropriate, all public submissions that it is required, under subsection (5), to consider.

*Note* For urgent scheduling decisions without public consultation, see section 10.12.

**10.12 Urgent scheduling before consultation**

- (1) Despite section 10.11, if the Authority is satisfied that urgent scheduling of a new substance is necessary in the interests of public health and safety, the Authority may make a scheduling decision without following the public consultation procedures.
- (2) The Authority must reconsider a scheduling decision mentioned in subsection (1) as soon as practicable after making the decision.

- (3) Section 10.09, and the public consultation procedures set out in sections 10.10 and 10.11, apply to the reconsideration of the scheduling decision as if the proposed scheduling were to be considered for the first time.

### **10.13 Scheduling where consultation is not finalised**

- (1) This section applies to a new substance that:
  - (a) meets the criteria for inclusion in the Scheduling Standard; and
  - (b) is contained in a therapeutic product that has been evaluated by the Authority, being:
    - (i) a Class 2 medicine; or
    - (ii) a medical device that incorporates a new substance.
- (2) Despite section 10.11, if the Authority:
  - (a) commences consultation on the proposed scheduling of a new substance to which this section applies; and
  - (b) subsequently grants a product licence in respect of the therapeutic product containing the substance;  
the Authority may determine on an interim basis, before the consultation procedures are completed, that the substance be included in the Scheduling Standard.
- (3) The Authority must reconsider the interim determination in conjunction with completion of the consultation procedures.

## **Division 10.4 Rescheduling of substances**

### **10.14 Proposals for rescheduling**

- (1) A proposal for the rescheduling of a substance included in the Scheduling Standard may be made, in writing, to the Authority by any person.
- (2) Subject to subsections (3), (4) and (5), the Authority must consider a proposal for rescheduling and:
  - (a) determine whether the schedule or schedules to the Scheduling Standard in which the name or a description of the substance, or of substances of that kind, is included are appropriate; and
  - (b) if the schedule or schedules are not appropriate — determine the appropriate schedule or schedules for inclusion of the substance; and
  - (c) if necessary in consequence of a determination under paragraph (a) or (b), vary the application of other parts of the Scheduling Standard to the substance.
- (3) If the proposal is made by a member of the Medicines Scheduling Committee, the proposal must comply with the relevant policy guidelines (if any) relating to the making of proposals by a member.

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- (4) If the proposal is made by a person who is not a member of the Medicines Scheduling Committee, the Authority is not required to consider the proposal unless the Authority is satisfied that:
  - (a) consideration of the proposal is necessary for reasons of public health and safety; or
  - (b) the proposal is likely to relate to an application for a product licence; and the prescribed fee (if any) payable in respect of the proposal has been paid.
- (5) A proposal must be supported by sufficient information, in a form acceptable to the Authority, to enable the application to be considered.

**10.15 Rescheduling on the Authority's initiative**

- (1) The Authority on its own initiative may reconsider the scheduling of a substance included in the Scheduling Standard if the Authority is satisfied that it is in the interests of public health and safety to do so.
- (2) On a reconsideration under subsection (1), the Authority may:
  - (a) determine whether the schedule or schedules to the Scheduling Standard in which the name or a description of the substance, or of substances of that kind, is included are appropriate; and
  - (b) if the schedule or schedules are not appropriate — determine the appropriate schedule or schedules for inclusion of the substance; and
  - (c) if necessary in consequence of a determination under paragraph (a) or (b), vary the application of other parts of the Scheduling Standard to the substance.

**10.16 Rescheduling — matters to be taken into account**

- (1) In making a decision under section 10.14 or 10.15, the Authority must take into account (if relevant) the matters mentioned in subsection 10.09 (1), having regard to subsection 10.09 (2).
- (2) The Authority must also take into account:
  - (a) any advice or recommendation of the Medicines Scheduling Committee on the proposed rescheduling; and
  - (b) any advice or recommendation of another expert advisory committee to which the Authority has referred the proposed rescheduling under section 10.17; and
  - (c) any public submissions made in accordance with section 10.18 relating to the proposed rescheduling.

### 10.17 Referral of proposed rescheduling

- (1) Before making a decision under section 10.14 or 10.15, the Authority must refer the proposed rescheduling, and any public submissions relating to the proposed rescheduling that the Authority is required under section 10.18 to consider, to the Medicines Scheduling Committee for the advice or recommendation of that committee on the proposed rescheduling.
- (2) The Authority may refer the proposed rescheduling to any other expert advisory committee for the advice or recommendation of that committee on the proposed rescheduling.
- (3) The Authority, or a member of an expert advisory committee, may prepare a submission relating to the proposed rescheduling for the consideration of the Medicines Scheduling Committee.

### 10.18 Rescheduling — public consultation

- (1) Before a meeting of the Medicines Scheduling Committee at which a proposed rescheduling is to be considered, the Authority must publish in the Authority Gazette a notice:
  - (a) stating:
    - (i) the proposed date of the meeting (the *meeting date*); and
    - (ii) the name or a description of each substance to be considered; and
    - (iii) subject to section 10.03, full details of each proposed rescheduling; and
  - (b) inviting public submissions in relation to any proposed rescheduling to be made to the Authority by a date mentioned in the notice as the closing date for public submissions (the *closing date*).
- (2) The closing date must be at least 4 weeks after publication of the notice.
- (3) The meeting date must be at least 2 weeks after the closing date.
- (4) The Authority must consider all public submissions that:
  - (a) address a matter mentioned in subsection 10.09 (1) or (2) that is relevant to the application; and
  - (b) are made by the closing date.
- (5) The Authority need not consider a public submission made after the closing date.
- (6) Subject to section 10.03, the Authority must publish on the Authority's website, or make available in such other manner as the Authority considers appropriate, all public submissions that it is required, under subsection (4), to consider.

*Note* For urgent rescheduling decisions without public consultation, see section 10.19.

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**10.19 Urgent rescheduling before consultation**

- (1) Despite section 10.18, if the Authority is satisfied that urgent rescheduling of a substance is necessary in the interests of public health and safety, the Authority may make a scheduling decision without following the public consultation procedures.
- (2) The Authority must reconsider a scheduling decision mentioned in subsection (1) as soon as practicable after making the decision.
- (3) Section 10.16, and the public consultation procedures set out in sections 10.17 and 10.18, apply to the reconsideration of the scheduling decision as if the proposed rescheduling were to be considered for the first time.

**Division 10.5 Notification and reconsideration of scheduling decisions**

**10.20 Notification of initial decisions**

- (1) As soon as practicable after making a scheduling decision about a substance (not being a decision on a reconsideration under this Division), the Authority must publish on the Authority's website, and in such other manner (if any) as the Authority considers appropriate:
  - (a) the decision; and
  - (b) the reasons for the decision; and
  - (c) a statement to the effect that any person who made a public submission in relation to the substance concerned may provide a further submission for reconsideration of the decision.
- (2) If the decision was made as a result of a proposal by a person for the scheduling or rescheduling of a substance, the Authority must notify the person in writing of the decision and the reasons for the decision.
- (3) A notice under subsection (2) must include a statement to the effect that the person who made the proposal may provide a further submission for reconsideration of the decision.
- (4) A failure to comply with this section does not affect the validity of the decision.

**10.21 Submissions for reconsideration**

- (1) A submission for reconsideration of a scheduling decision must be made, in writing, within 20 working days after the decision is published on the Authority's website under section 10.20, or within such further period as the Authority, in special circumstances, allows.
- (2) The submission must:
  - (a) address a matter mentioned in subsection 10.09 (1) or (2); and

- (b) be relevant to the scheduling decision.
- (3) A submission for reconsideration of a scheduling decision that was made as a result of a proposal by a person for the scheduling or rescheduling of a substance must not be on the basis of data not submitted in relation to the proposal.

#### **10.22 Notification and referral of reconsideration**

- (1) Subject to section 10.03, the Authority must publish on the Authority's website, and in such other manner (if any) as the Authority considers appropriate, details of any submission for reconsideration made to the Authority under section 10.21 and the grounds for the reconsideration.
- (2) The Authority may refer the reconsideration, and the grounds for the reconsideration, to the Medicines Scheduling Committee for the advice or recommendation of that committee.
- (3) If no submission for reconsideration of a scheduling decision is made to the Authority under section 10.21, the Authority must, as soon as practicable after the period mentioned in that section:
  - (a) publish a notice to that effect on the Authority's website; and
  - (b) if an amendment to the Scheduling Standard is required — comply with subsection 10.06 (3).

#### **10.23 Reconsideration of scheduling decisions**

- (1) If a submission for reconsideration of a scheduling decision is made to the Authority under section 10.21, the Authority must reconsider the decision.
- (2) In reconsidering the scheduling decision, the Authority must take into account any advice or recommendation of the Medicines Scheduling Committee relating to the reconsideration.
- (3) The Authority may:
  - (a) confirm the decision; or
  - (b) vary the decision; or
  - (c) set the decision aside and make a new decision in place of the decision.
- (4) A person who, as a delegate or subdelegate of the Managing Director, has made, or participated in making, a decision that is to be reconsidered, must not be involved in the making of the decision under subsection (3).

**Section 10.24**

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**10.24 Notification of decisions on reconsideration**

As soon as practicable after reconsidering a scheduling decision, the Authority must:

- (a) notify, in writing, any person who made a submission for reconsideration of the scheduling decision, of the result of the reconsideration and the reasons for it; and
- (b) publish the result and the reasons on the Authority's website, and in such other manner (if any) as the Authority considers appropriate; and
- (c) if an amendment to the Scheduling Standard is required — comply with subsection 10.06 (3).