



# Therapeutic Goods Amendment Regulations 2010 (No. 2)<sup>1</sup>

**Select Legislative Instrument 2010 No. 129**

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I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated 15 June 2010

QUENTIN BRYCE  
Governor-General

By Her Excellency's Command

MARK BUTLER  
Parliamentary Secretary for Health

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**1 Name of Regulations**

These Regulations are the *Therapeutic Goods Amendment Regulations 2010 (No. 2)*.

**2 Commencement**

These Regulations commence on 1 July 2010.

**3 Amendment of *Therapeutic Goods Regulations 1990***

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

**Schedule 1 Amendment**

(regulation 3)

**[1] Part 6, Division 3A**

*substitute*

**Division 3A Advisory Committee on Medicines Scheduling**

**Subdivision 3A.1 Preliminary**

**42ZCA Definitions for Division 3A**

In this Division:

***appointed member*** means a member of the Committee appointed by the Minister under subregulation 42ZCD (1).

***Committee*** means the Advisory Committee on Medicines Scheduling.

*Note* The Committee is established by section 52B of the Act.

***Committee member*** means an appointed member or a nominated member.

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*nominated member* means a member of the Committee nominated under subsection 52B (3) of the Act in accordance with regulation 42ZCE.

## **Subdivision 3A.2 Constitution of Committee**

### **42ZCB Membership of Committee**

For subsection 52B (2) of the Act, the Committee is to be constituted in accordance with this Subdivision.

### **42ZCC Committee members**

- (1) The Committee comprises each nominated member and no more than 6 appointed members.
- (2) A Committee member must have expertise in at least one of the following fields:
  - (a) the regulation of scheduled medicines in Australia;
  - (b) toxicology or pharmacology;
  - (c) clinical pharmacology;
  - (d) pharmacy practice;
  - (e) medical practice;
  - (f) consumer health issues relating to the regulation of therapeutic goods;
  - (g) industry issues relating to the regulation of therapeutic goods.
- (3) Membership of the Committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

### **42ZCD Appointed members**

- (1) An appointed member must be appointed in writing by the Minister.
- (2) The term of an appointment of an appointed member is as specified in the instrument of appointment but must not be longer than 3 years.

- (3) An appointed member must not be appointed for more than 3 consecutive terms.

**42ZCE Nominated members**

- (1) This regulation is made for subsection 52B (3) of the Act.
- (2) A nomination must be in writing.
- (3) The nomination must specify the term of the nominee's membership of the Committee.
- (4) The nominee becomes a member of the Committee when the nomination is given to the Minister.
- (5) A nominated member stops being a member if:
  - (a) the body that nominated the member gives the Minister written notice that the member's nomination is withdrawn; or
  - (b) the member, by written notice given to the Minister under subregulation 42ZCG (1), resigns from the Committee.
- (6) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory may, by written notice given to the Minister, nominate a member (the *temporary nominee*) to temporarily replace an existing member nominated by the Commonwealth, the State or Territory:
  - (a) during a vacancy in the existing member's office; or
  - (b) during any period, or all periods, when the existing member is:
    - (i) absent from duty or from Australia; or
    - (ii) for any other reason unable to perform the functions of a nominated member.
- (7) The temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee:
  - (a) when the circumstance giving rise to the temporary replacement commences; and
  - (b) until that circumstance ends.

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**42ZCF Appointment of the Chair and acting Chair**

- (1) The Minister must, in writing, appoint a Committee member to be the Chair of the Committee.
- (2) The Chair is appointed for the term stated in the appointment but may be reappointed for further terms.
- (3) The Minister may, in writing, appoint a Committee member to act as the Chair:
  - (a) during a vacancy in the office of the Chair, whether or not an appointment has previously been made to the office; or
  - (b) during any period, or during all periods, when the Chair is absent from duty or from Australia, or is, for any other reason, unable to perform the functions of the Chair.

*Note* Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

**42ZCG Resignation or vacancy**

- (1) A Committee member or Chair may resign by giving written notice to the Minister.
- (2) If the Chair ceases to be a Committee member, the position is taken to be vacant.

**42ZCH Termination of appointment**

- (1) The Minister may terminate an appointed member's appointment on any of the following grounds:
  - (a) physical or mental incapacity;
  - (b) misbehaviour;
  - (c) incompetence;
  - (d) bankruptcy;
  - (e) failing to comply with the disclosure of interest requirements mentioned in regulation 42ZCP.
- (2) The Minister must terminate an appointed member's appointment if:
  - (a) the member is convicted of an offence punishable by imprisonment for at least 1 year; or

- (b) if the member is absent without leave of absence from 3 consecutive meetings of the Committee.

**42ZCI Leave of absence**

- (1) The Minister may grant leave of absence to the Chair.
- (2) The Chair may grant leave of absence to a Committee member.

**42ZCJ Acting members**

- (1) The Minister may, in writing, appoint a person to act as an appointed member:
  - (a) during a vacancy in the office of an appointed member, whether or not an appointment has previously been made to the office; or
  - (b) during any period, or during all periods, when an appointed member is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.
- (2) A person appointed to act as an appointed member must have the expertise required for a substantive member.

*Note* Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

**Subdivision 3A.3 Committee meetings**

**42ZCK Committee meetings**

For subsection 52B (2) of the Act, the Committee is to hold meetings in accordance with this Subdivision.

**42ZCL Meeting procedure**

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

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- (2) The procedure of a meeting must be determined by the Committee in accordance with this Subdivision.
  - (3) If the Chair of the Committee considers it appropriate and efficient in the circumstances, the Chair may direct the Committee to meet by video conference or teleconference or to meet out of session.
  - (4) At a meeting, the Committee:
    - (a) must act with as little formality and as quickly as this Subdivision and a proper consideration of the issues before the Committee allow; and
    - (b) is not bound by the rules of evidence; and
    - (c) may obtain information about an issue in any way it considers appropriate; and
    - (d) may receive information in any way it considers appropriate; and
    - (e) must comply with any directions given, in writing, to the Committee by the Minister or the Secretary about the Committee's performance of its functions (other than a direction about advice given or proposed to be given by the Committee).
  - (5) For this regulation:

*out of session*, in relation to a meeting, means a meeting in which the members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

#### **42ZCM Presiding member**

- (1) The Chair must preside at a Committee meeting at which he or she is present.
- (2) If the Chair is unable to preside at a meeting, he or she must:
  - (a) select a member of the Committee to preside at the meeting; and
  - (b) advise the other Committee members of the selection.

- (3) If the Chair is temporarily absent from a meeting, the member chosen by the Committee members present must preside at the meeting.
- (4) A member presiding under subregulation (2) or (3) may exercise the powers and functions of the Chair.

#### **42ZCN Quorum**

A quorum exists at a Committee meeting when at least two-thirds of the Committee members are present.

#### **42ZCO 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.

*Note* Decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary under subsection 52B (4) of the Act.

- (2) The member presiding at a Committee meeting has a deliberative vote and, if the votes are equal, also has a casting vote.

#### **42ZCP Miscellaneous**

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

- (1) An appointed member is entitled to sitting fees and travel entitlements as determined by the Remuneration Tribunal.

##### *When Committee may establish subcommittees*

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

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*Disclosure of interests*

- (4) A Committee member who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) 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.
- (5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines, either be present during any deliberation of the Committee about the matter or take part in any decision of the Committee about the matter.
- (6) When the Committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not be present during any deliberation of the Committee and must not take part in making the determination.
- (7) A member of a subcommittee appointed by the Committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) 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.

*Seeking and providing further advice*

- (8) Any advice or recommendation given by the Committee to the Secretary may be given to another committee established under the Act or these Regulations for the advice of that committee.
- (9) In performing its functions, the Committee may seek advice from other persons.

*Validity of acts of members*

- (10) Anything done by a person purporting to be, or purporting to act as, a Committee member (including the Chair) is not invalid because:
- (a) the person had not yet been appointed; or
  - (b) there is a defect or irregularity in connection with the person's appointment; or
  - (c) the person's appointment had ceased to have effect.

*Records and reports*

- (11) The Committee must keep a record of its proceedings, and must prepare any other report about its activities that is requested by the Minister or the Secretary.

*Publication*

- (12) The Committee must publish details of any recommendations it makes.

**Division 3B      Advisory Committee on Chemicals Scheduling**

**Subdivision 3B.1      Preliminary**

**42ZCQ      Definitions for Division 3B**

In this Division:

***appointed member*** means a member of the Committee appointed by the Minister under subregulation 42ZCT (1).

***Committee*** means the Advisory Committee on Chemicals Scheduling.

*Note* The Committee is established by section 52C of the Act.

***Committee member*** means an appointed member or a nominated member.

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*nominated member* means a member of the Committee nominated under subsection 52C (3) of the Act in accordance with regulation 42ZCU.

## **Subdivision 3B.2 Constitution of Committee**

### **42ZCR Membership of Committee**

For subsection 52C (2) of the Act, the Committee is to be constituted in accordance with this Subdivision.

### **42ZCS Committee members**

- (1) The Committee comprises each nominated member and no more than 6 appointed members.
- (2) A Committee member must have expertise in at least one of the following fields:
  - (a) the regulation of scheduled chemicals in Australia;
  - (b) veterinary medicine or veterinary pathology;
  - (c) toxicology;
  - (d) industrial or domestic chemicals;
  - (e) agricultural or veterinary chemicals;
  - (f) clinical aspects of human poisoning;
  - (g) occupational health, particularly as a medical practitioner;
  - (h) consumer health issues relating to the regulation of chemicals;
  - (i) industry issues relating to the regulation of chemicals.
- (3) Membership of the Committee must, to the extent reasonably practicable, represent the widest possible range of the fields mentioned in subregulation (2).

### **42ZCT Appointed members**

- (1) An appointed member must be appointed in writing by the Minister.

- (2) The term of an appointment of an appointed member is as specified in the instrument of appointment but must not be longer than 3 years.
- (3) An appointed member must not be appointed for more than 3 consecutive terms.

**42ZCU Nominated members**

- (1) This regulation is made for subsection 52C (3) of the Act.
- (2) A nomination must be in writing.
- (3) The nomination must specify the term of the nominee's membership of the Committee.
- (4) The nominee becomes a member of the Committee when the nomination is given to the Minister.
- (5) A nominated member stops being a member if:
  - (a) the body that nominated the member gives the Minister written notice that the member's nomination is withdrawn; or
  - (b) the member, by written notice given to the Minister under subregulation 42ZCW (1), resigns from the Committee.
- (6) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory may, by written notice given to the Minister, nominate a member (the *temporary nominee*) to temporarily replace an existing member nominated by the Commonwealth, the State or Territory:
  - (a) during a vacancy in the existing member's office; or
  - (b) during any period, or all periods, when the existing member is:
    - (i) absent from duty or from Australia; or
    - (ii) for any other reason unable to perform the functions of a nominated member.

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- (7) The temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee:
- (a) when the circumstance giving rise to the temporary replacement commences; and
  - (b) until that circumstance ends.

#### **42ZCV Appointment of the Chair and acting Chair**

- (1) The Minister must, in writing, appoint a Committee member to be the Chair of the Committee.
- (2) The Chair is appointed for the term stated in the appointment but may be reappointed for further terms.
- (3) The Minister may, in writing, appoint a Committee member to act as the Chair:
  - (a) during a vacancy in the office of the Chair, whether or not an appointment has previously been made to the office; or
  - (b) during any period, or during all periods, when the Chair is absent from duty or from Australia, or is, for any other reason, unable to perform the functions of the Chair.

*Note* Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

#### **42ZCW Resignation or vacancy**

- (1) A Committee member or Chair may resign by giving written notice to the Minister.
- (2) If the Chair ceases to be a Committee member, the position is taken to be vacant.

#### **42ZCX Termination of appointment**

- (1) The Minister may terminate an appointed member's appointment on any of the following grounds:
  - (a) physical or mental incapacity;
  - (b) misbehaviour;
  - (c) incompetence;

- (d) bankruptcy;
  - (e) failing to comply with the disclosure of interest requirements mentioned in regulation 42ZCZF.
- (2) The Minister must terminate an appointed member's appointment if:
- (a) the member is convicted of an offence punishable by imprisonment for at least 1 year; or
  - (b) if the member is absent without leave of absence from 3 consecutive meetings of the Committee.

**42ZCY Leave of absence**

- (1) The Minister may grant leave of absence to the Chair.
- (2) The Chair may grant leave of absence to a Committee member.

**42ZCZ Acting members**

- (1) The Minister may, in writing, appoint a person to act as an appointed member:
  - (a) during a vacancy in the office of an appointed member, whether or not an appointment has previously been made to the office; or
  - (b) during any period, or during all periods, when an appointed member is absent from duty or from Australia, or is, for any reason, unable to perform the duties of the office.
- (2) A person appointed to act as an appointed member must have the expertise required for a substantive member.

*Note* Section 33A of the *Acts interpretation Act 1901* sets out various matters about acting appointments, including how long a person can act in a vacant office.

**Subdivision 3B.3 Committee meetings**

**42ZCZA Committee meetings**

For subsection 52C (2) of the Act, the Committee is to hold meetings in accordance with this Subdivision.

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**42ZCZB Meeting procedure – general**

- (1) The Chair of the Committee may give written notice to the Committee directing the Committee to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.
- (2) The procedure of a meeting must be determined by the Committee in accordance with this Subdivision.
- (3) If the Chair of the Committee considers it appropriate and efficient in the circumstances, the Chair may direct the Committee to meet by video conference or teleconference or to meet out of session.
- (4) At a meeting, the Committee:
  - (a) must act with as little formality and as quickly as this Subdivision and a proper consideration of the issues before the Committee allow; and
  - (b) is not bound by the rules of evidence; and
  - (c) may obtain information about an issue in any way it considers appropriate; and
  - (d) may receive information in any way it considers appropriate; and
  - (e) must comply with any directions given, in writing, to the Committee by the Minister or the Secretary about the Committee's performance of its functions (other than a direction about advice given or proposed to be given by the Committee).
- (5) For this regulation:

*out of session*, in relation to a meeting, means a meeting in which the members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

**42ZCZC Presiding member**

- (1) The Chair must preside at a Committee meeting at which he or she is present.

- (2) If the Chair is unable to preside at a meeting, he or she must:
  - (a) select a member of the Committee to preside at the meeting; and
  - (b) advise the other Committee members of the selection.
- (3) If the Chair is temporarily absent from a meeting, the member chosen by the Committee members present must preside at the meeting.
- (4) A member presiding under subregulation (2) or (3) may exercise the powers and functions of the Chair.

#### **42ZCZD Quorum**

A quorum exists at a Committee meeting when at least two-thirds of the Committee members are present.

#### **42ZCZE 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.

*Note* Decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary under subsection 52C (4) of the Act.

- (2) The member presiding at a Committee meeting has a deliberative vote and, if the votes are equal, also has a casting vote.

#### **42ZCZF Miscellaneous**

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

- (1) An appointed member is entitled to sitting fees and travel entitlements as determined by the Remuneration Tribunal.

##### *When Committee may establish subcommittees*

- (2) The Committee, with the approval of the Secretary, may establish subcommittees, consisting of Committee members and other persons.

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- (3) The function of the subcommittee is to inquire into, and report to the Committee on, any matter referred to the subcommittee that is within the functions of the Committee.

*Disclosure of interests*

- (4) A Committee member who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) 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.
- (5) The disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee otherwise determines, either be present during any deliberation of the Committee about the matter or take part in any decision of the Committee about the matter.
- (6) When the Committee is making a determination about a member who has made a disclosure, the member, and any other member who has a direct or indirect material personal interest (whether pecuniary or not) in the matter to which the disclosure relates, must not be present during any deliberation of the Committee and must not take part in making the determination.
- (7) A member of a subcommittee appointed by the Committee, who is aware that he or she has a direct or indirect material personal interest (whether pecuniary or not) 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.

*Seeking and providing further advice*

- (8) Any advice or recommendation given by the Committee to the Secretary may be given to another committee established under the Act or these Regulations for the advice of that committee.
- (9) In performing its functions, the Committee may seek advice from other persons.

*Validity of acts of members*

- (10) Anything done by a person purporting to be, or purporting to act as, a Committee member (including the Chair) is not invalid because:
- (a) the person had not yet been appointed; or
  - (b) there is a defect or irregularity in connection with the person's appointment; or
  - (c) the person's appointment had ceased to have effect.

*Records and reports*

- (11) The Committee must keep a record of its proceedings, and must prepare any other report about its activities that is requested by the Minister or the Secretary.

*Publication*

- (12) The Committee must publish details of any recommendations it makes.

**Division 3C      Joint meetings**

**42ZCZG   Joint meetings**

For section 52CA of the Act, the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling may hold joint meetings in accordance with this Division.

**42ZCZH   Procedure for joint meetings**

- (1) The Secretary may, if the Secretary considers it appropriate to do so, give written notice to the Committee members of both Committees directing the Committees to hold a joint meeting at the time and place, and to deal with the matters in the manner, stated in the notice.
- (2) At a joint meeting, the Committee members present at the meeting must vote on which Chair (or presiding member) is to be the Chair of the joint meeting.

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- (3) For the purpose of choosing a Chair, a Committee member may cast one vote in respect of each Committee of which he or she is a member.
- (4) There is a quorum at a joint meeting if there is a quorum for each Committee.
- (5) At a joint meeting:
- (a) decisions are to be made by a majority of the votes cast by the members present and voting; and
  - (b) each member has one vote in respect of each Committee of which he or she is a member.
- (6) A decision made at a joint meeting is taken to be a decision of each Committee for the purposes of any advice or recommendation provided to the Secretary by either Committee.
- Note* Decisions at a joint meeting relate to the recommendations and advice a Committee may provide to the Secretary under subsections 52B (4) and 52C (4) of the Act.
- (7) Each Committee must keep a record of the proceedings of the joint meeting.

## **Division 3D            Procedure for amending the                                  current Poisons Standard**

### **Subdivision 3D.1    Preliminary**

#### **42ZCZI    Definitions for Division 3D**

In this Division:

*business day* means a day that is not a Saturday, Sunday or public holiday in the Australian Capital Territory.

*Committee member* means a member of:

- (a) the Advisory Committee on Medicines Scheduling; or
- (b) the Advisory Committee on Chemicals Scheduling.

*expert advisory committee* means:

- (a) the Advisory Committee on Medicines Scheduling; or

- (b) the Advisory Committee on Chemicals Scheduling; or
- (c) the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling in joint session.

*first closing date* has the meaning given by paragraph 42ZCZK (1) (d).

*interim decision* means:

- (a) in Subdivision 3D.2 — a decision of the Secretary under regulation 42ZCZN; and
- (b) in Subdivision 3D.3 — a decision of the Secretary under paragraph 42ZCZV (a).

*proposed amendment* means a proposal to amend the current Poisons Standard under subsection 52D (2) of the Act on the Secretary's own initiative or in response to an application under section 52EAA of the Act.

*public submission* means a submission under this Division by a person who is not a Committee member.

*relevant submission* has the meaning given by paragraph 42ZCZQ (1) (a).

*second closing date* has the meaning given by paragraph 42ZCZP (c).

*Note* For *current Poisons Standard* see s 52A of the Act.

## **Subdivision 3D.2      Procedure if proposed amendment referred to expert advisory committee**

### **42ZCZJ    Application**

- (1) For subsection 52D (2) of the Act, this Subdivision sets out the procedure that is to be followed in amending the current Poisons Standard:
  - (a) if:
    - (i) a person applies to the Secretary under section 52EAA of the Act to amend the current Poisons Standard; and
    - (ii) the Secretary decides to refer the proposed amendment to an expert advisory committee; or

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- (b) if the Secretary decides:
- (i) to amend the current Poisons Standard on his or her own initiative; and
  - (ii) to refer the proposed amendment to an expert advisory committee.

*Note* This Subdivision does not limit the way the Secretary may exercise a power under subsection 52D (2) of the Act in other circumstances.

#### **42ZCZK Proposed amendment to be referred to expert advisory committee**

- (1) The Secretary must publish, in a manner the Secretary considers appropriate, a notice:
  - (a) specifying the expert advisory committee to which the proposed amendment will be referred; and
  - (b) specifying the date of the meeting of the committee; and
  - (c) setting out details of the proposed amendment; and
  - (d) inviting public submissions to be made to the committee by a date mentioned in the notice as the closing date for public submissions (the *first closing date*).
- (2) The first closing date must be at least 20 business days after publication of the notice.
- (3) The date of the meeting must be at least 10 business days after the first closing date.

#### **42ZCZL Consideration of public submissions**

- (1) At a meeting of an expert advisory committee to consider the proposed amendment, the committee must consider all public submissions received by the first closing date that:
  - (a) address a matter mentioned in section 52E of the Act; and
  - (b) are relevant to the proposed amendment.
- (2) The committee is not required to consider a public submission received after the first closing date.
- (3) Subject to subregulation (4), the Secretary must publish, in a manner the Secretary considers appropriate, all public submissions received on or before the first closing date.

- (4) The Secretary must not publish any information that the Secretary considers to be confidential information.

**42ZCZM Committee to advise Secretary**

After consideration of any public submissions received, the expert advisory committee must provide advice or a recommendation to the Secretary in relation to the proposed amendment.

**42ZCZN Interim decision of Secretary**

After considering the advice or recommendation of the expert advisory committee, the Secretary must, subject to regulation 42ZCZO, make an interim decision in relation to the proposed amendment.

**42ZCZO Secretary may make final decision if no interim decision required**

- (1) The Secretary may make a final decision without making an interim decision if no public submissions are received in response to an invitation under paragraph 42ZCZK (1) (d).
- (2) The Secretary must comply with regulation 42ZCZS after making the final decision.

**42ZCZP Call for further submissions**

As soon as practicable after making the interim decision, the Secretary must publish, in a manner the Secretary considers appropriate, a notice:

- (a) setting out the interim decision and the reasons for making the interim decision; and
- (b) if the interim decision is to amend the current Poisons Standard — specifying the proposed date of effect of the proposed amendment; and

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- (c) inviting persons who made a submission in response to the original invitation under paragraph 42ZCZK (1) (d) to make further submissions to the Secretary in relation to the interim decision within 10 business days after publication of the notice (the *second closing date*); and
  - (d) if the interim decision is in response to an application made under section 52EAA — inviting the person who made the application to make a submission in relation to the interim decision by the second closing date.

#### **42ZCZQ Reconsideration of interim decision**

- (1) If the Secretary receives further submissions on or before the second closing date, the Secretary must, as soon as practicable after the second closing date:
  - (a) consider all public submissions (the *relevant submissions*) made by the second closing date that:
    - (i) address a matter mentioned in section 52E of the Act; and
    - (ii) are relevant to the Secretary's interim decision; and
  - (b) reconsider the interim decision in light of those submissions and any advice received in response to a request under paragraph (2) (a).
- (2) In reconsidering the interim decision, the Secretary:
  - (a) may request advice from any committee or any person; and
  - (b) is not required to engage in further public consultation.
- (3) The Secretary need not consider a public submission made after the second closing date.
- (4) Subject to subsection (5), the Secretary must publish, in a manner the Secretary considers appropriate, all relevant submissions.
- (5) The Secretary must not publish any information that the Secretary considers to be confidential information.

#### **42ZCZR Final decision if there is an interim decision**

The Secretary may make a final decision by confirming, varying or setting aside the interim decision only:

- (a) after considering all relevant submissions and any advice received in response to a request under paragraph 42ZCZQ (2) (a); or
- (b) if there are no such submissions or advice.

#### **42ZCZS Publication of final decision**

After making a final decision under regulation 42ZCZR or 42ZCZO, the Secretary must:

- (a) publish, in a manner that the Secretary considers appropriate:
  - (i) the decision; and
  - (ii) the reasons for the decision; and
  - (iii) the date of effect of the decision; and
- (b) if the decision is to amend the current Poisons Standard — make the amendment.

*Note* The Secretary must comply with section 52E of the Act when amending the current Poisons Standard.

### **Subdivision 3D.3 Procedure if proposed amendments not referred to expert advisory committee**

#### **42ZCZT Application**

This Subdivision applies if the Secretary:

- (a) receives an application under section 52EAA of the Act to amend the current Poisons Standard; and
- (b) decides not to refer the proposed amendment to an expert advisory committee.

*Note* This Subdivision does not limit the way the Secretary may exercise a power under subsection 52D (2) of the Act in other circumstances.

**42ZCZU Final decision without interim decision**

- (1) If the Secretary decides to amend the current Poisons Standard in the manner set out in the application, the Secretary may make a final decision without making an interim decision.
- (2) The Secretary must comply with regulation 42ZCZX after making the final decision.

**42ZCZV Interim decision required if Secretary decides not to amend as requested**

If the Secretary decides not to amend the current Poisons Standard in the manner set out in the application, the Secretary must:

- (a) make an interim decision on the application having regard to the information provided by the applicant; and
- (b) give the applicant a written notice:
  - (i) setting out the interim decision and the reasons for the decision; and
  - (ii) advising the applicant that he or she may, within the period specified in the notice (not being less than 10 business days after the date of the notice), make a written submission to the Secretary about the interim decision.

**42ZCZW Final decision if there is interim decision**

If the Secretary makes an interim decision on the application, the Secretary may make a final decision on the application by confirming, varying or setting aside the interim decision only:

- (a) after considering any submission provided by the applicant within the time specified in the notice under paragraph 42ZCZV (b); or
- (b) if no submission is received from the applicant within that time.

#### **42ZCZX Publication of final decision**

After making a final decision under regulation 42ZCZU or 42ZCZW, the Secretary must:

- (a) publish, in a manner that the Secretary considers appropriate:
  - (i) the decision; and
  - (ii) the reasons for the decision; and
  - (iii) the date of effect of the decision; and
- (b) if the decision is to amend the current Poisons Standard — make the amendment.

*Note* The Secretary must comply with section 52E of the Act when amending the current Poisons Standard.

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#### **Note**

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See <http://www.frli.gov.au>.