

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2010 No. 129**

#### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods Amendment Regulations 2010 (No. 2)*

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Act also provides for a framework to be adopted by the states and territories (the states) allowing for a uniform approach to control the availability and accessibility, and to ensure the safe handling, of poisons (medicines and chemicals) in Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Regulations amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations) to repeal the current scheduling of medicines and chemicals arrangements including those relating to the constitution and meeting procedures for the National Drugs and Poisons Schedule Committee (the NDPSC). The Regulations substitute new scheduling arrangements for medicines and chemicals and set out new procedures to support these new scheduling arrangements. These procedural arrangements include procedures for amending the Poisons Standard by the Secretary of the Department of Health and Ageing, procedures for the appointment of members of the new advisory committees that provide advice and recommendations to the Secretary, constitution of each of those committees and procedures for committee meetings.

Subsection 52D(2) of the Act authorises the NDPSC to: amend the current Poisons Standard; or prepare a document (a new Poisons Standard) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard. Part 6-3 of the Act establishes the NDPSC as a statutory body, sets out its functions and activities and its responsibilities for the Poisons Standard, such as the publication of decisions by the NDPSC and the making of amendments. The current Part 6-3 of the Act therefore provides for the scheduling of medicines and chemicals by one Committee.

The Poisons Standard consists of decisions of the NDPSC regarding classification of medicines and chemicals into nine different Schedules signifying the degree of risk and the degree of control recommended to be exercised over their availability to the public. The states are responsible for imposing the legislative controls on the supply of poisons. Generally, these controls flow from the schedule in which the poison has been included.

The *Therapeutic Therapeutics Goods Amendment (2009 Measures No. 2) Act 2009* (the Amending Act) amended the Act to repeal the provisions relating to the NDPSC and to establish the Advisory Committee on Medicines Scheduling (ACMS) (section 52B) and the Advisory Committee on Chemicals Scheduling (ACCS) (section 52C) that provide advice and recommendations to the Secretary to the Department of Health and Ageing (the Secretary) in

relation to the scheduling of medicines and chemicals, respectively. The power to amend the Poisons Standard or to make a new Poisons Standard is now accorded to the Secretary under subsection 52D(2). These amendments commence on 1 July 2010.

New subsections 52B(2) and 52C(2) of the Act provide that the ACMS and the ACCS will be constituted and hold meetings in accordance with the Regulations. They also provide that the Commonwealth and state, are entitled to nominate a member of the ACMS and the ACCS in accordance with the regulations (refer to new subsection 52B(3) and 52C(3)). New section 52CA provides that the ACMS and the ACCS may hold joint meetings in accordance with the Regulations. In addition, subsection 52D(2) provides that, subject to the Act and the regulations, the Secretary may amend the Poisons Standard or prepare a document in substitution for the current Poisons Standard.

The Regulations set out the details of the new scheduling arrangements for medicines and chemicals as a consequence of the amendments implemented by the Amendment Act.

Details of the Regulations are set out in the [Attachment](#).

The amendments give effect to recommendations arising from the National Competition Policy *Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review, 2001), and those more recent recommendations of the Productivity Commission Research Report on *Chemicals and Plastics Regulation* (2008), which have been accepted by the Council of Australian Governments'.

The amendments have been developed in close cooperation with State and Territory Health Departments, through the National Coordinating Committee on Therapeutic Goods to ensure uniform scheduling throughout Australia. The supply and availability of scheduled medicines and chemicals is regulated through State and Territory legislation. Public consultation has been undertaken on the revised scheduling arrangements over an extensive period of time. More recently, consultation on the draft Regulations occurred between 29 January and 16 March 2010. Changes to the draft regulations were made following this consultation. The submissions received on the draft regulations and the responses to the issues raised have been published on the Therapeutic Goods Administration website.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on 1 July 2010.

## ATTACHMENT

**DETAILS OF THE THERAPEUTIC GOODS AMENDMENT REGULATIONS 2010  
(NO. 2)**Regulation 1 – Name of Regulations

This regulation provides that the name of the Regulations is the *Therapeutic Goods Amendment Regulations 2010 (No. 2)*.

Regulation 2 – Commencement

This regulation provides that the Regulations commence on 1 July 2010.

Regulation 3 – Amendment of *Therapeutic Goods Regulations 1990*

This regulation provides that Schedule 1 amends the *Therapeutic Goods Regulations 1990* (the Principal Regulations).

**SCHEDULE 1 –Amendments**Item [1] – Part 6, Division 3A

Item [1] substitutes a new Division 3A and insert new Divisions 3B, 3C and 3D in Part 6 of the Principal Regulations.

Divisions 3A, 3B, 3C and 3D provide for membership arrangements of the Advisory Committee on Medicines Scheduling, the Advisory Committee on Chemicals Scheduling, the procedures of committee meetings including joint meetings, administrative arrangements for the committees, and the procedures to amend the current Poisons Standard, respectively.

**Division 3A – Advisory Committee on Medicines Scheduling****Subdivision 3A.1 – Preliminary**Regulation 42ZCA – Definitions for Division 3A

Regulation 42ZCA sets out the definitions used for the purposes of interpreting Division 3A. Regulation 42ZCA provide for the definitions of the following: appointed member, Committee, Committee member and nominated member.

**Subdivision 3A.2 – Constitution of Committee**Regulation 42ZCB – Membership of Committee

Regulation 42ZCB provides for the Advisory Committee on Medicines Scheduling to be constituted in accordance with Subdivision 3A.2 of the Principal Regulations.

Regulation 42ZCC – Committee members

Subregulation 42ZCC(1) provides for the Committee to consist of nominated members (who are nominated under new subsection 52B(3) and in accordance with new regulation 42ZCE) and not more than 6 appointed members, who are considered to be Committee members for the purposes of the definition set out in regulation 42ZCA.

Subregulation 42ZCC(2) provides that the Committee members have expertise in at least one of the seven technical fields set out in paragraphs (a) to (g). The fields of expertise in this regard

are the regulation of scheduled medicines in Australia; toxicology or pharmacology; clinical pharmacology; pharmacy practice; medical practice; consumer health issues relating to the regulation of therapeutic goods; and industry issues relating to the regulation of therapeutic goods. Some members may have expertise in a combination of these fields of expertise but it does not mean that a person with an expertise in only one of those fields cannot be a member of the committee.

Subregulation 42ZCC(3) requires that the membership of the committee must, to the extent reasonably practicable, represent the widest possible range of fields mentioned in subregulation 42ZCC(2).

#### Regulation 42ZCD – Appointed members

Subregulation 42ZCD(1) requires that an ‘appointed member’ must be appointed by the Minister for Health and Ageing (the Minister), in a written instrument.

Subregulation 42ZCD(2) requires that the term of appointment of an appointed member is to be specified in the instrument of appointment signed by the Minister and limits the period of this appointment to three years.

Subregulation 42ZCD(3) allows for a reappointment of an appointed member but that reappointment must not be for more than three consecutive terms.

#### Regulation 42ZCE – Nominated members

Subregulation 42ZCE(1) sets out that the authority of this regulation based on new subsection 52B(3) of the Act which allows the Commonwealth, each state, the Australian Capital Territory and the Northern Territory (the states), to each nominate a member of the Committee in accordance with the Principal Regulations.

Subregulation 42ZCE(2) requires that the nomination by the Commonwealth, and each of the States or Territories be in writing.

Subregulation 42ZCE(3) requires the nomination to specify the term of the nominee’s membership of the Committee.

Subregulation 42ZCE(4) provides that a nominee becomes a member of the Committee when the nomination is given to the Minister.

Subregulation 42ZCE(5) provides a nominated member’s membership ceases if the nominating body withdraws the nomination by written notification to the Minister; or the member gives the Minister written notice of that member’s resignation from the committee in accordance with subregulation 42ZCG (1).

Subregulation 42ZCE(6) provides for the Commonwealth, and each state to nominate in writing a temporary nominee to replace the existing member on a temporary basis. Paragraphs (a) and (b) set out that this may occur when the office is vacant; or during any period when the existing member is absent from Australia, or for any reason unable to perform the functions of the office. The nomination of a temporary nominee is made at the same time as the nomination of a member of the Committee and the Commonwealth, or the states do not need to wait for those circumstances to occur before nominating a temporary nominee.

Subregulation 42ZCE(7) provides that the temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee, when any of the circumstances described in paragraphs 42ZCE(6)(a) and (b) commences and until that circumstance ends.

Regulation 42ZCF – Appointment of the Chair and acting Chair

Subregulation 42ZCF(1) provides for the Minister to appoint a Committee member to be the Chair of the Committee, in a written instrument.

Subregulation 42ZCF(2) provides for the Chair to be appointed for the period stated on the notice of appointment, and allows for the Chair to be appointed for further terms.

Subregulation 42ZCF(3) provides for the Minister to appoint, in writing, a member to act as the Chair when the office of the Chair is vacant (whether an appointment has previously been made to the office) or during any period when the Chair is overseas, absent from duty or for any other reason, unable to perform the functions of the Chair.

Regulation 42ZCG – Resignation or vacancy

Subregulation 42ZCG(1) provides that a Committee member or Chair may resign by giving written notice to the Minister.

Subregulation 42ZCG(2) provides that if the Chair ceases to be a Committee member, the position is taken to be vacant.

Regulation 42ZCH – Termination of appointment

Subregulation 42ZCH(1) provides that the Minister may terminate an appointed member's appointment based on any of the grounds set out in paragraphs (a) to (e). In this regard the grounds are physical or mental incapacity; misbehaviour; incompetence; bankruptcy; and failing to comply with the disclosure of interested requirements set out in regulation 42ZCP.

Subregulation 42ZCH(2) requires the Minister to terminate an appointed members appointment if either a member is convicted of an offence punishable by imprisonment for at least one year, or if a member is absent without leave of absence from three consecutive meetings of the Committee.

Regulation 42ZCI – Leave of absence

Subregulation 42ZCI(1) provides that the Minister may grant leave of absence to the Chair.

Subregulation 42ZCI(2) provides that the Chair may grant leave of absence to a Committee member.

Regulation 42ZCJ – Acting members

Subregulation 42ZCJ(1) provides that the Minister may appoint, in writing, a person to act as an appointed member during the vacancy in the office of an appointed member; or during any period; or during all periods, when an appointed member is absent from duty or from Australia; or whether or not an appointment has previously been made to the office, or is for any reason, unable to perform the duties of office.

Subregulation 42ZCJ(2) provides that an acting appointed member must have the expertise required for a substantive member.

### **Subdivision 3A.3 – Committee meetings**

#### Regulation 42ZCK – Committee meetings

Regulation 42ZCK provides for the purposes of new subsection 52B(2) of the Act, that the Committee is to hold meetings in accordance with Subdivision 3A.3 of the Principal Regulations.

#### Regulation 42ZCL – Meeting procedure

Subregulation 42ZCL(1) provides for the Chair of the Committee to notify the Committee, in writing, to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.

Subregulation 42ZCL(2) provides for procedure of a meeting to be determined by the Committee in accordance with Subdivision 3A.3 of the Principal Regulations.

Subregulation 42ZCL(3) provides for the Chair to allow for the Committee to meet by video teleconference or teleconference or to meet out of session.

Subregulation 42ZCL(4) provides for the conduct and set out procedures applying to Committee meetings as they relate to the consideration of issues before the Committee, obtaining and receiving information and compliance with certain directions. Subregulation 42ZCL(4) provides that 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 or submissions orally or in writing; and
- (e) must comply with any directions given, in writing, to the Committee by the Minister or Secretary to the Department of Health and Ageing about the Committee's performance of its functions (other than a direction about advice or to be given by the Committee).

Subregulation 42ZCL(5) provides for the definition of "out of session" as it relates to regulation 42ZCL, explaining that it is a meeting where members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

#### Regulation 42ZCM - Presiding member

Subregulation 42ZCM(1) provides that the Chair must preside at a meeting at which he or she is present.

Subregulation 42ZCM(2) authorises the Chair to select a member of the Committee to preside at the meeting where he or she is unable to preside, and advise the other committee members of the selection.

Subregulation 42ZCM(3) provides for the circumstance where the Chair is temporarily absent from a meeting, the member chosen by the Committee members present is required to preside at the meeting.

Subregulation 42ZCM(4) provides for the presiding member selected under subregulation 42ZCM(2) or (3) to exercise the powers and function of the Chair during the meeting.

Regulation 42ZCN – Quorum

Regulation 42ZCN provides for at least two-thirds of the Committee members present at the meeting to constitute a quorum.

Regulation 42ZCO – Voting

Subregulation 42ZCO(1) makes it clear that a decision made at a Committee meeting by a majority of the votes of the members present and voting is considered to be a decision of the Committee. The decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary of the Department of Health and Ageing (the Secretary) under new subsection 52B(4) of the Act.

Subregulation 42ZCO(2) provides for the member presiding at a meeting to have a deliberative vote and casting vote in those instances where the votes are equal.

Regulation 42ZCP – Miscellaneous*Sitting fees and travel entitlements*

Subregulation 42ZCP(1) provides for appointed members of the Committee to be entitled to fees and travel entitlements as determined by the Remuneration Tribunal.

*When Committee may establish subcommittees*

Subregulation 42ZCP(2) provides for the Committee to establish subcommittees, consisting of the Committee members and other persons, with the approval of the Secretary.

Subregulation 42ZCP(3) provides that a 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.

*Disclosure of interests*

Subregulations 42ZCP(4), (5), (6) and (7) addresses the circumstances where a Committee member has a conflict of interest in relation to a matter being considered, or is about to be considered at a Committee meeting.

Subregulation 42ZCP(4) provides that 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, must, without delay, disclose the nature of the interest at, or before, a meeting of the Committee.

Subregulation 42ZCP(5) provides that the disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee determines otherwise, be present at the deliberation of that matter or participate in the decision making in relation to that matter.

Subregulation 42ZCP(6) provides that when the Committee is making a determination about a member who made a disclosure, the member and any other member who has a direct or indirect material interest (whether pecuniary or not) in relation to the same matter must not be present during the deliberation and must not take part in making the determination. A similar provision for the disclosure of those kinds of conflicts of interest applies to members of a subcommittee appointed by the Committee.

Subregulation 42ZCP(7) requires a member of a subcommittee appointed by the Committee who is aware that he or she has conflict of interest in a matter being considered or to be considered at a meeting to disclose the nature of that interest at or before that meeting. This subregulation reflects the requirement applying to Committee members as set out in subregulation 42ZCP(4).

*Seeking and providing further advice*

Subregulation 42ZCP(8) provides for any advice or recommendation given by the Committee to the Secretary may be given to another committee under the Act, or the Principal Regulations for the advice of that committee.

Subregulation 42ZCP(9) allows the Committee to seek advice from other persons when performing its functions.

*Validity of acts of members*

Subregulation 42ZCP(10) provides that an administrative error with respect to a member's appointment does not invalidate anything done by that member.

*Records and reports*

Subregulation 42ZCP(11) requires the Committee to keep records of its proceedings, and prepare any other report about its activities at the request of the Minister or the Secretary.

*Publication*

Subregulation 42ZCP(12) requires the Committee to publish any recommendations it makes.

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

### **Subdivision 3B.1 – Preliminary**

Regulation 42ZCQ

Regulation 42ZCQ sets out the definitions used for the purposes of interpreting Division 3B.

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

Regulation 42ZCR – Membership of Committee

Regulation 42ZCR provides for the Advisory Committee on Chemicals Scheduling to be constituted in accordance with Subdivision 3B.2 of the Principal Regulations.

Regulation 42ZCS – Committee members

Subregulation 42ZCS(1) provides for the Committee to consist of nominated members (who are nominated under new subsection 52C(3) of the Act and in accordance with new regulation 42ZCU) and not more than six appointed members, who are considered to be Committee members for the purposes of the definition set out in regulation 42ZCQ.

Subregulation 42ZCS(2) provide sthat the Committee members must have expertise in at least one of the nine technical fields set out in paragraphs (a) to (i). The fields of expertise in this regard be the regulation of scheduled chemicals in Australia; veterinary medicine or veterinary pathology; toxicology; industrial or domestic chemicals; agricultural or veterinary chemicals; clinical aspects of human poisoning; occupational health, particularly as a medical practitioner; consumer health issues relating to the regulation of chemicals; and industry issues relating to the regulation of chemicals. Some members may have expertise in a combination of these fields of

expertise but it not mean that a person with an expertise in only one of those fields cannot be a member of the committee.

Subregulation 42ZCS(3) requires that the membership of the committee must, to the extent reasonably practicable, represent the widest possible range of fields mentioned in subregulation 42ZCS(2).

#### Regulation 42ZCT – Appointed members

Subregulation 42ZCT(1) requires that an ‘appointed member’ must be appointed by the Minister, in a written instrument.

Subregulation 42ZCT(2) requires that the term of appointment of an appointed member is to be specified in the instrument of appointment signed by the Minister and limits the period of this appointment to three years.

Subregulation 42ZCT(3) allows for a reappointment of an appointed member but that reappointment must not be for more than three consecutive terms.

#### Regulation 42ZCU – Nominated members

Subregulation 42ZCU(1) sets out that the authority of this regulation based on new subsection 52C(3) of the Amending Act, which allows the Commonwealth and each state, to each nominate a member of the Committee in accordance with the Principal Regulations.

Subregulation 42ZCU(2) requires that the nomination by the Commonwealth, and each of the States or Territories be in writing.

Subregulation 42ZCU(3) requires the nomination to specify the term of the nominee’s membership of the Committee.

Subregulation 42ZCU(4) provides that a nominee becomes a member of the Committee when the nomination is given to the Minister.

Subregulation 42ZCU(5) provides a nominated member’s membership ceases if the nominating body withdraws the nomination by written notification to the Minister; or the member gives the Minister written notice of that member’s resignation from the committee in accordance with subregulation 42ZCW(1).

Subregulation 42ZCU(6) provides for the Commonwealth and each state, to nominate in writing a temporary nominee to replace the an existing member on a temporary basis. Paragraphs (a) and (b) set out the circumstances when this may occur, when the office is vacant; or during any period when the existing member is absent from Australia, or for any reason unable to perform the functions of the office. The nomination of a temporary nominee can be made at the same time as the nomination of a member of the Committee and the Commonwealth, or the states do not need to wait for those circumstances to occur before nominating a temporary nominee.

Subregulation 42ZCU(7) provides that the temporary nominee becomes a member of the Committee, and the existing member stops being a member of the Committee, when any of the circumstances described in subregulation paragraphs 42ZCU(6)(a) and (b) commences and until that circumstance ends.

Regulation 42ZCV – Appointment of the Chair and acting Chair

Subregulation 42ZCV(1) provides for the Minister to appoint a Committee member to be the Chair of the Committee, in a written instrument.

Subregulation 42ZCV(2) provides for the Chair to be appointed for the period stated on the notice of appointment, and allows for the Chair to be appointed for further terms.

Subregulation 42ZCV(3) provides for the Minister to appoint, in writing, a member to act as the Chair when the office of the Chair is vacant (whether an appointment has previously been made to the office) or during any period when the Chair is overseas, absent from duty or for any other reason, unable to perform the functions of the Chair.

Regulation 42ZCW – Resignation or vacancy

Subregulation 42ZCW(1) provides that a Committee member or Chair may resign by giving written notice to the Minister.

Subregulation 42ZCW(2) provides that if the Chair ceases to be Committee member, the position is taken to be vacant.

Regulation 42ZCX – Termination of appointment

Subregulation 42ZCX(1) provides that the Minister may terminate an appointed member's appointment based on any of the grounds set out in paragraphs (a) to (e). In this regard the grounds are physical or mental incapacity; misbehaviour; incompetence; bankruptcy and failing to comply with the disclosure of interested requirements set out in regulation 42ZCZF.

Subregulation 42ZCX(2) requires the Minister to terminate an appointed members appointment if either a member is convicted of an offence punishable by imprisonment for at least one year, or if a member is absent without leave of absence from three consecutive meetings of the Committee.

Regulation 42ZCY – Leave of absence

Subregulation 42ZCY(1) provides that the Minister may grant leave of absence to the Chair.

Subregulation 42ZCY(2) provides that the Chair may grant leave of absence to a Committee member.

Regulation 42ZCZ – Acting members

Subregulation 42ZCZ(1) provides that the Minister may appoint, in writing, a person to act as an appointed member during the vacancy in the office of an appointed member; or during any period; or during all periods, when an appointed member is absent from duty or from Australia; or whether or not an appointment has previously been made to the office, or is for any reason, unable to perform the duties of office.

Subregulation 42ZCZ(2) provides that an acting appointed member must have the expertise required for a substantive member.

**Subdivision 3B.3 – Committee Meetings**Regulation 42ZCZA – Committee meetings

Regulation 42ZCZA provides for the purposes of new subsection 52C(2) of the Amending Act, that the Committee is to hold meetings in accordance with Subdivision 3B.3 of the Principal Regulations.

Regulation 42ZCZB – Meeting procedure - general

Subregulation 42ZCZB(1) provides for the Chair of the Committee to notify the Committee, in writing, to hold meetings at the times and places, and to deal with the matters in the manner, stated in the notice.

Subregulation 42ZCZB(2) provides for procedure of a meeting to be determined by the Committee in accordance with Subdivision 3B.3 of the Principal Regulations.

Subregulation 42ZCZB(3) provides for the Chair to allow for the Committee to meet by video teleconference or teleconference or to meet out of session.

Subregulation 42ZCZB(4) provides for the conduct and set out procedures applying to Committee meetings as they relate to the consideration of issues before the Committee, obtaining and receiving information and compliance with certain directions. Subregulation 42ZCZB(4) provides that 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 or submissions orally or in writing; and
- (e) must comply with any directions given, in writing, to the Committee by the Minister or Secretary about the Committee's performance of its functions (other than a direction about advice or is given by the Committee).

Subregulation 42ZCZB(5) provides for the definition of "out of session" as it relates to regulation 42ZCZB, explaining that it is a meeting where members take part by correspondence, email, telephone or in any other way that does not involve formal simultaneous meeting and voting.

Regulation 42ZCZC – Presiding member

Subregulation 42ZCZC(1) provides that the Chair must preside at a meeting at which he or she is present.

Subregulation 42ZCZC(2) authorises the Chair to select a member of the Committee to preside at the meeting where he or she is unable to preside, and advise the other committee members of the selection.

Subregulation 42ZCZC(3) provides for the circumstance where the Chair is temporarily absent from a meeting, the member chosen by the Committee members present is required to preside at the meeting.

Subregulation 42ZCZC(4) provides for the presiding member selected under subregulation 42ZCZC(2) or (3) to exercise the powers and function of the Chair during the meeting.

Regulation 42ZCZD – Quorum

Regulation 42ZCZD provides for at least two thirds of the Committee members present at the meeting to constitute a quorum.

#### Regulation 42ZCZE – Voting

Subregulation 42ZCZE(1) makes it clear that a decision made at a Committee meeting by a majority of the votes of the members present and voting is considered to be a decision of the Committee. The decisions of the Committee relate to the recommendations and advice the Committee provides to the Secretary under new subsection 52C(4).

Subregulation 42ZCZE(2) provides for the member presiding at a meeting to have a deliberative vote and casting vote in those instances where the votes are equal.

#### Regulation 42ZCZF – Miscellaneous

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

Subregulation 42ZCZF(1) provides for appointed members of the Committee to be entitled to fees and travel entitlements as determined by the Remuneration Tribunal.

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

Subregulation 42ZCZF(2) provides for the Committee to establish subcommittees, consisting of the Committee members and other persons, with the approval of the Secretary.

Subregulation 42ZCZF(3) provides that a 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.

##### *Disclosure of interests*

Subregulations 42ZCZF(4), (5), (6) and (7) addresses the circumstances where a Committee member has a conflict of interest in relation to a matter being considered, or is about to be considered at a Committee meeting.

Subregulation 42ZCZF(4) provides that 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, must, without delay, disclose the nature of the interest at, or before, a meeting of the Committee.

Subregulation 42ZCZF(5) provides that the disclosure must be recorded in the minutes of the meeting and the member must not, unless the Committee determines otherwise, be present at the deliberation of that matter or participate in the decision making in relation to that matter.

Subregulation 42ZCZF(6) provides that when the Committee is making a determination about a member who made a disclosure, the member and any other member who has a direct or indirect material interest (whether pecuniary or not) in relation to the same matter must not be present during the deliberation and must not take part in making the determination.

Subregulation 42ZCZF(7) requires a member of a subcommittee appointed by the Committee who is aware that he or she has conflict of interest in a matter being considered or to be considered at a meeting to disclose the nature of that interest at or before that meeting. This subregulation reflects the requirement applying to Committee members as set out in subregulation 42ZCZF(4).

*Seeking and providing further advice*

Subregulation 42ZCZF(8) provides for any advice or recommendation given by the Committee to the Secretary may be given to another committee under the Act, or these Regulations for the advice of that committee.

Subregulation 42ZCZF(9) allows the Committee to seek advice from other persons when performing its functions.

*Validity of acts of members*

Subregulation 42ZCZF(10) provides that administrative error with respect to a member's appointment does not invalidate anything done by that member.

*Records and reports*

Subregulation 42ZCZF(11) requires the Committee to keep records of its proceedings, and prepare any other report about its activities at the request of the Minister or Secretary.

*Publication*

Subregulation 42ZCZF(12) requires the Committee to publish any recommendations it makes.

**Division 3C – Joint meetings**42ZCZG – Joint Meetings

Regulation 42ZCZG sets out procedures relating to joint meetings of the Committees provided for under new section 52CA of the Amending Act to be in accordance with Division 3C.

42ZCZH – Procedure for joint meetings

Subregulation 42ZCZH(1) allows the Secretary ( if he or she considers it appropriate to do so), to notify, in writing, the Committee members of both Committees, of the direction to hold a joint meeting at a time and place, and to consider matters in the manner stated in the notice.

Subregulation 42ZCZH(2) requires the Committee members present at the meeting to vote on which Chair (or presiding member) is to be the Chair for the purposes of the joint meeting.

Subregulation 42ZCZH(3), for the purposes of choosing a Chair, allows for a Committee member to cast one vote in respect of each committee for which he or she is a member.

Subregulation 42ZCZH(4) makes it clear that there is a quorum at a joint committee meeting if there is a quorum for each committee.

Subregulation 42ZCZH(5) set out the voting process for joint meetings. Paragraph (a) provides that decisions made at the joint meeting are arrived at by a majority of the votes cast by the members present and voting. Paragraph (b) allows for each member to have one vote in respect of each Committee of which he or she is a member.

Subregulation 42ZCZH(6) provides that a decision made at a joint meeting is taken to be a decision of each Committee for the purposes of any advice or recommendation that is to be provided to the Secretary by either Committee.

Subregulation 42ZCZH(7) requires each Committee to keep a record of the proceedings of the joint meeting.

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

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

##### Regulation 42ZCZI – Definitions for Division 3D

Regulation 42ZCZI sets out the definitions used for the purposes of interpreting Division 3D of the Principal Regulations. The following terms are defined under this regulation: “business day”, “Committee member”, “expert advisory committee”, “first closing date”, “interim decision”, “proposed amendment”, “public submission”, “relevant submission” and “second closing date”.

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

##### Regulation 42ZCZJ – Application

Subregulation 42ZCZJ(1) sets out the procedures for amending the current Poisons Standard under subdivision 3D.2. These procedures cover circumstances when a person applies under new section 52EAA of the Act to the Secretary, and the Secretary decides to refer the amendment to an expert advisory committee; or if the Secretary decides to amend the current Poisons Standard on his or her own initiative; and refer the amendment to an expert advisory committee.

##### Regulation 42ZCZK – Proposed amendment to be referred to Advisory Committee

Subregulation 42ZCZK(1) sets out the procedures for public notification of a proposed amendment where the Secretary decides to refer to an expert advisory committee. The detail that is required to be included in the public notice is included in paragraphs (a) to (d) to this subregulation.

Subregulation 42ZCZK(2) sets out that the first closing date for receipt of public submission must be at least 20 business days (except Saturdays, Sundays and ACT public holidays) after publication of the notice.

Subregulation 42ZCZK(3) provides that the date of the meeting specified in the notice be at least 10 business days after the first closing date.

##### Regulation 42ZCZL – Consideration of public submissions

Subregulation 42ZCZL(1) provides that, at a meeting to consider the proposed amendment to the current Poisons Standard, a committee must consider all submissions on a proposed amendment, that are received by the closing date which (a) addresses a matter mentioned in new section 52E of the Act, and (b) that are relevant to the amendment.

Subregulation 42ZCZL(2) provides that the Committee need not consider any public submission received after the first closing date (definition of ‘first closing date’ is defined in subregulation 42ZCZI).

Subregulation 42ZCZL(3) provides that, subject to subregulation 42ZCZL(4), the Secretary is required to publish – in a manner the Secretary considers to be appropriate – all public submissions received on or before the closing date.

Subregulation 42ZCZL(4) provides that the Secretary must not publish any information in a public submission received and considered by the committee that the Secretary considers to be confidential information.

Regulation 42ZCZM – Committee to advise Secretary

This regulation requires the expert advisory committee to provide advice or a recommendation to the Secretary in relation to the proposed amendment after consideration of any public submissions received.

Regulation 42ZCZN – Interim decision of Secretary

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

Regulation 42ZCZO – Secretary may make final decision if no interim decision required

This regulation allows the Secretary to make a final decision, without making an interim decision in those instances where no public submissions are received in response to the invitation for submissions made under paragraph 42ZCZK(1)(d). The Secretary is required to comply with regulation 42ZCZS after making the final decision (subregulation 42ZCZO(2)). Regulation 42ZCZS relates to procedures with regard to the publication of the final decision.

Regulation 42ZCZP – Call for further submissions

This regulation requires the Secretary to publish a notice, in a manner the Secretary considers appropriate, details of the interim decision made under regulation 42ZCZN as soon as practicable after the decision is made. The notice must set out the following:

- (a) the interim decision and reasons for it;
- (b) if the interim decision is to amend the current Poisons Standard, specify the date of effect of the proposed amendment;
- (c) an invitation to persons who made a submission under paragraph 42ZCZK(1)(d) to make further submissions to the Secretary in relation to the interim decision within 10 business days after the publication of the notice; and
- (d) if the interim decision is in response to an application made under new section 52EAA inviting applicant for the proposed amendment to make a submission in relation to the interim decision by the closing date.

Regulation 42ZCZQ – Reconsideration of interim decision

Subregulation 42ZCZQ(1) sets out the procedures that the Secretary must undertake when reconsidering an interim decision and the proposed amendment referred to in subdivision 3D.2. The reconsideration process needs to commence as soon as practicable after the second closing date. Paragraph (a) requires the Secretary to consider all the public submissions that address a matter mentioned in new section 52E of the Act and that are relevant to the Secretary's interim decision; and paragraph (b) requires the Secretary to reconsider the interim decision in light of those submissions and any advice received in response to a request under paragraph (2)(a) of this regulation.

Subregulation 42ZCZQ(2) authorises the Secretary to request advice from any committee or any person when reconsidering the interim decision, but does not require the Secretary to engage in any further public consultation.

Subregulation 42ZCZQ(3) provides that the Secretary, when reconsidering the interim decision, need not consider any public submission made after the second closing date.

Subregulation 42ZCZQ(4) compels the Secretary to publish all relevant submissions received in relation to the reconsideration process of the interim decision. However,

Subregulation 42ZCZQ(5) provides that the Secretary must not publish any information in the submissions that the Secretary considers to be confidential information.

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

This regulation requires the Secretary to make a final decision by confirming, varying or setting aside the interim decision only after considering all relevant submissions and any advice received in response to a request under paragraph 42ZCZP(2)(a); or where there are no such submissions or advice.

#### 42ZCZS – Publication of final decision

Regulation 42ZCZS requires the Secretary, after making a final decision under 42ZCZO or 42ZCZR, to: publish the decision, the reasons for the decision and the date of effect of the decision, in a manner the Secretary considered appropriate; and if the decision is to amend the current Poisons Standard, to make that amendment.

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

#### 42ZCZT – Application

Regulation 42ZCZT sets out the situation where this Subdivision applies, as those instances where the Secretary receives an application under new section 52EAA of the Act to amend the current Poisons Standard and decides not to refer the proposed amendment to an expert advisory committee.

However, this Division does not limit the way the Secretary may exercise a power under new subsection 52D(2) of the Act in other circumstances.

#### 42ZCZU – Final decision without interim decision

Regulation 42ZCZU provide for the Secretary to make a final decision without making an interim decision to amend the current Poisons Standard, where the decision is to amend the Standard in the manner consistent with the proposed amendment described in the application under new section 52EAA. The Secretary is required to comply with the requirements under regulation 42ZCZX after making the final decision.

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

Regulation 42ZCZV sets out the requirements for the Secretary to comply with, in circumstances where the Secretary decides not to amend the current Poisons Standard in accordance with the proposed amendment set out in the application under new section 52EAA. Paragraph (a) of the regulation requires the Secretary to make an interim decision on the proposed amendment after having regard to the information provided by the applicant. Paragraph (b) requires the Secretary to give the applicant a written notice advising of the interim decision, the reasons for the decision and informing the applicant of their right to make a written submission to the Secretary about the interim decision, within the period specified in the notice (not being less than 10 business days after the date of the notice).

42ZCZW – Final decision if there is interim decision

Regulation 42ZCZW provides that where the Secretary makes an interim decision on the application to amend the current Poisons Standard, the Secretary may make a final decision on the application by confirming, varying, or setting aside the interim decision only if the condition set out in paragraph (a) or (b) is met. That is, the Secretary may only make a final decision after (a) considering any submission provided by the applicant within the time specified in the notice; or, under paragraph (b) if no submission is received from the applicant within that time.

42ZCZX – Publication of final decision

Regulation 42ZCZX requires the Secretary, after making a final decision under 42ZCZU or 42ZCZW, to: publish the decision, the reasons for the decision and the date of effect of the decision, in a manner the Secretary considered appropriate; and if the decision is to amend the Poisons Standard – make the amendment.