Draft Terms of Reference for the PHARMAC Consumer Advisory Committee

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Glossary of terms

"CAC" means the Consumer Advisory Committee.

"CAC Chair" means the Chairperson of the CAC.

"CAC Secretary" means the Secretary of the CAC.

"CE Act" means the Crown Entities Act 2004.

"Chief Executive" means the Chief Executive of PHARMAC, or their delegate.

"Deputy Chair" means the Deputy Chairperson of the CAC.

"Member" means a member of the CAC.

"**Minute(s)**" means the written record of discussion and recommendations made at a CAC meeting (including meetings by teleconference and recommendations made by other means of communication) which have been finalised by the CAC Chair.

"NZPHD Act" means the New Zealand Public Health and Disability Act 2000 and includes any regulations, amendments, re-enactments and replacements thereof.

"PHARMAC" means the Pharmaceutical Management Agency, a Crown Entity established under the NZPHD Act.

"Pharmaceutical(s)" means, as defined in the NZPHD Act, a medicine, therapeutic medical device, or related product or related thing.

"**Published Minute**" means that part of the CAC Minute published on the PHARMAC website at <u>http://www.pharmac.govt.nz/patients/CAC/ CACminutes</u>.

"Terms of Reference" means these Terms of Reference for the CAC.

1 Establishment

1.1 The CAC

The CAC is an advisory committee established by the PHARMAC Board as required by the New Zealand Public Health and Disability Act 2000 to '*provide input from a consumer or patient point of view*'.¹

2 Terms of Reference

2.1 Purpose of the CAC

The primary purpose of the CAC as described in the legislation is to provide the Board of PHARMAC with input from a consumer or patient point of view on matters related to PHARMAC's activities. Recognising the difficulties representing the wide range of disparate views held by consumers, it is not intended that the CAC represent all consumer views. The CAC's primary functions, therefore, are to provide advice to PHARMAC on how it can best access the diversity of consumer views and consider these when carrying out its role.

The CAC does not have a role in pharmaceutical funding decisions. Consumers are able to provide input directly into the funding decision making process by making a funding application and/or contacting PHARMAC directly about an active funding application or through consultation.

2.2 Activities of the CAC

The CAC's activities shall include, but not be restricted to, providing advice to PHARMAC from a consumer or patient point of view on:

- how PHARMAC can canvass and consider consumers' views on the processes involved in the assessment, prioritisation and funding of medicines and related issues of special concern to consumers and patients, and PHARMAC's operational policy and business improvement processes;
- how PHARMAC's implementation of decisions, including information and education related to those decisions is best communicated to consumers;
- PHARMAC's strategy, policy and operational activities which relate to funding decisions, and access to and optimal use of medicines, but not specific funding decisions;
- how the CAC can engage with consumers and patients to ensure it is aware of, and able to reflect their views (on the relevant matters as described in these Terms of Reference), in its advice to the PHARMAC Board; and
- other activities as required by PHARMAC.

¹ Section 50(1)(a), NZPHD Act.

3 Relationship Management

3.1 Relationship with PHARMAC

- 3.1.1 The CAC is an advisory committee established by PHARMAC to provide advice to PHARMAC from a consumer or patient point of view. The CAC may advise PHARMAC on matters described in these Terms of Reference, however PHARMAC is not bound to accept CAC's advice or follow its recommendations.
- 3.1.2 Minutes of each CAC meeting shall be provided to the PHARMAC Board. The PHARMAC Board's response to the CAC's recommendations will, where possible, be provided to CAC at its next meeting.
- 3.1.3 The CAC Chair (or in their absence, a delegated Member of the CAC approved in advance by the PHARMAC Board Chair), has the right to attend all meetings of the PHARMAC Board as an observer. The CAC Chair may participate in discussion at the invitation of the Board Chair but may not vote on any matter at that meeting. The CAC Chair may, subject to any specific confidentiality undertaking they have signed with the PHARMAC Board in relation to their participation as an observer, report back to the CAC on the discussions of the Board.
- 3.1.4 The PHARMAC Board Chair (or in their absence, a delegated PHARMAC Board member, approved in advance by the CAC Chair), has the right to attend all meetings of the CAC as an observer. The PHARMAC Board Chair may participate in discussion at the invitation of the CAC Chair but may not vote or have any role in determining recommendations on any matter at that meeting. The PHARMAC Board Chair may report back to the Board on the discussions of the CAC.

3.2 Relationship with PHARMAC staff

- 3.2.1 PHARMAC's Chief Executive or a delegate may attend part of or all of each CAC meeting to discuss consumer-related issues which are of concern to either the CAC and/or PHARMAC.
- 3.2.2 In addition to 3.2.1, PHARMAC staff member(s), may attend and participate in meetings of the CAC while reports or recommendations relevant to their area of work are discussed. In general, PHARMAC staff may respond to questions from the CAC and clarify understanding of discussion and recommendations as necessary.
- 3.2.3 PHARMAC staff will provide administrative and support services for the CAC (see below).

The CAC Secretary

- 3.2.4 A CAC Secretary is to be provided by PHARMAC to support the CAC and assist the CAC Chair in performing his or her role.
- 3.2.5 The agenda for each CAC meeting shall be set after consultation between the CAC Chair and the CAC Secretary, taking into account matters referred by PHARMAC to CAC for advice and any other relevant matters.
- 3.2.6 The agenda and related papers will be sent to Members of the CAC (subject to the deletion of any papers from a Member's pack due to a conflict of interest of that Member), ordinarily two weeks before the relevant meeting.
- 3.2.7 The CAC Secretary is responsible for ensuring a Minute of each meeting of the CAC (including by teleconference or other means of communications) is kept and for preparing the Published Minute.
- 3.2.8 The CAC Secretary, in agreement with the CAC Chair, is responsible for managing correspondence between the CAC Members and third parties.
- 3.2.9 The CAC Secretary is not a Member of CAC.

3.3 Indemnity for Members

3.3.1 PHARMAC indemnifies all Members against all costs, liabilities, expenses and claims Members may incur as a direct or indirect result of advice given in their capacity as Members. This indemnity only applies to circumstances where a Member has acted in good faith and in performance or intended performance of the CAC's functions.

4 Membership

4.1 Appointment of the CAC Members

- 4.1.1 The appointment process will be appropriate for the cultural background of the individual but generally PHARMAC staff will advertise widely (including to all individual consumers and consumer/patient groups listed on the PHARMAC consultation database) for applications from the general public for new Members.
- 4.1.2 PHARMAC will provide a position description for all potential applicants.
- 4.1.3 A short-list of applicants will be drawn up by the CAC Chair assisted by PHARMAC staff (usually two staff members). The candidates on the short-list will be interviewed by a panel which will comprise the CAC Chair, PHARMAC staff (usually two) and others as appropriate. Recommendations for appointment will then be sent to the PHARMAC Board to appoint the Members. The Board will be

advised of any differences of opinion between panel members and will make the final decision as to who should be appointed.

- 4.1.4 The CAC will consist of up to nine Members, including at least two Maori and at least one Pacific peoples' representatives. Where no suitable Maori or Pacific people's candidates are nominated, the Board will seek to identify a member with appropriate skills and experience from those communities. In making appointments to the CAC, the Board will endeavour to ensure the CAC has an appropriate mix of people:
 - who can demonstrate a connection to a particular community of consumers or patients;
 - who can reflect interests broader than those of a specific group;
 - who can demonstrate an understanding of issues related to medicine use;
 - from different age groups and genders;
 - from different locations (urban and rural); and
 - from different cultures.

In general, PHARMAC intends the focus to be on appointing members who provide input from a consumer, patient and community perspective, not the perspective of health professionals or commercial enterprises.

- 4.1.5 The standard term for CAC Members will be three years. Recognising the need to balance regularly refreshing consumer input with developing an understanding of PHARMAC's processes, the CAC members may, at the discretion of the PHARMAC Board, seek reappointment for an additional three year period. When deciding whether to reappoint a member PHARMAC may consider, among other things, the mix of the committee's experience, and the performance of the individual member. The length of both the first and second terms may be reduced by mutual agreement.
- 4.1.6 The Board will appoint the Chairperson of the CAC, after consultation with the CAC.

4.2 Review of Appointment

4.2.1 Concerns about the process followed in making an appointment should be addressed to the Chief Executive in writing and must be submitted within three months of the announcement of an appointment. PHARMAC may then undertake a review of the process followed. The results of the review will be discussed with the complainant including what, if any, resulting action will be taken.

- 4.2.2. PHARMAC will seek to undertake any review of an appointment process within three months of concerns being raised as described in paragraph 4.2.1 above, and can be made in respect of:
 - an individual's experience of the appointment process as an applicant;
 - the appointment process followed;
 - a challenge to the appointment of the successful candidate, where there appears to be a breach of the appointment process.

4.3 Termination of Appointment

- 4.3.1 Members will inform the PHARMAC Board Chair and the CAC Chair in writing of their intention to resign from the CAC at the earliest possible opportunity.
- 4.3.2 The PHARMAC Board Chair may at any time remove a Member (including the CAC Chair or Deputy Chair) from the CAC. The Chief Executive will inform the Member in writing of the termination of his/her membership.
- 4.3.3 In accordance with section 91 of the NZPHD Act, PHARMAC may not make any payment to, or otherwise compensate, any person in respect of the person ceasing to be a Member.

5 Induction and support of CAC Members

- 5.1 Every new Member will participate in an orientation and induction programme at the beginning of his or her appointment in order to gain an understanding of PHARMAC's structure, operations and processes. The induction will also aim to ensure that a new member has an understanding of the total environment (i.e. the public sector) in which CAC operates, and thus is able to contribute confidently to his or her work on the Committee.
- 5.2 The CAC Chair will, at PHARMAC's discretion, be provided with training in effective chairing skills when he/she takes over the role or as required.
- 5.3 Effective committee process training will, at PHARMAC's discretion, be facilitated by PHARMAC for the whole of CAC as required.

6 Review of Member Performance

6.1 The performance of each Member will be assessed, preferably at the end of the first year of the Member's term and at the end of the three years if the Member is seeking reappointment. The CAC Chair, in consultation with the Chief Executive, will assess the performance of each Member. The performance of the CAC Chair will be assessed by the Chair of the Board.

7 Remuneration of the CAC

- 7.1 The CAC Members will be remunerated in recognition of the services they provide to PHARMAC, including attendance at meetings and time spent preparing for meetings and for performing any other work as requested by PHARMAC.
- 7.2 The Cabinet Office Fees Framework determines the level of fees paid.
- 7.3 PHARMAC will cover travel and accommodation expenses for Members to attend meetings².
- 7.4 Recognising the desirability of Members increasing their understanding of consumer/patient perspectives on matters covered by the CAC Terms of Reference, CAC Members may seek funding to attend conferences and meetings where consumers and consumer/patient groups will be in attendance. Such events include, but are not limited to, activities related to PHARMAC's Access and Optimal Use programmes. PHARMAC will assess such requests and may take into account the following criteria, giving such weight to each criterion as it sees fit:
 - the opportunity for engaging and networking with consumers and patients;
 - attendance at the CAC meetings;
 - number of other CAC Members attending;
 - relevance to the CAC's activities described in these Terms of Reference;
 - cost;
 - balance of opportunities across the CAC members;
 - relevance to consumer issues of concern at the time.
- 7.5 Members who attend such meetings/events will be expected to report back to the CAC.

8 Responsibilities of the CAC Chairperson

8.1 Responsibilities of the CAC Chair

- 8.1.1 The CAC Chair is responsible for:
 - consulting with the CAC Secretary to set the agenda for the CAC meetings;

² Travel & Expense Policy for Board Members and Committee Members

- presiding at each meeting of the CAC;
- deciding on the appropriateness of a meeting being held via teleconference;
- permitting Members to disconnect from a meeting via teleconference;
- signing off the final version of the Minute of each meeting of the CAC;
- liaising with PHARMAC with regard to the resources to be allocated to the CAC and its members;
- assisting with the assessment and management of all actual and potential conflicts of interest, noting and signing interest declaration forms and ensuring consideration by the PHARMAC Board. For completeness, it should be noted that this does not remove or detract from Members' obligations to properly disclose interests;
- approving communications by Members related to the activities of the CAC with the media, professional associations, researchers and research organisations, having first obtained the consent of the PHARMAC Chief Executive to the act of communication and having first consulted with PHARMAC on the content;
- attending meetings of the Board of PHARMAC, where appropriate (as an observer) and, subject to confidentiality requirements, reporting back to the CAC Members on the discussion;
- delegating, in writing, any of his or her responsibilities where appropriate and in accordance with any PHARMAC delegation policy;
- determining who may attend the CAC meetings as an observer;
- working with the CAC Secretary to manage correspondence addressed to the CAC;
- consulting with the Chief Executive on the review of Members;
- working with Members to review the CAC's work/effectiveness as required;
- participating in the training/induction of new Members as appropriate;
- attending Chair training as required.

8.2 Responsibilities of Deputy Chair of the CAC

8.2.1 The Deputy Chair is responsible for acting as the Chair of the CAC when the CAC Chair is unable to, or delegates this role to the Deputy Chair.

9 Responsibilities of all Members

9.1 Full participation in CAC

9.1.1 All Members are responsible for:

- complying with all obligations set out in the CE Act (refer to Appendix B);
- reading and considering their response to all material provided relating to items on meeting agendas prior to each meeting;
- reviewing the draft Minute, providing feedback to the CAC Secretary and confirming that the Minute is an accurate record of the discussion prior to finalisation of the Minute, for meetings that they have attended;
- attending meetings;
- providing apologies if attendance at meetings is not possible;
- being available to attend teleconferences and/or responding by email between face to face meetings;
- attending, if available, PHARMAC events involving external stakeholders eg PHARMAC Forum, Access and Optimal Use events;
- acting as a discussion leader for any items allocated to them by the CAC Chair;
- attending induction and training.

9.2 Conflicts of interest

- 9.2.1 Members are to, at all times, fully disclose and appropriately manage any interests and conflicts of interest in the performance of their duties and obligations, consistent with their role as Members of a committee of a statutory entity. Members are to avoid, to the greatest extent possible, any conflict with the performance of their duties and obligations as Members. The legislative requirements for disclosure and management of conflicts are set out in Appendix B. Section 62 of the CE Act sets out the legal definition of being "interested in a matter". Further guidance on this issue is attached to the interests disclosure form set out in Appendix B.
- 9.2.2 A Member who reasonably believes they may have an actual or potential conflict of interest is to disclose the nature of that interest to the CAC and the PHARMAC Board as soon as practicable after they become aware of it.
- 9.2.3 Where a Member declares or discloses an interest of any kind or an actual or potential conflict of interest, this shall be recorded in an interest register, which is

to be circulated prior to each meeting of the CAC. The interests register is to be considered and confirmed as up to date at the commencement of each meeting.

- 9.2.4 Following the setting of the agenda for a meeting Members are to update the interests disclosure form set out in Appendix B with any actual or potential conflicts of interest arising as a result of the specific agenda items for that meeting, or otherwise. Members are to provide their updated interests disclosure form to the CAC Secretary prior to the papers being sent to Members and in any event no later than three weeks prior to the date of the relevant meeting.
- 9.2.5 Where a Member is "interested in a matter" (as defined in section 62 CE Act) relating to PHARMAC, they must not take part in any discussion or decision of the CAC relating to the matter, or otherwise participate in any activity of PHARMAC that relates to the matter. The Minutes of the meeting will record this fact.
- 9.2.6 The Member is to be disregarded for the purposes of forming a quorum for that part of the meeting of the CAC during which a discussion or decision in relation to the matter occurs or is made. If a quorum cannot be maintained, then the relevant matter is to be deferred to the next meeting.
- 9.2.7 Should the CAC Chair (or Deputy Chair, when the CAC Chair is "interested in a matter") consider that it is in the public interest to permit one or more Members, or Members with a specified class of interest, or take part in any discussion or decision of the CAC relating to a matter, or otherwise participate in any activity of PHARMAC that relates to a matter, they should apply for such permission from the PHARMAC Board Chair. The PHARMAC Board Chair may give such permission if they are satisfied it is in the public interest to do so and may state conditions that the Member(s) must comply with.
- 9.2.8 Where the PHARMAC Board Chair determines that it is "in the public interest" for a Member to continue to participate in a matter, despite any declared conflict of interest, this will be documented in the Minutes.

9.3 Confidentiality

- 9.3.1 Subject to any public law obligations of PHARMAC in relation to the disclosure of information (including under the Official Information Act 1982 ("OIA"), all information, documents and other material relating to matters on the CAC's agenda, as well as the proceedings of the CAC, which are marked as confidential, are confidential to the CAC and to PHARMAC. Members must comply with any communications regarding confidentiality obligations issued by PHARMAC and will, if required, sign confidentiality undertakings.
- 9.3.2 Members are required to store all material received from PHARMAC in a secure place until the matter has been finally determined by PHARMAC, after which time Members must either destroy the material (by secure destruction) or return it to PHARMAC.

9.4 External Communications and Public Statements

9.4.1 Members may only speak to the media, researchers or research organisations in relation to the activities of the CAC or PHARMAC and any matters discussed at or considered by the CAC at its meetings, if they have the prior agreement of the CAC Chair and the PHARMAC Chief Executive.

10 Management of meetings

10.1 Meetings of the CAC

- 10.1.1 The CAC Chair or the Deputy Chair is to preside at each meeting of the CAC unless the CAC Chair delegates authority to another CAC Member.
- 10.1.2 CAC meetings are normally held in Wellington no less than twice a year. CAC may also meet by teleconference or provide advice or make recommendations using email discussion for matters that arise between the regular face to face meetings. The CAC Secretary, PHARMAC Chief Executive and the CAC Chair will, acting together, select the dates for the CAC meetings.
- 10.1.3 The quorum for meetings of the CAC is five Members, of whom one Member must be either the CAC Chair or the Deputy Chair. In exceptional circumstances (for example where time is of the essence) the Chairperson may direct that the quorum for a particular meeting is to be four Members.
- 10.1.4 Members can request leave of absence from any particular CAC meeting.
- 10.1.5 Subject to the above, the CAC may regulate its internal procedures in such manner as it thinks fit.

10.2 Remote Media Conferences

- 10.2.1 The CAC may, if the CAC Chair agrees (and the meeting has a quorum), hold a meeting by contemporaneously linking together by remote media conferencing (such as teleconference or videoconference). To the extent practicable, the rules and procedures relating to the CAC meetings set out in section 10.1 will apply to a meeting held by remote media conference. In addition, the following rules shall apply:
 - (a) notice must have been given to every Member entitled to receive notice of a meeting of the CAC; and
 - (b) each Member taking part in a meeting by remote media conference must:
 - at the start of the meeting, acknowledge the Member's participation in the meeting to the other Members taking part;

- be able to hear the other Members taking part at all times throughout the meeting; and
- be able to individually express his or her view on advice or recommendations.
- 10.2.2 A Member may not leave a meeting held under this section by disconnecting his or her remote media connection unless they have first obtained the permission of the CAC Chair.
- 10.2.3 A Member is to be presumed to have been present, and to have formed part of the quorum, at all times during a remote media meeting unless he or she has been expressly permitted to leave.
- 10.2.4 A Member must ensure that their participation in a meeting is confidential and, in the event that their comments may be overheard by a third party they must declare this to other Members at the commencement of the meeting.

10.3 Observers

- 10.3.1 Observers may attend meetings at the invitation of the CAC Chair. The number of observers will be restricted to two per meeting. A potential observer must notify the CAC Chair of their desire to be invited to attend a CAC meeting and no later than one week prior to the meeting date. Attendance at a meeting is at the discretion of the Chair and an invitation will be given only for a single specified meeting. Meeting dates for the year will be published on the PHARMAC website at the beginning of each calendar year. The CAC Chair may also invite an observer from a consumer interest group(s) to attend a CAC meeting if he or she considers that an agenda item covers a topic of concern to that group.
- 10.3.2 Observers are not CAC Members and, unless the CAC Chair of the particular meeting otherwise agrees, observers will not have any rights to speak at or otherwise participate in the meeting.
- 10.3.3 Observers will be required to sign confidentiality undertakings, prior to attending any meeting of the CAC. At the discretion of the CAC Chair observers may be excluded from any discussions of a confidential or commercially sensitive nature. The attendance of observers at a meeting will be documented in the Minutes.
- 10.3.4 Observers should not, by their presence, affect any recommendations or advice of the CAC, either by influencing or constraining discussion at any the CAC meeting. If the CAC Chair determines that the presence of an observer is having such an effect, the CAC Chair may require the observer to leave the meeting.

10.4 Publication of the CAC Advice

10.4.1 Once the CAC Chair has received comments from Members and signed off the Minutes the Minutes will be provided to the Board for consideration.

- 10.4.2 PHARMAC will endeavour to publish the Minutes of the CAC meetings on the PHARMAC website within a month of the Board meeting at which the CAC minutes are considered by the Board.
- 10.4.3 Portions of the Minute may be withheld from publication in accordance with the Official Information Act 1982. The names of all observers and attendees at a meeting will be published where PHARMAC considers it appropriate.
- 10.4.4 In addition to the Published Minute the CAC Chair may provide a summary report of, or commentary on, the discussion at meetings, particular topics of interest to consumers, recent activities of the CAC and/or responses from the PHARMAC Board. This information may be published on the PHARMAC website or disseminated electronically.

11 Variation of Terms of Reference

11.1 These Terms of Reference set out the CAC's roles and responsibilities, but are not intended to cover every eventuality. They are to be interpreted flexibly and pragmatically, to allow CAC the scope to adapt as the need arises. These Terms of Reference may be varied or revoked (which may, where PHARMAC considers it appropriate, involve consultation) from time to time, by the PHARMAC Board.

12 Disputes

12.1 Any dispute or disagreement as to the meaning or application of any section in these Terms of Reference (except in relation to the appointment of the CAC referred to in section 4.1 above) is to be determined by the PHARMAC Board, whose decision is final.

13 Transitional Provisions

13.1 Each member of the CAC in office at the commencement of the Terms of Reference may continue in office for the remainder of his or her current term of appointment.

Appendix A: Relevant Statutory Provisions

New Zealand Public Health and Disability Act 2000

- 50 Board of PHARMAC to establish advisory committees
 - (1) The board of PHARMAC must establish the following advisory committees under clause <u>14(1)(a)</u> of Schedule 5 of the <u>Crown Entities Act 2004</u>:
 - (a) a pharmacology and therapeutics advisory committee to provide objective advice to PHARMAC on pharmaceuticals and their benefits:
 - (b) a consumer advisory committee to provide input from a consumer or patient point of view.
 - (2) [Repealed]
 - (3) [Repealed]
 - (4) Despite clause <u>14(1)(a)</u> of Schedule 5 of the <u>Crown Entities Act 2004</u>, the members of the pharmacology and therapeutics advisory committee are appointed by the Director-General in consultation with the board of PHARMAC.

Crown Entities Act 2004

43 No compensation for loss of office

A member of a statutory entity is not entitled to any compensation or other payment or benefit relating to his or her ceasing, for any reason, to hold office as a member.

Remuneration and expenses

47 Remuneration of members

(1) A member of a statutory entity is entitled to receive, from the funds of the entity, remuneration not within section 48 for services as a member at a rate and of a kind determined by—

- (a) the responsible Minister, in the case of a member of a Crown agent or autonomous Crown entity, in accordance with the fees framework; or
- (b) the Remuneration Authority in accordance with the <u>Remuneration Authority Act 1977</u>, in the case of—
 - (i) a member of an independent Crown entity; or

(ii) a member of a Crown agent or autonomous Crown entity that is a corporation sole.(2) The following office holders are not entitled to any remuneration for services as a member of the statutory entity in addition to his or her remuneration in respect of that office:

- (a) a Judge:
- (b) a member of Parliament:

(c) an employee (including a chief executive) within any part of the State services who is acting as a member of the statutory entity as a representative of all or any part of the State services.

48 Expenses of members

A member of a statutory entity is entitled, in accordance with the fees framework, to be reimbursed, out of the funds of the entity, for actual and reasonable travelling and other expenses incurred in carrying out his or her office as a member.

Individual duties of members

57 Duty not to disclose information

- (1) A member of a statutory entity who has information in his or her capacity as a member that would not otherwise be available to him or her must not disclose that information to any person, or make use of, or act on, that information, except—
 - (a) in the performance of the entity's functions; or
 - (b) as required or permitted by law; or
 - (c) in accordance with subsection (2); or

- (d) in complying with the requirements for members to disclose interests.
- (2) A member may disclose, make use of, or act on the information if-
 - (a) the member is first authorised to do so by the board or, in the case of a corporation sole, by the responsible Minister; and
 - (b) the disclosure, use, or act in question will not, or will be unlikely to, prejudice the entity.

Conflict of interest disclosure rules

62 When interests must be disclosed

- (1) In this section, matter means-
 - (a) a statutory entity's performance of its functions or exercise of its powers; or

(b) an arrangement, agreement, or contract made or entered into, or proposed to be entered into, by the entity.

- (2) A person is interested in a matter if he or she-
 - (a) may derive a financial benefit from the matter; or

(b) is the spouse, civil union partner, de facto partner, child, or parent of a person who may derive a financial benefit from the matter; or

(c) may have a financial interest in a person to whom the matter relates; or

(d) is a partner, director, officer, board member, or trustee of a person who may have a financial interest in a person to whom the matter relates; or

- (e) may be interested in the matter because the entity's Act so provides; or
- (f) is otherwise directly or indirectly interested in the matter.
- (3) However, a person is not interested in a matter—
 - (a) only because he or she is a member or an officer of a wholly-owned subsidiary of the entity or of a subsidiary that is owned by the entity together with another parent Crown entity or entities; or
 - (b) because he or she receives an indemnity, insurance cover, remuneration, or other benefits authorised under this Act or another Act; or
 - (c) if his or her interest is so remote or insignificant that it cannot reasonably be regarded as likely to influence him or her in carrying out his or her responsibilities under this Act or another Act; or
 - (d) if an entity's Act provides that he or she is not interested, despite this section.

63 Obligation to disclose interest

(1) A member who is interested in a matter relating to the statutory entity must disclose details of the interest in accordance with section $\underline{64}$ as soon as practicable after the member becomes aware that he or she is interested.

(2) A general notice of an interest in a matter relating to the statutory entity, or in a matter that may in future relate to the entity, that is disclosed in accordance with section $\underline{64}$ is a standing disclosure of that interest for the purposes of this section.

(3) A standing disclosure ceases to have effect if the nature of the interest materially alters or the extent of the interest materially increases.

64 Who disclosure of interests must be made to

The member must disclose details of the interest in an interests register kept by the statutory entity and to—

- (a) the chairperson or, if there is no chairperson or if the chairperson is unavailable or interested, the deputy or temporary chairperson; or
- (b) the responsible Minister, if there is neither a chairperson nor a deputy or temporary chairperson, or if both the chairperson and the deputy or temporary chairperson are unavailable or interested.

65 What must be disclosed

The details that must be disclosed under section 64 are-

- (a) the nature of the interest and the monetary value of the interest (if the monetary value can be quantified); or
- (b) the nature and extent of the interest (if the monetary value cannot be quantified).

66 Consequences of being interested in matter

A member who is interested in a matter relating to a statutory entity-

- (a) must not vote or take part in any discussion or decision of the board or any committee relating to the matter, or otherwise participate in any activity of the entity that relates to the matter; and
- (b) must not sign any document relating to the entry into a transaction or the initiation of the matter; and
- (c) is to be disregarded for the purpose of forming a quorum for that part of a meeting of the board or committee during which a discussion or decision relating to the matter occurs or is made.

67 Consequences of failing to disclose interest

(1) The board must notify the responsible Minister of a failure to comply with section <u>63</u> or section <u>66</u>, and of the acts affected, as soon as practicable after becoming aware of the failure.

(2) A failure to comply with section <u>63</u> or section <u>66</u> does not affect the validity of an act or matter.
(3) However, subsection <u>(2)</u> does not limit the right of any person to apply, in accordance with law,

for judicial review.

68 Permission to act despite being interested in matter

- (1) The chairperson of a statutory entity may, by prior written notice to the board, permit 1 or more members, or members with a specified class of interest, to do anything otherwise prohibited by section <u>66</u>, if the chairperson is satisfied that it is in the public interest to do so.
- (2) The permission may state conditions that the member must comply with.
- (3) The deputy or temporary chairperson may give the permission if there is no chairperson, or if the chairperson is unavailable or interested.
- (4) The responsible Minister may give the permission if there is neither a chairperson nor a deputy or temporary chairperson, or if both the chairperson and the deputy or temporary chairperson are unavailable or interested.
- (5) The permission may be amended or revoked in the same way as it may be given.
- (6) The board must disclose an interest to which a permission relates in its annual report, together with a statement of who gave the permission and any conditions or amendments to, or revocation of, the permission.

69 Entity may avoid certain acts done in breach of conflict of interest rules

(1) A statutory entity may avoid a natural person act done by the entity in respect of which a member was in breach of section $\underline{66}$.

(2) However, the act-

(a) may be avoided only within 3 months of the affected act being disclosed to the responsible Minister under section $\underline{67}$; and

(b) cannot be avoided if the entity receives fair value in respect of the act.

(3) An act in which a member is interested can be avoided on the ground of the member's interest only in accordance with this section.

70 What is fair value

(1) The entity is presumed to receive fair value in respect of an act that is done by the entity in the ordinary course of its business and on usual terms and conditions.

(2) Whether an entity receives fair value in respect of an act must be determined on the basis of the information known to the entity and to the interested member at the time the act is done.

71 Onus of proving fair value

(1) A person seeking to prevent an act being avoided, and who knew, or ought reasonably to have known, of the member's interest at the time the act was done, has the onus of establishing fair value.

(2) In any other case, the entity has the onus of establishing that it did not receive fair value.

72 Effect of avoidance on third parties

The avoidance of an act under section <u>69</u> does not affect the title or interest of a person to or in property that that person has acquired if the property was acquired—

- (a) from a person other than the entity; and
- (b) for valuable consideration; and
- (c) without knowledge of the circumstances of the act under which the person referred to in paragraph (a) acquired the property from the entity.

Miscellaneous provisions relating to board

77 Vacancies in membership of board

The powers and functions of a statutory entity are not affected by any vacancy in the membership of its board.

Employees

- 118 Crown entity to be good employer
 - (1) A Crown entity must, if it employs employees,—

(a) operate a personnel policy that complies with the principle of being a good employer; and(b) make that policy (including the equal employment opportunities programme) available to its employees; and

(c) ensure its compliance with that policy (including its equal employment opportunities programme) and report in its annual report on the extent of its compliance.

(2) For the purposes of this section, a good employer is an employer who operates a personnel policy containing provisions generally accepted as necessary for the fair and proper treatment of employees in all aspects of their employment, including provisions requiring—

(a) good and safe working conditions; and

- (b) an equal employment opportunities programme; and
- (c) the impartial selection of suitably qualified persons for appointment; and
- (d) recognition of—
 - (i) the aims and aspirations of Maori; and
 - (ii) the employment requirements of Maori; and
 - (iii) the need for involvement of Maori as employees of the entity; and

(e) opportunities for the enhancement of the abilities of individual employees; and

(f) recognition of the aims and aspirations and employment requirements, and the cultural differences, of ethnic or minority groups; and

(g) recognition of the employment requirements of women; and

(h) recognition of the employment requirements of persons with disabilities.

(3) For the purposes of this section, an equal employment opportunities programme means a programme that is aimed at the identification and elimination of all aspects of policies, procedures, and other institutional barriers that cause or perpetuate, or tend to cause or perpetuate, inequality in respect of the employment of any persons or group of persons.

Protections from liability of members, office holders, and employees

120 Protections from liabilities of statutory entity

A member, office holder, or employee of a statutory entity is not liable for any liability of the entity by reason only of being a member, office holder, or employee.

- 121 Immunity from civil liability
 - (1) A member of a statutory entity is not liable, in respect of an excluded act or omission,—
 (a) to the entity, unless it is also a breach of an individual duty under any of sections <u>53 to 57</u>:
 (b) to any other person.

(2) An office holder or employee is not liable to any person in respect of an excluded act or omission.

- (3) Nothing in this section affects-
 - (a) the making of an order under section <u>60</u>:
 - (b) the liability of any person that is not a civil liability:
 - (c) the right of any person to apply, in accordance with the law, for judicial review.

122 Indemnities in relation to excluded act or omission

(1) A statutory entity may only indemnify a member, office holder, or employee in respect of an excluded act or omission.

(2) An indemnity under subsection (1) is limited to-

- (a) liability for conduct; and
- (b) costs incurred in defending or settling any claim or proceeding relating to that liability.
- 123 Insurance for liability of member, office holder, or employee

A statutory entity may effect insurance cover for a member, office holder, or employee of the entity in relation to his or her acts or omissions, except an act or omission that is—

- (a) in bad faith:
- (b) not in the performance or intended performance of the entity's functions.

124 Saving of judicial protections from liability

A Judge who is appointed as a member of a statutory entity has the same immunities and limitations or other protections from liability when acting as a member of that entity as he or she would have as a Judge.

125 Breach of indemnity and insurance limits

(1) A member, office holder, or employee who is indemnified or insured by a statutory entity in breach of this Act must repay to the entity the cost of providing or effecting that indemnity or insurance cover, to the extent that the indemnity or insurance cover exceeds that which could have been provided or effected under this Act.

(2) The entity may recover the amount as a debt due in a court of competent jurisdiction.

126 Definitions for protections from liability

In sections 120 to 125,-

effect insurance includes pay, whether directly or indirectly, the costs of the insurance **employee** includes a person who was an employee at any time after the commencement of this Act but who is no longer an employee

entity's functions includes any function that an Act confers separately on a member, office holder, or employee of the entity

excluded act or omission means an act or omission by the member, office holder, or employee in good faith and in performance or intended performance of the entity's functions

indemnify includes relieve or excuse from liability, whether before or after the liability arises, and indemnity has a corresponding meaning

member includes a person who was a member at any time after the commencement of this Act but who is no longer a member

office holder includes a person who was an office holder at any time after the commencement of this Act but who is no longer an office holder.

Subpart 3—Miscellaneous provisions

- 135 Members, office holders, and employees are officials
 - (1) This section applies to-
 - (a) members, office holders, and employees of the following Crown entities:
 - (i) a statutory entity:
 - (ii) a Crown entity company:
 - (iii) a school board of trustees:
 - (iv) a Crown entity subsidiary that is wholly owned by 1 or more Crown entities referred to in subparagraphs (i) to (iii):
 - (b) office holders and employees of-
 - (i) a tertiary education institution:
 - (ii) a Crown entity subsidiary that is wholly owned by 1 or more tertiary education institutions or by 1 or more tertiary education institutions and 1 or more Crown entities referred to in paragraph (a)(i) to (iii).

(2) A person to whom this section applies is an official for the purposes of sections <u>105</u> and <u>105A</u> of the <u>Crimes Act 1961</u>.

(3) This section does not limit the meaning of official in section <u>99</u> of the <u>Crimes Act 1961</u>.

Reporting: Annual report

152 Disclosure of payments in respect of members, committee members, and employees

(1) The annual report must include, in respect of the Crown entity or, in the case of a Crown entity group, for each Crown entity in the group,—

- (a) ...
- (b) ...
- (c) ...
- (d) ...

(e) details of any indemnity provided by the entity during the financial year to any member, office holder, or employee; and

(f) details of any insurance cover effected by the entity during the financial year in respect of the liability or costs of any member, office holder, or employee.

(2) In subsection (1), member and office holder and employee include a person who was a member or office holder or employee at any time after the commencement of this Act but who is no longer a member, office holder, or employee.

Transitional and savings provisions

189 Existing protection from liability provisions

 (1) This section applies to a member, an office holder, or an employee of a Crown entity who is entitled, immediately before the date of commencement of this section, to be indemnified by a Crown entity in respect of any proceedings for any liability or costs arising from any act or omission as a member, office holder, or employee that occurred before that date.
 (2) This Act does not affect the member, office holder, or employee's entitlement to an indemnity if that entitlement is, in its overall effect, as favourable to that person as, or more favourable to that person than, the entitlement provided for in this Act.

190 Existing insurance cover

(1) This section applies to a member, office holder, or employee of a statutory entity who has insurance cover at the commencement of this section in respect of any liability or costs arising from any act or omission as a member, office holder, or employee.

(2) The insurance cover is not affected by the enactment of this Act.

(3) However, if the insurance cover expires, or the member, office holder, or employee is reappointed or re-employed, the insurance can be renewed or effected only if permitted by this Act or the entity's Act.

Schedule 5 - Board procedure for statutory entities (other than corporations sole)

Procedure of board

- 14 Board may appoint committees
 - (1) The board may, by resolution, appoint committees-
 - (a) to advise it on any matters relating to the entity's functions and powers that are referred to the committee by the board; or
 - (b) to perform or exercise any of the entity's functions and powers that are delegated to the committee, if the committee includes at least 1 member of the board and any other person or persons that the board thinks fit.
 - (2) A person must not be appointed as a member of a committee unless, before appointment, he or she discloses to the board the details of any interest the person may have if he or she were a member of that committee.
- 15 Provisions relating to committee members

Sections <u>43</u>, <u>47</u>, <u>48</u>, <u>57</u>, <u>77</u>, <u>118</u>, <u>120 to 126</u>, <u>135</u>, <u>152(1)(e)</u>, <u>(f)</u>, and <u>(2)</u>, <u>189</u>, and <u>190</u> apply to each member of a committee who is not a member of the board with necessary modifications.
 Sections <u>62 to 72</u> apply to each member of a committee who is not a member of the board as if the committee member were a board member and as if the disclosure must be made to both the committee and the board, and with other necessary modifications.

Appendix B: Conflicts of Interest declaration guidance for Members & Chairs

Members

In making a declaration please consider that your role or position may extend to a range of contexts and different issues will arise according to the context. Therefore please carefully consider the following questions, treating them as a prompt to help identify possible conflicts when contemplating a declaration:

1. What sectors do I work in / what bodies, groups or associations am I a member of / what personal or financial interests do I or members of my family have / what business or personal relationships do I have (including past involvement)?

Consider (without limitation):

- official positions e.g. director, shareholder, trustee;
- personal and social relationships;
- consultant/advisory roles (including provision of expert evidence or opinion);
- involvement in clinical research/development;
- political affiliations;
- your sources of income and other areas of financial benefit or opportunity(or that of your close family members);
- attendance at events funded by industry.
- 2. Thinking about my role(s) for PHARMAC or one of PHARMAC's committees, what types of information can I expect to see / what responsibilities will I have / what types of judgements or decisions will I be expected to make?

For example:

- Advice to Ministers of Parliament;
- Confidential commercial information from pharmaceutical suppliers;
- Confidential information about PHARMAC strategies;
- Patient information;
- PHARMAC Legal advice in relation to (but not limited to) commercial matters, litigation, intellectual property;
- Operational/financial information;
- Unpublished study information (i.e clinical research).
- 3. Is there any foreseeable possibility that one of my roles / duties / responsibilities with PHARMAC or a committee might intersect with one of my other interests / relationships / roles and that the latter might influence the way I carry out my PHARMAC/committee role?

Consider specifically whether confidential information you may see could be relevant to another role that you have, or whether your views or interests as a result of another role or relationship could potentially affect your role with PHARMAC or the committee.

When you have considered the above questions, determine whether there are any potential (though realistic - not purely hypothetical and remote) conflicts of interest that should be

declared to the PHARMAC Board and the CAC. This includes any potential for a perceived conflict, whether or not you would actually be influenced by the interest. It may be useful to bear in mind the perspective of someone negatively impacted by a decision and how they might argue that there was a conflict of interest that prevented you acting objectively in the event they wanted to challenge the process by which a particular outcome was reached. You should always err on the side of caution, and disclose more rather than less. If in doubt, disclose. In each case disclose in such a way that an independent party could properly understand the true nature and extent of the interest.

Chair

When assessing a declared actual or potential conflict of interest consider:

It is unmanageable?

- The person cannot or will not divest themselves of the conflict i.e. unavoidable; and
- is serious; or
- is pervasive and would affect so many of PHARMAC's/the committee's decisions that management mechanisms are not practical.

Is it Manageable?

- Where the person is prepared to divest themselves of or sever connection with the conflict; or
- the conflict is so minor or remote that it cannot reasonably be regarded as likely to influence the person in carrying out their responsibilities; or
- there is little risk of a negative public perception; or
- the conflict affects a confined area of PHARMAC's/the committee's operations and can be adequately "ring-fenced" from other aspects that it could, or could be seen to, affect.

What are the management and mitigation strategies?

- Divestment where the person agrees to divest themselves of the interest creating the conflict (this is likely to be necessary where the conflict of interest is serious and pervasive but avoidable through divestment).
- Severing connections resignation from one or other position or entity (this is likely to be necessary where the conflict of interest is serious and pervasive but avoidable by severence).
- Blind trust where assets can be transferred to a trust managed by trustees with nearly complete autonomy and the person retains very little knowledge or control over the transferred assets.
- Withdrawing from discussion must be declared and noted on each occasion in the meeting minutes.
- Abstaining from voting must be declared and noted on each occasion in the meeting minutes.
- Non-receipt of relevant information in addition to declaring an interest, withdrawing from the discussions and voting, the person agrees not to be given any information (written or oral) relating to the interest.

- Agreement not to act where the person does not participate in any other action concerning the interest e.g. signing documents relating to the interest on behalf of PHARMAC/the committee.
- Transferring the person (temporarily or permanently) to another position or project.
- Re-assigning certain tasks or duties to another person.
- Seeking a formal exemption (e.g. from the Board) to allow participation.
- Enquiring as to whether all affected parties will consent to the person's involvement.
- Declarations of interest where the interest is retained but is declared when related issues arise for discussion or decision (must be declared and noted on each occasion in the meeting minutes).
- Confidentiality agreements where the person agrees not to pass on confidential information.
- Imposing additional oversight or review over the person (e.g. peer review, where for example a person's role can only be performed by that particular person and the conflict is not viewed as particularly serious).

These methods can be used singly or in combination depending on the nature and extent of the conflict being considered. There may be some situations where a conflict is inevitable and unavoidable, and the matter cannot reasonably be dealt with without the person's involvement.