

1998

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**HEALTH LEGISLATION AMENDMENT BILL (NO,3) 1998**

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Aged Care,  
the Hon Dr Michael Wooldridge, MP)

## **HEALTH LEGISLATION AMENDMENT BILL (NO. 3) 1998**

### **OUTLINE**

This Bill amends the *National Health and Medical Research Council Act 1992* by addressing some of the administrative and procedural issues which have prevented the National Health and Medical Research Council (the Council) from discharging its statutory functions in an effective and efficient manner.

This Bill changes the public consultation provisions to introduce a more streamlined, single stage public consultation process when Council intends to issue guidelines or approve guidelines developed by other organisations. Where Council is making regulatory recommendations or engaging in a prescribed activity the existing two stage public consultation process is retained. The changes allow continued transparency and comprehensive public consultation with respect to Council processes but recognise that the existing two stage process is time consuming and cumbersome to administer in some particular instances.

The Bill also makes some minor changes to a principal committee name (the Medical Research Committee to be renamed the Research Committee) and to some of Council's committee operations. Provisions have been added which enable Principal Committees to appoint a Deputy Chairperson and extend the Council's power to delegate to a working committee and the Chairperson of the Council. These changes better reflect committee objectives and assist the smooth running of Council business.

### **FINANCIAL IMPACT**

There are no financial implications.

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### NOTES ON CLAUSES

#### Clause 1 – Short Title and Clause 2 – Commencement

The first two clauses deal with the short title of the Bill and with commencement dates of the legislation. Schedule 1 will come into effect on the date on which it receives Royal Assent.

#### Clause 3 – Schedule

This clause provides for the Act referred to in the Schedule to the Bill to be amended in the manner indicated.

#### Schedule 1 – Amendment of the National Health and Medical Research Council Act 1992

**Item 1** – amends section 4 (paragraph (b) of the definition of *reviewable action*) by changing the reference to the Medical Research Committee in line with changes made in item 7 to section 35 of the Act.

**Item 2** – amends subsection 8(3) to take into account renumbering of the public consultation provisions by items 3 to 6.

Subsection 8(3) requires the Australian Health Ethics Committee to comply with the statutory requirements for public consultation. This item does not change any of the requirements contained in this subsection.

**Item 3** – repeals and replaces sections 12 and 13.

This item replaces section 12 with a similar provision to the existing section 12 except that the new section 12 excludes reference to guidelines which are now dealt with separately. A two stage consultation process is retained for regulatory recommendations and prescribed activities. New section 12 now provides for a summary of a draft regulatory recommendation or outline of a prescribed activity to be publicly notified for the purposes of the second stage consultation and also requires notification as to where full copies can be obtained.

This item also inserts a new section 13 which outlines the public consultation process to be followed by Council before issuing guidelines. The single stage process takes place after a draft guideline has been written and requires Council to advertise its intention to issue a guideline and to include an outline of the draft guideline in the advertisement. The amendment also requires Council to state where copies of the draft guideline can be obtained and makes clear that Council must take into account submissions received before issuing a draft guideline.

**Items 4 and 5** – amend section 14 to include a reference to new section 13, allowing Council to take urgent interim action in relation to guidelines and thus retaining the intention of the existing section 14.

**Item 6** – inserts a new section 14A allowing Council to approve guidelines prepared by another person or body.

A number of organisations seek Council endorsement for guidelines they have developed, a situation not envisaged when the Act was originally drafted. As a result, under the existing legislation, Council can only endorse externally developed guidelines if it undertakes a two stage process of consultation, irrespective of whether public consultation had already been undertaken by the organisation.

Council recognises that many organisations are now implementing the standards Council endorsed in “*Guidelines for the Development and Implementation of Clinical Practice Guidelines*”. Because of this, those organisations are undertaking rigorous consultation during the development of guidelines. To require further rounds of consultation by Council is time consuming, costly and duplication of effort.

This item permits Council to scrutinise the development process of external organisations, certify that it accords with Council’s own rigorous consultation process, and when satisfied, endorse those externally developed guidelines.

Item 6 also inserts a new section 14B which replaces existing section 13. This section provides for consultation to be dispensed with or modified in certain circumstances. The renumbering of this section provides a more logical sequence to the consultation provisions. The new section also references all the preceding sections which refer to consultation by Council.

**Items 7 and 8** – amend section 35 so that all references to ‘Medical Research Committee’ become references to ‘Research Committee’ and all references to ‘medical research’ include references to ‘public health research’.

Whereas in the past medical research has been dealt with by the Medical Research Committee and there has been a separate public health research and development committee these two types of research are now to be dealt with by one committee with responsibility for medical and public health research and development.

**Item 9** – inserts a new section 37A making provision for matters relating to meetings of Principal Committees and the Executive Committee and the appointment and duties of Deputy Chairpersons of those Committees.

This item permits the appointment of Deputy Chairpersons to assist with the heavy workloads and commitments of committee chairpersons and specifies the duties and authority of the Deputy Chairperson.

**Item 10** – inserts in subparagraph 38(b)(iii) a reference to the Deputy Chairperson.

This item recognises that only in the absence of both the Chairperson and the Deputy Chairperson will Council need to appoint a member to preside at meetings.

**Items 11, 12 and 13** – insert into section 39 a reference to the Council being able to establish working committees, a power previously only given to Principal Committees.

The items give Council the authority to appoint working committees under the same terms and conditions as working committees appointed by Principal Committees.

**Items 14, 15 and 16** – amend subsections 42(2), 43(3) and 44(4) to take account of Council being given the power to establish working committees under item 11.

These items address leave of absence, resignation and termination of membership and ensure that such working committees are governed by the same provisions as working committees established by Principal Committees.

**Items 17 and 18** - amend paragraphs 56(2)(c) and 67(1)(a) to reflect the name change to 'Research Committee' provided for in item 7.

**Items 19 and 20** – insert new paragraphs (aa) and (ba) into subsection 82(2) to give Council the power to delegate to the Chairperson of the Council and to a working committee established by the Council.

Currently the Council can only delegate all or any of its powers to a Principal Committee, the Executive Committee and the Secretary to the Council. The addition of the Chairperson of Council would allow streamlining of administration and procedures. The addition of a working committee established by Council will allow that Committee to operate more effectively.