Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines

May 2011 version 1.1

Electronic document

ISBN Online: 1864964642

This document replaces *NHMRC standards and procedures for externally developed guidelines* (2007).

This document will apply to all externally developed clinical practice guidelines for which intention to seek NHMRC approval is registered on or after 1 January 2011.

Preferred citation

National Health and Medical Research Council. *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines*. Melbourne: National Health and Medical Research Council; 2011.

Revision history

The following table describes a summary of the changes made to this document since original publication.

Version	Date	Amendment notes
1	May 2011	First publication
1.1	January 2012	Minor formatting corrections

Contact:

National Health and Medical Research Council
Level 1
16 Marcus Clarke Street
Canberra ACT 2601

GPO Box 1421
Canberra ACT 2601

Ph: 61 2 6217 9000
Fax: 61 2 6217 9100
Email: nhmrc@nhmrc.gov.au
Website: **www.nhmrc.gov.au**

NHMRC Reference code: **CP133**

Table of contents

List of tables and figures

How to contact NHMRC

Email: clinicalguidelines@nhmrc.gov.au

Telephone: 03 8866 0400

At any time please contact NHMRC to:

- provide updates on the timeline for development of a clinical practice guideline seeking NHMRC approval
- ask for more information, including dates of NHMRC Council meetings to facilitate timing of guideline submission for consideration for approval
- submit documents as required
- enquire about a guideline submission.

Information on clinical practice guidelines developed for use in Australian health care settings can be accessed through the Clinical Practice Guidelines Portal www.clinicalguidelines.gov.au.

Proposed clinical practice guidelines should be listed on Guidelines in Development Register: www.clinicalguidelines.gov.au/in-development/register.

About NHMRC approval

NHMRC approval of a clinical practice guideline is generally valid for a maximum of five years, and applies only to the version of the guideline that was approved by NHMRC. Subsequent versions must be resubmitted for approval.

Approval of an externally developed clinical practice guideline indicates that NHMRC considers that the guideline is based on the systematic identification and synthesis of the best available scientific evidence and makes clear recommendations for health professionals practising in Australia.

NHMRC will only approve guidelines that meet all the mandatory requirements listed in Part 3 of this document. Developers are encouraged to meet the desirable requirements to improve guideline quality and implementability.

Guidelines with NHMRC approval are recognised in Australia and internationally as representing current medical knowledge and best practice in health care.

More information

Resources for developers of clinical practice guidelines and up-to-date information about the approval process is available at www.nhmrc.gov.au/guidelines/developers.htm.

1. Introduction

The National Health and Medical Research Council (NHMRC) has a statutory responsibility to provide leadership in the development of high-quality clinical practice guidelines in Australia. Under Section 14A of the Commonwealth National Health and Medical Research Council (NHMRC) Act 1992[1], NHMRC can also approve selected clinical practice guidelines developed by other organisations.

As part of this role, NHMRC sets standards in clinical practice guideline development (outlined in Box 1.1). Clinical practice guidelines should be based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian health care setting. The NHMRC requirements for developing clinical practice guidelines are designed to ensure that this standard is upheld.

The *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines* replace those described in *NHMRC standards and procedures for externally developed guidelines* (2007). The new procedures and requirements draw on Australian and international best practice and incorporate dimensions from internationally validated guideline appraisal instruments.[2-4]

This document applies to all new and revised clinical practice guidelines seeking NHMRC approval from 1 January 2011. Key changes to the approval process are outlined in Box 1.2.

BOX 1.1 Summary of NHMRC standard for clinical practice guidelines

To meet the NHMRC standard, clinical practice guidelines must:

- provide guidance on a clearly defined clinical problem based on an identified need
- be developed by a multidisciplinary group that includes relevant experts, end users and consumers affected by the clinical practice guideline
- include a transparent process for declaration and management of potential conflicts of interest by each member of the guideline development group
- be based on the systematic identification and synthesis of the best available scientific evidence
- make clear and actionable recommendations in plain English for health professionals practising in an Australian health care setting
- be easy to navigate for end-users
- undergo a process of public consultation and independent external clinical expert review
- incorporate a plan for dissemination including issues for consideration in implementation

Purpose

The purposes of this document are to:

- describe the NHMRC standard for clinical practice guidelines
- outline the procedures for NHMRC approval of clinical practice guidelines developed by external organisations (Part 2)
- set out the requirements that must be met in the preparation of clinical practice guidelines to ensure that the NHMRC standard is upheld (Part 3).

Further information, including forms and templates for aspects of the approval process, are available at http://www.nhmrc.gov.au/guidelines/information-guideline-developers.

Scope

Target users

This information is provided for developers of clinical practice guidelines who intend to seek NHMRC approval. Ideally, it should be read *before* beginning the process of developing a clinical practice guideline. This document may also be useful to funders of clinical practice guidelines who wish to be informed by the NHMRC standard.

NHMRC will consider for approval guidelines that have been produced under the auspices of expert organisations[i] including medical colleges, peak bodies representing medical specialists, medical special interest associations, professional societies, public or private health organisations, non-government agencies and federal or state government agencies.

The NHMRC does not consider for approval clinical practice guidelines:

- developed and issued by individuals who are not officially sponsored or supported by one of the above types of organisations
- developed, published or funded by industry groups (or organisations whose main source of funding is derived from industry groups) with a financial interest[ii] in the guideline clinical area.

Types of guidelines to which this document applies

These procedures and requirements apply to clinical practice guidelines developed for national use within Australia and published in full-text format.

New editions of previously published clinical practice guidelines seeking NHMRC approval (whether or not they were previously approved by NHMRC) should also follow the *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines* (2011), each time they are revised to include new clinical evidence. This document does not apply to guidelines published only in a web-based format with frequent, rapid updating.

i For an overview of the types of organisations that have developed NHMRC-approved guidelines, visit the NHMRC Clinical Practice Guidelines Portal (www.clinicalguideline.gov.au) and in the 'Browse by' field choose 'NHMRC approved' from the menu.

ii Information about conflict of interest is currently under development by NHMRC.

BOX 1.2 Summary of what has changed

Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines (2011) replaces *NHMRC standards and procedures for externally developed guidelines* (2007). Developers should note the following key differences:

- All clinical practice guidelines seeking NHMRC approval must now register on the Guidelines in Development Register (www.clinicalguidelines.gov.au/in-development) at the beginning of the process (Part 2: Procedures, Stage 1). Early notification prior to commencement will enable NHMRC to process this request and notify developers in a timely manner. Developers should ensure that timing of registration will enable them to submit progress reports at required intervals.
- All clinical practice guidelines approved by NHMRC must now include a brief (1-page) plain English summary (Part 3: Requirements, E.3).
- Developers are now required to circulate the public consultation draft to relevant government agencies, including the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC), and to the Director-General, Chief Executive or Secretary of each Australian health department (state, territory and Commonwealth) as part of the public consultation process.
- Developers are now required to identify and consult with key professional organisations (such as specialty colleges) and consumer organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline.
- Developers are now required to engage at least 2 reviewers, who must be independent of the guideline development process, to assess the guideline using the AGREE II instrument[3,5] prior to submission of the final draft guideline to NHMRC for approval. This enables the assessment of guidelines against internationally accepted appraisal instruments (Part 3: Requirements, D.15).
- Developers will be asked to nominate up to 6 potential reviewers who are clinical experts in area/s covered by the guideline and are independent of the guideline development process. NHMRC will engage independent clinical expert reviewers as part of the approval process (Part 2: Procedures, Stage 4).
- As part of the public consultation process, NHMRC will notify NHMRC Council Members that the public consultation draft is available for their comment as individuals or on behalf of their jurisdictions (Part 2: Procedures, Stage 2).
- The NHMRC Guidelines Assessment Register (GAR) program has ceased. Guideline developers are now responsible for accessing methodological expertise (Part 1: Introduction, Expertise and resources).

Before starting guideline development

Expertise and resources

Guideline development is a complex, lengthy and resource-intensive task. It is the responsibility of the developer organisation to ensure that the resources required (financial support, access to clinical and methodological expertise, and project management and administrative capacity) have been considered and secured prior to commencement.

During guideline development, NHMRC staff are available to provide developers with further information or clarification of the NHMRC standard. Developers are strongly advised to access methodological expertise, in addition to and separate from clinical or content expertise, to assist them in the systematic identification, appraisal and interpretation of clinical evidence.

In addition, NHMRC resources (Box 1.3) have been published to provide further guidance for developers. These resources are scheduled for revision by NHMRC from 2011.

BOX 1.3. NHMRC resources for guideline developers

A guide to the development, evaluation and implementation of clinical practice guidelines (1999)

This publication includes the accompanying handbooks:

How to review the evidence: systematic identification and review of scientific literature (2000)

How to present the evidence for consumers: preparation of consumer publications (2000)

How to prepare and present evidence-based information for consumers of health services: a literature review (1999)

How to put evidence into practice: implementation and dissemination strategies (2000)

How to use the evidence: assessment and application of scientific evidence (2000)

How to compare the costs and benefits: evaluation of the economic evidence (2001)

Using socioeconomic evidence in clinical practice guidelines (2003)

These publications are available at http://www.nhmrc.gov.au/guidelines/resources-guideline-developers

Managing timelines

Indicative times taken for NHMRC to respond at each stage of the approval process are summarised in Table 2.1 in Part 2. Developers are requested to make an accurate estimate of the guideline development timelines and key milestones (public consultation and submission of the final draft guideline for consideration for approval) at the beginning of the development process. It is the developer's responsibility to notify NHMRC if the timelines change during the development process. Delays may affect eligibility for consideration of the final draft guideline for approval (Part 2: Procedures, Stage 2: Providing a timetable of key milestones).

Version control

A clinical practice guideline seeking NHMRC approval should not be disseminated, prior to approval, other than for public consultation purposes. Drafts circulated for this purposes should be clearly marked as such.

For administrative purposes, the final draft guideline should be submitted electronically as plain text (e.g. Word document, rich text format document or PDF). Developers should be aware that amendments may be requested by NHMRC prior to approval.

Guideline implementation

NHMRC recognises that implementation of guideline recommendations is critical for clinical practice improvement. It should be considered throughout the development of the guideline. In practice, however, many organisations that develop clinical practice guidelines do not have a role in implementation, or do not have access to funding to implement guideline recommendations. Often, the working group responsible for developing the guideline recommendations is not the same group responsible for implementation.

In recognition of this, a set of requirements are included in Part 3: Requirements, G. It is a mandatory requirement that clinical practice guidelines seeking NHMRC approval must, as a minimum, contain a plan for dissemination of the guideline (Requirement G.1) and should highlight key guideline recommendations that are most likely to lead to improvements in health outcomes for consideration in implementation (Requirement G.2). It is a desirable requirement (Requirement G.3) that, where possible, a plan for implementing the guideline is also provided.

NHMRC requires that a document with the dissemination and /or implementation plan along with the key recommendations for implementation is submitted as a separate document to the main body of the clinical practice guideline for consideration of approval at Stage 4. NHMRC approval will cover the full guideline, but not the specific activities or the identified key recommendations contained within the dissemination or implementation plan. It will be the guideline developer's responsibility to liaise with the relevant authorities to put these activities into action.

2. Procedures for seeking NHMRC approval

Summary

The procedures are described as five stages in the following section. The responsibilities of the guideline developer and NHMRC at each stage are summarised in Table 2.1.

TABLE 2.1. Summary of procedures to seek NHMRC approval of clinical practice guidelines

STAGE	WHAT THE DEVELOPER MUST DO	WHAT NHMRC WILL DO
Stage 1. Register intention to seek NHMRC approval	**As soon as possible:**	
	Notify NHMRC of the intention to seek NHMRC approval via the Guidelines in Development Register. NB. Developers should ensure that the timing of registration of their guideline will enable them to submit progress report/s at the required intervals (see Stage 2).	Formally advise developer, in writing, of the CEO's decision whether to consider the guideline for approval. Normally this takes 2–4 weeks from date of registration, unless the CEO seeks advice from Council. Notify AHMAC if NHMRC agrees to consider guideline
MILESTONE: NHMRC AGREES TO CONSIDER GUIDELINE FOR APPROVAL		
Stage 2. Develop guideline in accordance with NHMRC requirements	**As soon as possible:**	
	Submit timeline of key milestones. An accurate estimate of date for planned public consultation is required.	Acknowledge the proposed timeline in writing.
	3–6 months before planned public consultation period:	
	Submit progress report (including nominations of potential clinical expert reviewers). Address any issues identified by NHMRC within one month from receipt of response to progress report.	Inform developer in writing if any major issues or gaps in the development process are identified (4–8 weeks from receipt of progress report).
	At any time:	
	Notify NHMRC in writing if timelines change.	Advise developer of any updates as required.

STAGE	WHAT THE DEVELOPER MUST DO	WHAT NHMRC WILL DO
Stage 3. Release draft guideline for public consultation	Confirm the start date of the public consultation period with NHMRC 2 weeks prior to the publication of the first notice of public consultation. Provide the draft guideline and details of public consultation, including dates, web links and submission requirements to NHMRC five days prior the start date of the public consultation period. Release draft guideline for public consultation in accordance with requirements (Refer to Part 3: F. Public consultation). Provide draft guideline to relevant stakeholders, including TGA, PBAC and MSAC, the Director-General, Chief Executive or Secretary of state, territory and Commonwealth departments of health, and key professional organisations (such as specialty colleges) and consumer organisations that will be involved in or affected by the implementation of guideline recommendations. Document and address all comments received during public consultation. Notify NHMRC of intended date for submission of final guideline draft for approval (at least 2 months prior to submission date).	Notify Council members of the public consultation period and how to access the draft. Request that Council members who wish to provide comments as individuals† do so directly to developer during the specified public consultation period. Encourage Council members to seek advice from their jurisdictions or other expert sources within their networks, as they see fit.
Stage 4. Submit final draft guideline	Submit final draft guideline to NHMRC for approval (at least two months prior to the Council meeting at which developer requests the final draft guideline to be considered).* Address any issues raised by reviewers as requested by NHMRC. Address any issues raised at or prior to Council meeting.	Arrange independent methodological and clinical expert review of final draft of guideline. Consider methodological and clinical expert reviewers' comments. Seek further information from developer in preparation of papers for Council consideration (if required). Inform developer in writing whether the guideline is approved by NHMRC (up to 4 weeks after Council meeting).
MILESTONE: NHMRC APPROVES GUIDELINE		
Stage 5. Publish approved clinical practice guideline	Publish and disseminate guideline within 16 weeks of date of NHMRC approval, in accordance with NHMRC publishing requirements.	Inform developer of the NHMRC publishing obligations and requirements. Once published, assess guideline for inclusion on Clinical Practice Guidelines Portal§ and announce in NHMRC publications (NHMRC Tracker[6] and NICS Update[7]).

AHMAC: Australian Health Ministers Advisory Council
Council: Council of the NHMRC
PBAC: Pharmaceutical Benefits Advisory Committee
CEO: NHMRC Chief Executive Officer
MSAC: Medical Services Advisory Committee
TGA: Therapeutic Goods Administration

Contact details for these agencies are available from NHMRC.

* Developers should approach NHMRC to request information on upcoming Council Meeting dates.

† Comments submitted at this Stage represent those of individual Council members and/or their jurisdictions, and not those of the NHMRC Council.

§ All clinical practice guidelines produced in Australia are assessed prior to inclusion on the NHMRC Clinical Practice Guidelines Portal (www.clinicalguidelines.gov.au/about.php).

Document preparation

It is the responsibility of the guideline developer to document all processes and to demonstrate how they meet the NHMRC mandatory requirements for approval. A list of documents required for submission to NHMRC is summarised in Table 2.2.

TABLE 2.2. Summary of documents required for NHMRC approval of clinical practice guidelines

DOCUMENT NAME	DESCRIPTION	SUBMISSION TIME
Progress report	Provides details of aspects of the guideline development process. The developer must submit a progress report to confirm the intention to seek NHMRC approval (progress report template available at http://www.nhmrc.gov.au/guidelines/resources-guideline-developers).	Approximately 6 months (and not later than 3 months) before the draft guideline is released for public consultation. If the timeline is altered due to delays in guideline development, NHMRC may request further progress reports.
Draft guideline	Draft guideline with content intended for use in clinical setting.	Public consultation draft and final draft versions required.
Technical report	A record of the evidence review process (refer to Part 3: Requirements for the information to be included).	Submitted with final draft for approval. Should also be made available with public consultation draft.
Administrative report	Non-technical information relating to process of guideline development (refer to Part 3: Requirements for the information to be included).	Submitted with final draft for approval. May also be made available with public consultation draft.
Dissemination plan	A document separate from the main guideline document which contains, at a minimum, details of the dissemination plan for the guideline. This document should also highlight key guideline recommendations that are most likely to lead to improvements in health outcomes, for consideration in implementation.	Submitted with final draft or approval. Should also be made available with public consultation draft.
Public consultation submissions summary	Documents details of public consultation submissions and guideline developer responses (further information on public consultation is available at: http://www.nhmrc.gov.au/guidelines/resources-guideline-developers).	Submitted with final draft or approval.

For NHMRC administrative purposes, developers must submit documents electronically in plain text (e.g. DOC, PDF or rich text format). Once approved, developers may choose to publish their final guideline in print, electronic or interactive online formats.

The information that is required to be included in the guideline (including appendices), the administrative report and the technical report is detailed in Part 3: Requirements. All information in the technical and administrative reports must be readily accessible to the public when the guideline is published (Part 3: Requirements E.11–E.12).

Stage 1. Register intention to seek NHMRC approval

Registration

The NHMRC Guidelines in Development Register (www.clinicalguidelines.gov.au/in-development) provides a central point of reference for Australian clinical practice guidelines that are planned or under development. It is designed to reduce duplication of effort and foster greater collaboration between guideline developers. The Guidelines in Development Register also acts as the entry point for developers of clinical practice guidelines to identify their intention to seek NHMRC approval of their final draft guideline.

Before proposing a new clinical practice guideline, it is the responsibility of guideline developers to undertake a formal needs analysis to inform the guideline scope. This should draw on information listed in the NHMRC Clinical Practice Guidelines Portal and Register (www.clinicalguidelines.gov.au), and include an assessment of burden of disease and identification of the clinical problem (including variation in clinical practice).

All developer organisations intending to seek NHMRC approval of clinical practice guidelines should register proposed guidelines on the NHMRC Guidelines in Development Register before starting the development process (www.clinicalguidelines.gov.au/in-development/registration-form).

NHMRC will notify developers when their proposed clinical practice guidelines have been listed on the NHMRC Guidelines in Development Register.

IMPORTANT

Early notification prior to commencement will enable NHMRC to process this request and notify developers in a timely manner. Developers should ensure that the timing of registration of a guideline seeking NHMRC approval will enable progress report submission timelines to be met.

Initial assessment of eligibility for approval consideration

Following registration, NHMRC will assess the scope of the proposed clinical practice guideline to determine whether the registered guideline will be considered by NHMRC for approval.

The final decision on whether to agree to consider a guideline for approval is made by the NHMRC's Chief Executive Officer (CEO). The CEO may choose to seek further advice from NHMRC Council before making this decision. NHMRC will formally advise the developer, in writing, of the CEO's decision.

Only guidelines intended to apply nationally will be considered for approval. NHMRC will not consider for approval guidelines developed for a specific local context or health service.

If the CEO declines to consider a guideline for approval, a reason will be stated.

When a guideline is accepted to be considered for NHMRC approval, NHMRC will routinely notify the Australian Health Ministers Advisory Council (AHMAC) to give state and territory health departments advance notice of current guidelines in development seeking NHMRC approval.

Stage 2. Develop guideline in accordance with NHMRC requirements

Provide a timetable of key milestones

When beginning the guideline development process, it is essential that the developer determines an accurate estimate of when the guideline will be released for public consultation, as well as an estimate of the final submission date.

At any time in the development process the developer must notify NHMRC if the dates of public consultation or final submission change, to allow the planned NHMRC-commissioned review process to be adjusted. At any time NHMRC may request more information from developer, if appropriate.

A realistic and accurate timeline is crucial, as it is a mandatory requirement (Part 3: Requirement C4) that the systematic review is current and includes evidence published within:[iii]

- 12 months of the date on which the draft guideline is released for public consultation
- 20 months of the date on which the final draft guideline is submitted to NHMRC for approval.

IMPORTANT

Estimates of timelines for public consultation and final submission must be as accurate as possible. Delays may affect eligibility for consideration of the final draft guideline for approval.

Evidence review

Each guideline should be based on a systematic review and critical appraisal of the current scientific literature (Part 3: Requirements, C). Further guidance on evidence review, including *NHMRC levels of evidence and grades for recommendations for developers of clinical practice guidelines* (2009), is available at http://www.nhmrc.gov.au/guidelines/resources-guideline-developers.

Progress report

To confirm the intention to seek NHMRC approval for a clinical practice guideline, the developer must submit the first progress report approximately six months (and not later than three months) before the draft guideline is released for public consultation (progress report template available at http://www.nhmrc.gov.au/guidelines/resources-guideline-developers). NHMRC will inform the developer in writing if any major issues or gaps in the development process are identified within 4–8 weeks from receipt of the progress report.

If delays in guideline development occur that alter the timeframes for the public consultation and/or final submission dates, further progress reports may be requested by NHMRC.

At this time developers will also be requested to nominate potential clinical expert reviewers for the final assessment at Stage 4. Guidance for developers on identifying appropriate potential clinical expert reviewers is available from http://www.nhmrc.gov.au/guidelines/resources-guideline-developers.

iii This is to ensure that evidence base used to support guideline recommendations is within two years of the publication date of the guideline.

Other documents the developer must prepare during Stage 2

In addition to the draft guideline, the draft technical and administrative reports (see Part 2: Document preparation) must be prepared during this stage.

The technical report must be submitted with final draft for approval. It should also be made available with public consultation draft.

The administrative report must also be submitted with final draft for approval. It may also be made available with the public consultation draft.

Stage 3. Release draft guideline for public consultation

Publishing a notice of public consultation

In accordance with Section 14A of the *NHMRC Act 1992* (Cwlth)[1] and *NHMRC Regulations* 2006 (Cwlth)[8],developers seeking NHMRC approval must publish a notice inviting public submissions on the draft guideline for a minimum period of 30 days (Part 3: Requirements F.1). In summary:

- The developer must publish a notice in at least one major national daily newspaper. The developer may also publish a notice in any other way the organisation or group of organisations considers appropriate.
- The notice must contain a summary of the draft guidelines and state where copies of the draft guidelines could be obtained. Developers should ensure that this public consultation draft guideline is clearly marked to indicate its draft status.
- The notice must identify the last day the developer will accept submissions, which must be, at a minimum, 30 days after the notice is first published.

Further detail regarding requirements for public consultation, including a suggested format for the consultation notice, is available at: http://www.nhmrc.gov.au/guidelines/resources-guideline-developers.

The developer may also undertake additional consultation at this time or at any time during guideline development.

Developers may wish to use additional methods to publicise their public consultation period (including media releases or public events).

If the public consultation draft refers to NHMRC approval, it must clearly indicate that the guideline has not yet been approved by NHMRC and that approval, if granted, would apply to the final draft that is yet to be submitted for consideration following any amendments made after public consultation. Before public consultation, developers should contact NHMRC (see How to Contact NHMRC) for advice on the permitted wording of references to NHMRC and NHMRC approval.

Notifying NHMRC of public consultation

Developers are requested to confirm the start date of the public consultation period with NHMRC two weeks prior to the publication of the first notice of public consultation.

Developers are requested liaise with the NHMRC staff to ensure the draft guideline and details of public consultation, including dates, web links and submission requirements are provided to NHMRC five days prior to the start date of the public consultation period.

When the draft clinical practice guideline is released for public consultation, NHMRC will notify Council members. Council members will be encouraged to consider the public consultation draft as individuals and/or seek expert advice from their jurisdictions or other expert sources within their networks, as they see fit. Comments and feedback from a Council member will be submitted the directly to the developer during the specified public consultation period.

Advice from relevant authorities

The guideline developer is required to send a public consultation draft guideline to the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department.

The guideline developer is also required to send a public consultation draft guideline to relevant government agencies, including Therapeutic Goods Administration (TGA), the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC), specifically highlighting recommendations in the draft clinical guideline that are relevant to these agencies (Part 3: Requirements, D.10 **and** F.3). These may include recommendations that:

- specify interventions that are not available or restricted in Australia (e.g. the use of medicines that are not registered by the TGA or are outside registered indications, or the use or medicines that are not listed for reimbursement by the PBS)
- require, or would be supported by, a change in service delivery (e.g. services for which patients and practitioners are not reimbursed through the Medicare Benefits Schedule).

Contact details for these agencies are available from NHMRC.

Consulting with other stakeholders

The guideline developers is required to identify and consult with key professional organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline. This may include specialist colleges whose members are target users, or which will disseminate the guideline to members, and foundations whose interest area/s are covered by the guideline.

The guideline developer is required to identify and consult with key consumer organisations that will be affected by the guideline.

After public consultation

The developer must document all the submissions lodged in response to the public consultation notice and record them in a summary table that sets out each comment received and a justification as to why each comment resulted in an amendment of the guideline or not. Information on preparing a public consultation submissions summary is available at: http://www.nhmrc.gov.au/guidelines/resources-guideline-developers.

Where advice has been specifically sought from relevant authorities and any other stakeholders, all responses (including nil response) should be documented and the resulting amendments or other actions clearly stated in the public consultation submissions summary table.

The public consultation submissions summary must be submitted to NHMRC with the final draft guideline at Stage 4. The final draft submitted for approval should include all amendments and changes made as a result of the public consultation comments.

Stage 4. Submit final draft guideline

Developers must notify NHMRC of the intended date for submission of the final draft guideline for approval at least two months prior to the intended submission date. Developers can request information from NHMRC (How to Contact NHMRC) on upcoming Council meeting dates. Final draft guidelines should be submitted at least two months prior the Council meeting at which developers request the draft guideline to be considered.

For example, developers who wish their guideline to be considered at a Council meeting scheduled for 1 July must notify NHMRC on or earlier than 1 March of their intention to submit. Developers must also submit the final draft guideline no later than 1 May.

Documents to be submitted at final draft stage

For administrative purposes, the final draft guideline should be submitted electronically as plain text (e.g. a Word document, rich text format document or PDF). Developers may choose to publish their final guideline in print, electronic or interactive online formats.

Developers should be aware that amendments to the final draft guideline may be requested by NHMRC. Accordingly, the final draft guideline should be marked to indicate its draft status. Before being considered for approval by NHMRC, the final draft guideline should not be circulated, other than for purposes of review by the writing group or guideline committee.

The following documents must be submitted with the final draft guideline:

- the technical report (described in Part 2: Procedures, Document Preparation)
- the administrative report (described in Part 2: Procedures, Document Preparation)
- the public consultation submissions summary (described in Stage 3)
- the dissemination plan (and implementation plan, if one has been developed) (described in Part 2: Procedures, Document Preparation).

Guideline reviews prior to Council consideration for approval

NHMRC will initiate independent methodological and clinical expert reviews of the final draft guideline.

Independent methodological review

The purpose of the independent methodological review is to assess the draft clinical practice guideline and related process documentation to determine whether the development process undertaken was appropriate to meet the NHMRC standard (i.e. NHMRC processes have been adhered to and NHMRC requirements have been met). Independent methodological reviewers will have expertise in evidence review methodology and guideline development. These reviewers will be selected by NHMRC after determining that they have no current or prior association with the guideline development process.

Independent clinical expert review

The purpose of the independent clinical expert review is to evaluate the appropriateness of the clinical recommendations, based on an overview of the body of evidence.

NHMRC will select clinical expert reviewers with:

- appropriate clinical content expertise
- no current or prior association with guideline development process
- no affiliations with the developer organisation or funding bodies.

Clinical expert reviewers will be asked to consider whether:

- the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline
- the risks and potential harms of recommendations been fully considered in the context of clinical practice, including any medicolegal implications
- other relevant guidelines exist on the same topic (including Australian guidelines, international guidelines or other well-referenced guidance) and, if so, whether these are in conflict with recommendations made in the guideline. If such conflicts are identified, the clinical expert reviewers will consider whether the new guideline recommendations are justified by current evidence and their rationale is clearly explained.

To streamline the time taken for NHMRC to engage appropriate clinical expert reviewers, developers are requested to nominate 6 potential clinical expert reviewers and provide a list of these with their progress report submitted at Stage 2. Guidance for developers on identifying appropriate potential clinical expert reviewers is available at: http://www.nhmrc.gov.au/guidelines/resources-guideline-developers.

After review

NHMRC may request amendments, clarification or further documentation as a result of reviewer comments prior to consideration by Council. This may need to occur quickly to meet timelines for Council meetings, and will be negotiated with developers individually, where appropriate.

Council and CEO will consider the final draft guideline and associated documentation along with the independent clinical expert and methodological reviewers' reports. The Chair of the multidisciplinary group convened to develop the guideline may be invited to attend the Council session to address any outstanding issues raised.

NHMRC may request additional amendments to the guideline prior to approval.

NHMRC will formally notify the guideline developer of the CEO's decision in writing up to four weeks after the Council meeting. If approved, NHMRC approval will be valid for a maximum of five years unless otherwise stipulated. Approval may be for a shorter period in clinical areas in which new evidence is emerging rapidly.

When NHMRC approval is declined

If a final draft guideline is not approved, NHMRC will advise the developer of the reasons for the decision. Any further matters arising, including matters relating to the reasons for refusal may be addressed to the CEO of the NHMRC for further consideration within 1 month of this notification.

Stage 5. Publish approved clinical practice guideline

Publishing obligations and requirements for NHMRC approved guidelines

After a clinical practice guideline is approved, NHMRC will inform the developer of publishing obligations. These include use of the mandatory NHMRC statement of approval and NHMRC logo. Guidelines developed by external organisations and approved by NHMRC may not be represented as developed or published by NHMRC. For example, a developer organisation may not use the expression 'an NHMRC guideline' or 'NHMRC recommendations' when promoting NHMRC approved clinical practice guidelines.

Developers should contact NHMRC (How to Contact NHMRC) to request further information on the publishing requirements following approval (including the use of the NHMRC logo and approval statement), and not proceed to printing or final layout until this had been addressed.

The developer must publish the clinical practice guideline within 16 weeks of the date of approval stated in the official notification. Following this, NHMRC will publish an approval announcement in NHMRC Tracker[6] subscription service and NICS Update[7] newsletter and provide information on the NHMRC website for readers on how to obtain the guideline and associated documents. All clinical practice guidelines produced in Australia, including NHMRC approved externally developed clinical practice guidelines, are assessed prior to inclusion on the NHMRC Clinical Practice Guidelines Portal (www.clinicalguidelines.gov.au).

The NHMRC will not assume any responsibility for the publication or dissemination of externally developed guidelines beyond what is stipulated above.

Companion publications

Developers may choose to develop companion documents, based on the evidence found in the guideline document, for consumers and health care professionals such as general practitioners and nurses. It is recommended that the intended audience of the companion documents should be involved in its development and that the draft documents be focus-tested with appropriate target user groups prior to finalisation.[9]

NHMRC does not provide approval for companion documents. Developers should not display the NHMRC logo or approval statement on companion documents.

3. Requirements for meeting the NHMRC standard

Introduction

This section sets out all the requirements that a guideline developer must fulfil before a clinical practice guideline will be considered for NHMRC approval. Developers should familiarise themselves with all the requirements before beginning the guideline development process.

The tables in this section indicate where each requirement must be documented as a minimum.

NHMRC will only approve guidelines that meet **all** of the conditions listed as "mandatory". Developers are encouraged to meet the desirable requirements to improve guideline quality and implementability.

IMPORTANT

NHMRC will only approve guidelines that meet **all** of the requirements listed as "mandatory". Developers are encouraged to meet the desirable requirements to improve guideline quality and implementability.

A. Governance and stakeholder involvement

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
A.1	The organisation/s responsible for developing and publishing the guideline is/are named.	Must be in Guideline but can also be in Administrative report
A.2	Sources of funding for guideline development, publication and dissemination are stated.	Must be in Guideline but can also be in Administrative report
A.3	A multidisciplinary group that includes end-users, relevant disciplines and clinical experts is convened to develop the purposes, scope and content of the guideline, and the process and criteria for selecting member are described.	Must be in Guideline but can also be in Administrative report
A.4	Consumers participate in the guideline development, and the processes employed to recruit, involve and support consumer participants are described.	Administrative report
A.5	A complete list of all the people involved in the guideline development process is provided, including the following information for each person: name, profession or discipline, organisational affiliation and role in the guideline development process.	Must be in Guideline but can also be in Administrative report
A.6	Potential competing interests are identified, managed and documented, and a competing interest declaration is completed by each member of the guideline development group.	Administrative report
A.7	A list of organisations formally endorsing the guideline is provided.	Must be in Guideline but can also be in Administrative report

REQUIREMENT		DOCUMENTED IN:
Desirable The guideline/development process should meet the following conditions, where applicable:		
A.2.1	The amount and percentage of total funding received from each funding source is stated.	Administrative report
A.4.1	The guideline development process includes participation by representatives of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities (as appropriate to the clinical need and context), and the processes employed to recruit, involve and support these participants are described.[iv]	Administrative report

B. Scope and purpose

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
B.1	The purpose of the guideline is stated, including the clinical questions (see Requirement C.1), issue or problems the guideline addresses.	Must be in Guideline but can also be in Technical report
B.2	The health care setting to which the recommendations apply is described, including the health system level (e.g. primary care, acute care) and clinical stage (e.g. whether the guideline covers prevention, screening, assessment, treatment, rehabilitation or monitoring).	Guideline
B.3.	The intended end users of the guideline are clearly defined, and any relevant exceptions are identified.	Guideline
B.4	The population to which the guideline recommendations will apply is defined (e.g. children, adolescents, adults or older adults) and population subgroups for which specific information is required are identified and described.	Guideline
B.5	Issues relevant to Aboriginal and Torres Strait Islander peoples (such as particular risks, treatment considerations or sociocultural considerations) are identified and described.	Guideline
Desirable The guideline/development process should meet the following conditions, where applicable:		
B.5.1	Issues relevant to special-needs groups such as culturally and linguistically diverse communities or groups with low socioeconomic status (e.g. particular risks, treatment considerations or sociocultural considerations) are identified and described.	Guideline

iv This is currently a desirable requirement due to insufficient best practice models for engagement with these groups. When appropriate guidance on how to meet this requirement has been developed it is intended that this will become mandatory.

C. Evidence review

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
C.1	Clinical questions addressed by the guideline are stated in a structured and consistent format to define the boundaries of the topic, i.e. by specifying the relevant population, intervention/s (e.g. treatment/s or diagnostic test/s), comparator/s and outcomes measured.	Technical report Guideline
C.2.	Systematic searches for evidence are undertaken and the search strategy is documented, including the search terms and databases searched.	Technical report
C.3.	The population groups specified in the search strategy include Aboriginal and Torres Strait Islander peoples and any population subgroups that have been identified (see Requirement B.4 and B.5).	Technical report
C.4.	The publication period covered by the searches is stated, and the latest date is within 12 months of the first day of public consultation and within 20 months of submission of the final draft guideline to NHMRC for approval.	Technical report
C.5.	The inclusion and exclusion criteria used to select studies for appraisal are described.	Technical report
C.6.	For each clinical question, the developer has provided an evidence table, which summarises the systematic assessment and critical appraisal of all studies that meet the inclusion criteria (i.e. the body of evidence on which a recommendation will be based). Each evidence table should include information on study design, outcomes, level of evidence, the findings of meta-analysis (if performed) and other relevant information.	Technical report
C.7	For each clinical question, the developer has provided an evidence statement form, which documents the synthesis and evaluation of the body of evidence to determine the grade of each recommendation, according to an NHMRC-approved method (NHMRC grades for recommendations[10] or GRADE[11]).	Technical report
C.8	For each recommendation, the developer has provided an evidence summary, which briefly states the outcomes of each clinical studies on which the recommendation was based, their level of evidence and reference details.	Guideline
C.9	A recommended date for future update of the guideline is identified.	Guideline
Desirable The guideline/development process should meet the following conditions, where applicable:		
C.3.1	The population groups specified in the search strategy include groups such as culturally and linguistically diverse communities or other groups for whom specific sociocultural factors (including ethnicity, gender, age, disability, socioeconomic status and location) in treatment or prevention outcomes should be considered.	Technical report
C.3.2	Search strategies include search terms to identify evidence related to consumers' perceptions and experiences.	Technical report
C.3.3	Dependent on the guideline scope, the search strategy is designed to identify evidence for all relevant alternatives for screening, prevention, diagnosis or treatment of the condition addressed by the guideline, including relevant complementary and alternative medicine approaches.	Technical report
C.3.4	Search strategies include search terms to identify evidence related to cost effectiveness and resource implications of practice.	Technical report
C.8.1	If gaps in the evidence are identified during the evidence review, these are described in the guideline and areas for further research are noted.	Guideline

D. Guideline recommendations

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
D.1	The wording of recommendations is specific, unambiguous, clearly describes the action/s to be taken by users and matches the strength of the body of evidence.[10-11]	Guideline
D.2	The wording of recommendations is written in plain English and is consistent throughout the guideline.	Guideline
D.3	For each evidence-based recommendation, the supporting references are listed and the grade of recommendation is indicated according to an NHMRC-approved method (NHMRC grades for recommendations[10] or GRADE[11]).	Guideline
D.4	Recommendations formulated in the absence of quality evidence (where a systematic review of the evidence was conducted as part of the search strategy) are clearly labelled as such. The preferred term for this type of recommendation is a consensus-based recommendation.	Guideline
D.5	Any further recommendations included in the guideline, where the subject matter is outside of the scope of search strategy, are clearly labelled as such. The preferred term for this type of recommendation is a practice point.	Guideline
D.6	The method used to arrive at consensus-based recommendations or practice points (Requirements D.4 and D.5) (e.g. voting or formal methods, such as Delphi) is documented.	Must be in Administrative report but can also be in Guideline
D.7	Areas of major debate about the evidence and the recommendations are identified and the various significant viewpoints are outlined in the guideline text (even if the guideline development working group members eventually reached a decision).	Guideline
D.8	The strengths and limitations of the body of evidence reviewed are described in the guideline text and areas of uncertainty are acknowledged.	Guideline
D.9	The guideline acknowledges current national guidelines approved by NHMRC or endorsed by major authorities, and any deviations from these are explicitly noted in the guideline text and the rationale provided.	Guideline
D.10	Where a guideline makes any recommendation/s specifying intervention/s that are not available or restricted in Australia,[v] the text clearly indicates this, and the developer has consulted the relevant authority/ies (see Requirements F.3).	Guideline
D.11	Where evidence is identified showing that Aboriginal and Torres Strait Islander peoples or other population groups have specific treatment or prevention outcomes, this evidence is clearly identified and considered in the formulation of the recommendations.	Guideline
D.12	The harms (risks or side effects) and benefits of each recommended intervention and its alternatives are described in the guideline text and the rationale for the recommendation is explained.	Guideline
D.13	Any safety, legal or potential misuse issues related to the clinical recommendations are identified and described in the guideline text.	Guideline
D.14	The potential impact of each recommendation on clinical practice or outcomes is described in the text.	Guideline

v Such as the use of medicines that are not registered by the Therapeutic Goods Administration or outside registered indications, the use of medicines that are not listed for reimbursement by the Pharmaceutical Benefits Scheme, or services for which patients and practitioners are not reimbursed through the Medicare Benefits Schedule.

REQUIREMENT		DOCUMENTED IN:
D.15	The guideline and recommendations have been assessed by at least two reviewers, independent of the guideline development process, using the AGREE II instrument.[3, 5]	Administrative report
Desirable The guideline/development process should meet the following conditions, where applicable:		
D.2.1	Recommendations are formulated using consistent grammar, syntax and wordings, so they can readily be adapted for electronic implementation strategies (e.g. electronic decision support systems and automatic data collection).	Guideline
D.8.1	Recommendations that are likely to be affected by new evidence after the guideline has been approved (e.g. major clinical trials underway at the time of guideline publication) are identified and the implications for the guideline recommendations are explained in the guideline text.	Guideline
D.9.1	Clinical recommendations that deviate from current practice are identified.	Guideline
D.9.2	The resource implications and cost effectiveness of any recommended practice, compared with current or established practice, are explicitly stated in the guideline text.	Guideline
D.11.1	Where evidence is identified showing that sociocultural factors (including ethnicity, gender, age, disability, socioeconomic status and location) affect treatment or prevention outcomes (see Requirement C.3.1), this evidence is clearly identified and considered in the formulation of the recommendations.	Guideline
D.12.1	Absolute measures of both efficacy and harm are stated for each management option where evidence is available, e.g. expressed as number needed to treat (NNT), number needed to screen (NNS), or number needed to harm (NNH) as relevant to the recommendation.	Guideline
D.13.1	Ethical issues are considered when formulating the recommendations and any such issues identified and described.	Guideline
D.16	If evidence for complementary and alternative medicine options is identified, the risks and benefits of these are stated in the guideline text and appropriate recommendations included.	Guideline
D.17	If there is a lack of rigorous evidence for a complementary and alternative medicine/therapy commonly used in practice, this is explicitly stated in the guideline text.	Guideline
D.18	Recommendations that consider consumer self-management options are included, where relevant.	Guideline
D.19	Recommendations emphasise consumer and carer involvement in treatment and care decisions, where relevant.	Guideline

E. Guideline structure and style

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
E.1	The guideline includes a title page listing: (i) the date of publication (ii) the authorship (organisation or individuals) (iii) the publisher (iv) copyright information including the copyright holder (v) address for requesting permission to reproduce material in the text (vi) the ISBN number[vi] (vii) a preferred citation for the guideline publication.	Guideline
E.2	The guideline is easy to navigate and includes a table of contents.	Guideline
E.3	The guideline includes a brief (e.g. 1-page) plain English summary.	Guideline
E.4	The guideline includes an executive summary that lists all recommendations and their grade using an NHMRC-approved method (NHMRC grades for recommendations[10] or GRADE[11]).	Guideline
E.5	A glossary of technical terms, acronyms and abbreviations is provided, and terms are used consistently throughout the guideline.	Guideline
E.6	Where medicines are mentioned in the guideline, generic names[vii] are used and brand names are avoided.	Guideline
E.7	The document design and layout enables recommendations to be identified easily within the text.	Guideline
E.8	References in the text are clearly identified and the citations clearly listed. For electronic references, the source location (e.g. website address) and date accessed is stated.	Guideline
E.9	Chapter and heading levels are consistent, clearly distinguishable by the document design and layout, and assist with the navigation throughout each topic of the guideline.	Guideline
E.10	The guideline information is sequenced in a logical manner which is applicable to the intended end user.	Guideline
E.11	The technical report is either (i) included in the guideline document, or (ii) provided in a readily accessible location, such as a website, which is indicated in the guideline.	Guideline
E.12	The administrative report is either (i) included in the guideline document, or (ii) provided in a readily accessible location, such as a website, which is indicated in the guideline**.**	Guideline

vi International Standard Book Numbers (ISBN) are obtained from an ISBN Agency and can only be obtained when the final document is available. Details available from the National Library of Australia: http://www.nla.gov.au/services/ISBN.html

vii If use of the generic name (recommended international non-proprietary name) does not provide sufficient clarity for users, developers should consult NHMRC before final approval stage.

REQUIREMENT		DOCUMENTED IN:
Desirable The guideline/development process should meet the following conditions, where applicable:		
E.2.1	An index is included.	Guideline
E.2.2	If the guideline is published in PDF format, bookmarks are provided to facilitate navigation.	Guideline
E.2.3	If the guideline is published as a web page, hyperlinks are provided to facilitate navigation.	Guideline
E.3.1	Plain English is used for all guideline text.	Guideline
E.4.1	A summary of recommendations is available as a separate document, and the guideline text states where to obtain this document.	Guideline
E.7.1	The design of the guideline (printed or electronic) is suitable for people with visual impairment.[viii]	Guideline

F. Public consultation

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
F.1	The process for public consultation on the draft guideline complies with Section 14A of the Commonwealth *National Health and Medical Research Council Act 1992*[1] and accompanying regulations[8].	Administrative report
F.2	Details of submissions received during public consultation and the response of the guideline development working group to the submissions (including whether, why and how the guideline was altered) are provided as a separate document to the NHMRC.	Public consultation submissions summary
F.3	During the public consultation period, the developer has undertaken and documented consultation with: – the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department – relevant authority/ies[ix], when a guideline makes any recommendation/s specifying interventions that are not available or restricted in Australia (see Requirement D.10).	Administrative report Public consultation submissions summary
F.4	The developer has identified and consulted with key professional organisations (such as specialty colleges) and consumer organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline.	Administrative report Public consultation submissions summary
Desirable The guideline/development process should meet the following conditions, where applicable:		
F.2.1	A version of the public consultation submissions summary is publicly available, with submissions de-identified.	Administrative report

viii Refer to Vision Australia (http://www.visionaustralia.org.au/info.aspx?page=1845&template=PrintReg).

ix Such as the use of medicines that are not registered by the Therapeutic Goods Administration or outside registered indications, the use of medicines that are not listed for reimbursement by the Pharmaceutical Benefits Scheme, or services for which patients and practitioners are not reimbursed through the Medicare Benefits Schedule.

G. Dissemination and implementation of guidelines

REQUIREMENT		DOCUMENTED IN:
Mandatory The guideline/development process must meet **all** the following conditions:		
G.1	A plan for the dissemination of the guideline is submitted as a separate document from the clinical practice guideline.	Dissemination plan
G.2	Key recommendations that are most likely to lead to improvements in health outcomes are highlighted for consideration in implementation.	Dissemination plan
Desirable The guideline/development process should meet the following conditions, where applicable:		
G.3	A practical implementation plan is provided as a separate document, based on considerations of the Australian health care context and identification of appropriate organisation/s where the key recommendations may be directed.	Implementation plan (may be part of dissemination plan)
G.4	Resources to support implementation of the guidelines are developed, such as summaries and other tools for different health care professionals, and the guideline indicates where these can be obtained.	Guideline
G.5	Accompanying consumer information is provided.	Guideline
G.6	Versions of the plain English summary and consumer information are available in different languages, if appropriate.	Guideline
G.7	Suggestions for local adaptation and adoption of the guideline are provided.	Guideline
G.8	Measures are developed for determining the extent to which key guideline recommendations are implemented.	Guideline
G.9	An evaluation strategy is developed and described to assess the extent to which guideline recommendations are adopted into routine practice.	Guideline

Abbreviations and special terms used

Administrative report	A report containing non-technical information about the guideline development process that must be made available to the public and NHMRC, but which is not required for inclusion in the guideline document. This report will include information such as a list of contributors, conflict of interest declaration and statement of funding (as detailed in Part 3: Requirements). The means by which this report can be accessed (electronic and/or in print) must be provided within the guideline.
AHMAC	Australian Health Ministers Advisory Council (http://www.ahmac.gov.au).
Body of evidence	All studies identified for each clinical question by the systematic literature search which meet the specified inclusion criteria.
Clinical practice guideline/s	Statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.[12]
Clinical practice	The performance of health professionals' within any health care setting.
Consumers	Members of the population using a specified health service or receiving a specified type of health care. Consumers can include patients and potential patients, carers and organisations representing consumers' interests. As a member of a committee, steering group or similar, consumer representatives voice the consumer perspective and takes part in the decision-making process on behalf of consumers.
Complementary medicine/s	Complementary medicines (also known as 'traditional', 'integrative' or 'alternative' medicines') include vitamin, mineral, herbal, aromatherapy and homoeopathic products. Refer to Schedule 14 of the Commonwealth *Therapeutic Goods Regulations 1990* for a list of the type of substances or products covered by the term 'complementary'. Active complementary medicine substances are defined in Section 52F of the Commonwealth *Therapeutic Goods Act 1989*. Essentially, if the substance is a designated active ingredient that has an established identity and tradition of use, it is a complementary medicine substance.
Companion document	A secondary publication directly adapted or derived from a clinical practice guideline as guidance for a particular group (e.g. patients or a particular health professional discipline), such as a consumer version of a guideline, clinical practice algorithm or summary publication.

Consensus-based recommendations	Recommendations formulated by the guideline development group, using a consensus-reaching process, in the absence of high-quality evidence (where a systematic review of the evidence was conducted as part of the guideline search strategy).
Council	The Council of the NHMRC, as established under Section 20 the Commonwealth *National Health and Medical Research Council Act 1992*.[1] The functions of the Council are to provide advice to the NHMRC Chief Executive Officer and perform other functions conferred on it.
Desirable requirement	Requirements which developers are encouraged to meet to improve guideline quality and implementability.
Evidence-based recommendation	Recommendations formulated by the guideline development group based on high-quality evidence and graded according to an NHMRC-approved method (where a systematic review of the evidence was conducted as part of the guideline search strategy).
Evidence summary	A summary prepared for each clinical practice guideline recommendation, which briefly summarises the body of evidence on which the recommendation was based, including outcomes, level of evidence and reference citation of clinical studies. http://www.nhmrc.gov.au/guidelines/resources-guideline-developers
Evidence tables	A table prepared for each clinical question addressed by a clinical practice guideline, which summarises the systematic assessment and critical appraisal of all studies that meet inclusion criteria (i.e. the body of evidence on which a recommendation will be based). Each evidence table should include information on study design, outcomes, level of evidence, the findings of meta-analysis (if performed) and other relevant information. http://www.nhmrc.gov.au/guidelines/resources-guideline-developers
Evidence statement form	A form summarising the development group's synthesis of the body of evidence for each clinical question, taking into account factors relating to the evidence base, consistency, clinical impact, generalisability and applicability of the body of evidence, which is used to support the formulation and grading of recommendations. An example of this form is found at Attachment 1 of *NHMRC levels of evidence and grades for recommendations for guideline developers (2009)*.[10]
External guideline developer (Developer)	An organisation, other than NHMRC, that is responsible for developing a clinical practice guideline (previously referred to as a third-party developer).

Final draft guideline	The draft clinical practice guideline that is submitted to NHMRC for consideration for approval after addressing issues raised at public consultation stage. Developers should be aware that amendments to the final draft guideline may be requested by NHMRC and thus it should be marked to indicate its draft status. A final draft guideline should not be circulated for clinical use prior to consideration by NHMRC for approval.
Grade of recommendation	A rating assigned to a clinical practice recommendation according to the strength of the evidence on which it is based. The NHMRC-preferred system for grading recommendations is described in *NHMRC levels of evidence and grades for recommendations for developers of guidelines* (2009)[10], where the overall grade of the recommendation based on consideration of the rating for each individual component of the body of evidence.
GRADE	The Grading of Recommendations Assessment, Development and Evaluation system[11], which is an international system for grading evidence when developing clinical practice guidelines.
Health professionals	Any health workers who provide health care and related medical services, including doctors, nurses, Aboriginal health workers and allied health professionals.
Independent clinical expert review	An NHMRC-commissioned evaluation of draft clinical practice guidelines by experts in the relevant clinical area/s, who were not involved in the guideline development process.
Independent methodological review	An NHMRC-commissioned evaluation of draft clinical practice guideline and related process documentation (including technical reports and administrative reports) by an expert in evidence review methodology and guideline development who was not involved in the guideline development process.
Level/s of evidence	A numerical rating assigned to a piece of published clinical evidence, that reflects the risk of bias in its study design. The NHMRC-preferred system for grading evidence is described in *NHMRC levels of evidence and grades for recommendations for developers of guidelines* (2009).
Mandatory requirement	Requirements that must be met to obtain NHMRC approval.
MBS	Medicare Benefits Schedule (http://www.health.gov.au/internet/mbsonline/publishing.nsf/Content/Medicare-Benefits-Schedule-MBS-1)

MSAC	Medical Services Advisory Committee (http://www.msac.gov.au). This committee advises the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures, in order to inform Australian Government decisions about public funding for new, and in some cases existing, medical procedures.
NHMRC	National Health and Medical Research Council.
PBAC	Pharmaceutical Benefits Advisory Committee (http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-committee3.htm), an independent statutory body established on 12 May 1954 under section 101 of the Commonwealth *National Health Act (1953)* to make recommendations and give advice to the Minister about which drugs and medicinal preparations should be made available as pharmaceutical benefits.
PBS	Pharmaceutical Benefits Schedule (http://www.pbs.gov.au).
Practice points	Points of guidance included in the guideline used to support evidence-based recommendations, where the subject matter is outside of the scope of search strategy, and which were formulated based on expert opinion using a consensus process.
Procedures	A set of tasks which must be carried out by developers seeking NHMRC approval of clinical practice guidelines.
Public consultation draft guideline	The interim version of the draft clinical practice guideline that is released for public consultation. Developers should ensure that this public consultation draft guideline is clearly marked to indicate its draft status.
Requirements	The set of conditions necessary for meeting the NHMRC standard for clinical practice guidelines.
Standard (NHMRC standard)	The NHMRC standard for high quality clinical practice guidelines (i.e. that clinical practice guidelines are based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian health care setting). This standard is met by fulfilling all the mandatory requirements set out in this document.

Technical report	A report containing information about the evidence review and recommendation formulation process used in the guideline development that must be made available to the public, but which is not required for inclusion in the main guideline document. This report will include information such as research questions, literature search strategies, evidence evaluation methodologies and evidence tables (as detailed in Part 3: Requirements). The means by which this report can be accessed (electronic and/or in print) must be provided within the guideline.
TGA	Therapeutic Goods Administration (http://www.tga.gov.au). The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.
User (end users)	The specific group or range of health workers for whom the clinical practice guidelines are intended, to inform their work in a health setting.

References

1. Commonwealth of Australia *National Health and Medical Research Council Act (1992)*. Available from: http://www.comlaw.gov.au/Details/C2006C00354.

2. A guide to the development, implementation and evaluation of clinical practice guidelines: NHMRC; 1999 [cited 2011 March]. Available from: http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm.

3. Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument. The AGREE Collaboration; 2010 [cited 2011 March]; Available from: http://www.agreetrust.org/resource-centre/agree-ii/.

4. Shiffman RN, Dixon J, Brandt C, Essaihi A, Hsiao A, Michel G, et al. The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline implementation. BMC medical informatics and decision making. 2005;5:23.

5. Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument: Training tools. The AGREE Collaboration; 2010 [cited 2011 March]; Available from: http://www.agreetrust.org/resource-centre/training/.

6. NHMRC Tracker. Available from: http://www.nhmrc.gov.au/media/newsletters.

7. NICS Update. National Health and Medical Research Council; Available from: http://www.nhmrc.gov.au/media/newsletters/nics-updates/all.

8. National Health and Medical Research Council Regulations 2006. Available from: http://www.austlii.edu.au/au/legis/cth/num_reg/nhamrcr2006n353o2006534.

9. How to present the evidence for consumers: preparation of consumer publications: NHMRC; 2000 [cited 2011 March]. Available from: http://www.nhmrc.gov.au/publications/synopses/cp66syn.htm.

10. NHMRC levels of evidence and grades for recommendations for developers of guidelines: NHMRC; 2009 [cited 2011 March]. Available from: http://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/evidence_statement_form.pdf.

11. Guyatt G, Oxman A, Vist G, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ. 2008;336(7650):924-6.

12. Institute of Medicine (IOM). Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011.