



Australian Government

**Government Response
to the Recommendations
of the Expert Committee on
Complementary Medicines
in the Health System**

March 2005

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**Foreword by the Hon Christopher Pyne MP
Parliamentary Secretary to the Minister for Health and Ageing**



The supply of safe, high quality and effective complementary medicines, timely access to these medicines, and the maintenance of a responsible and viable complementary medicines industry are important objectives for governments, healthcare practitioners, consumers and industry alike.

In April 2003, the recall of more than 1600 medicines manufactured by Pan Pharmaceuticals Limited brought the topic of complementary medicines to the forefront. In response to the issues raised at that time, the Australian Government moved quickly to assemble a group of experts to critically assess and recommend improvements to the regulatory, health system and industry structures for complementary medicines in Australia.

The high level review undertaken by the Expert Committee on Complementary Medicines in the Health System identified the need for the Australian regulator, the Therapeutic Goods Administration, to ensure that appropriate standards for all ingredients used in complementary medicines are legally enforceable and that the evidence required to be held by sponsors of complementary medicines to substantiate therapeutic claims be subject to more rigorous assessment. The Expert Committee also recommended that the relevant governments review the regulation of complementary healthcare practitioners, and that the Australian Government take a more active role in ensuring that consumers and healthcare practitioners have access to reliable information about complementary medicines and the skills to use such information to make informed decisions.

The Australian Government consulted widely on the Expert Committee's recommendations. Ninety submissions were received from individuals and organisations in Australia and New Zealand, including government, academia, industry, consumers and healthcare practitioners.

This Response to the Expert Committee's recommendations reinforces the Government's prime concern for public health and safety, and that Australians must have the same level of confidence in the safety and quality of complementary medicines as they can with their other medicines.

While the Government Response is presented in terms of current Australian regulatory requirements, any proposed implementation action that will bring change to the current Australian regulatory environment will require consultation with all affected stakeholders in Australia and New Zealand, in line with our commitment to the establishment of a joint scheme for the regulation of therapeutic products between our two countries.

The Government Response to the recommendations of the Expert Committee foreshadows a new and exciting direction for complementary medicines in Australia and will further enhance Australia's reputation as a supplier of high quality and safe medicines.

A handwritten signature in blue ink, appearing to read 'Chris Pyne', with a stylized flourish at the end.

Christopher Pyne MP

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Attachment 2 – Regulation Impact Statement for the Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System

1. Executive Summary

Introduction

This document details the Government Response to the recommendations made by the Expert Committee on Complementary Medicines in the Health System in their report – *Complementary Medicines in the Australian Health System*¹. Comment received following release of the report for consultation in Australia and New Zealand has been taken into consideration when preparing this Response.

The Government's strong commitment to ensuring public health and safety is the basis for accepting the majority of recommendations where the Australian Government has responsibility. The Government has accepted a package of initiatives that will further develop consumer awareness of and confidence in complementary medicines as well as enhance Australia's reputation as a supplier of high quality and safe medicines.

The recommendations of the Expert Committee and a summary of the Government Response to the recommendations are detailed in Chapter 2 – *Summary of Government Responses to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*. The Expert Committee's terms of reference are provided at Attachment 1.

The National Regulatory Controls for Complementary Medicines

The Government will promote the development and implementation of a range of initiatives to improve the regulation of complementary medicines. These include reviews of homoeopathic and herbal medicines, raw herbs and starting materials for extemporaneously compounded medicines, and compositional guidelines for ingredients used in complementary medicines.

The Government will establish enforceable standards of evidence to support claims for Listed complementary medicines and standards of quality for complementary medicines ingredients. To encourage greater consistency in the type of evidence to support therapeutic claims for medicines, the Therapeutic Goods Administration (TGA) will consult with the National Health and Medical Research Council (NHMRC). The Government will increase random and targeted monitoring of the evidence held by sponsors of Listed complementary medicines and require all sponsors to submit a summary of this to the TGA.

The penalty for refusing to provide the TGA with information supporting claims, when it is sought, will be increased. The Government will undertake stakeholder consultation to establish additional criteria to protect public health and safety with respect to manufacturing licences. The Government notes that the TGA is currently undertaking a review of labelling of medicines, including the need to better identify medicines subject to recall.

These initiatives will be progressed as part of the Government's commitment to the establishment of a joint scheme for the regulation of therapeutic products, and in consultation with stakeholders in Australia and New Zealand.

The Government will continue to ensure that Listed medicines do not contain ingredients under conditions known or suspected of causing birth defects.

¹ *Complementary Medicines in the Australian Health System* - Expert Committee on Complementary Medicines in the Health System. Report to the Parliamentary Secretary to the Minister for Health and Ageing, September 2003. Canberra, Commonwealth of Australia. <http://www.tga.gov.au/docs/pdf/cmreport.pdf>

Through the Australian Health Minister's Conference, the Government will refer the need to implement the early adoption by the States and Territories of nationally uniform legislation for access to and use of medicines. The TGA and the *National Medicines Policy* (NMP)² partners will develop a strategy to raise consumer awareness about the potential risk from medicines obtained through personal importation.

Adverse Reactions

To improve the ease with which adverse reactions to complementary medicines can be reported and improve access to information about adverse reactions, the Government will undertake a range of initiatives, including modification of reporting formats and improvement of database search capabilities. In addition, the Government will encourage the NMP partners to develop education and awareness strategies to improve the quality and extent of reporting of adverse reactions to complementary medicines.

Information and Advertising

The Government affirms its support for the need to identify the information requirements of healthcare practitioners and consumers in relation to complementary medicines and will help to meet these requirements.

As part of the arrangements for the proposed trans Tasman regulatory agency, the Government reaffirms its support for the development of an advertising scheme by the Interim Advertising Council (IAC) which will apply in Australia and New Zealand. The Government agrees that Internet advertising should come under the centralised complaints resolution mechanism in line with other forms of advertising and notes that the IAC will take this into account in developing its scheme.

Healthcare Practitioners

The Government notes that matters associated with the regulation of healthcare practitioners are a State and Territory responsibility. It will bring the recommendations of the Expert Committee relevant to healthcare practitioner regulation to the attention of the States and Territories through the Australian Health Ministers' Conference.

For the purpose of providing complementary medicine services free of the Goods and Services Tax (GST), the Government will review the definition of 'recognised professional' for membership of professional associations having uniform national registration requirements.

Industry

The Government will establish stakeholder groups to identify additional incentives for industry to encourage innovation, including examination of data protection and market exclusivity issues, as well as development and support of the evidence base for the use of complementary medicines.

The Government will review the membership of Australian Government bodies which advise on research and the use of medicines to ensure that there is appropriate and relevant expertise in complementary medicine.

² *National Medicine Policy*, 2000. Canberra, Department of Health and Aged Care.
<http://www.nmp.health.gov.au/pdf/nmp2000.pdf>

Until the needs and priorities for complementary medicine research have been identified, the Government does not believe that a decision can be made about the amount or extent of funding required. To determine the most appropriate means of identifying and supporting complementary medicine research needs, the NHMRC will consult with the Department of Health and Ageing. The Government will continue to work to ensure that the assessment of funding applications is based on fair, equitable and ethical grounds that make the best use of community resources.

The TGA will be asked to develop formal links with international centres involved in complementary medicine research and to coordinate a project to identify researchers and centres of excellence in complementary medicine research in Australia.

Administrative and Advisory Mechanisms

The Government agrees that the TGA should be the lead agency responsible for implementing the recommendations of the Expert Committee accepted by the Government.

As recommended by the Expert Committee, the Government will establish a mechanism to review the progress of implementing the recommendations accepted by the Government.

A detailed implementation plan, including timeframes and consultative arrangements will be released in the near future.

2. Summary of Government Responses to the Recommendations of the Expert Committee on Complementary Medicines in the Health System

The following table summarises the response by the Government to the recommendations of the Expert Committee on Complementary Medicines in the Health System.

The National Regulatory Controls for Complementary Medicines (Recommendations 1 – 19)

	Expert Committee recommendation	Government response and proposed implementation action
1	The TGA ensure that quality standards for all ingredients for use in complementary medicines are legally enforceable.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
2	Legally enforceable quality standards for ingredients in complementary medicines be introduced in consultation with stakeholders, with consultation to include the opportunity to review existing compositional guidelines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
3	The TGA ensure that ingredients with a chemical or biological profile that raises concern of teratogenicity not be permitted in Listed medicines.	<i>Accepted. This is consistent with the current situation for Listed medicines.</i>
4	The TGA's <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> ³ , as amended from time to time, be prescribed in the <i>Therapeutic Goods Regulations 1990</i> as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
5	Sponsors be required to submit to the TGA a summary of the evidence held by the sponsor that supports the efficacy of Listed and 'grandfathered' Registered complementary products on the Australian Register of Therapeutic Goods (ARTG) and at the time of Listing of new products or variations to existing products. The evidence must be consistent with the <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> .	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>

³ *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For Non-Registerable Medicines, including Complementary Medicines and other Listable Medicines)*, October 2002.

<http://www.tga.gov.au/docs/pdf/tgaccevi.pdf>

	Expert Committee recommendation	Government response and proposed implementation action
6	The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will develop a program to achieve this under arrangements for the trans Tasman therapeutic products regulatory agency. Any additional costs will be borne by the TGA and may be reflected in the TGA's fees and charges applying to complementary medicines.</i>
7	Mechanisms be established for stakeholders to advise the TGA of areas for priority targeting for the assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will develop appropriate mechanisms, in consultation with affected stakeholders, for implementation under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
8	The Office of Complementary Medicines (OCM) liaise with the Health Advisory Committee of the National Health and Medical Research Council (NHMRC) with a view to promoting both greater consistency between the NHMRC's designated levels of scientific evidence and the TGA's <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> , and a common understanding of the role and purpose of the <i>Guidelines</i> .	<i>Accepted. The TGA will consult with the NHMRC in updating the <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> to encourage greater consistency.</i>
9	The penalty for an offence under Section 22(3) of the <i>Therapeutic Goods Act 1989</i> , where a sponsor refuses to give the Secretary information that supports claims made by the sponsor when this is sought, be increased to at least 150 penalty units.	<i>Accepted in principle. Following agreement with New Zealand, this recommendation will be further examined under proposed arrangements for the trans Tasman therapeutic products regulatory agency.</i>
10	Homoeopathic medicines and related remedies making therapeutic claims be regulated to ensure they meet appropriate standards of safety, quality and efficacy and that: (a) the TGA, in consultation with stakeholders, undertake a review of the regulation of homoeopathic medicines and related remedies making therapeutic claims. (b) the review take into account the need to clearly differentiate these medicines from other complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>

	Expert Committee recommendation	Government response and proposed implementation action
11	The TGA, in consultation with stakeholders, and as a matter of priority, progress the review of the regulation of medicines containing herbal ingredients undertaken by the Complementary Medicines Evaluation Committee (CMEC), to ensure that these medicines meet appropriate standards of quality, safety and efficacy.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
12	The TGA, in consultation with the States and Territories and other stakeholders, coordinate a review of the regulation of raw herbs and other starting materials for the manufacture, dispensing or extemporaneous compounding of medicines to ensure that they meet appropriate standards of quality and safety.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will undertake this review, in consultation with affected stakeholders. The outcomes of this review would be implemented under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
13	Reference to ‘For Practitioner Dispensing Only’ products be removed from Therapeutic Goods Order No. 69 – <i>General Requirements for Labels for Medicines</i> ⁴ .	<i>Noted. Further consultation with stakeholders will be necessary before a decision is made on this recommendation. This matter will be progressed under arrangements for the proposed trans Tasman therapeutic products regulatory agency.</i>
14	The TGA review provisions in the <i>Therapeutic Goods Act 1989</i> for the immediate imposition of, or variation to, a condition of licensing, or revocation or suspension of a manufacturing licence for complementary medicines, to determine whether there might be more appropriate criteria to protect public health and safety than the current “imminent risk of death, serious illness or serious injury”.	<i>Accepted. Implementation will involve consultation with affected stakeholders as part of the trans Tasman therapeutic products regulatory agency legislation.</i>
15	The TGA, in consultation with stakeholders, review the way in which information on the label of a medicine can better assist with product identification of recalled medicines. The review should also consider appropriate ways to ensure that recalled medicines are not subsequently offered for unauthorised sale.	<i>Accepted. The Government notes that the TGA, through the Therapeutic Goods Committee, has undertaken a process of consultation with stakeholders, with a view to determining whether additional information may be necessary to facilitate identification of medicines subject to recall. The matter has been referred for further consideration under arrangements for the proposed trans Tasman therapeutic products regulatory agency.</i>

⁴ Therapeutic Goods Order No. 69 - *General Requirements for Labels for Medicines*, 2001. Canberra, Commonwealth Department of Health and Aged Care. <http://www.tga.gov.au/docs/pdf/tgo/tgo69.pdf>

Summary of Government Responses to the Recommendations of the Expert Committee

	Expert Committee recommendation	Government response and proposed implementation action
16	To protect public health and safety, the National Co-ordinating Committee on Therapeutic Goods (NCCTG) coordinate appropriate regulatory activity to prevent the sale of illegal complementary medicines, especially in ethnic communities.	<i>Noted.</i> The TGA will refer this matter to the NCCTG with a request that it coordinate appropriate regulatory activity.
17	To ensure consistent standards of quality, safety and efficacy and a fair and competitive environment for the supply of medicines in Australia, State and Territory governments be urged to adopt nationally consistent therapeutic goods legislation.	<i>Noted.</i> The Government notes that the establishment of a joint scheme under a treaty with New Zealand will result in national legislation relating to the quality, safety and efficacy of medicines, and that such legislation will have Australia-wide application.
18	The Australian Health Ministers' Advisory Council (AHMAC) be urged to promote early implementation across jurisdictions of a uniform approach to the legislation that regulates access to and use of medicines.	<i>Supported.</i> The Government will refer this matter to the Australian Health Ministers' Conference with a request that its members agree to implement a uniform approach to legislation regulating access to and use of medicines.
19	The TGA, in consultation with the <i>National Medicines Policy</i> (NMP) and its partners, develop a communication strategy to better inform consumers of the potential risks associated with the personal importation of complementary medicines that may not be manufactured to the same standards of medicines available in Australia.	<i>Accepted.</i> The TGA will develop a communication strategy in consultation with the NMP and its partners.

Adverse Reactions (Recommendations 20 – 24)

	Expert Committee recommendation	Government response and proposed implementation action
20	<p>The Minister encourage the <i>National Medicines Policy</i> (NMP) partners to develop and adequately resource a strategy to improve the quality and proportion of complementary medicines adverse reaction reports by health professionals and consumers to the TGA’s Adverse Drug Reactions Advisory Committee (ADRAC), including, but not limited to:</p> <p>(a) creating a greater awareness among all health professionals (including complementary healthcare practitioners) and consumers of the potential for complementary medicines to interact with other medicines and that this be within the context of other medicines interactions</p> <p>(b) encouraging medical practitioners to include questions in a non-judgmental way about complementary medicines use when taking patient history, and to include complementary medicines in adverse drug reaction reports</p> <p>(c) encouraging complementary healthcare practitioners and consumers to report adverse reactions to complementary medicines and further develop the system to facilitate reporting</p> <p>(d) improving dissemination of information associated with adverse reactions to complementary medicines</p> <p>(e) encouraging research on toxicology, safety and interactions between complementary medicines and other medicines.</p>	<i>Accepted.</i>
21	<p>The TGA actively pursue the inclusion of AUST L / AUST R numbers within the current Adverse Drug Reactions (Reporting) System (ADRS).</p>	<i>Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to the ADRS.</i>
22	<p>The TGA modify its web-based reporting form to facilitate inclusion of AUST L and AUST R numbers.</p>	<i>Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to its web-based reporting form.</i>

Summary of Government Responses to the Recommendations of the Expert Committee

	Expert Committee recommendation	Government response and proposed implementation action
23	The TGA develop the capability to search for a single active ingredient across multiple products in the ADRS database.	<i>Accepted. The TGA will investigate the feasibility of modifying the current database system, in consultation with affected stakeholders, and will implement the modifications accordingly.</i>
24	The TGA expand the <i>Australian Pharmacovigilance Guideline</i> ⁵ to include sponsors of complementary medicines.	<i>Accepted. The TGA, in consultation with its New Zealand counterparts, will develop and publish a pharmacovigilance guideline for sponsors of complementary medicines, in consultation with affected stakeholders.</i>

⁵ Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by Drug Safety and Evaluation Branch, July 2003. <http://www.tga.gov.au/adr/pharmaco.pdf>

Information and Advertising (Recommendations 25 – 26)

	Expert Committee recommendation	Government response and proposed implementation action
25	<p>The Department of Health and Ageing commission a study to determine the complementary medicines information and skills needs of healthcare professionals and consumers, options for conveying this information to stakeholders, and the costs and resources necessary to meet these needs.</p> <p>The terms of reference for the study should be as follows:</p> <p>(a) Consistent with the <i>National Medicines Policy</i> (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM)⁶, the proposed study shall</p> <ol style="list-style-type: none"> i. identify the information and skills needed by healthcare professionals and consumers in order to assess the quality of the evidence for the use or non use of complementary medicines ii. assess the extent to which these information and skill requirements are being achieved, and identify associated gaps and deficiencies iii. recommend strategies and initiatives to address any identified gaps and deficiencies iv. develop terms of reference for an independent post-implementation evaluation of recommended strategies and initiatives v. assess the financial and other resources needed to implement these strategies and initiatives. <p>(b) The study shall have regard to the following needs which have been adapted from <i>The National Strategy for Quality Use of Medicines</i> (QUM)</p> <p><i>Specific needs for consumers:</i></p> <ol style="list-style-type: none"> i. to ask for, assess and utilise objective information, resources and services to make decisions and take actions that enable the wise choice and use of medicines when required 	<p><i>Accepted. The Department of Health and Ageing will commission the proposed study.</i></p>

⁶ *The National Strategy for Quality Use of Medicines*, 2002. Canberra, Commonwealth Department of Health and Ageing. <http://www.nmp.health.gov.au/pdf/natstrateng.pdf>

	Expert Committee recommendation	Government response and proposed implementation action
	<p>ii. to become more aware of the risks and benefits of medicines, the possibility of non-medicine options and the importance of a healthy life-style</p> <p>iii. to understand the extent to which the regulatory process assesses the quality, safety and efficacy of complementary medicines</p> <p>iv. to develop skills and confidence to use medicines appropriately and to seek help to solve problems when they arise</p> <p>v. to become more aware of the place of medicines within the broader context of health services and society.</p> <p><i>Specific needs for healthcare professionals:</i></p> <p>i. to assist people to make informed decisions and learn more about health issues and health care, through the provision of information, education and discussion</p> <p>ii. to become more aware of the risks and benefits of medicines, the possibility of non-medicine options and the importance of a healthy life-style;</p> <p>iii. to utilise objective information, resources and services to make decisions and take actions that enable the wise choice and use of medicines when required</p> <p>iv. to continually develop knowledge and skills to use medicines appropriately.</p>	
26	<p>Internet advertising be considered part of mainstream advertising, and be subject to mainstream advertising requirements and protocols, including complaints resolution through a centralised complaints and appeals process. However, for practical reasons, Internet advertising may need to be exempt from centralised pre-clearance requirements.</p>	<p>Accepted. <i>This matter will be further developed by the Interim Advertising Council in consultation with stakeholders.</i></p>

Healthcare Practitioners (Recommendations 27 – 32)

	Expert Committee recommendation	Government response and proposed implementation action
27	All jurisdictions introduce legislation to regulate practitioners of traditional Chinese medicine and dispensers of Chinese herbs, based on existing Victorian legislation, as soon as possible.	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.
28	Health Ministers review the findings of the current New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate.	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.
29	All jurisdictions adopt the following as necessary attributes of effective, transparent and accountable self-regulatory structures for complementary healthcare practitioners: (a) a certification system which incorporates i. appropriate standards of training for membership, established via a consultative process with the profession and endorsed by the relevant educational / industry authorities ii. an established, transparent procedure for assessing practitioner qualifications, incorporating an examination where necessary iii. effective incentives to ensure practitioners seek and maintain certification iv. annual requirements for continuing professional development as a condition of continued certification (b) a code of ethics with which certified practitioners agree to comply (c) effective procedures for receiving, investigating and resolving consumer complaints (d) an established disciplinary system for enforcing conduct and continuing professional development requirements, able to investigate and apply sanctions where necessary, together with a process for appeals	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.

	Expert Committee recommendation	Government response and proposed implementation action
	<p>(e) effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements</p> <p>(f) external scrutiny and involvement of experts who are not members of the profession, to promote transparency, accountability and credibility.</p>	
30	The Australian Government give consideration to revising the definition of organisations whose members satisfy requirements for ‘recognised professionals’ for the provision of GST-free services, in line with the criteria listed in Recommendation 29.	<i>Accepted. Subject to State and Territory agreement.</i>
31	Regulatory bodies for healthcare practitioners who are currently regulated by statute (for example, medical practitioners) ensure that their policies and membership standards require their members who practice complementary healthcare or advise on complementary medicines to acquire appropriate skills and competencies.	<i>Noted. The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers’ Conference.</i>
32	<p>The Australian Government and States / Territories work together with the various professions to promote development of strong, independent and accountable self-regulatory arrangements for complementary medicine professions that satisfy the criteria listed in Recommendation 29, through:</p> <p>(a) support and advice, including short-term financial assistance where deemed necessary</p> <p>(b) involvement of the professional associations in policy development and committee processes</p> <p>(c) encouraging health funds and workers compensation insurers to restrict ‘approved provider’ status to members of an independent and accountable self-regulatory body</p> <p>(d) accreditation of education and training courses up to degree and diploma level, by vocational education and training and higher education bodies.</p>	<p><i>Supported. Except for provision of short-term financial assistance under recommendation 32(a).</i></p> <p><i>The Government will consult with the States and Territories, through the mechanisms of the Australian Health Ministers’ Conference, to promote the uniform adoption of self-regulatory arrangements which satisfy the criteria of recommendation 29.</i></p> <p><i>Any request for short-term financial assistance will be considered in the Budget process.</i></p>

Industry (Recommendations 33 – 40)

	Expert Committee recommendation	Government response and proposed implementation action
33	The National Health and Medical Research Council (NHMRC) convene an expert working group to identify the research needs (including efficacy, safety, cost-effectiveness, mechanism of action and capacity building), priorities and resources to address the use of complementary medicines consistent with the <i>National Medicines Policy</i> (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM).	<i>Accepted.</i> The NHMRC will consult with the Department of Health and Ageing and the TGA to determine the most appropriate means of identifying and supporting any research needs consistent with the NMP and QUM.
34	Dedicated funding be made available for complementary medicine research in Australia for a minimum of five years.	<i>Noted.</i> The Government believes no decision can be made prior to consideration of research needs and priorities. <i>However, in the interim, the Government is making available up to \$500,000 to fund a project or projects to investigate the value of the complementary medicine, glucosamine, in the management of osteoarthritis.</i>
35	The amount of funding available for complementary medicine research in Australia be determined on a <i>per capita</i> basis consistent with complementary medicine research funding in the USA.	<i>Not accepted.</i> The Government does not consider that funding should be tied to a specific formula, but that it should be based on research needs, which are yet to be determined (see Recommendation 33).
36	A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.	<i>Accepted.</i> The TGA will consult with the NHMRC and other stakeholders in coordinating this project.
37	The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication.	<i>Accepted.</i>
38	Organisations involved in awarding public funds for healthcare research ensure that: (a) applications for research funding in the area of complementary medicines are assessed by fair, equitable and ethical methods (b) the methods represent the best use of community resources to meet the current and future healthcare needs of the community.	<i>Noted.</i> The Government will continue to work to ensure that assessment of funding applications is based on fair, equitable and ethical grounds that make the best use of community resources.

	Expert Committee recommendation	Government response and proposed implementation action
39	<p>The TGA, in consultation with key stakeholders and as a matter of priority, convene a task group to review the registration process for complementary medicines, taking into account:</p> <p>(a) the complex nature of many complementary medicines and the associated difficulty of characterising ingredients and identifying the active ingredients / components</p> <p>(b) that it may not be feasible to undertake conventional pharmacokinetic and pharmacodynamic studies and measurements in clinical studies</p> <p>(c) that, for some indications, complementary medicines may offer a lower risk and potentially more cost effective option compared with other medicines.</p>	<p><i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will convene a task group of stakeholders and experts to review the registration process for complementary medicines.</i></p>
40	<p>The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.</p>	<p><i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will convene a stakeholder group.</i></p>

Administrative and Advisory Mechanisms (Recommendations 41 – 49)

	Expert Committee recommendation	Government response and proposed implementation action
41	The membership of all bodies that advise on the research and use of medicines (including the Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health And Rational use of Medicines (PHARM) Committee) be enhanced to ensure that each has sufficient members with knowledge of, and expertise in, complementary medicines.	<i>Accepted.</i> The Government will review the membership of Australian Government bodies which advise on the research and use of medicines.
42	APAC facilitate a consultation process with the complementary medicines sector and other stakeholders, to clarify the position of complementary medicines in the <i>National Medicines Policy</i> and <i>The National Strategy for Quality Use of Medicines (QUM)</i> .	<i>Accepted.</i> APAC has already commenced action to implement this recommendation.
43	<i>The National Strategy for Quality Use of Medicines (QUM)</i> fund more projects directed at education in the use of complementary medicines.	<i>Noted.</i> Any increase in the number of projects should be linked to the outcomes of the study to be undertaken in the implementation of recommendation 25.
44	Complementary medicines be included in the indicators to measure the quality use of medicines component of the <i>National Medicines Policy (NMP)</i> and <i>The National Strategy for Quality Use of Medicines (QUM)</i> , with the indicators to be revised periodically.	<i>Accepted.</i> APAC will review the indicators for the <i>National Medicines Policy</i> and the <i>National Strategy for Quality Use of Medicines</i> to ensure the inclusion of complementary medicines data.
45	The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.	<i>Accepted.</i>
46	The Complementary Healthcare Consultative Forum be formally disbanded subject to fulfilment of Recommendation 41.	<i>Accepted.</i> Subject to the outcome of recommendation 41. Relevant stakeholders will be consulted at the appropriate time, prior to any final decision to disband the Forum.
47	A plan to implement the Committee's recommendations be prepared within one month of the Government's response to the report, with the plan to clearly identify tasks, priorities, time lines and responsibilities.	<i>Accepted.</i> This implementation plan will be prepared by the TGA in collaboration with its New Zealand counterparts.

Summary of Government Responses to the Recommendations of the Expert Committee

	Expert Committee recommendation	Government response and proposed implementation action
48	Overall accountability for implementing the Committee's recommendations be clearly assigned to a single body.	<i>Accepted. The TGA, in consultation with other Australian and New Zealand government agencies where appropriate, will have overall responsibility for coordinating the implementation of the recommendations agreed to by Government.</i>
49	Implementation of the Committee's recommendations be formally reviewed at the end of 2004.	<i>Accepted. The Government will establish an appropriate process to undertake this review.</i>

3. Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System

3.1 Introduction

This document details the Government Response to the recommendations made by the Expert Committee on Complementary Medicines in the Health System (the Expert Committee) in their report – *Complementary Medicines in the Australian Health System*⁷. It addresses the forty-nine recommendations made by the Expert Committee to the Government arising from its examination of complementary medicines and their role in the Australian healthcare system.

The Government has consulted with the Australian and New Zealand communities on the recommendations of the Expert Committee by releasing the report and inviting comment. The ninety submissions received have been considered in formulating the Government Response to the report. The Government has also been advised by a group of stakeholders and experts in complementary medicine in formulating its Response, and will work in an active and consultative way with stakeholders to enable effective implementation of the initiatives identified in relation to the terms of reference considered by the Expert Committee.

The range of initiatives arising from the recommendations of the Expert Committee will be integrated within the framework of the *National Medicines Policy* (NMP)⁸. The Committee also identified a range of issues for further review. These initiatives will enhance public health and safety through the ongoing development of the regulatory system based on international best practice, and will support the ability of consumers to make informed decisions on their choices of health care, help maintain consumer confidence in complementary medicines, and assist in maintaining a responsible and viable complementary medicines industry.

These initiatives will also contribute to other Government policy areas including:

- evidence-based public health policy;
- investment in research and development;
- promotion of good health and prevention of disease;
- workforce development;
- intellectual property development;
- incentive schemes for industry and small business; and
- engagement of community and consumers in health care.

⁷ *Complementary Medicines in the Australian Health System* - Expert Committee on Complementary Medicines in the Health System. Report to the Parliamentary Secretary to the Minister for Health and Ageing, September 2003. Canberra, Commonwealth of Australia. <http://www.tga.gov.au/docs/pdf/cmreport.pdf>

⁸ *National Medicine Policy*, 2000. Canberra, Department of Health and Aged Care. <http://www.nmp.health.gov.au/pdf/nmp2000.pdf>

The Government agrees with the following fundamental principles recognised by the Expert Committee in its consideration of the role of complementary medicines in the Australian healthcare system:

- the need to protect public health and safety;
- the primacy of the right of consumers to be able to make informed choices on matters of health care; and
- the ethical responsibilities of all healthcare providers – from manufacturers to healthcare practitioners.

3.2 Regulation Impact Statement

The Government also recognises the need to demonstrate that additional regulation of complementary medicines and healthcare practitioners is necessary and that the costs and benefits of any proposed regulation must be assessed. Consistent with Government policy, a Regulation Impact Statement (RIS) has been prepared where the Government has accepted recommendations for changes to the regulatory system (see Attachment 2). RISs are undertaken to demonstrate the need for regulation and to ensure its impact is measured against the likely benefits to public health and safety. The Government will work in an active and consultative way with stakeholders to enable effective implementation of the recommendations agreed to in its Response. Where necessary, it will establish a range of measures to minimise the regulatory impact on the Australian complementary medicines industry and associated business. In many instances, and consistent with the Expert Committee's recommendations, the Government has agreed that further stakeholder consultation is necessary in order to determine the need and scope of regulatory change. Once the need for regulatory change has been determined, and in considering its options, the Government will then be in a position to prepare a RIS for the proposed changes. The Government also notes that a RIS must be prepared for any regulatory changes considered by the Australian Health Ministers' Conference. In accepting recommendations 2, 4, 5 and 10 it is also noted that, following stakeholder consultation, the Government will undertake to prepare a further RIS for the proposed changes.

3.3 Trans Tasman Considerations

The Australian and New Zealand Governments have agreed to establish a joint scheme for the regulation of therapeutic products, including complementary medicines. A joint agency will be established to administer the joint scheme in both Australia and New Zealand, and is expected to commence operations in mid-2005. Thus, many of the recommendations in the report of the Expert Committee and the Australian Government Response to this report have implications for the way that complementary medicines will be regulated under the joint scheme in both Australia and New Zealand.

Given the impending establishment of the joint agency, there will be little or no opportunity for amending current Australian legislation to implement any of the recommendations of the report. Therefore, the implementation of any of the report's recommendations that require legislative change will need to be implemented through the Ministerial Council Rules for the joint scheme. The Ministerial Council, consisting of the Australian and New Zealand Health Ministers, is responsible for the development of Rules.

While the report of the Expert Committee and the Australian Government Response are written in terms of current Australian regulatory requirements, it is fully acknowledged that any implementation action that will change the current Australian regulatory

arrangements for complementary medicines will require comprehensive consultation with Australian and New Zealand stakeholders, including the New Zealand Government.

3.4 The National Regulatory Controls for Complementary Medicines (Recommendations 1 – 19)

The Government recognises its obligation to ensure public health and safety, but takes into account the need to avoid unnecessary regulatory burden. There is a general expectation in the Australian community that therapeutic products should be safe, effective and of high quality, and that the Government will set standards and regulations to meet these expectations. At the same time, those who manufacture and market therapeutic products expect that regulation will be the minimum necessary, appropriate and commensurate with the assessed risks of their respective products, and consistent with practice in countries with similar public health regulatory policy. Accordingly, the Government has responded to community expectations by establishing and maintaining a regulatory system that aims to protect public health and safety while seeking to minimise compliance costs.

The Government accepts recommendations 1 and 2 regarding legally enforceable quality standards, noting the need to consult with stakeholders on the development and adoption of quality standards, and the options for their enforcement. Quality standards currently underpinned by legislation will not be reviewed.

The Government accepts recommendation 3 relating to ingredients having a chemical or biological profile which raises concerns of teratogenicity. This is consistent with current policy. The Government currently recognises that the potential teratogenic effects of substances may be dose related. It reaffirms its position that such ingredients should not be included in low risk medicines at such a level or in such a way that they pose a risk. In addition to dose restrictions and warning statements on labels, as is the current case for vitamin A, the TGA will address the possible risk posed to pregnant women who exceed the recommended dose either deliberately, or accidentally as can occur with the use of multiple products, through appropriate means which may include information to consumers as well as healthcare practitioners (as recommended in recommendation 25).

The Government believes it is important that the TGA *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (the Guidelines) continue to recognise evidence based on the traditional use of certain ingredients as well as the National Health and Medical Research Council (NHMRC) designated levels of scientific evidence, and therefore accepts recommendation 8. The Government notes that the Guidelines are scheduled for review in consultation with stakeholders to enhance applicability to all modalities of complementary medicines. The Government accepts inclusion of the updated Guidelines in the relevant regulations as proposed in recommendation 4, subject to consultation with stakeholders and preparation of a RIS which justifies such inclusion. The Government will seek to involve the NHMRC in future development of the evidence Guidelines to encourage greater consistency. This action will be taken under arrangements for the proposed trans Tasman therapeutic products regulatory agency.

The Government notes that complementary medicines, while not currently assessed pre-market for efficacy, are nevertheless required under the *Therapeutic Goods Act 1989* (the Act) to meet efficacy criteria. Sponsors of complementary medicines are currently required to hold evidence supporting the claims made for their products, and an application for Listing of a complementary medicine must be accompanied by a statutory declaration by

the sponsor that such evidence is held. The Government, through the TGA, will increase its monitoring of the evidence held by sponsors, to ensure that the current requirements of the law are being met. Any additional administrative costs of this activity will be borne by the TGA and may be reflected in increased fees or charges for the complementary medicines industry.

To simplify this process for both sponsors and the TGA, sponsors will be required to submit a brief summary of the evidence they hold, which supports the efficacy of Listed complementary medicines and also for those Registered complementary medicines not previously assessed by the TGA for efficacy. The Government therefore accepts recommendations 5 and 6. Development of the format and content for the summaries of evidence, and an education and awareness campaign for sponsors, will be undertaken in consultation with stakeholders in Australia and New Zealand and will be introduced under arrangements for the proposed trans Tasman therapeutic products regulatory agency. There will also be an adequate timeframe allowed for sponsors to comply with the new requirements.

The establishment of a system to enable industry and other stakeholders to advise the TGA on the priority targeting of audits on information held by sponsors (recommendation 7) is accepted. The development of appropriate mechanisms will be undertaken by the TGA in collaboration with its New Zealand counterpart and in consultation with affected stakeholders. The proposal to increase the penalty for offences under Section 22(3) of the *Therapeutic Goods Act 1989* (the Act) for refusing to provide relevant information (recommendation 9) to more accurately reflect the seriousness of failure to provide information necessary to confirm the quality, safety and efficacy of the product is accepted in principle. This recommendation will be examined further in the context of the development of arrangements for the trans Tasman therapeutic products regulatory agency. The Government will consult with stakeholders before implementing any changes arising from this recommendation.

The Government supports the proposed reviews of homoeopathic medicines and related remedies making therapeutic claims (recommendation 10), herbal ingredients (recommendation 11) and the regulation of raw herbs and other starting materials for extemporaneous compounding of medicines (recommendation 12) which will also address the issue of quality standards and complementary medicines. The Government notes that the review of herbal ingredients commenced some time ago under the auspices of the Complementary Medicines Evaluation Committee but has not yet been completed. The Government is pleased to note the support offered by stakeholder groups and industry associations for involvement in the implementation of these recommendations. The Government, through the TGA, will monitor and coordinate the progress and outcomes of the individual reviews as recommended in recommendation 48, and will consider any additional recommendations which may arise from this process. The reviews of homoeopathic medicines, of herbal ingredients and of raw herbs for extemporaneous compounding (recommendations 10, 11 and 12) should be carried out under the arrangements for the proposed trans Tasman therapeutic products regulatory agency, and will involve consultation with affected stakeholders in Australia and New Zealand.

The Government considers it is important that the requirement for some complementary medicines to be labelled '*For Practitioner Dispensing Only*' under Therapeutic Goods Order No. 69 – *General Requirement for Labels for Medicines* be reviewed. However, given the concerns expressed by some stakeholders in response to this particular recommendation,

the Government will undertake further stakeholder consultation before finalising its position on recommendation 13. Any action arising from this recommendation will be made under arrangements for the proposed trans Tasman therapeutic products regulatory agency.

The Government is keen to determine the most appropriate criteria under which regulatory action may be necessary to protect public health and safety by imposing conditions on manufacturing licences or by revoking or suspending licences. The review of the current provisions in the Act will be conducted in consultation with affected stakeholders in Australia and New Zealand as part of the arrangements for the proposed trans Tasman therapeutic products regulatory agency, and any proposed changes in the legislation will need to be justified through a RIS. The Government therefore accepts recommendation 14.

The Government is pleased to note that the TGA, in conjunction with stakeholders, has already considered issues relating to the role of the label of a medicine and product identification through introduction of performance based labelling, completion of the review of the *Uniform Recall Procedure*⁹, the current review of the *Code of Good Wholesaling*¹⁰ and the recent discussion paper by the Therapeutic Goods Committee *Medicine Labelling - Medicine Label Improvements to Assist Product Recall*¹¹. The Government accepts recommendation 15, noting that the TGA has already commenced action to determine whether additional information may be necessary on medicine labels to facilitate the process of recalling medicines. After consideration by the Therapeutic Goods Committee, the matter has been referred for further consideration under arrangements for the proposed trans Tasman therapeutic products regulatory agency. The review processes undertaken by the TGA involve extensive consultation with stakeholders, and any new regulation proposed will be the subject of a RIS.

The Government notes recommendation 16, and the TGA will request the National Co-ordinating Committee on Therapeutic Goods (NCCTG) to coordinate appropriate regulatory activity by the States and Territories.

The Government fully supports nationally consistent therapeutic goods legislation which will apply in all States and Territories to ensure Australia-wide common standards in the supply, access to and use of medicines. The Government notes that the establishment of a trans Tasman therapeutic products regulatory agency under a treaty with New Zealand will result in national legislation relating to the quality, safety and efficacy of medicines which will have Australia-wide application, and it is therefore unnecessary to proceed with recommendation 17.

In relation to recommendation 18, the Government notes that proposed legislation for the trans Tasman therapeutic products regulatory agency will adopt recommendations made by the Galbally Review (*Review of Drugs, Poisons and Controlled Substances Legislation*¹²)

⁹ *Uniform Recall Procedure for Therapeutic Goods*, 2001. Canberra, Commonwealth of Australia.

<http://www.tga.gov.au/docs/pdf/urptg.pdf>

¹⁰ *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, November 1991. Canberra, Commonwealth Department of Health, Housing and Community Services.

<http://www.tga.gov.au/docs/pdf/gmpgwp.pdf>

¹¹ *Medicine Labelling - Medicine Label Improvements to Assist Product Recall* (Consultation paper), March 2004. Canberra, Australian Government Department of Health and Ageing.

<http://www.tga.gov.au/consult/2004/medlabel.pdf>

¹² *Review of Drugs, Poisons and Controlled Substances Legislation*, January 2001.

<http://www.tga.gov.au/docs/html/rdpdf.htm>

in relation to the scheduling of medicines. The model proposed for the new agency will be supportive of, and will encourage, nationally consistent legislation for the scheduling of medicines. Nevertheless, the Government will continue to advocate, through its membership of the Australian Health Ministers' Conference, a uniform approach by States and Territories to legislation restricting access to and use of medicines. The Government therefore supports recommendation 18.

The Government accepts recommendation 19, and will ask the TGA to develop a communication strategy, in consultation with the NMP partners, to better inform consumers of the risks associated with the personal importation of medicines.

3.5 Adverse Reactions (Recommendations 20 – 24)

A key focus of the Government's *The National Strategy for Quality Use of Medicines* (QUM)¹³ is the safe use and optimal use of medicines and the need to address such problems as adverse reactions to medicines, including interactions between complementary medicines and other medicines.

The TGA, as part of its post-market regulatory activities, aims to identify unsafe medicines and to minimise the risks associated with their use. To assist in this process, the TGA maintains a well-established system for the reporting of adverse reactions to medicines. Sponsors of all medicines included in the Australian Register of Therapeutic Goods (ARTG) are required by law to report any adverse reactions involving their products to the TGA. In addition, there is a voluntary "blue card" system enabling health professionals and other members of the community to report adverse reactions. The TGA records all adverse reaction information in a database – the Adverse Drug Reaction (Reporting) System (ADRS) – which enables analysis of adverse reaction patterns and permits intervention to manage identified risks where necessary.

The Government accepts recommendations 20 – 24.

Reports of adverse reactions to complementary medicines received by the TGA currently comprise only a small proportion (about 3 percent) of the total reports received. This may in part be because sponsors of complementary medicines have been unaware of their reporting obligations. Recent amendments to the Act have imposed additional reporting requirements on sponsors and manufacturers of medicines to ensure that the TGA is notified about adverse events associated with their products.

The Government notes the view expressed by many in the complementary medicines industry that a reason for the small number of reports of suspected reactions to complementary medicines is that adverse reactions occur at a much lower rate than in the case of prescription or over-the-counter (OTC) medicines. Whether or not this is the case, the Government considers there is a need to encourage the reporting by health professionals and consumers of suspected adverse reactions to complementary medicines which do occur, to improve the TGA's ability to identify products or ingredients which might be implicated in causing adverse reactions (recommendation 20 a-c).

The current infrastructure underpinning the activities of the NMP partners supports dissemination and implementation of evidence and information needs for prescription and

¹³ *The National Strategy for Quality Use of Medicines*, 2002. Canberra, Commonwealth Department of Health and Ageing. <http://www.nmp.health.gov.au/pdf/natstrateng.pdf>

OTC medicines. The same infrastructure can be utilised to incorporate any additional information generated by adverse reaction reporting for complementary medicines.

The Government agrees that the information disseminated, or the regulatory action taken in relation to the safety of products in the marketplace, must be based on evidence developed through research.

There is an increasing demand that such evidence be made available to sponsors and the public in an accessible and comprehensive form. It is also important that the decisions made by regulatory bodies, such as the TGA, are transparent, with evidence on which those decisions are made open to public scrutiny without compromising commercial confidentiality. The Government, in implementing these recommendations, will seek ways to improve access to information and evidence in relation to adverse reactions.

Currently the majority of reports of suspected adverse reactions do not identify the Registration or Listing number of the product (the unique AUST R or AUST L number under which the product is included in the ARTG). However, this level of identification is necessary in most cases for the TGA to be able to identify the sponsor and the manufacturer of the product involved, and to initiate action involving recall of products.

Complementary medicines typically contain a larger number of ingredients than prescription or over-the-counter medicines. Consequently, the identification of a particular ingredient as a potential cause of an adverse reaction is often far more difficult in a complementary medicine. Currently, it is not possible to search the ADRS database for individual ingredients of complementary medicines.

The Government notes that, under the proposed arrangements for a trans Tasman therapeutic products regulatory agency, AUST R and AUST L numbers will be replaced by a system of product licence identifiers. The TGA will consult with affected stakeholders in collaboration with its New Zealand counterpart to investigate options for the inclusion of appropriate product identifiers and for modifying the ADRS to include a facility to search the database for individual ingredients (recommendations 21, 22 and 23). The cost of carrying out these modifications cannot be estimated until an initial study has been carried out, and will be borne by the TGA. The modification of the TGA's web-based reporting form will be undertaken under arrangements for the trans Tasman therapeutic products regulatory agency.

The Government notes that the TGA has recently updated its reporting system to facilitate easier reporting and for assessing suspected adverse reactions to medicines. The enhancements introduced include a facility to lodge reports using the Internet or a "1800" telephone service. There has been targeted advertising of the web-based reporting system in journals aimed specifically at complementary medicine manufacturers and practitioners, and the ADRS has been upgraded to allow easier identification of the ingredients of products.

The *Australian Pharmacovigilance Guideline*¹⁴, as published by the TGA, provides guidance to sponsors of prescription medicines on their responsibilities, including the need for collection of data and provision of relevant reports to the TGA. The TGA, in collaboration with its New Zealand counterpart, will publish a similar document offering guidance for sponsors of OTC and complementary medicines. This will achieve the implementation of recommendation 24.

¹⁴ Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by Drug Safety and Evaluation Branch, July 2003. <http://www.tga.gov.au/adr/pharmaco.pdf>

3.6 Information and Advertising (Recommendations 25 – 26)

The National Strategy for Quality Use of Medicines (QUM) has been developed as the implementation framework for one of the four objectives of the Government's NMP, namely that "consumers and health practitioners should have timely access to accurate information and education about medicines and their use".

Healthcare practitioners in Australia, whether medical practitioners and pharmacists practising within the conventional Western model of clinical medicine, or those practising within different frameworks, are being asked with increasing frequency by their patients to consider the use of complementary medicines in their management plan, or at least to provide information about complementary medicines.

The Government accepts recommendations 25 and 26.

The Government recognises that access to reliable information is fundamental to all healthcare practitioners who prescribe medicines, or provide consumers with advice on medicines. To determine the information needs of healthcare practitioners and consumers in relation to complementary medicines, it will be necessary to undertake a study to ascertain both the information needs of stakeholders and the most effective ways of conveying such information to those stakeholders.

The Government believes it is important to determine the skills needed by complementary healthcare practitioners to provide information about complementary medicines, the most effective ways in which these skills can be acquired, and the costs and benefits to the community. Encouraging all practitioners to acquire and maintain the relevant skills in relation to communication about complementary medicines will not only provide greater safety for consumers but will also improve the information available to support consumer decisions about the use of complementary medicines.

In this regard, the Government notes that a number of nationally endorsed qualifications in the Health Training Package at levels from Certificate IV to Advanced Diploma in complementary medicines already exist in the regulated vocational education and training system. These qualifications were developed by the Community Services and Health Industry Skills Council (CSHISC) and industry stakeholders in response to demonstrated industry demand, and underwent a rigorous consultation process involving State and Territory health departments and professional bodies before endorsement by the National Training Quality Council. Consequently any response to Recommendation 25 should be undertaken in the context of the National Training Framework. The CSHISC will be consulted and involved in the proposed study and in the development of existing or new competencies and learning / teaching resources so that, where required, they can be included in the Health Training Package.

The Government notes that the Expert Committee regarded the identification of the complementary medicines information and skills needs of consumers and healthcare practitioners as having the highest priority of the recommendations made. The Government accepts recommendation 25 and agrees that it should be progressed at the appropriate time, taking into account the full range of views expressed about the Expert Committee report and the Government Response. The Government believes this work should also incorporate issues related to the potential risks associated with the personal importation of complementary medicines (recommendation 19).

In preparing plans for such a study, the Government notes that it will be important to:

- consult with stakeholders in planning and conducting the study; and
- coordinate the proposed study with the consumer information initiatives currently being undertaken within the context of the NMP and the initiatives of the Interim Advertising Council (IAC) and the joint trans Tasman therapeutic products regulatory agency.

In accepting recommendation 26, the Government notes the creation of the IAC to develop proposed arrangements for the advertising of all therapeutic products under the proposed trans Tasman therapeutic products regulatory agency. The IAC has taken this recommendation into account in further developing its proposals.

Under legislative changes which have been passed by Parliament but are yet to come into effect, Internet advertising of medicines will be regulated in the same way as advertising in other media. Advertisements appearing on the Internet are not currently subject to pre-approval, and it is intended to continue to exempt Internet advertising from requiring pre-approval under the new legislative provisions. However, Internet advertising will be brought within the centralised complaints resolution mechanism together with other forms of advertising. Internet advertising is also subject to the provisions of the *Trade Practices Act 1974*. The Australian Competition and Consumer Commission is able to investigate complaints about breaches by Internet sites operating from both within and outside Australia.

3.7 Healthcare Practitioners (Recommendations 27 – 32)

In Australia there is minimal regulation of complementary healthcare practitioners.

The studies undertaken to date suggest that the practice of complementary medicine and, in particular, the prescription of herbal products, can in some circumstances be associated with significant risk to consumers, and it is likely that a case can be made for some form of regulation to address issues that will minimise the risk to public health and safety.

The Government notes that the regulation of complementary healthcare practitioners is a State and Territory government responsibility, and that the role of the Australian Government is limited to providing support where necessary.

In relation to recommendations 27 and 28, the Government notes that New South Wales is moving towards implementation of proposals for regulation of traditional Chinese medicine, and that Queensland has not decided whether to implement such proposals at this stage. Any introduction of statutory regulation will require action by the States and Territories. Consideration by the States and Territories of such ongoing studies as the Victorian Government review of naturopathy and Western herbal medicine¹⁵, will need to be undertaken in full consultation with stakeholders.

The Government notes the attributes proposed in recommendation 29 of effective, transparent and accountable self-regulatory structures for complementary healthcare practitioners, and the necessity for full consultation with stakeholders as to which of the several possible models for self-regulation may eventuate under State and Territory regulation following the reviews referred to in recommendation 28. Compliance with these self-regulatory structures would ensure that complementary medicine practitioners are appropriately qualified, work within

¹⁵ <http://www.dhs.vic.gov.au/pdpd/workforce/pracreg/naturopathy.htm>

appropriate standards of ethical and professional behaviour, and would provide consumers with avenues of complaint and redress against unethical or unprofessional conduct. The Government notes that the actions proposed in recommendations 27, 28 and 29 cover matters which are State and Territory responsibilities. The Government will bring these matters to the attention of the States and Territories through the Australian Health Ministers' Conference.

The Government notes that the current criteria for conferring "recognised professional" status on organisations under taxation legislation were introduced at the time of commencement of the GST in July 2000. In view of the actions recommended in the Expert Committee's report which relate to the regulation of practitioners at State and Territory level, and the encouragement given to the development of self-regulatory systems having a range of positive attributes to cover all practitioners, it would be appropriate to review the provisions which permit services to be provided on a GST-free basis once satisfactory progress has been made by the States and Territories on the matters covered by recommendations 27, 28 and 29.

Subject to agreement by the States and Territories on these recommendations, the Government accepts recommendation 30 and will conduct a review of how organisations may demonstrate they meet the criteria in recommendation 29, in consultation with other relevant government agencies and stakeholders. The review will need to consider, amongst other things, an appropriate mechanism for the ongoing provision of advice to the Australian Taxation Office on which organisations meet the criteria. The Department of the Treasury will undertake a review of the GST legislation to assess what changes, if any, may be required, including an assessment of the financial impact on Government revenue of any change to the current provisions.

This review should occur following the finalisation of arrangements for the proposed trans Tasman therapeutic products regulatory agency.

It may be appropriate that recognised professional status be extended to members of organisations able to demonstrate their compliance with the attributes proposed under recommendation 29, whether under a scheme of voluntary self-regulation or under State / Territory statutory requirements.

The Government notes that the matters covered by recommendation 31 also fall within the responsibilities of the States and Territories. It will bring the recommendation to the attention of the States and Territories through the Australian Health Ministers' Conference.

The Government supports recommendation 32 regarding working with the various professions to promote the development of self-regulatory arrangements for complementary medicine professions having the appropriate attributes, and will consult with the States and Territories, through the Australian Health Ministers' Conference, on the most appropriate way to move in this direction. The Government is unable at this time to support recommendation 32(a) in relation to the provision of short-term funding to assist in the development of self-regulatory arrangements, and any requests for such funding will need to be considered in the Budget process.

3.8 Industry (Recommendations 33 – 40)

The Government agrees that it is important to identify research needs and priorities in relation to complementary medicines to ensure that public funding is used effectively.

The Government notes the view of some members of the complementary healthcare industry that the NHMRC may have a bias against complementary healthcare in the allocation of funding for health and medical research. The Government retains confidence in the processes of the NHMRC in allocating research funding.

The Government accepts that all bodies that advise on the research and use of medicines be enhanced to ensure that each has members with knowledge of, and expertise in, complementary medicines (see recommendation 41), and will review the membership of Government bodies advising on research and use of medicines (see page 30).

The Government accepts recommendation 33. The need for priority research into complementary medicines / therapies has not been identified through the NHMRC's priority setting processes to date. The NHMRC will therefore consult with the Department of Health and Ageing, the TGA and other stakeholders to determine the most appropriate means of identifying and supporting any research needs consistent with the NMP and QUM.

The complementary medicines industry may also seek funding under the Government's industry innovation programs, including the recently-established Commercial Ready program, which will support research and development, proof-of-concept, technology diffusion and early-stage commercialisation activities. Initiatives in the *Backing Australia's Ability – Building our Future through Science and Innovation*¹⁶ package may also be relevant to the research and commercialisation needs of industry and the research community.

The Government notes recommendation 34, which proposes dedicated funding for complementary medicine research, but believes no decision can be made on this issue prior to further consideration of the research needs and priorities of the complementary healthcare sector. Any additional funding provided by the Government will need to be based on identified needs which cannot be met through existing programs.

However, as an interim measure the Government is making available up to \$500,000 to fund a project or projects to investigate the value of the complementary medicine, glucosamine, in the management of osteoarthritis. The NHMRC will call for research proposals to investigate the economic benefits of glucosamine in the management of this disease. Osteoarthritis, the most common form of arthritis affecting over a million Australians, often results in significant disability and impaired quality of life. In addition, the cost of interventions for osteoarthritis is high. There is some evidence which suggests that glucosamine may be at least as effective at relieving pain associated with osteoarthritis as more conventional products.

The Government is unable to accept that funding of complementary medicine research should be tied to a specific formula. It considers that funding of complementary medicine research, like the funding of other health and medical research, must be on the basis of demonstrated need and cost effectiveness. The Government therefore does not accept recommendation 35.

Submissions received from some members of the complementary medicines industry stated that a database of researchers and centres of excellence already exists and therefore there is no need for recommendation 36 to be undertaken. However, other submissions indicate that the existence of any such database is not widely known. In accepting this recommendation, the

¹⁶ *Backing Australia's Ability – Building our Future through Science and Innovation*, 2004. Canberra, Commonwealth of Australia. <http://backingaus.innovation.gov.au/default2004.htm>

Government notes the need for consultation with stakeholders to ensure that work that has already been undertaken in this area is disseminated.

It is difficult to gauge the extent to which research into complementary medicines is being duplicated between institutions, both within Australia and overseas. The Government notes that the NHMRC has a database that can identify researchers working in specific areas of research, including complementary medicine, if they have applied for funding. The establishment of a database to identify researchers and centres of excellence in complementary medicine research, and the development of formal links with appropriate international research centres, would assist in identifying duplication and ensuring that research funding for complementary medicine in Australia is targeted effectively. The Government therefore accepts recommendation 36. The TGA will coordinate this action and will consult with the NHMRC and other stakeholders on the further development of a suitable database, taking into account any privacy and data-matching issues raised by the use of information already held by the Government. The Government also accepts recommendation 37, and notes that the TGA will consult with its New Zealand counterpart in developing links with appropriate research centres.

Some areas of the industry expressed concern regarding the appropriateness of having the TGA, as a regulator of medicines, develop links with international centres involved in complementary medicines research, as proposed in recommendation 37. In accepting the recommendation, the Government notes these concerns, but considers that the TGA is the most appropriate existing body to undertake this function, at least initially. However, in the longer term, the Government acknowledges that it may be possible to identify or even develop a more appropriate body to undertake the role.

The Government notes recommendation 38 and that no specific evidence has been advanced to demonstrate deficiencies in the way in which funding for healthcare research is allocated by organisations awarding public funds. The Government will continue to work to ensure that funding is based on fair, equitable and ethical grounds that make the best use of community resources.

The Government accepts recommendations 39 and 40, and will ask the TGA, in collaboration with its New Zealand counterpart, to convene two task groups as proposed, both including relevant stakeholders and experts: one to review the registration process for complementary medicines, and the other to identify incentives to encourage innovation and research in complementary medicines. The terms of reference will include the matters referred to in the relevant recommendations.

3.9 Administrative and Advisory Mechanisms (Recommendations 41 - 49)

The Government accepts recommendation 41, and will consult with Australian Government bodies that advise on the research and use of medicines to ensure that each includes appropriate knowledge and expertise in complementary medicine. The Government is pleased to note that the Chair of the Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee has already given consideration and support to the issue of the membership of PHARM as proposed in recommendation 41. In line with the current strategic plan, PHARM will work with the relevant key stakeholders to support implementation of the recommendations, including consumer information and awareness campaigns, and developing a climate of research awareness through training, education and models of care.

The Government is pleased to note that the Australian Pharmaceutical Advisory Council (APAC) is in the process of addressing the issue of APAC membership by inclusion of complementary medicine practitioners and researchers able to support the range of modalities in the area of complementary medicines. The Government accepts recommendations 42 and 45 and notes that APAC is implementing recommendation 42 to facilitate a consultation process to clarify the position of complementary medicines and the NMP, and that it has agreed to be renamed the Australian Medicines Advisory Council as proposed in recommendation 45, a strategy previously supported by APAC membership but not yet implemented.

The Government notes recommendation 43 for the funding of an increased number of projects under QUM directed at education in the use of complementary medicines, but considers that this should be linked to the outcomes of the study proposed to determine the complementary medicines information and skills needs of consumers and healthcare professionals as proposed in recommendation 25.

The Government is pleased to note that representative complementary medicines industry organisations have previously been involved in the development of QUM indicators, and the current edition of QUM indicators, in part, already addresses the role of complementary medicines and QUM. The Government accepts recommendation 44, and will ask APAC to review QUM indicators in relation to complementary medicines.

The Complementary Healthcare Consultative Forum (CHCF) was convened as an outcome of an earlier review in complementary medicines which also addressed, amongst other issues, the role of the complementary medicines industry in Australia. The CHCF has not met since having fulfilled its initial purpose, but has not been formally disbanded.

The Government recognises that the complementary medicines industry is still in its formative years in the NMP framework and notes the opposition raised by some stakeholders regarding disbanding of the CHCF because of the perceived need to have a specific means of providing industry advice to the Government. However, in line with the Government's intention to ensure that complementary medicines are appropriately recognised in the NMP, the Government accepts recommendation 46, subject to the achievement of recommendation 41. The Government recognises that further consultation with stakeholders, and the review of the implementation of the Expert Committee's recommendations by the end of 2004 as proposed in recommendation 49, may result in reconsideration of individual recommendations where necessary.

The Government considers that, in support of the recommendations of the Expert Committee and the continued involvement of all stakeholders, it will be necessary to develop an implementation plan within a short time of finalising the Government Response. The Government therefore accepts recommendation 47. The TGA will be responsible for developing the implementation plan, including timeframes for meeting each of the accepted recommendations, in consultation with other Australian and New Zealand stakeholders as necessary, including the TGA's New Zealand counterpart.

The Government accepts recommendation 48. The TGA will assume the coordinating role on behalf of the Government for overall accountability for the implementation of the recommendations as agreed in the Government Response, in consultation with other Australian and New Zealand Government agencies where appropriate.

It is the intention of the Government, through the implementation of the initiatives proposed by the Expert Committee, that complementary medicines should be reinforced as an integral component of the NMP, including the ongoing development and implementation of the NMP through relevant committees and programs. In supporting a package of recommendations to maintain and develop consumer confidence and awareness in complementary medicines, as well as to maintain Australia's reputation as a supplier of high quality and safe complementary medicines, the Government will monitor and review the progress and outcome of the implementation of each of the recommendations it has supported. It therefore accepts recommendation 49.

Expert Committee on Complementary Medicines in the Health System

Terms of Reference

The Expert Committee will consider the regulatory, health system and industry structures necessary to ensure that the central objectives of the *National Medicines Policy*¹ are met in relation to complementary medicines. The supply of safe, high quality and efficacious complementary medicines, the quality use of and timely access to these medicines and the maintenance of a responsible and viable complementary medicines industry are important objectives for Governments, healthcare practitioners, consumers and industry.

The Expert Committee will examine and provide advice on:

- The national system of regulatory controls required to ensure that complementary medicines meet appropriate standards of quality, safety and efficacy;
- The information needs of consumers of complementary medicines;
- The education, training, and regulation requirements for healthcare practitioners who are supplying complementary medicines and / or providing advice or delivering care to consumers of complementary medicines;
- The potential for interaction between complementary medicines and prescribed medicines used by consumers and the means to provide this information to healthcare practitioners;
- The nature and extent of restrictions required on advertising (including Internet advertising) of complementary medicines to consumers; and
- The regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia.

¹ *National Medicine Policy, 2000*. Canberra, Department of Health and Aged Care.
<http://www.nmp.health.gov.au/pdf/nmp2000.pdf>

**Regulation Impact Statement
for the Government Response to
the Recommendations of the
Expert Committee on Complementary
Medicines in the Health System**

Background

The use of complementary therapies and complementary medicines in Australia is widespread. In 2000, it was estimated that 52 per cent of the population used at least one non-medically prescribed complementary medicine and that 23 per cent visited at least one complementary healthcare practitioner. The current annual retail turnover of complementary medicines is estimated at \$800 million, with an additional 20 per cent of Australia's output being exported.

The Expert Committee on Complementary Medicines in the Health System (the Expert Committee) was convened by the Government in May 2003 to reassure and maintain public confidence in Australia's reputation as a supplier of high quality and safe medicines following the recall of more than 1600 complementary medicines from the Australian marketplace. The recall was the result of the failure to maintain appropriate manufacturing and quality control standards by Pan Pharmaceuticals Limited, a manufacturer of over-the-counter medicines, prescription drugs and complementary medicines. Following the recall, consumer groups, health professionals, researchers and practitioners raised concerns about the level of trust placed in complementary medicines. The role of complementary healthcare practitioners also came under public scrutiny.

The Expert Committee was asked to consider the regulatory, health system and industry structures necessary to ensure that the central objectives of the *National Medicines Policy 2000* (NMP) are met in relation to complementary medicines, and to examine and provide advice on:

- the national system of regulatory controls required to ensure that complementary medicines meet appropriate standards of quality, safety and efficacy;
- the information needs of consumers of complementary medicines;
- the education, training, and regulation requirements for healthcare practitioners who are supplying complementary medicines and / or providing advice or delivering care to consumers of complementary medicines;
- the potential for interaction between complementary medicines and prescribed medicines used by consumers and the means to provide this information to healthcare practitioners;
- the nature and extent of restrictions required on advertising (including Internet advertising) of complementary medicines to consumers; and
- the regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia.

Since finalisation of the report of the Expert Committee, the Australian and New Zealand Governments have agreed to the establishment of a joint scheme for the regulation of therapeutic products, including prescription, over-the-counter and complementary medicines, medical devices, and blood and blood products. A new joint agency will be established to administer the joint scheme in both Australia and New Zealand, and is expected to commence operations in mid-2005.

The joint scheme will apply in both Australia and New Zealand to address:

- regulation of the manufacture, supply, import, export and promotion of therapeutic products;
- setting of standards in relation to the quality, safety and efficacy or performance of therapeutic products and their manufacture, supply, import, export and promotion;
- post-market monitoring of therapeutic products; and
- enforcement of the requirements of the joint scheme.

The primary policy objective for the joint scheme is to manage the risks to public health and safety associated with the use of therapeutic products. The joint scheme will:

- regulate therapeutic products for safety, quality and efficacy to ensure that the benefits of use will outweigh the risks if the product is used appropriately;
- regulate products in accordance with international best practice, adopting a globally harmonised approach where possible; and
- ensure that the health and safety objectives are met while minimising costs to businesses and Government, and without imposing unnecessary trade barriers.

Australia's entry into the joint regulatory arrangement with New Zealand was contingent on the inclusion of complementary medicines into the Agreement. The massive recall in Australia and New Zealand of medicines manufactured by Pan Pharmaceuticals Limited reinforced the view that it is appropriate for all medicines to continue to be regulated under the current single regulatory framework.

The range of initiatives arising from the recommendations of the Expert Committee will be integrated within the framework of the NMP, the objectives of which are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The Expert Committee recommended a number of other matters for further review. These recommendations have been accepted by the Government, except for those matters falling outside the responsibilities of the Government. These have been noted and will be referred to more appropriate bodies for further consideration. In some cases, action has already been taken to implement the recommendation.

A table summarising the Government's response to all 49 recommendations of the Expert Committee is at Appendix 1.

Consultation

The report of the Expert Committee was presented to the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, in September 2003. The Parliamentary Secretary released the report for public comment on 31 October 2003, and requested that submissions be received by the end of January 2004 (although extensions of time were allowed upon request). Copies of the report were forwarded to all major stakeholder organisations, and the report was published on the Therapeutic Goods Administration's (TGA's) website and made available for purchase from the TGA. The Parliamentary Secretary requested the New Zealand Minister of Health to undertake a process of consultation in New Zealand.

Ninety submissions were received from individuals and organisations in Australia and New Zealand. Those making submissions included complementary medicines suppliers and industry organisations; complementary medicines practitioners, practitioner associations and training institutions; other professional medical and healthcare associations; academic institutions; consumer organisations; government agencies responsible for the regulation of healthcare practitioners; Commonwealth, State and Territory Ministers and government departments and agencies; non-profit organisations; and individual consultants, experts and consumers.

In formulating its response to the recommendations of the Expert Committee, the Government has also been advised by a group of stakeholders and experts in complementary medicine in formulating its response, and will work in an active and consultative way with stakeholders to enable effective implementation of the initiatives accepted by the Government.

Recommendations of the Expert Committee

The Expert Committee made 49 recommendations relating to a range of matters, including:

- quality standards for ingredients;
- standards of evidence required to support claims;
- regulation of homoeopathic, herbal and extemporaneously compounded products;
- the need for nationally consistent therapeutic goods legislation;
- the need for a uniform approach to scheduling;
- adverse reactions reporting;
- criteria for suspension or revocation of manufacturing licences;
- labelling requirements to assist product recall;
- information and education needs of consumers and practitioners;
- regulation of Internet advertising;
- regulation, education and training of practitioners;
- identification of research needs;
- incentives to encourage innovation and research;
- funding of research into complementary medicines;
- inclusion of complementary medicines expertise on TGA expert committees; and
- a review of the registration process for complementary medicines.

Not all of these recommendations relate to regulatory action by the Australian Government. Many relate to proposed reviews or administrative actions by the TGA or other government agencies.

Some of the Expert Committee's recommendations relate to matters which fall within the responsibilities of the States and Territories. In these cases, it is proposed that the Government note the recommendation and refer it to the appropriate forum, which in most cases will be the Australian Health Ministers' Conference or one of its subsidiary bodies, for further consideration and development (see Appendix 1). In such cases, it is not possible to prepare a Regulation Impact Statement (RIS) relating to these recommendations, but it is acknowledged that a RIS will need to be prepared at the appropriate time in accordance with Council of Australian Governments requirements if proposals for regulatory action are developed by the bodies concerned.

Appendix 1 summarises the Government's response to each of the 49 recommendations of the Expert Committee. The four recommendations which are covered by this Statement are also listed in Table 1.

Any changes to the regulation of medicines resulting from the recommendations of the Expert Committee will apply to medicines imported into, exported from, manufactured in or supplied in Australia, as currently applies under current regulations.

The Government notes that the matters covered by recommendation 9 of the report of the Expert Committee, relating to the penalties applicable to offences under section 22(3) of the *Therapeutic Goods Act 1989* (the Act) are being considered under the proposed arrangements for the trans Tasman therapeutic products regulatory agency.

Table 1: Recommendations of the Expert Committee covered by this Statement.

	Expert Committee recommendation	Proposed Government response
2	Legally enforceable quality standards for ingredients in complementary medicines be introduced in consultation with stakeholders, with consultation to include the opportunity to review existing compositional guidelines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
4	The TGA <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> ¹ , as amended from time to time, be prescribed in the <i>Therapeutic Goods Regulations 1990</i> as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
5	Sponsors be required to submit to the TGA a summary of the evidence held by the sponsor that supports the efficacy of Listed and ‘grandfathered’ Registered complementary products on the Australian Register of Therapeutic Goods (ARTG) and at the time of Listing of new products or variations to existing products. The evidence must be consistent with the <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> .	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
10	Homoeopathic medicines and related remedies making therapeutic claims be regulated to ensure they meet appropriate standards of safety, quality and efficacy and that: (a) the TGA, in consultation with stakeholders, undertake a review of the regulation of homoeopathic medicines and related remedies making therapeutic claims. (b) the review take into account the need to clearly differentiate these medicines from other complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>

¹ *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For Non-Registerable Medicines, including Complementary Medicines and other Listable Medicines)*, October 2002.
<http://www.tga.gov.au/docs/pdf/tgaccevi.pdf>

Quality standards for ingredients of complementary medicines (Recommendation 2)

The problem to be addressed

Complementary medicines are defined in the Act as:

“therapeutic goods consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and:

- (a) a traditional use; or
- (b) any other use prescribed in the regulations”.

Generally, before a medicine can be manufactured, imported, exported, or marketed in Australia, it must be included in the Australian Register of Therapeutic Goods (ARTG). A sponsor of the medicine must apply to the TGA to achieve inclusion in the ARTG, which is based on one of two processes, depending on the level of risk posed by the ingredient(s) or medicine submitted.

- **Registration** is required for higher-risk medicines, including all prescription medicines and most over-the-counter medicines. A sponsor who wishes to achieve registration must submit detailed information to the TGA in support of the quality, safety and efficacy of the medicine, and a detailed evaluation of this information;
- **Listing** is the process applied to most complementary and other low-risk medicines, including some over-the-counter medicines. The sponsor must submit information to satisfy the TGA as to the safety and quality of the medicine. Sponsors are required to certify that they hold information supporting the therapeutic claims they make for their products but are not required to submit this evidence of efficacy to the TGA.

The majority of complementary medicines are included in the ARTG as Listed rather than Registered medicines. A sponsor who wishes to include a new ingredient in a Listed medicine, that is, an ingredient not previously approved for use by the TGA, must submit information on the quality and safety of the ingredient for evaluation by the TGA. Once approved, the ingredient can then be included in any other Listed medicine, in accordance with the terms of the Listing process.

Schedule 4 of the *Therapeutic Goods Regulations 1990* (the Regulations) sets out the criteria which ingredients permitted in Listed medicines are required to meet. Schedule 4 permits the use of herbal substances which are already permitted in other medicines included in the ARTG for supply in Australia or which are not included in Part 4 of the Schedule. Part 5 of the Schedule may impose limits on the quantities of certain ingredients permitted in Listed medicines.

The majority of complementary medicines contain herbal substances as ingredients. The Regulations define “herbal substances” as preparations of plants and certain other defined organisms, and specify the method of preparation.

Ingredients of herbal origin may be complex and contain a great number and variety of chemical components, some of which may be biologically active and some of which may be toxic to some degree. The quality of a herbal substance, including the quantities of active substances which may be present in the preparation and the levels of any toxic substances

which may be present, can vary widely and depends largely on factors such as the part of the plant which is used and the method of its preparation. The large number of different components present in a typical herbal substance has meant that the composition of many such substances and the characteristics of their components have not been studied in any detail.

Many herbal substances have been subject to traditional methods of preparation over many years, which has resulted in some consistency of quality in the final ingredient. The use of these substances as ingredients in complementary medicines is often permitted on the basis of their long history of safe use. Over recent years, however, there has been a move towards non-traditional methods of preparation of many herbal substances, including the use of non-traditional solvents and methods of extraction, presumably to maximise the extraction of selected components of the herbal substance. Such use of non-traditional methods is likely to result in wide variation in the composition of the final ingredient, and raises concerns about the safety of ingredients prepared by non-traditional methods. By definition, an ingredient used in a complementary medicine must have a history of use, and it may not be appropriate to conclude without further assessment that substances prepared by non-traditional methods can be safely included in complementary medicines.

The Act defines the *British Pharmacopoeia* (BP) as the source of acceptable standards for therapeutic goods, unless other defined standards apply to particular substances. These are mandatory standards. In many cases, the TGA recognises published international scientific monographs as acceptable standards for particular ingredients of therapeutic goods where there is no BP standard. A limited number of herbal substances are listed in the BP, and few internationally accepted monographs exist for herbal substances. The only compositional guideline² available for a herbal substance in many cases is that supplied by the sponsor of the medicine. Compliance with compositional guidelines is not mandatory.

There is no way for consumers to know whether a complementary medicine product contains ingredients prepared by non-traditional methods. Consumers have no way of knowing whether the ingredients, or components in the ingredients, which contribute to the efficacy of a product are present at the levels or in the proportions on which traditional claims for the product may be based. Nor can consumers be confident of the absence of substances at levels which may cause adverse effects in the shorter or longer term.

The Government is unable to state specifically the extent of the problem in this case, as no detailed studies have been undertaken as to the extent of non-traditional methods of preparation. However, advances in technology, together with increasing competition, are likely to increase the incentive for manufacturers to adopt non-traditional methods of preparation. The majority of complementary medicines ingredients of herbal origin are not required to comply with mandatory compositional specifications, and this means there are many approved ingredients to which non-traditional methods of preparation might be applied.

As there are no mandatory compositional specifications for the majority of complementary medicines ingredients, and no mandatory limits for components which may be hazardous, the TGA does not have a firm legislative basis for regulatory action. Further, while some sponsors adhere to the compositional guidelines, others may choose to ignore them. This can create an unfair advantage, with the potential to impact negatively on safety and efficacy, for those sponsors not meeting the compositional guidelines.

² A compositional guideline is a summary of descriptions, tests and limits that define the composition and relevant characteristics of a complementary medicine ingredient.

Compositional guidelines developed by sponsors usually do not include upper or lower limits on individual components other than the main components which characterise the particular ingredient, as there are many components present and the significance of most of these in relation to the claims made for the product is not known. Detailed analysis of all components in a complementary medicines ingredient would be costly and often impractical because of the numbers and concentrations of different components. Analysis is therefore usually restricted to identification and quantitation of a limited number of ingredients and / or components.

Objectives

The Government's objectives in considering this matter are:

- to ensure the safety and quality of complementary medicines ingredients; and
- to provide consumers with an adequate level of confidence that claims based on traditional methods of preparation remain applicable to products prepared by non-traditional methods.

Options for managing the quality of ingredients

The main options for managing the quality of ingredients of complementary medicines are as follows.

Option 1: Maintain the *status quo*, ie. require mandatory adherence to BP standards and other specified TGA standards where these exist, and allow sponsors to use non-mandatory compositional guidelines where there are no mandatory standards.

Option 2: Require mandatory compliance with agreed compositional standards, as proposed by recommendation 2 of the report of the Expert Committee.

Impact analysis

The parties which may be affected by regulatory action are:

- industry, including manufacturers, importers and suppliers, and contract testing laboratories, some of whom will be small businesses;
- complementary medicine practitioners;
- consumers of complementary medicines; and
- government agencies (principally the TGA).

Option 1

This option would maintain the *status quo*, whereby it would be mandatory to comply with standards published in the BP and TGA Therapeutic Goods Orders, but compliance with other published standards would be voluntary. For the majority of complementary medicine ingredients there would be no compositional standard applicable to all sponsors.

This option would not impose any additional costs on any parties compared with the current situation. However:

- some sponsors would gain a financial advantage by choosing compositional specifications of lower quality;
- as consumers and practitioners generally have no readily-available means of judging the quality of complementary medicines ingredients, they would continue to be unable to rely on the quantities of active ingredients or their components present in many complementary medicines, or the presence of components at levels which may be hazardous and cause adverse effects in the short or long term;
- there would continue to be major differences in quality resulting from differences in the composition of ingredients for which there are no mandatory standards;
- there would in most cases be no single compositional specification against which the TGA could take regulatory action – for example, for non-compliance in relation to certain active ingredients or contaminants.

Option 2

This option would involve continued mandatory compliance with the BP and other TGA standards where they exist, and mandatory compliance with other agreed compositional specifications, including published international monographs. Mandatory compositional specifications would be developed in consultation with stakeholders.

The consequences of adopting this option may include withdrawal of some products from the market because they are unable to meet mandatory compositional specifications, and some products may not enter the market which might otherwise have done so, for the same reasons. However, mandatory compositional specifications would be developed in consultation with affected sponsors, and any changes would be phased in with an agreed lead time for compliance. There would be greater assurance of safety and quality for those products remaining on the market, although the price to consumers of some products may increase because of the need to meet mandatory compositional specifications.

Industry

Industry would bear the costs of extending compliance of current ingredients to agreed mandatory compositional specifications. However, as testing of products to compositional specifications must occur at some point, the additional costs would mainly be in changing methods of analysis to accord with new requirements and in the purchase of ingredients to meet the agreed mandatory specifications. Any additional costs to industry are likely to be passed on to consumers. The impact is likely to be proportionally greater for small business than for other industry sectors, because of the generally smaller batch sizes of complementary medicines produced by small businesses.

Ingredients supplied for manufacture of complementary medicines would be required to meet agreed compositional specifications, and industry should therefore benefit from being able to place greater reliance on the composition of ingredients, and consequently their safety and efficacy. Industry may also benefit from greater consumer confidence in complementary medicines, leading to increased acceptance and use.

Consumers

Consumers would be able to have greater confidence in the quality and safety of complementary medicines because the ingredients would be required to comply with compositional specifications. There would be less potential for product ‘failure’ in the marketplace, eg. recall because of quality issues. This may increase consumer acceptance and use of complementary medicines. Consumers may face some cost increases in products because of the need for industry to comply with compositional guidelines.

Practitioners

Practitioners may face some additional costs resulting from compliance by industry with mandatory compositional specifications. They may also benefit from greater consumer acceptance of complementary medicines, which may lead to increased use of practitioner services.

Government

The TGA should benefit from greater certainty regarding the compositional specifications that ingredients are required to meet. Currently the TGA is faced with the possibility of testing similar ingredients to a variety of different standards. The introduction of mandatory compositional standards would reduce the number of different tests for similar components which the TGA may need to undertake. The overall effect on TGA costs of enforcement of the standards is uncertain, but these costs are more likely to be reduced than increased.

Consultation

Submissions received in response to the report of the Expert Committee were generally supportive of the proposal, but raised the following issues.

Industry

- some supported a review of existing compositional guidelines but did not see the need for mandatory guidelines in view of what is perceived as the low-risk nature of complementary medicines;
- urged the use of other recognised Pharmacopoeia and existing international monographs in preference to the development of unique Australian standards.

Practitioners

- raised the question of whether there are sufficient accredited laboratory resources available for testing of ingredients.

Consumers

- all submissions received supported the principle that ingredients for complementary medicines should have to meet the same level of quality standards as ingredients for other medicines, and would support strengthening of the recommendation.

Conclusion and recommended option

Both costs and benefits would be higher for industry (and particularly for small business), practitioners and consumers under Option 2. Costs to government are likely to be lower under Option 2. Overall, the benefits of adopting Option 2 are believed to outweigh the costs. Further, Option 1 clearly does not provide sufficient protection to consumers or practitioners of complementary medicines.

Option 2 clearly comes closer than Option 1 to meeting the Government's objectives in relation to the safety, quality and efficacy of complementary medicines ingredients. It is therefore proposed that Option 2 be adopted.

Implementation

The TGA will continue to rely on recognised published standards such as the BP and other TGA standards for individual ingredients or products where these are available. Where BP standards do not exist, the TGA will consult stakeholders on the use of recognised international monographs where these are available. Where neither source is available, the TGA will seek to develop suitable compositional standards in consultation with its stakeholders. Sponsors will be given adequate lead time to comply with new compositional standards before they become mandatory.

Evidence to support indications and claims (Recommendations 4 and 5)

The problem to be addressed

One of the common concerns raised about complementary medicines relates to the relationship between the therapeutic claims made for the medicine and the adequacy of the evidence held by sponsors of Listed medicines to support the claims.

In many cases, the claims made are based on a history of traditional use of the medicine for the treatment or prevention of particular conditions, and there is little available information based on scientific studies of the claims. In a limited number of cases, scientific studies have been undertaken and evidence to support the claim may be available.

In 2000, the TGA, after extensive consultation with the complementary medicines industry, complementary medicines experts, the National Health and Medical Research Council (NHMRC) and others, published the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (the *Guidelines*). This document was developed to provide guidance to sponsors on the types and levels of evidence required to support health-related claims made for their products. The *Guidelines* take into account the NHMRC's guidelines on designated levels of scientific evidence. Although compliance with the *Guidelines* is not mandatory, sponsors are required to certify that they hold information to support the claims made for their products, and there are penalties in the *Therapeutic Goods Act 1989* for false certification. In the absence any regulatory standard for the information required to be held by sponsors, the *Guidelines* represent the minimum level and type of evidence which would be acceptable to the TGA, and in this way may be regarded by sponsors as having quasi-regulation status.

While Listed medicines are required to meet efficacy criteria, the TGA does not generally evaluate claims made for Listed medicines. There are currently no requirements in legislation as to the evidence which must be supplied to the TGA in support of efficacy claims for Listed medicines. However, a sponsor applying for the Listing of a medicine in the ARTG must provide the TGA with, amongst other things, a statutory declaration to the effect that the sponsor holds the necessary information to support the claims made for the product. This evidence can be based on scientific studies or traditional use.

As Listed complementary medicines are low-risk products, the TGA has undertaken only a limited number of targeted audits of the information actually held by sponsors, usually based on concerns raised about the claims being made for the products in question. In most cases, the TGA has found the information held by the sponsor to be inadequate to support the claims being made. To ensure that the type and level of evidence is sufficient to support claims for Listed medicines, the Expert Committee recommended that the TGA *Guidelines* be underpinned by regulation.

While the results of the TGA's limited audits may not justify a conclusion that there is widespread non-compliance with the *Guidelines*, there is nevertheless a strong belief amongst consumer organisations, the medical profession, the conventional medicines industry and even some parts of the complementary medicines industry that claims made for some complementary medicines cannot be justified. Some groups have argued that complementary medicines should have to meet the same standards of quality, safety and efficacy as all other medicines, and that their classification as low-risk products should not justify allowing unevaluated claims. This view is inconsistent with current TGA policy that evidence of efficacy for low-risk medicines is not required to be evaluated prior to supply of the medicine.

False or unjustified claims may not only mislead consumers into using products which are ineffective, but may lead them into abandoning or not seeking alternative treatment which might be effective, or into losing confidence in the effectiveness of complementary medicines.

Current legislation requires sponsors to hold information supporting claims, but the quality of this information is not specified. While some sponsors hold information of the quality (type and level) indicated in the TGA *Guidelines*, others may choose not to meet these requirements. This can create a financial advantage for the sponsors choosing not to comply, and result in the supply of products whose claims are not supported by appropriate evidence.

Objectives

The Government's objectives in considering this matter are to ensure that the claims made for complementary medicines can be justified on the basis of information held by sponsors, and that sponsors do in fact have a level and type of evidence sufficient to support the claims made for the product.

Options for improving compliance with the TGA Guidelines

The following are the main options identified to achieve improved compliance with the TGA *Guidelines*.

Option 1: Maintain the *status quo*, ie. voluntary compliance with the TGA *Guidelines*.

Option 2: Voluntary compliance with the TGA *Guidelines*, together with mandatory submission by the sponsor of a brief summary of the evidence held by the sponsor to support the claims.

Option 3: Mandatory compliance with the TGA *Guidelines*, together with mandatory submission by the sponsor of a brief summary of the evidence held to support the claims, as proposed by recommendations 4 and 5 of the Expert Committee.

Each of these options would be supported by a program of random and targeted auditing by the TGA (or its successor agency) of the information held by sponsors, and by penalties under the applicable legislation against refusal by sponsors to provide information about the evidence they hold.

Impact analysis

The parties which may be affected by regulatory action in this area are:

- industry, including manufacturers, importers and suppliers, some of whom will be small businesses;
- complementary medicine practitioners;
- consumers of complementary medicines;
- government agencies (principally the TGA).

Option 1

This option would involve maintaining the *status quo*, and there would be no changes to costs and benefits to any parties.

The present situation would continue, in which there are concerns on the part of many sectors of the community about the level of compliance with the TGA *Guidelines*, and a likelihood that some consumers would be misled by the claims made for some complementary medicine products.

Option 2

This option would differ from the *status quo* only in that sponsors would be required to submit brief summaries of the evidence they purport to hold and which supports the claims made for their products.

Industry

There would be increased costs of preparing the summaries of evidence. These costs may be proportionally greater for small businesses, as the batch sizes of the products for which the claims are made would be relatively smaller. However, as sponsors currently certify that they hold the evidence necessary to support their claims, it should not be a major task to prepare brief summaries of the evidence held, and the costs of doing so should not be large.

Industry may face some increased costs resulting from the TGA's monitoring of the summaries of evidence. While it is not intended that the TGA will routinely evaluate the

summaries received, it is expected that some targeted auditing of the summaries will occur as part of the TGA's routine monitoring of compliance with its requirements. Where this targeted auditing of the summaries suggests there may be cause for concern about the information held by sponsors, the TGA may in some cases proceed to audit the information held. This would represent an extension of the current program of limited audits carried out by the TGA, and may impose additional costs on some sponsors. Offsetting these increases would be the reduced need for the TGA to take regulatory action in respect of claims which cannot be supported. Any changes in costs to the TGA may be reflected in marginal changes in its fees or charges to industry under the 100% cost recovery policy.

A benefit to sponsors is that the summaries of evidence should assist them to focus on the type and level of evidence they hold and its adequacy to support the claims made for their products.

Some sponsors may choose to cancel the Listing of some products because they decide the evidence they hold does not in fact support the claims made.

The complementary medicines industry may benefit from consumers' increased confidence that evidence exists to support the claims made for those complementary medicine products that remain on the market. This may lead to greater willingness on the part of consumers and healthcare practitioners to use complementary medicines.

Practitioners

The Listing of some products on the ARTG may be cancelled. This may result in a reduction in the range of products available for practitioners to recommend or supply; however, the products removed from the market would generally be those for which the claims made cannot be justified on the basis of evidence held by the sponsor.

The removal of products for which the claims made cannot be justified may increase consumer confidence in those remaining on the market. Consumers may seek increased access to other complementary medicines products through practitioners because of their increased confidence that evidence exists to support the claims made.

Consumers

The range of products available to consumers may be reduced because of the removal of some products from the market. However, these products would generally be those for which the claims made cannot be justified on the basis of evidence held by the sponsor. This may increase consumer confidence in the products remaining on the market.

Consumers would have greater protection from false or misleading claims made about complementary medicines, and this may lead to increased acceptance and use of complementary medicines products.

Government

While it is not intended that the TGA would evaluate the summaries received, it is expected that some targeted auditing of the summaries would occur as part of the TGA's routine monitoring of compliance with its requirements. In those cases where auditing of the summaries raises concerns about the information held by sponsors, it is likely that the TGA

will proceed to audit that information. This may represent an increase in TGA auditing activity, and may result in some increases in costs to the TGA.

The TGA may benefit from a reduction in the need to take regulatory action against sponsors making unsupported claims.

It is not possible to estimate at this time whether there will be a net cost increase or decrease to the TGA under this option. Any changes in TGA costs are likely to be reflected eventually in its fees and charges to industry under the 100% cost recovery policy.

Option 3

Under this option, compliance with the TGA *Guidelines*, following review in consultation with stakeholders, would become mandatory. Subject to the outcome of the proposed review, the TGA does not at this stage propose that the provision allowing for the use of evidence based on traditional use of complementary medicines should be removed. Sponsors would be required to hold evidence in accordance with the *Guidelines* to support the claims made for their products. Currently, sponsors are required only to certify that they hold evidence which supports the claims made for their products, and there are penalties for making a false certification. Making compliance with the *Guidelines* mandatory would mean a sponsor who did not hold the necessary evidence would thereby commit an offence. Sponsors would not be required to submit the evidence to the TGA, but would be required to submit a brief summary of the evidence.

Industry

As for Option 2, with the following additional considerations.

Any additional costs associated with holding the evidence to support claims should be minimal, as sponsors currently certify that they hold information which supports the claims made for their products. As the *Guidelines* have been formulated to represent the minimum level and type of evidence which would be acceptable to the TGA, the only sponsors who will be disadvantaged and face additional costs will be those who have made incorrect certifications in the past and do not in fact hold evidence which meets the *Guidelines*. These sponsors will face the choice of either obtaining the necessary level and type of evidence, modifying the claims made for the products, or withdrawing the products from the market.

While the TGA would carry out some targeted auditing of the brief summaries of evidence, and these might lead in some cases to auditing of the information held by sponsors, the level of auditing is unlikely to be significantly higher than for Option 2. Any increase in TGA costs may be offset wholly or partly by a reduction in the need for regulatory action by the TGA against sponsors making unsupported claims.

As consumers would be entitled to have even greater confidence in complementary medicines products under this option than under Option 2, benefits to the industry from increased acceptance of complementary medicine products could be expected to be greater.

Practitioners

As for Option 2, with the possibility of additional benefits from increased consumer confidence in complementary medicine products following the removal from the market of products for which there is not evidence meeting the *Guidelines*.

Consumers

As for Option 2, except that this option may result in the removal of a greater number of products from the market for which claims cannot be justified from the evidence held by sponsors. This may further reduce the range of products available to consumers, but would provide more protection from unjustified claims and may therefore result in greater consumer confidence in the complementary medicines industry and greater willingness to use complementary medicines.

Government

As for Option 2, but with the likelihood of some additional increases in TGA costs resulting from auditing of the evidence held by sponsors as part of its routine monitoring program. These may be wholly or partly offset by further decreases in the costs of TGA regulatory action against sponsors making unsupported claims.

Consultation

While there was significant support for the proposed changes, submissions received in response to the recommendations of the Expert Committee raised a number of issues in relation to recommendations 4 and 5 of the report. The main issues raised are outlined below.

A number of organisations, including complementary medicines industry bodies, practitioner associations and some State pharmacy regulatory authorities, expressed concern about requiring mandatory compliance with guidelines, which they considered should be "living documents" and thus able to be amended easily. They suggested adoption of guidelines by regulation might hinder their further development. However, it is anticipated that the TGA *Guidelines*, after review in consultation with stakeholders, would be adopted under the Rules to be developed by the Therapeutic Products Ministerial Council responsible for the proposed trans Tasman therapeutic products regulatory agency, and could be readily amended from time to time as necessary.

A number of submissions from industry and practitioner bodies expressed a view that the TGA *Guidelines* should be reviewed before there is any move towards mandatory compliance. The TGA acknowledges the need for review, which will be carried out in consultation with stakeholders in Australia and New Zealand. There will also be an adequate lead-time allowed for sponsors to achieve compliance with any new requirements. The review of the *Guidelines* will be subject to the Australian Government's requirements for preparation of a RIS.

A number of industry submissions questioned whether the TGA *Guidelines* would adequately provide for evidence which is based on traditional use, particularly after the proposed process of consultation to promote greater consistency with the NHMRC's designated levels of scientific evidence, as proposed in recommendation 8 of the report of the Expert Committee.

The TGA does not propose to remove the current provisions in the *Guidelines* which allow the use of evidence based on traditional use.

A number of industry submissions expressed concern about the costs to the TGA, and hence industry via cost recovery, of assessing the summaries of evidence to be provided by sponsors, and the potential delays in approval of applications for Listing of medicines arising from the TGA's assessment process. The TGA does not intend to assess each summary of evidence as part of its approval process. The TGA will retain the summaries of evidence as a reference in the event that any question arises about the veracity of claims made for a particular medicine, and for audit purposes as part of the TGA's routine monitoring program.

A submission from a consumer association said that the provision of summaries of evidence should be seen as a temporary compromise only, and that the TGA should aim to fully assess the evidence held in respect of all Listed medicines within 5 years.

Many submissions raised matters which in the opinion of the organisations concerned should be addressed in the TGA *Guidelines*.

Conclusion and recommended option

Options 2 and 3 would involve some additional costs to industry compared with the *status quo*, which may be offset by benefits arising from greater consumer confidence in the complementary medicines industry. Option 3 should not involve significantly greater costs to industry than Option 2, and neither cost should be major since industry currently certifies that it holds information to support the claims made for its products. The only sponsors to be disadvantaged under either option would be those who have provided incorrect certification to the TGA and do not in fact hold the necessary quality of evidence. Industry may benefit from increased consumer confidence through increased acceptance and use of complementary medicines by consumers.

Under Options 2 and 3, healthcare practitioners may have access to fewer products because of the removal from the market of those making unjustified claims. However, they should also benefit from increased consumer confidence in complementary medicines, and increased demand for their services as a result.

Consumers would benefit from both Options 2 and 3 in that, while they may no longer have access to products for which the claims made cannot be justified, they would have increased protection from unjustified claims in respect of the products remaining on the market. This may lead to increased consumer confidence in the claims made by complementary medicines.

Option 3 best meets the Government's objectives in considering this matter. It provides the greatest level of consumer protection and should result in the greatest increase in consumer confidence and informed decision making in relation to complementary medicines. As the costs to industry for Option 3 should not be significantly higher than for Option 2, Option 3 is the preferred option.

Implementation

The TGA *Guidelines* will be adopted by regulation, but only following review of the *Guidelines* in consultation with stakeholders in Australia and New Zealand. Subject to the outcome of the proposed review, the TGA does not at this stage propose that the provision

allowing for the use of evidence based on traditional use of complementary medicines should be removed. The introduction of the revised *Guidelines*, and the requirement for sponsors to submit brief summaries of evidence, will be further progressed under the arrangements for the proposed trans Tasman therapeutic products regulatory agency, and will be adopted under the Rules to be established for the new joint agency by the Therapeutic Goods Ministerial Council, consisting of the Minister for Health and Ageing and the New Zealand Minister of Health. The lead-time to be given for compliance with any new requirements, including the submission of summaries of evidence, will be determined in consultation with stakeholders.

Following the introduction of mandatory compliance with the *Guidelines*, the TGA (or its successor agency) will commence a program of targeted auditing of the information held by sponsors, to ensure that the requirement is being met.

Regulation of homoeopathic medicines (Recommendation 10)

The problem to be addressed

A “homoeopathic preparation” is defined in the Regulations as a preparation that is:

- (a) formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate; and
- (b) prepared according to the practices of homoeopathic pharmacy using the methods of:
 - (i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or
 - (ii) serial trituration in lactose.

The practice of homoeopathic medicine is based upon the central tenet “like cures like”, and the principle of homoeopathic pharmacy whereby a mother tincture or starting material is subjected to serial dilution and succussion. However, the mere dilution of an ingredient does not make it a homoeopathic preparation unless the preparation is formulated on the principle of “like cures like”.

Homoeopathic preparations are generally regarded as low-risk medicines, and consequently have been exempted from many of the requirements applying to other medicines. These preparations are currently not required to be included in the ARTG if they meet certain criteria, namely:

- all the ingredients are present at a dilution greater than 1000-fold serial dilution of a mother tincture;
- the preparation is not required to be sterile;
- it does not contain ingredients of human origin, or ingredients derived from specified parts of specified animal species; and
- the indications for the product do not include treatment of a prohibited or restricted representation, as referred to in the *Therapeutic Goods Advertising Code*.

Homoeopathic preparations which are more dilute than a 1000-fold dilution of a mother tincture, and which are not required to be sterile, are not required to be manufactured under

licence, and are thus not subject to the Australian Code of Good Manufacturing Practice (GMP).

While homoeopathic preparations meeting the above criteria are exempt from the requirements detailed, they are still subject to certain provisions of the Act, for example the requirement to meet labelling standards. However, the absence of any requirement for the TGA to evaluate or review the majority of homoeopathic products on the market means that they rarely come to the attention of the TGA.

The problem to be addressed

The Government's objectives in considering this matter are to ensure that homoeopathic medicines meet adequate standards of quality, safety and efficacy, in accordance with the objectives of the NMP and the Act.

It has become evident to the TGA in recent times that a number of substances not currently approved as ingredients in Listed medicines are being presented on the market as homoeopathic preparations. There also appear to be some products on the market which have not been prepared in accordance with homoeopathic principles or practice.

There is a monograph in the BP which deals with homoeopathic preparations. However, this is a quality standard only, and while the quality of homoeopathic ingredients is important, the BP monograph does not identify the ingredients which may be recognised as valid homoeopathic ingredients.

Unless there is some assurance that homoeopathic preparations are manufactured under compliance with GMP, no amount of testing would be adequate to ensure the quality and safety of the final product. Although a product could be tested to ensure that certain ingredients are present, this would not provide certainty that the homoeopathic ingredients are present in the declared concentrations or that potentially harmful ingredients or contaminants are not present.

The post-market monitoring of manufactured homoeopathic medicines and subsequent regulatory action is limited because most are exempt from the requirement to be Listed or Registered in the ARTG, and the TGA therefore has no official record of their existence on the market. Medicines which are not Listed in the ARTG are not included in the TGA's random post-market monitoring program, which aims to ensure that Listed medicines meet minimum standards of quality, safety and efficacy. In addition, the exemption from inclusion in the ARTG means these products are not required to have an AUST L number (the unique number under which a Listed product is identified in the ARTG), and this makes accurate identification of exempt homoeopathic medicines more difficult for the purposes of adverse reaction reporting, product recall and post-market monitoring.

There are also other issues of safety which need consideration. While homoeopathic preparations are generally regarded as low-risk products, some safety issues are similar to those for Listed medicines. Excipients included in the medicine can pose risks of toxicity or interactions with other medicines. There are recorded cases of adverse reactions to homoeopathic medicines, and there may be risks of aggravation of the condition being treated in some cases (eg. asthma). These risks may not be understood, and adverse reactions may not be recognised, by people who self-medicate with homoeopathic preparations. There are also safety issues raised by products such as those described as "homoeopathic vaccines",

which, while purportedly prepared in accordance with homoeopathic principles, may pose risks to consumers who rely on them to be efficacious in preventing serious illnesses. Where the TGA has investigated complaints regarding homoeopathic medicines, it has concluded in some instances that they have not been prepared in accordance with homoeopathic principles.

To avoid consumer confusion between homoeopathic medicines and conventional medicines, homoeopathic medicines should be presented in a manner that clearly indicates their nature.

Finally, it should be noted that most homoeopathic medicines, unlike all other medicines Listed or Registered in the ARTG, are not required to be manufactured under a licence issued by the TGA, and are therefore not required to meet GMP requirements, if they are more dilute than a 1000-fold dilution of a mother tincture and are not required to be sterile. This raises the potential for contamination and lack of quality control in manufacture. Consumers do not have the comfort of knowing that the manufacturing process is subject to a similar level of scrutiny to that under which other medicines must be manufactured.

Options for managing homoeopathic medicines

Option 1: Maintain the *status quo*, ie. only homoeopathic medicines meeting certain criteria are required to be Listed in the ARTG, and the remainder continue to be minimally regulated.

Option 2: The TGA, in consultation with stakeholders, develop a code of practice as the basis for a system of voluntary self-regulation or co-regulation. The code of practice would provide guidance on addressing the quality, safety and efficacy of homoeopathic medicines, and would include any other matters necessary to ensure these products are clearly differentiated from other medicines.

Option 3: Homoeopathic medicines be regulated on the basis of proposals to be developed by the TGA, in consultation with stakeholders, to ensure they meet appropriate standards of quality, safety and efficacy and are clearly differentiated from other medicines, as proposed in recommendation 10 of the report of the Expert Committee.

Impact analysis

The parties which may be affected by regulatory action in this area are:

- industry, including manufacturers, importers and suppliers, some of whom will be small businesses;
- complementary medicine practitioners;
- consumers of complementary medicines;
- government agencies (principally the TGA).

Option 1

There would be no additional costs or benefits arising from maintenance of the *status quo*. However, the current unsatisfactory situation would prevail in relation to the quality, safety and efficacy of homoeopathic medicines which have not been prepared in accordance with homoeopathic principles or manufactured under a process complying with GMP. It would continue to be difficult for the TGA to identify most homoeopathic products on the market and therefore to conduct an adequate post-market monitoring program.

Option 2

Industry

A voluntary code of practice would involve some additional costs for the complementary medicines industry. These costs may be proportionally greater for small businesses because of the relatively small sizes in which batches of homoeopathic medicines are produced within this sector. Full compliance with a code of practice covering quality, safety and efficacy of homoeopathic medicines would result in many products having to be reformulated or relabelled, and some may need to be removed from the market. There would also be costs for industry in participating in the administration of a voluntary code of practice, eg. the costs of developing and reviewing the code of practice, considering complaints about non-compliance and imposing sanctions. These costs are likely to be passed on to consumers.

There may be benefits to industry arising from increased consumer acceptance of, and demand for, homoeopathic products.

Practitioners

There may be some product cost increases resulting from additional costs to industry, and some reduction in the range of products on the market. However, the removal of non-complying and unsafe products from the market may increase consumer confidence in and acceptance of homoeopathic medicines, and may result in increased demand for these products by consumers.

Consumers

There may be some increased costs to consumers resulting from industry passing on any additional costs incurred through compliance with a voluntary code of practice. There is also likely to be some reduction in the range of products on the market.

Consumers would benefit from compliance with a code of practice along the lines proposed, as this would increase the likelihood that homoeopathic medicines are formulated in accordance with homoeopathic principles, are labelled correctly and are safe to use. Compliance with a code of practice, and removal of non-complying products from the market, should increase consumer confidence in the quality, safety and efficacy of those products remaining on the market, and may result in increased demand.

Government

There will be increased costs to the TGA arising from the development of a code of practice in consultation with stakeholders, and in participation in the ongoing administration of a code of practice. These costs may be reflected eventually in increases in TGA fees or charges.

Option 3

Industry

Regulation of homoeopathic medicines would involve additional costs for the complementary medicines industry. As for Option 2, these costs may be proportionally greater for small

businesses because of the smaller batch sizes in which complementary medicines are generally produced within this sector. Many products would have to be reformulated or relabelled, and some may need to be removed from the market. Manufacturers may be required to comply with GMP principles, and this would impose additional costs. Although the final form of the regulation would not be determined until a review had been conducted by the TGA in consultation with stakeholders, it is likely there would also be costs to industry in the form of TGA fees for Listing of homoeopathic products and annual charges for inclusion of the products in the ARTG. These costs would be greater than for Option 2 and are likely to be passed on to consumers.

There may be benefits to industry arising from increased consumer acceptance of, and demand for, homoeopathic products manufactured in accordance with mandatory requirements, including manufacture in compliance with GMP principles.

Practitioners

There would probably be some product cost increases resulting from additional costs to industry, and some reduction in the range of products on the market. These effects are likely to be greater than for Option 2. However, the removal of non-complying, unsafe and misleading products from the market may increase consumer confidence in and acceptance of homoeopathic medicines, and may result in increased demand for these products by consumers.

Consumers

There are likely to be some increased costs to consumers resulting from industry passing on any additional costs incurred through compliance with a regulatory regime. There is also likely to be some reduction in the range of products on the market, as products not complying with mandatory requirements are removed from the market. These effects are likely to be greater than for Option 2.

Consumers would benefit from regulation to ensure the quality safety and efficacy of homoeopathic medicines, as this should ensure that homoeopathic medicines are formulated in accordance with homoeopathic principles, are manufactured in accordance with principles of GMP, are labelled correctly and are safe to use. There may also be an increase in consumer confidence arising from the knowledge that all homoeopathic medicines would be subject to inclusion in the ARTG and therefore potential scrutiny of quality, safety and efficacy by the TGA. Regulation as proposed in recommendation 10 should increase consumer confidence in and acceptance of homoeopathic medicines, and may result in increased demand. This effect is likely to be greater than for Option 2.

Government

There would be increased costs to the TGA arising from the regulation of homoeopathic medicines to ensure these products meet acceptable standards of quality, safety and efficacy. These additional costs would arise from the administrative actions required to include the products in the ARTG, to manage fees and charges, to ensure compliance with GMP requirements, and to undertake post-market surveillance and testing of products. These costs may be reflected eventually in increases in TGA fees or charges which would be greater than those for Option 2.

Consultation

Most submissions received in response to the recommendations of the Expert Committee supported the proposed changes. A number of submissions from practitioner organisations and practitioner education colleges expressed the view that a case had not been made for the regulation of homoeopathic medicines, given the low-risk nature of the products. Other sectors of the complementary medicines industry strongly supported the principle that all medicines should have to meet appropriate standards of quality, safety and efficacy.

Conclusion and recommended option

Option 1 involves the least costs to both industry and government, but would allow homoeopathic products to remain on the market for which there is usually no evidence of compliance with homoeopathic principles or acceptable standards of safety, quality and efficacy. Products which are not required to be on the ARTG cannot be readily identified by the TGA for the purposes of post-market monitoring. Option 3 would involve the greatest costs to industry and government, but would provide the highest level of protection to consumers by ensuring homoeopathic products comply with recognised formulation principles, are manufactured under principles of GMP, are included in the ARTG (and therefore can be identified in the market) and meet acceptable standards of quality, safety and efficacy.

It would be undesirable to allow the present situation to continue by taking no action. Option 2, the adoption of a code of practice, represents a position intermediate in costs and benefits between Options 1 and 3. However, it is unlikely that a sufficient level of compliance with a voluntary code of practice would be achieved. Option 3 best meets the Government's objectives of ensuring that homoeopathic medicines meet adequate standards of quality, safety and efficacy and is the preferred option.

Implementation

The TGA or its successor agency will undertake a review of the regulation of homoeopathic medicines, in consultation with stakeholders in Australia and New Zealand, with a view to developing proposals for the regulation of these products to ensure they meet appropriate standards of quality, safety and efficacy.

It is likely that this review will be completed under the auspices of the proposed trans Tasman therapeutic products regulatory agency, which is due to commence in mid-2005, and that the proposals developed will be considered by the Therapeutic Products Ministerial Council responsible for the new joint agency. The Council will consist of the Minister for Health and Ageing and the New Zealand Minister of Health.

As part of the development of more detailed proposals for the regulation of homoeopathic medicines, a further RIS will be prepared by the responsible agency that will examine the impacts of all options including the *status quo*.

Summary of Government Responses to the recommendations of the Expert Committee on Complementary Medicines in the Health System

Note that it will be necessary in some cases for Regulation Impact Statements to be prepared by the appropriate agency in relation to specific proposals, following further consideration of the recommendations of the Expert Committee and consultation with stakeholders.

	Expert Committee recommendation	Government response and proposed implementation action
1	The TGA ensure that quality standards for all ingredients for use in complementary medicines are legally enforceable.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
2	Legally enforceable quality standards for ingredients in complementary medicines be introduced in consultation with stakeholders, with consultation to include the opportunity to review existing compositional guidelines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
3	The TGA ensure that ingredients with a chemical or biological profile that raises concern of teratogenicity not be permitted in Listed medicines.	<i>Accepted. This is consistent with the current situation for Listed medicines.</i>
4	The TGA's <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> ³ , as amended from time to time, be prescribed in the <i>Therapeutic Goods Regulations 1990</i> as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
5	Sponsors be required to submit to the TGA a summary of the evidence held by the sponsor that supports the efficacy of Listed and 'grandfathered' Registered complementary products on the Australian Register of Therapeutic Goods (ARTG) and at the time of Listing of new products or variations to existing products. The evidence must be consistent with the <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> .	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>

³ *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims (For Non-Registerable Medicines, including Complementary Medicines and other Listable Medicines)*, October 2002.
<http://www.tga.gov.au/docs/pdf/tgaccevi.pdf>

	Expert Committee recommendation	Government response and proposed implementation action
6	The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will develop a program to achieve this under arrangements for the trans Tasman therapeutic products regulatory agency. Any additional costs will be borne by the TGA and may be reflected in the TGA's fees and charges applying to complementary medicines.</i>
7	Mechanisms be established for stakeholders to advise the TGA of areas for priority targeting for the assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will develop appropriate mechanisms, in consultation with affected stakeholders, for implementation under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
8	The Office of Complementary Medicines (OCM) liaise with the Health Advisory Committee of the National Health and Medical Research Council (NHMRC) with a view to promoting both greater consistency between the NHMRC's designated levels of scientific evidence and the TGA's <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> , and a common understanding of the role and purpose of the <i>Guidelines</i> .	<i>Accepted. The TGA will consult with the NHMRC in updating the <i>Guidelines for Levels and Kinds of Evidence to Support Indications and Claims</i> to encourage greater consistency.</i>
9	The penalty for an offence under Section 22(3) of the <i>Therapeutic Goods Act 1989</i> , where a sponsor refuses to give the Secretary information that supports claims made by the sponsor when this is sought, be increased to at least 150 penalty units.	<i>Accepted in principle. Following agreement with New Zealand, this recommendation will be further examined under proposed arrangements for the trans Tasman therapeutic products regulatory agency.</i>
10	Homoeopathic medicines and related remedies making therapeutic claims be regulated to ensure they meet appropriate standards of safety, quality and efficacy and that: (a) the TGA, in consultation with stakeholders, undertake a review of the regulation of homoeopathic medicines and related remedies making therapeutic claims. (b) the review take into account the need to clearly differentiate these medicines from other complementary medicines.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>
11	The TGA, in consultation with stakeholders, and as a matter of priority, progress the review of the regulation of medicines containing herbal ingredients undertaken by the Complementary Medicines Evaluation Committee (CMEC), to ensure that these medicines meet appropriate standards of quality, safety and efficacy.	<i>Accepted. Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans Tasman therapeutic products regulatory agency.</i>

	Expert Committee recommendation	Government response and proposed implementation action
12	The TGA, in consultation with the States and Territories and other stakeholders, coordinate a review of the regulation of raw herbs and other starting materials for the manufacture, dispensing or extemporaneous compounding of medicines to ensure that they meet appropriate standards of quality and safety.	<i>Accepted.</i> The TGA, in collaboration with its New Zealand counterparts, will undertake this review, in consultation with affected stakeholders. The outcomes of this review would be implemented under arrangements for the trans Tasman therapeutic products regulatory agency.
13	Reference to ‘For Practitioner Dispensing Only’ products be removed from Therapeutic Goods Order No. 69 – <i>General Requirements for Labels for Medicines</i> ⁴ .	<i>Noted.</i> Further consultation with stakeholders will be necessary before a decision is made on this recommendation. This matter will be progressed under arrangements for the proposed trans Tasman therapeutic products regulatory agency.
14	The TGA review provisions in the <i>Therapeutic Goods Act 1989</i> for the immediate imposition of, or variation to, a condition of licensing, or revocation or suspension of a manufacturing licence for complementary medicines, to determine whether there might be more appropriate criteria to protect public health and safety than the current “imminent risk of death, serious illness or serious injury”.	<i>Accepted.</i> Implementation will involve consultation with affected stakeholders as part of the trans Tasman therapeutic products regulatory agency legislation.
15	The TGA, in consultation with stakeholders, review the way in which information on the label of a medicine can better assist with product identification of recalled medicines. The review should also consider appropriate ways to ensure that recalled medicines are not subsequently offered for unauthorised sale.	<i>Accepted.</i> The Government notes that the TGA, through the Therapeutic Goods Committee, has undertaken a process of consultation with stakeholders, with a view to determining whether additional information may be necessary to facilitate identification of medicines subject to recall. The matter has been referred for further consideration under arrangements for the proposed trans Tasman therapeutic products regulatory agency.
16	To protect public health and safety, the National Co-ordinating Committee on Therapeutic Goods (NCCTG) coordinate appropriate regulatory activity to prevent the sale of illegal complementary medicines, especially in ethnic communities.	<i>Noted.</i> The TGA will refer this matter to the NCCTG with a request that it coordinate appropriate regulatory activity.
17	To ensure consistent standards of quality, safety and efficacy and a fair and competitive environment for the supply of medicines in Australia, State and Territory governments be urged to adopt nationally consistent therapeutic goods legislation.	<i>Noted.</i> The Government notes that the establishment of a joint scheme under a treaty with New Zealand will result in national legislation relating to the quality, safety and efficacy of medicines, and that such legislation will have Australia-wide application.

⁴ Therapeutic Goods Order No. 69 – *General Requirements for Labels for Medicines*, 2001. Canberra, Commonwealth Department of Health and Aged Care. <http://www.tga.gov.au/docs/pdf/tgo/tgo69.pdf>

	Expert Committee recommendation	Government response and proposed implementation action
18	The Australian Health Ministers' Advisory Council (AHMAC) be urged to promote early implementation across jurisdictions of a uniform approach to the legislation that regulates access to and use of medicines.	<i>Supported. The Government will refer this matter to the Australian Health Ministers' Conference with a request that its members agree to implement a uniform approach to legislation regulating access to and use of medicines.</i>
19	The TGA, in consultation with the <i>National Medicines Policy</i> (NMP) and its partners, develop a communication strategy to better inform consumers of the potential risks associated with the personal importation of complementary medicines that may not be manufactured to the same standards of medicines available in Australia.	<i>Accepted. The TGA will develop a communication strategy in consultation with the NMP and its partners.</i>
20	<p>The Minister encourage the <i>National Medicines Policy</i> (NMP) partners to develop and adequately resource a strategy to improve the quality and proportion of complementary medicines adverse reaction reports by health professionals and consumers to the TGA's Adverse Drug Reactions Advisory Committee (ADRAC), including, but not limited to:</p> <p>(a) creating a greater awareness among all health professionals (including complementary healthcare practitioners) and consumers of the potential for complementary medicines to interact with other medicines and that this be within the context of other medicines interactions</p> <p>(b) encouraging medical practitioners to include questions in a non-judgmental way about complementary medicines use when taking patient history, and to include complementary medicines in adverse drug reaction reports</p> <p>(c) encouraging complementary healthcare practitioners and consumers to report adverse reactions to complementary medicines and further develop the system to facilitate reporting</p> <p>(d) improving dissemination of information associated with adverse reactions to complementary medicines</p> <p>(e) encouraging research on toxicology, safety and interactions between complementary medicines and other medicines.</p>	<i>Accepted.</i>
21	The TGA actively pursue the inclusion of AUST L / AUST R numbers within the current Adverse Drug Reactions (Reporting) System (ADRS).	<i>Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to the ADRS.</i>

	Expert Committee recommendation	Government response and proposed implementation action
22	The TGA modify its web-based reporting form to facilitate inclusion of AUST L and AUST R numbers.	<i>Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to its web-based reporting form.</i>
23	The TGA develop the capability to search for a single active ingredient across multiple products in the ADRS database.	<i>Accepted. The TGA will investigate the feasibility of modifying the current database system, in consultation with affected stakeholders, and will implement the modifications accordingly.</i>
24	The TGA expand the <i>Australian Pharmacovigilance Guideline</i> ⁵ to include sponsors of complementary medicines.	<i>Accepted. The TGA, in consultation with its New Zealand counterparts, will develop and publish a pharmacovigilance guideline for sponsors of complementary medicines, in consultation with affected stakeholders.</i>
25	<p>The Department of Health and Ageing commission a study to determine the complementary medicines information and skills needs of healthcare professionals and consumers, options for conveying this information to stakeholders, and the costs and resources necessary to meet these needs.</p> <p>The terms of reference for the study should be as follows:</p> <p>(a) Consistent with the National Medicines Policy (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM)⁶, the proposed study shall</p> <ol style="list-style-type: none"> i. identify the information and skills needed by healthcare professionals and consumers in order to assess the quality of the evidence for the use or non use of complementary medicines ii. assess the extent to which these information and skill requirements are being achieved, and identify associated gaps and deficiencies iii. recommend strategies and initiatives to address any identified gaps and deficiencies iv. develop terms of reference for an independent post-implementation evaluation of recommended strategies and initiatives v. assess the financial and other resources needed to implement these strategies and initiatives. <p>(b) The study shall have regard to the following needs which have been adapted from <i>The National Strategy for Quality Use of Medicines</i> (QUM)</p>	<i>Accepted. The Department of Health and Ageing will commission the proposed study.</i>

⁵ Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by Drug Safety and Evaluation Branch, July 2003. <http://www.tga.gov.au/adr/pharmaco.pdf>

⁶ *The National Strategy for Quality Use of Medicines*, 2002. Canberra, Commonwealth Department of Health and Ageing. <http://www.nmp.health.gov.au/pdf/natstrateng.pdf>

	Expert Committee recommendation	Government response and proposed implementation action
	<p><i>Specific needs for consumers:</i></p> <ul style="list-style-type: none"> i. to ask for, assess and utilise objective information, resources and services to make decisions and take actions that enable the wise choice and use of medicines when required ii. to become more aware of the risks and benefits of medicines, the possibility of non-medicine options and the importance of a healthy life-style iii. to understand the extent to which the regulatory process assesses the quality, safety and efficacy of complementary medicines iv. to develop skills and confidence to use medicines appropriately and to seek help to solve problems when they arise v. to become more aware of the place of medicines within the broader context of health services and society. <p><i>Specific needs for healthcare professionals:</i></p> <ul style="list-style-type: none"> i. to assist people to make informed decisions and learn more about health issues and health care, through the provision of information, education and discussion ii. to become more aware of the risks and benefits of medicines, the possibility of non-medicine options and the importance of a healthy life-style; iii. to utilise objective information, resources and services to make decisions and take actions that enable the wise choice and use of medicines when required iv. to continually develop knowledge and skills to use medicines appropriately. 	
26	<p>Internet advertising be considered part of mainstream advertising, and be subject to mainstream advertising requirements and protocols, including complaints resolution through a centralised complaints and appeals process. However, for practical reasons, Internet advertising may need to be exempt from centralised pre-clearance requirements.</p>	<p>Accepted. <i>This matter will be further developed by the Interim Advertising Council in consultation with stakeholders.</i></p>
27	<p>All jurisdictions introduce legislation to regulate practitioners of traditional Chinese medicine and dispensers of Chinese herbs, based on existing Victorian legislation, as soon as possible.</p>	<p>Noted. <i>The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.</i></p>

	Expert Committee recommendation	Government response and proposed implementation action
28	Health Ministers review the findings of the current New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners and move quickly to implement statutory regulation where appropriate.	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.
29	<p>All jurisdictions adopt the following as necessary attributes of effective, transparent and accountable self-regulatory structures for complementary healthcare practitioners:</p> <p>(a) a certification system which incorporates</p> <ul style="list-style-type: none"> i. appropriate standards of training for membership, established via a consultative process with the profession and endorsed by the relevant educational / industry authorities ii. an established, transparent procedure for assessing practitioner qualifications, incorporating an examination where necessary iii. effective incentives to ensure practitioners seek and maintain certification iv. annual requirements for continuing professional development as a condition of continued certification <p>(b) a code of ethics with which certified practitioners agree to comply</p> <p>(c) effective procedures for receiving, investigating and resolving consumer complaints</p> <p>(d) an established disciplinary system for enforcing conduct and continuing professional development requirements, able to investigate and apply sanctions where necessary, together with a process for appeals</p> <p>(e) effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements</p> <p>(f) external scrutiny and involvement of experts who are not members of the profession, to promote transparency, accountability and credibility.</p>	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.
30	The Australian Government give consideration to revising the definition of organisations whose members satisfy requirements for 'recognised professionals' for the provision of GST-free services, in line with the criteria listed in Recommendation 29.	<i>Accepted, subject to the prior agreement of the States and Territories.</i>

	Expert Committee recommendation	Government response and proposed implementation action
31	Regulatory bodies for healthcare practitioners who are currently regulated by statute (for example, medical practitioners) ensure that their policies and membership standards require their members who practice complementary healthcare or advise on complementary medicines to acquire appropriate skills and competencies.	<i>Noted.</i> The Government notes that this is a State and Territory responsibility, and will bring the matter to the attention of the States and Territories through the Australian Health Ministers' Conference.
32	The Australian Government and States / Territories work together with the various professions to promote development of strong, independent and accountable self-regulatory arrangements for complementary medicine professions that satisfy the criteria listed in Recommendation 29, through: <p>(a) support and advice, including short-term financial assistance where deemed necessary</p> <p>(b) involvement of the professional associations in policy development and committee processes</p> <p>(c) encouraging health funds and workers compensation insurers to restrict 'approved provider' status to members of an independent and accountable self-regulatory body</p> <p>(d) accreditation of education and training courses up to degree and diploma level, by vocational education and training and higher education bodies.</p>	<i>Supported.</i> Except for provision of short-term financial assistance under recommendation 32(a). <p>The Government will consult with the States and Territories, through the mechanisms of the Australian Health Ministers' Conference, to promote the uniform adoption of self-regulatory arrangements which satisfy the criteria of recommendation 29.</p> <p>Any request for short-term financial assistance will be considered in the Budget process.</p>
33	The National Health and Medical Research Council (NHMRC) convene an expert working group to identify the research needs (including efficacy, safety, cost-effectiveness, mechanism of action and capacity building), priorities and resources to address the use of complementary medicines consistent with the <i>National Medicines Policy</i> (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM).	<i>Accepted.</i> The NHMRC will consult with the Department of Health and Ageing and the TGA to determine the most appropriate means of identifying and supporting any research needs consistent with the NMP and QUM.
34	Dedicated funding be made available for complementary medicine research in Australia for a minimum of five years.	<i>Noted.</i> The Government believes no decision can be made prior to consideration of research needs and priorities. <p>However, in the interim, the Government is making available up to \$500,000 to fund a project or projects to investigate the value of the complementary medicine, glucosamine, in the management of osteoarthritis.</p>

	Expert Committee recommendation	Government response and proposed implementation action
35	The amount of funding available for complementary medicine research in Australia be determined on a <i>per capita</i> basis consistent with complementary medicine research funding in the USA.	<i>Not accepted. The Government does not consider that funding should be tied to a specific formula, but that it should be based on research needs, which are yet to be determined (see Recommendation 33).</i>
36	A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.	<i>Accepted. The TGA will consult with the NHMRC and other stakeholders in coordinating this project.</i>
37	The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication.	<i>Accepted.</i>
38	Organisations involved in awarding public funds for healthcare research ensure that: (a) applications for research funding in the area of complementary medicines are assessed by fair, equitable and ethical methods (b) the methods represent the best use of community resources to meet the current and future healthcare needs of the community.	<i>Noted. The Government will continue to work to ensure that assessment of funding applications is based on fair, equitable and ethical grounds that make the best use of community resources.</i>
39	The TGA, in consultation with key stakeholders and as a matter of priority, convene a task group to review the registration process for complementary medicines, taking into account: (a) the complex nature of many complementary medicines and the associated difficulty of characterising ingredients and identifying the active ingredients / components (b) that it may not be feasible to undertake conventional pharmacokinetic and pharmacodynamic studies and measurements in clinical studies (c) that, for some indications, complementary medicines may offer a lower risk and potentially more cost effective option compared with other medicines.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will convene a task group of stakeholders and experts to review the registration process for complementary medicines.</i>
40	The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.	<i>Accepted. The TGA, in collaboration with its New Zealand counterparts, will convene a stakeholder group.</i>
41	The membership of all bodies that advise on the research and use of medicines (including the Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health And Rational use of Medicines (PHARM) Committee) be enhanced to ensure that each has sufficient members with knowledge of, and expertise in, complementary medicines.	<i>Accepted. The Government will review the membership of Australian Government bodies which advise on the research and use of medicines.</i>

	Expert Committee recommendation	Government response and proposed implementation action
42	APAC facilitate a consultation process with the complementary medicines sector and other stakeholders, to clarify the position of complementary medicines in the <i>National Medicines Policy</i> and <i>The National Strategy for Quality Use of Medicines</i> (QUM).	<i>Accepted.</i> APAC has already commenced action to implement this recommendation.
43	<i>The National Strategy for Quality Use of Medicines</i> (QUM) fund more projects directed at education in the use of complementary medicines.	<i>Noted.</i> Any increase in the number of projects should be linked to the outcomes of the study to be undertaken in the implementation of recommendation 25.
44	Complementary medicines be included in the indicators to measure the quality use of medicines component of the <i>National Medicines Policy</i> (NMP) and <i>The National Strategy for Quality Use of Medicines</i> (QUM), with the indicators to be revised periodically.	<i>Accepted.</i> APAC will review the indicators for the <i>National Medicines Policy</i> and the <i>National Strategy for Quality Use of Medicines</i> to ensure the inclusion of complementary medicines data.
45	The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.	<i>Accepted.</i>
46	The Complementary Healthcare Consultative Forum be formally disbanded subject to fulfilment of Recommendation 41.	<i>Accepted.</i> Subject to the outcome of recommendation 41. Relevant stakeholders will be consulted at the appropriate time, prior to any final decision to disband the Forum.
47	A plan to implement the Committee's recommendations be prepared within one month of the Government's response to the report, with the plan to clearly identify tasks, priorities, time lines and responsibilities.	<i>Accepted.</i> This implementation plan will be prepared by the TGA in collaboration with its New Zealand counterparts.
48	Overall accountability for implementing the Committee's recommendations be clearly assigned to a single body.	<i>Accepted.</i> The TGA, in consultation with other Australian and New Zealand government agencies where appropriate, will have overall responsibility for coordinating the implementation of the recommendations agreed to by Government.
49	Implementation of the Committee's recommendations be formally reviewed at the end of 2004.	<i>Accepted.</i> The Government will establish an appropriate process to undertake this review.