Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Implementation of the Government Response to the Recommendations of the Expert Committee On Complementary Medicines In The Health System

Progress Report

February 2006

Introduction

Following the suspension of Pan Pharmaceuticals Limited's manufacturing licence in 2003, the Australian Government established the Expert Committee on Complementary Medicines in the Health System (ECCMHS). The Expert Committee, chaired by Dr Michael Bollen AM, had members with expertise in complementary medicines research, practitioner training, clinical practice, pharmacy, industry and consumer issues.

The Expert Committee's Report contained 49 recommendations covering the regulation of complementary medicines and complementary healthcare practitioners, research and the information and education needs of healthcare practitioners and consumers to improve community confidence in, and the viability of the complementary medicines industry in Australia. A copy of the Expert Committee Report can be found at www.tga.gov.au/docs/html/cmreport1.htm

The ECCMHS found that the two-tiered, risk-based system for medicines, including complementary medicines, was appropriate to support the quality, safety and efficacy of both Registered and Listed complementary medicines. The recommendations it made were aimed at strengthening a system that already leads the world in the regulation of complementary medicines.

Following stakeholder consultation in Australia and New Zealand to help inform its response to the recommendations of the ECCMHS, the Australian Government accepted 35 of the 49 recommendations, accepted another recommendation in principle; and one relating to complementary medicine research funding was not accepted. The remaining 12 recommendations, the majority of which were outside the direct responsibility of the Australian Government, were supported or noted. Attachment A summarises the recommendations of the ECCMHS and the Government Response to the recommendations.

The Therapeutic Goods Administration (TGA) was nominated by the Government as being responsible for coordinating the implementation of the Government Response. The Government's response can be found at www.tga.gov.au/cm/cmresponse.htm

An audit of progress with implementing the Government Response was conducted to gain a clear indication of progress to date, to identify key stakeholders, and to inform the development of an Implementation Plan for further action. Areas with responsibility for implementing the Government Response, including the TGA, other areas of the Department of Health and Ageing (DoHA), the Department of Education, Science and Training, and the Department of Industry, Tourism and Resources, were consulted.

Overview

Implementation of 19 of the recommendations is underway, two of which relating to improving the reporting of adverse events related to complementary medicines are completed (21 and 22). Specific plans and timelines are now in place for all remaining recommendations for which Australian Government action is required.

A number of the recommendations are dependent on others being completed before implementation can commence. While the preliminary work for many recommendations has begun, full implementation will be dependent on the proposed joint Australia New Zealand regulatory scheme for therapeutic products coming into effect.

National Regulatory Controls (Recommendations 1 – 19)

Excellent progress has been made with implementing the 19 recommendations under the Regulatory Controls heading. The TGA has primary carriage of most of these recommendations, with 1, 2, 6, 9 10, 11, 12, 15 already underway, 3 and 17 requiring no further action, and concrete plans in place for all the others. The implementation of the proposed joint Australia New Zealand regulatory scheme for therapeutic products will influence the completion date for many of the recommendations in this group, and the interdependencies between recommendations will also play a part in determining the other completion dates in the implementation schedule.

Adverse Reactions (Recommendations 20 – 24)

Recommendations 21 and 22, seeking the inclusion and promotion of AUST R & AUST L numbers in adverse drug reaction reporting have been completed.

Information and Advertising (Recommendations 25 - 26)

The DoHA is currently refining the scope of the study of information and skills needs for consumers and health professionals (Recommendation 25).

Healthcare Practitioners (Recommendations 27 – 32)

The recommendations relating to the regulation and self-regulatory arrangements for complementary healthcare practitioners have been referred to the Australian Health Workforce Officials' Committee, a sub-committee of the Australian Health Ministers Advisory Council. The Committee recently established a Regulation sub-Committee to examine *inter alia* mechanisms for the nationally consistent regulation of Traditional Chinese Medicine Practitioners.

There is a review of the Vocational Education and Training sector's Health Training Package being conducted by the Community Services and Health Industry Skills Council. The Complementary and Alternative Healthcare training packages are currently under review. Further details can be found at http://www.cshisc.com.au/view_page.asp?ID=56

Industry (Recommendations 33 – 40)

The TGA is continuing to work with the NHMRC to estimate the costs involved in identifying research priorities for Complementary Health research in line with Recommendation 33.

In addition, work has begun on identifying Complementary Health research funded by NHMRC over the past five years. Work will continue to clarify the dictionary of key terms the NHMRC can use to accurately identify funded Complementary Health research.

Administrative and Advisory Mechanisms (Recommendations 41 – 49)

The Minister for Health and Ageing, the Hon Tony Abbott MP, announced a review of the operational arrangements of the Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health And Rational use of Medicines (PHARM) Committee. Implementation of recommendations such as 41 and 45 will be dependent on the outcomes of this review.

APAC and PHARM will continue to operate during the course of the review, and APAC has set up a working party to consider how it can contribute to the implementation of the Government Response.

The Government Response nominated TGA to take responsibility for coordinating the implementation of its response. The TGA has appointed the Complementary Medicines Implementation Reference Group (CMIRG) to help advise and oversee this work.

Key review mechanisms for the implementation process include two annual reports, scheduled for July/August 2006 and 2007, and an 18 month progress report scheduled for February 2007.

Conclusion

Implementation of many of the recommendations has begun and some have been completed. An important outcome of the audit process has been the identification of stakeholders who have a role to play in consultation and in giving effect to the recommendations of the ECCMHS.

A number of the recommendations are dependent on others being completed before implementation can commence. While the preliminary work for many recommendations has begun, full implementation is dependent on the joint Australia New Zealand regulatory scheme for therapeutic products coming into effect.

Summary of Government Responses to the Recommendations of the Expert Committee On Complementary Medicines In The Health System

	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.	*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.*
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.	*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.*
3	The TGA ensure that ingredients with a chemical or biological profile that raises concern of teratogenicity not be permitted in Listed medicines.	*Accepted. This is consistent with the current situation for Listed medicines.*
4	The TGA's *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*, as amended from time to time, be prescribed in the *Therapeutic Goods Regulations 1990* as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines.	*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.*
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 *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*.	*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.*
6	The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.	*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.*

	Expert Committee recommendation	Government response and proposed implementation action
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.	*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.*
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 *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*, and a common understanding of the role and purpose of the *Guidelines*.	*Accepted. The TGA will consult with the NHMRC in updating the Guidelines for Levels and Kinds of Evidence to Support Indications and Claims to encourage greater consistency.*
9	The penalty for an offence under Section 22(3) of the *Therapeutic Goods Act 1989*, 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.	*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.*
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.	*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.*
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.	*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.*
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.	*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.*

	Expert Committee recommendation	**Government response and proposed implementation action**
13	Reference to 'For Practitioner Dispensing Only' products be removed from Therapeutic Goods Order No. 69 – *General Requirements for Labels for Medicines*.	*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.*
14	The TGA review provisions in the *Therapeutic Goods Act 1989* 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".	*Accepted. 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.	*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.*
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.	*Noted. 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.	*Noted. 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.*

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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.	*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.*
19	The TGA, in consultation with the *National Medicines Policy* (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.	*Accepted. The TGA will develop a communication strategy in consultation with the NMP and its partners.*
20	The Minister encourage the *National Medicines Policy* (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: (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 (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 (c) encouraging complementary healthcare practitioners and consumers to report adverse reactions to complementary medicines and further develop the system to facilitate reporting (d) improving dissemination of information associated with adverse reactions to complementary medicines (e) encouraging research on toxicology, safety and interactions between complementary medicines and other medicines.	*Accepted.*
21	The TGA actively pursue the inclusion of AUST L / AUST R numbers within the current Adverse Drug Reactions (Reporting) System (ADRS).	*Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to the ADRS.*

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22	The TGA modify its web-based reporting form to facilitate inclusion of AUST L and AUST R numbers.	*Accepted. In consultation with affected stakeholders, the TGA will investigate and implement the necessary modifications to its web-based reporting form.*
23	The TGA develop the capability to search for a single active ingredient across multiple products in the ADRS database.	*Accepted. The TGA will investigate the feasibility of modifying the current database system, in consultation with affected stakeholders, and will implement the modifications accordingly.*
24	The TGA expand the *Australian Pharmacovigilance Guideline* to include sponsors of complementary medicines.	*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.*
25	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. The terms of reference for the study should be as follows: (a) Consistent with the National Medicines Policy (NMP) and *The National Strategy for Quality Use of Medicines* (QUM), the proposed study shall 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. (b) The study shall have regard to the following needs which have been adapted from *The National Strategy for Quality Use of Medicines* (QUM) *Specific needs for consumers:* 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	*Accepted. The Department of Health and Ageing will commission the proposed study.*

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	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. *Specific needs for healthcare professionals:* 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	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.	*Accepted. This matter will be further developed by the Interim Advertising Council in consultation with stakeholders.*
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.	*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.*
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.	*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.*

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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 (e) effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements (f) external scrutiny and involvement of experts who are not members of the profession, to promote transparency, accountability and credibility.	*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.*
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.	*Accepted, subject to the prior agreement of the States and Territories.*
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.	*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.*

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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: (a) support and advice, including short-term financial assistance where deemed necessary (b) involvement of the professional associations in policy development and committee processes (c) encouraging health funds and workers compensation insurers to restrict 'approved provider' status to members of an independent and accountable self-regulatory body (d) accreditation of education and training courses up to degree and diploma level, by vocational education and training and higher education bodies.	*Supported. Except for provision of short-term financial assistance under recommendation 32(a).* *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.* *Any request for short-term financial assistance will be considered in the Budget process.*
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 *National Medicines Policy* (NMP) and *The National Strategy for Quality Use of Medicines* (QUM).	*Accepted. 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.	*Noted. The Government believes no decision can be made prior to consideration of research needs and priorities.* *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.*
35	The amount of funding available for complementary medicine research in Australia be determined on a *per capita* basis consistent with complementary medicine research funding in the USA.	*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).*
36	A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.	*Accepted. 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.	*Accepted.*

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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.	*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.*
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.	*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.*
40	The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.	*Accepted. The TGA, in collaboration with its New Zealand counterparts, will convene a stakeholder group.*
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.	*Accepted. 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 *National Medicines Policy* and *The National Strategy for Quality Use of Medicines* (QUM).	*Accepted. APAC has already commenced action to implement this recommendation.*
43	*The National Strategy for Quality Use of Medicines* (QUM) fund more projects directed at education in the use of complementary medicines.	*Noted. 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.*

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44	Complementary medicines be included in the indicators to measure the quality use of medicines component of the *National Medicines Policy* (NMP) and *The National Strategy for Quality Use of Medicines* (QUM), with the indicators to be revised periodically.	*Accepted. APAC will review the indicators for the National Medicines Policy and the National Strategy for Quality Use of Medicines to ensure the inclusion of complementary medicines data.*
45	The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.	*Accepted.*
46	The Complementary Healthcare Consultative Forum be formally disbanded subject to fulfilment of Recommendation 41.	*Accepted. 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.	*Accepted. 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.	*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.*
49	Implementation of the Committee's recommendations be formally reviewed at the end of 2004.	*Accepted. The Government will establish an appropriate process to undertake this review.*