Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

Implementation of the Government Response to the Recommendations of the Expert Committee on Complementary Medicine in the Health System

Progress Report

October 2006

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Table of Contents

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Report of Progress October 2006

Introduction

In April 2003, the Therapeutic Goods Administration (TGA) initiated the recall of more than 1600 complementary medicines from the Australian marketplace. It was the largest recall of medicines in Australia. The recall was a result of the failure of one medicine manufacturer to maintain appropriate manufacturing and quality-control standards. Following the recall, consumer groups, health professionals, researchers and practitioners raised concerns about the level of trust that could be placed in complementary medicines. The role of complementary healthcare practitioners also came under scrutiny.

The Expert Committee

The Australian Government established the Expert Committee on Complementary Medicines in the Health System n May 2003, to reassure the public, and maintain confidence in Australia's reputation as a supplier of high quality and safe medicines. The Expert Committee was asked to consider the regulatory, health system and industry structures necessary to ensure that the objectives of the National Medicines Policy (NMP) were met in relation to complementary medicines.

The Expert Committee's Report contained 49 recommendations which covered six key areas:

- regulatory controls;
- adverse reactions;
- information and advertising;
- healthcare practitioners;
- industry; and
- administrative and advisory mechanisms.

The Government Response

To assist the Government in making its response to the Expert Committee's recommendations, the Report was released for public consultation in both Australia and New Zealand during 2004, with over 90 submissions received.

The Australian Government released its response in March 2005, accepting 35 of the 49 recommendations, and providing in-principle acceptance to one other recommendation. Twelve recommendations, the majority of which were outside the direct responsibility of the Australian Government, were supported or noted. One recommendation was not accepted.

The Therapeutic Goods Administration (TGA) was nominated by the Government as being responsible for coordinating the implementation of the Government

response. The TGA established the Complementary Medicines Implementation Reference Group to provide advice on and oversee the implementation of the Government Response. The Reference Group is chaired by Dr Michael Bollen, who was also Chair of the Expert Committee, and includes representatives and experts in complementary medicine research, education, industry and consumer matters.

An Implementation Plan for the Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System was finalised in October 2005, following an audit of progress by the TGA.

The audit helped to identify the complex array of interdependencies between recommendations, with a number of recommendations being dependent on others being completed before implementation can commence. In addition, the audit identified the multiple stakeholders involved and the number of these stakeholders who have a role to play in giving effect to the recommendations. Overall, the work done during the audit provided a firm foundation from which to regularly monitor further progress with implementing the Government Response.

The Australia New Zealand Therapeutic Products Authority

On 10 December 2003, the Australian and New Zealand Governments signed an agreement to establish a joint regulatory scheme for therapeutic products.

The joint scheme will regulate medicines (including complementary medicines) and medical devices and is expected to come into force on the passage of legislation and ratification of the treaty in the second half of 2007. Many of the Expert Committee's regulatory recommendations are being implemented as part of the proposed joint Australia New Zealand regulatory scheme.

Consultation on the draft legislation and regulations (Rules and Managing Director's Orders) commenced in May 2006 and will continue into March 2007.

The website (www.anztpa.org) keeps stakeholders informed on current and past developments towards the establishment of a joint agency and includes progress reports, discussion documents, media releases and frequently asked questions.

Further information is also available on the Australian Therapeutic Goods Administration Internet site (www.tga.gov.au) and the New Zealand Medsafe Internet site (www.medsafe.govt.nz).

Activities in Other Portfolios

Therapeutic products regulation is not the only area of government activity that helps to ensure the public's confidence in complementary medicines and the complementary healthcare practitioners who recommend them, or in promoting a strong and viable complementary medicines industry.

For example, in July 2006, the Council of Australian Governments (COAG) agreed that a national professional registration scheme for health practitioners would be established.

The scheme would apply to the nine occupational groups that are currently subject to statutory registration in all jurisdictions. The inclusion under the scheme of other health occupations currently registered in a limited number of jurisdictions will be determined during implementation of the scheme through assessment against criteria agreed by a ministerial council comprising Commonwealth, State and Territory Health Ministers. The subsequent inclusion of new professions will also be covered by this process.

In addition, the Department of Education, Science and Training (DEST), through the Community Services and Health Industry Skills Council, is undertaking a review of the Health Training Package. The Training Package includes national vocational and technical education qualifications and competency standards for a range of complementary and alternative healthcare practitioners, and is expected to be endorsed by the National Quality Council by early 2007.

AusIndustry (part of the Department of Industry, Tourism and Resources) delivers a range of more than 30 business products, including innovation grants, tax and duty concessions, small business services, and support for industry competitiveness worth nearly $2 billion each year to about 10,000 small and large businesses.

To help customers with product and eligibility information, AusIndustry has *customers service managers* located in 26 offices across Australia, a national hotline and website, plus almost 60 *Small Business Field Officers* in regional areas.

The Department of Industry, Tourism and Resources (DITR) will be working with complementary medicines industry groups over the next year on the appropriateness and accessibility of their grants programs, research funding and other initiatives.

Progress with Implementing the Government Response

Overview

Significant progress has been made in implementing the *Government Response to the recommendations of the Expert Committee on Complementary Medicines in the Health System* during 2005-06. Appendix 1 provides a summary of the Government's Response to each of the Expert Committee's recommendations, along with a brief update of implementation progress to date.

Of the 36 recommendations accepted or accepted in principle by the government[i], implementation activity has been completed for 8 of those recommendations[ii]. Implementation activity is currently underway for a further 17 recommendations[iii],

[i] *Recommendations accepted or accepted-in-principle by the government: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 30, 33, 36, 37, 39, 40, 41, 42, 44, 45, 46, 47, 48, 49 (see Appendix 1).*

[ii] *Accepted recommendations that have been completed: 9, 21, 22, 26, 41, 44, 47, 48 (see Appendix 1).*

[iii] *Accepted recommendations underway: 1, 2, 5, 6, 7, 10, 11, 12, 14, 15, 20, 25, 33, 39, 40, 42 49 (see Appendix 1).*

and implementation activity will occur sometime in the future for 10 recommendations[iv]. No implementation action was required for one recommendation (recommendation 3).

Those recommendations that were noted or supported in the Government response[v] that were outside the Australian Government's jurisdiction were referred to the States and Territories for consideration. The government has completed its undertakings in relation to 7 of the recommendations[vi], and no action was required for a further two recommendations (recommendations 17 & 38). Recommendation 18, relating to a uniform approach to the legislation governing access to and use of medicines, is being implemented as part of the proposed joint regulatory process as well as through other joint Commonwealth, State and Territory action.

One recommendation (recommendation 35) relating to dedicated research funding for complementary medicines according to a specific formula was not accepted in the government response.

A number of regulatory recommendations have been implemented as a result of amendments to the Therapeutics Goods Act which were passed by the Australian Parliament during the first half of 2006. Many more recommendations have been or are in the process of being implemented as part of the establishment of the Australia New Zealand Therapeutic Products Authority.

The complex interdependencies between recommendations means that some recommendations are dependent on one or more others being completed before work on implementing them can commence. An example is recommendation 19 which relates to the development of a communication strategy to inform consumers of the risks associated with the personal importation of complementary medicines, which will need to be informed by the study of information and skills needs for consumers and healthcare practitioners being undertaken in response to recommendation 25.

Another example of a recommendation being dependent on other factors is recommendation 13, relating to reviewing the need for "Practitioner Dispensing Only" products which the government undertook to conduct once the proposed joint regulatory scheme had been established.

The following sections of this report provide information on implementation activity within each of the six key areas covered by the Expert Committee. The table in Appendix 1 provides a summary of progress with each recommendation against the government response, and the Gantt Chart at Appendix 2 shows an indicative timeline for the completion of each of the recommendations.

To maintain consumer confidence in the quality, safety and effectiveness of medicines supplied in Australia, an important feature of the TGA's risk management approach to both Listed and Registered complementary medicines is an appropriate level of post-market regulatory activity.
The essential elements of this systematic risk-based approach include:

- *targeted and random desk-based audits of Listed products;*
- *monitoring of adverse reactions to complementary medicines;*
- *targeted and random laboratory testing of products and ingredients;*
- *targeted and random surveillance in the market place;*
- *an effective, responsive and timely recalls procedure;*
- *audit of GMP; and*
- *effective controls for the advertising of therapeutic goods.*

The Regulation of Complementary Medicines in Australia http://www.tga.gov.au/cm/cmreg-aust.htm

National Regulatory Controls (Recommendations 1 – 19)

In its response to the Expert Committee's recommendations, the Government recognised its dual obligations to ensure public health and safety, while at the same time minimising the cost of compliance for the complementary medicine

[iv] *Accepted recommendation where implementation is planned for the future: 4, 8, 19, 23, 24, 30, 36, 37, 45, 46 (see Appendix 1).*
[v] *Recommendations noted or supported by the government: 13, 16, 17, 18, 27, 28, 29, 31, 32, 34, 38, 43 (see Appendix 1).*
[vi] *Noted or Supported recommendations where the government has completed its undertakings: 16, 27, 28, 29, 31, 32, 34 (see Appendix 1).*

industry. The Government accepted 14[vii] of the 19 recommendations regarding national regulatory controls, and gave in-principle acceptance to another[viii]. It supported recommendation 18 which urged a uniform approach by the States and Territories to the regulation of access and use of medicines, and noted the remaining 3[ix] recommendations in the national regulatory controls category.

Recommendations 1 and 2 regarding legally enforceable quality standards for complementary medicines are being implemented as part of the arrangements for the proposed establishment of the Australia New Zealand Therapeutics Products Authority (ANZTPA). Consultations are being conducted between May 2006 and March 2007 in both countries on the proposed legislative and regulatory arrangements that will underpin the work of the joint Authority.

Recommendation 3, regarding the need to ensure that ingredients with chemical or biological profiles that raised concerns about teratogenicity were not permitted for use in Listed medicines, was already, and continues to be, consistent with current Government policy, and therefore required no implementation action.

The TGA is planning to undertake a review of the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* during 2006-07 so that the *Guidelines* can be incorporated into the regulations for the proposed joint regulatory scheme, in line with the Government's response to recommendation 4. The review of the *Guidelines* will include liaison with the National Health and Medical Research Council (NHMRC) to ensure greater consistency between the *Guidelines* and the NHMRC's levels of scientific evidence while at the same time continuing to recognise evidence based on the traditional use of certain complementary medicine as outlined in the Government's response to recommendation 8.

Sponsors of Listed medicines (to be referred to as Class I medicines under the proposed Australia New Zealand therapeutic products legislation) will be required to submit a summary of the evidence supporting the claims made for their products at the time of listing their products once the proposed joint regulatory scheme comes into effect (recommendation 5). The TGA has been systematically increasing its random targeting and assessment of the evidence held by sponsors (recommendation 6) of Listed medicines, so that they now randomly assess approximately 20% of all new products listed.

The TGA and MedSafe NZ established a stakeholder group during early 2006 to provide advice on the mechanisms and stakeholders that need to be included in the mechanisms to provide advice on the priority targeting of assessments of sponsor-held evidence (recommendation 7). On the advice of the stakeholder group, a broader group will be established under the proposed joint regulatory scheme to provide priority targeting advice.

New penalties and sanctions were introduced in the TGA Amendment Act in May 2006, which allows for penalties of up to 50,000 penalty points, or 5 years' imprisonment where a sponsor refuses to give information to support the claims

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[vii] *National Regulatory Controls recommendations accepted: 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12, 14, 15, 19 (see Appendix 1).*

[viii] *National Regulatory Controls recommendation accepted-in-principle: 9 (see Appendix 1).*

[ix] *National Regulatory Controls recommendations noted: 13, 16, 17 (see Appendix 1).*

being made by their medicines to the Secretary of the Department of Health and Ageing (recommendation 9).

Regulation of herbal and homeopathic medicines is being introduced as part of the proposed joint regulatory arrangements, as outlined in the Government's response to recommendations 10 and 11. Consultation on the regulation of homeopathic and related medicines took place in Australia (including a Regulation Impact Statement) and New Zealand from May – August 2006.

The TGA is consulting with industry about the feasibility of implementing an industry-based quality code for the use of raw herbs and starting materials in the manufacture, dispensing or extemporaneous compounding of complementary medicines as a preliminary step towards addressing recommendation 12.

The issues surrounding "For Practitioner Dispensing Only" have been raised in Australia and New Zealand as part of the consultations on the proposed labelling arrangements under the joint regulatory scheme. In line with the Government Response to recommendation 13, further examination of these issues is planned to occur after the establishment of the proposed joint regulatory authority.

Provisions are included in the Therapeutic Goods Act to allow the Government to take appropriate and timely action to protect public health safety by imposing conditions on licences or by revoking or suspending licences (recommendation 14).

A comprehensive review of labelling requirements has been undertaken as part of the move to the proposed joint Australia New Zealand regulatory scheme, and the resulting draft labelling rules have taken recommendation 15 into account. Recommendation 15 sought to better assist with product identification of recalled medicines, and the TGA has measures in place to ensure that recalled medicines are not subsequently offered for unauthorised sale.

The Government agreed to refer recommendation 16, relating to the coordination of appropriate regulatory activity to prevent the sale of illegal complementary medicines, to the National Coordinating Committee on Therapeutic Goods (NCCTG). The TGA referred this matter to the NCCTG in May 2006, with a request that the members undertake the appropriate action to implement the recommendation.

Recommendation 17 recommended that State and Territory governments adopt nationally consistent therapeutic goods legislation, and recommendation 18 sought a uniform approach to legislation regulating access to and use of medicines. These issues are being addressed as part of the implementation of the proposed Australia New Zealand regulatory scheme, and will be achieved once the Authority is established.

A communications strategy to inform consumers of the potential risks associated with the personal importation of complementary medicines (recommendation 19) will be informed by the findings and outcomes from the study of the information and skills needs of consumers and health practitioners to enable informed decisions about the use of complementary medicines (recommendation 25), which

is currently underway. The TGA website currently contains information for consumers on the personal importation of medicines.

Adverse Reactions (Recommendations 20 – 24)

A key focus of the Government's *National Strategy for the Quality Use of Medicines* (QUM) is the safe 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 Expert Committee made 5 recommendations in relation to adverse reactions, all of which were accepted in the Government Response.

The Adverse Drug Reactions Unit of the TGA has promoted the reporting of adverse events associated with complementary medicines during 2005-06, and the National Prescribing Service is actively looking at providing more information to health care professionals and consumers on complementary medicines, including promoting the reporting of adverse medicine events (recommendation 20).

Two of the recommendations (21 and 22) relating to improving the reporting of complementary medicine related adverse medicine events have been implemented. AUST L and AUST R numbers are now included on paper and electronic adverse drug reporting forms.

The Adverse Drug Reactions Reporting System (ADRS) is the database which holds information on all reported adverse drug events in Australia. While it is possible to search the database for a single ingredient, the process involves the manual searching of records (recommendation 23). Upgrading the database to allow more convenient automated single ingredient searches is one of a number of enhancements to the ADRS on the TGA's work program. It is not currently possible to estimate when the enhancement is likely to take place.

A Consultation Paper on Product Vigilance in the Australia New Zealand Therapeutic Products Authority, incorporating Pharmacovigilance guidelines for over-the-counter and complementary medicines has been developed & is expected to be finalised during 2007 (recommendation 24).

Information and Advertising (Recommendations 25 – 26)

Consumers and healthcare practitioners, whether practising within the conventional Western model of clinical medicine or within different frameworks, are increasingly seeking information about complementary medicines. The Expert Committee made two recommendations to the Government with the aim that consumers and healthcare practitioners could have access to reliable information about complementary medicines, and the skills to interpret information and make informed decisions about the use of complementary medicines. The Government accepted both recommendations.

The Department of Health and Ageing have commissioned the National Prescribing Service (NPS) to undertake key aspects of the study of consumer and health practitioner information and skills needs in line with the Expert Committee's recommendation 25.

Internet advertising is now subject to the same requirements, protocols and complaints resolution processes as mainstream advertising (with the exception pre-clearance requirements).

Healthcare Practitioners (Recommendations 27 – 32)

The Expert Committee considered evidence that there were sustainable but significant risks associated with the practice of some forms of complementary healthcare practice, such as Traditional Chinese Medicine, Western and/or Ayurvedic herbal medicine and naturopathy, and made 6 recommendations concerning the regulation, and self-regulation of complementary healthcare practitioners. In its response, the Government recognised that the regulation of healthcare practitioners was a matter for the States and Territories, and undertook to refer these recommendations to the Australian Health Ministers' Conference.

GPs have a high level of interest in complementary therapies. Government regulation and registration of complementary therapies is seen by GPs as important in order to ensure professional standards of practice. Given the high level of interest, provision of undergraduate and postgraduate education in complementary therapies could be considered. In addition, the development of clinical guidelines would be of benefit.

Aust Fam Physician 2000 Jun; 29(6):602-6

In January 2006, the recommendations regarding the regulatory and self-regulatory arrangements for complementary healthcare practitioners were referred to the Australian Health Workforce Officials Committee (AHWOC), a Sub-Committee of the Australian Health Ministers' Advisory Committee.

Subsequently, the Council of Australian Governments (COAG) agreed at their meeting in July 2006 that a national professional registration scheme for health practitioners would be established.

The inclusion under the scheme of complementary healthcare occupations currently registered in Victoria will be determined during implementation of the scheme through assessment against criteria agreed by a ministerial council comprising Commonwealth, State and Territory Health Ministers.

The report by Lin *et al* on the practice and regulatory requirements for Naturopathy and Western Herbal Medicine (WHM) that was undertaken for the Victorian Government[x] bear out the Expert Committee's findings that there is sufficient risk to public health to require national registration of complementary healthcare practitioners.

The COAG process will also consider the regulation of professions not currently registered in any jurisdiction as part of establishing the national professional registration scheme.

As outlined in the Government response, once satisfactory progress has been made by the States and Territories on the regulatory and self-regulatory matters covered by recommendations 27 – 29, the Australian Government could review the current provisions pertaining to "recognised professional" status being provided to certain organisations to enable GST-free services to be provided.

Industry (Recommendations 33 – 40)

In considering the regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia, the Expert Committee made 8 recommendations aimed at promoting a stronger

[x] *Lin V, Bensoussan A, Myers S P, McCabe P, Cohen M, Hill S, Howse G: The Practice and Regulatory Requirements of Naturopathy and Western Herbal Medicine, La Trobe University, Nov 2005*

focus on research into complementary medicines, as well as other ways to promote innovation in the complementary medicines industry. The Government accepted 5 of the 8 recommendations[xi], noted two recommendations[xii], and rejected a recommendation that complementary medicine research be allocated according to a *per capita* formula.

The National Health and Medical Research Council (NHMRC) will host a workshop for complementary medicine researchers in late 2006, and TGA and NHMRC have begun work on developing the key words to enable searching of the NHMRC database to accurately identify NHMRC funded Complementary Medicine research projects (recommendations 33 & 36).

The TGA convened a joint stakeholder group to consider recommendations 39 and 40 regarding the regulatory and other options to encourage innovation and research in complementary medicines in Australia and New Zealand. The stakeholder group met twice in the first half of 2006 and has developed advice for the TGA and MedSafe NZ on possible ways forward. Part of that advice involves proposals that the Departments of Industry in both countries working with the complementary medicines industry groups to provide advice on accessing their funding and innovation programs, and working with Intellectual Property regulators in both countries to assist complementary medicines groups to increase their awareness of the IP options relevant to their business.

As part of the move to the proposed Australia New Zealand joint regulatory scheme for therapeutic products, the TGA in collaboration with MedSafe NZ will convene a stakeholder group to review the role of the complementary medicine registration process in promoting or providing a barrier to complementary medicines innovation and research in Australia and New Zealand.

Administrative and Advisory Mechanisms (Recommendations 41 – 49)

The Expert Committee made a range of recommendations on the administrative and advisory mechanisms it considered necessary to strengthen the integration of complementary medicines into the National Medicines Policy and the National Strategy on the Quality Use of Medicines, and to guide the implementation of the Expert Committee's recommendations. The Government accepted 8[xiii] of the nine recommendations, and noted recommendation 43 relating to the funding of projects directed at education in the use of complementary medicines.

Implementation of a number of the recommendations in relation to administrative and advisory mechanisms is dependent on the outcomes of the review of the operational arrangements of the Australian Pharmaceutical Advisory Council (APAC). Progression of these recommendations will be further considered once the outcomes from the APAC review are known.

An update of progress with implementing the Government Response was published on the TGA web-site in February 2006. It is expected that this information will be updated regularly.

[xi] *Industry recommendations accepted by the Government: 33, 346, 37, 39, 40 (see Appendix 1).*

[xii] *Industry recommendations noted by the Government: 34 & 38 (see Appendix 1).*

[xiii] *Administrative and Advisory recommendations accepted by the Government: 41, 42, 44, 45, 46, 47, 48, 49 (see Appendix 1).*

Details of the Complementary Medicines Implementation Reference Group, including members' names and professional affiliations, together with Terms of Reference will also be published on the web-site.

A Communications Strategy is being developed to ensure relevant stakeholders and the public can be kept informed of progress with implementing the Government Response.

Conclusion

There has been a great deal of progress with implementing the *Government Response to the recommendations of the Expert Committee on Complementary Medicines in the Health System* in the year since its release in March 2005.

Many of the regulatory recommendations currently being implemented will not come into effect until the establishment of the proposed joint regulatory scheme. Therefore, any delay in the implementation of the joint Authority will also delay the implementation of the Government Response.

Of the 45 recommendations for which Australian Government activity was pledged in the response, activity in relation to 14 of the recommendations has been completed, with a further 19 recommendations currently being acted upon. Twelve recommendations remain to be acted upon, of which most are expected to be commenced during 2007.

Appendix 1 - Government Response to the Expert Committee's recommendations and progress on implementation to 30 June 2006

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*This recommendation is being implemented under arrangements for the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). Consultation on the legislative and regulatory underpinnings of ANZTPA is being undertaken in Australia and New Zealand between May 2006 and March 2007.*	**Underway**
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.*	*Implementation of this recommendation is being undertaken as part of the proposed joint regulatory scheme.*	**Underway**
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.*	*This is consistent with the current situation for Listed medicines.* ***No further action is required.***	**No action required**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*A review of the Guidelines is planned to occur during 2006-07 so that they can be included in the regulatory arrangements (Managing Director's Orders) of the proposed Australia New Zealand regulatory scheme. Consultation will occur on the draft revised Guidelines in Australia and New Zealand as part of the review.*	**Planned**
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.*	*This requirement is being introduced under arrangements for the proposed joint regulatory scheme.*	**Underway**
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.*	*The TGA has increased the proportion of random and targeted assessment of sponsor-held evidence to approximately 20% of all newly listed medicines.*	**Underway**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The TGA and MedSafe NZ established a stakeholder group during early 2006 to provide advice on the mechanisms and stakeholders that need to be included for the successful implementation of this recommendation. On the advice of the stakeholder group, a broader group will be established under the proposed joint regulatory arrangements to provide priority targeting advice.*	**Underway**
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.*	*This issue will be dealt with as part of the review of the* Guidelines for Levels of Evidence to Support Indications and Claims *under recommendation 4.*	**Planned**
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.*	*Recommendation 9 has been implemented. New penalties and sanctions, of up to 50,000 penalty points, or 5 years' imprisonment, were introduced in the TGA Amendment Act in May 2006.*	**Completed**
10	Homoeopathic medicines and related remedies making therapeutic claims be regulated to ensure they meet appropriate standards of safety, quality and efficacy	***Accepted.*** *Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced*	*Regulation of herbal and homeopathic medicines is being introduced as part of the proposed joint regulatory scheme. Consultation on the regulation of*	**Underway**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
	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;	*under arrangements for the trans Tasman therapeutic products regulatory agency.*	*homeopathic and related medicines is taking place in Australia (including a Regulation Impact Statement) and New Zealand from May – August 2006.*	
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.*	*Regulation of herbal and homeopathic medicines is being introduced as part of the proposed Australia New Zealand regulatory scheme. Consultation on the regulation of homeopathic and related medicines is taking place in Australia (including a Regulation Impact Statement) and New Zealand from May – August 2006.*	**Underway**
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.*	*The TGA has consulted with Industry about implementing an industry-based set of standards for the use of raw herbs and starting materials in the manufacture, dispensing or extemporaneous compounding of complementary medicines.*	**Underway**
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.*	*Consultation on the need to remove 'For Practitioner Dispensing Only' will occur after the establishment of the joint regulatory scheme.*	**Planned**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*Provisions are included in the Therapeutic Goods Act to allow the Government to take appropriate and timely action to protect public health safety by imposing conditions on licences or by revoking or suspending licences.*	**Completed**
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.*	*A comprehensive review of labelling requirements including two rounds of public consultation has been undertaken as part of developing the ANZTPA legislation. The draft labelling rule will be part of the ANZTPA consultation process scheduled for March 2007.*	**Underway**
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.*	*The TGA has referred this matter to the NCCTG with a request that it coordinate appropriate regulatory activity.*	**Government Action Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The establishment of the proposed Australia New Zealand Therapeutic Products Authority will result in national legislation relating to the quality, safety and efficacy of medicines, and will therefore finalise the implementation of this recommendation.*	**No action required**
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.*	*This recommendation will be implemented as part of the proposed joint regulatory scheme as well as through changes to be implemented as part of the Galbally review.*	**Underway**
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.*	*A communication Strategy will be developed as information becomes available from the implementation of Recommendation 25.*	**Planned**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
20	The Minister encourage the *NMP* partners to develop & adequately resource a strategy to improve the quality & proportion of complementary medicines adverse reaction reports by health professionals & consumers to ADRAC including but not limited to: a) creating a greater awareness among **all** health professionals & consumers of the potential for complementary medicines to interact with other medicines & that this be within the context of other medicines interactions b) encouraging doctors to include questions in a non-judgmental way about complementary medicines use when taking patient history & to include complementary medicines in adverse drug reaction reports c) encouraging complementary healthcare practitioners & consumers to report adverse reactions to complementary medicines & 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 & interactions between complementary medicines and other medicines.	***Accepted.***	*The Adverse Drug Reactions Unit and National Prescribing Service are both promoting the reporting of adverse events associated with complementary medicines. Other aspects of this recommendation are linked to a number of other recommendations.*	**Underway**
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.*	*This recommendation has been implemented. The ADRS has sought AUST L and AUST R details since February 2005.*	**Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*This recommendation has been implemented. The ADRS updated its web-based report forms to include a request for AUST L and AUST R details in February 2005.*	**Completed**
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.*	*It is possible to search for a single ingredient on the ADRS database but the process is cumbersome. An update of the system is on the ADR work program, and will be competing for funding in 2007-08.*	**Planned**
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.*	*A Consultation Paper on Product Vigilance in the Australia New Zealand Therapeutic Products Authority, incorporating Pharmacovigilance guidelines for over-the-counter and complementary medicines has been developed & is expected to be finalised during 2007.*	**Planned**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
25	DoHA commission a study to determine the complementary medicines information $ skills needs of healthcare professionals & consumers, options for conveying this information to stakeholders, & the costs & resources necessary to meet these needs. The terms of reference for the study should be as follows: a) Consistent with the NMP & QUM the proposed study shall i. identify the information & skills needed by healthcare professionals & 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 & skill requirements are being achieved, & identify associated gaps and deficiencies iii. recommend strategies & initiatives to address any identified gaps & deficiencies iv. develop terms of reference for an independent post-implementation evaluation of recommended strategies & initiatives v. assess the financial & other resources needed to implement these strategies & initiatives b) The study shall have regard to the following needs which have been adapted from the QUM strategy's Specific needs for consumers: i. to ask for, assess & utilise objective information, resources & services to make decisions & take actions that enable the wise choice & use of medicines when required; ii. to become more aware of the risks & benefits of medicines, the possibility of non-medicine options & the importance of a healthy life-	***Accepted***. *The Department of Health and Ageing will commission the proposed study.*	*The Department of Health and Ageing has asked the National Prescribing Service to undertake the study. The first phase of the project, consisting of research, consultation and focus groups with consumers and healthcare practitioners, is expected to be completed in late 2006.*	**Underway**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
	style; iii. to understand the extent to which the regulatory process assesses the quality, safety & efficacy of complementary medicines; iv. to develop skills & confidence to use medicines appropriately & 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 & society. Specific needs for healthcare professionals: i. to assist people to make informed decisions & learn more about health issues & health care, through the provision of information, education & discussion; ii. to become more aware of the risks & benefits of medicines, the possibility of non-medicine options & the importance of a healthy life-style; iii. to utilise objective information, resources & services to make decisions & take actions that enable the wise choice & use of medicines when required; iv. to continually develop knowledge & 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.*	*This recommendation has been implemented. Internet advertising is now regarded as mainstream advertising and subject to centralised complaints resolution processes. Internet advertising is exempt from pre-clearance requirements.*	**Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The Government has implemented its response to this recommendation. The issue was referred to the Australian Health Workforce Officials Committee, which is a sub-Committee of the Australian Health Ministers' Advisory Council, in January 200 and will be implemented as part of the COAG arrangements for a national professional registration scheme.*	**Government Action Completed**
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.*	*The Government has implemented its response to this recommendation. The issue was referred to the Australian Health Workforce Officials Committee, which is a sub-Committee of the Australian Health Ministers' Advisory Council, in January 2006 and will be implemented as part of the COAG arrangements for a national professional registration scheme.*	**Government Action Completed**
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	***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.*	*The Government has implemented its response to this recommendation. The issue was referred to the Australian Health Workforce Officials Committee, which is a sub-Committee of the Australian Health Ministers' Advisory Council, in January 2006 and will be implemented as part of the COAG arrangements for a national professional registration scheme. The referral letter asked the Committee to consider the appropriate regulatory and self-regulatory structures required to ensure the health and safety of consumers.*	**Government Action Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
	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.			
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.*	*The Australian Government will review the definitions once sufficient regulatory and self-regulatory arrangements are in place (as per Recommendations 27 - 29).*	**Planned**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The Government has implemented its response to this recommendation. The issue was referred to the Australian Health Workforce Officials Committee, which is a sub-Committee of the Australian Health Ministers' Advisory Council, in January 2006 and will be implemented as part of the COAG arrangements for a national professional registration scheme.*	**Government Action Completed**
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.*	*The Government has implemented its response to this recommendation. The issue was referred to the Australian Health Workforce Officials Committee, which is a sub-Committee of the Australian Health Ministers' Advisory Council, in January 2006 and will be implemented as part of the COAG arrangements for a national professional registration scheme. In addition, a review of the Health Training Package including national vocational and technical education complementary healthcare qualifications and competency standards is being conducted.*	**Government Action Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The NHMRC will host a workshop for complementary medicine researchers in 2006-07.*	**Underway**
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.*	*The Government believes no decision can be made on dedicated research funding prior to consideration of research needs and priorities. The Government has funded a research project to investigate the value of glucosamine in the management of osteoarthritis.*	**Government Action Completed**
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).*	*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).*	**Not Accepted – No action required**
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.*	*The TGA will work on developing this database in consultation with NHMRC and complementary medicines researchers during 2006-07.*	**Planned**

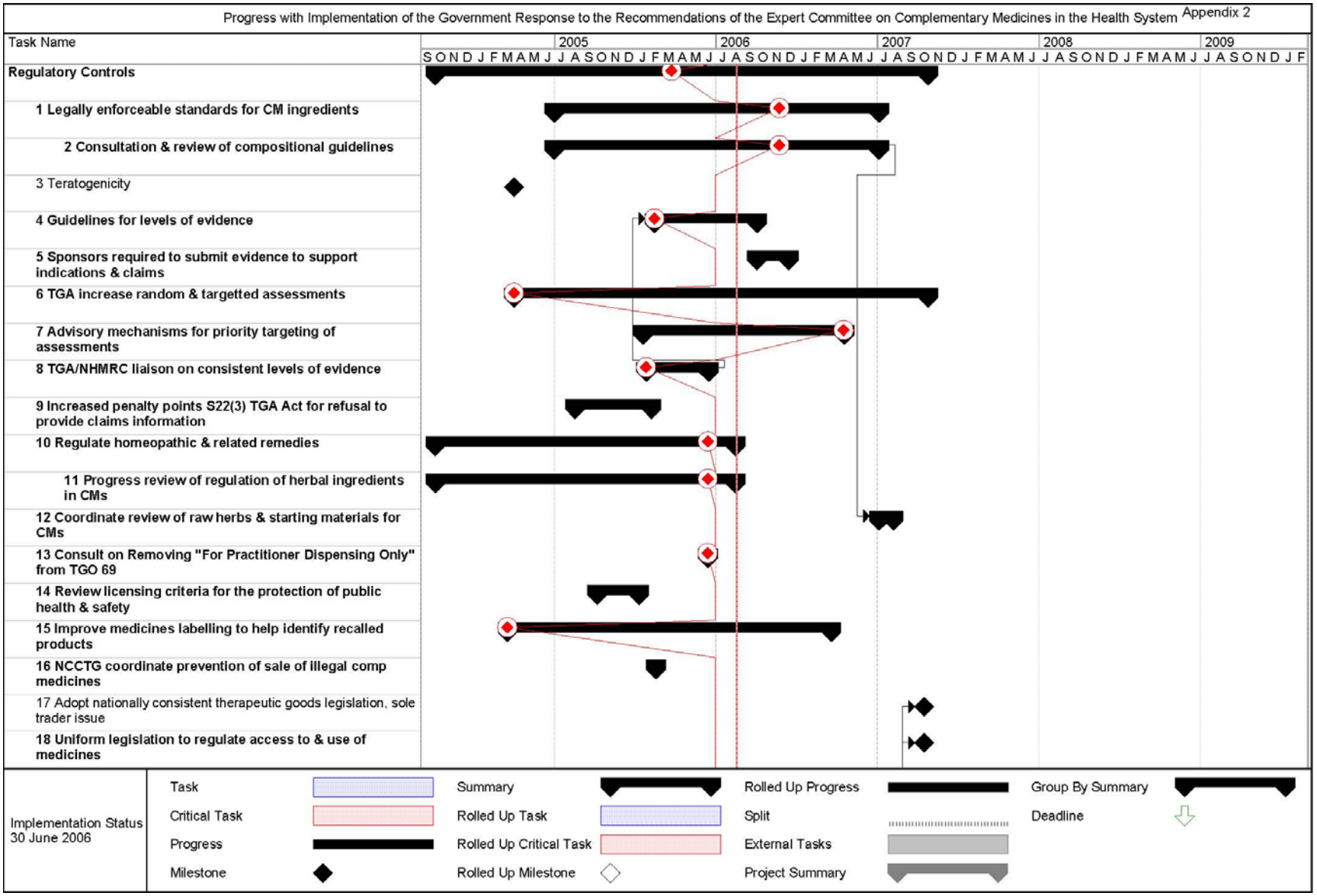
	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
37	The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication.	***Accepted.***	*TGA has good links with international CM research. Consultation on establishing formal links with research agencies will occur during 2006-07.*	**Planned**
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.*	*No further action required. The Government undertakes regular, independent reviews of publicly funded research programs which report on these issues.*	**No action required**
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.*	*This recommendation was considered by a joint Australia New Zealand stakeholder group in conjunction with recommendation 40 in the early half of 2006. A further Australia New Zealand group will be convened during 2006-07 to review the registration process for complementary medicines as recommended.*	**Underway**

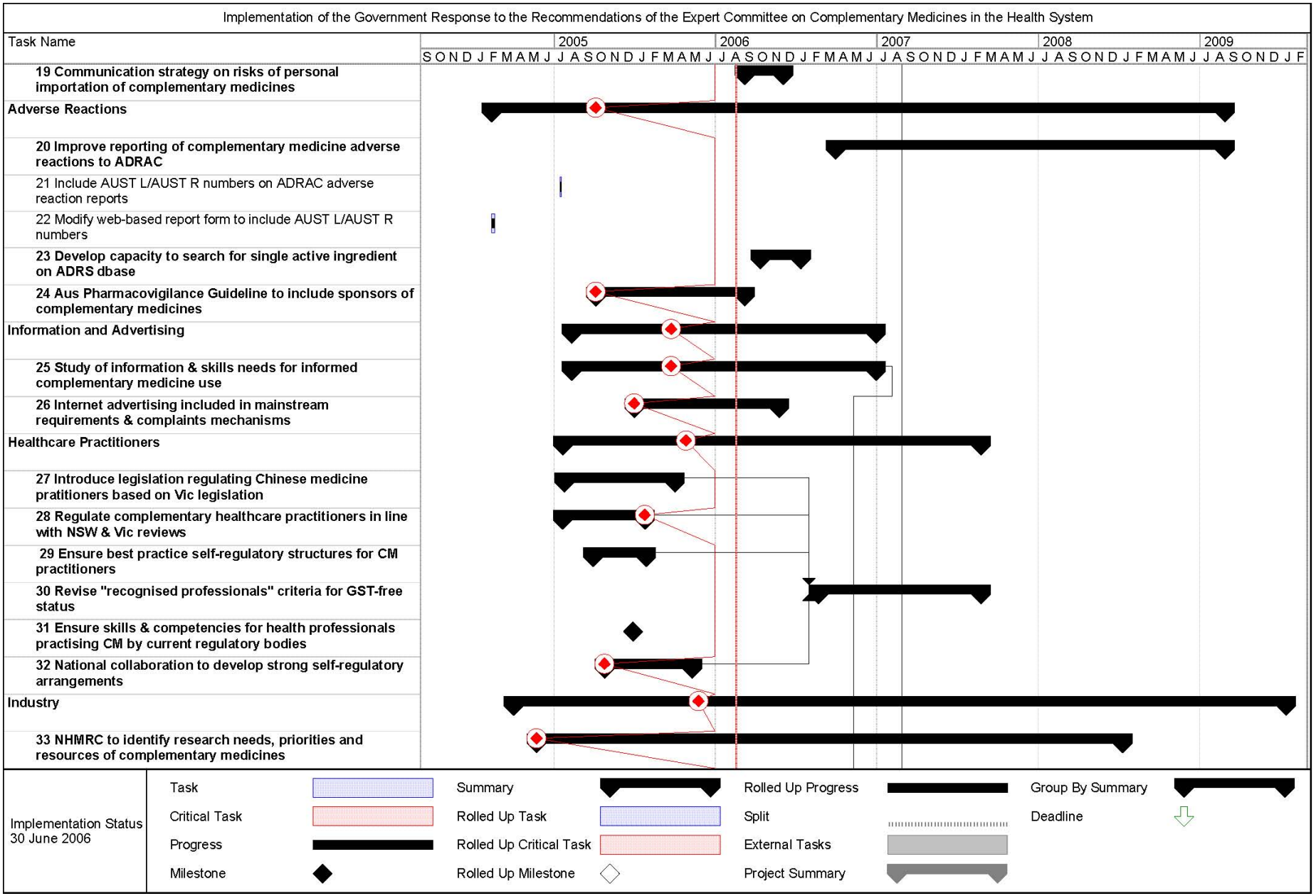
	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
40	The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.	***Accepted***. *The TGA, in collaboration with its New Zealand counterparts, will convene a stakeholder group.*	*A joint Australia New Zealand stakeholder group met during 2006 and provided advice on a range of issues to help promote complementary medicine innovation and research.*	**Underway**
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.*	*This recommendation has been implemented. APAC & PHARM now have members with Complementary Medicines expertise.*	**Completed**
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.*	*An APAC working group is developing information for consumers, complementary medicine and other health practitioners to clarify the position of complementary medicines within the National Medicines Policy and in the Quality Use of Medicines.*	**Underway**
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.*	*The National Strategy for QUM does not distribute funding. Education needs will be considered after the National Prescribing Service study into the information and skills needs of consumers and practitioners (recommendation 25) has been completed.*	**Planned**

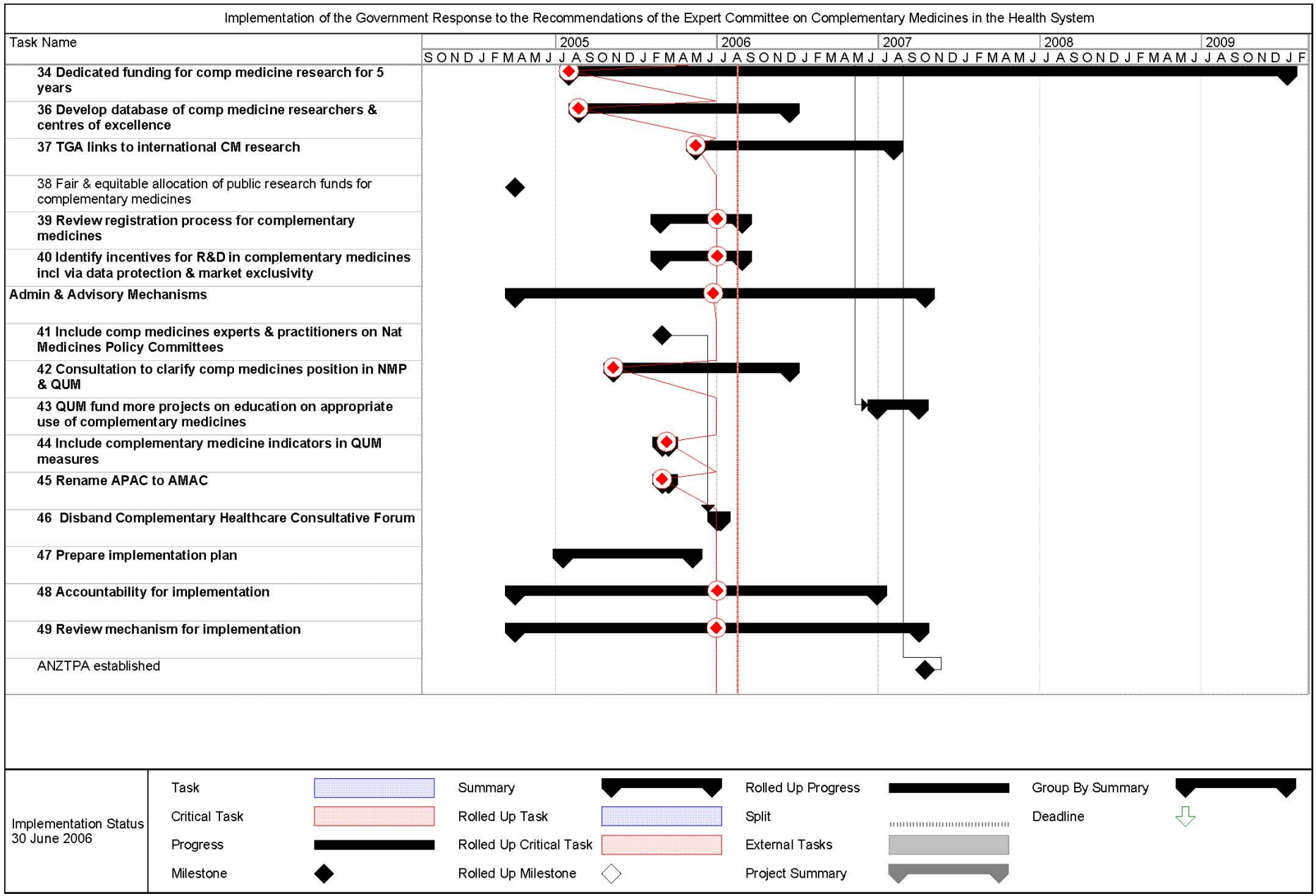
	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
44	Complementary medicines be included in the indicators to measure the quality use of medicines component of the *National Medicines Policy* (NMP) and *The National Strategy for Quality 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.*	***Accepted.** The QUM indicators are currently applicable to complementary medicines. National Medicines Policy indicators are currently under development and will include complementary medicines in their scope.*	**Underway**
45	The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.	***Accepted**.*	*The implementation of this recommendation will be reviewed once an operational review of APAC has been finalised.*	**Planned**
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.*	*The implementation of this recommendation will be reviewed after the operational review of APAC has been finalised.*	**Planned**
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.*	*The implementation of this recommendation is completed. Implementation is being coordinated by TGA, in consultation with other affected government agencies, and overseen by the Complementary Medicines Implementation Reference Group.*	**Completed**
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.*	*The TGA is responsible for coordinating the implementation of the Government Response to the recommendations. Implementation is overseen by the Complementary Medicines Implementation Reference Group.*	**Completed**

	Expert Committee recommendation	Government response and proposed implementation action	Progress to 30 June 2006	Status
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.*	*The Complementary Medicines Implementation Reference Group, made up of representatives and experts in complementary medicine research, education, industry and consumer matters advises the TGA on and reviews implementation of the Government Response.*	**Underway**

Appendix 2 - Progress on the Government Response to the Expert Committee's recommendations and progress on implementation to 30 June 2006




Implementation of the Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System
Task Name
2005
2006
2007
2008
2009
S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F
19 Communication strategy on risks of personal importation of complementary medicines
Adverse Reactions
20 Improve reporting of complementary medicine adverse reactions to ADRAC
21 Include AUST L/AUST R numbers on ADRAC adverse reaction reports
22 Modify web-based report form to include AUST L/AUST R numbers
23 Develop capacity to search for single active ingredient on ADRS dbase
24 Aus Pharmacovigilance Guideline to include sponsors of complementary medicines
Information and Advertising
25 Study of information & skills needs for informed complementary medicine use
26 Internet advertising included in mainstream requirements & complaints mechanisms
Healthcare Practitioners
27 Introduce legislation regulating Chinese medicine pratitioners based on Vic legislation
28 Regulate complementary healthcare practitioners in line with NSW & Vic reviews
29 Ensure best practice self-regulatory structures for CM practitioners
30 Revise "recognised professionals" criteria for GST-free status
31 Ensure skills & competencies for health professionals practising CM by current regulatory bodies
32 National collaboration to develop strong self-regulatory arrangements
Industry
33 NHMRC to identify research needs, priorities and resources of complementary medicines
Implementation Status 30 June 2006
Task
Critical Task
Progress
Milestone
Summary
Rolled Up Task
Rolled Up Critical Task
Rolled Up Milestone
Rolled Up Progress
Split
External Tasks
Project Summary
Group By Summary
Deadline


Implementation of the Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System
Task Name
2005
2006
2007
2008
2009
S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F
34 Dedicated funding for comp medicine research for 5 years
36 Develop database of comp medicine researchers & centres of excellence
37 TGA links to international CM research
38 Fair & equitable allocation of public research funds for complementary medicines
39 Review registration process for complementary medicines
40 Identify incentives for R&D in complementary medicines incl via data protection & market exclusivity
Admin & Advisory Mechanisms
41 Include comp medicines experts & practitioners on Nat Medicines Policy Committees
42 Consultation to clarify comp medicines position in NMP & QUM
43 QUM fund more projects on education on appropriate use of complementary medicines
44 Include complementary medicine indicators in QUM measures
45 Rename APAC to AMAC
46 Disband Complementary Healthcare Consultative Forum
47 Prepare implementation plan
48 Accountability for implementation
49 Review mechanism for implementation
ANZTPA established
Implementation Status 30 June 2006
Task
Critical Task
Progress
Milestone
Summary
Rolled Up Task
Rolled Up Critical Task
Rolled Up Milestone
Rolled Up Progress
Split
External Tasks
Project Summary
Group By Summary
Deadline