Complementary Medicines

in the Australian Health System

Expert Committee on Complementary Medicines in the Health System

Report to the Parliamentary Secretary to the Minister for Health and Ageing

September 2003

ISBN 1 920746 18 8

Complementary Medicines in the Australian Health System

Expert Committee on Complementary Medicines
in the Health System

Report to the Parliamentary Secretary
to the Minister for Health and Ageing

September 2003

This page has been left blank intentionally.

CONTENTS

CHAIRMAN'S PREFACE

Complementary medicines and therapies have been widely accepted in the Australian community over the past twenty years. Australian consumers have been increasingly using a combination of mainstream and complementary medicine to meet their health needs, resulting in the complementary healthcare industry becoming significant both economically and as an employer.

In May 2003, the widespread, and sometimes ill-informed, publicity surrounding the unprecedented recall of complementary and other medicines manufactured by Pan Pharmaceuticals Limited, resulted in heightened interest about the role of complementary medicine in Australia.

Conflicting statements in the media about the industry inevitably confused the many users of complementary medicine. Large and small businesses, including pharmacies, health shops and supermarkets, faced the frequently chaotic process of withdrawing products from sale and determining whether they would be reimbursed for a large range of unsaleable medicines. Some commentators raised questions about consumer safety and the health benefits of complementary medicines and therapies.

In view of these questions, and to give the community and healthcare practitioners confidence that the Australian Government was taking the necessary steps to examine complementary medicines and their role in the health system, the Government established the Expert Committee on Complementary Medicines in the Health System. The Committee met for the first time in June 2003. It agreed to be outcome-focused, seeking in the short time frame that it had to complete its work, to be definitive where possible but also to identify and recommend ways forward when information was not readily available or further consultation was considered necessary.

Given the short time frame within which it was operating, the Committee determined that it would be impractical and potentially inequitable to call for submissions. The deliberations of the Committee were confidential, but members could consult within their own networks once initially cleared by the Chairman. Members could also provide concise papers addressing topics within their area of expertise.

In considering its terms of reference, the Committee recognised three fundamental principles: firstly, the need to protect public health and safety; secondly, the primacy of the right of consumers to be able to make informed choices on matters of healthcare; and thirdly, the ethical responsibilities of all healthcare providers — from manufacturers to healthcare practitioners.

In Australia, consumers can choose the healthcare they feel they need, whether seeking prevention, cure or improved sense of wellbeing. In doing so, they should have access to reliable information about the services and medicines they choose, to enable them to have a better understanding about the likely benefits and outcomes of their choices. The *National Medicines Policy* embraces principles of access, standards of quality, safety and efficacy, quality use, and a

responsible and viable industry that are applicable to all medicines, including complementary medicines.

Healthcare providers, whether mainstream or complementary, have a responsibility to behave in an ethical manner at all times. All who participate in the healthcare industry must be factual and honest about the likely benefits and limitations of the diagnostic approaches, treatments or products being offered, recognising that making unsubstantiated claims or taking advantage of desperate or insufficiently informed people is unacceptable behaviour and should be subject to professional sanctions or disciplinary action.

One of the key prerequisites of ethical behaviour of every healthcare provider is to do no harm. The concept of harm encompasses at least three components:

– direct harm — resulting in adverse patient/client outcomes including side effects, medicine interaction or encouraging withdrawal of current therapy
– indirect harm — as the result of delay in implementing appropriate treatment or by creating unreasonable expectations that might otherwise discourage patients and their families from accepting and dealing effectively with their health problem
– economic harm — encouraging expenditure on ineffective, unnecessary or unsafe medicines and therapies without providing an awareness of the unproven nature of the treatment or modality being offered might also lead to direct or indirect harm if money is otherwise no longer available for living essentials or more-appropriate healthcare management.[1]

The Committee recognised the risk-based approach to the regulation of medicines and the difference in the assessment process between Listed complementary medicines, of which there are approximately 15,400 in the Australian Register of Therapeutic Goods, and Registered complementary medicines. Members also needed to understand the distinction between the level and type of evidence required to support the indications and claims for Listed complementary medicines and that required for higher risk, Registered medicines.

The Committee has endeavoured to address its terms of reference diligently and, notwithstanding some vigorous debate, at all times, cooperatively. The breadth of the Committee's terms of reference meant that it was not able to arrive at definitive recommendations in every instance. In some cases, it has suggested further investigations or consultations.

ACKNOWLEDGMENTS

The Committee has been especially grateful for the excellent agenda papers prepared by the Committee Secretariat headed by Dr David Briggs with valued support from Mrs Vikki James, Dr John Hall and Mr Ian Haupt (Focal Point Consulting). The high quality of these papers enabled the Committee to rapidly acquire a wide range of information and improved understanding about matters relating to the terms of reference.

[1] Source: after the NSW Medical Board memo on complementary medicine.

Despite the disparate backgrounds represented on the Committee, members addressed their tasks with courtesy, a high degree of collegiality and respect for one another's opinions. Chairing such a large committee might have proved very difficult were it not for the generous support and encouragement given by all members, for which I shall remain indebted.

Michael Bollen AM

This page has been left blank intentionally.

EXECUTIVE SUMMARY

INTRODUCTION

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

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, Pan Pharmaceuticals Limited, 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.

1.1 Expert Committee

In May 2003, to reassure the public, and maintain confidence in Australia's reputation as a supplier of high quality and safe medicines, the Australian Government established the Expert Committee on Complementary Medicines in the Health System.

The 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. Central to the NMP, is *The National Strategy for Quality Use of Medicines* (QUM). The goal of QUM is to optimise the use of medicines to improve health outcomes for all Australians.

The Committee's terms of reference required it to examine and provide advice to the Government on:

- regulatory controls covering standards of quality, safety and efficacy for complementary medicines
- consumer information
- education and training of healthcare practitioners
- interactions between complementary and prescribed medicines
- restrictions on advertising
- activities to promote an innovative, responsible and viable complementary medicines industry.

1.2 Complementary Medicines

'Complementary therapies' include a diverse group of health-related therapies and disciplines that are not considered to be a part of mainstream medical care in Australia. 'Complementary medicines' include herbal medicines, vitamin and mineral supplements, other nutritional supplements, traditional medicines such as Ayurvedic medicines and traditional Chinese medicines (TCM), homoeopathic medicines, and aromatherapy oils.

Complementary medicines are included in an established adverse reaction reporting system in Australia. In 2002, approximately 94 per cent of Adverse Drug Reaction (ADR) reports received by the TGA's Adverse Drug Reactions Unit (ADRU) related to prescription medicines, and 3 per cent each to over-the-counter (OTC) and complementary medicines. While a very high proportion of ADR reports to the TGA from sponsors about conventional medicines originate from health professionals, the majority of reports from sponsors[2] about complementary medicines appear to originate from consumers.

An innovative, responsible and viable complementary medicines industry is dependent on incentives to encourage research to underpin the quality, safety and efficacy of complementary medicines and to develop new products, and appropriate regulatory controls to safeguard against the actions of irresponsible manufactures and sponsors. There is a substantial gap between the extensive use of complementary medicines and the evidence to support that use. For various reasons, including lack of financial incentive, there is relatively little research being undertaken in Australia to support the use of complementary medicines.

1.3 Practitioners

The number and type of healthcare practitioners who supply or provide advice to consumers on complementary medicines is large and varied. The group ranges from complementary healthcare practitioners such as naturopaths, TCM practitioners, and herbalists, to medical practitioners who may or may not provide complementary medicines to patients but who nevertheless need to be aware of the complementary and other medicines that patients may be using. Reliable data on the composition of the complementary healthcare workforce are difficult to obtain.

There are primarily two approaches to the regulation of healthcare practitioners: statutory regulation and self-regulation. In Australia, few complementary healthcare professions are regulated under (State and Territory) legislation. A nationally agreed process for assessing the need for statutory regulation of unregulated health occupations has been in place since 1995. It requires that occupational regulation of an unregulated profession proceed only if agreed by a majority of jurisdictions and only if the profession meets specific criteria designed to facilitate the process of regulatory assessment. Legislation to regulate traditional Chinese medicine practitioners has been in place in Victoria since 2000. Both Victoria and New South Wales were undertaking reviews of complementary healthcare professions at the time this report was being prepared.

[2] A sponsor of a therapeutic good is the person or company responsible for applying to the TGA to have their goods included on the Australian Register of Therapeutic Goods.

1.4 Regulatory Framework

The *Therapeutic Goods Act 1989* (the Act), which came into effect on 15 February 1991, sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia. The objective of the Act is to provide a national framework for the regulation of therapeutic goods in Australia, and to ensure their quality, safety and efficacy, and timely availability. The regulatory controls for medicines are primarily the responsibility of Australia's national regulator, the Therapeutic Goods Administration (TGA), in cooperation with State and Territory governments and the medicines industry.

The TGA uses a 'risk-management' approach to regulating medicines supplied in Australia. Higher risk (Registered) medicines are individually evaluated for quality, safety and efficacy.

Registered medicines include both prescription and non-prescription medicines. Low risk (Listed) medicines are individually assessed by the TGA for quality and safety before supply, but *not* for efficacy. However, sponsors of Listed medicines must hold evidence to support the indications and claims made for these medicines.

The TGA carries out a range of assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard. Overall control of therapeutic goods is exerted through five main processes:

– pre-market evaluation and approval of registered products intended for supply in Australia
– licensing of manufacturers in accordance with international standards under Good Manufacturing Practice
– post-market monitoring, through testing, adverse event reporting, surveillance activities, and response to public inquiries
– development, maintenance and monitoring of the systems for Listing medicines
– assessment of medicines for export.

The Australian Register of Therapeutic Goods (ARTG), a database maintained by the TGA, includes details of all therapeutic goods that are imported into, supplied in, or exported from Australia. There are approximately 16,000 complementary medicines included in the ARTG.

The TGA recovers its operating costs primarily through annual charges, evaluation and assessment fees, and licence fees from the therapeutic goods industry. These charges and fees cover all activities that fall within the scope of the Act, including regulation of the industry, the public health responsibilities of the TGA, responsibilities to consumers for information on products and the TGA's support for the industry generally (i.e. facilitation of exports and international harmonisation of standards).

1.5 Information

The *National Medicines Policy* (NMP) states that, to achieve optimum use of medicines, "consumers and health practitioners should have timely access to accurate information and education about medicines and their use".

The primary source of information about a non-prescription medicine is its label. It is the one source of information that is always available when people choose a medicine and when they use it.

It is important that the label includes information that enables the product to be used safely and effectively, and that the information is presented in a way that enables the consumer to easily find, understand and act appropriately on this information.

Health professionals, including complementary healthcare practitioners, pharmacists and general practitioners, are an important source of advice to consumers about complementary medicines. Professional bodies, both those representing complementary healthcare practitioners and those representing professionals working within mainstream medicine, have emphasised the need for their members who use and/or advise on complementary medicines to acquire and maintain knowledge through undergraduate, vocational and continuing education. In addition to the knowledge required to inform their patients, practitioners also need the skills to convey this information.

The general growth in Internet usage and some overseas studies suggest that the Internet is being used increasingly as an information source about complementary medicines.

1.6 Advertising

The advertising of therapeutic goods in Australia is administered under co-regulatory arrangements involving key stakeholder groups, i.e. government, industry, advertisers, media, consumers, and healthcare professionals.

Advertisements[3] for therapeutic goods are subject to the advertising requirements of the Act and the supporting Therapeutic Goods Regulations 1990 (which legislatively underpin the *Therapeutic Goods Advertising Code* (TGAC), and reference the *Trade Practices Act 1974* and other relevant laws).

Advertisements to the general public for therapeutic goods appearing in specified media (e.g. newspapers, magazines, television and radio) must be approved before being published or broadcast.

Currently, the advertising regulations do not apply to *bona fide* news, public interest or entertainment programs.[4] The Australian Competition and Consumer Commission (ACCC) more appropriately handles false and misleading claims that may appear in these media.

Internet advertising is regulated broadly in the same manner as other 'advertisements'. However, advertisements appearing on the Internet currently do not require pre-approval and complaints are dealt with under the peak industry associations' codes of practice.

[3] "'Advertisement' in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods." *(Therapeutic Goods Act 1989),* Section 3(1)

[4] Section 3.3, *Therapeutic Goods Advertising Code*

Recent legislative changes[5] (passed but not yet proclaimed) will bring Internet advertising into the scope of broadcast advertising, where regulatory arrangements are well defined. However, for practical reasons, the TGA intends to exempt Internet advertising from pre-approval requirements.

Complaints relating to advertisements appearing in specified print media and the broadcast media are handled by a centralised Complaints Resolution Panel (CRP), comprising representatives from all key stakeholder groups.

There are also complaints-handling committees established under the voluntary codes of practice administered by the peak industry associations. These committees primarily consider complaints about non-specified advertisements for therapeutic goods. These include leaflets, flyers, catalogues brochures, and shelf talkers distributed via letterbox drop, point of sale etc. These committees also consider complaints about advertisements directed exclusively to health-care professionals (which are not subject to the public advertising regulatory requirements incorporated in the TGAC).

As part of the transition to a joint trans Tasman agency to regulate therapeutic products, an Interim Advertising Council (IAC) has been established. The IAC aims to bring the different Australian and New Zealand arrangements into a single regulatory framework.

FINDINGS

2.1 The National Regulatory Controls for Complementary Medicines

2.1.1 The current model of a single regulatory framework for medicines is appropriate for the regulation of complementary medicines in Australia.

Australians expect that therapeutic goods will be safe, effective and of good quality, and that government will set standards and regulations to meet these expectations. At the same time, those manufacturing and marketing therapeutic products expect that regulation should be the minimum necessary, appropriate and commensurate with the assessed risk of their respective products, and consistent with international practice.

The NMP was premised on a single regulatory framework for all medicines, including complementary medicines. The TGA uses a risk management approach to regulating medicines in Australia. This determines the level of scrutiny applied to the assessment of individual medicines. Medicines used to treat serious forms of disease, conditions or disorders, or which need to be managed under medical supervision, are subject to a high level of scrutiny and evaluation to ensure that they meet appropriate standards of quality, safety and efficacy. Other medicines, for example most complementary medicines, present lower risk and are not subject to the same level of evaluation. They are assessed by the TGA for only quality and safety, and *not* efficacy, before market entry. All medicines are subject to post-market regulatory activities to ensure that they meet appropriate standards of quality, safety and efficacy.

[5] *Therapeutic Goods Amendment Act (No. 1) 2003* <http://www.tga.gov.au/docs/html/tgaa0301.htm>

The Committee concluded that the current national regulatory framework for medicines provides a level of scrutiny and evaluation consistent with risk, and is appropriate for the regulation of complementary medicines (subject to enhancements recommended in Section 2.1.2). The Committee noted that this framework may not be well understood by either practitioners or consumers.

2.1.2 The current two-tiered, risk-based regulatory system for complementary medicines should be maintained, but with some enhancements.

The two-tiered, risk-based system for medicines, including complementary medicines, is generally considered sufficient and relevant to meet appropriate standards of quality, safety and efficacy for Registered and Listed complementary medicines. The evaluation process undertaken by the TGA for Registered complementary medicines is risk-based and considered appropriate to support the quality, safety and efficacy of these medicines. The process is consistent with that applied to over-the-counter (OTC) and prescription medicines of similar risk. To encourage greater use of the registration process for complementary medicines, the Committee considered that the TGA should review the current requirements, taking into account the complex nature of many complementary medicines (see *Executive Summary* Section 6.1.4).

In reviewing the regulatory controls for Listed (low risk) complementary medicines, the Committee identified a number of situations where the current regulatory provisions and the transparency of the TGA's processes for evaluating medicines need to be enhanced. In particular, the Committee considered that consumers may not be aware that Listed medicines have not been evaluated by the national regulator for efficacy before their supply. The Committee considered there is an ethical responsibility on government to ensure that consumers are informed about this difference between Listed and Registered complementary medicines.

Some members considered that the current two-tiered regulatory system does not allow consumers and others to adequately distinguish between those medicines that have and have not been scientifically evaluated for efficacy by the TGA.

2.1.3 The Guidelines for Levels and Kinds of Evidence to Support Indications and Claims *provide a sufficient framework to assess the efficacy of Listed complementary medicines.*

The Committee considered that the TGA's *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* provides a sufficient framework to assess the efficacy of Listed complementary medicines and should be prescribed for this purpose. However, some members expressed concern that many sponsors of medicines, including complementary medicines, may not be equipped to substantiate claims for efficacy through a critical assessment of the available evidence.

2.1.4 *The* Guidelines for Levels and Kinds of Evidence to Support Indications and Claims *should 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.*

Listed complementary medicines are included in the ARTG via a simple, low cost and streamlined electronic application process. The streamlined approach to assessment for low risk complementary medicines allows timely market access with a level of pre-market evaluation of the components permitted in each medicine that provides an assurance of the safety and quality of the product.

At the time of Listing, sponsors must certify that they hold the evidence to support indications and claims included in the ARTG for the product. The indications/claims on Listed medicines are not subject to pre-market evaluation by the TGA at the time of Listing. The evidence held by sponsors must be sufficient to substantiate that the indications and claims are true, valid and not misleading. Generally, the evidence held by sponsors is not evaluated by the TGA. The type and level of evidence considered necessary for this purpose is not specified in legislation. To provide an equitable and enforceable base for the type and level of evidence considered necessary to support indications and claims for Listed medicines, the *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods* should be prescribed.

2.1.5 *There should be increased random and targeted auditing of sponsors of Listed complementary medicines to ensure that evidence of efficacy is held.*

Adherence to the levels of evidence framework provided by the *Guidelines* to support the efficacy of complementary medicines is important to the credibility and viability of the complementary medicines industry. The marketing of products that do not have evidence of efficacy was considered by the Committee to be unethical. To provide assurance to stakeholders that sponsors hold evidence to support the indications and claims included in the ARTG for their products, the Committee recommended that the TGA should increase random and targeted auditing of the evidence held by sponsors.

2.1.6 *Sponsors of Listed medicines should submit to the TGA a summary of the evidence they hold to support the efficacy of their products.*

To assist sponsors to focus on their obligation to hold evidence to support the efficacy of Listed complementary medicines, sponsors should be required to submit to the TGA a summary of the evidence on which the efficacy of their product is based, when the product is Listed on the ARTG. These summaries of evidence would be assessed randomly by the TGA as part of the requirement to include the sponsor's product on the ARTG as routine assessment could prove to be a major task.

The Act defines the quality standards applicable to all therapeutic goods. In many instances, there are no applicable standards for ingredients in complementary medicines and a sponsor must develop a compositional guideline. Quality is a critical determinant of the safety of complementary and other medicines. The Committee believes that compositional guidelines should be legally enforceable.

The safety of Listed medicines, based on the evaluation of individual ingredients, is commensurate with the assessed risk and benefit of the products, and is generally satisfactory. However, a particular concern is the use of any medicine in pregnancy. Low risk, Listed complementary medicines should not contain ingredients for use under conditions where they are known or suspected of causing birth defects.

2.1.7 The current penalties for breaches of the conditions of Listing of complementary medicines under Section 26A(2) of the Therapeutic Goods Act 1989*, including the requirement that the applicant holds information or evidence to support any claim relating to the medicine, are generally sufficient to deter repeat offenders.*

The current penalties for breaches of the conditions of Listing of complementary medicines under Section 26A(2) of the Act, including the requirement that the applicant holds information or evidence to support any claim relating to the medicine, are generally sufficient to deter repeat offenders. However, the current penalty for offences under Section 22(3) of the Act should be increased from 60 to at least 150 penalty units.

2.1.8 Homoeopathic medicines and related remedies that make therapeutic claims should be regulated to ensure they meet appropriate standards of safety, quality and efficacy.

It is evident that a number of substances currently not permitted in Listed medicines are being presented on the market as homoeopathic preparations. It is also possible that some of these products are being formulated with little or no regard to homoeopathic principles or practice. The current definition of 'homoeopathic preparation' should be amended to make it clear that only ingredients consistent with homoeopathic principles and practice are considered homoeopathic preparations.

A homoeopathic medicine should be adequately described to ensure that it is clearly differentiated from those medicines not consistent with the homoeopathic or a related paradigm. Any misrepresentation of homoeopathic medicines as other medicines needs to be addressed as a priority.

The regulation of homoeopathic medicines and other remedies or medicines with similar paradigms should be reviewed.

2.1.9 The regulation of herbal ingredients for use in medicines should be reviewed.

The current regulatory system permits Listed complementary medicines to contain a wide range of herbal ingredients and preparations.

Most herbal medicines prepared and prescribed according to tradition are likely to be low risk. However, the Committee noted that the use of non-traditional methods of preparation, including use of non-traditional solvents, can quantitatively and/or qualitatively change the chemical profile of the preparation. Variations in the solvent concentration and amount of herbal material used to prepare herbal extracts may affect both the safety and the therapeutic profile of the preparation.

The use of dry/fresh weight equivalence to describe the amount of plant material used to produce a herbal ingredient, and the term 'standardisation' to describe the 'potency' or consistency of herbal ingredients, have the potential to mislead consumers.

The Committee endorsed a recommendation of the Complementary Medicines Evaluation Committee (CMEC) that, in consultation with stakeholders, and as a matter of priority, a review of the regulation of medicines containing herbal ingredients be undertaken.

2.1.10 Standards for extemporaneously compounded medicines should be reviewed.

While some starting materials used by practitioners when dispensing or extemporaneously compounding medicines for patients are subject to TGA assessment for quality, safety and efficacy (for example, ingredients that are either pre-packaged for other therapeutic purposes, or formulated as a dosage form), raw herbs and some other starting materials are not. Concerns over the failure of good handling and manufacturing of these products, including the possible substitution of herbs and adulteration, led the Committee to recommend the need to review the controls for raw herbs and other starting materials used in dispensed and extemporaneously compounded complementary medicines to ensure that they meet appropriate standards of quality and safety.

2.1.11 Reference to 'For Practitioner Dispensing Only' products should be removed from Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines.

'For Practitioner Dispensing Only' products are complementary medicines that are supplied in a dispensing pack to a (registered) complementary healthcare practitioner. The only difference between 'For Practitioner Dispensing Only' products and other complementary medicines is that the former do not need to have a statement of their purpose on the label. A particular concern relating to 'For Practitioner Dispensing Only' products was the possibility that these products might be prescribed by persons who are inadequately qualified. Most members of the Committee considered that there was greater public good to be served by requiring all products to be labelled with the indications and claims in the ARTG, recognising that this would still allow for practitioners to prescribe as appropriate.

2.1.12 The current 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, should be reviewed 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".*

The TGA is obliged to give due notice of cancellation or suspension of a licence to manufacture medicines, unless failure to act immediately would create imminent risk of death, serious illness or serious injury. Significant risk to public

health and safety can result from conditions that might not lead to actual imminent risk of death, serious illness or serious injury. To more adequately protect public health and safety, options for immediate regulatory action associated with significant risk of harm should be explored.

2.1.13 Information should be placed on the labels of all medicines to better assist with product identification of recalled medicines.

The Committee considered there was some scope for improving aspects of the recall process, and putting in place procedures and policies to better manage the nature and extent of consumer and retailer response. In particular, consideration should be given to including information on labels to better assist with product identification of recalled medicines. Consideration should also be given to ways of ensuring that recalled products cannot subsequently be offered for sale.

2.1.14 The potential public health and safety issues associated with the availability of illegal complementary medicines, especially in ethnic communities, should be brought to the attention of the National Co-ordinating Committee on Therapeutic Goods.

Complementary medicines that are manufactured overseas and are not listed on the ARTG are being illegally imported and sold in Australia, particularly in ethnic communities. A recent survey of such products indicated that they present an unacceptable risk to consumers. It is important that the Australian Government and the States and Territories work together to ensure the protection of consumers, and that action be taken to curtail the illegal importation and sale of these medicines.

2.1.15 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 should be urged to adopt nationally consistent therapeutic goods legislation.

Not all State and Territory governments have adopted therapeutic goods legislation that mirrors the Australian Government's *Therapeutic Goods Act 1989* (the Act). Without this legislation, 'sole' traders can manufacture therapeutic goods that are exempt from the Act. Companies operating in this manner can create unfair competition and adopt standards for quality, safety and efficacy inappropriate to the level of risk associated with the goods.

2.1.16 State and Territory governments should be urged to adopt a nationally consistent system of access (Scheduling) to medicines.

The *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) sets out the Schedules that the National Drugs and Poisons Schedule Committee (NDPSC) has decided should apply to medicinal ingredients and components in medicinal ingredients. While States and Territories generally adopt the SUSDP Schedule, some have not done so.

Complementary medicine healthcare practitioners with an appropriate level of training, professional skill and competency should be allowed access to certain more potent complementary medicines that are otherwise restricted under

various State and Territory controlled substances legislation. An appropriate Schedule in the SUSDP could be used nationally for this purpose.

2.1.17 Consumers should be better informed about the potential risks of importing medicines for personal use.

It is important that consumers be aware that medicines imported for personal use may not be approved for use in Australia and may be of unknown quality, safety and efficacy.

3.1 Adverse Reactions

3.1.1 The TGA has a well-developed system for evaluating and responding to reports of adverse reactions to medicines.

The TGA has a well-developed system for evaluating and responding to reports of adverse reactions to medicines. An adverse reaction reporting system for therapeutic goods in Australia is well established. The 'Blue Card' system is a voluntary reporting system that covers all medicines and most health professionals. However, the reporting of adverse reactions to complementary medicines needs to be improved.

3.1.2 Reporting of adverse reactions to complementary medicines to the TGA needs to be improved.

The current adverse reaction reporting system may be biased away from complementary medicines, because complementary medicines are usually self-prescribed and their use may not be reported should a problem arise. The range of health professionals and consumers encouraged to participate in adverse reaction reporting of complementary medicines should be increased.

3.1.3 The TGA's Adverse Drug Reaction Reporting System (ADRS) database should be further improved to encourage reporting of AUST L and AUST R numbers and to facilitate searching for single ingredients in multi-ingredient complementary medicines.

The Committee acknowledges the improvements the TGA has made to its Adverse Drug Reaction (Reporting) System (ADRS). However, the ADRS database does not support searching for individual ingredients in multi-ingredient products, such as most complementary medicines. The ability to search for a single active ingredient across multiple products in the ADRS database would be an extremely useful addition to facilitate the task of analysing complementary medicine reports.

4.1 Information and Advertising

4.1.1 Government needs to take a more active role in ensuring that consumers have access to reliable information about complementary medicines, and the skills to interpret information and make informed decisions.

The fundamental value of information is that it underpins decision-making. Informed medicine decisions by consumers should promote better health outcomes, fewer adverse reactions, a greater sense of personal control over health care, and more value for the consumer health dollar.

Given the importance of providing good quality information to consumers, and the difficulties they appear to have in accessing it, the Committee considered that government should take a more active role in ensuring the availability of accurate, reliable information.

To be effective, information must be tailored to its audience(s). Throughout its deliberations, the Committee was frustrated by the lack of research about consumer information needs and skills in relation to complementary medicines. The Committee concluded that the highest priority should be to better understand information needs and skills of consumers and healthcare professionals, identify gaps, and to develop related strategies.

4.1.2 Consumers should be better informed about the regulatory framework for medicines, the differences in the processes for assessing the efficacy of Listed and Registered complementary medicines, and the levels of evidence for the efficacy of Listed complementary medicines.

Unlike Registered medicines, which have undergone pre-market evaluation for efficacy by the TGA, consumers and healthcare professionals cannot be similarly assured about the efficacy of Listed medicines.

Some members of the Committee thought that information about efficacy could be useful to consumers. In particular, a summary of the information provided by sponsors to support product efficacy could be made available to the public, perhaps via the TGA website (see *Executive Summary* Section 2.1.2). Some Committee members were opposed to this approach. Ultimately, the Committee agreed that, while summary efficacy evidence should be collected (subject to workable implementation arrangements being developed), publication should be considered only once the arrangement had been in place long enough for any problems associated with widespread publication to become apparent.

The Committee considered that consumers should have access to information about broader aspects of the regulatory process so that they could be better informed about the reliance they could place on the claims and indications for both Listed and Registered medicines.

4.1.3 *Internet advertising should be considered part of mainstream advertising, and be subject to mainstream advertising requirements and protocols, including complaints resolution.*

The Internet is a significant and growing medium for advertising complementary medicines. However, there are widespread concerns about the general quality of health information on the Internet.

Against this background, a majority of the Committee thought that Internet advertising of complementary medicines should be treated as mainstream advertising, and regulated as such. The only exception might be pre-approval requirements, which the Committee accepted may be impractical.

4.1.4 *The new advertising control framework being developed as part of the transition to a trans Tasman agency needs to ensure that communications by health professionals, educators and scientists are not unduly restricted.*

The Committee noted the extensive review of advertising controls that is being undertaken in the lead-up to the proposed establishment of a trans Tasman agency to regulate therapeutic products. The Committee was concerned that, while the advertising framework being developed for the trans Tasman agency is fundamentally sound, essential exchanges of information between health professionals, educators and scientists could be frustrated if it were to be too narrowly implemented.

The Committee wanted to make its concerns clear to those developing the new advertising arrangements, and encourage them to take care to ensure that they do not unreasonably constrain the dissemination of information and views by health professionals, educators and scientists that are in the public interest.

5.1 Healthcare Practitioners

5.1.1 *Governments should move more quickly to nationally consistent, statutory regulation (where appropriate) of complementary healthcare professions.*

There is clear evidence that the practices of TCM (including acupuncture and Chinese herbal medicine), Western herbal medicine, Ayurvedic herbal medicine and naturopathy have inherent risks of adverse outcomes.

The Committee strongly supported the Australian Health Ministers' Advisory Council (AHMAC) resolutions in favour of nationally consistent regulatory arrangements, the development of model legislation in one jurisdiction for application in other jurisdictions, and the AHMAC criteria for regulation of unregistered health occupations. However, given the risks, the Committee was concerned at the delays in moving to implementation. All jurisdictions should, as soon as possible, introduce legislation to regulate TCM practitioners, based on existing legislation in Victoria.

The Committee strongly supported the current New South Wales and Victorian reviews concerning regulation of complementary healthcare practitioners, and

considers that all States and Territories should review these findings and move quickly to implement statutory regulation where justified.

5.1.2 Effective self-regulation needs to be more actively encouraged for all complementary healthcare professions.

Australian experience has shown that moves towards statutory regulation of complementary healthcare professions are likely to take some time. In addition, irrespective of the extent and timing of any moves towards statutory regulation, there will be groups of complementary healthcare practitioners for which such statutory regulation is not justified.

Against this background, transparent and accountable self-regulation needs to be encouraged actively for all healthcare professions involved in dispensing or advising consumers on complementary medicines, including those for which statutory regulation is appropriate but unlikely to be achieved in the short term.

A strong, self-regulatory framework brings a number of benefits. In particular, the involvement of practitioners means that education, training and enforcement standards are likely to be informed by a thorough understanding of technical issues and the market in which the profession operates.

The Committee noted that conventional healthcare practitioners such as pharmacists, nurses and medical practitioners, and some complementary healthcare practitioners, have developed clearly stated and enforceable ethical frameworks for the services they deliver. It considered that similar standards need to be in place for all complementary healthcare professions.

The Committee was concerned about the Australian Taxation Office's apparent acceptance of a wide range of organisations for the purpose of determining who are able to continue to supply goods and services tax-free (GST-free) services. The Committee believed this could be interpreted as *de facto* recognition of bodies that are not representative of their professions, and militates against the development of strong, cohesive and representative professional bodies.

5.1.3 Education and training of all practitioners who prescribe or advise on the use of complementary medicines needs to be strengthened and encouraged.

Educational standards amongst Australian trained complementary medicine practitioners are extremely variable, and neither the public nor other healthcare practitioners have a reliable way of assessing who is sufficiently or appropriately qualified for safe, competent practice. The Committee strongly supports the view that high-quality, accredited training of practitioners is vital in protecting the public. It considered that the responsibility for training standards should rest with the appropriate professional body, that partnerships between higher education and professional bodies are important, and that all practitioners should receive independently accredited training.

6.1 Industry

6.1.1 The objectives of the National Medicines Policy *are interdependent and require a responsible and viable medicines industry.*

A viable, innovative and responsible complementary medicines industry is dependent on research to support quality, safety, efficacy, and cost-effectiveness, and to develop new products. There is currently little or no incentive to support the development of complementary medicines if there is no possibility of data protection and/or market exclusivity. By comparison with the United States of America and the United Kingdom, research infrastructure for complementary medicine in Australia is not well developed. There is need for dedicated government funding for complementary medicines research.

6.1.2 Incentives are needed to encourage innovation and research in complementary medicines.

An innovative, responsible and viable complementary medicines industry is dependent on incentives to encourage innovation and research to underpin the quality, safety and efficacy of complementary medicines, and to develop new products. Other stakeholders, such as healthcare professionals, also require incentives to undertake research into complementary medicines.

There is a need to identify ways to support innovation and complementary medicine research by industry, especially for products which are not patentable or 'off patent' (as is the case for many complementary medicines). Currently, there is little or no financial incentive to support the development of new indications and new complementary medicines if there is little or no possibility of market exclusivity or protection of data.

6.1.3 There is need for dedicated government funding for complementary medicines research.

Industry alone cannot be expected to support complementary medicines research. This is in part because of the lack of financial incentives, and in part because, like mainstream medical research, there is a social responsibility for government to fund such research.

In the United States of America and the United Kingdom, 'seed' funding and dedicated funding are available, and have provided impetus to establish and continue an effective complementary medicine research program. To encourage the development of research infrastructure in Australia, funding should be allocated on a *per capita* basis comparable to the extent of complementary medicine research funding in the USA.

6.1.4 The disparity between public funding for prescription/over-the-counter (OTC) medicines research and complementary medicines research needs to be addressed.

The Committee noted the apparent disparity between public funding for prescription/OTC medicines research and that for complementary medicines research, and the possibility of a bias against complementary medicines research.

6.1.5 Relatively few sponsors use the registration process for complementary medicines.

Compared with other medicines, some complementary medicines may offer lower risk and more cost-effective options for the prevention and treatment of some diseases, conditions and disorders. Stakeholders should be encouraged to undertake research to generate the data needed to support the Registration of complementary medicines.

Relatively few sponsors use the registration process for complementary medicines. There are several possible reasons for this, including lack of clarity and transparency of the evaluation process and difficulty in meeting the current data requirements for the Registration process, including clarity regarding the evidence required for efficacy. The TGA should review the process for Registration of complementary medicines, taking into account the complexity of many complementary medicines and the difficulty in identifying the components responsible for their medicinal activity.

7.1 Administrative and Advisory Mechanisms

7.1.1 Committees providing advice on the research and use of medicines should have members with expertise and practical experience in the use of complementary medicines

Complementary medicines are included within the definition of medicines in the NMP and QUM. Government medicines policies and programs should be informed by advisory committees whose membership embraces expertise in complementary medicines.

The Committee was particularly eager that the complementary medicines industry should pursue a proactive role in the APAC, taking advantage of the opportunities that APAC provides to raise and address the range of complementary medicines issues. The Complementary Healthcare Consultative Forum, having fulfilled its initial purpose, is no longer needed and should be formally disbanded.

7.1.2 The National Strategy for Quality Use of Medicines *(QUM) should focus greater attention on complementary medicines.*

The Committee concluded that APAC should facilitate a consultation process with the complementary medicines sector and other stakeholders to clarify the position of complementary medicines in the NMP and QUM.

Of the 136 indicators being used to measure the implementation and effect of the QUM, none explicitly incorporates complementary medicines. The Committee concluded that complementary medicines merit greater attention than they currently receive under the strategy.

In addition, the Committee found that there is a particular need to fund consumer and practitioner education initiatives relating to complementary medicines. This role falls within the ambit of the QUM strategy, and should not be left by default to the TGA, with resultant pressure on cost recovery from industry.

7.1.3 Accountability for the implementation of the Committee's recommendations needs to be clearly assigned, adequate resources need to be provided, and the process must be actively managed and reviewed.

In addition to government endorsement of the Committee's recommendations, the successful and timely implementation of the recommendations will require careful management and adequate resourcing. Successful implementation will also rest on a clear sense of priorities, responsibilities, and timing.

The Committee concluded that an implementation plan should be developed as a first step following the Government's response to this report, and that the plan should be completed within one month. Appendix 3 outlines the Committee's expectations of a practical implementation timetable.

The Committee was firmly of the view that overall responsibility for implementing its recommendations needs to be clearly assigned to a single position or body, which would be held accountable for ensuring that implementation proceeds in a timely fashion. In addition, progress with implementation should be reviewed towards the end of 2004.

The Committee was also concerned that adequate resources be made available to enable its recommendations to be taken forward. In doing so, the Committee was mindful that the TGA's activities are fully funded via cost recovery from industry. As a general proposition, the Committee believed that only those initiatives that are clearly part of the TGA's regulatory role should be funded in this way. Where this is not the case (such as consumer education under the QUM), funding should be derived from existing sources or additional funds should be explicitly provided.

RECOMMENDATIONS

The National Regulatory Controls for Complementary Medicines

1. The TGA ensure that quality standards for all ingredients for use in complementary medicines are legally enforceable.
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.
3. The TGA ensure that ingredients with a chemical or biological profile that raises concern of teratogenicity not be permitted in 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.
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*.

6. The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.
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.
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*.
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.
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.
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.
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.
13. Reference to 'For Practitioner Dispensing Only' products be removed from Therapeutic Goods Order No. 69 – *General Requirements for Labels for Medicines*.
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".

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.
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.
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.
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.
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.

Adverse Reactions

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.

21. The TGA actively pursue the inclusion of AUST L/AUST R numbers within the current Adverse Drug Reactions (Reporting) System (ADRS).
22. The TGA modify its web-based reporting form to facilitate inclusion of AUST L and AUST R numbers.
23. The TGA develop the capability to search for a single active ingredient across multiple products in the ADRS database.
24. The TGA expand the *Australian Pharmacovigilance Guideline* to include sponsors of complementary medicines.

Information and Advertising

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 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.

Healthcare Practitioners

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.

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.

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.

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.

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.

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.

Industry

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).
34. Dedicated funding be made available for complementary medicine research in Australia for a minimum of five years.
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.
36. A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.
37. The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication.
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.
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.
40. The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.

Administrative and Advisory Mechanisms

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.
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).
43. *The National Strategy for Quality Use of Medicines* (QUM) fund more projects directed at education in the use of complementary medicines.
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.
45. The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.
46. The Complementary Healthcare Consultative Forum be formally disbanded subject to fulfilment of Recommendation 41.
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.
48. Overall accountability for implementing the Committee's recommendations be clearly assigned to a single body.
49. Implementation of the Committee's recommendations be formally reviewed at the end of 2004.

1 INTRODUCTION

ESTABLISHMENT OF THE EXPERT COMMITTEE ON COMPLEMENTARY MEDICINES IN THE HEALTH SYSTEM

In April 2003, the Therapeutic Goods Administration (TGA), Australia's national regulator of medicines, initiated the recall of more than 1600 complementary medicines from the Australian marketplace. It was the largest recall of medicines in Australia and heightened interest in complementary medicines. The recall was a result of the failure of one medicine manufacturer, Pan Pharmaceuticals Limited, to maintain appropriate manufacturing and quality control standards.

Following the recall, consumer groups, health professionals, researchers and practitioners raised concerns regarding the level of trust that can be placed in complementary medicines. These concerns included doubts about the reliance consumers may have in the information available about complementary medicines and confidence in their effectiveness.

The role of complementary healthcare practitioners also came under scrutiny. The level of education and training of practitioners, lack of qualification and registration requirements, and the variability of regulation across jurisdictions, raised questions about the extent to which the community can depend on their expertise and advice.

In order to reassure the public and maintain confidence in Australia's reputation as a supplier of high quality and safe medicines, the Australian Government considered it necessary to establish an expert committee to examine the role of complementary medicines in the Australian healthcare system. On 12 May 2003, the Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, established the Expert Committee on Complementary Medicines in the Health System (the Committee).

In particular, the Committee was asked to examine and provide advice on the regulatory controls covering appropriate standards of quality, safety and efficacy, consumer information, education and training of healthcare practitioners, interactions between complementary and prescribed medicines, restrictions on advertising, and activities to promote an innovative, responsible and viable complementary medicines industry.

1.1 Terms of Reference

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

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

The Committee was requested to examine and provide advice on:

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

INDUSTRY SIZE AND SIGNIFICANCE

Australians are becoming increasingly active in their pursuit of sustained and improved health and wellbeing by exploring, among other things, complementary healthcare. Complementary therapies and medicines are an important part of the Australian healthcare system and are used by a substantial proportion of the population both here and overseas.[6]

MacLennan *et al.*[7] reported in their 2000 study that 52.1 per cent of the Australian population surveyed used at least one non-physician-prescribed alternative (complementary) medicine. In addition, a significant increase in visits to complementary medicine practitioners (such as acupuncturists, reflexologists, aromatherapists and herbal therapists) was seen compared with the findings published in an earlier paper.[8]

As consumers have become more interested in complementary medicines, the revolution in information technology has allowed easy access to sources of complementary medicine information on the Internet and in print and electronic media. The advertising and marketing of alternative and complementary medicines has also grown rapidly, increasing community awareness, exposure to new products and the possibility of greater control of their own healthcare.

[6] Harris P, Rees R, 2000. The prevalence of complementary and alternative medicine use among the general population: a systematic review of the literature. *Complementary Therapies in Medicine*, 8, 88–96.

[7] MacLennan AH, Wilson DH, Taylor AW, 2002. The escalating cost and prevalence of alternative medicine. *Preventive Medicine*, 35, 166–173.

[8] MacLennan AH, Wilson DH, Taylor AW, 1996. Prevalence and cost of alternative medicine in Australia. *The Lancet*, 347, 569–573.

The estimated monetary outlay on complementary medicines was reported by MacLennan *et al.* to be nearly twice the patient expenditure on pharmaceutical medicines during 1992–1993.

Specific information regarding the size of the complementary medicines market is difficult to find. The Australian Bureau of Statistics (ABS) does not recognise a separate complementary medicines sector when compiling market data (information is dispersed among other ABS data pertaining to the food, grocery, pharmaceutical and cosmetics sectors). In addition, many complementary medicine companies are privately and not publicly owned.

Collection of comprehensive data on the size and growth of the industry is further complicated by the lack of a single representative body that collects and collates industry data. However, the following information provides some recent indications:

– "the consumer healthcare product sector of the Australian medicines manufacturing industry has domestic sales of approximately $1.5 billion per annum"[9]
– pharmacy sales of dietary supplements are estimated to have increased by 10.4 per cent in the 12 months to December 2002[10]
– Blackmores Ltd's sales increased by 6.5 per cent in 2002[11]
– Mayne Group Limited's nutraceuticals sales[12] for July–December 2002 rose by 13.3 per cent compared with the corresponding period in 2001
– AZTEC Information Services (estimated) the overall (nutraceuticals) market grew by 8.5 per cent for the 12 months to December 2002.[13]

Further estimates provided by industry suggest that the current annual retail turnover of complementary medicines in Australia is approximately $800 million, with an additional 20 per cent of Australian output being exported.

1.2 Regulatory Analysis

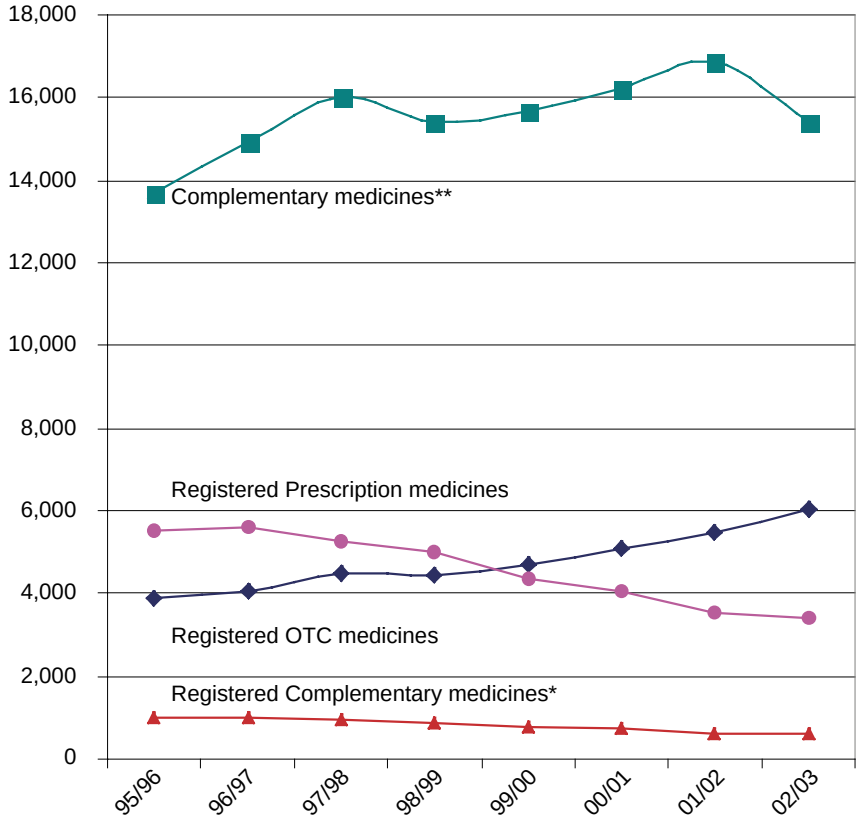
The number of entries for Listed and Registered non-prescription (complementary and over-the-counter (OTC)) medicines on the Australian Register of Therapeutic Goods (ARTG) provides another estimate of the status of the complementary medicines industry in Australia (Figure 1.1).

The recall of more than 1600 complementary medicines from the Australian marketplace in April 2003 is reflected in the change in the number of Listed complementary medicines on the ARTG.

It should be noted, however, that while these figures provide an indicator of the number of complementary medicines which may be available on the Australian market, they do not indicate whether the products are actually available for sale or supply, or give sales volumes for these products.

[9] AZTEC Information Systems data. <www.aztec.com.au/aztec> 22 July 2003.
[10] ASMI Web site: <www.asmi.com.au/industry.htm> 22 July 2003.
[11] *Annual Report 2002*, Blackmores Ltd: Five Year History. <http://www.blackmores.com.au/images/PDF/2002_Annual_Report.pdf>
[12] Derived from *Information Compendium for the 6Months to 31 December 2002*, Mayne Group Ltd. <http://203.89.220.44/upload/documents/compendium.pdf 22> July 2003.
[13] *Information Compendium for the 6 Months to 31 December 2001*, Mayne Group Ltd. <http://203.89.220.44/upload/documents/compendium.pdf> 22 July 2003.

Figure 1.1 Number of products on the Australian Register of Therapeutic Goods (ARTG), 1995–2003.



* The numbers of Registered OTC and Registered complementary medicines have been extrapolated, based on the estimate that 15 per cent of all Registered non-prescription medicines on the ARTG are Complementary medicines.

** The numbers of Complementary medicines has been extrapolated, based on the estimate that Complementary medicines represent approximately 90 per cent of all Listed medicines.

NATIONAL MEDICINES POLICY (NMP) AND THE QUALITY USE OF MEDICINES FRAMEWORK

1.3 A Brief History

Australia's long history of quality medicines policies began with the *National Health Act 1953*. The activities of the World Health Organization (WHO) in the 1980s led many countries, including Australia, to establish national medicinal drug policies to ensure the availability of essential, affordable drugs of acceptable quality, safety and efficacy.

The work of the Consumers' Health Forum (CHF) in the late 1980s and early 1990s led to the establishment of both the Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health and Rational use of Medicines (PHARM) Committee.

A Policy on the Quality Use of Medicines was published and endorsed by the Australian Ministry of Health in 1992 and, in December 1999, APAC revised the Australian Medicinal Drug Policy, and the new *National Medicines Policy* (NMP) 2000[14] was released.

1.4 *National Medicines Policy*

The *National Medicines Policy* (NMP) is a framework based on partnerships which aims to improve positive health outcomes for all Australians through their access to, and wise use of, medicines.

In developing the NMP, Australian, State and Territory governments, health educators, health practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media, recognised the benefits of a national policy and resolved to work together as partners to promote the objectives of the policy. Each partner accepted that all must be engaged in a cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines.

Figure 1.2 schematically depicts the committees and agencies with major responsibilities for the various components of the NMP. It seeks to identify only major committees and agencies, and is not intended to be exhaustive.

It is recognised that the responsibilities and activities of the committees may cover more than one component of the policy, but for simplicity the committees have been listed under the component of the policy under which they were established, or for which they bear primary responsibility. Healthcare practitioners, professional organisations, consumer agencies, registering authorities and the pharmaceutical industry also have responsibilities under the NMP.

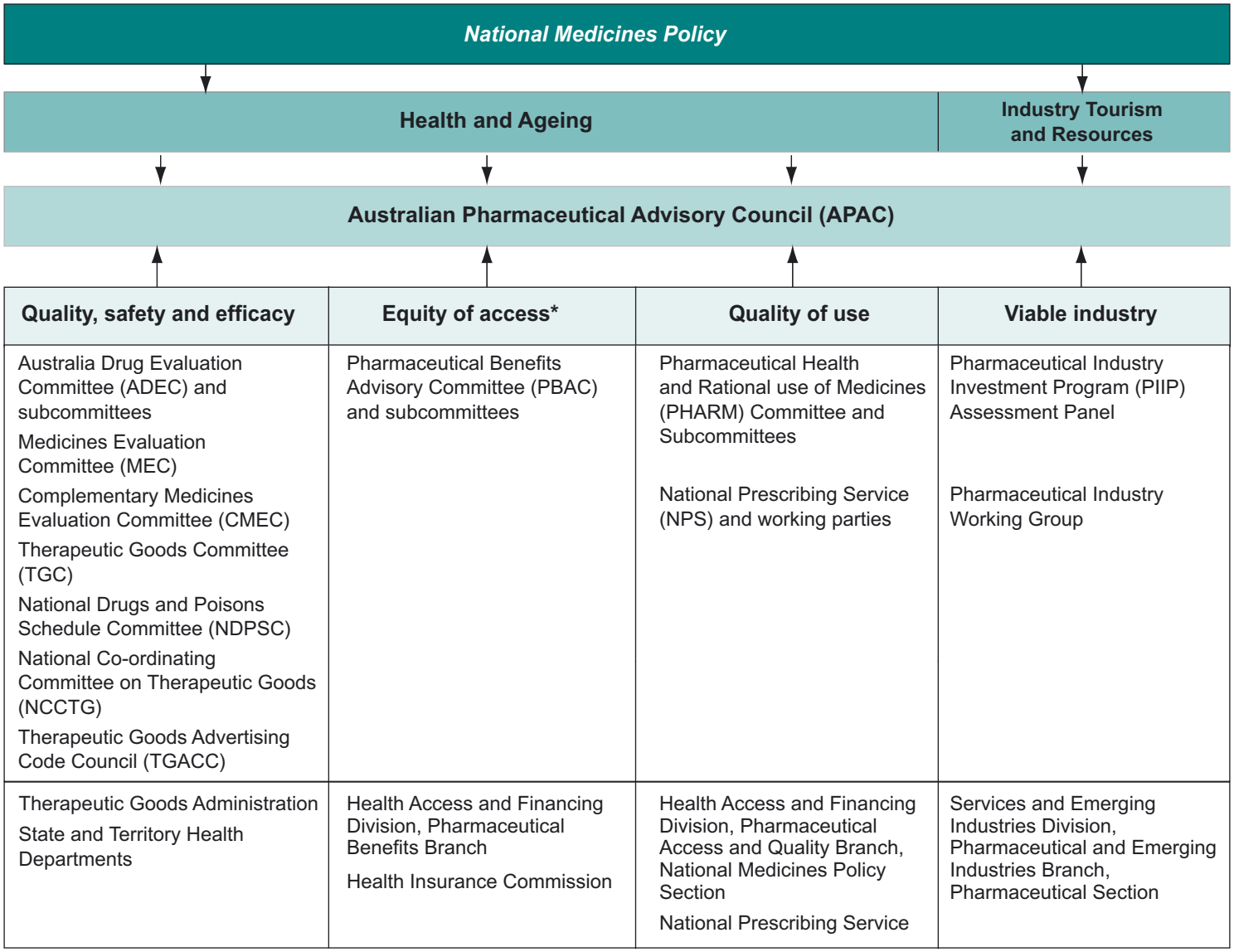
There are other agencies, not acknowledged in Figure 1.2, whose primary responsibility is not to the NMP, but whose responsibilities and subsequent activities have a major impact on the NMP. These include, for example, the Australian Competition and Consumer Commission (ACCC).

Details of committees such as PHARM and APAC are given in Chapter 7 – *Administrative and Advisory Mechanisms*.

Medicines, prescription and non-prescription, including complementary medicines, have a significant impact on both health and health expenditure.

[14] *National Medicines Policy,* 2000. Canberra, Commonwealth Department of Health and Aged Care. <http://www.health.gov.au/haf/nmp/pdf/nmp2000.pdf>

Figure 1.2 Committees and agencies with major responsibilities for the various components of the *National Medicines Policy*.



Goals	Quality, safety and efficacy	Equity of access*	Quality of use	Viable industry
Committees involved	Australia Drug Evaluation Committee (ADEC) and subcommittees Medicines Evaluation Committee (MEC) Complementary Medicines Evaluation Committee (CMEC) Therapeutic Goods Committee (TGC) National Drugs and Poisons Schedule Committee (NDPSC) National Co-ordinating Committee on Therapeutic Goods (NCCTG) Therapeutic Goods Advertising Code Council (TGACC)	Pharmaceutical Benefits Advisory Committee (PBAC) and subcommittees	Pharmaceutical Health and Rational use of Medicines (PHARM) Committee and Subcommittees National Prescribing Service (NPS) and working parties	Pharmaceutical Industry Investment Program (PIIP) Assessment Panel Pharmaceutical Industry Working Group
Operational units	Therapeutic Goods Administration State and Territory Health Departments	Health Access and Financing Division, Pharmaceutical Benefits Branch Health Insurance Commission	Health Access and Financing Division, Pharmaceutical Access and Quality Branch, National Medicines Policy Section National Prescribing Service	Services and Emerging Industries Division, Pharmaceutical and Emerging Industries Branch, Pharmaceutical Section

Source: Adapted from *The National Strategy for Quality Use of Medicines*, 2002

* Applies to prescription medicines only

It is essential that Australia has a well-developed and practical NMP to ensure:

– optimum access to and use of high quality medicines
– a rational funding system
– a viable local medicines industry.

The NMP focuses first on people's needs and brings the skills, experience and knowledge of individual partners to bear on four central objectives, namely:

1. timely access to the medicines that Australians need, at a cost individuals and the community can afford

   The Australian Government's Pharmaceutical Benefits Scheme (PBS) helps improve the health of all Australian residents by ensuring they have timely access to necessary and lifesaving medicines at an affordable price.

2. medicines meeting appropriate standards of quality, safety and efficacy

   The Australian community expects that medicines and medical devices in the marketplace are safe and of high quality, to a standard at least equal to that of comparable countries. The TGA provides a national framework for the regulation of therapeutic goods in Australia. It also ensures the quality, safety and efficacy of therapeutic goods.

3. quality use of medicines

   Australia has a *National Strategy for Quality Use of Medicines* (QUM) which is central to the NMP.[15] The *National Strategy for QUM* is intended to assist the QUM partners, healthcare consumers, health practitioners and educators, healthcare facilities, the medicines industries, the media, healthcare funders and purchasers, and governments, in becoming more aware of the QUM framework and approach. This will enable them to integrate their own activities with the *National Strategy*.

and

4. maintaining a responsible and viable medicines industry.

The first three objectives of the NMP require the continued existence of a responsible and viable medicines industry in Australia.

> In the NMP, the term 'medicine' includes prescription and non-prescription medicines, including complementary healthcare products.

1.5 *The National Strategy for Quality Use of Medicines* (QUM)

The goal of QUM is to optimise the use of medicines to improve health outcomes for all Australians. QUM recognises that many people maintain their health without using medicines, while for others, medicines play an important role in maintaining health, preventing illness and curing disease.

QUM sits firmly within the framework of the NMP. It acknowledges that the four objectives of the NMP are interdependent and that this interdependence must be recognised and fostered in order to achieve the goal of the Policy.

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

For example, it is not possible to have QUM if people cannot afford the medicines they need. Nor is it possible to have QUM if the available medicines are not safe or effective, just as it is not sensible to have high-quality, effective medicines unless they are used appropriately.

The key focus of QUM is to ensure medicines are used:

- judiciously – ensuring that the best possible treatment plan is chosen
- appropriately – ensuring that when medicines are needed they are carefully selected, managed, monitored and reviewed
- safely – minimising misuse, overuse and under-use of medicines and taking appropriate actions to solve medication problems such as adverse events
- efficaciously – ensuring that medicines achieve the goals of therapy by delivering beneficial changes in actual health outcomes.

> In *The National Strategy for Quality Use of Medicines*, the term 'medicine' includes prescription, non-prescription and complementary medicines.

1.5.1 QUM Principles

Principles that that have been developed to underpin the quality use of medicines include:

1. The primacy of consumers
2. Partnership
3. Consultative, collaborative, multidisciplinary activity
4. Support for existing activity
5. Systems based approaches

1.5.2 Key Partners

All partners have a role to play in achieving QUM. The key partners of *The National Strategy for Quality Use of Medicines* include consumers, health practitioners, health educators, healthcare facilities, the medicines industries, the media, healthcare funders and purchasers, and government.

1.5.3 Building Blocks

Six key building blocks have been identified as fundamental to the QUM. They are:

– policy development and implementation
– facilitation and coordination of QUM initiatives
– provision of objective information and assurance of ethical promotion of medicines
– education and training
– provision of services and appropriate interventions
– strategic research, evaluation and routine data collection.

COMPLEMENTARY MEDICINES – WHAT ARE THEY?

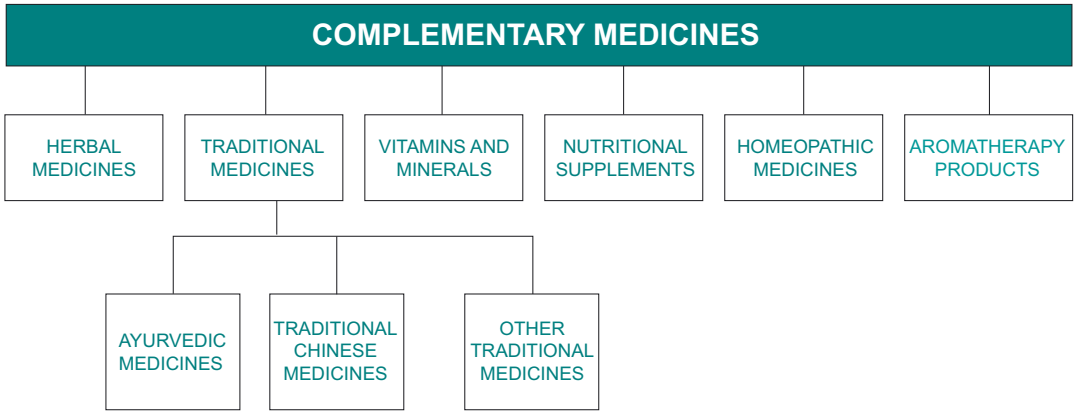
More and more Australians are looking for positive health and lifestyle outcomes through the use of complementary medicines. The majority of alternative (complementary) medicine users appear to be doing so not so much as a result of being dissatisfied with conventional medicine but more because they find these healthcare alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life.[16]

1.6 Medicines

There is no internationally accepted collective term to describe the group of products regulated in Australia as complementary medicines, and no clear distinction between complementary medicines and other medicines on the basis of their purpose of use.

Complementary medicines in Australia include herbal medicines, vitamin and mineral supplements, other nutritional supplements, traditional medicines such as Ayurvedic medicines and traditional Chinese medicines (TCM), homoeopathic medicines, and aromatherapy oils (where they make therapeutic claims) (see Figure 1.3).

Figure 1.3 Classes of complementary medicines.



Other terms used to describe complementary medicines include ‘natural medicines’, ‘non-conventional medicines’ and ‘holistic medicines’.

NB. The regulatory definition of complementary medicines is given and discussed in Chapter 2 – *The National Regulatory Controls for Complementary Medicines*.

1.7 Therapies

The UK House of Lords Select Committee on Science and Technology, 6th Report, on Complementary and Alternative Medicine,[17] uses the term

[16] Astin JA, 1998. Why patients use alternative medicine: results of a national study. *Journal of the American Medical Association*, 279(19), 1548–1553.

[17] House of Lords, 2000. Select Committee on Science and Technology, 6th Report, *Complementary and Alternative Medicine*, The Stationary Office, London. <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm>

'Complementary and Alternative Medicine' (CAM) to refer to the diverse group of health-related therapies and disciplines which are not considered to be a part of mainstream medical care. It further advises that CAM embraces those therapies which may either be provided alongside conventional medicine (complementary) or which may, in the view of their practitioners, act as a substitute for it.

The Cochrane Collaboration further describes CAMs as: "a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period".[18]

NCCAM, the American National Center for Complementary and Alternative Medicine,[19] suggests that CAM practices are best described as those not currently considered an integral part of conventional medicine. Implicit in this definition is the acknowledgment that, as CAM practices are proven safe and effective, they may become adopted into mainstream healthcare practice.

A glossary of complementary medicine systems and therapies is contained in Appendix 2.

REGULATION OF COMPLEMENTARY MEDICINES IN AUSTRALIA (OVERVIEW)

1.8 Policy

There is a general expectation in the Australian community that therapeutic products will be safe, effective and of good quality, and that the government will set standards and regulations to meet these expectations.

At the same time, those manufacturing and marketing therapeutic products expect that regulation should be the minimum necessary, appropriate and commensurate with the assessed risk of their respective products, and consistent with international practice.

The Australian Government recognises its obligation to ensure that public health and safety is upheld without unnecessary regulatory burden. Accordingly, it has responded to community expectations by establishing a regulatory system that aims to protect public health and safety while imposing minimal compliance costs.

Although the Australian Government does not possess explicit constitutional powers for the regulation of therapeutic goods, it uses a combination of constitutional powers. The combination of these powers has enabled the enactment of specific legislation and the operation of Australian public health and safety regulatory functions.

The Australian Department of Health and Ageing plays a key role through the provision of policy advice, and the TGA is the main government agency responsible for the regulation of medicines in Australia. There are also several TGA committees that play an important role, providing advice on the regulation of medicines. These committees include expert members who are non-

[18] As cited in: Zollman C, Vickers A, 1999. What is complementary medicine? *British Medical Journal*, 319, 693–696.

[19] National Center for Complementary and Alternative Medicine (NCCAM), 2002. *What Is Complementary and Alternative Medicine (CAM)?*, May 2002, USA. Last Modified: 21 October 2002. <http://nccam.nih.gov/health/whatiscam/>

government officials, such as healthcare practitioners and professionals with experience in health, industry and consumer matters.

1.9 Legislative Framework

1.9.1 Therapeutic Goods Act 1989

The *Therapeutic Goods Act 1989* (the Act), which came into effect on 15 February 1991, sets out the legal requirements for the import, export, manufacture and supply of medicines in Australia. The overall objective of the Act is to ensure the quality, safety, efficacy, and timely availability of therapeutic goods supplied in or exported from Australia. The Act details the requirements for listing or registering all therapeutic goods in the Australian Register of Therapeutic Goods (ARTG), as well as many other aspects of the law, including advertising, labelling, and product appearance. Some regulatory provisions relating to medicines, such as the scheduling of substances and the safe storage of therapeutic goods, are covered by State or Territory legislation rather than by Commonwealth law.

The Australian community expects that medicines and medical devices in the marketplace will be safe and of high quality, and of a standard at least equal to that of comparable countries.

The Act is supported by the Therapeutic Goods Regulations 1990 (the Regulations), and various Orders and Determinations that provide further details of matters covered in the Act. The Act is a Commonwealth Act. It provides a substantially uniform national system of controls over therapeutic goods, facilitating trade between the States/Territories and benefiting both consumers and industry.

1.10 Jurisdictions

Before the introduction of the Act, there were considerable discrepancies in, and inconsistencies between, regulatory controls for therapeutic goods enacted at a State/Territory level, including different requirements for the pre-market evaluation of therapeutic goods in different jurisdictions.

In recognition of the difficulties inherent in this system, all jurisdictions agreed in the late 1980s that the Australian Government should develop legislation, to be adopted by all States and Territories, achieving a national system of regulatory controls in relation to therapeutic goods.

The use of Australian Government regulation has ensured consistency in:

- pre-market approval of therapeutic products, including Good Manufacturing Practice (GMP)
- post-market surveillance
- advertising of products
- standards for labelling.

1.11 Role of the Therapeutic Goods Administration (TGA)

Established in 1991, the TGA (a Division within the Australian Government Department of Health and Ageing) administers the national system of regulatory controls for the quality, safety, efficacy and timely availability of therapeutic goods used in or exported from Australia. The TGA recovers 100 per cent of its operating costs through fees and charges collected from the therapeutic goods industry. This covers all activities which fall within the scope of the Act including regulation of the industry, the TGA's public health responsibilities, responsibilities to consumers for information on products and TGA's support for the industry generally (e.g. facilitation of exports and international harmonisation of standards). The TGA collects its revenue primarily through annual charges, evaluation and assessment fees and licence fees.

The TGA is responsible for regulating the supply in Australia of therapeutic goods including prescription and non-prescription medicines, the latter including complementary medicines. Essentially, any product for which therapeutic claims are made, must be entered in the Australian Register of Therapeutic Goods (ARTG) before the product can be supplied in Australia. The ARTG is a computer database of information about therapeutic goods for human use approved for supply in, or exported from, Australia.

The TGA uses a 'risk management' approach to regulating medicines supplied in Australia. The risk[20] associated with a particular medicine or a medicinal ingredient determines the assessment process applied by the TGA. Higher risk medicines are individually evaluated for quality, safety and efficacy and must be included on the ARTG as Registered medicines. Registered medicines include both prescription and non-prescription medicines.

Low risk medicines are individually assessed by the TGA for compliance with legislation and are included in the ARTG as Listed medicines. Listed medicines are assessed by the TGA for quality and safety before inclusion in the ARTG, but not for efficacy. This means that the TGA has not evaluated them individually before supply to determine whether they are effective. It is a legal requirement that sponsors hold information to substantiate all of their products' indications and claims, and this evidence may be called for and evaluated by the TGA, should a concern arise.

> Most complementary medicines included in the ARTG are Listed medicines.

The TGA carries out a range of assessment and monitoring activities to ensure that all therapeutic goods available in Australia are of an acceptable standard.

At the same time, the TGA aims to ensure that the Australian community has access, within a reasonable time, to therapeutic advances.

Overall control of therapeutic goods is exerted through five main processes:

– pre-market evaluation and approval of registered products intended for supply in Australia

[20] Risk is not an absolute concept. It is an assessment of the potential of a product to do harm to those it is intended to help, or to others (such as children) who may come in contact with it — regardless of whether the harm results from following or disregarding the directions for use.
Source: *Medicines Regulation and the TGA*, December 1999. Canberra, Commonwealth Department of Health and Aged Care. <http://www.tga.gov.au/docs/pdf/medregs.pdf>

– licensing of manufacturers in accordance with international standards under GMP
– post-market monitoring, through sampling, adverse event reporting, surveillance activities, and response to public inquiries
– development, maintenance and monitoring of the systems for listing of medicines
– assessment of medicines for export.

1.11.1 The Office of Complementary Medicines (OCM)

In December 1998, a working party of industry, consumer and government representatives was established under the Chairmanship of Senator Grant Tambling to consider the regulation of complementary medicines by the TGA.

A package of improvements and refinements in the regulation of complementary medicines, developed by the working party, was subsequently endorsed by all bodies. It included major policy reforms, legislative amendments and new administrative procedures to facilitate advice and consultation, and information initiatives.

The legislation underpinning the new initiatives was proclaimed on 1 April 1999 and Senator Tambling officially launched the reform package, including the new OCM, in late April 1999.

Within the TGA, the OCM was created to focus exclusively on the regulation of complementary medicines. It is staffed by qualified and experienced personnel with an understanding of complementary medicines and related issues.

The OCM was established to:

– provide a genuine government focus for the regulation of complementary medicines
– increase the transparency of complementary medicines regulation
– develop more formal and lasting links with the industry, the academic community, consumers and government.

Responsibilities of the OCM include:

– consulting and liaising with interest groups to foster cooperation and confidence in the regulatory arrangements for complementary medicines
– evaluating data in order to make assessments for Listed and Registered complementary medicines
– providing support to the Complementary Medicines Evaluation Committee (CMEC) (for more information on CMEC, see Section 7.2.3 of Chapter 7)
– providing advice to the Minister and TGA on the regulation of complementary medicines and associated matters.

1.12 Other Australian Regulatory Bodies

1.12.1 Food Standards Australia New Zealand (FSANZ)

Food Standards Australia New Zealand (FSANZ) (known until recently as the Australia New Zealand Food Authority, ANZFA, and formerly the National Food Authority, NFA) is a statutory authority operating under the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

FSANZ works in partnership with the Australian, State and Territory governments and the New Zealand Government, to protect the health and safety of the people in Australia and New Zealand by maintaining a safe food supply.

The TGA works closely with the FSANZ, particularly with respect to products at the food/medicines interface.

The differentiation between food and medicines is defined through the *Therapeutic Goods Act 1989* and the FSANZ Act. Where necessary, both Acts enable the regulators to declare a product as a 'therapeutic good' or a 'food' respectively, to maintain clarity at the food-medicine interface (see also Chapter 4, Section 4 – *Food Labelling and Advertising*).

1.12.2 Australian Competition and Consumer Commission (ACCC)

The Australian Competition and Consumer Commission (ACCC) was formed in 1995 by the merger of the Trade Practices Commission and the Prices Surveillance Authority.

An independent statutory authority, the Commission administers the *Trade Practices Act 1974* and the *Prices Surveillance Act 1983* and has additional responsibilities under other legislation.

In broad terms, the Act covers anti-competitive and unfair market practices, mergers or acquisitions of companies, product safety/liability, and third-party access to facilities of national significance.

The Commission is the only national agency dealing generally with competition matters and the only agency with responsibility for enforcement of the *Trade Practices Act 1974* and the associated State/Territory application legislation.

Interactions between the TGA and the ACCC are strong, and occur on an 'as needs' basis. For example, a Commissioner of the ACCC was invited to overview consumer protection issues that arise in the promotion of complementary medicines and the role of the *Trade Practices Act 1974* in relation to the review of the *Therapeutic Goods Advertising Code*.

Healthcare products subject to the controls of the ACCC include those that do not fall within the legislative definition of a therapeutic good. These products are treated as consumer goods and are not regulated by the TGA. The ACCC may also, however, take action against a therapeutic good where it contravenes the *Trade Practices Act 1974*.

TRANS TASMAN AGENCY

The Australian and New Zealand governments have agreed in principle to establish a single trans Tasman agency to regulate therapeutic products, including medicines[21] and medical devices. This initiative will harmonise the regulation of therapeutic products between both countries under the Trans Tasman Mutual Recognition Arrangement (TTMRA), in which Australia and New Zealand have agreed to take steps that will lead to a more integrated trans Tasman economy.

The new agency will replace the Australian TGA and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe). The primary objective of the Agency will be to safeguard public health and safety in Australia and New Zealand through regulation of the quality, safety and efficacy (or performance) of therapeutic products. The Agency will be accountable to the Australian and New Zealand governments. The ongoing cost of regulation will be recovered from industry.

Currently, officials in Australia and New Zealand are developing the final details of:

– a treaty between Australia and New Zealand to establish the Agency and the joint regulatory scheme
– the regulatory scheme and legislation to be administered by the Agency
– the Agency's infrastructure and administrative arrangements
– transitional arrangements.

The Agency is expected to commence operation on 1 July 2005 after the entry into force of a treaty between the two countries.

1.13 Towards a Joint Agency – Implications for Advertising

One of the challenges facing a trans Tasman agency is the harmonisation of regulatory practices and guidelines. In preparation for this, reviews of the current legislative requirements and regulatory arrangements in Australia and New Zealand are currently under way.

A *Review of Advertising Therapeutic Products in Australia and New Zealand* was undertaken in 2002 to develop an advertising scheme, including approval and complaints processes, that could be adopted as part of a trans Tasman therapeutic products agency.

A wide range of stakeholders in Australia and New Zealand was consulted during the course of the review. The final report is available from the TGA and Medsafe websites.

An Interim Advertising Council (IAC) has been established to consider and further develop the Review's recommendations.

The IAC will report to the TGA and Medsafe in early 2004 with recommendations on the implementation of a trans Tasman therapeutic products advertising

[21] This includes products currently regulated in Australia as complementary medicines. Subject to the outcomes of a Parliamentary Health Select Committee inquiry in New Zealand, it is anticipated that products currently supplied in New Zealand as herbal medicines, homoeopathic medicines and dietary supplements (other than food-type dietary supplements) will also be regulated by the Agency. A report from the Health Select Committee inquiry is expected in late 2003.

scheme. The Australian and New Zealand Ministers for Health will then decide on the final model for this scheme.

The Committee, in considering the nature and extent of restrictions required on advertising (including Internet advertising) of complementary medicines to consumers, requested, and was provided with, a briefing on the current status of the work of the IAC. The Committee's findings and recommendations on these matters is detailed in Chapter 4 – *Information and Advertising*.

The Committee felt that rather than replicate the work of the IAC, or pre-empt its findings, the most appropriate way to address advertising issues would be to document areas of concern as identified by the Committee, and recommend that these be given careful consideration by the IAC when formulating its own recommendations.

COMMITTEE OPERATION

The first meeting of the Committee took place in Sydney (the city most central to Committee Members) on 29 May 2003, two weeks after the Government's announcement of the Review.

With six meetings planned to address the wide-ranging Terms of Reference, and one further meeting scheduled for the preparation of the final report, the challenge of meeting the initial deadline of 15 August 2003, soon became apparent.

Accordingly, on 20 June 2003, the Parliamentary Secretary extended the deadline by six weeks until 26 September 2003.

The first six meetings were held approximately every fortnight and the final meeting was convened on 23 September 2003 to focus on preparation of the final report.

The Secretariat support for the Committee was provided by the OCM of the TGA, with assistance from Focal Point Consulting. An adviser to the Parliamentary Secretary to the Minister for Health and Ageing was also present.

Table 1.1 details the membership of the Committee.

1.14 Committee Membership

Members of the Committee were selected on the basis of their expertise in areas of the complementary medicines industry, not as representatives of stakeholder groups.

The Government decision to include these members in the Committee was made on the basis that they were considered to have the appropriate depth and breadth of expertise to consider matters under the Committee's Terms of Reference.

Table 1.1 Committee membership.

NAME	AFFILIATION	EXPERTISE
Dr Michael Bollen (Chair)	Former member of the National Health and Medical Research Council (NHMRC) Principal, BMP Healthcare Consulting Pty Ltd	Quality use of medicines, healthcare delivery, consumer medicines information and general medical practice
Dr John Aloizos	Chair, Australian Pharmaceutical Advisory Council (APAC)	Implementation of all aspects of National Medicines Policy and general medical practice
Associate Professor Alan Bensoussan	Centre for Complementary Medicine Research, University of Western Sydney Member, Expert Advisory Panel to Complementary Medicines Evaluation Committee (CMEC)	Use and evaluation of complementary medicines and therapies in clinical practice; practitioner education and training
Dr Kerry Breen	Chair, NHMRC Australian Health Ethics Committee	Ethical issues associated with the promotion and use of medicines
Professor Terry Campbell	Head, UNSW Department of Medicine, St Vincent's Clinical School, Sydney Member, Pharmaceutical Benefits Advisory Committee (PBAC)	Clinical pharmacology
Mr Philip Daffy	Consultant to the complementary medicines industry, including the Complementary Healthcare Council of Australia (CHC)	Product development complementary medicines
Dr Paul Dugdale	Chief Health Officer, ACT Department of Health	State and Territory issues associated with practitioner regulation, regulation of dispensed and extemporaneously compounded complementary medicines
Associate Professor John Eden	University of New South Wales, School of Women's and Children's Health	Use of complementary medicines and therapies in medical practice, particularly in women's health
Mr Ross Johnston	Vice President Manufacturing Operations Asia Pacific, Wyeth	Quality assurance in the manufacture of complementary, OTC and prescription medicines
Professor Alastair MacLennan	Department of Obstetrics and Gynaecology, University of Adelaide	Complementary medicine epidemiology and safety of complementary medicines
Mr David McLeod	Naturopath, Fellow with the Australian Acupuncture and Chinese Medicine Association	Use of complementary medicines in complementary medicine practice; practitioner education and training
Professor Stephen Myers	Director, Australian Centre for Complementary Medicine Education and Research, University of Queensland/Southern Cross University, Member of CMEC	Use and evaluation of complementary medicines in medical practice; practitioner education and training

Table 1.1 (cont'd)Committee membership.

NAME	AFFILIATION	EXPERTISE
Mr Anthony Nunan	Principal – Parade Pharmacy; Nunan's Watsonia Pharmacy; Heath's Road Medical Clinic Pharmacy Chairman – Australian Medicines Handbook	Small business issues; quality use of medicines; postgraduate pharmacist education and training; pharmacy
Ms Juliet Seifert	Executive Director, Australian Self-Medication Industry (ASMI)	Quality use of medicines and industry issues, including complementary medicines
Associate Professor Anne Tonkin	Department of Clinical and Experimental Pharmacology University of Adelaide, Former Chair of CMEC	Evaluation of efficacy and clinical pharmacology, medical education
Mr Darin Walters	Chief Executive Officer, Blackmores Ltd	Complementary medicines industry
Professor Bill Webster	Head, Department of Anatomy and Histology, University of Sydney Member of CMEC	Toxicology and the safety of complementary medicines
Associate Professor Heather Yeatman	Head, Graduate School of Public Health, University of Wollongong Member of CMEC Member, Food Standards Australia New Zealand (FSANZ) Board	Consumer issues associated with the use of complementary medicines, food and nutrition

1.15 Modus Operandum

1.15.1 Broader Consultation

It was acknowledged from the outset that the work of the Committee might benefit from consultation with other parties. Consultation was at the discretion of individual Members. It was agreed that Members should exercise due regard to confidentiality in discussing, with other parties, issues associated with Committee meetings, and that permission from the Chair should be obtained before any external consultation was undertaken.

Presentations to the Committee

Members of the Committee specifically requested detailed information about two issues within their Terms of Reference. This was facilitated by presentations to the Committee as detailed:

National Prescribing Service Telephone-Based Information Services

Mr Craig Patterson from the National Prescribing Service Limited (NPS) gave a presentation to Members on the Therapeutic Advice and Information Service (for health professionals) and the *Medicines Line* service (for consumers).

Practitioner Regulation

Ms Anne-Louse Carlton from the Service and Workforce Policy Branch, Department of Human Services, Victoria gave a presentation on the Review of Practitioner Regulation in Australia (most particularly that being undertaken in Victoria).

1.15.2 Submissions

Given the short time frame within which it was operating, the Committee determined that it would be impractical and potentially inequitable to call for submissions. The deliberations of the Committee were confidential, but members could consult within their own networks once initially cleared by the Chair. Members could also provide concise papers addressing topics within their area of expertise.

1.15.3 Conflict of Interest

Members of the Committee were made particularly aware of the potential for conflicts of interest in contributing to the work of the Committee. Accordingly, Members declared their interests, both pecuniary and non-pecuniary, before the first meeting. In addition, the Chair provided the opportunity for Members to declare any situation or circumstance which could influence their suitability to participate in discussions where it was felt that 'undue influence' could affect (or be perceived to affect) the findings of the Committee

1.15.4 Final Report

The Committee agreed that the final report should strive to represent the consensus position of the Committee on the wide range of issues. Where consensus could not be reached, an undertaking was given that, in compiling the final report, every effort would be made to reflect any differences in points of view among Members.

The aim for the final report was that it should strive to convey constructive, direction-setting options to Government, recognising that not all issues raised in the course of the Committee's deliberations, would be able to be resolved.

This page has been left blank intentionally.

2 THE NATIONAL REGULATORY CONTROLS FOR COMPLEMENTARY MEDICINES

TERM OF REFERENCE ADDRESSED

This chapter focuses on the term of reference that requires the Committee to examine and provide advice on:

> *the national system of regulatory controls required to ensure that complementary medicines meet appropriate standards of quality, safety and efficacy.*

The Committee considered that some matters relating to the regulation of complementary medicines were more appropriately addressed in Chapter 3 – *Adverse Reactions*, Chapter 4 – *Information and Advertising*, and Chapter 6 – *Industry*.

BACKGROUND

2.1 The Regulatory Framework for Complementary Medicines in Australia

The regulatory arrangements for complementary medicines are primarily the responsibility of the Therapeutic Goods Administration (TGA), in cooperation with State and Territory Governments and industry. These particular partners, together with healthcare practitioners and consumers, need to undertake cooperative action to maintain an efficient, contemporary registration and scheduling process consistent with the community interest and the principles of best practice.

Australians expect that therapeutic products will be safe, effective and of good quality and that the government will set standards and regulations to meet these expectations. At the same time, those manufacturing and marketing therapeutic products expect that regulation should be the minimum necessary, appropriate and commensurate with the assessed risk of their respective products and consistent with international practice.

The *Therapeutic Goods Act 1989*[22] (the Act) came into effect in February 1991. The TGA is responsible for administering the provisions of the Act. The overall objective of the Act is to ensure the quality, safety, efficacy, and timely availability of therapeutic goods, including medicines, supplied in or exported from Australia. While the Act provides a substantially uniform national system of controls over therapeutic goods, other Commonwealth and separate State and Territory legislation may apply to certain therapeutic goods.

[22] Commonwealth of Australia, *Therapeutic Goods Act 1989* as amended.

The TGA maintains the Australian Register of Therapeutic Goods (ARTG). The ARTG includes details of all therapeutic goods that are imported into, supplied in, or exported from Australia. It is a legal requirement that, unless specifically exempt or excluded, all therapeutic goods must be included in the ARTG before their importation, exportation, manufacture, or supply. In general, only therapeutic goods that have been assessed or evaluated by the TGA are included in the ARTG.

There are approximately 16,000 complementary medicines included in the ARTG (see Chapter 1 – *Introduction* for details).

2.2 Australian Regulatory Guidelines for Complementary Medicines

The TGA, in consultation with the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council of Australia (CHC), is developing regulatory guidelines specifically for complementary medicines. A Consultation Group, comprising members from the TGA, ASMI and CHC with experience in the regulation and manufacture of complementary medicines, was established to assist in the development of a draft of the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) for stakeholder consultation. As development of the new complementary medicine guidelines has proceeded, the draft documents have been published on the TGA's website to allow comment.[23]

The content of the ARGCM is intended to reflect both the nature of complementary medicines and the current Australian requirements for their regulation. The ARGCM will:

– provide information to help sponsors of complementary medicines to meet their obligations under therapeutic goods legislation
– help ensure that applications to the TGA relating to complementary medicines uniformly meet all essential regulatory requirements so that applications may be processed successfully within minimum time frames
– enhance clarity and transparency of processes leading to the Registration and Listing of complementary medicines in the ARTG.

2.2.1 Joint Australia/New Zealand Regulatory Agency

It is expected that the ARGCM will provide a basis for the development of new guidelines for complementary medicines under a joint Australia/New Zealand trans Tasman regulatory agency. In the future, as part of the trans Tasman joint regulatory project for complementary medicines, there will be further stakeholder consultation to develop guidelines for use in a joint agency environment.

2.3 Complementary Medicines: Regulatory Definition

For the purpose of regulating complementary medicines, the Act (Section 52F, Definitions) and the Therapeutic Goods Regulations 1990[24] (the Regulations) respectively define what is a complementary medicine and designate the types of

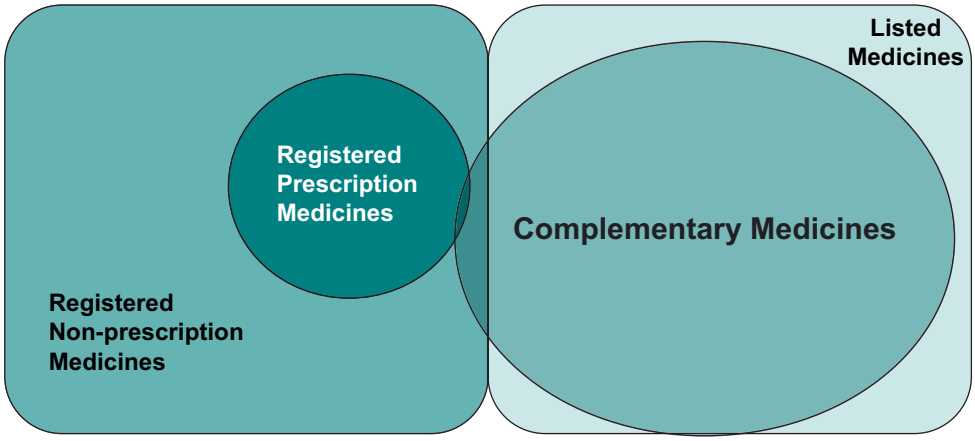
[23] *Australian Regulatory Guidelines for Complementary Medicines* <www.tga.gov.au/docs/html/argcm.htm>.

[24] Commonwealth of Australia, Therapeutic Goods Regulations 1990 as amended. The objective of the Regulations is to prescribe in matters in respect of the manufacture, supply, advertising, registering or listing of medicines so as to make it necessary or convenient to carry out or give effect to the Act.

active ingredients that may be used in such medicines. A complementary medicine is defined as a therapeutic good consisting wholly or principally of one or more designated active ingredients (the Regulations: Schedule 14, Designated active ingredients), each of which has a clearly established identity and a traditional use. Traditional use means use of the designated active ingredient that is well documented, or otherwise established, according to the accumulated experience of many traditional healthcare practitioners over an extended period; and accords with well-established procedures of preparation, application and dosage. Medicines not meeting the definition cannot be regulated as complementary medicines.

Complementary medicines may be included on the ARTG as Listed or Registered medicines. Registered complementary medicines may be non-prescription, over-the-counter (OTC) medicines or medicines available only on prescription from a medical practitioner or other authorised prescriber registered under a law of a State or Territory (see Figure 2.1).

Figure 2.1 Schematic depiction of different types of complementary medicines.



2.4 Complementary Medicines: Quality, Safety and Efficacy

In supporting the overall objective of the Act to ensure the quality, safety, efficacy, and timely availability of therapeutic goods supplied in or exported from Australia, the TGA's regulatory processes include three key elements: the licensing and audit of manufacturers, pre-market assessment of products and a range of post-market activities. These elements are summarised below.

2.4.1 Licensing and Audit of Manufacturers

The Act requires each Australian manufacturer of medicinal products for human use to hold a manufacturing licence. It is an offence, carrying heavy penalties, to manufacture therapeutic goods without such a licence, unless the goods are exempt from this requirement. Licence holders are required to comply with the manufacturing principles of the Act. These manufacturing principles require compliance with Good Manufacturing Practice (GMP).

A basic principle of GMP is that quality cannot be assured by testing a finished product alone. Testing a finished product for compliance with a regulatory specification is just one component in the quality assurance chain. Regulatory specifications, such as those in a pharmacopoeial monograph, are aimed at selected quality parameters. The specifications are developed on the understanding that the product has been manufactured in accordance with the principles of GMP and in conformity with the TGA-approved formulation.

A finished-product specification cannot control for contamination, adulteration or substitution from all possible sources. This is particularly the case for many complementary medicines that may contain chemically complex herbal ingredients and/or multiple ingredients.

Australian manufacturers of medicinal products are required to comply with the *Australian Code of GMP for Medicinal Products*.

The Code sets out requirements relating to the following:

– *Quality management*. This is necessary to ensure that each batch of product is of the required quality and safety
– *Personnel*. Personnel are required to have the appropriate qualifications, experience and training, and observe appropriate standards of hygiene
– *Premises and equipmen*t. The design, location and construction of premises and equipment must be appropriate for the products being manufactured
– *Documentation*. Documentation must permit tracing of batch history
– *Production*. Production controls must ensure that products of the requisite quality are manufactured
– *Quality control*. The system of quality control must ensure that all batches of products are in compliance with established specifications before their release.

Compliance with the *Australian Code of GMP for Medicinal Products* is ascertained by carrying out pre-licensing audits and, thereafter, regular on-site audits of manufacturers of medicinal products. The purpose of the audit is to assess compliance with the relevant manufacturing standard, the conditions specified in the manufacturing licence and with the relevant marketing authorisations relating to the medicinal products being manufactured. The scheduling and frequency of these audits is based on a risk-management approach that takes account of factors such as:

– type of product manufactured
– the results of previous GMP audits
– significant changes within the company, e.g. changes to key personnel, building, equipment or products
– reports of adverse drug reactions and medicine problems
– results of testing by TGA Laboratories arising from random or targeted sampling of products
– recalls of products not meeting safety and/or quality standards

– adverse comments from other agencies/bodies
– post-licensing surveillance investigations
– intelligence ‘tip offs’.

Most manufacturers are audited at two-yearly intervals, which is consistent with international practice. More frequent audits may be scheduled depending on the various risk factors outlined above.

The TGA has GMP inspection agreements with other countries and organisations to obtain inspection reports, GMP certificates and other GMP-related information about overseas manufacturers exporting or wishing to export medicinal products to Australia.

2.4.2 Pre-market Assessment

Important developments in the pre-market assessment process in the TGA’s regulatory system for complementary medicines were based on a regulatory reform package introduced into legislation in 1999. The reforms, among other things, applied a risk-based approach to determine appropriate standards for pre-market assessment and evaluation (and post-market activities).

The pre-market assessment procedure undertaken by the TGA is determined by risk. In determining risk and the evaluation process to be applied, a number of factors are taken into consideration. These include:

– the toxicity of the ingredients (itself a complex of factors)
– whether the medicine is indicated for a serious form of a disease, condition or disorder, or for the treatment, cure, management or prevention of a disease, condition or disorder
– whether the use of the medicine is likely to result in significant side effects, including interactions with other medicines
– whether there may be adverse effects from prolonged use or inappropriate self-medication.

Based on risk, the TGA has a two-tiered approach to regulation of therapeutic goods. Medicines that are assessed to be of higher risk on the medicines risk continuum, are individually evaluated for quality, safety and efficacy. If, following evaluation, they are approved by the TGA for supply, the products are included in the ARTG as Registered medicines. Efficacy is usually assessed by examining data from controlled clinical trials. Registered medicines include both prescription and non-prescription medicines.

Listed medicines are of lower risk than Registered medicines. Most complementary medicines included in the ARTG are Listed medicines. There are approximately 15,200 Listed complementary medicines and approximately 800 Registered complementary medicines included in the ARTG. Listed and Registered medicines can be differentiated on the product label by the designation, respectively, of AUST L or AUST R followed by a unique number. The assessment of Listed medicines, their inclusion in the ARTG, the evaluation of quality and safety of new complementary medicine ingredients for use in

Listed medicines and the evaluation of registered complementary medicines and their inclusion in the ARTG, is managed within the TGA by the Office of Complementary Medicines (OCM).

Listed (low risk) complementary medicines are included in the ARTG via a simple, low-cost and streamlined electronic application process. Listed medicines are low risk because they may contain only ingredients that have been evaluated by the TGA to be low risk, they must be manufactured by licensed manufacturers in accordance with the principles of GMP and they may carry indications only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions. Listed medicines may not refer to serious forms of disease, disorders or conditions and, generally, must not indicate that they are for treatment, cure, management or prevention of disease, disorders or conditions.

The Listing Process

In contrast to the evaluation process for Registered medicines, Listed medicines may be supplied following application to the TGA by the sponsor[25] of the product and self-certification, and validation by the TGA that certain key requirements of the legislation are being met. Listed medicines are not individually evaluated by the TGA before they are released onto the market.

When a sponsor submits an application to the TGA to include a medicine on the ARTG as a Listed medicine, the following product details are required:

– name of the sponsor
– product name
– export name(s) of the product (if different from the product name)
– dosage form (e.g. capsule, tablet, cream etc.)
– route of administration (oral, topical etc.);
– manufacturer/s of the product
– names and quantities of the active ingredients
– names of excipient ingredients (colours, flavours, binders etc.)
– indications for the product
– directions for use (in certain circumstances)
– container type and size and/or closure type (in certain circumstances)
– quantities of excipients that are restricted by quantity or concentration (in certain circumstances)
– any mandatory warning statements resulting from certain ingredients or indications included with the product.

At the time of submitting a Listing application to the TGA, the sponsor certifies that the goods that are the subject of the application meet the requirements of Section 26A(2) (a)–(k) inclusive and, if applicable, subsection 26A(3) of the Act. In certifying under Section 26A(2) (a)–(k) of the Act, the sponsor makes a legally binding statement that:

– the medicine is eligible for listing

[25] A sponsor of a therapeutic good is the person or company responsible for applying to the TGA to have their goods included on the ARTG. The sponsor must be a resident of Australia or carrying on business in Australia.

- the medicine is safe for the purposes for which it is to be used
- the medicine presentation is not unacceptable, and the medicine conforms to every standard (if any) applicable to the medicine and to every requirement (if any) relating to advertising applicable under the Regulations
- for medicines manufactured in Australia, each step has been carried out by a person who is the holder of a licence to carry out that step (before a sponsor uses an overseas manufacturer, they are required to seek pre-clearance by the TGA that the manufacturer is of an acceptable standard)
- the medicine complies with all prescribed quality or safety criteria
- the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*[26]
- the applicant holds information or evidence to support any claim that the applicant makes relating to the medicine (see later discussion of *Guidelines for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods*)
- the information included in, or with, the application is correct.

Ingredients Permitted in Listed Medicines

Listed medicines may be supplied only if they contain active ingredients permitted under Schedule 4 of the Regulations.[27] Schedule 4 outlines those goods that must be included in the part of the ARTG for Listed goods. These include:[28]

> "preparations containing as their therapeutically active ingredients only vitamins, minerals, herbal substances or other substances specified in Part 5 of this Schedule, or a combination of those substances where:
>
> (a) the preparation:
>
> i is not included in a Schedule to the Poisons Standard; and
>
> ii is not of a kind required to be sterile; and
>
> (b) the vitamins consist only of vitamins or their salts specified in Part 2 of this Schedule; and
>
> (c) the minerals consist only of minerals or their salts specified in Part 3 of this Schedule; and
>
> (d) the herbal substances are not included in Part 4 of this Schedule; and
>
> (e) the herbal substance is present in therapeutic goods included in the ARTG for supply in Australia;
>
> (f) if a substance mentioned in Division 2 of Part 5 is an ingredient – the preparation is not supplied:
>
> i in a form that contains the substance in excess of the maximum amount per dosage for that form as mentioned in column 2 of the table in that Division for that substance; and
>
> ii without the information about daily dosage mentioned in column 3 of the table for that substance;
>
> iii unless the indications proposed by the sponsor of the preparation are in the treatment of a condition referred to in clause 4 of the *Therapeutic Goods Advertising Code*."[29]

[26] Commonwealth of Australia, *Customs Act 1901* as amended.
[27] Commonwealth of Australia, *Schedule 4*, Therapeutic Goods Regulations 1990 as amended.
[28] Commonwealth of Australia, *Schedule 4, Part 1, Item 3*, Therapeutic Goods Regulations 1990.
[29] Therapeutic Goods Advertising Code Council, *Therapeutic Goods Advertising Code*.

With the exception of herbal ingredients, Schedule 4 of the Regulations includes lists of ingredients that may be included in Listed medicines. In the case of herbal ingredients, any herbal ingredient that is currently included in a therapeutic good included in the ARTG may be used in Listed medicines unless it is included in a Schedule or otherwise restricted in the *Standard for the Uniform Scheduling of Drugs and Poisons*[30] (SUSDP) (the Poisons standard) (see later discussion), or included in Part 4 of Schedule 4 or otherwise restricted by Part 5 (Division 2) of the Regulations. A consolidated list of substances that may be used as active ingredients in Listed medicines, including herbal substances, is available on the TGA's website <www.tga.gov.au/docs/html/listsubs.htm>. To be consistent with their use in low-risk medicines, some ingredients in the list are subject to conditions. These include advisory or warning statements on product labels, limits on plant part and/or preparations, quantitative limits, or component-related restrictions.

The majority of substances that can be included in Listed medicines are those that were included in therapeutic goods supplied in Australia before the Act came into operation in 1991. These goods were included in the ARTG with little assessment ('grandfathered'). However, as part of the 'grandfathering' process and subsequent ongoing review, some herbal substances were not considered to be low risk and were excluded from use in Listed medicines.

Listed Medicines: Special Consideration of Herbal Ingredients

Herbal substances can be found in a wide range of complementary medicines. They comprise the active ingredients in herbal medicines formulated according to European, Chinese, Ayurvedic and other traditions. Herbal ingredients are also often included in vitamin and mineral supplements, sunscreens (as excipients[31]) and registered medicines.

Herbal ingredients are chemically complex and contain a wide range of chemical components. Typically, herbal preparations consist of active components, secondary components, and accompanying compounds. For most herbs, the active components have not been identified or verified. These components differ in their biological activity, adverse effects and interactions with each other. The biological activity of herbal preparations may result from additive, synergistic or antagonistic effects of their components. Plant components that may not be active themselves may affect the stability, solubility, and bioavailability of the active component(s). Herbal components may also differ in the extent to which they are soluble in extraction solvents such as water and alcohol. The use of non-traditional methods of preparation, including use of non-traditional solvents, can quantitatively and/or qualitatively change the component profile. Such a change may affect both the safety and the therapeutic profile of the preparation.

The current regulatory system permits Listed medicines to contain a wide range of herbal ingredients and preparations. Part of determining the eligibility of a herbal substance for use as an ingredient in Listed medicines is whether the substance meets the definition of a 'herbal substance' as prescribed in the Regulations.

[30] Commonwealth of Australia, *Standard for the Uniform Scheduling of Drugs and Poisons*.
[31] An 'excipient' is an ingredient of a medicine other than an active ingredient.

Herbal Substance: Regulatory Definition

The TGA's *Approved Terminology for Medicines*[32] classifies herbal ingredients as 'herbal substances'. Herbal substances are preparations of plants and other organisms, such as fungi and blue–green algae, that are treated as plants in the *International Code of Botanical Nomenclature.*[33] The definition of 'herbal substance' in the Regulations includes details of acceptable production processes. Processes not specifically included in the definition (for example, fermentation) are not acceptable, without pre-market evaluation, for producing a herbal substance for use in Listed medicines.

The definition effectively describes the types of herbal ingredients that can be included in Listed medicines in the ARTG. In a regulatory context, 'herbal substance' is referred to in Schedule 4 of the Regulations, which describes those therapeutic goods that must be included in the part of the ARTG for Listed goods, and is defined in the Regulations (Regulation 2, Interpretation):

> "'herbal substance' means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin):
>
> (a) that is obtained only by drying, crushing, distilling, extracting, expressing, comminuting, mixing with an inert diluent substance or another herbal substance or mixing with water, ethanol, glycerol or aqueous ethanol; and
>
> (b) that is not subjected to any other treatment or process other than a treatment that is necessary for its presentation in pharmaceutical form."

The above definition of herbal substance:

– excludes preparation methods involving fermentation and/or obtaining selected components through chemical reactions and precipitation; but

– can include complex multi-step extraction processes using a wide range of solvents provided that these are, in most cases, driven off (water, ethanol and glycerol may remain).

To be considered low risk, a herbal substance must meet the following criteria[34] (Regulations, Schedule 4 Part 1 Item 3):

1. the herbal substance is present in therapeutic goods included in the ARTG for supply in Australia; that is, it must have been previously present in products 'approved' for use in Australia; and
2. the preparation must be a herbal substance as defined in the Regulations; and
3. the ingredient, or a component in the ingredient, must not be a poison; that is, included in a Schedule or in Appendix C or Appendix G to the SUSDP; and
4. the ingredient must not have been identified as posing a safety risk and have been included in the Regulations, Schedule 4 Part 4.

[32] Therapeutic Goods Administration, 1999. *Approved Terminology for Medicines*. July 1999. <www.tga.gov.au/docs/html/aan.htm>

[33] *International Code of Botanical Nomenclature*. <http://www.bgbm.fu-berlin.de/iapt/nomenclature/code/SaintLouis/0000St.Luistitle.htm>.

[34] Where a herbal ingredient is homoeopathically prepared, separate criteria apply [see Therapeutic Goods Regulations 1990, *Schedule 4 Part 1 Items 4A and 5*].

The first and second criteria refer to previously supplied herbal ingredients and were specified as a practical means of identifying herbal ingredients used in traditional herbal medicine or established pharmaceutical practice as low risk. The third and fourth criteria exclude those substances considered not to be of sufficiently low risk to be suitable for use as ingredients in Listed medicines.

The definition of herbal substance was intended to cover the more usual traditional herbal preparations, such as fresh and dry herbs, essential oils, tinctures, decoctions, infusions and simple extracts. The rationale for this approach was that where there was a history of traditional use or established pharmaceutical practice, herbal medicines prepared and prescribed according to that tradition were likely to be low-risk. On this basis, such substances were considered suitable for use in Listed medicines.

If a herbal ingredient, or a component in a herbal ingredient, was considered to cause unacceptable side effects, it was excluded from the low-risk category by the third and fourth criteria, namely by inclusion in the SUSDP or in the Regulations, Schedule 4, Part 4.

If evidence based on a history of use has been used to support the safety of a herbal substance, then it is important that any preparation of that substance eligible for use should have a chemical composition equivalent to that used historically. In addition, the dosage, dosage form and route and schedule of administration should also be consistent with that tradition or history. If this is not the case, the ingredient may present a different risk profile to the ingredient used historically. This does not necessarily mean that the substance is unsuitable for use in Listed medicines, but that it should undergo evaluation and approval before being used (see *Evaluation of Ingredients for Use in Listed Complementary Medicines: Process* – below).

Over recent years, the methods used to process some herbs have moved from traditional to non-traditional. In traditional herbal medicine and established pharmaceutical practice, herbal extracts are usually prepared using water, alcoholic beverages and ethanol as solvents. More recently, non-traditional solvents have been used, including acetone, carbon dioxide, ethyl acetate, hexane, propylene glycol and toluene, presumably in an effort to maximise the concentration of selected components at the expense of others. In addition, methods including critical phase extraction, multiple-step extractions and techniques isolating selected components or groups of components have been used. Non-traditional extraction methods or other non-traditional processes are likely to produce substances that have a considerably different compositional profile from those substances produced using traditional preparation methods. In many cases, there may not have been sufficient time to observe the use of novel preparations in a traditional setting to provide the experience to support the safety of these preparations.

It is inappropriate to rely entirely on evidence of a history of use to support the safety of these substances. This issue is broader than that of an ingredient not meeting the definitional requirements of a herbal substance. In fact, many herbal ingredients prepared non-traditionally will meet the definition and potential concerns over their safety need to be addressed. A general review of herbal

regulation is planned under the proposal to establish a joint trans Tasman regulatory agency and this potential safety concern will be part of that review.

Evaluation of Ingredients for Use in Listed Complementary Medicines: Process

New ingredients for use in Listed complementary medicines are evaluated by the TGA in response to an application from a sponsor. Based on the data supplied by the sponsor and other data, a comprehensive evaluation report is prepared by the staff of the OCM. The evaluation report is put forward for consideration by the Complementary Medicines Evaluation Committee (CMEC), an independent, expert statutory committee.

Whether a regulatory system is effective depends to a large extent on its access to professional expertise. The membership of CMEC is broad, to provide the range of expertise required to advise on issues of quality and safety and efficacy in complementary medicines. In addition, the considerations of the CMEC may be supplemented with advice from expert advisers. The CMEC makes recommendations to the TGA about how the ingredient should be regulated, and the TGA makes a regulatory decision based on those recommendations and any other factors deemed relevant. With the range of expertise available to the regulatory system, the TGA has been able to respond appropriately to the concerns of consumers, industry and government. Since the inception of the CMEC in 1998, 164 new ingredients for use in Listed complementary medicines have been approved by the TGA. This has given rise to a range of new Listed products containing these ingredients.

The parameters considered when evaluating a complementary medicine substance are quality and safety. Quality aspects are evaluated for the purpose of characterising the substance and establishing a compositional guideline for it. Quality is a critical determinant of the safety of complementary medicines and other medicines. Medicines should be controlled to make sure that they contain the specified ingredients and do not contain unsafe amounts of adulterants, contaminants or active ingredients.

In addition to the direct health risks associated with inadequate quality control, there is an indirect risk that the medicine may not be effective. This may compromise, delay, or replace effective action.

The safety evaluation determines whether the substance, once characterised, is of sufficiently low risk, so as to allow its inclusion as an ingredient in Listed medicines.

Ingredients for Use in Listed Complementary Medicines: Quality

The Act defines the quality standards applicable to all therapeutic goods. For regulatory purposes, the *British Pharmacopoeia* (BP) is the source of official standards. The BP is supplemented by Therapeutic Goods Orders (TGOs), which are developed by the TGA through a process of industry and other stakeholder consultation in response to a particular need. This may occur where there is no coverage by the BP or where Australian-specific requirements are appropriate. Examples are TGO 69 which sets out requirements for labels for therapeutic goods and TGO 56 which describes the tests and acceptance

criteria to be applied to tablets, capsules and pills in those cases where there is no specific BP monograph. Quality standards for specific products may also be established through the listing/registration process.

Where a new complementary substance is covered by a monograph in the BP, this standard must be applied in its entirety, unless otherwise justified to the TGA. The requirements of applicable general monographs of the BP must also be met, except where a justification for not doing so is authorised by the TGA.

The TGA considers the suitability of other national or international pharmacopoeial monographs or standards for the substance on a case-by-case basis. In many instances, there are no applicable monographs, and a compositional guideline must be developed by the sponsor. The TGA is currently developing regulatory guidelines for complementary medicines, including guidance for the quality and safety of complementary medicine substances. This will include criteria for compositional guidelines (see Section 2.2 – *Australian Regulatory Guidelines for Complementary Medicines*). A compositional guideline is a summary of descriptions, tests and limits that defines the composition and relevant characteristics of the substance. Where the pharmacopoeial monograph or standard sufficiently characterises the substance, a separate compositional guideline is not required. It should be noted that a monograph or standard is designed to provide a means of controlling the quality of a substance. It is not intended to characterise the material to the extent required for entry in the ARTG. The compositional guideline should allow for characterisation as well as quality control of the substance.

Compositional guidelines or monographs from other national pharmacopoeias or other standards for complementary medicine substances have no legal basis and, as such, it is not mandatory for sponsors to comply with them.

Ingredients for Use in Listed Complementary Medicines: Safety

The safety of complementary medicine substances for use in Listed medicines is established through an evaluation process that aims to ensure that any substance approved for use in Listed products is of 'low risk'. Once established as low risk, many complementary medicine substances need no further controls on their use in Listed medicines.

However, where risks or potential risks are identified in association with the use or uses of a particular substance (for example, in its use by particular population subgroups, such as children or pregnant women, or in its interactions with other medicines), certain restrictions and/or controls may be imposed to manage the risk, but the substance may still be eligible, with restrictions, for use in Listed medicines.

Such options include the use of label advisory information, restrictions on dosage, route of administration, plant part or plant preparation, and/or restriction of the form in which the substance can be presented.

The information and data are normally supplied by the sponsor who is requesting evaluation of the substance. In evaluating safety, it is important to distinguish the situation where risk has been evaluated, from the situation where

there are insufficient data to identify risk. Care needs to be taken to avoid mistaking the absence of reliable evidence of risk for reliable evidence of the absence of risk. Sometimes substances have been deemed unsuitable by the CMEC for use in Listed medicines, not because of direct evidence of their hazard, but because of insufficient evidence to provide assurance of safety.

The criteria used to assess the safety of a complementary medicine substance recognise the need for a level of evaluation commensurate with the level of risk. These criteria also acknowledge that the conventional safety data package available for prescription and non-prescription OTC medicines is rarely available for assessing a complementary medicine substance. However, in the absence of conventional toxicity data, there are other data for complementary medicine substances that can be used to support the safety evaluation.

In evaluating new complementary medicine substances, it is recognised that there may be well-established medicinal, food or other uses of the substance or products containing the substance, that can be used to support or establish safety. Well-established use implies that a sufficient number of people were treated or otherwise exposed to the substance, or to products containing the substance (or substances justified as essentially similar to the substance), over a period of time sufficient to support the safety of the substance for its intended purpose.

Many substances have been used for decades, hundreds of years, or longer. The long-term use of some substances may have created a comprehensive body of experience in the published literature. A substance or product containing the substance that has a long history of use is expected to have useful bibliographic data and information published in official pharmacopoeias and scientific reference textbooks.[35]

By definition, a complementary medicine substance must have a tradition of use.[36] Safety may be established by detailed reference to the published literature, the submission of original study data, or a combination of both. Where there is sufficient evidence based on human experience to support safety, conventional studies involving animal and *in vitro* studies may not be necessary. Where such human experience is deficient, or there are suspicions of effects that are difficult or impossible to detect with confidence in population or in clinical studies, the safety assessment needs to be supported with other studies unless otherwise justified. The absence of reports of untoward effects associated with a particular substance is not assurance that use of a medicine is safe.

Generally, while it is relatively easy to identify substances in a traditional setting that are so hazardous that they produce acute adverse effects in a significant proportion of users, or produce unusual acute effects, it is more difficult to identify adverse effects that develop over a long period, occur infrequently, occur in a small population sub-group, develop from interaction with other medicines or food, or that may be ascribed to an underlying disease or common health problem.

If experience of use is deficient, or there is reason to suspect effects that are difficult to detect in a traditional setting or through historical use, safety should be supported by appropriate studies such as single and repeated dose toxicity, immunotoxicity, toxicity to reproduction, genotoxicity and carcinogenicity.

[35] The inclusion of a substance in official pharmacopoeias or reference textbooks may contribute to the substantiation of the substance as a complementary medicine substance (refer to Section 52F, Definitions, Traditional Use, *Therapeutic Goods Act 1989*).

[36] Section 52F, Definitions, Traditional Use, *Therapeutic Goods Act 1989.*

Documentation submitted to the TGA by a sponsor should cover all aspects of safety assessment and must include a review of the relevant literature, taking into account pre- and post-marketing studies and, where possible, epidemiological studies and, in particular, comparative epidemiological studies that involve exposure to the substance. It is acknowledged above that the nature of complementary medicine substances is such that the data package may be incomplete, and particular attention must be paid to any missing information. Justification must be provided to demonstrate why an acceptable level of safety can be supported although some studies are lacking. Post-marketing experience with other products containing the same or similar substance may assist in the overall safety assessment.

In supporting safety, the greater the consistency of the evidence from different studies, the greater the strength of the evidence. Sponsors are required to ensure that the data submitted are relevant to the particular substance and reflect the totality (balance and range) of the evidence available. Sponsors are required to submit all relevant data and not focus only on data which support safety, while discounting data that do not. The studies relied on by a sponsor to support safety should be largely consistent with the surrounding body of evidence.

Wide variation in outcomes of studies and inconsistent or conflicting results of studies raise serious questions about the adequacy of a sponsor's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies. In some instances, for example, the differences in results might be attributable to differences in dosage, dosage form, route and schedule of administration, the population tested, or other aspects of study methodology. If several studies of different quality have been considered, greater weight should be given to the studies of higher quality.

Table 2.1 gives a summary of data used by the TGA to assess the safety of a complementary medicine substance and the objectives of the data.

Table 2.1 Data and objectives to support the safety evaluation of complementary medicine substances for use in Listed medicines.

Data	Objective
Biological activity	To describe the role of the substance in human metabolism
Toxicology	To describe what is known about and, where possible, quantify, potential risk associated with the use of the substance
Clinical trials	To report the results of use of the substance by humans under clinical trial conditions to identify risks from the experience of use in humans. The TGA does not use the data to evaluate efficacy
Adverse reactions	To determine the nature, severity and frequency of adverse reactions where there has been a history of use of the substance

Listed Complementary Medicines: Efficacy

Consistent with their low risk, Listed complementary medicines may carry only certain indications and claims for the symptomatic relief of conditions (other than serious disease, disorders, or conditions), health maintenance, health enhancement and risk reduction (see Table 2.2). Registered complementary medicines may carry higher level claims. Claims on Registered complementary medicines are subject to pre-market evaluation comparable to that undertaken for other medicines of similar risk.

Table 2.2 Indications and claims permitted for Listed (low-risk) complementary medicines.

Health maintenance
Health enhancement
Nutritional support
Symptomatic relief of non-serious diseases, disorders and conditions
May aid or assist in the management of non-serious diseases, disorders and conditions
Reduction in the risk of a particular non-serious disease, disorder, condition, symptom or ailment

The Act requires that, at the time of Listing, sponsors must certify that they hold the evidence to support indications and claims made in relation to Listable goods. The indications/claims on Listed medicines are not subject to pre-market evaluation at the time of Listing. The evidence held by sponsors must be sufficient to substantiate that the indications and claims are true, valid and not misleading.

In order to facilitate compliance with the requirement to hold appropriate evidence to support particular claims, the TGA and the CMEC have developed guidelines to assist sponsors in determining the appropriate evidence to support indications and claims made in relation to Listed medicines (*Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*; see <www.tga.gov.au/docs/pdf/tgaccevi.pdf>). In particular, the *Guidelines* relate to Listable complementary medicines, sunscreens and other Listable medicines. Claims can be based on scientific evidence or evidence of traditional use. In consultation with key stakeholders, the *Guidelines* are reviewed from time to time.

Where there is a public health or safety concern about the claim(s) for a product or range of products, or the claim(s) appear to be wilfully misleading, or in response to a complaint about the product, the TGA may call upon sponsors to provide the evidence they hold to support the claim(s) for evaluation. If the claims are not substantiated by the evidence, the product may be cancelled from the ARTG.

Registered Complementary Medicines: Evaluation for Quality, Safety and Efficacy

Registered complementary medicines are products that contain an active ingredient that is not permitted for use in Listed medicines or that carry 'high level' or otherwise Registrable indications/claims[37] as defined in the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*.

[37] Claims relating to the treatment, management, prevention or cure of diseases or disorders, or which in any other way refer to a serious disease, or treatment of specific named vitamin or mineral deficiency diseases.

Registered complementary medicines are evaluated to the comparable standards of quality, safety and efficacy as required for OTC and prescription medicines, depending on the risk associated with the individual product.

Based on the data supplied by the sponsor and other data, a comprehensive evaluation report is prepared by the staff of the OCM. The evaluation report is put forward for consideration by the CMEC. The CMEC makes recommendations to the TGA as to the suitability or otherwise for inclusion of the product on the ARTG as a Registered medicine, and the TGA makes a regulatory decision based on those recommendations and any other factors deemed relevant. In the case of Registered complementary medicines for which serious disease claims are made (i.e. indications similar to those for prescription medicines), these products are evaluated by the OCM and reviewed by the CMEC in consultation with the Australian Drug Evaluation Committee (ADEC), the prescription medicines expert committee.

Labelling and Medicines Information

All medicines that are sold in Australia must comply with legislative requirements set out in Commonwealth and State/Territory therapeutic goods legislation. This includes information that must appear on the label of the medicine:

– the product name
– the name and quantities of all active ingredients
– the identity of ingredients that are 'restricted ingredients' because they are known to present a risk to some consumers (e.g. certain preservatives, peanut products, lactose)
– the name of the dosage form (e.g. tablet)
– the quantity of the goods (e.g. 100 tablets)
– required warning statements
– storage conditions, batch number and expiry date
– directions for use of the medicine
– the name and address of the sponsor
– a statement of the purpose of use (i.e. indications or claims)[38]
– the registration or listing number (e.g. AUST L 12456).

Detailed information on *General Requirements for Labels for Medicines*[39] (Therapeutic Goods Order No. 69) is available on the TGA website.

The Regulations require that sponsors supply a Consumer Medicine Information (CMI) document with the following classes of medicines:

– medicines containing ingredients that are listed in Schedule 3 to the SUSDP and which were approved on or after 4 July 1995
– medicines that are supplied only with a prescription from a medical practitioner.

[38] Where the goods are in a dispensing pack supplied solely to a complementary healthcare practitioner, and the label has the words 'For Practitioner Dispensing Only', the statement for the intended purpose of the goods is not required. An instruction label must be affixed following consultation with the practitioner.

[39] Therapeutic Goods Order No. 69, *General Requirements for Labels for Medicines*. <www.tga.gov.au/docs/pdf/tgo69.pdf>.

The CMI may be provided in the primary pack (i.e. as a package insert) or in electronic form via pharmacy computers. All applications to the TGA to include a medicine on the ARTG as a Registered medicine that contains a Schedule 3 ingredient or a prescription medicine must include a draft CMI for TGA approval. It is an offence for the sponsor to supply these products without a CMI. The CMI must be written in language that will be readily understood by patients. Sponsors are encouraged to follow the useability guidelines, *Writing About Medicines for People: Useability Guidelines for Consumer Medicine Information*.[40] The requirements for the contents of the CMI are specified in Schedule 12 (Prescription medicines) and Schedule 13 (medicines containing Schedule 3 ingredients) to the Regulations. One of the requirements for CMI in Schedules 12 and 13 is that it must be consistent with 'Product Information' (PI). For this reason, 'pharmacist only' and prescription medicines must also have a PI. The PI must be approved by the TGA. The PI document contains technical information intended for prescribers and pharmacists. It should not be confused with CMIs or other package inserts that are an extension of the labelling. The requirements for a CMI and a PI are not applied to lower risk medicines, such as Listed complementary medicines. The issue of labelling is considered in the Chapter 4 – *Information and Advertising*.

2.5 Export of Medicines

The export of medicines from Australia, including prescription, OTC and complementary medicines, is regulated by the TGA in order to protect health and safety by ensuring that medicines originating from Australia are of a similar quality and safety standard to those supplied domestically.

The TGA:

- requires that medicines exported from Australia comply with necessary quality and safety standards
- approves the supply of medicinal products for export
- issues export certificates (including certificates issued under the World Health Organization (WHO) Certification Scheme[41])
- communicates with other regulatory authorities to maintain awareness of any potential quality and safety issues
- medicines already approved for supply in Australia.

Medicines, including complementary medicines, approved for supply in Australia are automatically approved also for export by the sponsor or their agent, subject to other applicable export legislation. If a product has to include specific label warning statements in order to be eligible for Listing in the ARTG, and it is also to be exported, these warning statements must remain on the label in order for the Australian Listing approval to extend to the exported product. Warning statements may be omitted only where the product is solely for export. Similarly, if any labelling changes result in non-compliance with TGA labelling requirements, a 'solely for export' listing is required.

[40] Sless D, Wiseman R, 1997. *Writing about medicines for people: Useability Guidelines for Consumer Medicine Information*. 2nd Edition. Canberra, Australian Government Publishing Service.

[41] Australia is a participant in the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. This scheme is intended to ensure the quality and safety of medicines which are ultimately sold in countries other than those where they were manufactured. The TGA, as part of its responsibilities under the WHO Certification Scheme, issues Certificates of a Pharmaceutical Product to commercial exporters.

2.5.1 'Solely for Export' Medicines

Medicines intended solely for export, including products that would be regarded as complementary medicines in Australia, must be Listed (not Registered) on the ARTG before export. Broadly, they must:

– be safe for their intended purpose of use
– be manufactured under GMP
– meet any standards applicable under Section 10 of the Act
– not be of an unacceptable presentation.

Efficacy requirements are similar to those applying to other Listed products on the ARTG, and sponsors must hold evidence in support of claims made on 'solely for export' products. Warning statements on 'solely for export' products are often associated with the types of indications permitted for the product within the regulatory framework of the country of destination. It is the sponsor's responsibility to ensure that any warning statements needed are included on the product label as required by the importing countries.

The export regulatory framework aims to provide some level of protection to the international community in terms of the safety and quality of products, while acknowledging that there are often valid reasons why products are not supplied on the Australian market. As part of the TGA's commitment to supporting a strengthened understanding in the importing country of the regulatory status of the product in Australia, the TGA may include a statement on the export certificate for 'export only' medicines, rather than simply certifying that the product is not licensed in the exporting country (as is required under the WHO Certification Scheme where this is the case). In the extremely small number of instances (approximately five per year) where an application is received by the TGA for a product that contains a therapeutic substance not previously evaluated in Australia, any evidence that the applicant can provide to demonstrate that the substance/product is approved in the country of destination, or that the importing country has no objection to the TGA Listing the product for export to that country, is generally sufficient to gain export approval.

2.6 The Role of Scheduling in Controlling Access to Medicines

The *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) sets out the Schedules that the National Drugs and Poisons Schedule Committee (NDPSC) has decided should apply to different substances, including medicinal ingredients and components in medicinal ingredients. The NDPSC is comprised of State and Territory government members and other persons, such as technical experts and representatives of various sectional interests.

The decisions of the NDPSC in relation to the SUSDP have no force in Commonwealth law, but are recommended for incorporation into State and Territory drugs/poisons legislation. Controls placed on market access to medicines included in the SUSDP and, to a lesser degree, on market conduct, come into effect when the Schedules are adopted into State and Territory legislation.

The SUSDP sets out Schedules into two broad categories – those that relate to medicines (Schedules 2, 3, 4 and 8) and those that relate to poisons (Schedules 5, 6 and 7). Schedule 9 covers substances that are prohibited. In addition to the Schedules, the SUSDP includes a number of appendixes. The appendixes fall into two broad categories: those imposing controls and those that are equivalent to the schedules. For example, Appendix F sets out warning statements to apply to certain substances, while Appendix C includes a list of substances that are totally prohibited but are not the illegal drugs associated with Schedule 9.

While States and Territories generally adopt the SUSDP Schedules, some jurisdictions have chosen not to do so in a few cases. There is considerable variation in the extent to which the appendixes to the SUSDP are adopted, and while State and Territory legislation may include similar provisions, the extent to which these reflect the SUSDP control level is much more variable than for the Schedules.

Full details of the controls and purpose of the Schedules may be obtained from the *Review of Drugs, Poisons and Controlled Substances Legislation Final Report – Parts A and B*.[42]

The level of restriction on access applied by the current medicines, poisons and controlled substances legislation is based on the hazardous properties of the substances, and the risks associated with supplying and using products containing them. The level of risk is assessed by the NDPSC and is reflected in its scheduling decision (inclusion in a schedule or appendix of the SUSDP) and any additional requirements (e.g. warning statements on the product label). The access controls attached to scheduled medicines can be broadly described as follows:

– Those which restrict supply to a pharmacy (or, in some rural areas, a licensed poisons seller), where the product may be supplied over the counter without a prescription. These products are those included in Schedules 2 and 3 of the SUSDP; Schedule 3 requires the pharmacist to be involved in the supply. The extent of the required involvement varies across jurisdictions.

– Those where the medicines can be obtained only from a pharmacy on the prescription of a doctor, dentist, or other authorised prescriber. These products are included in Schedule 4 of the SUSDP.

– Those where additional restrictions over and above the need for a prescription are imposed. For example, requirements:

  • for registration of the patient and authorisation to prescribe, controlled substances (i.e. those likely to cause dependence or be abused) – these products are covered by Schedule 8, some by Schedule 4 and Appendix D of the SUSDP

  • restricting those who can prescribe certain substances to certain specialists (e.g. dermatologists, physicians)

  • limiting the circumstances in which a substance can be prescribed (e.g. where the prescriber has ensured that the possibility of pregnancy is excluded before prescribing).

[42] *Review of Drugs, Poisons and Controlled Substances Legislation Final Report – Parts A and B*. <www.tga.health.gov.au/docs/html/rdpdfr.htm>.

Listed Complementary Medicines

Ingredients, or ingredients containing components, included in a Schedule or otherwise restricted by the SUSDP (e.g. inclusion in Appendix C), may not be used in Listed medicines, including complementary medicines.

Registered Complementary Medicines

Complementary medicines that contain an ingredient or component included in a Schedule, or otherwise restricted by the SUSDP, or have an indication inappropriate for a Listed medicine must be included in the ARTG as Registered medicines (i.e. such medicines must be evaluated for quality, safety and efficacy and approved by the TGA before supply). Where a registered complementary medicine is included in a Schedule in the SUSDP, all requirements of that Schedule apply to that medicine.

2.7 Post-Market Regulatory Activity

The streamlined approach to assessment for low-risk complementary medicine products (Listed medicines) addresses the need to improve market access to quality, new complementary medicines, while maintaining public health and safety. It allows for timely market access, but with a level of pre-market evaluation of the components of each medicine that provides an assurance of the safety and quality of the product. However, to ensure a high level of public health and safety, 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
– effective controls for the advertising of therapeutic goods.

Laboratory Testing

Laboratory testing involves selecting random and targeted products for analysis. As laboratory testing is resource and time-intensive, a risk-based approach guides all aspects of the testing program.

The random testing of complementary medicines is linked to the random sample of products that are selected as part of the OCM's desk-based audit of Listed medicines for compliance with legislation. The type of laboratory testing undertaken by the TGA (e.g. level of active ingredient, presence of contaminants) is determined largely by the results of the desk-based audit.

The selection of samples for targeted laboratory testing is based on the anticipated presence of ingredients or constituents associated with increased risk. The level of risk associated with these ingredients or constituents in the various classes of products is broadly expressed as higher, medium or lower. Classes of products identified as high risk are targeted, and specific products are selected for priority laboratory testing.

In addition, testing occurs in response to problems identified by the OCM, Surveillance, Manufacturer Assessment, and Adverse Drug Reaction areas of TGA, by reports from overseas regulatory authorities and other areas.

Adverse Drug Reaction Reporting

An adverse reaction reporting system for therapeutic goods in Australia is well established. The Australian 'Blue Card' scheme covers all medicines and most health professionals. In addition, sponsors of all medicines included in the ARTG are under an obligation to report adverse reactions to the TGA. Consideration is being given to improving the effectiveness of the system for reporting problems arising from the use of complementary medicines. Adverse drug reaction reports received by the TGA for both Registered and Listed medicines are entered onto the TGA's Adverse Drug Reaction (Reporting) System (ADRS) database. Reports of serious reactions are initially reviewed by a medical officer in the Adverse Drug Reactions Unit (ADRU) and, additionally, are reviewed by the Adverse Drug Reactions Advisory Committee (ADRAC), which meets eight times a year. In addition, the ADRAC reviews all reports of reactions (whether serious or not) to complementary medicines, vaccines, and new drugs (i.e. those marketed in the previous three years). A summary of all reports to complementary medicines, including ADRAC/ADRU comments, is sent to the CMEC for comment and advice to the TGA.

Laboratory testing of medicines or enforcement activity (via the TGA's Surveillance Unit) may be arranged by ADRU in consultation with the OCM before a report is reviewed by ADRAC, or on the advice of ADRAC or CMEC. The ADRU performs literature searches and obtains advice from the OCM relating to the safety of complementary medicines. As well as receiving Australian reports of adverse reactions, the ADRU has regular meetings with overseas agencies. The ADRU is also a member of the WHO pharmacovigilance network, and has access to the WHO international database of adverse drug reaction reports. In 2002, approximately 94 per cent of ADR reports received by the ADRU related to prescription medicines, and 3 per cent each to OTC and complementary medicines.

Adverse reactions associated with complementary medicines, including the potential for interaction with prescription medicines, are considered in Chapter 3 – *Adverse Reactions*.

Recall of Medicines

A procedure for the timely recall of medicines is an important post-market activity to protect public health and safety. Recalls are managed under the *Uniform Recall Procedure for Therapeutic Goods 2001*.[43] This procedure is the result of an agreement between the therapeutic goods industry and Australian Government and State/Territory health authorities. Its purpose is to define the action to be taken by health authorities and sponsors when therapeutic goods for use in humans are to be removed from supply or use, or subject to corrective action, for reasons relating to their quality, safety or efficacy.

Overall responsibility for coordination of recalls lies with the Australian Recall Co-ordinator, who is an officer of the TGA. When the need for a recall has been established, the sponsor of the affected goods assumes the responsibility for recovery of the goods, or for corrective action, while the Australian Recall Co-ordinator assists by advising the sponsor of the procedures, by notifying agreed third parties and by monitoring the overall action.

The overall aim of the TGA's post-market regulatory activities for complementary medicines is to support the timely identification and appropriate regulatory responses to problems with the formulation, manufacture, labelling and advertising of these medicines.

2.8 Complementary Medicines Which Do Not Need to Be Included in ARTG

Certain complementary medicines are exempt from Listing or Registration by the TGA. These include:

– raw herbs (unless packaged for supply as a therapeutic good)
– starting materials (unless packaged for supply as a therapeutic good or formulated as a dosage form)
– homoeopathic medicines (conditions apply)
– personal use imports (conditions apply)
– medicines used solely for experimental purposes in humans (conditions apply)
– medicines dispensed or extemporaneously compounded for a particular person for therapeutic application to that person (this allows complementary healthcare practitioners, such as herbalists and homoeopaths, to prepare medicines for individual patients, see below). Access to some medicinal ingredients is restricted by State and Territory legislation.

2.9 Personal Importation of Medicines

The Act allows individuals, through importation for personal use, to gain limited access to medicines that are not on the ARTG. Personal importation occurs when:

– an individual either brings a therapeutic good into Australia on their person or arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier

[43] *Uniform Recall Procedure for Therapeutic Goods, 2001*. <http://www.tga.gov.au/docs/pdf/urptg.pdf>

– the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

Products imported for personal use, that are not approved for use in Australia, may be of unknown quality, safety and efficacy. Individuals importing such products may be at risk. Further, if an individual suffers adverse consequences from taking such a product, information about the goods and redress may be difficult to obtain. Details about access to medicines via personal importation are on the TGA website.[44]

2.10 Medicines Dispensed or Extemporaneously Compounded

Certain medicines do not need to be included in the ARTG. This includes medicines (other than medicines used for gene therapy) that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person.[45] This allows complementary healthcare practitioners, such as pharmacists, herbalists and homoeopaths, to prepare medicines for individual patients that do not need to be assessed or evaluated by the TGA for quality, safety or efficacy. The exemption applies to medicines prepared for individual patients, either following consultations with that particular patient, or to fill a prescription for that particular patient. The exemption does not cover situations where the practitioner makes up medicines in advance, in anticipation of patients who may come onto the premises and ask for that medicine.

Access to some medicinal ingredients is restricted by State and Territory drug and poisons legislation. For example, ingredients included in Schedule 4 of the SUSDP are only available on prescription from a medical practitioner registered under a law of a State or Territory. Depending on the level of access control, some ingredients are not available for dispensing or extemporaneous compounding by complementary healthcare practitioners, such as herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners. Most herbal ingredients are not subject to restricted access and may be used for preparing medicines that are dispensed or extemporaneously compounded. Some ingredients used by practitioners in dispensing or extemporaneous compounding of medicines for patients are subject to TGA legislation. For example, ingredients that are either prepackaged for other therapeutic purposes, or formulated as a dosage form (such as medicines 'For Practitioner Dispensing Only'), are subject to TGA assessment for quality, safety and efficacy as appropriate and are included on the ARTG.

In addition to the exemption of dispensed or extemporaneously compounded medicines to be included in the ARTG, herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation where the preparation is for use in the course of his or her business and:

(a) the preparations are manufactured on premises that the person carrying on the business occupies and that he or she is able to close so as to exclude the public; and

[44] Therapeutic Goods Administration, *Access to Unapproved Therapeutic Goods via Personal Importation*. <www.tga.gov.au/docs/pdf/unapproved/personalimp.pdf>.
[45] Commonwealth of Australia, *Schedule 5, Item 6*, Therapeutic Goods Regulations 1990.

(b) the person carrying on the business:

i) supplies the preparation for administration to a particular person after consulting with that person; and

ii) uses his or her own judgment as to the treatment required

are exempt from the requirement for the product to be manufactured under GMP.[46]

The exemption from the requirement to hold a licence to manufacture preparations for a particular patient applies only where the medicine is extemporaneously prepared for the patient following consultation with the patient. When the medicine is manufactured by a herbalist, nutritionist, naturopath, practitioner of traditional Chinese medicine or homoeopathic practitioners under the above conditions, the product is also exempt from the requirement to be included in the ARTG.

The application of a label to a medicinal preparation is regarded as a manufacturing step. Herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners may therefore apply a label to a preparation and, if this is done extemporaneously for a patient following consultation with that patient, the medicine is exempt from inclusion in the ARTG and the requirement to be manufactured under GMP. If the label is applied to a pre-prepared medicine, the medicine itself, unless exempt, must included in the ARTG prior to its supply, and the manufacture of the product must be licensed by the TGA.

Products at the food/medicine interface that are dispensed or extemporaneously prepared, will need to be carefully monitored to ensure that they comply with appropriate therapeutic goods or food legislation.

2.11 TGA Regulatory Action on Pan Pharmaceuticals Limited

2.11.1 Regulatory Action Taken

On Monday 28 April 2003, the TGA suspended for six months the licence held by Pan Pharmaceuticals Limited to manufacture medicines, after TGA inspectors found numerous, serious manufacturing breaches by the company. Pan Pharmaceuticals Limited, a publicly listed company, was at the time of the action Australia's largest contract manufacturer of complementary medicines. It also manufactured some OTC medicines, including pain relievers and allergy and cold and flu preparations.

The TGA is obliged to give notice of the cancellation or suspension of a licence to manufacture medicines unless failure to act immediately would create imminent risk of death, serious illness or serious injury. The TGA convened an Expert Advisory Group with members drawn from the CMEC and Medicines Evaluation Committee (MEC) to advise the TGA on the potential for the observed manufacturing deficiencies to affect the safety of medicines manufactured by Pan Pharmaceuticals Limited, and specifically whether any product manufactured by the company could pose a risk to the community.

[46] Commonwealth of Australia, *Schedule 8, Item 4*, Therapeutic Goods Regulations 1990.

The Expert Advisory Group met on Wednesday 23 April 2003. The Expert Advisory Group concluded that it lacked confidence in any products manufactured by the company, and considered that these products posed risks to consumers of death, serious illness and serious injury; that these risks would increase over time; and that the risks could be realised at any time.

In accordance with this advice, the TGA was obliged to immediately suspend Pan Pharmaceuticals Limited's manufacturing licence in order to protect the health and safety of the Australian community. This was done on 28 April 2003.

The TGA considered the suspension of the licence of Pan Pharmaceuticals Limited for six months to be the minimum time necessary for the company to remedy the problems identified. For Pan Pharmaceuticals Limited to regain its licence, it would need to work to ensure its processes complied with GMP, including standards on documentation, production, and quality control, and then be re-audited by the TGA to ensure compliance.

Recalled Products

Following the licence suspension of Pan Pharmaceuticals Limited, the TGA immediately required the recall and cancellation of 219 products that were manufactured and sponsored by Pan Pharmaceuticals Limited for the domestic market. Additionally, about 1600 products manufactured by Pan Pharmaceuticals Limited for other sponsors were recalled, some 40 of which were later also cancelled from the ARTG. A further approximately 1650 products which Pan Pharmaceuticals Limited exported were cancelled from the ARTG. More than 620 products manufactured by Pan Pharmaceuticals Limited, but supplied by other companies, have been identified as export products, and sponsors of these products were asked to cease their supply. Regulatory authorities around the world were notified of the suspension of the licence of Pan Pharmaceuticals Limited.

Based on information from Pan Pharmaceuticals Limited and other sponsors, products manufactured by Pan Pharmaceuticals Limited were being exported to 62 countries. Countries particularly affected were New Zealand, Singapore, Taiwan, South Africa, China, Hong Kong, United Kingdom, Malaysia.

Publication of a List of Products to Be Recalled

Lists of recalled products were published in major-capital-city newspapers and were included in all non-capital-city dailies and regional newspapers. As a public service, the TGA undertook this advertising on behalf of sponsors (whose legal responsibility it is to advertise the recall of their products, as defined in Section G of the *Uniform Recall Procedure for Therapeutic Goods 2001*[47]), in an effort to ensure that as many people as possible had access to the list of products that are subject to the recall. Had the TGA not undertaken this service, consumers would have needed to read between some 400 to 500 separate advertisements, placed by each sponsor affected by the recall.

The TGA's website provided details of products affected by the recall. A booklet containing a consolidated list of products was also provided by the TGA to pharmacies, through the Pharmacy Guild of Australia.

[47] *Uniform Recall Procedure for Therapeutic Goods, 2001*. <http://www.tga.gov.au/docs/pdf/urptg.pdf>

Inquiries from the Public

A consumer call centre was established to take telephone calls from the community in relation to the recall of Pan Pharmaceuticals Limited manufactured products. The call centre was staffed by 160 phone operators around the clock, and received 320,000 calls in its first two days of operation.

The TGA website, which on an average day receives around 500 hits, received more than 70,000 hits a day after the suspension of Pan Pharmaceuticals Limited's manufacturing licence was announced. The website was updated continuously to reflect the complete list of products subject to the recall, and to provide other information to assist the community.

2.11.2 New Legislative Provisions and Offences to Strengthen the National Regulatory Framework

The Government introduced legislation to strengthen the regulatory framework to provide the TGA with enhanced powers to deal with breaches of regulatory requirements, and to address difficulties that have arisen as a result of the Pan Pharmaceuticals Limited recall. The legislative amendments were passed by the Australian Parliament and received Royal assent on 27 May 2003.

The purpose of the amendments was to tighten the existing requirements placed on manufacturers and sponsors of therapeutic goods, to further ensure the quality, safety and efficacy of therapeutic goods that are supplied in, or exported from, Australia. The need for these amendments was identified after the failure of Pan Pharmaceuticals Limited to meet the requirements of good manufacturing practice, and the difficulties encountered in quickly identifying affected therapeutic goods for the purposes of recall.

The experience highlighted the need to more clearly define the responsibilities and obligations of both sponsors and manufacturers of therapeutic goods, and the need for such persons to be held more accountable for their statutory responsibilities and obligations. The offences and penalties were considered to require strengthening, to provide a more adequate deterrent to breaches of standards and other statutory requirements designed to maintain the safety and quality of therapeutic goods. The increased penalty levels are higher than for similar offences in the Criminal Code, such as falsifying documents, because of the potential to expose the general public to an unacceptable level of risk.

A summary of the legislative amendments is given below:

– increase in the maximum penalties for a range of existing offences under the Act, including where there has been a failure to comply with standards, false statements made in applications for entry of goods on the ARTG, breach of a condition of a manufacturing licence (including failure to comply with the manufacturing principles), false statements made in a conformity assessment declaration and the counterfeiting of therapeutic goods
– new penalties for falsification of any document that has been created, retained or issued for the purposes of the Act, and for supplying goods originating from a manufacturer or manufacturing site that has not been notified to the Secretary

- expansion of the compulsory public notification and recall provisions which may be used where there is a problem with a product or its manufacture
- insertion of a 'fit and proper person' test into the provisions for granting a manufacturing licence or conformity assessment certificate and suspending or revoking a manufacturing licence or conformity assessment certificate
- insertion of new statutory conditions of licence to ensure compliance with the manufacturing principles and reporting of adverse effects known to a manufacturer
- requirement for sponsors of therapeutic goods to maintain records of all manufacturers involved in the manufacture of each batch of therapeutic goods, and have them available for inspection at any time, or risk cancellation of the goods from the ARTG, as well as requiring them to notify the Secretary of any change of manufacturer
- provision for better identification of therapeutic goods in the event of a recall or where a sponsor applies for re-entry to the ARTG of previously cancelled goods
- requirement for inclusion of manufacturer details on the labels of medicines
- improvements for adverse event reporting for Listed goods.

FINDINGS

2.1.1 The current model of a single regulatory framework for medicines is appropriate for the regulation of complementary medicines in Australia.

Better health outcomes for all Australians are addressed through their access to and wise use of medicines. The overall aim of the National Medicines Policy (NMP) is to meet medication and related service needs, so that optimal health outcomes and economic objectives are achieved.

The Australian Pharmaceutical Advisory Council (APAC), through a partnership approach, develops, promotes, influences and assists in the implementation of the NMP. APAC has recognised the need for the health system to examine the shifting of incentives from curative to preventive models to ensure the long-term sustainability of the aims and objectives of the NMP. The beneficial role of complementary medicines in promoting wellbeing and in treating illness, needs to be acknowledged within this framework.

The NMP was premised on a single regulatory framework for all medicines, including complementary medicines. The TGA uses a risk management approach to regulating medicines in Australia. This determines the level of scrutiny applied to the assessment of individual medicines. Medicines used to treat serious forms of diseases, conditions or disorders, or which need to be managed under medical supervision are subject to a high level of scrutiny and evaluation to ensure that they meet appropriate standards of quality, safety and

efficacy. Other medicines, for example, many complementary medicines, present lower risk and are not subject to the same level of evaluation and are only assessed for quality and safety before market entry. All medicines are subject to post market regulatory activities to ensure that they meet appropriate standards of quality, safety and efficacy.

The current national regulatory framework provides a level of scrutiny and evaluation consistent with risk and, subject to enhancements as recommended in the following section, was endorsed by the Committee as appropriate for the regulation of complementary medicines.

2.1.2 The current two-tiered, risk-based regulatory system for complementary medicines should be maintained, but with some enhancements.

The overall objective of therapeutic goods legislation is to ensure the quality, safety, efficacy, and timely availability of therapeutic goods supplied in or exported from Australia. At the same time, those manufacturing and marketing therapeutic products expect that regulations, including standards, will be appropriate, commensurate with the assessed risk of their products and consistent with international practice.

The two-tiered, risk-based system for complementary medicines is generally considered sufficient and relevant to meet appropriate standards of quality, safety and efficacy for Registered and Listed complementary medicines. Some members considered that the current two-tiered regulatory system does not allow consumers and others to adequately distinguish those medicines that have been scientifically evaluated for efficacy by the TGA from those that have not. This concern and the important ethical matters that this issue raises is considered in Chapter 4 – *Information and Advertising*.

In reviewing the current regulatory controls for complementary medicines, the Committee identified a number of situations where the regulatory system requires additional controls to support the quality, safety and efficacy of Listed complementary medicines (see *Listed Complementary Medicines* on next page).

Registered Complementary Medicines

Registered complementary medicines are of higher risk than Listed medicines. Each registered medicine undergoes individual evaluation by the TGA for quality, safety and efficacy prior to supply in Australia. The rigour of evaluation applied to Registered complementary medicines is comparable to that of other medicines of similar risk.

Depending on the level of risk, there may be restrictions placed on access to registered medicines and/or other conditions, such as label warnings or type of container, imposed on their use. The level of control imposed on Registered medicines is subject to State and Territory legislation relating to drugs, poisons and controlled substances. The level of control is based on the properties of the medicinal ingredients and the risks associated with the supply and use of products containing these ingredients. The level of risk associated with the use

of a medicinal ingredient is assessed by the National Drugs and Poisons Schedule Committee (NDPSC), and the control required is reflected in its scheduling decision (inclusion in a schedule or appendix of the SUSDP) and any additional requirements (e.g. warning statements on the product label). This process aims to ensure that, among other things, the use of these products is supported by adequate information to enable consumers to select, in the case of certain non-prescription medicines (including some complementary medicines), and use all medicines safely and effectively. On this basis, interface with a suitably qualified professional is seen to be a prerequisite for the supply of medicines covered by these schedules.

Where an ingredient or a component in an ingredient in a registered complementary medicine is included in a Schedule in the SUSDP, all requirements of that Schedule apply to that medicine. Registered medicines not included in a Schedule in the SUSDP may be available from supermarkets and other retail outlets.

Registered medicines, included in a Schedule in the SUSDP may, depending on the level of control for their safe use, be available only from a pharmacy, require the supervision of a pharmacist to advise the consumer on their safe and effective use, or be available only from a pharmacy on the prescription of a doctor or other authorised prescriber.

The evaluation process undertaken by the TGA for registered complementary medicines is risk-based and is appropriate to support the quality, safety and efficacy of these medicines. The process is consistent with that applied to other medicines of similar risk. However, to encourage greater use of the registration process for complementary medicines, the TGA should review the current requirements taking into account the complex nature of many complementary medicines (see Chapter 6 – *Industry*). The risk-based controls on access and/or conditions of use of registered medicines that are developed by the NDPSC and applied through State and Territory legislation, are appropriate to support the safe and effective use of affected medicines.

Listed Complementary Medicines

Quality of Listed Medicines

For regulatory purposes, the BP is the source of official standards. The BP is supplemented by TGO. Where there is no BP standard for a substance for use in a Listed medicine, the TGA considers the suitability of other national or international pharmacopoeial monographs or standards. In many instances, there are no applicable monographs and a compositional guideline must be developed by the sponsor.

The Committee noted that compositional guidelines or monographs from other national pharmacopoeias or other standards for complementary medicine substances have no legal underpinning and, as such, it is not mandatory for sponsors to comply with them. This situation arose from strong resistance by some industry members to making a compositional guideline a legally binding requirement for a complementary medicine substance. However, there are other

industry views seeking compositional guidelines to be underpinned in therapeutic goods legislation, just like those for substances included in the BP and TGOs.

Quality is a critical determinant of the safety of complementary medicines and other medicines. The Committee believes that, where there is no BP monograph, compositional guidelines or other suitable pharmacopoeial monographs should be legally enforceable standards. It was recognised that the preparation of compositional guidelines for some ingredients, for example some herbals, would be complex, and that this proposal would also have implications for the existing ingredients covered by compositional guidelines and for the many complementary medicine substances that do not have a compositional guideline. Priority should be given to enforcing existing compositional guidelines that included parameters important to safety. The implementation of this proposal is a major task, and consultation with key stakeholders will be critical.

Safety of Listed Medicines

The safety of Listed medicines, based on the evaluation of individual ingredients, is commensurate with the assessed risk and benefit of the products, and is generally satisfactory. A particular safety concern is the use of medicines in pregnancy.

Medicines, including complementary medicines, will inevitably be taken during early pregnancy because most women do not know they are pregnant until four weeks gestation. While for the vast majority of medicines there is no evidence to suggest they cause birth defects, there is also very little direct evidence that they are safe for use in pregnancy. The reassuring aspect of many Listed medicines in this regard, is that they tend have few potent pharmacological properties, a factor which may render them of lower risk to the foetus. There is a need to balance the consumer's right to know about safety of use in pregnancy with the potential for anxiety and alarm created by a label or other statement that safety in pregnancy has not been established. For Registered medicines, the potential risk of birth defects is considered as part of the assessment of risks and benefits. For low-risk medicines, the Committee considers it unacceptable that ingredients be permitted in Listed medicines for use under conditions known or suspected of causing birth defects.

Efficacy of Listed Medicines

While all Listed medicines should ideally be assessed for efficacy by the TGA before their supply, the current system of control is practical and generally commensurate with the risk and benefit of the products.

2.1.3 The *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* provide a sufficient framework to assess the efficacy of Listed complementary medicines.

The TGA, in consultation with the CMEC and industry, developed the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (the *Guidelines*) and published them in 2000. They provide guidance for sponsors as

to the type and level of evidence considered necessary to support indications and claims for Listed medicines. The *Guidelines* were developed from the National Health and Medical Research Council (NHMRC) levels of evidence, and adapted to suit the specific challenges of making evidence-based claims for complementary medicines. The *Guidelines* underwent broad consultation before their introduction and have been widely embraced across the complementary medicines industry. The risk-based framework provided by the *Guidelines* assists the complementary medicines industry to determine the data needed to establish the efficacy of Listed medicines, and is critical to support to the reputation of the industry.

Some members expressed concern that many sponsors of medicines, including complementary medicines, may not be equipped to substantiate claims for efficacy through a critical assessment of the available evidence, and that when the TGA undertakes a review of the evidence held by these sponsors, the evidence will be found wanting. They also suggested that the TGA liaise with the NHMRC to harmonise the approaches used to critically evaluate the evidence of efficacy between the two agencies.

To facilitate an appreciation by the NHMRC of the nature and purpose of the TGA's *Guidelines*, and to explore options for greater consistency between the NHMRC's designated levels of evidence used in evaluating clinical practice guidelines and the levels of evidence designated in the *Guidelines*, the Committee recommends that the Office of Complementary Medicines should liaise with the Health Advisory Committee of the NHMRC.

2.1.4 The *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* should 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.

When a sponsor submits an application to the TGA to include a medicine in the ARTG as a Listed medicine, the sponsor certifies that the information supplied in the application is complete, true and correct. The sponsor also certifies that they hold evidence to support the indications and claims in the ARTG. The type and level of evidence considered necessary for this purpose is not specified in legislation, and a sponsor may base their certification on whatever evidence they believe appropriate. To provide an equitable and enforceable base for the type and level of evidence considered the minimum necessary to adequately support indications and claims for Listed medicines, the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* should be prescribed for this purpose.

2.1.5 There should be increased random and targeted auditing of sponsors of Listed complementary medicines to ensure that evidence of efficacy is held.

An important feature of the TGA's risk-management approach to the regulation of complementary medicines is a range of post-market regulatory activities. This

includes, among other things, random and targeted desk-based audits of Listed complementary medicines for compliance with legislation, but generally does not include an evaluation of the evidence held by a sponsor to support the claims and indications included in the ARTG. However, the TGA may request the evidence following a complaint or other concern about the indications and claims made for a particular product.

Adherence to the levels of evidence framework provided by the *Guidelines* to support the efficacy of complementary medicines is considered by the Committee to be important to the credibility and viability of the complementary medicines industry. The marketing of products that do not have evidence of efficacy is considered by the Committee to be unethical.

To provide assurance to stakeholders that sponsors are complying with the requirement to hold evidence to support the indications and claims included in the ARTG for their products, the TGA should undertaken increased random and targeted auditing of the evidence held by sponsors.

The complementary medicines industry works towards ensuring the integrity of the sector, and contributes to this through active surveillance of competitors. Actions taken for non-compliance range from initiating complaint procedures through one of the industry associations, to formal notification to TGA of perceived breaches of the Act.

Industry believes that, through its representative associations, it would able to contribute to effective utilisation of TGA resources by advising on prioritisation of targeted auditing of sponsor-held evidence supporting indications and claims.

The Committee believed that mechanisms should be established to permit industry and other stakeholders to advise the TGA of areas for priority targeting for audits of sponsor-held evidence supporting indications and claims.

2.1.6 Sponsors of Listed medicines should submit to the TGA a summary of the evidence they hold to support the efficacy of their products.

In view of the importance to the credibility and viability of the industry, to assist sponsors to focus on the need to hold evidence to support efficacy of Listed complementary medicines, when the product is Listed on the ARTG, sponsors should be required to submit to the TGA a summary of the evidence on which indications and claims of their product is based. The requirement to submit a summary of the evidence on which efficacy of their product is based should also be applied to Listed complementary medicines already on the ARTG and to 'grandfathered' Registered[48] complementary medicines. The purpose of the summary of evidence is to ensure that sponsors of complementary medicines that have not been evaluated for efficacy by the TGA hold the appropriate data to support efficacy. The summary of evidence will be assessed by the TGA only as part of its random and targeted post-market activities. Depending on the assessment of the summary, this may lead to full TGA evaluation of efficacy data held by the sponsor.

[48] 'Grandfathered' medicines refers to medicines supplied in Australia before the *Therapeutic Goods Act 1989* came into force. These medicines were automatically entered into the Australian Register of Therapeutic Goods (ARTG) with little further assessment, including of efficacy. As part of the 'grandfathering' process, some medicines were not considered appropriate for supply in Australia and were not entered in the ARTG.

2.1.7 The current penalties for breaches of the conditions of Listing of complementary medicines under Section 26A(2) of the *Therapeutic Goods Act 1989*, including the requirement that the applicant holds information or evidence to support any claim relating to the medicine, are generally sufficient to deter repeat offenders.

When a sponsor submits an application to the TGA to include a medicine on the ARTG as a Listed medicine, the sponsor certifies that the information supplied in the application is complete, true and correct, and the goods that are the subject of the application meet the requirements of Section 26A(2) of the *Therapeutic Goods Act 1989* (the Act), including certifying that the applicant holds evidence to support the indications and claims made.

It is an offence under Section 22(2A) of the Act for the applicant, in connection with a certification of any matter under Section 26A(2), to make a statement that is false or misleading in a material particular (for example, if the applicant certifies they hold evidence of a kind specified by the TGA, but does not).

The maximum penalty is 12 months imprisonment and/or 1000 penalty units (each penalty unit = $110). For a company, the maximum penalty is 5000 units or $550,000.

Under Section 28(6) of the Act, it is a statutory condition that, for every medicine listed under Section 26A, in relation to any claim made in the application to list the goods, at the time of making the claim, the sponsor of the goods had information or evidence that supported the claim and that complied with any requirements prescribed in the Therapeutic Goods Regulations 1990 (the Regulations). It is a further condition that the sponsor retains this information or evidence at all times while the goods remain Listed, and that this information be surrendered to the Secretary (of the Australian Department of Health and Ageing) when the latter asks for it. The TGA has the power to prescribe in the Regulations the amount, standard or type of information or evidence required.

To date, the TGA has not prescribed the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* for this purpose. Breach of any of the above conditions is a ground for the Secretary to cancel the product from the ARTG under Section 30(2)(c) of the Act.

Where a sponsor refuses to give the Secretary information that supports claims made by the sponsor when this is sought, this may also be an offence under Section 22(3), which states that a person is guilty of an offence if therapeutic goods are Registered or Listed in relation to a person, and that person engages in conduct that breaches a condition of the Registration or Listing of the goods. The maximum penalty for this offence is 60 penalty units. The offence where a sponsor refuses to give the Secretary information that supports claims when it is sought, can be applied in addition to other sanctions under the Act (which may include cancellation of the product from the ARTG). To more accurately reflect the seriousness of a failure to provide information necessary to establish quality, safety and efficacy of product, the Committee recommends that the current penalty for offences under Section 22(3) of the Act should be increased from 60 to at least 150 penalty units.

2.1.8 Homoeopathic medicines and related remedies that make therapeutic claims should be regulated to ensure they meet appropriate standards of safety, quality and efficacy.

Currently in Australia, products containing homoeopathic medicines are regulated under the Act. Homoeopathic medicines are considered to be low-risk medicines. Where a homoeopathic preparation meets certain conditions it may not need to be included in the ARTG and, in some cases, exempt from the requirement to be manufactured under GMP.

A homoeopathic product is exempt from inclusion in the ARTG if:

– all the ingredients in the preparation are present at a dilution greater than a 1000-fold serial dilution of the mother tincture
– the preparation is not required to be sterile
– it does not contain ingredients of human origin, or ingredients derived from the animals and parts specified in Schedule 5, Item 8 of the Regulations.

The current definition for 'homoeopathic preparation' included in the Regulations is based upon the central tenet of homoeopathy – *Similia similibus curentur* or 'let like cure like', and the principles of homoeopathic pharmacy – serial dilution and succussion of a stock.[49]

Where an ingredient meets the definition of 'homoeopathic preparation', and meets the conditions set out under Schedule 5, Item 8 of the Regulations, it may be exempt from the requirement to be included in the ARTG. This does not apply where the homoeopathic preparation is included in a product with other ingredients requiring inclusion in the ARTG.

Where products need not be included in the ARTG, they are effectively removed from regulation by the TGA, as when they meet this exemption they are generally also exempt from the need to be manufactured under GMP.

However, exempt homoeopathic goods must still comply with the requirements for labels for medicines,[50,51] even when exempt from the requirement to be included in the ARTG.

Unless exempt homoeopathic remedies are brought to the attention of the TGA, the products are not reviewed in any way. This makes it difficult to identify those products making claims inconsistent with a homoeopathic remedy. It has become evident that a number of substances currently not permitted in Listed

[49] Stocks are substances, products or preparations used as starting materials for the production of homoeopathic preparations. A stock is usually one of the following: for raw materials of botanical or zoological origin, a mother tincture or a glycerol macerate; for raw materials of chemical or mineral origin, the substance itself.

[50] Therapeutic Goods Order No. 69. *General requirements for labels for medicines* <www.tga.gov.au/docs/pdf/tgo69.pdf>.

[51] The label requirements of Therapeutic Goods Order No. 69 in themselves have raised issues with regard to homoeopathic remedies as therapeutic goods, as they require the inclusion of an indication on the label. Specific unqualified indications are generally not in accordance with the philosophy of homoeopathy, as a particular remedy is usually only appropriate for a specific 'symptom picture' rather than for a particular condition. For example, a 'headache' might indicate any one of a number of remedies, dependent upon factors such as whether the headache is better or worse for pressure or touch, hot or cold, morning or evening etc. It is probably not appropriate for a particular homoeopathic remedy to claim to "assist in the management of headaches". This would require the user to be familiar with the type of headache that particular remedy might be used for (which they may in fact know from the name of the remedy itself).

medicines are being presented on the market as homoeopathic preparations. Whilst these goods may be *bona fide* homoeopathic remedies, it is also possible that they are being formulated with little or no regard to homoeopathic principles or practice. The current exemption provisions applying to homoeopathic remedies are intended to apply only where ingredients meet the current definition of 'homoeopathic preparation' in the Regulations.

Consistent with the current definition, the dilution of an ingredient *does not* make it a homoeopathic preparation. A homoeopathic preparation must also be "formulated for use on the principle that it is capable of producing in a healthy person symptoms similar to those which it is administered to alleviate", in other words, it should comply with the principle of 'like cures like'.

However, it is very difficult to apply the principle of 'like cures like' where there is no evidence required of a proving or a symptom picture for the substance in the first place. The current definition of 'homoeopathic preparation' should be amended to make it clear that only *bona fide* homoeopathic ingredients are considered to be homoeopathic preparations.

A homoeopathic medicine should be adequately described to ensure that it is clearly differentiated from those medicines not consistent with the homoeopathic paradigm. Any misrepresentation of homoeopathic medicines as other medicines needs to be addressed as a priority.

Consideration also needs to be given to the regulation of other remedies or medicines with similar, but not consistent, paradigms. As with homoeopathic medicines, these types of remedies, such as flower essences, gem essences, and other 'vibrational' remedies, are likely to be of low risk to the consumer. However, it is essential that these remedies be defined so that they may be managed and regulated if appropriate.

2.1.9 The regulation of herbal ingredients for use in medicines should be reviewed.

A review of the regulation of herbal substances in complementary medicines undertaken by the CMEC was considered by the Committee. The CMEC review identified a number of core issues associated with the quality, safety and efficacy of herbal substances and herbal medicines and their regulation. The CMEC considered that, in consultation with stakeholders, the following issues need to be addressed:

– the adequacy, or otherwise, of the current regulatory definition of 'herbal substance' for identifying those low-risk herbal ingredients prepared according to traditional herbal medicine and/or established pharmaceutical practice
– the naming of herbal-derived substances which do not meet the definition of 'herbal substance' so that they are not represented as herbal substances
– the regulation of complex and non-traditional herbal extracts that may be significantly different in chemical profile to the original herb and/or the traditional extract on which safety and efficacy was originally based

– the use of the expression of dry/fresh weight equivalence to describe the amount of plant material used to produce a herbal ingredient and whether this may have the potential to mislead consumers, who may interpret this term as meaning equivalent therapeutic efficacy
– the need for limits on the variation in the solvent concentration used to prepare a herbal substance
– the need for limits on the variation in concentration ratio (the ratio of the weight of the herbal material in an extract to the weight of the dried material used to make the extract) used to prepare a herbal substance
– the need to define the term 'standardisation' for describing the 'potency' or consistency of herbal ingredients.

The Committee endorsed the CMEC recommendation that, in consultation with stakeholders, and as a matter of priority, a review of the regulation of medicines containing herbal ingredients be undertaken.

2.1.10 Standards for extemporaneously compounded medicines should be reviewed.

Complementary healthcare practitioners, such as pharmacists, herbalists and homoeopaths, may prepare certain medicines for individual patients that do not need to be assessed or evaluated by the TGA for quality, safety or efficacy. This exemption applies to medicines prepared for individual patients, either following consultation with that particular patient, or to fill a prescription for that particular patient.

While some starting materials used by practitioners when dispensing or extemporaneously compounding medicines for patients are subject to TGA assessment for quality, safety and efficacy (for example, ingredients that are either pre-packaged for other therapeutic purposes, or formulated as a dosage form), raw herbs and other starting materials are not.

In 1996, the Victorian Department of Human Services, the New South Wales Department of Health and the Queensland Department of Health commissioned a report on the practice of traditional Chinese medicine (TCM) in Australia. The report,[52] found that the division of responsibility between State/Territory and Australian governments regarding standards for Chinese therapeutic substances resulted in inadequate coverage, and posed a potential public health risk. The risks associated with the use of these substances (there have been a number of fatalities), were considered highly significant and underpinned the recommendation in Victoria for occupational regulation of the TCM profession. The report identified substantial problems associated with the failure of good handling and manufacture of these products. Cases were cited of lack of standardisation, contamination with heavy metals, inadvertent and deliberate substitution of other herbs, and adulteration with pharmaceutical medicines.

These problems, while demonstrated in Chinese herbal medicine, are not limited to Chinese herbs. The problems outlined above apply to herbal medicines from other countries and other traditional medicine systems.

[52] Bensoussan A, and Myers SP, 1996. *Towards a Safer Choice. The Practice of Traditional Chinese Medicine in Australia*. Faculty of Health, University of Western Sydney, Sydney.

The Committee considers that the same quality standards applied by the TGA to herbal and other complementary medicine ingredients should also apply to raw herbs and other starting materials used by healthcare practitioners in dispensing or extemporaneously compounding medicines.

Access to raw herbs and other starting materials is essential to the conduct of a viable herbal medicine practice, and any consideration of the regulation of these ingredients should involve all key stakeholders, including healthcare practitioners, the TGA and State and Territory governments.

The review of standards for raw herbs and other starting materials should also consider appropriate standards for the quality, safety and efficacy of dispensed or extemporaneously compounded complementary medicines produced by complementary healthcare practitioners when exemptions from the requirement to be included on the ARTG and to hold a manufacturing licence to manufacture preparations also apply.

2.1.11 Reference to 'For Practitioner Dispensing Only' products should be removed from Therapeutic Goods Order No. 69 – *General Requirements for Labels for Medicines.*

The regulation of 'For Practitioner Dispensing Only' complementary medicine products is specifically addressed in the Therapeutic Goods Order No 69 – *General Requirements for Labels for Medicines* (TGO 69). 'For Practitioner Dispensing Only' products are complementary medicines that are supplied in a dispensing pack to a (registered) complementary healthcare practitioner with the words 'For Practitioner Dispensing Only' included on the label. These medicines must generally meet the same standards required for other Listed or Registered complementary medicines.

The difference between 'For Practitioner Dispensing Only' products and other Listed or Registered complementary medicines is that the former do not need to include a statement of their purpose on the label. Other medicines must include therapeutic indications and claims on the label.

'For Practitioner Dispensing Only' products are intended for supply by a complementary healthcare practitioner to a person after consultation with that person. An instruction label must be affixed to the product before supply to the person.

TGO 69 defines 'complementary healthcare practitioner' as "persons who are registered under a law of a State or Territory as herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths". For the purpose of TGO 69, complementary healthcare practitioners who are not registered practitioners under a law of a State or Territory are not regarded as 'complementary healthcare practitioners' for the purpose of being supplied with 'dispensing packs' 'For Practitioner Dispensing Only'.

A particular concern relating to 'For Practitioner Dispensing Only' products was the possibility that these products might be prescribed by persons who are inadequately qualified. The majority of members of the Committee considered that there was greater public good to be served by requiring all products to be labelled with the indications and claims on the Australian Register of Therapeutic Goods (ARTG), recognising that this would still allow for practitioners to prescribe as appropriate.

Medicines Dispensed or Extemporaneously Compounded by Complementary Healthcare Practitioners

It is important to distinguish 'For Practitioner Dispensing Only' products from those that are dispensed or extemporaneously compounded by complementary healthcare practitioners. The latter products are dispensed or extemporaneously compounded for a particular person for therapeutic application to that person.[53]

Complementary healthcare practitioners, such as pharmacists, herbalists and homoeopaths, can prepare medicines for individual patients that, unlike 'For Practitioner Dispensing Only' products, do not need to be assessed or evaluated by the TGA for quality, safety or efficacy. The exemption applies to medicines prepared for individual patients, either following consultations with that particular patient, or to fill a prescription for that particular patient.

In addition, herbalists, nutritionists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners engaged in the manufacture of any herbal, homoeopathic or nutritional supplement preparation are exempt from the requirement for the products to be manufactured under GMP. The exemption applies only where the medicine is extemporaneously prepared for the patient following consultation with the patient.

2.1.12 The current 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, should be reviewed 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".

The TGA is obliged to give notice of cancellation or suspension of licence to manufacture medicines unless failure to act immediately would create imminent risk of death, serious illness or serious injury.

The Committee was informed of the circumstances ("imminent risk of death, serious illness or serious injury"[54]) by which regulatory action involving the immediate imposition of, or variation to, a condition of licensing, or revocation or suspension of a manufacturing licence for therapeutic goods, can occur.

In April 2003, the TGA immediately suspended the licence held by Pan Pharmaceuticals Limited to manufacture medicines. In this case, a special Expert Advisory Group concluded that it lacked confidence in any products manufactured by the company, and considered that they created risks to consumers of death, serious illness and serious injury; that these risks would increase over time; and that the risks could be realised at any time.

[53] Commonwealth of Australia, *Schedule 5, Item 6*, Therapeutic Goods Regulations 1990.
[54] Commonwealth of Australia, *Therapeutic Goods Act 1989*, Sections 40 (3) a and 41 (2).

In accordance with this advice, to protect the health and safety of the Australian community, the TGA immediately suspended Pan Pharmaceuticals Limited's manufacturing licence.

While it is essential to have provisions for the immediate imposition of, or variation to, a condition of licensing or revocation/suspension of a manufacturing licence which lead to imminent risk of death, serious illness or serious injury, the criteria are not sufficient to protect public health. Significant risk to public health and safety can result from conditions which might not lead to actual imminent risk of death, serious illness or serious injury.

For example, the current provisions would not permit *immediate* variation, cancellation or suspension of a licence to manufacture under circumstances that could result in a significant risk of harm. To more adequately protect public health and safety, options for immediate regulatory action associated with significant risk of harm should be explored. An approach to this issue could focus on the identification of 'critical deficiencies' during GMP audits of manufacturers. The Committee considered that this issue should be investigated further and that the TGA, in consultation with its stakeholders, be asked to review options for immediate cancellation of, or variation to a condition of licensing, or revocation/suspension of a manufacturing licence, that are more appropriate for complementary medicines.

2.1.13 Information should be placed on the labels of all medicines to better assist with product identification of recalled medicines.

The Committee considered there was some scope for improving certain aspects of the recall process and putting in place procedures and policies to better manage the nature and extent of the consumer and retailer response. In particular, consideration should be given to including information on labels to better assist with product identification of recalled medicines. Consideration should also be given to ways of ensuring that recalled products are not subsequently offered for sale.

2.1.14 The potential public health and safety issues associated with the availability of illegal complementary medicines, especially in ethnic communities, should be brought to the attention of the National Co-ordinating Committee on Therapeutic Goods.

Complementary medicines manufactured overseas that are not listed on the ARTG are being illegally (unless they are exempt or excluded from this requirement) imported and sold in Australia, particularly in ethnic communities.

The results of a recent survey undertaken by Queensland Health, in partnership with Griffith University and the University of Queensland, investigated both the quality and regulatory compliance of formulated Chinese medicines available for sale in Asian-style supermarkets and herbalists in south-eastern Queensland. Thirty per cent of the products investigated were not included on the ARTG. Inappropriate labelling, the level of heavy metals, the presence of Scheduled

ingredients in some formulations and concern over the efficacy of the products, present an unacceptable risk to consumers. From a public health perspective, the availability of such products to consumers is of concern.

Anecdotal evidence suggests that many of these products enter the country as 'personal imports' and subsequently find their way into the retail market. While recognising the rights of individuals to source complementary products for their own treatment, concern exists that individuals may be exploiting and undermining the intent of the national system for personal importation of medicines. Further investigation is required to better understand how these products enter the retail market.

It is important that the Australian Government and the States and Territories work together to ensure the protection of consumers, and that action is taken to curtail the illegal importation and sale of these medicines, particularly in ethnic communities. The National Co-ordinating Committee on Therapeutic Goods (NCCTG) is a committee of the Australian Health Ministers' Advisory Council (AHMAC) with functions that include taking action needed to bring about coordination of legislative and administrative controls on therapeutic goods. It is seen as the appropriate body to coordinate the regulatory action necessary to ensure that the illegal importation and sale of these medicines is curtailed.

2.1.15 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 should be urged to adopt nationally consistent therapeutic goods legislation.

Not all State and Territory governments have adopted therapeutic goods legislation that mirrors the Commonwealth Government's *Therapeutic Goods Act 1989* (the Act). New South Wales and Tasmania have enacted legislation that adopts the Act by reference. Victoria adopted legislation, in the same terms as the Act, in 1995, but is currently considering the 'adopt by reference' approach. Without this provision, traders operating solely within a State or Territory boundary are exempt from the requirements of the Act. 'Sole' traders may therefore manufacture therapeutic goods that are exempt from the Act, and companies operating in this manner do not have to meet GMP requirements and may use ingredients, subject to State and Territory legislation, that may not be permitted under the Therapeutic Goods Regulations 1990. Provided these medicines do not cross jurisdictions, they are legal within their own jurisdiction.

Market distortions resulting from 'sole' trader provisions can create unfair competition for companies that must meet the standards established under the Act if they operate across State borders. This distortion may also result in standards for quality, safety and efficacy that are not appropriate to the level of risk associated with the goods.

Action is required to close this loophole and establish a nationally consistent standard for the manufacture of all therapeutic goods in Australia.

2.1.16 State and Territory governments should be urged to adopt a nationally consistent system of access (Scheduling) to medicines.

The SUSDP sets out the Schedules that the NDPSC has decided should apply to different substances, including medicinal ingredients and components in medicinal ingredients. Controls placed on market access to medicines included in the SUSDP and, to a lesser degree, on market conduct, come into effect when the Schedules are adopted into State and Territory legislation. While States and Territories generally adopt the SUSDP Schedule, some jurisdictions have chosen, in a few cases, not to do so.

The level of restriction on access applied by the current medicines, poisons and controlled substances legislation is based on the hazardous properties of the substances and the risks associated with supplying and using products containing them.

The scheduling process aims to ensure that, among other things, the use of these products is supported by adequate information to enable consumers to select, in the case of certain non-prescription medicines (including some complementary medicines), and use all medicines safely and effectively. On this basis, interface with a suitably qualified professional is seen to be a prerequisite for the supply of medicines covered by these schedules.

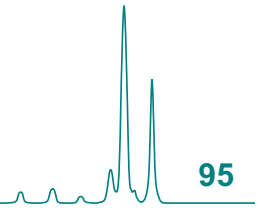
Complementary medicine healthcare practitioners with an appropriate level of professional skill and competency should have access to certain more potent complementary medicines that are otherwise restricted under various State and Territory controlled substances legislation. It was considered that an appropriate Schedule in the SUSDP could be used nationally to identify otherwise restricted substances that could be used by practitioners with an appropriate level of professional skill and competency.

To facilitate the development of a nationally consistent approach to the Scheduling of medicines, the Australian Health Ministers' Conference would appear to be the most appropriate body to progress this matter. The Committee strongly endorses the new administrative arrangements recommended in *The Review of Drugs, Poisons and Controlled Substances Legislation* (Recommendation 7) for scheduling medicines.

2.1.17 Consumers should be better informed about the potential risks of importing medicines for personal use.

Individuals can legally import most therapeutic goods for personal use under the TGA's Personal Importation Scheme. However, certain criteria, such as the quantity that can be imported in any twelve-month period, must be met, and it is illegal to supply goods imported under this Scheme to persons outside the importer's immediate family.

The Scheme does not allow either the importation of drugs prohibited by Customs legislation or injectable drugs that contain material of human or animal origin (except insulin), unless an import permit has been obtained from the TGA.



It is important for consumers to be aware that medicines imported for personal use may not be approved for use in Australia and may be of unknown quality, safety and efficacy. Individuals importing such products may be at risk. Further, if an individual suffers adverse consequences from taking such a product, information about the goods and redress may be difficult to obtain.

RECOMMENDATIONS

1. The TGA ensure that quality standards for all ingredients for use in complementary medicines are legally enforceable.
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.
3. The TGA ensure that ingredients with a chemical or biological profile that raises concern of teratogenicity not be permitted in 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.
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*.
6. The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines.
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.
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*.
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.
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.

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.
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.
13. Reference to 'For Practitioner Dispensing Only' products be removed from Therapeutic Goods Order No 69 – *General Requirements for Labels for Medicines*.
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".
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.
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.
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.
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.
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.

This page has been left blank intentionally.

3 ADVERSE REACTIONS

TERM OF REFERENCE ADDRESSED

This chapter focuses on the term of reference that requires the Committee to examine and provide advice on:

> *the potential for interactions between complementary medicines and prescribed medicines and to provide advice on how this information should be made available to healthcare practitioners.*

BACKGROUND

A key focus of *The National Strategy for Quality Use of Medicines* (QUM) is to ensure that all medicines are used safely – minimising misuse, overuse and under-use of medicines and taking appropriate actions to solve medication problems such as adverse events, including interactions between complementary medicines and other medicines. In its deliberation on the issue of interactions between medicines, the Committee considered this matter in the broader context of adverse reactions and the safety of complementary medicines.

3.1 Post-Market Regulatory Activities

To ensure a high level of public health and safety, an important feature of the Therapeutic Goods Administration's (TGA's) risk management approach to the regulation of both Listed and Registered complementary medicines is the application of a range of post-market regulatory activities (see Chapter 2 – *The National Regulatory Controls for Complementary Medicines* for details). These activities aim, among other things, to identify unsafe or potentially unsafe medicines and to take appropriate action to minimise the risk associated with their use. An essential element of this approach is to monitor adverse reactions to medicines (adverse drug reactions) [ADRs].

3.2 Adverse Drug Reaction Reporting System

An adverse reaction reporting system for therapeutic goods in Australia is well established. The Australian 'Blue Card' system is a voluntary reporting system that covers all medicines and most health professionals. In addition, sponsors of all medicines included in the Australian Register of Therapeutic Goods (ARTG) are under an obligation to report adverse reactions to the TGA.

The TGA's Adverse Drug Reactions Unit (ADRU) considers that some sponsors of complementary medicines have not been aware of their reporting obligations. Recent amendments to the *Therapeutic Goods Act 1989* (the Act) have imposed additional reporting requirements on sponsors and manufacturers to help ensure that they notify the TGA about adverse events in connection with the use of therapeutic goods.

While a very high proportion of reports to the TGA from sponsors about conventional medicines originate from health professionals, the majority of reports from sponsors about complementary medicines appear to originate from consumers.

Adverse reaction reports received by the TGA for both Registered and Listed medicines are entered into the Adverse Drug Reaction (Reporting) System (ADRS) database.

Reports of serious reactions are initially reviewed by a medical officer in ADRU and, additionally, are reviewed by the Adverse Drug Reactions Advisory Committee (ADRAC), which meets eight times a year. In addition, ADRAC reviews all reports of reactions (whether serious or not) to complementary medicines, vaccines, and new drugs (those marketed in the last three years). A summary of all reports to complementary medicines, including ADRAC/ADRU comments, is sent to the Complementary Medicines Evaluation Committee (CMEC) for comment and advice to the TGA.

Laboratory testing of medicines or enforcement activity (via the TGA's Surveillance Unit) may be arranged by ADRU in consultation with the TGA's Office of Complementary Medicines (OCM) before a report is reviewed by ADRAC, or on the advice of ADRAC, or on the advice of CMEC. ADRU performs literature searches and obtains advice from the OCM relating to the safety of complementary medicines.

Decisions that may be taken on ADR reports include the following:

- no further action if reaction is a well-known, non-serious reaction
- no further action unless or until additional similar reports are received
- request for additional information from the reporter
- analysis of the ADRU database reports to investigate potential safety signals
- request for information from the medicine sponsor or manufacturer
- publication in the *Australian Adverse Drug Reactions Bulletin*[55] or medical journals to raise awareness of the reaction
- referral to other areas of the TGA for further investigation
- discussion of the reaction with international medicines regulatory agencies
- recommendation to amend the medicine's product information
- recommendation to restrict the availability of the medicine
- recommendation to remove the medicine from the market.

3.3 International Collaboration

As well as receiving Australian reports of adverse reactions, the ADRU has regular meetings with overseas agencies. In 1968, the World Health Organization (WHO) instigated a system of international collaboration in the monitoring of adverse drug reactions (ADRs). The aim was to make it easier to detect adverse drug reactions not revealed during clinical trials, with the aid of combined reports from a number of countries.

[55] The *Australian Adverse Drug Reactions Bulletin*, a quarterly publication, provides useful information on adverse reactions, including important issues arising from reports submitted to ADRAC. The *Bulletin* is distributed to medical practitioners, pharmacists and other health professionals and is available electronically at: <http://www.tga.gov.au/adr/aadrb.htm>.

Some years later, the WHO Collaborating Centre for International Drug Monitoring was created in Uppsala, Sweden (the Uppsala Monitoring Centre; UMC). National drug-monitoring centres in around 54 countries currently interchange adverse reactions information via the UMC. ADRU is a member of the WHO pharmacovigilance network, and has access to the WHO international database of adverse drug reaction reports.

3.4 Recent Improvements to the TGA's Adverse Drug Reaction Reporting System for Complementary Medicines

The TGA has recently updated the existing framework of reporting and assessing suspected adverse reactions to medicines and that this could provide a useful starting point for developing a systematic complementary medicines adverse reaction reporting system. Recent improvements to support greater reporting of adverse reactions to complementary medicines include:

– ADR reporting may now be made via a web interface. It is thought that this may increase ADR reporting from those groups who do not generally report via the Blue Card system, which includes both consumers and complementary medicine practitioners
– a '1800' telephone number has been established to facilitate reporting of adverse reactions (telephone 1800 044 114)
– an advertisement entitled "Adverse Drug Reactions Reporting Online" was placed in the *Journal of the Australian Traditional-Medicine Society*, 9(2), 101 (2003), promoting the web-based reporting system
– the ADRS has been upgraded. While this has not improved 'searchability' in relation to complementary medicines (that is, most complementary medicines are still entered into the database by product name rather than by active ingredients), the TGA's new Strategic Information Management Environment (SIME) makes it much easier to determine the ingredients of a product on the ARTG, which facilitates the TGA's task of analysing complementary medicine reports.

The TGA has a continuous program of developing and improving its computer software. The ability to search for a single active ingredient across multiple products in the ADRS database would be an extremely useful addition.

3.5 Limitation of Overseas Adverse Reaction Reporting Systems for Complementary Medicines

Some of the substances that are intended for use in complementary medicines within the therapeutic goods regulatory domain in Australia are available for supply in other countries under significantly less-stringent regulatory controls. In most countries, the products that contain complementary medicine substances are regulated as foods, food ingredients, food additives or dietary supplements. Foods are generally not required to undergo pre-market evaluation, and post-market regulatory activity within food domains is rarely, if ever, as rigorous as in therapeutic domains. In particular, it rarely includes a formal system for ADR

reporting. Substances and products regulated under less rigorous controls may not provide a high degree of assurance of their safety-in-use, particularly if there are limitations in ADR reporting.

3.6 Adverse Reaction Reports in Australia

In 2002, approximately 94 per cent of ADR reports received by the ADRU related to prescription medicines, and three per cent each to over-the-counter (OTC) and complementary medicines.

The small number of reports received by the ADRU of suspected adverse reactions to complementary medicines is considered to be, in part, due to the fact that complementary medicines are, by and large, low risk products and have a low propensity for adverse effects. It is also due, in part, to the fact that the current ADRAC system is potentially biased away from complementary medicines because complementary medicines are usually self-prescribed and their use may not be reported should a problem arise.

Among the factors that may contribute to under-reporting is that consumers may presume that complementary medicines are safe, use them without the supervision of a healthcare practitioner, and may be unaware of who regulates them. The TGA, in consultation with stakeholders, is currently developing consumer-focused labelling for medicines. A range of issues will be considered, including the use of toll-free telephone numbers to sponsors, *Medicines Line*, etc. that will be of assistance in providing information to consumers and may facilitate reporting of adverse reactions. A recent report by MacLennan *et al.*[56] on the use of complementary medicines in Australia estimated that 57 per cent of users did not tell their doctor that they were taking these medicines. A current objective of the TGA is to improve post-market surveillance of medicines in all sectors, including complementary medicines. This includes monitoring for suspected adverse reactions to complementary medicines. Drew and Myers[57] have previously commented on the need for monitoring of adverse reactions to complementary medicines, including the need for an avenue for consumers to report, and for medical practitioners to routinely ask for information about, complementary medicine use.

The TGA has indicated that, with some adjustments, the existing ADRAC framework of reporting and assessing suspected adverse reactions to medicines could provide a useful starting point for developing a systematic complementary medicines adverse reaction reporting system.

In 2001, ADRU received 11,118 reports of suspected adverse reactions to medicines in Australia. Table 3.1 lists the origin of these reports.

Table 3.1 Origin of adverse reaction reports to the TGA in 2001.

Number of reports	Source of reports
4070	General practitioners
3075	Hospitals
2829	Industry
1144	Other (includes consumers, pharmacists, specialists, dentists, other healthcare professionals)

[56] MacLennan AH, Wilson DH, Taylor AW, 2002. The escalating cost and prevalence of alternative medicine. *Preventive Medicine*, 35, 166–173.

[57] Drew AK, Myers SP, 1997. Safety issues in herbal medicine: implications for the health professions. *Medical Journal of Australia*, 166, 538–541.

3.7 Consumer Reporting Study

In the late 1990s, the Pharmaceutical Health And Rational use of Medicines (PHARM) committee funded an ADR project entitled "Increasing the Frequency, Quality and Breadth of Adverse Drug Reaction Reporting by Consumers and Health Professionals" under PHARM's Quality Use of Medicines Evaluation Program (QUMEP).

This ADR program was conducted in Queensland and, for the first time in Australia, consumers had the opportunity to report ADRs via a telephone medicines information line. Analysis of the reasons for the medication misadventures reported by consumers demonstrated that feedback from consumers can help in reducing harm associated with medication use. One in four of the reports to the Queensland consumer ADR line resulted in an ADR report to ADRAC. Reports by consumers to the Queensland ADR line included reports of ADRs to complementary medicines.

In 2002, the Australian Council for Safety and Quality in Health Care supported the concept of a national trial on consumer reporting of adverse medicine events to build upon the project in Queensland. The national project on consumer reporting of adverse medicine events is planned for 2003. Reports on complementary medicine use are expected in the project.

3.8 Medicines Interactions

An interaction is clinically relevant when the therapeutic activity and/or toxicity of a medicine is changed to such an extent that a dosage adjustment of the medication or medical intervention is required. An interaction is considered to be an alteration either in the pharmacodynamics and/or pharmacokinetics of a medicine caused by concomitant use of other medicines, intake of certain foods, or social habits such as smoking tobacco and drinking alcohol. Other factors may also interact to alter the disposition of a medicine, such as age, gender, physical activity, ethnic origin and time of administration.

For almost all complementary medicines, detailed pharmacodynamic and pharmacokinetic data and *in vitro* and/or *in vivo* interaction studies are not available. Difficulty in obtaining this information is complicated by the chemical complexity and multi-ingredient nature of many complementary medicines. In addition, for the majority of complementary medicines, the active component(s) is not known. Consequently, the knowledge base from which predictions of potential medicine/medicine interactions can be made is limited and is largely reliant on known class effects (e.g. inhibitors or inducers of enzymes mediating the metabolism of a medicine).

There are currently 152,691 reports of adverse reactions in the ADRS database. Two thousand and fifty of these reports (1.3 per cent) have been coded as *possible* drug interactions. In 2002, approximately 240 adverse reaction reports from a total of 12,000 reports involved complementary medicines. It is likely that only a small number of these involved possible interactions between complementary and prescription medicines.

Where a clinically relevant interaction between a complementary medicine and a prescription medicine has been established, the TGA, following consultation with the CMEC, has required a label warning on the medicine(s) and has undertaken alerts to healthcare practitioners (including notification in the *Australian Adverse Drug Reactions Bulletin*) and to consumers.

FINDINGS

3.1.1 The TGA has a well-developed system for evaluating and responding to reports of adverse reactions to medicines.

Reports of serious adverse reactions to the TGA are initially reviewed by a medical officer in the ADRU and are also reviewed by ADRAC, which meets eight times a year. In addition, ADRAC reviews all reports of reactions (whether serious or not) to complementary medicines, vaccines, and new drugs. A summary of all reports to complementary medicines, including ADRAC/ADRU comments, is sent to the CMEC for comment and advice to the TGA.

3.1.2 Reporting adverse reactions to complementary medicines to the TGA needs to be improved.

The small number of reports received by ADRU of suspected adverse reactions to complementary medicines is considered to be, in part, due to the fact that complementary medicines are, by and large, low risk products and have a low propensity for adverse effects. It may also be due, in part, because the current ADRAC system is biased away from complementary medicines because complementary medicines are usually self-prescribed and their use may not be reported should a problem arise.

Among the factors that may contribute to under-reporting is that consumers may presume that complementary medicines are safe, use them without the supervision of a healthcare practitioner, and may be unaware who regulates them.

In addition, the Committee noted that health professionals have claimed that barriers such as limited time, lack of knowledge of the system, lack of confidence in the association between drug administration and an adverse event prevent their reporting ADRs. The Committee also noted other reasons given for limited ADR reporting in Australia are the narrow range of health professionals who are actively encouraged to participate in the system, limited direct-from-consumer reporting, and the lack of attention paid to the role of complementary medicines in their aetiology.

3.1.3 The TGA's Adverse Drug Reaction Reporting System (ADRS) database should be further improved to encourage reporting of AUST L and AUST R numbers and to facilitate searching for single ingredients in multi-ingredient complementary medicines.

The Committee acknowledges the improvements the TGA has made to its ADRS. However, the ADRS database does not support searching for individual ingredients in multi-ingredient products, which includes most complementary medicines.

The Committee noted the TGA's new SIME system was set up as a database for tracking single medicines rather than for tracking single ingredients across a range of different medicines. This is in accord with the data model in the previous TGA database and the data model in existence in other databases, for example, the WHO database. However, the Committee considered that the ability to search for a single active ingredient across multiple products in the ADRS database would be an extremely useful addition to facilitate the task of analysing complementary medicine reports.

The utility of many ADR reports involving complementary medicines appears to be limited because of the lack of recorded product information to unequivocally determine the identity of the product, especially the AUST L/AUST R number. The Committee recommended that the current reporting system should be modified to encourage the reporting of AUST L/AUST R numbers.

RECOMMENDATIONS

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.

21. The TGA actively pursue the inclusion of AUST L/AUST R numbers within the current Adverse Drug Reactions (Reporting) System (ADRS).
22. The TGA modify its web-based reporting form to facilitate inclusion of AUST L and AUST R numbers.
23. The TGA develop the capability to search for a single active ingredient across multiple products in the ADRS database.
24. The TGA expand the *Australian Pharmacovigilance Guideline* to include sponsors of complementary medicines.

4 INFORMATION AND ADVERTISING

TERMS OF REFERENCE ADDRESSED

This chapter focuses on the terms of reference that require the Committee to examine and provide advice on:

The information needs of consumers of complementary medicines

The nature and extent of restrictions required on advertising (including Internet advertising) of complementary medicines to consumers.

BACKGROUND

4.1 *The National Strategy for Quality Use of Medicines* (QUM)

The 'quality use of medicines' is one of the four objectives of the *National Medicines Policy* (NMP). The Policy states that to achieve optimum use of medicines, "consumers and health practitioners should have timely access to accurate information and education about medicines and their use".

The QUM stresses the primacy of consumers, and states that consumer involvement in all aspects of the policy is critical. The strategy notes that information should be:

- balanced and accurate
- informed by evidence and based on agreed standards
- available in a timely manner, accessible and understandable by users
- provided in a variety of forms suitable for users
- independently sourced, with no advertising associated with it
- relevant to the wants and needs of users, recognising the heterogeneity and diversity of the Australian community, including differences across culture, health beliefs, health literacy, skills, education, language, geographic isolation, health status, access to information technology and socioeconomic status
- evaluated for its usefulness, acceptability and effectiveness
- inclusive of user groups in its development.

"Provision of objective information and assurance of ethical promotion" is identified as one of six 'building blocks' which "are considered fundamental to QUM".

Specific resources and initiatives considered necessary for achieving QUM include:

- independent medicines information services for health practitioners and consumers
- objective information integrated with information technology developments.

4.2 Scheduling of Medicines

The *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) sets out the Schedules that the National Drugs and Poisons Schedule Committee (NDPSC) has decided should apply to different substances, including medicinal ingredients and components of medicinal ingredients. Controls on market access and, to a lesser degree, on market conduct, come into effect when the Schedules are adopted into State and Territory legislation.

Scheduling seeks to ensure, amongst other things, that the use of these products is supported by adequate information to enable consumers to select (in the case of certain over-the-counter (OTC) medicines, including some complementary medicines) and use all medicines safely and effectively. Currently, the restrictions are intended to facilitate this information being provided through:

– health professionals, especially medical practitioners at the time of consultation and pharmacists at the time of supply
– written information, including product labelling and Consumer Medicine Information (CMI).

Use of the Schedules to apply controls is intended to achieve the level of control that is appropriate for the degree of risk posed by the substance, while still allowing freedom of choice for consumers on a self-medication basis. More specifically, the objective of restricting access is to prevent medicinal misadventure by ensuring that, where the consumer's lack of knowledge and understanding could lead to significant harm, professional advice and counselling are available to redress that information deficit.

Underlying the controls imposed on medicines through the SUSDP is an assumption that consumers are *not* fully informed about the consequences of their choices and that it would be difficult for them to independently gain an adequate knowledge and understanding of:

– the active ingredients and products needed to treat particular conditions
– the risks associated with particular ingredients
– the way in which products containing certain ingredients need to be used safely and to achieve optimal health benefits
– the potential interactions with other medicines or foods
– contraindications with certain medical conditions.

4.3 Medicines Labelling and Consumer Medicine Information

The primary source of information about a non-prescription medicine is its label. It is the one source of information that is always available when people choose a medicine and when they use it. It is important that the label includes the correct information to enable the product to be used safely and effectively and also that the information is presented in a way that enables the consumer to easily find, understand and act appropriately on this information.

All medicines that are sold in Australia must comply with legislative requirements set out in Australian Government and State therapeutic goods legislation. Information that must appear on a medicine label includes:

- the product name
- the name and quantities of all active ingredients
- the identity of ingredients that are 'restricted ingredients' because they are known to present a risk to some consumers (e.g. hydroxybenzoate preservatives, peanut products, lactose)
- the name of the dosage form (e.g. tablet)
- the quantity of the goods (e.g. 100 tablets)
- required warning statements
- storage conditions, batch number and expiry date
- directions for use of the medicine
- the name and address of the sponsor
- a statement of the purpose of use (i.e. indications or claims)[58]
- the registration or listing number (e.g. AUST L 12456).

The TGA issued the *Review of Labelling Requirements for Medicines: Consumer-focused Labelling – a Way Forward?* as a 'consultation report' in March 2002. The report had two main thrusts – consolidation of label warning statements in Australian Government legislation (these are currently regulated by the States) and a 'consumer focused' approach to the labelling of medicines.

The latter issue involved consideration of the introduction of CMI for all registered medicines (in a suitable form or on the label) and a consideration of how "performance based principles may be applied with the aim of improving the performance of labels for the benefit of consumers". Provision of CMI is mandatory for prescription and 'Pharmacist Only' medicines, but not for 'Pharmacy Only' or unscheduled medicines. The TGA has proposed that CMI should be mandatory for all Registered medicines.

Under these proposals, the mandatory label content would still apply (as above), but labels would be designed according to a set of principles based on quality research, and tested on panels of consumers to ensure that consumers were able to find information on the label, understand it and act appropriately on it.

These requirements would be applied through an industry code of practice that would be referenced, and therefore legislatively underpinned, in the medicines labelling order. A working group covering major stakeholders (including the TGA) is currently developing the code. Work on the code is expected to be finalised by the end of 2003.

[58] Where the goods are in a dispensing pack supplied solely to a complementary healthcare practitioner, and the label has the words 'For Practitioner Dispensing Only', the statement for the intended purpose of the goods is not required. An instruction label must be affixed following consultation with the practitioner.

4.4 Food Labelling and Advertising

Unless otherwise expressly prescribed, the *Australia New Zealand Food Standards Code*[59] currently states that any label on or attached to a package containing food, or an advertisement for food, generally, shall not include:

- a claim for therapeutic or prophylactic action or a claim described by words of similar import
- the word 'health' or any word or words of similar import as a part of or in conjunction with the name of the food
- any word, statement, claim, expressed or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person
- the name of or a reference to any disease or physiological condition.

However, a review of this prohibition on health claims being able to be made for food is currently being undertaken. Should there be exceptions to the prohibition, it will be essential that the regulation of food health claims is such that it preserves the integrity of Australia's food–medicine interface, with a level playing field for the regulation of claims on either side of the interface.

4.5 Health Professionals

The paucity of research (particularly in Australia) in relation to complementary medicine utilisation has made it difficult for the Committee to assess where healthcare practitioners rank as a source of advice to consumers. Indeed, in the United States of America (USA) "… several surveys reported that books, magazines, health food stores and even fitness and/or nutrition classes were more useful sources of information than were physicians or dietitians/nutritionists".[60]

Nonetheless, it seems that health professionals, including complementary healthcare practitioners, pharmacists and general practitioners, are an important source of advice to consumers about complementary medicines. This is supported by data from *Medicines Line* (see below), which shows that 15 per cent of its callers were referred by healthcare practitioners.

Professional bodies, both those representing complementary healthcare practitioners and those representing professionals working within the Western clinical model of medicine, have emphasised the need for their members who use and/or advise on complementary medicines to acquire and maintain relevant knowledge through undergraduate, vocational and continuing education. This has been supported by reviews in the United Kingdom (UK) and USA. (See Chapter 5 for details.)

In addition to the knowledge required to inform their patients, practitioners also require the skills to convey this information. The UK Consumers Association has argued for the strengthening of communication skills of healthcare professionals as one of its three main recommendations to "improve the exchange of information between patients, health care professionals, governing bodies and pharmaceutical companies".[61]

[59] Standard 1.1A.2

[60] Greger JL, 2001. Dietary supplement use: consumer characteristics and interests. *The Journal of Nutrition*, 131, 1339S–1343S.

[61] Consumers Association, 2003. Media release: *Informed Patients Are a Virtue: Time to Revolutionise Patient Information*. London.

In addition to advising their patients about which medicines to take, some complementary healthcare practitioners (most notably traditional Chinese medicine practitioners, Western herbalists, and homoeopaths) both prescribe and dispense medicines.

This contrasts with prescription medicines (where there is a separation between the two activities) and raises questions about professional ethics. These need to be addressed as part of the wider issue of practitioner regulation (see Chapter 5 – *Healthcare Practitioners*).

4.6 Telephone Services

Medicines Line, a national information service, provides consumers with access to information about medicines including prescription medicines, OTC medicines, complementary medicines, and herbal and natural therapies. *Medicines Line* is provided by National Prescribing Service Limited (NPS) and operated by a consortium, including the Pharmaceutical Society of Australia and Mater Pharmacy Services. It has a membership base of 32 peak health bodies, representing both consumers and health professionals.

Medicines Line received nearly 5000 calls between September 2002 and February 2003. Data presented to the Committee show that some 6 per cent of these calls related to complementary medicines, ranking them fourth on the list of medicine classes of interest to callers (behind antidepressants, antihypertensives, and medications for hyperacidity/ulcers). Some 44 per cent of callers (overall) have previously sought information from healthcare practitioners or support groups, with 15 per cent of calls referred from practitioners. Approximately 43 per cent of callers were referred to healthcare practitioners (including complementary practitioners) for follow-up.

Several public hospitals also provide medicines information via telephone. The Committee was unable to identify the extent to which these services convey information about complementary medicines.

4.7 Internet

The Internet is a significant and growing source of information. According to the Australian Bureau of Statistics, use of the Internet by Australian adults increased from 31 per cent in 1998 to 58 per cent in 2002.[62]

The lack of research data, the ubiquitous nature of the Internet, and the absence of pre-approval requirements for Internet advertising mean that the nature and extent of Internet-sourced information about complementary medicines is difficult to ascertain. However, the general growth in Internet usage and some overseas studies suggest that the Internet is being used increasingly as an information source about complementary medicines. The House of Lords Select Committee on Science and Technology considered that "health information is arguably the most common topic searched for on the Internet, and there is a bewildering number of sites with information in this area".[63] In evidence before the Committee, the British Complementary Medicine Association stated that there had been a "proliferation of sites".[64]

[62] Australian Bureau of Statistics, *Household Use of Information Technology*, Australia, 2003, Canberra.

[63] House of Lords, 2000. Select Committee on Science and Technology, 6th Report, *Complementary and Alternative Medicine*. The Stationery Office, London <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/idselect/idsctech/123/12301.htm>

[64] House of Lords, 2000. Select Committee on Science and Technology, *op. cit.*

The White House Commission on Complementary and Alternative Medicine Policy found that information to help consumers make informed choices about complementary medicines was "too often … nonexistent, inaccurate or difficult to find".[65]

4.8 Advertising

The advertising of therapeutic goods in Australia is administered under co-regulatory arrangements involving key stakeholder groups, i.e. government, industry, advertisers, media, consumers, and healthcare professionals.

Advertisements[66] for therapeutic goods are subject to the advertising requirements of the *Therapeutic Goods Act 1989* (the Act) and the supporting Therapeutic Goods Regulations 1990 (which legislatively underpin the *Therapeutic Goods Advertising Code* (TGAC), and reference the *Trade Practices Act 1974* and other relevant laws).

It should be noted, however, that the relevant provisions of the Regulations (Part 2) do not apply to advertising to a range of specified health professionals, including, among others, medical practitioners, and members of identified professional bodies.[67] The Regulations also do not apply to "advice or information given directly to a patient … in the course of treatment of that patient"[68] by these same professionals.

The TGAC specifies the requirements for advertising of therapeutic goods to consumers. The objective of the TGAC is to ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a socially responsible manner that promotes the quality use of therapeutic goods and does not mislead or deceive the consumer. In April 2000, the TGAC was significantly amended from a 'prohibitions-based' to a 'principles-based' document.

Australia's framework for advertising controls also includes a self-regulatory component, comprising voluntary codes of practice with 'built-in' complaint-handling mechanisms. The peak industry associations administer these voluntary codes.

Advertisements to the general public for therapeutic goods appearing in specified media (e.g. newspapers, magazines, television and radio) must be pre-approved prior to their publication or broadcast.

Currently, the advertising regulations do not apply to *bona fide* news, public interest or entertainment programs[69] (although these terms are not defined). The Australian Competition and Consumer Commission (ACCC) more appropriately handles false and misleading claims that may appear in these media (including books).

[65] White House Commission on Complementary and Alternative Medicine Policy, 2002. *White House Commission on Complementary and Alternative Medicine, Final Report*. <http://www.whccamp.hhs.gov/finalreport.html>, p68

[66] "'Advertisement' in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods." *(Therapeutic Goods Act 1989)*

[67] These bodies are listed in Schedule 1 to the Therapeutic Goods Regulations 1990.

[68] Regulation 4 (3), Therapeutic Goods Regulations 1990, as amended.

[69] Section 3.3, *Therapeutic Goods Advertising Code*

4.8.1 Complaints Handling

Complaints relating to advertisements for therapeutic goods published in specified media and the broadcast media are handled by a centralised Complaints Resolution Panel (CRP), established under the Regulations and comprising representatives from all key stakeholder groups.

There are also complaints handling committees established under the voluntary codes of practice administered by the peak industry associations. These committees comprise industry representatives as well as several independent, external representatives (including a TGA observer). These committees primarily consider complaints about non-specified advertisements for therapeutic goods, e.g. leaflets, flyers, catalogues, brochures, and 'shelf talkers' distributed via letterbox drop, point of sale etc. These committees also consider complaints about advertisements directed exclusively to healthcare professionals (which are not subject to the public advertising regulatory requirements incorporating the TGAC).

While requiring compliance with the TGAC, these codes of practice include additional, 'ethical/industry' requirements which are not necessarily prescribed by law. The complaint committees can impose sanctions under the relevant codes, and government agencies such as the TGA and ACCC expect industry participants to comply with the findings of these committees, irrespective of whether or not the company in question is a member of the particular industry association.

In the few cases where the complaint committees are unable to achieve a satisfactory outcome, the matter is referred to the TGA and/or ACCC for appropriate action.

4.8.2 Internet Advertising

Internet advertising is regulated broadly in the same manner as other 'advertisements'. However, advertisements appearing on the Internet currently do not require pre-approval and complaints are dealt with under the industry associations' code of practice.

Recent legislative changes[70] (passed but not yet proclaimed) will bring Internet advertising into the scope of broadcast advertising, where regulatory arrangements are well defined.

These arrangements include pre-approval of advertisements, and complaints handling via the CRP, unless the means of advertising is specifically excluded. For practical reasons, the TGA intends to exempt Internet advertising from pre-approval requirements. However, following further proposed amendments, the CRP would be specifically empowered to handle complaints regarding Internet advertising.

These powers over advertising through the Internet will be achieved by defining the Internet as part of the 'broadcast media'. In view of the self-identity Internet advertising has developed, ultimately it would be desirable for it to be regulated as an entity in its own right.

[70] *Therapeutic Goods Amendment Act (No. 1) 2003* <http://www.tga.gov.au/docs/html/tgaa0301.htm>

The provisions of the Act and Regulations are confined to Australian corporations and/or individuals who import, export, manufacture or supply therapeutic goods to, from, or between the States and Territories of Australia. As a result, the TGA does not have jurisdiction to action complaints if the company and/or its Internet site is based in, or on a server in, another country.

Under these circumstances, the ACCC, as a member of the International Consumer Protection Enforcement Network (ICPEN), is able to investigate and action complaints about overseas Internet sites.

The ICPEN is an international organisation that consists of a network of 31 member countries. Its role includes dealing with consumer problems that arise with international transactions in goods and services, such as E-commerce fraud and international postal scams. It shares a database on fair trading laws in member jurisdictions and targets Internet fraud with Internet Sweep Days. The 2002 Sweep Day focused on Internet sites promoting misleading claims about health products. TGA officers took part in the 2002 Sweep Day.

4.8.3 Proposed Changes to Advertising Control Arrangements

As part of the transition to a joint trans Tasman agency to regulate therapeutic products, an Interim Advertising Council (IAC) has been established. The IAC aims to bring the different Australian and New Zealand arrangements into a single regulatory framework.

The work of the IAC is being informed by a *Review of Advertising Therapeutic Products in Australia and New Zealand*[71], which was released in March 2003.

The IAC will be making recommendations on the legislative framework for a new joint advertising scheme, including governance arrangements, enforcement, compliance and sanctions, and approaches to developing a risk-based framework under which advertisements should be subject to regulatory approval before being released.

The IAC will be recommending three key principles which are proposed to be included in the legislation governing the joint agency, which embody the spirit in which advertising for therapeutic products should occur. These will be to the effect that:

1. Advertisements must comply with the Therapeutic Products Act(s) and Rules and the Therapeutic Products Advertising Code.
2. Advertisements must be truthful and not misleading. Claims must be valid and have been substantiated
3. Advertisements must observe a high standard of social responsibility.

The IAC is also developing a draft joint advertising code, to be given a legislative basis, which will set the standards for the regulation of advertisements of therapeutic products in Australia and New Zealand.

[71] Toogoolawa Consulting Pty Ltd November 2002, *Report of a Review of Advertising Therapeutic Products in Australia and New Zealand*. Commonwealth of Australia. <http://www.tga.gov.au/docs/html/advrev.htm>

The IAC is developing a definition of 'advertisement' proposed for inclusion in the advertising code. An initial proposal includes communications:

– promoting the use, sale or supply of therapeutic products
– promoting services embracing the use, sale or supply of therapeutic products
– imparting information or seeking to educate with a view to promoting the use, sale or supply of therapeutic products.

The definition had been made necessarily broad, to ensure that the various kinds of generic information and advertising undertaken in relation to therapeutic products is subject to the key provisions of the advertising legislation.

The IAC will be considering and consulting on these issues, and reporting to the Australian and New Zealand regulatory authorities in early 2004.

FINDINGS

4.1.1 Government needs to take a more active role in ensuring that consumers have access to reliable information about complementary medicines, and the skills to interpret information and make informed decisions.

The QUM emphasis on accurate information and reliable, independent sources of information is soundly based and was strongly endorsed by the Committee.

The fundamental value of information is that it underpins decision-making. Informed medicine decisions by consumers should promote better health outcomes, fewer adverse reactions, a greater sense of personal control over health care, and more value for the consumer health dollar.

While good information promotes good decisions and better consumer outcomes, the reverse is also true. The Committee concluded that the information available to consumers about complementary medicines is variable, some of it is unreliable, and reliable information is difficult to identify and access. At a time when evidence-based medicine is much encouraged, evidence-based information about complementary medicines appears to be hard to find.

Consumers' information about complementary medicines comes from many sources. Some of it is fragmented, unreliable and provided in language that is difficult to understand. The advent of the Internet, in particular, has produced an explosion in available information. However, the nature of the Internet, with a considerable volume of information sourced outside the reach of effective safeguards, makes it difficult to ensure that it is accurate and reliable.

Given the importance of good information to consumers, and the difficulties they appear to have in accessing it, the Committee came to the view that government should take a more active role in ensuring the availability of accurate, reliable information. This could occur in a number of ways.

The Committee was advised that consumers want to be able to source reliable medicines information from government. This is supported by the *Review of Drugs, Poisons and Controlled Substances Legislation Final Report – Parts A* and *B*, which recommended that the Australian Government fund a consumer information service to provide independent, comprehensive, high-quality advice in relation to the safe and effective use of medicines. One option could be to extend the scope of the Health*Insite* website, to incorporate both medicines information and links to other reliable sources.

The Committee also noted that government, and in particular the TGA, has a rich database of medicines information that could be used to better inform consumers (and others, such as healthcare practitioners and researchers) about medicines.

Other avenues for improving consumer information include information campaigns (which could link to the current campaign to promote better use of prescription medicines subsidised by the Pharmaceutical Benefits Scheme), seminars and workshops, media resource kits, and sponsored projects by community and professional organisations.

As a rule, the Committee thought that information provided to consumers needed to be consistent with the current TGA *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*.

If it is to be effective, information must be tailored to its audience(s). It is essential that information initiatives are framed against an understanding of what information consumers need, and what drives consumption of complementary medicines. The need to inform ethnic communities about the hazards associated with personal importation of medicines (see Chapter 2 for details) is but one example.

While improving the accuracy, reliability and accessibility of complementary medicines information is important, the value of the information is greatly diminished without the ability to interpret it, and to discriminate between reliable and unreliable information. Consumers need the skills to interpret information, and to make good, informed decisions. Again, the Committee considered that government has a role in helping to develop these skills.

Throughout its deliberations, the Committee was frustrated by the lack of research about consumer information needs and skills in relation to complementary medicines. A number of other reviews have confirmed that this information gap exists internationally, not just in Australia.[72,73,74]

Against this background, the Committee concluded that the priority at this point is to better understand information needs and skills, identify gaps, and develop appropriate strategies that include (where appropriate and justified by the study findings) the measures outlined previously. The Department of Health and

[72] Malcolm L, Medawar C, 2001. *Towards a consumer-led strategy for the quality use of medicines in Australia*. Commonwealth Department of Health and Aged Care, Canberra. <http://www.health.gov.au/haf/nmp/consumers/external.htm>

[73] House of Lords, 2000. Select Committee on Science and Technology, *op. cit.*

[74] White House Commission on Complementary and Alternative Medicine Policy, 2002. *op. cit.*

Ageing should commission a study to undertake these tasks, under the aegis of the QUM Strategy.

4.1.2 Consumers should be better informed about the regulatory framework for medicines, the differences in the processes for assessing the efficacy of Listed and Registered complementary medicines, and the levels of evidence for the efficacy of Listed complementary medicines.

One of the most important reasons people consume complementary medicines is to maintain or improve their health. It follows that better information about the effectiveness of these medicines is likely to lead to better consumption decisions.

Most complementary medicines are considered to be of relatively low risk, and under the Australian regulatory system are not evaluated for efficacy before supply. Unlike the situation with Registered medicines, where the medicines have undergone pre-market evaluation for efficacy by the TGA, consumers and healthcare professionals cannot be similarly assured of the efficacy of Listed medicines. However, available Australian research indicates that consumers want to assess complementary medicines information for themselves, and that these medicines should be shown to be effective to the same level as prescribed medicines.[75]

Some members of the Committee came to the view that some of the information provided to the TGA as part of the pre-market assessment process (see Recommendation 5) could be useful to consumers, and should be made available to them. In particular, they recommended that a summary of the information provided by sponsors to support product efficacy could be made available to the public, perhaps via publication on the TGA web site. If this were done, proprietary information (such as clinical trial details) would need to be kept confidential, and care would be required to ensure that undue costs were not imposed on medicine sponsors.

Some Committee members were opposed to the publication of summary efficacy data because it could allow some sponsors to duplicate information provided by their competitors, and generally increase the effort required by the regulator, thus raising costs to industry. Ultimately, the Committee agreed that, while summary efficacy evidence should be collected as part of the Listing process (subject to workable implementation arrangements being developed), publication should be considered only once the arrangement had been in place long enough for any problems to become apparent.

Information about efficacy can also be provided in other ways, including via labelling and Consumer Medicine Information (CMI). In the study proposed above, the Committee thought that the scope should include consideration of the level of evidence of efficacy, within a hierarchy of evidence, by whom the evidence of efficacy was assessed, and the nature of the evidence (scientific and/or traditional).

[75] MacLennan AH, Wilson DH, Taylor AW, 2002. The escalating cost and prevalence of alternative medicine. *Preventive Medicine*, 35, 166–173.

The Committee believed that consumers should have access to information about broader aspects of the regulatory process. In the aftermath of the Pan Pharmaceuticals recall and more recent findings of poor manufacturing practice, there are inevitably some questions about the effectiveness of the regulatory system. The Committee considered that Australia has a first-class regulatory system, and that consumers, in particular, should have confidence in it.

Some members considered that the current two-tiered regulatory system does not allow consumers and others to adequately distinguish those medicines that have been scientifically evaluated by the TGA and those that have not. It could be argued that this situation is unethical. Consumers need to be properly informed about the reliance they can place on the regulatory system. It is important they understand both what it does and what it does *not* do.

The way in which consumers are informed about the regulatory system is a matter that should be considered as part of the study mentioned previously.

4.1.3 Internet advertising should be considered part of mainstream advertising, and be subject to mainstream advertising requirements and protocols, including complaints resolution.

The Internet is a significant and growing medium for advertising complementary medicines. There are widespread concerns about the general quality of health information on the Internet (a US study published in 2002 reviewed 79 studies of health information quality, and concluded that only seven found quality to be adequate[76]).

Against this background, the majority of the Committee thought that Internet advertising of complementary medicines should be treated as mainstream advertising, and regulated as such. The only exception might be pre-approval requirements, which the Committee accepts may be impractical.

The Committee noted that regulatory amendments proposed by the TGA would achieve these objectives, and thus supports them.

4.1.4 The new advertising control framework being developed as part of the transition to a trans Tasman agency needs to ensure that communications by health professionals, educators and scientists are not unduly restricted.

The Committee noted the extensive review of advertising controls that is being undertaken in the lead up to the proposed establishment of a trans Tasman agency to regulate therapeutic products. It also noted that the new arrangements will be finalised after the completion of the Committee's work.

The Committee was concerned that, while the advertising framework being developed for the trans Tasman agency is fundamentally sound, essential exchanges of information between health professionals, educators and scientists could be frustrated if it is too narrowly implemented.

[76] Eysenbach G, Powell J, Kuss O, Sa E-R, 2002. Empirical studies assessing the quality of health information for consumers on the World Wide Web: a systematic review. *The Journal of the American Medical Association*, 287, 2691–2700.

The Committee was worried, in particular, about the breadth of the proposed first draft definition of advertisement (to include "imparting information or seeking to educate with a view to promoting the use, sale or supply of therapeutic products") and the associated requirement for compliance of *all* advertisements to health professionals and consumers. There was concern that activities such as public lectures and *bona fide* news publications could be unreasonably caught by the proposed new provisions.

The Committee wanted to make its concerns clear to those developing the new advertising arrangements, and encourage them to take care to ensure that they do not unreasonably constrain the dissemination of information and views that are in the public interest. Informal feedback from the IAC was that it had noted these concerns, and was taking them into account when developing the proposed new advertising framework.

RECOMMENDATIONS

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 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.

5 HEALTHCARE PRACTITIONERS

TERM OF REFERENCE ADDRESSED

This chapter focuses on the term of reference that requires the Committee to examine and provide advice on:

> *the education, training, and regulation requirements for healthcare practitioners who are supplying complementary medicines and/or providing advice or delivering care to consumers of complementary medicines.*

BACKGROUND

5.1 Practitioners

The number and type of healthcare practitioners who supply or provide advice to consumers on complementary medicines is large and varied. The group ranges from complementary healthcare practitioners such as naturopaths, traditional Chinese medicine (TCM) practitioners, and herbalists, to medical practitioners who may or may not provide complementary medicines to patients but need to be aware of the complementary medicines that patients may be using.

The New South Wales Health Department has categorised healthcare practitioners who provide complementary health services into three main groups:[77]

– registered health professionals working within the Western clinical model of medicine who have a formal qualification and a registration mechanism, e.g. medical practitioners, and pharmacists

– unregistered health professionals working within the Western clinical model of medicine who have a formal qualification but no formal registration mechanism, e.g. dietitians and psychotherapists

– practitioners working outside the Western clinical model of medicine, referred to as 'alternative' or 'complementary' healthcare practitioners.

5.1.1 Medical Practitioners

In 2000, there were approximately 56,000 medical practitioners in Australia, most of whom (approximately 47,000) were clinicians responsible for diagnosing and/or treating patients.[78] General practitioners (GPs) play an important role in providing advice to patients on complementary medicines. Over 90 per cent of GPs surveyed in Perth in 1999 indicated that, in the preceding nine months, over 30 patients had approached them for advice on complementary therapies.

[77] NSW Health Department, 2002. *Regulation of Complementary Health Practitioners – Discussion Paper*. NSW Health Department. <http://www.health.nsw.gov.au/quality/files/compmed_paper.pdf>

[78] Australian Institute of Health and Welfare, 2003. *Medical Labour Force 2000*. Bulletin No. 5. AIHW Cat.No.AUS-33. AIHW, Canberra. <http://www.aihw.gov.au/publications/aus/bulletin05/index.html

The list of complementary therapies included herbal medicine, homoeopathy, naturopathy and aromatherapy. However, most patient inquiries did not concern the use of complementary medicines.[79]

Additionally, studies have indicated that a significant number of GPs prescribe, administer or themselves use complementary therapies such as meditation, acupuncture and massage.[80] GPs also refer patients to complementary healthcare practitioners. The study of Perth GPs also noted that "none of the therapies referred to or used most often by Perth GPs involve ingestion or restriction of other products which may react with current medical treatment"[81].

5.1.2 Other Registered Health Professionals

There were over 14,000 pharmacists working in Australia in 1999, with the majority (80 per cent) working as community pharmacists[82]. Most community pharmacies in Australia sell complementary medicines and pharmacists play an important role in providing advice to consumers.

Nurses are also likely to provide advice on complementary medicines, although in the literature the focus of nursing interest appears to have been in complementary therapy modalities such as massage, acupuncture, meditation or aromatherapy.

5.1.3 Complementary Healthcare Practitioners

There are only rough estimates of the size of the complementary healthcare workforce.

The *1996 Census of Population and Housing* recorded approximately 4700 persons employed in complementary healthcare occupations: 1939 as naturopaths, 1710 as chiropractors, 464 as acupuncturists, 259 as osteopaths and 352 as natural therapists not elsewhere covered.

In 1996, it was separately estimated that the TCM practice workforce included 1500 practitioners whose primary health occupation was TCM.[83] It was anticipated that this population would double by the year 2000, with over 1100 students due to graduate from TCM-qualifying programs during the subsequent four years. It was estimated that there were at least 2.8 million consultations per year in TCM, which included 1.8 million consultations by non-medical practitioners.

In 2003, a workforce survey was undertaken of Western herbalists and naturopaths.[84] It is estimated that there are approximately 1750 individuals practising these professions, who account for 1.9 million consultations per year.

The Committee has not been able to obtain any other reliable information on the numbers of practitioners in complementary healthcare disciplines.

[79] Hall K, Giles-Corti B, 2000. Complementary therapies and the general practitioner: a survey of Perth GPs. *Australian Family Physician*, 29(6), 602–606.

[80] Pirotta MV, Cohen MV, Kotsirilos V, Farish SJ, 2000. Complementary therapies: have they become accepted in general practice? *Medical Journal of Australia*, 172, 105–109.

[81] Hall K, Giles-Corti B, *op. cit.*

[82] Australian Institute of Health and Welfare, 2003. *Pharmacy Labour Force to 2001*. AIHW Cat. No. HWL-25. Canberra, AIHW. <http://www.aihw.gov.au/publications/hwi/plf01/index.html>

[83] Bensoussan A, Myers SP, 1996. *Towards a Safer Choice. the Practice of Traditional Chinese Medicine in Australia*. Faculty of Health, University of Western Sydney, Sydney.

[84] Bensoussan A, Myers SP, Wu SM, O'Connor K, 2003. *A Profile of Naturopathic and Western Herbal Medicine Practitioners in Australia*. Centre for Complementary Medicine Research, University of Western Sydney, Sydney.

5.2 Professional Bodies

As with complementary healthcare practitioners, it is difficult to obtain reliable and comprehensive information on the organisations that purport to represent these practitioners. The Committee heard a range of estimates extending well beyond a hundred organisations. Schedule 1 to the Regulations (which concerns advertising directly to practitioners) alone lists some 41 bodies.

From 1 July 2003, a complementary medicine practitioner must be a 'recognised professional' to continue to supply services free of the goods and services tax (GST). The legislation defines a 'recognised professional' as a "practitioner registered under State or Territory law, or where there is no such law, a practitioner who is a member of a professional association with uniform national registration requirements".

The Australian Taxation Office (ATO) is understood to have recognised a significant number of professional associations for GST-exemption purposes.

As part of the GST reform package, the Australian Government allocated $500,000 to assist acupuncture, herbal medicine and naturopathy professional associations meet the definition of recognised professional for the purpose of providing GST-free services. This funding was provided to five professional associations representing the majority of complementary health practitioners, to establish uniform registration or regulation systems.

Three of the organisations that were funded, the Australian Traditional Medicine Society, the Australian Natural Therapies Association and Federation of Natural and Traditional Therapists, have established the Complementary Medicine Professional Associations Council.

5.3 Practice Risks

There are likely to be some risks associated with any healthcare practice. The extent of risk to the public is a threshold consideration for governments in determining whether to regulate a profession via legislation (see below).

The New South Wales discussion paper on regulation of complementary health practitioners[85] identifies two types of risk: risks associated with specific practices and/or modalities, and risks that are generic. The latter includes recommendations that patients withdraw from appropriate medical therapy; failure to detect serious underlying disease or to refer a patient on; mental trauma; unsubstantiated claims of therapeutic benefit; sexual misconduct; and financial exploitation.

Although complementary healthcare practice may be relatively safe compared to Western medicine, it is not risk-free, and fatalities have occurred. Importantly, it appears to pose greater risks than some regulated healthcare practices, such as osteopathy and chiropractic.

[85] NSW Health Department, 2002. *op. cit.*

5.4 Education and Training

5.4.1 Registered Healthcare Practitioners

Increasing acceptance among registered healthcare practitioners that many patients are using complementary medicines has led to moves, both in Australia and internationally, for educational institutions to include complementary medicines in course content.

Medical Practitioners

The Australian Medical Association acknowledges the increasing use of complementary medicine by patients and medical practitioners, and has emphasised the need for medical practitioners to obtain a basic understanding of complementary medicines through undergraduate, vocational and continuing education.[86] It believes that medical practitioners need to be informed about complementary medicines and that information sources, similar to those for mainstream medicines, should be developed for use by medical practitioners. This would assist in informing medical practitioners and enable medical practitioners to provide advice to patients.

Postgraduate courses in complementary medicine and therapies for medical practitioners are increasingly becoming available at tertiary institutions. A survey of Perth GPs found that 62 per cent of respondents indicated that they would like to undertake future training in complementary medicine modalities such as acupuncture, meditation, herbal medicine and hypnosis.[87]

The Australian Medical Council (AMC), in its role as a standards body for medical education in Australia, developed a position statement in 2000 on the role of what the AMC termed 'unorthodox' medical practice and medical education. Through its *Educational Guidelines for Medical Schools*, the AMC provides generic goals and objectives for medical education at the medical schools that it accredits. The AMC acknowledged that, due to the increasing popularity of complementary medicines among the population, medical graduates need to have an understanding of the scope of unorthodox medical practices, the needs that these practices meet, their effectiveness and safety, the extent of their use, and their costs. Medical practitioners also need to have the skills to discuss these issues with their patients.[88] It was noted that, at that time, all medical schools in Australia were addressing issues relating to unorthodox medical practice and that more than half were planning to expand their course offerings in this area.

Recent reviews in both the United States of America (the White House Commission on Complementary and Alternative Medicine Policy)[89] and the United Kingdom (House of Lords Select Committee on Science and Technology Report on Complementary and Alternative Medicine)[90] have identified the

[86] Australian Medical Association, 2002. *AMA Position Statement: Complementary Medicine*. <http://www.ama.com.au/web.nsf/doc/SHED-5FK4U9>

[87] Hall K, Giles-Corti B. *op. cit.*

[88] Australian Medical Council, 2000. *Undergraduate Medical Education and Unorthodox Medical Practice: AMC Position Statement.*

[89] White House Commission on Complementary and Alternative Medicine Policy, 2002. *White House Commission on Complementary and Alternative Medicine Policy, Final Report.* <http://www.whccamp.hhs.gov/finalreport.html>

[90] House of Lords, 2000. Select Committee on Science and Technology, 6th Report, *Complementary and Alternative Medicine*. The Stationary Office, London. <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/idselect/idsctech/123/12301.htm>

importance of training medical practitioners, so that their knowledge and understanding of complementary medicines enables them to have informed discussions with their patients.

This requires students to be familiar with the potential uses of complementary medicines, the procedures involved, their potential benefits, and their main weaknesses and dangers. Both reports also acknowledge that the vast majority of medical schools do include content on complementary medicines in their curricula, although there was a wide variation between medical schools in students' level of exposure to complementary and alternative medicines.

As studies on complementary medicines have only been included in medical school curricula relatively recently, these reviews concluded there was also a need to increase awareness among medical practitioners who are currently practising, through continuing professional development. The House of Lords Report recommended that the Royal Colleges support familiarisation of their members with complementary and alternative medicines through continuing professional development opportunities. The White House Report recommended that curricula be developed for postgraduate and continuing education programs.

Pharmacists

It is the policy of the Pharmaceutical Society of Australia that pharmacists who provide complementary medicines have an obligation to provide information and advice to consumers as they do with prescription medicines,[91] and complementary medicines are a component of the Society's continuing professional education arrangements. A survey in the *Australian Pharmacy Trade* (June 2000) found that 84 per cent of pharmacists believe that more information and training on complementary medicines is needed.

The Royal Pharmaceutical Society of Great Britain, in line with the Pharmaceutical Society of Australia, expects members to have sufficient competency and knowledge in the area when they provide advice to consumers on complementary medicines. The society states that pharmacists have a professional responsibility only to offer advice on homoeopathic or herbal medicines or other complementary medicines if they have undertaken suitable training or have specialised knowledge.[92] A survey of community pharmacists undertaken in 1997/98 found that 40 per cent of those who responded had received or undertaken some level of training, such as undergraduate course lectures, privately funded courses or employer-provided training, in complementary medicine.[93]

Registered Nurses

The Royal College of Nursing Australia has issued a position statement on complementary therapies in nursing practice. It states that use of complementary therapies in nursing practice is appropriate where a nurse practices within the limits of their skill and knowledge and that the College will resolve to support the profession in its attempt to integrate complementary therapies into nursing practice.

[91] Pharmaceutical Society of Australia 1997, *Policy – Complementary Medicines*. <http://www.psa.org.au/ecms.cfm?id=56>

[92] Royal Pharmaceutical Society of Great Britain, 1999. *Report on Complementary and Alternative Medicine. Response to the House of Lords Science and Technology Committee Sub Committee III.* <http://www.rpsgb.org.uk/pdfs/scireportcompmed.pdf>

[93] Barnes J, cited in Royal Pharmaceutical Society of Great Britain, 1999. *op. cit.*

The New South Wales Nurses Registration Board has also developed a policy statement on the use of complementary therapies by nurses. Nurses are expected to maintain a knowledge base and are responsible for ongoing education in their chosen areas of practice, and to be aware of their competency in the therapy and limits to which they can practice. Nurses are also required to observe the code of professional conduct that is adopted by the Board as well as legislative requirements.

5.4.2 Complementary Healthcare Practitioners

There is a general shortage of reliable data on the qualifications of complementary health practitioners in Australia.

Figures from the *1996 Census of Population and Housing* indicate that there were 2794 natural therapy professionals with a bachelor degree or higher qualification or at least five years of relevant experience.

Tertiary education courses in private colleges in Australia have been provided in naturopathy for four decades and in TCM for over three decades. Four courses that lead to a primary qualification in TCM are currently offered in Australian universities, and two in naturopathy. There are also training programs offered by private colleges that have achieved accreditation at the degree level from State educational authorities.

The majority of practitioners of herbalism and naturopathy services may not have qualifications at the bachelor degree level. Bachelor degree level courses in these disciplines have only become available relatively recently and, in any event, lack of qualifications is not a barrier to practice. A survey[94] of members of the Australian Natural Therapists Association found that 20 per cent of respondents had a Bachelors or Masters Degree in complementary medicine, while 71 per cent had a Diploma or Advanced Diploma, confirming that most education and training currently available to complementary health practitioners is in the Vocational Education and Training Sector.

A number of professional organisations, such as the Australian Traditional Medicine Society, The Australian Natural Therapies Association and the Federation of Natural and Traditional Therapists, have an educational standard of Advanced Diploma. It is expected that standards will continue to increase.

Training packages for some complementary medicines, such as Western herbal medicine, Ayurvedic medicine, homoeopathy and naturopathy, have been established by the Australian National Training Authority.

In New Zealand, private training institutes are the avenue through which most complementary medicine practitioners have obtained their qualifications. Most of these institutes are registered with the New Zealand Qualifications Authority. As is the case in Australia, there are several professional bodies that regulate their membership and some of these groups may require their membership to undertake continuing professional development.[95]

[94] Hale A, 2002. *Survey Data of the Australian Natural Therapists Association as Part of the Uniform National Registration Systems Project for Suitably Qualified Practitioners in Naturopathy, Herbal Medicine and Acupuncture*. Australian Natural Therapists Association, Maroochydore. <http://www.anta.com.au/survey.htm>

[95] Ministerial Advisory Committee on Complementary and Alternative Health, 2003. *Complementary and Alternative Medicine: Current Policies and Policy Issues in New Zealand and Selected Countries: Discussion Document.* Ministry for Health, Wellington, New Zealand. <http://www.newhealth.govt.nz/maccah/publications/htm>

5.5 Regulation of Complementary Healthcare Practitioners

There are essentially two approaches to the regulation of healthcare practitioners: statutory regulation and self-regulation. Co-regulation is a hybrid of these approaches and is on the continuum between statutory regulation and self-regulation.

The primary objective of statutory regulation is to ensure that the practice of any form of health care is safe to the public. When mutual recognition legislation was introduced across all States and Territories in the early 1990s, the policy rationale for occupational regulation of the health professions was clarified.

A nationally agreed process, established by the Australian Health Ministers' Advisory Council (AHMAC), has been in place since 1995. It states that occupational regulation of an unregulated profession is to proceed only if agreed by a majority of jurisdictions, and only if the profession meets specific criteria designed to facilitate the process of regulatory assessment.

The six criteria are summarised in Table 5.1, and include that it must be demonstrated that a professional practice presents serious risks to public health and safety, and that these risks can be minimised by regulation. In addition, regulation must be practical and possible to implement, the existing regulatory and other mechanisms must fail to address the health and safety issues identified, and the benefits to the public of regulation must clearly outweigh the potential negative impact of the regulation.[96]

Table 5.1 Criteria for assessing the need for statutory regulation of unregulated health occupations as agreed by the AHMAC in 1995.

Criterion 1	Is it appropriate for Health Ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within the domain of another Ministry?
Criterion 2	Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?
Criterion 3	Do existing regulatory or other mechanisms fail to address health and safety issues?
Criterion 4	Is regulation possible to implement for the occupation in question?
Criterion 5	Is regulation practical to implement for the occupation in question?
Criterion 6	Do the benefits to the public of regulation clearly outweigh the potential negative impact of such regulation?

The AHMAC Criteria have been reinforced by the implementation, since 1996, of the National Competition Policy, which requires that any restrictions on competition that are contained in legislation must satisfy the competition test, that is, the legislation should not restrict competition unless it can be demonstrated that: a) the benefits of the restriction to the community as a whole outweigh the costs; and b) the objectives of the legislation can only be achieved by restricting competition.

A 1996 workforce survey of TCM practitioners and a 2003 workforce survey of naturopaths and Western herbalists identified significant benefits from the introduction of occupational regulation.[97,98]

[96] Australian Health Ministers' Advisory Council, 1995. *Criteria for Assessing the Need for Statutory Regulation of Unregulated Health Occupations.* AHMAC, Canberra.
[97] Bensoussan A, Myers SP, 1996. *op. cit.*
[98] Bensoussan A, Myers SP, Wu SM, O'Connor K, 2003. *op. cit.*

Overall, practitioners perceived a more positive than negative change in professional status, standards of practice, standards of education, access to research infrastructure, postgraduate education, access to scheduled herbs and products, quality of herbs and products, and definition of occupational boundaries.

Practitioners were unsure of the likely effect of government regulation of practice on practitioner income, amount of litigation, patient cost, freedom of practice, and medical influence on practice. Respondents perceived no category of change as likely to be influenced in an overall negative fashion by the introduction of government regulation.

5.5.1 Recent Regulatory Initiatives

In 1996, the AHMAC agreed that the Victorian Government should lead the review of the practice of TCM. In addressing the AHMAC criteria for TCM, it was apparent that significant risks occurred in practice and that occupational regulation was appropriate for this profession. The Victorian Government developed a model for occupational regulation and passed the *Chinese Medicine Registration Act* in 2000. The Chinese Medicine Registration Board of Victoria registers Chinese herbal medicine practitioners, acupuncturists and dispensers of Chinese herbs and conducts investigations into complaints about registrants' professional conduct or fitness to practice. The stated purpose of this legislation is to protect the public.

The New South Wales (NSW) Department of Health issued a discussion paper on regulation of complementary health practitioners in September 2002. Comments were invited and submissions were received up to mid-April 2003. The stated result of the consultation process will be the development of a departmental position paper regarding the regulation of complementary health practitioners in NSW. The Committee understands that this should be issued in the latter part of 2003, and that any legislative initiatives are likely to proceed on a profession-by-profession basis.

In October 2002, Victoria commenced a review of health practitioner regulation in that State. The review is to focus on examining the current Victorian model of regulation; canvassing profession-specific options for reform; and updating relevant registration acts to contain common core provisions. The review timetable aims for Cabinet approval of legislation by February–March 2004.

At the time of the Victorian TCM review, it was understood that the findings pertaining to herbal medicine were not, on the whole, occupation-specific and that other practitioners using herbal medicine may pose similar risks to public health. Data were gathered in the 2003 workforce survey of the adverse events reported by naturopaths and Western herbalists to nutritional and homoeopathic medicines, which suggest that these areas are not without risk and should be subject to more extensive investigation.

Victoria has since commissioned a year-long research project on the risks, benefits and regulatory requirements for the professions of naturopathy and Western herbal medicine. The study is to be undertaken by a consortium led by La Trobe University, with a final report due by 30 June 2004.

To date, an assessment has not been undertaken to quantify the risks to public safety by complementary medicine practitioners that do not prescribe herbal medicine, including nutritionists, homoeopaths and aromatherapists.

In June 2002, the National Herbalists' Association of Australia (NHAA), in conjunction with the Federation for Natural and Traditional Therapists, published a discussion paper on a proposed model for self-regulation of the complementary medicine professions. The paper proposed a single Australian Council of Complementary Medicine, with six participating colleges.

The model was designed with a view to meeting the ATO requirements for establishing a single, uniform national accreditation scheme for the GST-free complementary medicine professions. However, since the ATO has determined that it will accept multiple schemes, the NHAA has put on hold further work on the scheme.

New Zealand established a Ministerial Advisory Committee on Complementary and Alternative Health in June 2001. It is funded to June 2004. A consultation process is under way, based on a discussion document issued in April 2003.[99] The discussion document notes that the New Zealand approach differs from other Western countries, in that it regulates on a national rather than State-by-State basis, and is proposing a single route to statutory regulation through a single, overarching act containing a framework for the governance and functions of registering authorities.

FINDINGS

5.1.1 Governments should move more quickly to nationally consistent, statutory regulation (where appropriate) of complementary healthcare professions.

There is clear evidence that the practice of TCM (including acupuncture and Chinese herbal medicine), Western herbal medicine, Ayurvedic herbal medicine and naturopathy have inherent risks of adverse outcomes, both predictable and unpredictable, which can (in extreme cases) be life-threatening. All of these professions involve the ingestion of herbal and other medicines, which can result in toxicity or allergic reactions.[100]

These inherent risks are containable but significant, and have resulted in a number of serious injuries and deaths. Injuries resulting from complementary medicine usage are also likely to be under-reported. The inherent risks may be exacerbated by:

– use of complementary medicine treatments in combination with Western clinical care and/or a failure of complementary medicine practitioners to refer to Western clinicians as necessary, for example, in cases of diabetes or epilepsy. Thus, recognition of the limits of a complementary medicine practitioner's scope of practice and adequate training in Western medicine are vital

[99] Ministerial Advisory Committee on Complementary and Alternative Health, 2003. *op. cit.*
[100] Bensoussan A, Myers SP, 1996. *op. cit.*

– practitioners who are untrained or poorly trained in their specific complementary medicine practice. There is evidence that practitioners who have not adhered to adequate standards and appropriate procedures have presented a threat to public health and safety[101]
– contaminated, adulterated or substituted herbal or other preparations used in patient treatment.

These factors, together with the increasing patronage of complementary medicine practitioners for primary care purposes or in combination with Western treatments, and the increasing numbers of practitioners with widely variable training offering complementary medicine, are likely to result in an increased propensity for realisation of these risks.

Medical stakeholders opposed to statutory registration for any complementary medicine profession have argued that statutory registration will confer undue recognition on professions whose practices are unproven, and that the evidence of harm caused by these professions is insufficient to justify legislative regulation. Others argue that these professions should establish uniform standards for training and practice before statutory registration should be considered by government.

The argument for uniform standards in advance of statutory registration presents a dilemma for these professions. With no enforceable barriers to entry to practice, and multiple, separate professional associations representing practitioners' interests,[102] consensus on standards of training is virtually impossible to achieve. It would require those with little or no training to agree that degree level training is required (the standard promoted by a number, but not all, of the peak professional associations).

Notwithstanding the fact that a strong *prima facie* case has been developed for legislatively based regulation of those professions involved in the ingestion of herbal medicines, the process of practice review and developing and implementing statutory regulation is unacceptably slow. This is evidenced by the time taken to regulate TCM practitioners in Victoria, and the subsequent failure of other jurisdictions to adopt the Victorian regime which it had been agreed would provide a model for all.

The Committee strongly supported the AHMAC resolutions in favour of nationally consistent regulatory arrangements, the development of model legislation in one jurisdiction for application in other jurisdictions, and the AHMAC criteria for regulation of unregistered health occupations. However, given the established risks, the Committee was concerned at the delays in moving to implementation. Further delays must be regarded as unacceptable, and all jurisdictions should introduce legislation to regulate TCM practitioners, based on the Victorian legislation, as soon as possible.

The Committee strongly supported the current NSW and Victorian reviews concerning regulation of complementary healthcare practitioners, and considers that all States and Territories should review the findings and move quickly to implement statutory regulation where justified.

[101] Bensoussan A, Myers SP, Wu SM, O'Connor K. 2003 *op. cit.*
[102] Bensoussan and Myers identified 23 separate professional associations representing practitioners of TCM and over 100 separate associations for the professions of naturopathy and Western herbal medicine.

5.1.2 Effective self-regulation needs to be more actively encouraged for all complementary healthcare professions.

Australian experience has shown that any moves towards statutory regulation of complementary healthcare professions are likely to take some time. In addition, irrespective of the extent and timing of any moves towards statutory regulation, there will be groups of complementary healthcare practitioners for which statutory regulation is not justified.

Against this background, transparent and accountable self-regulation needs to be actively encouraged for all healthcare professions involved in dispensing or advising consumers on complementary medicines, including those for which statutory regulation is appropriate but unlikely to be achieved in the short term.

A strong self-regulatory framework brings a number of benefits. In particular, the involvement of practitioners means that education, training and enforcement standards are likely to be informed by a thorough understanding of technical issues and the market in which the profession operates.

The Committee noted that conventional healthcare practitioners such as pharmacists, nurses and medical practitioners, and some complementary healthcare practitioners, have developed clearly stated and enforceable ethical frameworks for the care they deliver. It considered that similar standards need to be in place for all complementary healthcare professions.

To be effective, self-regulation requires transparent and accountable structures that are independent of any single professional association and are designed to protect the public rather than promote the interests of the profession concerned. The Committee considers that necessary attributes include:

- a certification system which incorporates:
  - appropriate standards of training for membership, established via a consultative process with the profession and endorsed by the relevant educational/industry authorities
  - an established, transparent procedure for assessing practitioner qualifications, incorporating an examination where necessary
  - effective incentives to ensure practitioners seek and maintain certification
  - annual requirements for continuing professional development (CPD) as a condition of continued certification
- a code of ethics with which certified practitioners agree to comply
- effective procedures for receiving, investigating and resolving consumer complaints
- an established disciplinary system for enforcing conduct and CPD requirements, able to investigate and apply sanctions where necessary, together with a process for appeals

– effective incentives for compliance with codes of practice as well as sanctions for non-compliance with standards of practice and other membership requirements
– external scrutiny and involvement of experts in the system who are not members of the profession, to promote transparency, accountability and credibility.

The Committee concluded that a reduction in the existing large number of organisations that claim to represent the various complementary healthcare disciplines is a key element of any move towards effective self-regulation.

In this regard, the Committee was concerned about the ATO's apparent acceptance of a wide range of organisations for the purpose of determining who may supply GST-free services. The Committee believed this could be interpreted as *de facto* recognition of bodies that are not representative of their professions, and militates against the development of strong, cohesive and representative professional bodies.

5.1.3 Education and training of all practitioners who prescribe or advise on the use of complementary medicines need to be strengthened and encouraged.

Educational standards amongst Australian-trained complementary medicine practitioners are extremely variable, due in large part to the plethora of professional associations and the lack of common standards to which they subscribe. The result is that neither the public nor other healthcare practitioners have a reliable way of assessing who is sufficiently or appropriately qualified for safe, competent practice.

The White House Commission recommended that there should be increased support for complementary medicine from the Federal and State governments and the private sector in the United States. This support would assist in evaluating and expanding complementary and alternative medicine faculty, curricula and program development.

The end result would be greater consumer satisfaction through the provision of complementary medicine from a skilled complementary health workforce.[103] The Commission also recommended that complementary medicine training courses should have greater uniformity and be accredited by national bodies (although it was noted that the development of national standards would be difficult for reasons associated with federalism and the variety of complementary and alternative medicine disciplines that are currently taught).

The United Kingdom (UK) House of Lords Select Committee on Science and Technology considered there was a great variation in the standards of many complementary and alternative medicines training institutions. As a result, the Select Committee recommended that training courses should become more standardised and be accredited by professional bodies. Their report noted that the quality and training within each therapy was closely linked to how successful each individual therapy had been in overcoming internal divisions and coming together under the auspices of a single body that had agreed to core objectives for education and regulation.

[103] White House Commission on Complementary and Alternative Medicine Policy, 2002. *op. cit.*

It was also important that education should continue beyond the attainment of an initial qualification. Both reports recognised that there were currently very few opportunities for postgraduate education and training in complementary medicine.

The White House Commission recommended that further research was required to determine the type of postgraduate education and training that would be beneficial to practitioners. It noted that continuing education needed to be further developed and provided to all healthcare professionals, and that currently there were more continuing education programs for conventional healthcare professionals than there were for complementary practitioners. In the UK, continuing professional education was considered to be uncommon in complementary and alternative medicines, and even among those disciplines that were viewed as being well developed, CPD was uneven. It was recommended that CPD be a core requirement for members of these associations.[104]

The Committee endorsed the consistent findings of both UK and US reviews. In particular, the Committee strongly supports the view that:

– high quality, accredited training of practitioners is vital in protecting the public
– responsibility for training standards should rest with the appropriate professional body
– partnerships between higher education and professional bodies are important
– all practitioners should receive independently accredited training.

RECOMMENDATIONS

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.

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.

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

[104] House of Lords, 2000. Select Committee on Science and Technology, *op. cit.*

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.

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.

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.

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.

6 INDUSTRY

TERM OF REFERENCE ADDRESSED

This chapter focuses on the term of reference that requires the Committee to examine and provide advice on:

> *the regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia.*

To protect and ensure a viable and responsible medicines industry in Australia, the Committee considered it essential that there be appropriate regulatory controls to safeguard against the actions of irresponsible medicines manufacturers and sponsors.[105] The Committee's consideration of regulatory controls to support a viable and responsible industry are detailed in Chapter 2.

BACKGROUND

6.1 The *National Medicines Policy* and the Medicines Industry

The Committee has been asked to examine and provide advice on the regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia. The Committee has been requested to consider its response in the context of the central objectives of the *National Medicines Policy* (NMP).[106]

The NMP is a framework based on partnerships that was launched in December 1999 (see Chapter 1). Each of the partners accepted that all must be engaged in a cooperative endeavour to bring about better health outcomes for all Australians, focusing especially on people's access to, and wise use of, medicines. The NMP recognises the importance of the medicines industry in, and the significant contribution it makes to, both health outcomes and economic development in Australia.

The NMP focuses first on people's needs and brings individual partner's skills, experience and knowledge to bear on the central objectives, namely:

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

The four objectives of the NMP are interdependent. For example, it is not possible to engender the quality use of medicines if people cannot afford the medicines they need. Nor is it possible to have quality use of medicines if the available medicines are not safe or effective, just as it is not sensible to have

[105] A sponsor of a therapeutic good is the person or company responsible for applying to the TGA to have their goods included on the ARTG. The sponsor must be a resident of Australia or carrying on a business in Australia.

[106] *National Medicines Policy, 2000.* Commonwealth Department of Health and Aged Care, Canberra. <http://www.health.gov.au/haf/nmp/pdf/nmp2000.pdf>

high-quality, effective medicines unless they are used appropriately. Three of these objectives of the NMP require the continued existence of a responsible and viable medicines industry in Australia.

All partners of the NMP need to enact their part of progressing the NMP in a manner that is both cognisant and respectful of the interrelationships and expertise of other partners. Different partners, or groups of partners, bear responsibility for the various outcomes, and to varying degrees. In broad terms, however, it is recognised that industry has prime carriage of work in advancing the main NMP objectives by identifying further opportunities and:

- providing medicines in a timely fashion at reasonable cost
- adhering to high research and development, manufacturing and regulatory standards
- ensuring truthful, balanced and understandable information is provided to health practitioners and consumers about medicines
- ensuring the best and most efficient practices are followed.

Other partners contributing to a responsible and viable medicines industry include:

- governments, by
  - promoting a regulatory system consistent with risk
  - promoting a regulatory system that is open and transparent and which facilitates timely access to medicines
  - where appropriate, a reimbursement regime for medicines
  - pursuing international harmonisation
  - ensuring a stable and conducive business environment for the industry
- consumers, by recognition of the benefits of accessing quality medicines and information
- health practitioners, by working with industry in research and development and educational initiatives.

6.2 *The National Strategy for Quality Use of Medicines*

A viable medicines industry is an important player in assisting the quality use of medicines (see Chapter 5 for the definition of the quality use of medicines), by supporting research and development, continuing professional education, ethical promotion, and the availability of appropriate information about medicines for consumers and health practitioners.

Efforts to ensure the quality use of medicines can have various effects on industry. For some conditions, where medicines appear to be under-used, quality use can increase sales and company profitability. However, in some cases, reducing over-use of certain medicines would reduce their sales.

The provision of good information about medicine use should assist quality use and also reduce adverse events, which may in turn help the industry by reducing

company liability. Product information needs to be factual and balanced for both healthcare practitioners and consumers. Product promotion that aims to achieve maximum market share can lead to irrational use inconsistent with the quality use of medicines.

6.3 Coordination of Industry Policy and Health Policy

The NMP recognises the need for industry policy and health policy to be coordinated to provide:

– a consistent and supportive environment for the complementary medicines industry
– appropriate returns for the research and development, manufacture, and supply of complementary medicines.

In consideration of the above needs, the following principles are important:

– the globalised economy encompasses the manufacture and sale of medicines, and the Australian (or Australian and New Zealand) market is scarcely large enough for economies of scale
– exports, especially to our region, must be encouraged
– the need for regulatory standards and their application to be harmonised (especially with Europe and North America, but more particularly with New Zealand and Asia)
– over-regulation and needlessly intrusive controls increase costs that may take the competitive edge away from Australian products
– at all times the medicines industry must serve the interests of consumers.

6.4 The Industry

Specific information regarding the size of the complementary medicines market in Australia is difficult to find as there are no audits, as such, on the complementary medicine industry and the industry is not uniformly covered by a single representative or governing body. Estimates of the current annual turnover of complementary medicines are approximately $800 million for retail and a further 20 per cent being exported (see Chapter 1 – *Introduction* for details).

6.5 Regulatory Controls

6.5.1 Listed Medicines

Evidence to Support Indications and Claims

Listed medicines may be supplied following application to the TGA by a sponsor of a product, and self-certification (and validation by the TGA) that certain key requirements comply with legislation. The *Therapeutic Goods Act 1989*[107] (the Act) requires that, at the time of Listing, sponsors must certify they hold the evidence to support indications and claims made in relation to Listable goods. The data held by a sponsor are confidential to the sponsor and are not in the public domain.

[107] *Therapeutic Goods Act 1989*. <http://scaleplus.law.gov.au/html/pasteact/0/400/top.htm>

However, much of the data used to support indications and claims for Listed complementary medicines are available in the scientific and traditional medicine literature, which means that more than one sponsor may use the same sources of evidence to support identical claims (see Chapter 2 – *The National Regulatory Controls for Complementary Medicines* for the Committee's consideration of evidence to support indications and claims for Listed medicines).

New Ingredients for Use in Listed Complementary Medicines

New ingredients for use in Listed complementary medicines are evaluated for quality and safety by the TGA in response to an application from a sponsor. Based on the data supplied by the sponsor and other data, a comprehensive evaluation report is prepared by the staff of the Office of Complementary Medicines (OCM). The evaluation report is put forward for consideration by the Complementary Medicines Evaluation Committee (CMEC), an independent expert statutory committee. Significant data must be submitted by a sponsor to the TGA as part of the evaluation of new substances for their suitability for use in Listed medicines.

While applications for new substance evaluation are treated as 'commercial in confidence' by the TGA, CMEC recommendations are published on the TGA website. For example, notice is given that the CMEC has recommended to the TGA that a particular substance is suitable for use in Listed medicines. However, before the substance is eligible for use, the TGA must make a decision to accept the CMEC recommendation and make formal notification in the Australian Government Gazette.

Once the substance is gazetted, a Compositional Guideline for the substance may be published on the TGA website and comment invited on the tests and limits that define the composition and description of the substance (see Chapter 2 – *The National Regulatory Controls for Complementary Medicines*.

Currently, Compositional Guidelines do not have legislative standing and are published by the TGA for comment before finalisation, alerting any interested party. The call for comment on the Composition Guideline may result in some compositional specifications being broadened (without compromising safety), which may permit other sponsors to comply with the guideline and reduce the commercial incentive for innovation in developing new substances for use in Listed medicines. This disadvantages the company that has developed a well-defined substance and has undertaken research to support its evaluation and use in Listed medicines.

When a complementary medicine substance is approved for use as an ingredient in Listed medicines, any sponsor may use that ingredient, provided that the sponsor meets any regulatory requirements and holds appropriate evidence to support the indications and claims included in the Australian Register of Therapeutic Goods (ARTG) for the product.

Registered Medicines

Registered complementary medicines, depending on the risk associated with the individual product, are evaluated to the comparable standards of quality,

safety and efficacy as required for over-the-counter (OTC) and prescription medicines.

Based on the data supplied by the sponsor, and other data, a comprehensive evaluation report is prepared by the staff of the OCM. The evaluation report is put forward for consideration by the CMEC.

The CMEC makes recommendations to the TGA as to the suitability or otherwise for inclusion of the product on the ARTG as a Registered medicine, and the TGA makes a regulatory decision based on those recommendations and any other factors deemed relevant.

In the case of Registered complementary medicines for which serious disease claims are made (see Chapter 4 for definition of serious disease), these products are evaluated by the OCM and reviewed by the CMEC in consultation with the prescription medicines expert committee, the Australian Drug Evaluation Committee (ADEC).

To date, relatively few sponsors use the registration process for complementary medicines.

6.5.2 New Regulatory Safeguards for a Responsible Industry

To protect and ensure a viable and responsible medicines industry in Australia, the Committee considered it essential that regulatory controls should provide safeguards against irresponsible actions by medicines manufacturers and sponsors.

Following the failure of Pan Pharmaceuticals Limited to meet its regulatory obligations, and the resulting recall of medicines (see Chapters 1 and 2), the Australian Government introduced legislation to strengthen the regulatory framework. The legislative amendments were passed by the Parliament and received Royal assent on 27 May 2003. They provide the TGA with enhanced powers to deal with breaches of regulatory requirements, and to address difficulties that arose as a result of the recall. The Committee has considered regulatory controls in Chapter 2.

According to Australia's NMP, international competitiveness will be achieved only if Australian industry can operate in a global environment. Thus, regulatory partners should be committed to early achievement of harmonisation of standards and/or mutual recognition, and to the promotion of a strong export culture consistent with standards and ethics endorsed by the World Health Organization.

Intellectual property protection should be in line with international standards, and medical research and innovation supported.

6.6 Complementary Medicines Research

A viable and innovative complementary medicines industry is dependent on research to underpin the quality, safety and efficacy of complementary medicines and to develop new products.

There is a substantial body of clinical research in complementary medicine. The Cochrane Controlled Trials Register records 641 clinical trials of acupuncture, 666 of herbal medicine, and 124 of homoeopathy, as of August 2003. However, the field of application of complementary medicine is very diverse, and many complementary medicine trials are criticised as methodologically weak. The Committee considered that there are several obstacles peculiar to complementary medicine research that deserve attention:

– There is difficulty in securing intellectual property (e.g. patenting a product) to justify research investment. Many complementary medicines are based on traditions of practice. This presents some difficulties in claiming prescriptions/treatments as new intellectual property, and if intellectual property cannot be protected, then there is limited market advantage for a company to justify research investment. The lack of 'market exclusivity' for most complementary medicines was noted as a disincentive for industry to support research in these medicines.
– Some complementary medicines have low scientific credibility; their mechanisms of action are unclear. This may be a deterrent to scientific review committees when prioritising research funds.
– Many complementary medicines are complex interventions (many components). This poses enormous challenges to pharmacological research in understanding the potentially synergistic effects of numerous herbal components.
– Complementary medicine treatments are often individualised (tailored to the patient) and based on a different diagnostic process to those of mainstream medicine. Some complementary medicine practices use theories that differ from those of mainstream medicine to diagnose and guide treatment. Hence, to be faithful to the modality under examination, some methodological accommodation may be required in a randomised control trial of a complementary medicine. This increases the complexity and cost of complementary medicine research.

There is a substantial gap between the extensive use of complementary medicines and the evidence to support that use. While complementary medicines may improve health, reduce disease, and reduce health costs, the Committee considered that industry alone cannot be expected to support the research to answer these questions. This is, in part, because of difficulties identified above, and in part because, like conventional medical research, there is a social responsibility for government to fund such research.

The Committee noted the disparity between public funding for prescription/OTC medicines research and that for complementary medicines research, the apparent lack of success of applications for research grants involving complementary medicines and especially the possibility of a bias directed against complementary medicines.

6.6.1 *International Approaches to Funding Complementary Medicine Research*

United Kingdom

The UK House of Lords Select Committee on Science and Technology – 6th Report on *Complementary and Alternative Medicine*[108] recommended that dedicated research funding be made available to develop a few centres of excellence for conducting complementary medicine research.

Funds are to be dedicated to the area for a limited period, to help develop the infrastructure needed to underpin substantial high-quality research, which will then attract more substantial funds. Host institutions have been identified to provide methodological advice, skills development and research support, and post-doctoral research fellowships have been made available to these centres of excellence. Applicants and host institutions jointly develop proposals for these post-doctoral research fellowships. The advantages of this method are that it invests in enthusiasm, while maintaining a broad competition base, and creates a supportive environment that allows for mentoring, appropriate review and generation of quality proposals. This process also helps to develop the infrastructure needed to underpin substantial high-quality research, which will then attract more substantial funds.

USA

The White House Commission on Complementary Medicine and Alternative Medicine Policy[109] recommended that:

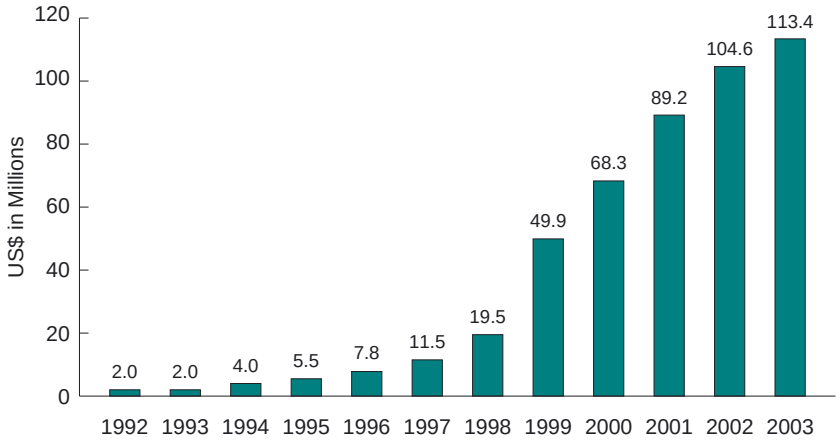
- federal agencies should receive increased funding for clinical, basic and health services research on complementary medicine
- Congress and the administration should consider legislative and administrative incentives to stimulate private sector investment on research on complementary medicine products that may be patentable
- federal, private and nonprofit sectors should support research on complementary medicine modalities and approaches that are designed to improve self-care and behaviours that promote wellness
- federal, private and nonprofit sectors should support innovative research on core questions posed by complementary medicine in frontier areas of scientific study that might expand our understanding of health and disease.

The US Senate has dedicated money for complementary medicine research. The Office of Complementary and Alternative Medicine was established in 1992 and has grown to become the National Centre for Complementary and Alternative Medicine (NCCAM), the 27th Institute of the National Institutes of Health. In 2003, it had a budget of $US113.4 (Figure 6.1) to fund research projects and to strengthen research infrastructure. The NCCAM funds 11 key focus centres, in part to draw complementary medicine practitioners and experts into the fold of a larger research enterprise.

[108] House of Lords 2000. Select Committee on Science and Technology. 6th Report. *Complementary and Alternative Medicine*, The Stationary Office, London. <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm>

[109] White House Commission on Complementary and Alternative Medicine Policy, 2002. *White House Commission on Complementary and Alternative Medicine Policy, Final Report.* <http://www.whccamp.hhs.gov/finalreport.html>

Figure 6.1 US National Center for Complementary and Alternative Medicine funding, 1992–2003. Source: NCCAM website <http://nccam.nih.gov>



Germany

In Germany, health insurers, research foundations and the State provide funding for some complementary medicine research projects.

FINDINGS

6.1.1 The objectives of the *National Medicines Policy* are interdependent and require a responsible and viable medicines industry.

The objectives of the *National Medicines Policy* (NMP) are interdependent and require a responsible and viable medicines industry in Australia. Industry has prime carriage of work in advancing the main NMP objectives by:

- providing medicines in a timely fashion at reasonable cost
- adhering to high research and development, manufacturing and regulatory standards
- ensuring truthful, balanced and understandable information is provided to health practitioners and consumers about medicines
- ensuring best and most efficient practices are followed
- identifying further opportunities.

Other partners also contribute to a responsible and viable medicines industry, namely:

- governments, by
  - promoting a regulatory system consistent with risk

- promoting a regulatory system which is open and transparent which facilitates timely access to medicines
- where appropriate, a reimbursement regime for medicines
- pursuing international harmonisation
- ensuring a stable and conducive business environment for the industry

– consumers, by recognition of the benefits of accessing quality medicines and information

– health practitioners, by working with industry in research and development and educational initiatives.

A viable, innovative and responsible complementary medicines industry is dependent on research to support quality, safety, efficacy, cost-effectiveness and to develop new products.

6.1.2 Incentives are needed to encourage innovation and research in complementary medicines.

When the TGA approves a substance for use as an ingredient in Listed medicines, any sponsor may use that ingredient provided that the sponsor holds appropriate evidence to support the indications and claims included in the ARTG for the product. Where a Compositional Guideline is required for a substance (see Chapter 2 – *The National Regulatory Controls for Complementary Medicines*) the TGA calls for comment before finalisation of the guideline. Comment on the Compositional Guideline may result in some specifications being broadened and may permit other sponsors to comply with the guideline reducing commercial incentive for innovation in developing new substances for use in Listed medicines. This disadvantages the company which has developed a well defined substance and has undertaken research to support its evaluation and use in Listed medicines.

An innovative, responsible and viable complementary medicines industry is dependent on incentives to encourage innovation and research to underpin the quality, safety and efficacy of complementary medicines and to develop new products. Other stakeholders, such as healthcare professionals, also require incentives to undertake research into complementary medicines.

There is a need to identity ways to support innovation and complementary medicine research by industry, especially for products which are not patentable or ‘off patent’ (as is the case for many complementary medicines). Currently there is little or no financial incentive to support the development of new indications and new complementary medicines if there is little or no possibility of market exclusivity or the protection of data.

There is a substantial gap between the extensive use of complementary medicines and the evidence to support that use. For various reasons, including lack of financial incentive, there is relatively little research undertaken in Australia to support the use of complementary medicines.

6.1.3 There is need for dedicated government funding for complementary medicines research.

Whilst complementary medicines may improve health, reduce disease, and reduce health costs, industry alone cannot be expected to support the research to answer these questions. This is partly because of the lack of financial incentives for industry, and partly because, like mainstream medical research, there is a social responsibility for government to fund such research.

Approaches in the UK and the USA, where 'seed' funding and dedicated funding were available, provided sufficient impetus to establish and continue an effective complementary medicine research program. By comparison, the research infrastructure for complementary medicine in Australia is not well developed.

Funding should be sought on a *per capita* basis, comparable with the extent of complementary medicine research funding in the USA.

6.1.4 The disparity between public funding for prescription/over-the-counter (OTC) medicines research and complementary medicines research needs to be addressed.

The Committee noted the disparity between public funding for prescription/OTC medicines research and that for complementary medicines research, and the apparent lack of success of applications for research grants involving complementary medicines and especially the possibility of a bias directed against complementary medicines.

6.1.5 Relatively few sponsors use the registration process for complementary medicines.

The Registration of a medicine is product-specific, which provides data protection and market exclusivity. Sponsors should be encouraged to undertake the research necessary to generate the data required for Registration of complementary medicines.

To date, relatively few sponsors use the Registration process for complementary medicines. This may be due to:

– lack of incentives, including the protection of data and lack of patentability
– difficulties encountered in meeting the current data requirements for the Registration process
– lack of clarity and transparency of the evaluation process for Registration
– lack of guaranteed time lines provided by the TGA for the Registration of complementary medicines.

Compared with other medicines, complementary medicines may offer lower risk and more cost-effective options for the prevention and treatment of some diseases, conditions and disorders. To explore options for increasing the number of applications to the TGA for the Registration of complementary medicines, the TGA should, in consultation with stakeholders and as a priority, review the process for Registration of complementary medicines taking into account:

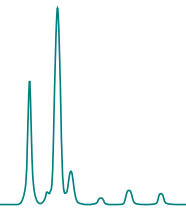
– the complex nature of many complementary medicines and the associated difficulty of characterising ingredients and identifying the active ingredient/components
– that in clinical studies it may not be feasible to undertake conventional pharmacokinetic and pharmacodynamic studies and measurements
– that, for some indications (especially those with preventive rather than treatment functions), complementary medicines may offer a lower risk and potentially more cost-effective option compared with other medicines.

In considering the process for the Registration of complementary medicines, and consistent with the TGA's risk-based approach to regulation, the review should consider the application of a risk matrix that acknowledges various categories of risk to provide guidance on the requirements for Registration.

RECOMMENDATIONS

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).
34. Dedicated funding be made available for complementary medicine research in Australia for a minimum of five years.
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.
36. A database be established to identify researchers and centres of excellence to facilitate complementary medicine research in Australia.
37. The TGA develop formal links with appropriate international centres involved in complementary medicine research to facilitate coordination of research effort and minimise duplication.
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.

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.
40. The TGA convene a stakeholder group to identify incentives to encourage innovation and research in complementary medicines, including data protection and market exclusivity.



7 ADMINISTRATIVE AND ADVISORY MECHANISMS

Administrative and advisory bodies are important means through which policy is developed and implemented.

In responding to its terms of reference, the Committee has made a number of findings and recommendations about what it believes should be done. In doing so, the Committee was conscious that the manner in which the TGA, other government agencies and various advisory committees are involved in carrying forward the initiatives that flow from this report will be critical in determining their success.

BACKGROUND

7.1 The Office of Complementary Medicines

The Office of Complementary Medicines (OCM) is a unit within the Therapeutic Goods Administration (TGA).

In December 1998, a working party of industry, consumer and government representatives was established under the Chairmanship of Senator Grant Tambling to consider the regulation of complementary medicines by the TGA.

A package of improvements and refinements to the regulation of complementary medicines was developed by the working party and subsequently endorsed by all bodies. It included major policy reforms, legislative amendments and new administrative procedures to facilitate advice and consultation, and information initiatives.

The legislation underpinning the reform package was proclaimed on 1 April 1999 and the new initiatives, including the new OCM, were officially launched in late April 1999.

Within the TGA, the OCM was created to focus exclusively on the regulation of complementary medicines. It is staffed by qualified and experienced personnel with an understanding of complementary medicines and related issues.

The OCM was established to:

– provide a genuine government focus for the regulation of complementary medicines
– increase the transparency of complementary medicines regulation
– develop more formal and lasting links with the industry, the academic community, consumers and government.

Responsibilities of the OCM include:

– consulting and liaising with interest groups to foster cooperation and confidence in the regulatory arrangements for complementary medicines
– evaluating data in order to make assessments for Listed and Registered complementary medicines
– providing support to the Complementary Medicines Evaluation Committee (see below)
– providing advice to the Minister and TGA on the regulation of complementary medicines and associated matters.

7.2 Advisory Bodies

7.2.1 Australian Pharmaceutical Advisory Council (APAC)

The Australian Pharmaceutical Advisory Council (APAC) was formed in 1991, reflecting the Australian Government's support for the *National Medicines Policy* (NMP) framework and a partnership approach to policy development. The APAC represented an opportunity for all interested parties to contribute positively on a multi-lateral and consensus basis to the development and conduct of the NMP. Policies were developed and implemented over several years, with a further major review during 1999. In late 1999, the revised policy was launched with whole-of-government support.

The APAC includes representatives of peak health professions, pharmaceutical, over-the-counter (OTC) and complementary medicines industries, and consumer organisations, as well as government members with an interest in the application and implementation of Australia's NMP.

The APAC's mission is to "through a partnership approach, develop, promote, influence and assist in the implementation of the *National Medicines Policy* in Australia".[110] This involves:

– advising and making recommendations to the Minister on identified priority issues
– identifying specific issues where success is dependent on cooperation between specific stakeholders
– facilitating and coordinating actions on priority issues relevant to the NMP
– monitoring outcomes
– evaluating effectiveness.

7.2.2 Pharmaceutical Health And Rational use of Medicines (PHARM) Committee

The Pharmaceutical Health And Rational use of Medicines (PHARM) Committee was first established as a working party in 1991, then upgraded to full committee status in October 1992. Membership of the PHARM Committee is by appointment by the Minister for Health and Ageing.

[110] *National Medicines Policy*, Canberra, Australian Government Department of Health and Ageing. Last Modified: 20 November 2002. <http://www.health.gov.au/haf/nmp/advisory/apac.htm>

This multidisciplinary committee:

– promotes and reviews the Quality Use of Medicines (QUM) policy
– oversees its implementation
– provides expert advice to the Minister for Health and Ageing and the Department of Health and Ageing on the QUM strategy.

7.2.3 Complementary Medicines Evaluation Committee (CMEC)

The reform package which resulted in the creation of the OCM also included the Complementary Medicines Evaluation Committee (CMEC) (initially established in December 1997) becoming a statutory expert committee under the *Therapeutic Goods Act 1989* (with expert advisers to be called upon as and when required).

In addition to evaluating new substances for use in complementary medicines, CMEC considers the level and quality of evidence to support indications and claims included in the ARTG for products, and the level and quality of evidence to support the safety of long-term continuous use of complementary medicines.

The TGA provides the secretariat and supports the functions of CMEC.

7.2.4 National Co-ordinating Committee on Therapeutic Goods (NCCTG)

The National Co-ordinating Committee on Therapeutic Goods (NCCTG) was established in 1971 by the Federal Executive Council (which was itself established by section 62 of the Constitution to "advise the Governor-General in the government of the Commonwealth").

In 1986, the Federal Executive Council Order creating the NCCTG was revoked to facilitate the establishment of the NCCTG as a committee of the Australian Health Ministers' Advisory Council (AHMAC).

The functions of the Committee include taking actions necessary to bring about coordination of legislative and administrative controls on therapeutic goods and to make recommendations to the AHMAC as necessary.

The Committee is serviced by the TGA.

7.2.5 The National Drugs and Poisons Schedule Committee (NDPSC)

The National Drugs and Poisons Schedule Committee (NDPSC) was established under section 52B of the *Therapeutic Goods Act 1989* and is comprised of State and Territory government members and other persons appointed by the Minister, such as technical experts and representatives of various sectional interests.

The NDPSC publishes the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) which contains the decisions of the NDPSC in relation to medicines scheduling. These decisions have no force in Commonwealth legislation but are recommendations for incorporation into State and Territory drugs/poisons legislation.

The TGA provides the secretariat and supports the functions of the NDPSC.

7.2.6 External Reference Panel on Interface Matters (ERPIM)

The External Reference Panel on Interface Matters (ERPIM) consists of representatives from the TGA, Food Standards Australia New Zealand (FSANZ), State/Territory and New Zealand health authorities, the Australian Quarantine Inspection Service, industry and consumers.

The Panel was established, to provide advice on matters at the interface between therapeutic goods and foods.

7.3 Quality Use of Medicines Indicators

The Department of Health and Ageing has developed a set of indicators[111] to measure the implementation and effect of Australia's *National Strategy for Quality Use of Medicines* (QUM). The indicators were developed through a consultative process and "generally seek to cover both prescription and OTC medicines in Australia". It is noted, however, that available data are limited to prescription medicines in some instances.

The QUM indicators are of three types: process indicators, impact indicators and outcome indicators. There are 67 process indicators, 63 impact indicators, and 6 outcome indicators.

FINDINGS

7.1.1 Committees providing advice on the research and use of medicines should have members with expertise and practical experience in the use of complementary medicines

Available evidence shows that the use of complementary medicines in Australia is widespread, and that the complementary medicines industry is significant in terms of monetary turnover. The QUM explicitly includes complementary medicines within its definition of medicines.

It follows that government medicines policy and programs should be informed by advisory committees whose membership incorporates expertise in complementary medicines.

Several members of the Committee serve on advisory bodies (including APAC), and all believe that there would be benefit in enhancing these committees to include members with specific knowledge and expertise in complementary medicines. In particular, there is a need to include experienced complementary healthcare practitioners.

APAC provides the primary forum for the engagement of all stakeholders in discussion, debate and resolution of issues arising from the application of the NMP. Given its role and broad membership, the Committee considered that APAC should be the vehicle for Government consultation on complementary medicines.

[111] Department of Health and Ageing, 2002. *Manual of Indicators to Measure the Quality Use of Medicines Component of Australia's National Medicines Policy,* 2nd Edition. Canberra. <http://www.nmp.health.gov.au/pdf/manualqum.pdf>

The Committee was concerned in particular that the complementary medicines industry pursue a proactive role in APAC, taking advantage of the opportunities APAC provides to raise and address the range of complementary medicines issues. The Complementary Healthcare Consultative Forum, having fulfilled its initial purpose, is no longer required and should be formally disbanded.

The Committee also considered that the names of advisory bodies should reflect their roles as accurately as possible. Given the breadth of its role, the Committee believes that APAC should be renamed the 'Australian Medicines Advisory Council'.

7.1.2 *The National Strategy for Quality Use of Medicines* (QUM) should focus greater attention on complementary medicines.

Of the 136 indicators being used to measure the implementation and effect of the QUM, none explicitly incorporates complementary medicines. Several of the process indicators make reference to professions involved in the use of medicines. While medical, pharmacy and nursing professions are identified, no reference is made to complementary healthcare professions, either individually or as a group. Impact indicators (such as reports of adverse drug reactions) similarly fail to cite complementary healthcare professions when identifying professional groups.

The QUM database[112] lists 1134 projects. A search of the database for 'complementary medicines' identified only 10 projects.

The Committee supported the range of QUM initiatives that have been adopted, and accepted that the relatively low risk of most complementary medicines and the lack of related data mean that the focus of projects and data gathering under the QUM is appropriately on prescription medicines. Nevertheless, the Committee concluded that complementary medicines merit greater attention than they currently receive under the QUM.

The Committee concluded that APAC should facilitate a consultation process with the complementary medicines sector and other stakeholders to clarify the position of complementary medicines in the NMP and the QUM.

In addition, the Committee found that there is a particular need to fund consumer and practitioner education initiatives relating to complementary medicines. This role falls within the ambit of the QUM strategy, and should not be left by default to the TGA, with resultant pressure on cost recovery from industry.

7.1.3 Accountability for the implementation of the Committee's recommendations needs to be clearly assigned, adequate resources need to be provided, and the process must be actively managed and reviewed.

In addition to Government endorsement, successful and timely implementation of the Committee's recommendations will require careful management and adequate resourcing.

[112] *Quality Use of Medicines – Ensuring Australians Use Medicine Wisely:* QUM Database Search, Canberra, Commonwealth Department of Health and Ageing. Last Updated: 22 September 2003. <http://www.qummap.health.gov.au/>

The Committee was aware that implementation would require the active involvement of a number of parties, including State and Territory governments, Australian Government agencies, advisory committees, and industry and consumer representatives. It was also conscious that there is a logical progression through some of its recommendations (e.g. significant changes to consumer information mechanisms should follow the proposed study of information needs and strategies), and that many of them would be progressed through existing mechanisms (such as advisory committees and various trans Tasman initiatives).

In this environment, active coordination will be needed to avoid related steps becoming disconnected or disjointed. Successful implementation will also rest on a clear sense of priorities, responsibilities, and timing.

The Committee concluded that an implementation plan should be developed as a first step following the Government's response to this report, and that the plan should be completed within the following month. The outline at Appendix 3 reflects the Committee's expectations of a practical implementation timetable.

The Committee was firmly of the view that overall responsibility for implementing its recommendations needs to be clearly assigned to a single position or body, and that they be held accountable for ensuring that implementation proceeds in a timely fashion. In addition, a review of progress with implementation should occur towards the end of 2004. This would be designed to ensure that any unnecessary delays or problems are identified and corrective action taken. The prospect of a review would also provide an incentive to proceed with implementation as quickly as possible.

The Committee was also concerned that adequate resources be made available to enable its recommendations to be taken forward, and that costings will need to be developed. In doing so, the Committee was mindful that the TGA's activities are fully funded via cost recovery from industry. As a general proposition, the Committee believed that only those initiatives that are clearly part of the TGA's regulatory role should be funded in this way. Where this is not the case (such as consumer education under the QUM strategy), funding should be derived from existing sources or additional funds should be explicitly provided.

RECOMMENDATIONS

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.

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).

43. *The National Strategy for Quality Use of Medicines* (QUM) fund more projects directed at education in the use of complementary medicines.

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.

45. The Australian Pharmaceutical Advisory Council (APAC) be renamed the Australian Medicines Advisory Council.

46. The Complementary Healthcare Consultative Forum be formally disbanded subject to the fulfilment of Recommendation 41.

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.

48. Overall accountability for implementing the Committee's recommendations be clearly assigned to a single body.

49. Implementation of the Committee's recommendations be formally reviewed at the end of 2004.

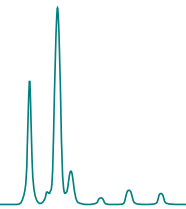
This page has been left blank intentionally.

APPENDIX 1

ABBREVIATIONS

ABS	Australian Bureau of Statistics
ACCC	Australian Competition and Consumer Commission
ADEC	Australian Drug Evaluation Committee
ADR	adverse drug reaction
ADRAC	Adverse Drug Reactions Advisory Committee
ADRS	Adverse Drug Reaction (Reporting) System
ADRU	Adverse Drug Reactions Unit (of the TGA)
AHMAC	Australian Health Ministers' Advisory Council
AMC	Australian Medical Council
APAC	Australian Pharmaceutical Advisory Council
ARGCM	*Australian Regulatory Guidelines for Complementary Medicines*
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self-Medication Industry
ATO	Australian Taxation Office
AUST L	ARTG Listing (number)
AUST R	ARTG Registration (number)
BP	British Pharmacopoeia
CHC	Complementary Healthcare Council of Australia
CHF	Consumers' Health Forum
CM	Complementary Medicine (aka in USA and UK as CAM, Complementary and Alternative Medicine)
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicine Information
CMPAC	Consumer Medicine Professional Associations Council
CPD	Continuing Professional Development
CRP	Complaints Resolution Panel
ERPIM	External Reference Panel on Interface Matters
FSANZ	Food Standards Australia New Zealand (formerly ANZFA)
GMP	Good Manufacturing Practice
GP	general practitioner
GST	goods and services tax
IAC	Interim Advertising Council
ICPEN	International Consumer Protection Enforcement Network
MEC	Medicines Evaluation Committee

NCCAM	National Center for Complementary and Alternative Medicine (of USA)
NCCTG	National Co-ordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NHAA	Natural Herbalists' Association of Australia
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health (of USA)
NMP	*National Medicines Policy*
NPS	National Prescribing Service Limited
NSW	New South Wales
OCM	Office of Complementary Medicines (of the TGA)
OTC	over-the-counter (medicines)
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PHARM	Pharmaceutical Health and Rational use of Medicines (Committee)
PI	Product Information
PIIP	Pharmaceutical Industry Investment Program (Assessment Panel)
QUM	*The National Strategy for Quality Use of Medicines*
SUSDP	*Standard for the Uniform Scheduling of Drugs and Poisons*
TCM	traditional Chinese medicine
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
TGAC	*Therapeutic Goods Advertising Code*
TGACC	Therapeutic Goods Advertising Code Council
TGO	Therapeutic Goods Order
TTMRA	Trans Tasman Mutual Recognition Arrangement
UK	United Kingdom
USA	United States of America
WHO	World Health Organization



APPENDIX 2

GLOSSARY OF COMPLEMENTARY HEALTHCARE PRACTITIONERS

This glossary was compiled based primarily on the descriptions contained in the New South Wales Health Department discussion paper,[113] with supplementation from the Victorian Government website – *Better Health Channel*,[114] the House of Lords Report,[115] *The Desktop Guide to Complementary and Alternative Medicine – An Evidence Based Approach*,[116] the American Association of Naturopathic Physicians and the *Gale Encyclopedia of Alternative Medicine*.[117] This list is not intended to be all-inclusive, but rather it is an attempt to provide an indication and framework for the main types of complementary medicines and to identify those modalities utilising complementary medicines.

TRADITIONAL MEDICINE SYSTEMS

1.1 Traditional Chinese Medicine

Traditional Chinese medicine (TCM) is diverse and is used to treat both acute and chronic illness. Modalities used in practice include Chinese herbal medicine (including plant, animal and mineral substances), acupuncture, Chinese massage, dietary and lifestyle advice, and specific techniques such as moxibustion and cupping, breathing, movement, meditation, orthopaedic manipulations and surgery.

1.1.1 Acupuncture

Acupuncture involves the stimulation of specific points on the skin, usually by the insertion of needles for therapeutic or preventative purposes. The original form of acupuncture was based on the principles of TCM which state that the workings of the human body are controlled by a vital force or energy called 'qi', which circulates between the organs along channels called meridians.

Traditional acupuncturists use an Oriental medicine framework for referring to disturbances thought to cause symptoms, however many conventional healthcare professionals who practice acupuncture have dispensed with such

[113] NSW Health Department, 2002. *Regulation of Complementary Health Practitioners – Discussion Paper*. NSW Health Department. <http://www.health.nsw.gov.au/quality/files/compmed_paper.pdf>

[114] *Better Health Channel: Reliable Health Information and Services – Quality Assured by the Victorian (Australian) Government*. <www.betterhealth.vic.gov.au>

[115] House of Lords 2000. Select Committee on Science and Technology. 6th Report. *Complementary and Alternative Medicine*, The Stationary Office, London. <http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm>

[116] Ernst E (Ed.) 2001. *The Desktop Guide to Complementary and Alternative Medicine – An Evidence Based Approach*. Harcourt Publishers Ltd, Edinburgh.

[117] Helwig D, 1995. Kampo medicine. *Gale Encyclopedia of Alternative Medicine*. <http://www.findarticles.com/cf_dls/g2603/0004/2603000471/p1/article.jhtml?term=kampo+medicine>

concepts, with acupuncture points thought to correspond to physiological and anatomical features.

Traditional acupuncturists may use various adjunctive therapies including the following:

Moxibustion

Moxibustion is a technique used in TCM in which a stick or cone of burning mugwort (*Artemesia vulgaris*) is placed over an inflamed or affected area on the body. The cone is placed on an acupuncture point and burned. The cone is removed before burning the skin. The purpose is to stimulate and strengthen the blood and the life energy, or qi, of the body.

Cupping

Cupping is a technique used in TCM for certain health conditions. Glass or bamboo cups are placed on the skin with suction, which is believed to influence the flow of energy and blood in the body.

Chinese Herbal Medicine

Chinese herbalism is the most prevalent of the ancient herbal traditions. Chinese herbs are ascribed qualities such as cooling (yin) or stimulating (yang) and used according to these qualities in the patient.

Herbalists generally use unpurified plant extracts containing different constituents. Often several different herbs are used together. Diagnostic principles differ from those used by conventional practitioners.

Chinese herbs can be toxic as they contain active principles. Herbal extracts contain plant material with pharmacologically active constituents. The active principle(s) of an extract, which is in many cases unknown, may exert its effects at the molecular level, for example, it may have an enzyme-inhibiting effect.

When used in conjunction with Western medicine, it is important to be aware of their interactions, including interactions with Western prescription and non-prescription pharmaceuticals. It is also important that practitioners have an understanding of the herbs' indications and contraindications.

1.2 Ayurvedic Medicine

Ayuredic medicine is a traditional Indian style of medicine. Although incorporating lifestyle advice and physical therapies, it is principally practised in Australia as a form of herbal medicine. Some similarities can be seen between this Indian form of therapy and traditional Chinese methods in the way diagnosis is made by questioning the patient as well as examination of the pulse and tongue.

Ayurvedic medicine is concerned with physical, mental, and emotional aspects of wellbeing, and with our interaction with our environment. Prescriptions consist of herbal and mineral mixtures.

1.3 Kampo Medicine[118]

Kampo (sometimes spelled kanpo) is a Japanese variant of TCM that involves the extensive use of herbs. The name is derived from the Japanese symbols *kan*, which means China and *po*, which means medicine.

Kampo treatment has become very much integrated into the Japanese healthcare system. It is widely available from hospitals and physicians there, and is the most popular form of complementary healthcare in contemporary Japan. Kampo herbal preparations are sold by many Japanese pharmacies.

The World Health Organization (WHO) reports that Japan has the highest per capita consumption of herbal medicine in the world. In additional to herbal treatments, Kampo practitioners may also administer acupuncture, moxibustion and manipulative therapies.

1.4 Western Herbal Medicine

Herbal medicine refers to the therapeutic use of relatively crude and therefore chemically complex plant extracts, or simply the herb in its dried form. In this way herbal medicines are distinct from plant-derived pharmaceutical medicines, which contain single chemical compounds extracted from plants in their pure form.

Western Herbal Medicine is a form of botanical medicine that comes from the European tradition. It derives from the use of plant medicines in the Greek, Roman and Egyptian civilisations. Over time significant influences from herbal traditions from other parts of the world have occurred, most notably from North America and Asia. Since the European colonisation of North America, plants used by the North American Indian cultures have been incorporated into this tradition. Plant materials are used either fresh, dried or as liquid or solid plant extracts (fluid extracts or tablets) for both internal and external treatment.

OTHER SYSTEMS

1.5 Anthroposophical medicine[119]

'Anthroposophy' describes people in terms of their physicality, their soul and their spirit. Anthroposophical medicine aims to stimulate a person's natural healing forces through studying the influence of their soul and spirit on their physical body. While anthroposophical medicine uses herbal, mineral and homoeopathic ingredients, the anthroposophical paradigm differentiates the use of these ingredients in anthroposophical medicines from their uses in the fields of phytotherapy, naturopathy and homoeopathy.

1.6 Homoeopathy

Homoeopathy is a system of treating patients using very low dose preparations according to the principle 'like should be cured by like', that is, a therapeutic method using preparations of substances whose effects when administered to healthy subjects correspond to the manifestations of the disorder (symptoms, clinical signs and pathological states) in the unwell patient.

[118] Helwig D, 1995. *op. cit.*
[119] House of Lords, 2000. Select Committee on Science and Technology. *op. cit.*

Homoeopaths believe that minute doses of a substance can stimulate the body to fight back against disease (that is, 'like cures like'). The theory is that if an overdose of a substance causes a particular set of symptoms, a greatly watered-down dose of the same substance will strengthen the body's immune system sufficiently for the body to heal itself.

There are around 2000 homoeopathic remedies with recorded therapeutic effects. These remedies can be prescribed in a number of forms, but tablets and liquid preparations are most common.

1.7 Bach and other flower remedies[120]

The theory behind flower remedies is that flowers contain the life force of the plant and this is imprinted into water through sun infusion, which is used to make the flower remedy. Flower remedies are often used to help patients let go of negative thoughts; usually flower remedies are ingested.

1.8 Nutritional medicine[121]

This term is used to cover the use of nutritional methods to address and prevent disease, through diet and nutritional supplements. It is often used to address allergies and chronic digestive problems. The difference between nutritional medicine and dietetics is that nutritional therapists work independently in accordance with naturopathic principles and focus on disorders which they believe can be attributed to nutritional deficiency, food intolerance or toxic overload.

They believe these three factors are involved in a wide range of health problems. Dieticians usually work under medical supervision, using diets to encourage healthy eating and tackle a narrower range of diseases. Nutritional therapists often use exclusion diets and herbal remedies to tackle patients' problems.

1.9 Aromatherapy[122]

Aromatherapy is the therapeutic use of essential oils made from plants and flowers. It is a healing art that aims to rejuvenate body, mind and spirit. The different smells (aromas), and the chemical constituents of the oils, are said to produce different emotional and physiological reactions. Essential oils can be massaged into the skin, added to bath water or vaporised in an oil burner.

1.10 Naturopathy[123]

Naturopathic medicine is a distinct system of primary health care – an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic medicine is distinguished by the principles which underlie and determine its practice. These principles are based upon the objective observation of the nature of health and disease, and are continually re-examined in the light of scientific advances. Methods used are consistent with these principles and are chosen upon the basis of patient individuality. Naturopathic physicians are primary healthcare practitioners, whose diverse techniques

[120] House of Lords, 2000. Select Committee on Science and Technology. *op. cit.*
[121] House of Lords, 2000. Select Committee on Science and Technology. *op. cit.*
[122] *Better Health Channel*. *op. cit.*
[123] American Association of Naturopathic Physicians definition of naturopathic medicine. Prepared for the Select Committee on The Definition of Naturopathic Medicine.

include modern and traditional, scientific and empirical methods. The following principles are the foundation for the practice of naturopathic medicine.

1.10.1 Principles

The Healing Power of Nature (Vis Medicatrix Naturae)

The healing power of nature is the inherent self-organising and healing process of living systems which establishes, maintains and restores health. Naturopathic medicine recognises this healing process to be ordered and intelligent.

It is the naturopathic physician's role to support, facilitate and augment this process by identifying and removing obstacles to health and recovery, and by supporting the creation of a healthy internal and external environment.

Identify and Treat the Causes (Tolle Causam)

Illness does not occur without cause. Causes may originate in many areas. Underlying causes of illness and disease must be identified and removed before complete recovery can occur. Symptoms can be expressions of the body's attempt to defend itself, to adapt and recover, to heal itself, or may be results of the causes of disease.

The naturopathic physician seeks to treat the causes of disease, rather than to merely eliminate or suppress symptoms.

First Do No Harm (Primum Non Nocere)

Naturopathic physicians follow three precepts to avoid harming the patient:

– Naturopathic physicians utilise methods and medicinal substances which minimise the risk of harmful effects, and apply the least possible force or intervention necessary to diagnose illness and restore health.
– Whenever possible, the suppression of symptoms is avoided as suppression generally interferes with the healing process.
– Naturopathic physicians respect and work with the *vis medicatrix naturae* in diagnosis, treatment and counselling, for if this self-healing process is not respected the patient may be harmed.

*Doctor As Teacher (*Docere*)*

The original meaning of the word 'doctor' is teacher. A principal objective of naturopathic medicine is to educate the patient and emphasise self-responsibility for health. Naturopathic physicians also recognise and employ the therapeutic potential of the doctor–patient relationship.

Treat the Whole Person

Health and disease result from a complex of physical, mental, emotional, genetic, environmental, social and other factors. Since total health also includes spiritual health, naturopathic physicians encourage individuals to pursue their

personal spiritual development. Naturopathic medicine recognises the harmonious functioning of all aspects of the individual as being essential to health. The multifactorial nature of health and disease requires a personalised and comprehensive approach to diagnosis and treatment. Naturopathic physicians treat the whole person, taking all of these factors into account.

Prevention

Naturopathic medical colleges emphasise the study of health as well as disease. The prevention of disease and the attainment of optimal health of patients are primary objectives of naturopathic medicine. In practice, these objectives are accomplished through education and the promotion of healthy ways of living.

Naturopathic physicians assess risk factors, heredity and susceptibility to disease, and make appropriate interventions to prevent illness in partnership with their patients. Naturopathic medicine asserts that one cannot be healthy in an unhealthy environment, and is committed to the creation of a world in which humanity may thrive.

1.10.2 Practice

Naturopathic Methods

Naturopathic medicine is defined primarily by its fundamental principles. Methods and modalities are selected and applied based upon these principles in relationship to the individual needs of each patient. Diagnostic and therapeutic methods are selected from various sources and systems and will continue to evolve with the progress of knowledge.

Naturopathic Practice

Naturopathic practice includes the following diagnostic and treatment modalities: utilisation of all methods of clinical and laboratory diagnostic testing, including diagnostic radiology and other imaging techniques; nutritional medicine, dietetics and therapeutic fasting; medicines of mineral, animal and botanical origin; hygiene and public health measures; naturopathic physical medicine, including naturopathic manipulative therapies; the use of water, heat, cold, light, electricity, air, earth, electromagnetic and mechanical devices, ultrasound, and therapeutic exercise; homoeopathy; acupuncture; psychotherapy and counselling.

MANIPULATIVE THERAPIES

1.11 Massage Therapy

Massage therapy is the manipulation of the soft tissue of whole body areas to bring about generalised improvement in health, such as relaxation, improved sleep, or specific physical benefits such as relief of muscular pain.

1.12 Shiatsu

Shiatsu is a form of massage therapy. Slow, downward applications of pressure are generally used by shiatsu practitioners to correct the circulation of energy, or 'ki', around the body. Shiatsu often stands out from other forms of massage through its use of not only thumbs and hands to apply pressure, but also elbows, knees, and even feet. Very gentle stretching is often involved, especially in *zen* shiatsu which is almost a cooperative routine between patient and therapist. As with acupressure, shiatsu is performed on a fully clothed patient, with all skin-to-skin contact kept to an absolute minimum. A treatment is often preceded by a *hara* (abdominal) diagnosis to allow the practitioner to concentrate on the most important areas for the patient's health.

1.13 Reiki

Reiki is an Eastern massage technique that involves lightly placing the hands on the patient to direct healing energies. Many schools of philosophy exist within the reiki paradigm, from those that concentrate on the physical aspect of the therapy, to those with strong esoteric foundations.

The five goals of a reiki treatment are the relaxation and removal of physical and emotional tension, the dispersion of stagnant or obstructed energy, detoxification, the endowment of healing energy, and the regulation of the natural vibrational frequency of the body.

1.14 Chiropractic

Chiropractic therapy is primarily concerned with the relationship between the spine, nervous system, and muscular system. The chiropractic technique of manipulating the vertebrae of the spine back into optimum position is well known. Less well known is the practice of manipulating muscular tissue and joints elsewhere in the body, which is used alongside massage and spinal manipulations to correct functional problems and eliminate pain.

1.15 Osteopathy

Osteopathy is a commonly sought therapy for the alleviation of muscular and skeletal complaints, such as headache, neck pain, back ache, joint pain, carpal tunnel syndrome and other repetitive strain injuries, and instances of compression of nervous structures, as in sciatica.

A consultation with an osteopath typically involves a detailed musculo-skeletal examination, as well as some discussion of lifestyle factors. The physical examination will include an analysis of posture, spinal alignment, and soft tissue tone. An osteopath may request x-rays or similar diagnostic evaluations to assist with making a diagnosis. Treatment may include manipulations of joints and/or massage of muscular tissue.

OTHER THERAPIES

1.16 Chelation Therapy

Chelation therapy consists of slow-drip intravenous injections of EDTA (ethylenediamine tetraacetic acid), a synthetic amino acid, combined with aerobic exercise, a special diet and no smoking. EDTA treatment has been around since the 1940s, when it was developed to treat lead poisoning. The word 'chelate' is derived from the Greek word for claw and apparently refers to the alleged removal of plaque and calcium deposits from arteries and veins by EDTA.

1.17 Magnetic Field Therapy[124]

Magnetic field therapy involves the use of permanent or pulsed magnetic fields applied to the head or other parts of the body and is often used with acupuncture.

[124] Ernst E, 2001. *op. cit.*

APPENDIX 3

IMPLEMENTATION TIMETABLE