Needs Analysis for education in Integrative and Complementary Medicine for general practitioners in Australia

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Introduction

The purpose of the Needs Analysis document is to clarify the need for ongoing education for general practitioners in the field of Integrative Medicine.

The evidence suggests there is widespread use of complementary medicine and therapies by individuals in Australia and the majority of general practitioners currently lack adequate knowledge in this area to provide evidence-based, holistic, quality care to patients.

We welcome feedback and respectful dialogue on this important area of healthcare.

Definitions

Definition of Integrative Medicine

Integrative Medicine refers to the blending of conventional and complementary medicines and therapies with the aim of using the most appropriate of either or both modalities to care for the patient as a whole.¹

Integrative Medicine, like general practice, also embraces and encourages a holistic approach to practice incorporating patient involvement in self health care, prevention and lifestyle interventions. The RACGP defines general practice as ‘the provision of primary continuing comprehensive whole patient medical care to individuals, families and their communities’.²

Integrative Medicine encompasses more than complementary medicine, although the integration of complementary medicine is an important and obvious aspect of Integrative Medicine.

Integrative Medicine does not reject or compete with conventional health care and overlaps significantly with what is currently widely accepted as quality general practice. Integrative medicine seeks to broaden conventional health care by emphasising principles that some doctors and patients believe are undervalued in conventional medical practice. The practice of Integrative Medicine emphasises a number of issues including:³

- a focus on wellness and illness prevention
- being holistic in nature by focusing on physical, psychological, spiritual, social and lifestyle issues
- incorporating evidence based, safe and ethical complementary therapies and medicines
- individualising the approach to any particular patient or clinical situation using the best of all available modalities in conjunction with informed patient choice
- integrating all of the above into conventional medical care, and
- acknowledging that advances in health care will be dependent on scientific advances, improvements in health care delivery systems, cultural change as well as practitioner and patient education.

Definition of Complementary Medicine (CM) by the National Center for Complementary and Alternative Medicine (NCCAM)

Complementary and alternative medicine, as defined by NCCAM, is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.⁴

NCCAM classifies natural, complementary and alternative medicines into five categories, or domains:

1. Alternative Medical Systems
   Alternative medical systems are built upon complete systems of theory and practice such as homeopathic and naturopathic medicine, traditional Chinese medicine and Ayurveda.

2. Mind-Body Interventions
   These interventions include patient support groups, meditation, prayer, spiritual healing, and therapies that use creative outlets such as art, music, or dance.
3. **Biologically Based Therapies**
These therapies include the use of herbs, foods, vitamins, minerals, dietary supplements.

4. **Manipulative and Body-Based Methods**
These methods include chiropractic or osteopathic manipulation, and massage.

5. **Energy Therapies**
Energy therapies involve the use of energy fields. They are of two types:
- Biofield therapies such as qi gong, Reiki, and Therapeutic Touch, and bioenergetic therapies involving the use of pulsed electromagnetic fields, such as pulsed fields, magnetic fields, or alternating-current and/or alternating and direct-current fields.

In this document when the term ‘complementary medicine’ is used it refers to both natural and complementary medicines and therapies.

**Definition of CM by the Therapeutic Goods Administration**
In Australia, the TGA define CM as ‘medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products.’\(^5\) CMs also comprise ‘traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines’. These are regulated as medicines under the Therapeutics Goods Act 1989 (the Act).\(^6\)

The TGA is responsible for administering the provisions of the Therapeutic Goods Act. The overall objective of the Act is to ensure the quality, safety, efficacy, and timely availability of therapeutic goods, including medicines and medical devices that are supplied in or exported from Australia. The Act came into effect in February 1991.

**Definition of CM by the National Prescribing Service**
The NPS has released four publications since 2007, the findings of which are summarised throughout this document.\(^7\),\(^8\),\(^9\),\(^10\)

The NPS defines CM by referencing the Therapeutic Goods Regulation as:
‘...a therapeutic good consisting ... of one or more designated active ingredients ... which has a clearly established identity and a traditional use ... that is well documented ... 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.’\(^11\)

In their 2008 survey assessing attitudes and needs by consumers, the NPS used the term “natural medicines”, not CM, in their questions.\(^8\)

**Definition of holistic medicine and/or therapies**
These combine complementary and conventional approaches that support the physical, social, psychological, emotional and spiritual wellbeing to help achieve optimal health. The holistic or health model looks at maximising or supporting all aspects of a person’s health that may lead to the disease being healed by the body. Health promoting and lifestyle advice, such as advice in dietary changes, stress management, exercise, and the environment, are integral to holistic medicine.\(^12\)

**Definition of Traditional Medicine (TM) by The World Health Organisation (WHO)**
The WHO define TM as the “sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses”.\(^13\)
RACGP Integrative Medicine Curriculum for Australian General Practice

The RACGP recognises the need for ongoing education in the area of Integrative Medicine. This is reflected in the Integrative Medicine statement in the RACGP Curriculum for Australian General Practice. The RACGP curriculum review includes wide consultation with a variety of stakeholders and community groups to look at existing or new content areas for the curriculum. Integrative Medicine has been identified as a specific content area. Support has been further demonstrated by the RACGP through the establishment of the IM Network within the Specific Interests Faculty.

The RACGP is responsible for setting and maintaining standards of clinical care, education, training and research for general practice in Australia. General practice training, as determined by the standards set and maintained by the RACGP, is intended to equip graduates with both core clinical skills and the ability to assess and address the learning needs arising from differing clinical contexts over a professional lifetime and Integrative Medicine is recognised as part of this training.

The RACGP curriculum Integrative Medicine statement provides a professional benchmark for expected level of care in the provision of Integrative Medicine related services.

RACGP-AIMA Position Statement on Complementary Medicine

This paper, endorsed by RACGP Council at its August 2005 meeting, emphasizes the importance of general practitioner training, continuing professional development (CPD) and standards for safe ethical practice in the area of Integrative Medicine. In addition the paper emphasizes the importance of evidence-based method, research and regulation.

Rationale:

General Practitioner prescribing and use of CM.

The use of Integrative Medicine and CM by medical practitioners, particularly general practitioners (GPs) as a part of routine clinical practice is increasing.

A national survey of a random sample of Australian GPs found Australian GPs have accepted some complementary therapies, namely acupuncture, massage, yoga, chiropractic, hypnosis and meditation, and consider them as ‘mainstream’. The majority of doctors believe these therapies to be effective and safe. The findings are similar to a previous report by Pirotta et al. 2000. This study found whilst most GPs have little formal training in complementary medicine, some GPs did report training in meditation (26%), acupuncture (23%), vitamin and mineral therapy (23%), massage (17%), hypnosis (14%), herbal medicine (14%), and yoga (13%). It also found GPs expressed an interest in learning more about these therapies. As a general rule, GPs showed a preference to refer to medically trained doctors who practice CM.

The National Prescribing Service national survey of GPs and pharmacists research provides information on the current attitudes of Australian GPs and community pharmacists towards CMs, how they communicate with consumers, their current information use and their needs and preferences to be confident in providing evidence-based information. This survey of GPs indicated approximately 30% of GPs in Australia are practicing Integrative Medicine, by combining orthodox medicine with CM. The findings of this study provide a unique insight into GP attitudes and needs with respect to CM and are summarised in Table 1.

Table 1 Summary of key findings from NPS health professional study 2008 relating to GPs

<table>
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<tr>
<th>Description</th>
<th>Percentage</th>
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<tr>
<td>One-third of GPs reported practicing integrative medicine/care, which was</td>
<td>33%</td>
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<td>defined in the survey as ‘a holistic approach to health care that integrates</td>
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<td>conventional medical care with complementary therapies’.</td>
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<td>About 90% of GPs had recommended at least one CM in the last 12 months.</td>
<td>90%</td>
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<td>More than three-quarters of the GPs had recommended vitamins, minerals,</td>
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<td>fish oil and glucosamine.</td>
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<td>Over 80% of the surveyed GPs agreed with the statement that CMs need more</td>
<td>80%</td>
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<td>scientific testing</td>
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Only 38% of GPs felt they were confident discussing CMs with patients.

- Only about half of the surveyed GPs often or always incorporate questions about CMs use when asking the medication history of a new patient.

About half of the GPs reported having a good working knowledge of glucosamine, and the remaining half knew some general details. Around 40% of general practitioners reported having minimal or no knowledge about black cohosh and ginkgo biloba.

- Less than 40% of the surveyed GPs were aware of some potential side effects and drug-CMs interactions of ginkgo biloba, glucosamine and black cohosh. Only 38% of GPs were aware that black cohosh has been linked to liver damage.

More than half of the GPs sought CMs information about safety (interactions, adverse effects and contraindications), evidence of effectiveness, dose and indications for use.

- GPs drew their information on CMs from a range of sources, with a number of these sources perceived as being of little use. The most popular sources used by GPs for CMs information were trade journals such as Medical Observer and Australian Doctor (75.5%), MIMS (67.8%), Internet search engines (66.9%), peer-reviewed medical journals (62.3%) and colleagues (55.2%).

- The CMs resources most frequently reported by GP users as being moderately to very useful were CMs textbooks (67%), specific websites (60%), Internet searches (55%), CMs journals (50%) and drug information phone services (50%).

Many GPs identified a clear and urgent need for further research to be conducted on the efficacy and safety of CMs and for high-quality CMs information resources to be provided. This would assist their knowledge about CMs and facilitate communication with patients about CMs.

- The top five CMs that GPs would like good quality information about are fish oil, glucosamine, coenzyme Q10, St John’s wort and Ginkgo biloba.

- GPs described a need for future resources to be easily accessible, brief and credible in authorship and regularly updated.

- The type of CMs information preferred by GPs during a consultation with a patient includes brief fact sheets (both Internet and paper versions), answers to specific questions (via Internet) and a database of interactions (via Internet and prescribing software).

In terms of professional development, GPs would prefer to attend seminars and workshops and read paper versions of peer-reviewed medical journals. Around half or more GPs in the current survey said they would definitely or probably participate in seminars and workshops if they were organised by an authoritative body such as NPS, Divisions of General Practice or RACGP.

Whilst these statistics indicate a changing attitude of GPs towards CMs, overall training, education and understanding of CM, including efficacy and safety issues is still poor and limited. The RACGP needs to develop appropriate high quality training to enable GPs to access reliable information about CMs to ensure that patients are provided with safe, evidence based clinical practice.

**Consumer attitudes toward, needs and prevalence of use of CMs**

The increased demand for CMs is largely driven by the public. The community has increasing access to information and various CM practitioners and therapies. There are a variety of reasons why a patient may want to trial a CM. Reasons for this choice may include philosophical and cultural beliefs, consumers wanting a more holistic approach to healthcare, lack of availability of orthodox approaches to assist with particular health issues, and concerns if individuals have suffered adverse events from previous orthodox treatments. A study by MacLennan et al revealed approximately 52% of the Australian population used CMs and about 26% have consulted practitioners of CM. Extrapolated figures from this study indicate Australians spent approximately $1.31 billion on CMs in 2004. The study also revealed women were more likely to use CMs than men, particularly between the ages of 25 to 44 years of age, users of CM were more highly educated and higher income earners than those who did not use CMs. Vitamins (39%), herbal medicines (21%) and mineral (14%) supplements were most commonly used and supplements were mostly self-prescribed to ‘promote general health’.
The study also revealed concerning figures showing 53% of participants used CMs without the knowledge of their GP.

A 2008 survey by the National Prescribing Service, demonstrated about two thirds of consumers have used one or at least one CM in the previous 12 months, with 28% on a regular basis. A national population-based survey estimated the number of visits to complementary and alternative medicine practitioners by adult Australians in the 12 month period (69.2 million) was almost identical to the estimated number of visits to medical practitioners (69.3 million). Patients generally express a high level of satisfaction with CMs irrespective of attitudes towards efficacy, which is possibly related to misperceptions regarding reduced risks of adverse effects compared to conventional therapies.

According to statistics on the Australian Social Trends (2008), people who visited a complementary health therapist in the previous 2 weeks were ‘more likely to have certain healthy behaviours than were either the total population, or people who had consulted any other health professional’. They were more likely to consume minimum recommended serves of fruit and vegetables, partake in regular exercise (high or moderate level) and be non-smokers. There was no difference in alcohol consumption between the two groups.

Studies demonstrate that there are a number of belief systems and rationales behind consumer choices to use complementary medicines. These include:

- They have more internal beliefs about the control of their health
- They are more responsible for their health
- They can influence their own state of health by physical means and through a psychological equilibrium
- Community has greater access to information and various CM practitioners & therapies
- Philosophical & cultural reasons
- Wanting a more holistic approach to healthcare
- No other orthodox approaches available. Patients are usually not rejecting orthodox medicine
- Looking for options to improve well-being
- Many consumers believe CMs are effective & safe, and are usually unaware many lack scientific evidence for effectiveness

Consumer use of and need for information resources regarding CM

A recent survey by the NPS aimed to identify what consumers want to know about CMs. It was a Computer Assisted Telephone interview of 612 respondents over 18 year old who were asked questions about:

- Personal use
- Previous information seeking & preferences
- Attitudes to CMs
- Socio-demographic information

Note: CMs in this study were referred to as ‘natural medicines and natural health products’.

A broader literature review of the studies of the attitudes and information needs of consumers and healthcare professionals prepared by the NPS drew similar conclusions.
consumers frequently seek information from friends & family but prefer information from their doctor or pharmacist and information about CMs are commonly sourced on the internet and self-prescribed. They also found the most commonly used CMs are vitamins followed by herbal medicines and mineral supplements. The researchers noted most consumers used CMs for the promotion of general health and prevention of illness and less commonly for the treatment of health conditions. Some respondents with serious disease states used CMs and those who experienced adverse effects from orthodox therapies used CM to alleviate symptoms. Consumers generally indicated high levels of satisfaction with CMs but often had limited knowledge of potential risks with CMs, the scientific evidence and variability of information quality available about CMs. The author of the study concluded, ‘Given the highly variable quality of CM information, the ideal would be to empower consumers and healthcare professionals to evaluate available information’. 

The Doctor-Patient relationship

The doctor patient relationship may be affected when patients choose to use CMs. A legal article by Brophy suggests the doctor has a duty of care to ‘provide information about reasonably available complementary and alternative medicine treatments where that information would be material to the particular patient … given the high rate of patient self-prescribing, it is necessary for a doctor to open a dialogue with a patient about complementary and alternative medicine to address safety concerns’. 

In a discussion paper published in the Medical Journal of Australia, the authors emphasised when doctors are faced with patients wanting to trial CM they should be: 

- honest with patient’s direct questioning about CM
- establish the patient’s understanding of CM and why they use it
- take into account the burden of their illness and provide information on their expressed preferences
- discuss the risks and benefits of both CM and orthodox treatment
- adequately inform patients about available CM that has been shown to be safe and effective, and those that are shown to be ineffective
- become familiar with qualified and competent complementary medicine practitioners (both medical and non-medical) to whom referrals are made
- continue the relationship with the patient and provide ongoing monitoring of their health.

These points serve as a useful ethical framework and guidelines for doctors when faced with patients wanting to integrate CM into their healthcare.

It is vital to empower patients to be active participants in their healthcare, to promote self-care and help them make well informed decisions and choices. It is also important doctors respect choices made by patients and maintain honesty regarding their own limitations such as knowledge of CM.

When considering initiating any new therapy (orthodox or CM), it is important to understand and consider:
- the risks versus the benefits
- the scientific evidence
- the clinical relevance and potential outcome
- the costs to the patient
- the available alternatives, for example other therapies or doing nothing

The scientific evidence

Scientific evidence is the basis of and is essential to the practice of Medicine. Evidence on efficacy and safety should be the basis of defining which CMs are useful and which are not.
To date research in CM has been limited due to a number of factors such as; lack of adequate funding, the type of CM used, difficulty extrapolating results to similar therapies with subtly different formulations, the variable quality of the studies and lack of patenty rights to draw any firm conclusions about their potential role in health care. In saying this, there is also a large body of scientific evidence emerging for CM world-wide. This evidence should be made accessible to the health profession and public, and also integrated into recommended national guidelines of treatment for specific health conditions. Once a therapy or medicine, be it orthodox or complementary, has a good basis of scientific evidence to prove its efficacy and safety, then the medical practitioner has a legal and ethical obligation to use the best treatment possible which is most suitable for the individual patient.

There are many CMs that are not evidence-based to date. This may not mean that they are ineffective for the reasons outlined above. These CMs obviously need to be used cautiously until they are adequately tested and their potential benefits weighed against any potential risks. The primary aim of AIMA and the IM network is to provide education about the evidence base and risk factors of common CM and therapies used by the community.

**Adverse reactions and Risks of CMs**

Compared to pharmaceuticals, the overall risk associated with the use of CMs is low. Australian TGA data from adverse events reported to the Australian Drug Reactions Advisory Committee (ADRAC) arising from the use of listed CMs from 2004 to 2008, shows that there were a total of 656 total reports where a CM was the sole suspected possible, probable or certain cause of an adverse patient reaction, with 7 possible death outcomes associated with a CM. During the same period there were 38,337 cases where a medicine (prescription, over the counter medication and other products registered on the Australian Register of Therapeutic Goods (ARTG) was the sole suspected possible, probable or certain cause of an adverse patient reaction, and there were 1014 possible death outcomes. In many cases the contribution of the suspected medicine to the death is uncertain, however based on the information reported it is not possible to entirely exclude the possibility that the suspected medicine contributed to the fatal outcome.

An NPS study discussed in detail in Part 1 of this analysis showed it is clear there is an urgent need for GPs to learn more about adverse reactions with CMs. The study revealed about 40% of general practitioners reported having minimal or no knowledge about black cohosh and ginkgo biloba, and less than 40% of the surveyed GPs were aware of some potential side effects and drug-CMs interactions of ginkgo biloba, glucosamine and black cohosh. Only 38% of GPs were aware that black cohosh has been linked to liver damage despite an ADRAC report published in 2005. This highlights a concern that needs to be addressed through better education about risks associated with CMs and the need to report adverse events possibly associated with CMs to ADRAC. A new Advisory Committee on the Safety of Medicines will commence from 2010. ‘In line with the world-wide trend of placing greater emphasis on monitoring and managing the safety of medicines after they have been registered, the TGA will from 2010 replace ADRAC with an expert advisory committee established in its own right under the Therapeutic Goods Act. This new statutory expert committee - the Advisory Committee on the Safety of Medicines (ACSM) will encompass the activities and functions of ADRAC but will have broader terms of reference commensurate with the increasing prominence of pharmacovigilance in Australia and world-wide.'

Based on the statistics above, the level of reporting for CMs is relatively low compared with pharmaceuticals, considering the widespread usage of CMs in Australia. There may be a number of factors contributing to this, other than CMs having a relatively favorable safety profile, including significant under-reporting due to patients failing to communicate adverse events to their medical practitioner about the use of CMs and medical practitioners failing to report adverse events to ADRAC.

Reports can easily be made electronically on the TGA website or by filling in the blue card and posting to ADRAC. Furthermore, the ADRAC bulletin regularly reports common or serious
adverse reactions to CM. Subscribers to the ADRAC-Bulletin email list will receive an email notifying them when the latest issue of the Australian Adverse Drug Reactions Bulletin is available on the TGA Internet site (normally once every two months) or to subscribe, go to: http://www.tga.gov.au/adr/adrac-bulletin-subscribe.asp [accessed 23 December 2009]. The new advisory committee will continue this role from 2010.

Currently available CM resource information

Recently the NPS commissioned a review of CMs information resources aimed at identifying high quality resources for use by Australian health professionals and consumers. A variety of information sources about CM are available to consumers and health professionals but these sources are of variable quality. The review was conducted by a consortium of researchers from the National Prescriber Services, Mater Hospital Pharmacy Services in Brisbane, the University of Queensland and Bond University. CM information resources were tested against a broad range of criteria encompassing currency, coverage, transparency and content quality to produce a short-list of resources. These resources were evaluated across three domains: technical quality, content quality and clinical utility. Resources were then ranked according to whether their total scores and the scores for each of the three domains were above the upper 95% confidence interval for the mean scores for all the individual resources. The top 6 identified as the highest quality (Tier 1), based on their total score, and scores for all three domains (technical quality, content quality and clinical utility) being above the upper 95% confidence interval of the mean of all short-listed resources are listed in Table 2.

Table 2. NPS Complementary Medicines Information Resources. Top 6 resources identified (tier 1).7

| Natural Standard Professional Database package |
| Natural Medicines Comprehensive Database (Health Professional Edition) |
| Natural Standard Professional Database - Professional monographs |
| Herbal Medicines & Dietary Supplements package |
| Natural Standard Professional Database - Bottom line monographs |
| MedlinePlus: Drugs, Supplements & Herbal Information |

Three resources were identified as high quality (Tier 2) based on their total score, and two of the scores for the three domains being above the upper 95% confidence interval of the mean of all short-listed resources. They are included in Table 3.

Table 3. NPS Complementary Medicines Information Resources. Top 3 resources identified (tier 2)7

| Natural and Alternative Treatments: EBSCO. |

The NPS recommended that organisations responsible for providing information to consumers and health professionals about CMs such as drug information services have access to one or both Natural Standard Professional Database or the Natural Medicines Comprehensive Database (Health Professional Edition) and to the high quality resources (Tier 1 and 2).7

Conclusion

Integrative Medicine provides a holistic approach to health care which is essentially patient-centred. Ideally any form of CM to be considered by a patient and treating doctor should be evidence-based and safe, and that all care should be well coordinated and patient-centred. Care of any patient needs to be flexible, respectful of their individual needs and choices. It does require that the GP/medical practitioner have a basic understanding of CMs, know where to access any information from reliable sources, be honest about the level of knowledge in this area and consider referral to a trusted health practitioner (medically or non-medically trained) if their knowledge is limited. The GP needs to weigh the benefits of any CM therapy with any
risks associated with its use. Also it is vital to monitor the patient carefully for any response to the use of CMs, report any adverse reactions and clearly document if a patient is refusing any orthodox or conventional treatment. The evidence presented previously clearly demonstrates that there is a great need to further educate the medical profession on the efficacy and safety of CM and to encourage practice of integrative medicine in order to provide, safe, holistic care to patients.

Education need is based on the findings summarized throughout this document that include:

- Widespread use of CM by 2/3rds of Australians, yet a significant proportion do not tell their doctors they are using CMs.\(^{33,34,35,36}\)
- Consumer preference to discuss the use of CMs with their doctors.\(^{10,11}\)
- Widespread prescribing of CMs by GPs yet only 38% of GPs felt they were confident discussing CMs with patients.\(^4\)
- Potential risks and adverse reactions associated with CMs.\(^{37}\)
- More than half of the GPs seek information on CMs information about safety (interactions, adverse effects and contraindications), evidence of effectiveness, dose and indications for use, highlighting the need for education in this area.\(^4\)
- Little knowledge in adverse reactions in risks associated with CM. For example less than 40% of the surveyed Australian GPs were aware of some potential side effects and drug-CMs interactions of commonly used CMs such as *Ginkgo biloba*, glucosamine and black cohosh, and that black cohosh has been linked to liver damage.\(^4\)
- GPs are interested in professional development in CM and Integrative Medicine. They would prefer to attend seminars and workshops, and read paper versions of peer-reviewed medical journals. Over 50% of GPs are interested in attending seminars and workshops organised by an authoritative body such as NPS, the Divisions of General Practice or the RACGP.\(^4\)
- Availability of high quality CM information resources for use by Australian health professionals and consumers.\(^7\)
References


14 Royal Australian College of General Practitioners. Specific interests in General Practice within the RACGP - a discussion paper. 2009. Available at: www.racgp.org.au/gpissues/specificinterests


28 Statistics provided by the Office of Medicines Safety Monitoring at the Therapeutic Goods Administration. 25th March 2009.


