

Highlighting

COMPLEMENTARY MEDICINE RESEARCH



FACT SHEET

The safety of complementary medicines

An increasing number of Australians are choosing to use some form of complementary medicine (CM). Like any decision concerning your health, decisions about using CM are important.

The National Institute of Complementary Medicine (NICM) has developed a number of Fact Sheets to assist you in your decision making about CM. They provide basic information, answers to frequently asked questions, issues to consider, and sources for further information.

Take charge of your health by being an informed consumer. If you are unsure about any answers or uncomfortable with your understanding of some of the issues, you should talk to a healthcare professional, such as your doctor, pharmacist, community health nurse or complementary healthcare practitioner.

What is complementary medicine?

CM encompasses a diverse range of therapies and health products that aim to prevent, treat or manage illness. Some CM therapies offer a complete system of diagnosis and treatment, others complement conventional medical practices with supportive therapy.

CM includes the principal CM disciplines such as acupuncture, chiropractic, herbal medicine, homeopathy, naturopathy and osteopathy. It also includes long-established and traditional systems of healthcare such as Ayurvedic medicine and traditional Chinese medicine and therapies which are most often used to complement conventional medicine such as manipulative and mind-body practices including acupuncture, massage, counselling, hypnotherapy and meditation. There are many other treatments such as Bach and other flower remedies, crystal therapy and radionics.

What are complementary medicines?

Complementary medicines (CMs) are therapeutic products that are used in a wide range of CM therapies. For example, herbal preparations in a medicinal form are used in Western herbal medicine, traditional Chinese medicine, naturopathy, homeopathy and Ayurvedic medicine.

In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are regulated as medicines. The Therapeutic Goods Administration (TGA), a Division of the Commonwealth Department of Health and Ageing, is the responsible body for regulating medicines.

The regulatory requirements for the supply of complementary medicines

Australian Register of Therapeutic Goods

The TGA maintains the Australian Register of Therapeutic Goods (ARTG), a database that includes details of all therapeutic goods, including complementary medicines that may be legally supplied in Australia. Information about the active ingredients, presentation (capsule, tablet, etc), indications, and conditions of entry in the ARTG, name and address of the sponsor of the product as well as other information is available from the TGA's public register (www.tga.gov.au).

Listed and registered Complementary Medicines

CMs available for supply in Australia are included on the ARTG as Listed (low risk) or Registered (higher risk) medicines. You can tell whether a product is on the ARTG by looking to see whether there is the designation AUST L or AUST R on the product's label. Most, but not all, CMs included in the ARTG are Listed medicines and therefore considered as low risk medicines.

Listed complementary medicines may only contain ingredients permitted by the TGA for use in low risk medicines. The indications and claims for use of these products can only relate to health maintenance, health enhancement or non-serious, self-limiting conditions. Generally, they may not refer to a serious form of a disease or condition or indicate they are for treatment or prevention. Sponsors of the product must hold sufficient evidence to support the indications and claims made for their products. This evidence may be audited by the TGA.

Registered complementary medicines are considered to pose a higher risk or have indications or claims of a more serious nature so they are assessed individually for quality, safety and efficacy.

All CMs, whether Listed or Registered, must be manufactured under the same, internationally recognised, code of Good Manufacturing Practice (GMP) as other medicines.

Post-Market Regulatory Activity

In addition to setting stringent regulations at the time of product manufacture and distribution, the TGA has a risk management approach that includes an appropriate level of post-market regulatory activity. This helps to underpin the quality, safety and effectiveness of all medicines, including both *Listed* and *Registered* CMs.

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
- controls for the advertising of therapeutic goods.

Adverse Reaction Reporting

Although stringent regulation aims to improve the quality and safety of medicine, no medicine is completely safe at all times. One important aim of post-market activities is 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, including complementary medicines.

An adverse reaction reporting system for medicines 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. All adverse reaction reports received by the TGA for complementary medicines are reviewed. The review may result in a various outcomes, including further analysis of database reports to investigate potential safety signals, publication in the TGA's Medicines Safety Update (see <http://www.tga.gov.au/adr/msu.htm>) or in medical journals to raise awareness of the reaction and/or removal of the product from the market.

Special provisions for complementary medicines prepared by healthcare professionals

Certain medicines do not need to be included in the ARTG. This allows complementary healthcare practitioners, such as herbalists

and naturopaths, to prepare medicines on their premises so that individualised treatments can be delivered. Hence, 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, the medicines are not subject to requirement to be manufactured under the code of GMP as other manufactured medicines. These provisions assume that the healthcare practitioner is appropriately qualified and skilled to safely prepare the medicine and counsel their patients about its safe and effective use. It is therefore important that you choose your practitioner carefully (see Choosing a Complementary Medicine Practitioner Fact Sheet).

Access to some medicinal ingredients is restricted by legislation. This is generally based on their potential to be unsafe or be abused. Depending on the level of restriction, some ingredients can only be supplied in a pharmacy, or by a pharmacist or on prescription by a doctor, dentist or other authorised prescriber.

Ingredients restricted in this way are not available for dispensing or extemporaneous compounding by complementary healthcare practitioners, such as herbalists, naturopaths, practitioners of traditional Chinese medicine or homoeopathic practitioners. However, most herbal and nutritional ingredients are not subject to restricted access and CM practitioners have a wide range of medicinal ingredients to prescribe.

Other CM ingredients may be restricted as prohibited imports, under quarantine arrangements and under the *Environment Protection and Biodiversity Conservation Act 1999* as either native species and/or identified under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Labelling and medicines information

Certain information must be included on medicine labels. Always read the label carefully to ensure that the medicines are used correctly. Note any special instructions for use, ingredients that you may be sensitive to, and warning or precautionary statements. Labels must declare:

- the product name
- the name and quantities of all active ingredients
- the identity of ingredients that are known to present a risk to some consumers (e.g. certain preservatives, peanut-derived ingredients, lactose)
- the name of the dosage form (e.g. tablet)
- the quantity of the medicine (e.g. 100 tablets)
- required warning statements (e.g. the medicine is not suitable for children; St John's Wort affects the way many prescription medicines work, including oral contraceptives. Consult your doctor)

- special 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 the medicine's use (i.e. indications or claims)
- the unique Registration or Listing number (e.g. AUST L 12456).

Things to consider before using complementary medicine

Gather information on the CM therapy or product that interests you. Consider the accuracy of the information, how up to date it is and whether it comes from a reliable source. Scientific studies about the safety and effectiveness of the treatment are important to consider in addition to traditional information.

People are increasingly turning to the internet as a source of health information. While the internet provides access to a massive amount of useful information, it also leads users to information of questionable quality. NICM has identified a range of international and Australian sites that provide information on CM under the health information section of the NICM website - www.nicm.edu.au

To help in your decision making, consider the following questions:

- What benefits do I hope to achieve with CM?
- Which CM approach is suitable and feasible for me?
- Are there better alternatives?
- What is the evidence that supports the quality, safety and effectiveness of this CM?
- What are the risks associated with using this CM therapy or product?
- Should I get more information from a CM practitioner who has expertise in this area of CM?

If you are unsure about the answers to these questions or uncomfortable with your understanding of some of the issues, you should talk to a healthcare professional, such as your doctor, pharmacist, or complementary healthcare provider.

Using complementary medicines safely

As with any medical treatment, there can be risks with CM therapies and medicines. These risks depend on the specific therapy and the reasons for undertaking the therapy.

How a person might respond to a CM therapy depends on many things, including the person's state of health, age and sex and how the therapy is to be used. You should be aware that individuals can respond differently to the same treatment – irrespective of whether it is a CM or conventional treatment.

It is always a good idea to discuss any health options you are considering, including CM options, with your trusted health professionals such as your doctor, pharmacist; community health nurse or CM practitioner. Before deciding on a CM therapy or product, tell them about the therapy or products you are considering and ask any questions you may have. They may know about the therapy and be able to advise you on its general safety, use, and effectiveness. Ideally, they should be able to provide guidance about whether it is safe and likely to provide benefits in your particular situation. Be very cautious about using a CM therapy as a replacement for any proven treatment or as a reason to postpone seeing your doctor about a medical problem.

If you are already receiving CM treatment, or using a CM product, tell your healthcare practitioner about it. Give them a full picture of what you do to manage your health. Some CM approaches can have a positive impact on your overall wellbeing however others can cause side effects or interact with conventional medicines. This will help them receive better advice and ensure that your healthcare is coordinated and safe.

Consult your healthcare practitioner before arranging therapy for a child or if you are pregnant, intending to become pregnant or breastfeeding, if you are a senior, have been diagnosed with a serious disease or significant previously diagnosed medical condition, or are scheduled for an operation.

If you experience any adverse events that you associate with taking a medicine it is important that you report them. This not only allows your own therapy to be investigated but it may provide an important signal about the safety-in-use of the medicine. Reports can be made to your healthcare providers or there is a phone-in service for consumers to directly report adverse events - *Consumer Adverse Medicine Events Line* (Ph 1300 134 237). Reports can also be made to the TGA via the Internet (www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase). You can also obtain information about medicines safety from the TGA (see Adverse Reaction Reporting above).

Use of complementary medicines for children

A wide range of CMs are used by children, including herbal medicines and nutritional supplements. Unfortunately there are few high-quality studies which have examined how CMs may affect children and results from studies in adults do not necessarily apply to children. Children are not small adults. Their immune and central nervous systems are not fully developed, so they may respond to treatments differently than adults. This is especially true for infants and young children.

Remember, 'natural' does not necessarily mean safe. CMs can have side effects, and these may be different in children than in adults.

In addition to asking your child's healthcare provider what is known about whether a CM therapy or product works and is safe for children, consider these points when making decisions about using CM:

- Ensure that your child has received an accurate diagnosis from a healthcare provider and that CM treatment do not replace or delay conventional medical care.
- If you decide to use CMs for your child, do not increase the dose or length of treatment beyond what is recommended (more is not necessarily better).
- Be aware that CMs may interact with conventional medicines and medical procedures as well as other CMs.
- If your child experiences an effect from a CM that concerns you, contact your child's health care provider.
- Store CMs in a safe place, out of the sight and reach of children.

Standardisation and herbal medicines

Herbal medicines contain many different compounds and are very complex entities. In many instances, the complete range of active components present in a herbal medicine are not yet known. Some commercially manufactured herbal medicines contain standardised ingredients. This means a specific ingredient, such as a recognised therapeutic compound or quality marker, is adjusted to be present within an acceptable manufacturing tolerance amongst all batches. This provides herbal medicines with some degree of chemical consistency.

Consumers may perceive that standardisation always provides assurance of effectiveness of the product. However, with

chemically complex ingredients such as herbal ingredients, this may not be the case as identification of the components responsible for biological activity is not always known. The TGA is working with the CM industry to provide better and more consistent information about the potency of herbal CMs. Hopefully, in the near future this will make it easier to compare CMs.

Is it safe to use imported complementary medicines?

Under certain circumstances an individual may import medicines, including CM medicines, for personal use by, either bringing the medicine into Australia on their person or arranging for the product to be sent to them from overseas.

These products may be of unknown quality, safety and efficacy and individuals importing such products may be at risk. This is particularly the case with CMs where the regulation and enforcement may not be as rigorous as in Australia. Further, if an individual suffers adverse consequences from taking such a product, information about the product and redress may be difficult to obtain.

CMs that have been imported into Australia and included in the Therapeutic Goods Administration's ARTG for supply in Australia are required to meet a standard of manufacture comparable to that required by Australian manufacturers and must also meet other standards consistent with the Australian requirements for Listed and Registered CMs.

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