Complementary Medicines

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In Australia, medicinal products containing herbs, vitamins and minerals; nutritional supplements; homoeopathic products; and certain aromatherapy products are referred to as 'complementary medicines'. The term also includes traditional medicines, such as traditional Chinese medicines, Ayurvedic medicines and Australian indigenous medicines. Complementary medicines have also been referred to as 'alternative medicines', 'natural medicines' and 'holistic medicines'. In Australia , it is a $5.2 billion industry.

'Herbal substance' means all or part of a plant or substance (other than a pure chemical or a substance of bacterial origin) that is: a. 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. not subjected to any other treatment or process other than a treatment or process that is necessary for its presentation in a pharmaceutical form.

Complementary medicines are defined under the *Therapeutics Goods Act 1989* and may be used in a therapeutic regimen for the maintenance of health, or the prevention or alleviation of a disease or ailment. Their use and preparation do not necessarily rely on evidence of efficacy based on western medical practice or philosophy, but may be entirely, or in some part, based on traditional knowledge and use.

Australian regulations

CAMs are commonly regulated as non-prescription medicines in Australia. Like other marketed medicines, those that make therapeutic claims must be included in the Australian Register of Therapeutic Goods (ARTG). CAMs included in the ARTG are evaluated using a risk based pre-market assessment to determine whether they should be 'listed' or 'registered'.
The principles of the National Medicines Policy apply to matters relating to the quality, safety and efficacy of CAMs in Australia.

Listed medicines

Most CAMs included in the ARTG are listed medicines. CAMs that are listed contain unscheduled substances, present a low-level risk and make low-level therapeutic claims. Evidence supporting safety and efficacy of individual listed medicines must be made available to the Therapeutic Goods Administration (TGA) on request.

Consumers should be aware that the TGA may accept 'traditional use' as supporting evidence.
Listed CAMs may only carry indications and claims for the symptomatic relief of conditions (other than serious disease, disorders or conditions), health maintenance, health enhancement and risk reduction. CAMs listed with the TGA include an **'AUST L'** number on the label (e.g. AUST L 67974).
The form and dose of the active constituents in listed medicines can vary, and individual sponsors identify an effective therapeutic dose for the intended use.
Processing methods, plant quality and the part used vary considerably and will influence the effective dose of particular constituents for each product. Consumers need to be aware of comparative doses and dose forms, and of listed medicines with similar names. Careful reading of the label will identify the plant part or process used, and the dose or dry-weight-equivalent dose (for herbal products).

Registered medicines

CAMs deemed to present a higher therapeutic risk or make higher level therapeutic claims are classified by the TGA as registered medicines. Registered complementary medicines may be non-prescription or prescription medicines. Data supporting safety, quality and efficacy must be submitted to the TGA for evaluation before marketing. Registered medicines have an **'AUST R'** number on the product label.

Global guidelines

Different cultural groups and countries have differing levels of CAM use and regulatory controls.

The World Health Organisation promotes regulation of products, practices and providers to ensure safety, efficacy and quality of CAMs, based on available evidence.

Quality assurance

Herbal medicines contain constituents with levels that may vary depending on the part of the plant used, the plant's stage of ripeness, the geographic area where
the plant is grown and storage conditions. Different extraction and manufacturing processes can also cause quantitative and therapeutic differences between products and batches of the same product. Ingredients may be 'standardised' to an accepted concentration of an identified constituent and provide batch-to batch reproducibility of the constituent. Products of St John's wort (*Hypericum perforatum*), for example, may be labelled as containing 300 mg of a standardised herb extract containing 0.3% hypericin per dose.

Standardisation is not a measure or guarantee of efficacy or potency of the product. Full product standardisation requires the application of quality standards to the growing, harvesting, processing and manufacturing stages.

Herbal preparations are considered therapeutically equivalent if they have, or would be reasonably likely to have, comparable therapeutic effects when used at the recommended doses. To establish this, it is necessary to show that the preparations contain a similar range and concentration of constituents, including any known active constituents, or have a similar therapeutic action on the body. For example, a *Ginkgo biloba* leaf extract prepared by a process different from one for which clinical efficacy in the treatment of dementia has been demonstrated must be proven to be therapeutically equivalent before it can be used in a similar manner.

All manufacturers of CAMs in Australia must be licensed and comply with the principles of good manufacturing practice. The TGA undertakes inspections and audits to identify issues such as the substitution of plant species and heavy metal adulteration.

Marketing

CAMs must be labelled in English, showing the therapeutically active ingredients and the plant part used, the dose or dry-weight-equivalent dose, and any warnings or cautionary statements necessary for correct and safe use.

The *Therapeutic Goods Act 1989* gives effect to the Therapeutic Goods Advertising Code, which aims to ensure that all marketing and advertising of therapeutic goods to consumers embraces the quality use of therapeutic goods, is socially responsible, and does not mislead or deceive the consumer. Advertising should not encourage consumers to self-medicate for conditions that require expert advice. The code prohibits promotion of CAMs for the treatment, cure or prevention of HIV and AIDS, neoplastic diseases, sexually transmitted diseases or mental illness. The code requires that the approval of the TGA be obtained before promotion of CAMs for treatment or prevention of serious forms of a range of other diseases.

Marketing intended exclusively for healthcare professionals is governed by industry codes of practice and is not subject to the Therapeutic Goods Advertising Code.

Please note, that media, and sporting personalities (paid handsomely by their sponsors) are not experts on drugs, medicines or nutrition. They are there to con you

Adverse effects

When recommending or providing advice on CAMs to consumers, it is important that pharmacists evaluate the potential harms and benefits of CAM therapy.

Some individuals are at increased risk of adverse events, especially when CAMs are co-administered with prescription medicines. Individuals at increased risk include those:

-taking medicines with a narrow therapeutic index
-taking multiple medicines
-are older
-are children
-diagnosed with a chronic medical condition
-with impaired liver or kidney function

-are frail or otherwise vulnerable.

Information on adverse effects has been derived from experience from the CAM's traditional uses, clinical trials and post-marketing surveillance. Pharmacists play an important role in recognising and reporting adverse reactions to the TGA's Advisory Committee on the Safety of Medicines (ACSOM) (see 'Clinical monographs', Section D, for more information).

Surgery

Some CAMs have effects that increase the risk of complications during or after surgery. For example, some have anticoagulant or antiplatelet effects, or interfere with the action of anaesthetics. Consequently, it is recommended that certain CAMs are ceased before surgery. Pharmacists should advise consumers to discuss their use of CAMs with their medical practitioner before planned surgery, as some CAMs may need to be ceased 7–14 days before surgery. CAMs that might need to be ceased before surgery include: *artichoke*, *astragalus*, *bilberry*, *capsicum*, *celery*, *chamomile (German)*, *coenzyme Q10*, *cranberry*, *devil's claw*

dong quai
evening primrose oil
feverfew
fish oil
garlic
ginger
ginkgo biloba
ginseng (Asian and Siberian)
glucosamine
grape seed
green tea
guarana
horse chestnut
kelp
pau d'arco
red clover
saw palmetto
St John's wort
willow bark.

Chemotherapy: Studies have identified a high rate of CAM use among patients with cancer or undergoing treatment for cancer. These patients should be encouraged to, openly discuss any use of CAMs with their medical practitioner(s) *prior* to commencing treatment, to avoid drug interactions, adverse reactions or diminished efficacy. The Cancer Council of Australia can provide both health professionals and patients with information on the use of CAMs in association with cancer treatment.

Pregnancy and breastfeeding: The reported frequency of CAM use during pregnancy in Australia is estimated to be between 10% and 56%, and is believed to be increasing. No medicine, either conventional or complementary, should be taken during pregnancy or breastfeeding unless the benefit outweighs the potential risks to the mother and infant. Women considering CAM use during pregnancy or breastfeeding should be provided with detailed advice on both the potential harms and the potential benefits, to assist them to make an informed decision. Few scientific trials have studied the use of conventional medicines in pregnancy and breastfeeding, and even fewer have addressed the use of CAMs.

However, several international agencies, such as the Organization of Teratology Information Specialists (www.otispregnancy.org) and Motherisk(www.motherisk.org), are conducting epidemiological research on pregnancy outcomes associated with various herbal remedies, and publish excellent fact sheets on their websites. The Royal Women's Hospital Drug Information Centre has published a list of CAMs to avoid during pregnancy and breastfeeding.10.

Contraindications(when not to use them) that need to be taken into account when counselling consumers about the use of CAMs are listed. However, evidence-based information in this area is limited. Health care Professionals should consider individual patient characteristics to assess potential clinical relevance.

Interactions Drug interactions represent one of the greatest safety risks with the use of CAMs; however, available data vary widely in quality and reliability.

This talk will look at the evidence of efficacy and possible toxicities of the following CAMs

Black cohosh	Many claims; evidence equivocal, some toxicities.
Coenzyme Q10	Many claims; evidence equivocal
Cranberry	Urinary tract infections- evidence equivocal
Fish oils	Cardiovascular disease, rheumatoid arthritis- good evidence
Ginkgo	Many claims-evidence poor
Ginseng	Many claims-evidence poor
Glucosamine	Osteoarthritis-evidence equivocal
Probiotics	Gastrointestinal tract disorders- evidence good
Red clover	Many claims; evidence equivocal/poor
Saw Palmetto	Benign prostatic hyperplasia (BPH)-evidence equivocal
St Johns Wort	Depression- good evidence- many, many drug interactions
Homeopathy	A nonsensical belief system- disproved over and over again
Mega-vitamins	Many claims evidence poor

It is important that consumers who wish to utilise CAMS should check with conventional health-care providers such as medical practitioners and/or pharmacists. This is particularly important if the consumer is already being treated with conventional medicines.