

Victorian Therapeutics Advisory Group
(VicTAG)

**Complementary Medicines Resource
Document**

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Complementary and Alternative Medicines

Use of Complementary and Alternative Medicines (CAMs) by Inpatients

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Complementary and Alternative Medicines

Preamble

This resource document has been developed by VicTAG as a model that can be adapted to the needs of individual health care facilities in accordance with hospital policy and the approval of the hospital's Drug and Therapeutics Committee. The model aims to encourage open disclosure and discussion about the use of CAMs by patients and their health care providers in order to promote patient safety and minimise adverse events.

- Currently 50 to 60% of the adult population use CAMs on at least an annual basis. Australian data suggest that 39% of people taking CAMs will also consume conventional medicines. CAMs are also commonly administered by parents or guardians to paediatric or dependant patients.
- Information about CAMs is variable. Some CAMs have good quality evidence about their benefits and risks, whereas others have very limited information about their effects. For this reason, interactions with other medicines, conditions and procedures can be unpredictable. Use of CAMs can lead to adverse drug interactions and increase the risk of bleeding during or after surgery.
- It is important to be open-minded and non-judgmental about CAMs and encourage patients/carers to inform healthcare professionals if they have been using them, and if they wish to continue their use while in hospital.
- Taking a positive, pro-active approach to CAM usage is important in order to maintain a positive professional relationship with the patient/carer and apply an evidence-based approach to minimizing patient harm.

Definitions

The primary body that regulates drug registration in Australia is the Therapeutics Goods Administration (TGA). It is a requirement under the *Therapeutic Goods Act 1989* (the Act) that medical products to be imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods (ARTG) as either a registered medicine or a listed medicine. In order for a product to be included in the ARTG, a sponsoring company is required to make an application, which usually consists of a form accompanied by data to support the quality, safety and efficacy of the product. Individually compounded medicines prepared for an individual do not have to be registered or listed.

Registered medicines

Prescription medicines

Medicines assessed as having a higher level of risk must be registered (not listed). The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data.

Prescription medicines fit into the sub-category of registered medicines as high-risk registered products. This group includes all prescription medicines (ie. medicines with ingredients which are included in Schedule 4 or Schedule 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons*) and some specified products such as sterile injectables.

These medicines are identified by an 'Aust R' number on their packaging e.g. for Lipitor®, the Aust R number is 59603.

Non-prescription (OTC) medicines

Low-risk Registered products are non-prescription medicines. They usually contain ingredients which are described in Schedule 2, Schedule 3, and sometimes Schedule 5 or 6 of the *Standard for the Uniform Scheduling of Drugs and Poisons*. Products in this category are considered to be lower risk than prescription medicines. However, they still require a high level of scrutiny, for example to ensure adequate labelling for appropriate use.

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Listed medicines

Listed medicines are usually considered to be relatively benign, so the regulations allow for sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment.

They are all unscheduled medicines (ie. not described in the *Standard for the Uniform Scheduling of Drugs and Poisons*) with well-known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. These are assessed by the TGA for quality and safety but not efficacy.

This does not mean that they do not work. It simply means that the TGA has not evaluated them individually to see if they work. It is a requirement under the Act that sponsors hold information to substantiate all of their product's claims. For example, sunscreens can be a listed product yet, they must have complied with testing under the Australian standard for sunscreens.

These medicines are identified by an 'Aust L' number on their packaging e.g. for CoEnzyme Q®, the Aust L number is 69050.

Complementary and alternative medicines (CAMs)

CAMs describe a group of products that are not presently considered to be part of 'conventional medicine'. People use CAMs in a variety of ways. CAMs used alone are often referred to as 'alternative therapies'. CAMs used in addition to 'conventional medicine' are referred to as 'complementary' or 'integrative'. CAMs include vitamin, and mineral supplements, herbal medicines, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils.

CAMs may be either registered or listed, depending on their ingredients and the claims made. Most CAMs included in the ARTG are listed and some are registered. Individually compounded CAMs prepared for an individual and some other CAMs (particularly those imported from overseas) are usually not registered or listed. The quality of such products may vary or not be known.

Special Access Scheme (SAS)

The SAS refers to arrangements that provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. It requires approval from the TGA or from a delegate appointed to act on TGA's behalf.

Hospital Formulary

Within the hospital, medications can be:

(a) **Available on the formulary.** This means that doctors in the hospital are authorised to prescribe them and the hospital is able to supply them. There can be some restrictions on who can prescribe formulary medications and these restrictions usually relate to cost and safety. Some formulary items may also be prescribed by nursing staff e.g., paracetamol. To be available on the formulary, medications must be assessed by the Drug and Therapeutics Committee or equivalent body that is responsible for drug therapy within the hospital. This committee has the authority to add any medicinal compound to the formulary. Some CAMs may be available on the hospital formulary for example calcium supplements, folic acid, vitamin and mineral supplements etc.

(b) **Non formulary items.** Many medications that are registered or listed for use by the TGA are not on the formulary. This may be because they are new products and an application for inclusion on the formulary has not been made, there may be no perceived need for that medication to be available on the formulary e.g., a similar medication of the same class may already be available, or a decision may have been made not to include the medication on the formulary because of concerns about cost, safety or efficacy. If a patient is already using a non formulary medication when admitted to hospital they may be asked to provide their own supply in circumstances when the medication is not readily available within the hospital.

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When non formulary items, including CAMs, are being prescribed frequently a submission should be made to the hospital's Drug and Therapeutics Committee or equivalent body for formulary inclusion. The hospital Drug and Therapeutics Committee or equivalent body will then evaluate the safety and efficacy of the medications.

Other Definitions

Guardian – the term guardian, as used in these guidelines, refers to those who have the legal right to make decisions on behalf of a patient, this may include parents.

Carer – the term carer as used in these guidelines refers to any person who may assist in the care of a patient and includes parents, guardians, other family members and friends. A carer is not able to make decisions on behalf of a patient unless they have been legally appointed as a guardian.

Guideline statement

This guideline is not an endorsement for or against general use of CAMs, rather, it is an acknowledgement by the hospital that CAMs are widely used by the public. This guideline aims to provide procedures within the hospital for the handling of CAMs and can be modified in accordance with local hospital policy as approved by the hospital's Drug and Therapeutics Committee.

The hospital has a duty of care to all patients to ensure that any materials, drugs, substances or equipment supplied to or used by inpatients including any CAMs used within the hospital, whether patient/carer administered or not, are used as safely as possible taking into account quality, safe dosage and storage, and usage.

This guideline applies to CAMs where use is initiated by in-patients or by their guardians, and the CAM(s) is/are brought into the hospital to be administered during their stay in hospital. **It does NOT apply where use of the CAMs is initiated and prescribed by hospital clinicians.** These fall within general hospital policies about the supply, administration, and safe storage of medicines.

The fundamental requirements within the guidelines are:

- It is the patient's or their guardian's prerogative if they wish to continue using CAMs, however, they must discuss this with their treating doctor(s), particularly if the CAMs will be taken during their inpatient stay.
- The treating doctor(s) must decide whether to approve usage or advise the patient or their guardian against use. The doctor should also advise the patient and their carers of any changes to their primary treatment which are necessary because of the patient's use of CAMs and document this in the medical record.
- When the use of CAMs is approved by the doctor they must be prescribed on the Medication Chart and be administered by the nursing staff.
- When the doctor advises the patient or their guardian that use of CAMs is not recommended but the patient or their guardian wishes to continue using these CAMs, the patient or their guardian is required to sign a usage statement listing products used without their doctor's approval and self medicate with documentation on the CAM Self Medication Chart. The doctor should also sign the usage statement to indicate that they have advised against the use of the listed CAMs during the hospital stay and note why they have recommended against the use of the listed CAMs.
- The CAM Self Medication Chart must be kept with the Medication Chart. A note should be made on the Medication Chart to indicate that the CAM Self Medication Chart is being used.
- When CAMs are prescribed on the Medication Chart or recorded on the CAM Self Medication Chart a full description of the product including active ingredient(s), brand name, strength and the dosage must be recorded.

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- Patients and their carers are responsible for the procurement of their own supply of CAMs (unless they are available on the hospital formulary and prescribed by a medical officer).
- The hospital and the treating doctor(s) do have a duty to advise a patient or their guardian of any risks which may arise given the patient's or their guardian's wish to continue with any CAMs. The hospital and the treating doctor(s) may determine, in the patient's best interest, that they should not provide any treatment or service which will increase any risk to a patient's health, given the patient's or their guardian's wish to continue use of any CAMs. In all circumstances the doctor(s) should ensure that the advice given and the decision of the patient is clearly documented in the medical record.
- Suspected adverse drug reactions or interactions involving CAMs should be reported to the Adverse Drug Reaction Advisory Committee (ADRAC) in the same manner as for 'conventional medications'. The same hospital procedures for handling suspected adverse drug reactions or interactions should be applied to both CAMs and 'conventional' medicines.

Responsibilities

Responsibilities of patient or guardian

- To notify clinical staff of any CAMs they are using and/or wish to use during their inpatient stay.
- To obtain approval from their treating doctor if they wish to use CAMs during the inpatient stay.
- If the patient or their guardian is advised by their treating doctor that use of any CAMs is not recommended and the patient or their guardian wishes to use the CAMs against medical advice, the patient or their guardian is required to:
 1. Sign a usage statement listing the products.
 2. Self medicate with documentation on the CAM Self Medication Chart.
 3. Notify nursing staff when doses are required.
 4. Inform nursing staff when doses are administered.
- To supply any CAMs not available on the hospital formulary.
- To give the CAMs, in their original packaging clearly labelled with the patient's name, to nursing staff to safely store in the locked ward cupboard, locked bedside locker, drug trolley or other medication storage facility.

Responsibilities of hospital clinical staff

- Hospital clinical staff should not administer CAMs or permit the administration of CAMs by patients or carers except according to the hospital policy.
- On admission, medical, nursing and pharmacy staff should specifically ask patients and carers about use of CAMs when taking the medication history.
- On admission patients and their carers should be provided with the CAM patient information brochure.
- Discuss with the patient and their carers the use of CAMs with the aim of ensuring that:
 - the patient and their carers can distinguish between CAMs that may be helpful and those that are potentially harmful.
 - the patient and their carers are advised:
 - of the importance of disclosing information about use of CAMs to health care professionals because interactions with other prescribed and over the counter medications can be unpredictable. In certain cases there is strong evidence to say that these interactions are harmful.
 - that quality control is not guaranteed with all CAMs in the same way as conventional medicines.
 - the possibility of any risk of interaction with their primary treatment.
 - the possibility of any risks associated with a procedure.
 - of any potential adverse effects.

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- how to report any adverse effects or withdrawal effects associated with using CAMs.
- Communicate with other health professionals involved in the care of the patient regarding the use of CAMs as required with the patient's or guardian's permission.

Responsibility of the treating doctor(s)

- To seek information about the potential effects and quality of the patient's CAMs
- Provide information about the potential effects and quality of the patient's CAMs to the patient and their carers.
- To ensure that the patient and their carers have been provided with the CAM patient information brochure.
- Decide whether to approve the use of CAMs or advise against use of CAMs during the hospital stay.
- If the decision is to approve use of CAMs during the inpatient stay then to prescribe the CAMs on the Medication Chart as with other pre-admission medication. A full description of the product including active ingredient(s), brand, strength and dosage must be recorded.
- If the decision is to advise against use then to advise the patient and their carers that the use of the specified CAMs is not recommended and explain why they are not recommended and document this in the patient's medical record.
- Advise the patient and their carers of any changes to their primary treatment which are necessary because of the patient's use of CAMs and document this in the patient's medical record.
- If the patient or their guardian wish to continue the use of CAMs against medical advice then to:
 1. Document this decision and the CAMs being used in the patient's medical record.
 2. Ask the patient or their guardian to sign the usage statement listing the products being used against medical advice.
 3. Sign the usage statement and document the reasons why the products are not recommended.
 4. Ask the patient or their guardian to complete the CAM Self Medication Chart.
- Ensure that any use of CAMs is recorded in the patient's medical record and on the discharge summary (including if they are not used during inpatient stay). The information recorded should include:
 - discussions regarding the approval process;
 - the name of the CAMs being used;
 - when and how administered;
 - in what dosage; and
 - who is responsible for administration.
- Record and report any adverse reactions as per hospital guidelines.

Responsibility of nursing staff

- Monitor use and safe storage of CAMs.
- Safely store CAMs in the locked ward cupboard, locked bedside locker, drug trolley or other medication storage facility.
- Provide CAMs to patients and their carers when they are to 'self administer' a dose.
- Only administer CAMs when prescribed on the medication chart.

Resources

Useful resources for information about CAMs

- Hospital Drug Information Centre
- Altmedex (from Clinician's Health Channel)
- Review of Natural Products (Facts & Comparisons)
- AusDI – herbal monographs

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- Herbal Medicines (Pharmaceutical Press, UK)
- Natural Medicines Comprehensive Database (<http://www.naturaldatabase.com/>)
- Braun L and Cohen M. Complementary medicine interactions Part 1. The Journal of Complementary Medicine 2004; 8 : 78-85
- Braun L and Cohen M. Complementary medicine interactions Part 2. The Journal of Complementary Medicine 2004; 10 : 88-91
- Braun L and Cohen M. Complementary medicine interactions Part 3. The Journal of Complementary Medicine 2004; 11 : 70-82
- Braun L and Cohen M. Herbs and natural supplements – an evidenced based guide. Elsevier Australia. 2004

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Appendix 2.

Complementary & Alternative Medicines (CAM) Usage Statement for Inpatients

AFFIX IDENTIFICATION LABEL

Or print name and UR Number

1. Read the hospital's CAM guideline and discuss with the patient or guardian
2. Provide patient or guardian with a Complementary & Alternative Medicines Brochure
3. Obtain the signature of the patient or guardian for CAMs usage against medical advice
4. Document the reasons for the recommendation and sign the CAM usage statement

Background

CAMs describe a group of products that are not presently considered to be part of 'conventional medicine'. People use CAMs in a variety of ways. CAMs used alone are often referred to as 'alternative therapies'. CAMs used in addition to 'conventional medicine' are referred to as 'complementary' or 'integrative'. CAMs include vitamin, and mineral supplements, herbal medicines, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils.

This hospital has a duty of care to all patients to ensure that CAMs used within the hospital, whether self-administered by the patient or guardian or not, are used as safely as possible, taking into account quality, safe dosage and storage and appropriate use. If inpatients wish to use CAMs within this hospital, they may use them only within the guidelines.

For the full guideline refer to the pharmacy department.

If a patient or their guardian wishes to use CAMs while he/she is an inpatient, he/she must first discuss it with his/her treating doctor. If the doctor recommends against use but the patient or guardian still wishes to use the CAMs they must sign the CAM use against medical advice statement.

COMPLEMENTARY AND ALTERNATIVE MEDICINE USE AGAINST MEDICAL ADVICE

Patient/guardian section

I.....(patient/guardian) of.....

.....(address)

wish to continue use of the following Complementary or Alternative Medicines (CAMs) during this admission, commencing on/...../.....(admission date) (list CAM(s))

.....

.....

.....

AGAINST THE ADVICE OF THE TREATING DOCTOR Dr

I have been advised that continuing use of these CAMs is not, in the opinion of the above named doctor, in my/the above named patient's best medical interests. Despite receiving this advice, I wish to continue use of the CAM(s) listed above.

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Appendix 3 Patient information brochure

Using Complementary and Alternative Medicines (CAMs)

What are complementary and alternative medicines (CAMs)?

CAMs describe a group of products that are not presently considered to be part of conventional medicine. People use CAMs in a variety of ways. CAMs used alone are often referred to as 'alternative' therapies. CAMs used in addition to 'conventional' medicine are referred to as 'complementary' or 'integrative'. CAMs in Australia include herbal medicine, vitamin and mineral supplements, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils. An herbal practitioner or naturopath or your general practitioner may have prescribed these. You may have purchased them from a pharmacy, supermarket, health food store, on-line or you may have prepared them at home using ingredients passed on by generations of family members.

How can I be sure that CAMs are safe and effective?

A common misconception with CAMs is that many people think that because they are "natural" they are safe. However harmful effects have occurred and can be quite serious, such as liver poisoning. It is therefore important to discuss **all** medicines including CAMs with your doctor. In Australia, registered medicines are required to meet strict standards. Most medicines prescribed by your doctor are TGA **registered**. This means that there are scientific studies to prove that they are safe **and** effective. An 'Aust R' number on their packaging identifies these medicines. Medicines can also be TGA **listed**. Listed medicines are considered to be **safe**, but there may be limited information to say that they are effective. These medicines have an 'Aust L' number on the label.

If a medicine or CAM does not have an Aust R or L number there is limited information to say that it is **safe and effective** and the quality of the product may vary or not be known.

Use of CAMs in hospital

Information about CAMs is variable. Some CAMs have good quality evidence about their benefits and risks, whereas others have very limited information about their effects. For this reason their interactions with other medicines, conditions and procedures can be unpredictable. We want to provide you with the best care we can. By telling medical staff, nursing staff or the pharmacist about ALL your medicines including CAMs, we can discuss with you the risks or benefits about continuing them while you are in hospital.

You need to tell your doctor, nurse and pharmacist about:

- ◆ All medicines prescribed by your GP and any specialists.
- ◆ Patches, HRT (hormone replacement therapy), eye drops, inhalers.
- ◆ Creams, ointments or lotions used for medical conditions.
- ◆ CAMs, eg Naturopathy, homeopathy, health shop products.
- ◆ Pharmacy medicines available without a prescription.
- ◆ Vitamins, mineral, supplements and herbs.
- ◆ Preparations prescribed by your naturopath or herbalist.
- ◆ Traditional herbal preparations used by your family.

If in doubt, ask your doctor, nurse or pharmacist.

CAMS and interactions with other medicines

Over half of the Australian population use CAMs each year. Many will take conventional medicines at the same time. Information about interactions is increasing, but some effects are still unpredictable. For your safety, your doctor may recommend that you cease your CAMs when new medication is started.

For example the following CAMs may increase the risk of bleeding in patients who are taking warfarin, though the effect can depend on the amount you are taking:

Carnitine, Celery, Dong Quai, Evening Primrose Oil, Fish Oils, Garlic, Ginger, Ginkgo, Korean Ginseng, Picosanol, Vitamin E.

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These are only examples and it is important that you speak to your doctor or pharmacist to see if there is any risk of interactions between your CAMs and conventional medicines.

CAMs and surgery

If you are booked or admitted for surgery you should always tell your doctor or pharmacist about all your medicines, including CAMs. Some CAMs can lead to complications during or after surgery.

For example the following CAMs may increase your risk of bleeding during or after surgery, though the effect can depend on the amount you are taking:

Celery, Devil's Claw, Dong Quai, Feverfew, Vitamin E, Garlic, Ginkgo, Korean Ginseng, Green Tea, Policosanol.

Other CAMs can affect blood pressure and blood sugar which may cause problems when you have an anaesthetic.

Your doctor may advise stopping your CAMs for about a week before surgery to minimise the risk of complications. However, if you have any concerns about stopping your CAMs you should discuss this with your doctor. The products listed are only examples and it is important to provide your doctor with a full list of all the medicines you are taking, including CAMs.

What if I wish to keep taking CAMS in hospital?

If you wish to continue taking CAMs during your hospital stay discuss this with your treating doctor. Occasionally we may advise you to stop taking CAMs, because of concerns about possible interactions with conventional medicines, risks associated with a procedure or with your medical condition. If your doctor recommends that you stop your CAMs during your hospital stay but you wish to continue using them we will ask you to sign a usage statement. Your doctor will explain the reasons why you should stop taking any CAMs

If I get side effects from starting or stopping CAMS should I report this?

It is important that you tell medical staff, nursing staff or the pharmacist about any side effects that you think may be caused by starting or stopping CAMS so that they can be reported. This information may help healthcare professionals to assess the benefits and risks both for you and for other patients in the future.

Will the hospital supply CAMs?

If you are continuing the use of CAMs during your admission, you may use your own supply of CAMs during your hospital stay. These will be locked safely in the hospital's medicine cupboard, in accordance with our medicines policy. You can ask the nursing staff for them when you need them. The hospital will not be responsible for supplying or administering CAMs unless prescribed by your doctor.

Our responsibilities

- To ask you about all of your medicines.
- To advise you about the safety of all medicines.

Your responsibilities

- To tell us about **all** of your medicines.
- To tell us if you wish to continue taking a complementary medicine while you are in hospital.
- To supply your own complementary medicines while you are in hospital.
- To give all your medicines to the nurses for safe storage.

Where can I obtain more information about CAMs?

You should always discuss your CAMs with your doctor or pharmacist.

The NPS Medicines Line is a consumer medication information service that is available on weekdays during normal business hours on 1300 888 763

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Interpreter Services

Patients and carers who experience English language difficulties may ask to have a professional interpreter to assist with any queries about the information provided. Please ask the staff to make arrangements for an interpreter to visit whilst in hospital. Telephone interpreter service 131450

This brochure is available in translation.

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Appendix 4

Flowchart for use of CAMs

