

# SATAG

Quality use of medicine for a healthier South Australia



# South Australian Therapeutics Advisory Group

## Guidance Document

**The Handling of Patient Requests for the Use  
of Complementary and Alternative Medicines  
in South Australian Public Hospitals**

**December 2008**

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## Purpose

The purpose of this document is to provide South Australian public hospitals with guidelines on the use of complementary and alternative medicines (CAMs) alongside conventional medical or surgical treatment for patients admitted to South Australian public hospitals.

This guidance applies to CAMs which are not listed on the relevant hospital formulary and their use is continuing at the request of the patient or their guardian.

CAMs are defined as substances taken with therapeutic intent that may or may not be listed or registered on the Australian Register of Therapeutic Goods (ARTG) including vitamins and mineral supplements, herbal medicines, other nutritional supplements, traditional medicines such as ayurvedic and Chinese medicines, homeopathic medicines and aromatherapy oils.

CAMs do not include off-label use of medicines, that is the use of a medicine for a purpose that is outside of the scope of its approved use (indication) by the Therapeutic Goods Administration, or proscribed (illicit) drugs.

## Background

South Australian public hospitals should not promote the use of substances without any proven benefit, or which may cause unexpected morbidity. While acknowledging the significant use of CAMs within the Australian community, the safety, quality, efficacy and appropriateness of these therapies cannot always be confirmed. In addition, interactions with prescribed medications are largely unknown and patient safety may be jeopardised when they are used in combination. Hospitals have a duty of care to patients and staff to ensure a favourable risk / benefit relationship for all therapeutic goods used with the hospitals. Patients in this context include the foetus and the breastfeeding infant.

It is acknowledged that patients may wish to continue use of CAMs whilst admitted. This guidance recommends a position for adoption by South Australian public hospitals to assist patients, medical, nursing and pharmacy staff to appropriately handle requests for use of CAMs.

## Guidance

### 1. Guiding Principles

1. A person's right to self-determination in medical treatment needs to be balanced with the professional judgement of medical, nursing and pharmacy staff to ensure that the person is not placed at risk of harm.
2. Hospitals should not generally support the use of CAMs by inpatients while under the care of the hospital and should generally not initiate CAMs for inpatients.
3. Hospitals should endeavour to educate patients in regard to the issues relating to use of CAMs.
4. CAMs may be prescribed for continuity at the discretion of the treating medical officer. All prescribed CAMs are to be documented and administered according to standard hospital procedures.
5. Hospitals should only allow self-administration of CAMs by inpatients after clinical review of safety implications and on the written instruction of the treating medical officer.

6. If a patient insists on use of complementary medicines against medical advice, the patient should be asked to sign a declaration form (**Appendix 2**) acknowledging the risks associated with use of the complementary medicine under these circumstances.
7. Hospital staff should not to be involved in the administration of non-prescribed CAMs.
8. During pregnancy or breastfeeding safety of the foetus/infant is paramount. If a CAM is to be taken data on the safety of the product in these situations will need to be ascertained.
9. Financial resources of hospitals should not be used to support the procurement or use of CAMs. The patient/legal guardian is responsible for the provision and cost of CAMs prescribed.
10. CAMs prescribed or administered at a South Australian public hospital must carry an Aust L or Aust R number on the label, which indicates that the product is listed or registered on the ARTG.

This guidance recognises and addresses the reality that hospitals:

1. cannot legally enforce removal of medicines brought into hospital by patients, nor effectively prevent medicines being brought into hospital by patients' legal guardians, relatives or friends; and
2. cannot effectively prevent self-administration by patients if they are determined to do so.

## **2. Procedure**

An overview of the procedure is provided in **Appendix 1**.

### **2.1 Patient Admission**

On admission to the hospital, the clinical team should obtain a detailed medication history from the patient and document in the patient's medical records all prescription, over-the-counter medicines or CAMs the patient may be taking. If the patient is taking CAMs they should be informed of the hospital policy. The CAM should be ceased whilst admitted if the patient agrees. If the patient has brought in their own CAMs, they should be advised that self-medication while an inpatient is not supported. The patient should be offered the choice of returning these products to a relative or friend for safe-keeping or secure in-hospital storage by the nursing staff or pharmacy. If stored by the hospital, the medicines will be returned at discharge and in accordance with hospital policy on handling of patients' own medicines brought into hospital.

### **2.2 Patient/Legal Guardian Requesting Treatment with a CAM**

If a patient/legal guardian requests the use of CAMs during admission, the clinical team should be informed. It is the medical officer's duty to discuss hospital policy with the patient. If the patient still wishes to use the CAM:

- The medical officer should contact a pharmacist or Drug Information Centre for safety and efficacy data.
- The pharmacist or medical officer should record the product's Aust L or Aust R number.
- The pharmacist should try to identify any known contraindications with the patient's disease state and/or interactions with co-prescribed medications, and the dosing recommendations.
- Products not having an Aust L or Aust R number should not be prescribed or administered within the hospital, as their quality and safety cannot be assured. The

patient should be advised that the use of such products will not be sanctioned while the patient is an inpatient of the hospital. The medical officer should consider the possibility that the patient may nevertheless self-administer the CAM without the knowledge of the staff, and the effect this might have on the patient's overall management, including their prescribed medication.

### **2.3 Identification of Contraindications**

Where there are published data on a potential adverse interaction, or the efficacy of co-prescribed medications is compromised, the patient should again be informed of the risks and advised against use of CAMs. The Consumer Advisor may be involved if necessary. All consultations should be recorded in the patient's medical record.

If the patient refuses to comply with the medical officer's advice to cease the CAM, and refuses to allow the hospital to store the CAM during their admission, there should be a presumption that the patient may self-administer the CAM, despite being advised this is against hospital policy. The medical officer should therefore consider amending or ceasing the co-prescribed conventional therapy to minimise any risk to the patient.

This process, including information provided to the patient, should be clearly documented in the patient's medical record.

### **2.4 No Contraindications Identified**

If no contraindications are identified, the patient should again be informed of the potential for unknown risks and the possibility that it may have adverse effects on the co-prescribed therapy. The medical officer may further advise against use of the CAM if they consider this to be in the patient's best interest. The Consumer Advisor and/or Safety and Quality Manager may be involved if necessary. All consultations should be recorded in the patient's medical record.

### **2.5 Patient Insisting on Continuing the CAM Despite Advice Against Doing So**

If the patient insists on using CAMs but the medical officer is not prepared to prescribe it:

- The medical officer should advise the patient of his/her decision and clearly document his/her decision and the information given to the patient in the patient's medical record.
- If the patient refuses to comply with the medical officer's advice to cease CAMs, and refuses to allow the hospital to store the CAM during their admission, there should be a presumption that the patient may self-administer the CAM. The medical officer should therefore consider whether alterations to the co-prescribed conventional therapies are required to minimise any risk to the patient.
- When the patient chooses to continue use against the medical officer's advice, the patient/legal guardian should be required to sign a declaration form (**Appendix 2**) listing the products used without the medical officer's approval. The medical officer should also sign the statement and document the reason(s) why the CAM is not recommended to be continued.

If the patient insists on using CAMs and the medical officer is prepared to prescribe it:

- The patient/legal guardian is to be advised that they are responsible for the cost and provision of the CAM.
- The medical officer should prescribe the CAM on the inpatient medication chart, clearly identifying its name, strength, dose, frequency and route of administration as well as annotate the order with "patient's own supply".
- The registered midwife or registered nurse responsible for the patient's care should take possession of the CAM and after checking for an Aust L or Aust R number,

should accept the product and store it with the patient's other prescribed medications. The registered midwife or registered nurse should also be provided with information about the product.

- The administration by nursing staff of prescribed CAMs should be documented on the patient's inpatient medication chart as for conventional medicines.
- Unauthorised self-administration of CAMs should not be permitted.
- The discussions and final decision to use CAMs should be clearly documented in the patient's medical record. This should include a statement that there are potential unknown risks and the patient has been advised of this.
- The discharge letter should state that, on insistence by the patient or legal guardian, a CAM was administered during the patient's admission. The name and dose of the CAM should be documented, along with any warnings the medical officer feels necessary.

The medical officer prescribing a CAM that is not included on the hospital formulary takes professional responsibility for any consequence arising from the use of the product.

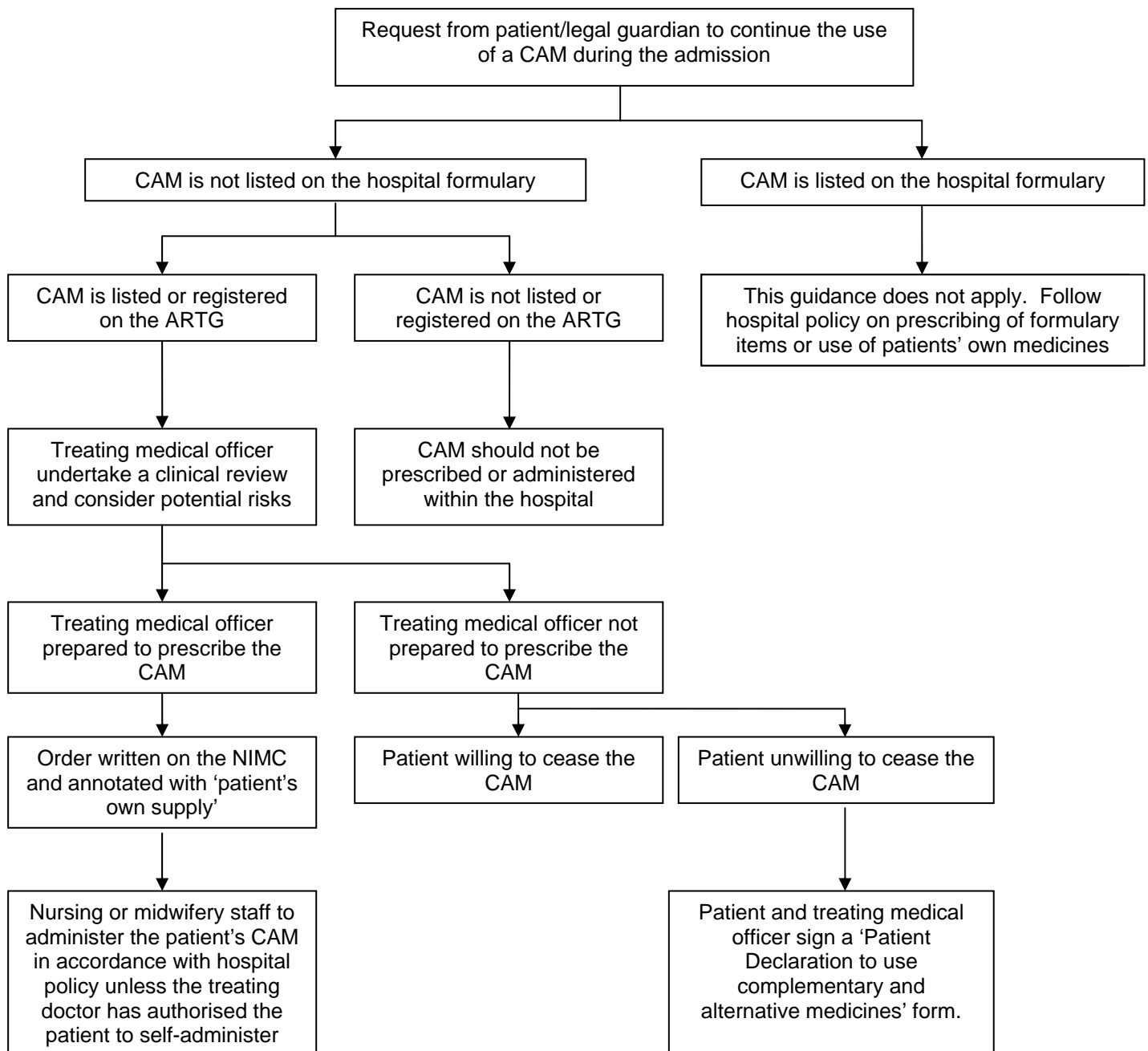
The prescribing medical officer is responsible for recording any suspected adverse reactions in the patient's medical record as well reporting to the hospital's Drug and Therapeutics Committee and the Adverse Drug Reactions Advisory Committee (ADRAC).

If there is a matter of dispute requiring consideration, the case may be presented to Medical Administration who may convene a committee consisting of representatives from the Drug and Therapeutics Committee, Ethics Committee and the treating Unit (preferably the medical officer) to assist in deciding the hospital's final position on the use of the CAM.

## **2.6 Non-Oral/Non Parenteral CAMs**

- Use of non-oral CAMs should be reviewed by the medical officer to consider if any contraindications exist.
- If there is any risk of exposure to other patients or staff, the CAM should not be used (e.g. aromatherapy).

Flowchart: Overview of Procedure



<b>Patient declaration to use complementary or alternative medicine(s)</b>  <b>(Page 1 of 2)</b>	<b>Affix Patient Identification Label Here</b>		
	Surname	UR Number	
	Given Name	DOB	Sex
	Address		
	Suburb Town	Postcode	
This form is to be completed giving due consideration to the <i>insert policy name</i> of the <i>insert hospital name</i> .			
<b>Declaration of the medical officer (to be completed by the medical officer obtaining the patient's declaration).</b>			
<b>Tick (✓) the boxes or cross out and initial any changes or information not appropriate.</b> <input type="checkbox"/> I have informed the patient/patient's guardian of the risks involved in their continuing use of the complementary or alternative medicine(s) listed below. <input type="checkbox"/> I have recommended that the patient cease use of the complementary or alternative medicine(s) listed below. <input type="checkbox"/> I have given the patient / patient's guardian opportunity to discuss the risk of continuing use of the complementary or alternative medicine(s) listed below. <input type="checkbox"/> The patient / patient's guardian has indicated that the patient will continue to use the complementary or alternative medicine(s) listed below.			
<b>List the complementary or alternative medicine(s) that the patient is using.</b> Include Aust L/R number where available.			
<b>List the specific risks to this patient that have been identified relating to their continuing use of the complementary or alternative medicine(s) listed above.</b>			
<b>Details of the medical officer obtaining the patient's declaration.</b>			
Full Name ( <i>Please print</i> )		Position/Title	
Signature		Date	
<b>Details of the medical officer with overall responsibility for treatment (if different).</b>			
Full Name ( <i>Please print</i> )		Position/Title	
Signature		Date	

MR \_\_\_\_\_ PATIENT DECLARATION TO USE CAMs

<b>Patient declaration to use complementary or alternative medicines</b>  <b>(Page 2 of 2)</b>	<b>Affix Patient Identification Label Here</b>	
	Surname	UR Number
	Given Name	DOB      Sex
	Address	
	Suburb/Town	Postcode
<b>Patient's Declaration</b>		
Please read the information carefully and tick (✓) the following to indicate that you have understood the information that has been provided to you. Any specific concerns should be discussed with your doctor <b><u>prior to signing the declaration form.</u></b>		
<input type="checkbox"/> The doctor has explained my / the patient's medical condition and prognosis to me.		
<input type="checkbox"/> The doctor has also explained the risks associated continuing use of complementary or alternative medicine(s) listed over the page, including the risks that are specific to me/the patient and the likely outcomes.		
<input type="checkbox"/> I understand that I have the right to change my mind and not take the complementary or alternative medicine(s) at anytime, including after I have signed this form. I understand that I must tell the doctor if this occurs.		
<input type="checkbox"/> I declare that I / the patient intend/s to use complementary or alternative medicine(s) listed over the page against the doctor's advice.		
<b>Details of the Person Signing the Declaration</b>		
Relationship to the person intending to continue use of the complementary or alternative medicine(s)		
<input type="checkbox"/> Self <input type="checkbox"/> Parent <input type="checkbox"/> Guardian		
Full Name ( <i>Please print</i> )		
Signature		Date
<b>Interpreter's Declaration</b>		
Specific Language Requirements (if any) _____		
Interpreter service required? <input type="checkbox"/> Yes <input type="checkbox"/> No		
I confirm that I have accurately interpreted the contents of this form, the risk information and related conversation(s) between the patient / person giving consent and the doctor.		
Interpreter's Full Name ( <i>Please print</i> )		
Signature		Date