

# SHPA Standards of Practice for the Provision of Consumer Medicines Information by Pharmacists in Hospitals

*These are standards of professional practice and not standards prepared or endorsed by Standards Australia. They are not legally binding.*

## INTRODUCTION

These standards supersede the previously published SHPA standards of practice for the provision of consumer medicines information by pharmacists in hospitals.<sup>1</sup> They have been prepared to assist pharmacists to understand their legal and professional obligations in relation to consumer medicines information (CMI).<sup>2-6</sup> The standards have been produced in parallel with the Pharmaceutical Society of Australia's 'Consumer medicine information and the pharmacist' guidelines.<sup>7</sup> These practice standards take into consideration:

- legal and regulatory requirements;
- educational effectiveness;
- good pharmacy practice; and
- advice on professional indemnity issues.<sup>8</sup>

## DEFINITION AND OBJECTIVE

### Definition

CMI is brand and dose form specific, manufacturer-produced information about drug products conforming with *Therapeutic Goods Regulations 1990*. These require CMI to be produced by the manufacturer, consistent with the approved product information (PI) and provided either as a package insert, leaflet or electronically for all prescription drugs and pharmacist-only medicines. CMI is currently available for all prescription medicines, as listed in Schedule 10 of the Regulations to the *Therapeutic Goods Act 1989* and most pharmacist-only medicines. At present, CMI is only available in English and may not be available for investigational and clinical trial drugs.

### Objective

Australian Pharmaceutical Advisory Council's 'Guiding principles to achieve continuity in medication management' require that consumers and/or carers receive both verbal counselling and written information to support management of their medicines.<sup>9</sup> It is the pharmacist's legal and professional obligation to ensure that consumers have the necessary up-to-date information to make informed decisions about their medicines. CMI may be used by pharmacists to help meet these obligations by incorporation into the medication education process to reinforce the verbal counselling by the pharmacist, which accompanies the provision of medicines.

The goals for using CMI are:

- to provide accurate, relevant and up-to-date medicines information appropriate to the consumer or carer, in order to increase knowledge about their medicines; and
- to enhance therapeutic outcomes by encouraging proper use of medicines and to minimise, where possible, the potential for adverse drug reactions and drug interactions due to inappropriate use.

## EXTENT AND OPERATION

Pharmacists should use their knowledge and experience to tailor the application of these practice standards to individual situations.

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## POLICIES AND PROCEDURES

Hospital policies should be developed in cooperation with the drug committee and/or ethics committee governing the use of CMI including exclusion criteria for types of consumers who are too ill or unconscious (e.g. intensive care units) or where the information may be considered detrimental to their condition (e.g. acute psychotic illness). There will be occasions when it may be appropriate to personalise the manufacturer's CMI, to provide supplementary information when a medicine is prescribed for a condition other than those mentioned in the CMI, or situations when no CMI is available (discussed below).

### General Circumstances

Consumers admitted to hospital, their parents (in the case of children) or carers, should be informed that CMI is available. This may be achieved through inclusion of a statement in the hospital's pre-admission information, ward information leaflet, or pharmacy services leaflet distributed on admission. Posters advertising availability of information such as CMI could be positioned in outpatient clinic areas and in pharmacy waiting areas.

CMI should be issued for all new medicines commenced in hospital and this may occur while the consumer is in the ward or at the time of discharge. If all consumers receiving CMI are unable to be individually counselled, pharmacists should establish a system of prioritisation in order to reach those consumers likely to receive maximum benefit (Appendix 1).

### Special Circumstances

In some circumstances, it may be inappropriate or impractical to provide information such as CMI at the time a medicine is provided. These situations would include emergency, theatre or critical/intensive care situations. The principles underlying the provision of CMI in these circumstances remains unchanged, and mechanisms should be developed to make consumers and/or carers aware of CMI availability retrospectively.

### Provision of CMI

CMI may be offered to consumers each time a product is dispensed. Whether this is appropriate is a matter for professional judgment. Pharmacists should access the most current version of the CMI. Specific circumstances where CMIs should be provided include:

- when a medicine is first provided;
- when a significant change to the CMI has been notified by the sponsor;
- when the dosage form has been changed (e.g. from injection to tablet);
- when the brand of medicine has been changed;
- with each supply of medicine for which there are valid reasons for regular reinforcement of information, e.g. medicine is teratogenic or cytotoxic, major contraindications to the use of a medicine, consumer has special needs;
- at the request of the consumer; and
- at regular intervals (e.g. every 6 months) for medicines used for long-term therapy.

### *Inpatients*

The availability of CMI should be reinforced to inpatients by pharmacists on their ward rounds. Pharmacists should consider CMI as an aid for medication counselling and education, in accord with SHPA standards of practice for clinical pharmacy.<sup>10</sup> Processes will need to be developed for distributing CMI to inpatients. It is recommended that CMI be handed to consumers, with encouragement to read it and ask questions of the pharmacist on subsequent ward visits. Care should be taken on discharge to ensure that CMI provided during admission remain relevant.

Day patients and day surgery patients should receive CMI for medicines received as an inpatient which may cause side effects once they leave hospital.

CMI should be accessible in patient care areas, including pre-admission clinics and emergency departments for use by pharmacists and other health professionals. Electronic distribution is the preferred method to ensure access to current versions. Various mechanisms may be employed, e.g. software access, trusted Internet sites.

Where appropriate, CMI should be incorporated into group education programs such as cardiac rehabilitation and diabetes education.

The guidelines and principles relating to continuity in medication management and the guidelines for medication management in residential aged-care facilities, provide a benchmark for operational standards between the hospital and community.<sup>9,11</sup> Providing medicine information such as CMI, as part of the discharge planning and informed decision making is clearly stated. Pharmacists and other health professionals should refer to these documents when developing their own hospital policies.

### *Parents, Carers, Agents*

A consumer's privacy and confidentiality of their health information must be protected. This extends to ensuring that the medicine details contained in the CMI are kept confidential. Parents, carers and agents are all third parties and confidentiality concerns are the same for each. Pharmacists may legally disclose information to a carer/agent when they are satisfied the consumer has given actual or implied consent for the particular disclosure to be made. Pharmacists must consider the circumstances and use their professional judgment. In some circumstances it would be acceptable to place the CMI in an envelope marked to the attention of the consumer and the agent requested to ask the consumer to contact the hospital pharmacy department should they have further queries.

### **Using CMI when Counselling**

Education about medicines in the hospital setting is a multidisciplinary activity involving pharmacy, medical and nursing staff to varying extents. It will be necessary to involve all relevant staff in determining how best to incorporate CMI into the hospital's medication education process. It is recommended that pharmacists take a leading role in this process. When providing CMI, pharmacists have legal and professional obligations to ensure that consumers understand, as best they can, the information provided. Pharmacists should be familiar with the content of specific CMI before education commences. Pharmacists may also provide additional information, using professional judgment in each situation.

This is also an excellent opportunity to educate consumers about active ingredient names and to discuss brand name issues. This will help to minimise brand confusion, e.g. taking multiple brands of the same medicine.

For non-English speaking consumers every effort should be made to obtain the assistance of an interpreter.

### *Personalising the CMI*

The information contained in the CMI is general in nature and it may need to be personalised for individual consumers. Care should be taken to:

- highlight parts of the CMI which are relevant and ensure that consumers understand the information provided;
- provide further relevant information, e.g. about the disease;
- annotate the CMI with additional information, if appropriate, clearly identified and signed by the pharmacist; and
- not otherwise alter or abbreviate the CMI.

Alterations and abbreviations (cut-down versions prepared by a hospital) of the CMI may expose the pharmacist to legal action under product liability laws.<sup>8</sup>

### *Assessing the Consumer's Level of Knowledge*

Prior to issuing CMI, pharmacists should question the consumer to determine what counselling is needed (Appendix 2).

### *Going Through the CMI with the Consumer*

CMI should be used in an interactive manner and consumers encouraged to ask questions. Appropriate sections of the CMI should be used to reinforce information (Appendix 2).

### *Non-Approved/Investigational Uses of Medicines*

Sometimes a medicine may be prescribed for a condition or age group other than those mentioned in the CMI. This may be for an indication for which marketing approval has not been obtained in Australia, as may occur with some medicines used in paediatrics. When these situations occur pharmacists should:

- confirm, if necessary, the use of the medicine with the consumer and/or prescriber;
- provide an explanation as to why some of the CMI information may not be relevant and to point out the parts (e.g. adverse effects) that will still be useful;
- provide supplementary printed information from other sources (see Non-Manufacturer Issued Medicines Information or Supplementary Medicines Information); and
- counsel in the normal way with emphasis on why the medicine is being used for their particular condition.

### **Withholding CMI**

Pharmacists should refer to the National Health and Medical Research Council's 'General guidelines for medical practitioners on providing information to patients' for guidance on the limited circumstances where withholding information from a consumer is reasonable.<sup>12</sup> Pharmacists are strongly advised against withholding CMI.<sup>8</sup>

### **Non-Manufacturer Issued Medicines Information**

Written medicines information from sources other than the manufacturer should only be used when there is no manufacturer produced CMI (such as investigational drugs, clinical trial medicines). Such information may be needed to meet the pharmacist's duty of care.

Any hospital-produced information should be approved by the drug and therapeutics committee or other appropriate hospital committee. It should be clearly annotated with the hospital name and dated.

### **Supplementary Medicines Information**

It may be useful to supplement CMI with further written information to assist the consumer's understanding of their condition or medication management, particularly for non-approved uses and in paediatrics. CMI must always be given, when available, as well as the supplementary information. Pharmacists must use their judgment and discretion in each situation to ensure that the consumer's best interests are served.

If a 'highlight' summary of medicines information is provided as part of an information kit, e.g. cardiac rehabilitation, cytotoxic therapy, then this should mention that a complete CMI is available for that medicine and the complete CMI must also be included in the kit. Hospital-produced information should be approved by the drug and therapeutics committee or other appropriate hospital committee. It should be clearly annotated with the hospital name and dated. It should include a footnote informing the consumer when a complete CMI is available (and attached to the hospital leaflet). For example: 'A consumer medicines information leaflet is available for this medicine and should be attached. The hospital leaflet contains supplementary information for your condition and treatment. If you require further information please speak to your pharmacist or doctor.'

## TRAINING AND EDUCATION

Pharmacists should be trained in accessing the CMI and be aware of the hospital's policies and procedures on medication counselling and provision of CMI. Suitably trained and supervised technicians in clinical pharmacy support roles can assist in gathering CMI and distributing them to consumers prior to counselling by pharmacists!<sup>11</sup>

## RESOURCES

Hospitals should be resourced to support provision of CMI to patients. Resources include personnel, space, computers, and printers in patient care areas to generate CMIs of suitable quality. Stored hard copy CMI should be kept to a minimum to ensure currency.

## STAFFING STRUCTURE AND LEVELS

There should be sufficient pharmacists to ensure all at-risk and priority patients are verbally counselled and receive CMI where appropriate and to provide CMI to all other patients in accord with hospital policy (Appendix 1).

## QUALITY ASSURANCE AND DOCUMENTATION

Good records assist medication management and provide evidence of professional services. Provision of CMI should be documented in accord with hospital policy to aid communication within the healthcare team and to avoid unnecessary multiple issuing of CMI. It may also be recorded in the pharmacy department information system. Documentation should include:

- when CMI is provided to the consumer;
- the use of printed supplementary information; and/or
- occasions where CMI is declined, withheld or unable to be provided and the reasons for such a decision.

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11. Australian Pharmaceutical Advisory Council. Guidelines for medication management in residential aged care facilities. 3rd ed. Canberra: AGPS; 2002.

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## Appendix 1. Guide to identification of at-risk and priority consumers for CMI and medication counselling

This list is a guide to enable identification of consumers who may have special needs, and are more likely to receive benefit from medication counselling. It is not a definitive or exhaustive list and pharmacists should use their judgment when determining the CMI and counselling requirements of individuals. Consumers who are:

- commencing a medicine for the first time
- referred
- with chronic disease states
- taking drugs with narrow therapeutic index, e.g. warfarin
- taking drugs with a high incidence of serious adverse reactions
- taking drugs with special administration requirements, e.g. inhaler
- on multiple medications or complex drug regimens
- having established medicines altered
- having the brand of established medicines altered
- identified as having difficulties in managing their own medicines
- elderly or from the paediatric population
- from non-English speaking backgrounds

## Appendix 2. A suggested medication counselling approach

### Useful questions for consumers prescribed a new medicine

*What have you been told this medicine is for?*

Check understanding of the condition and purpose of the medicine; determine which areas of the CMI are appropriate and if printed supplementary information is needed. Supplementary questions: *What problem/symptoms is the medicine supposed to help? What is the medicine supposed to do?* Allow CMI sections on uses and actions to be highlighted.

*Could you tell me how you've been told to take it?*

Check understanding of the dosage and frequency of dosage. Supplementary questions: *How often have you been told to take the medicine? How much are you supposed to take? What do the label directions mean to you? What did your doctor tell you to do if you miss a dose? How will you store this medicine?* Allow CMI sections on dosage, administration, duration of therapy, missed doses and storage to be highlighted. Variations from CMI need to be noted and explained to the consumer.

*What did the doctor tell you to expect while taking the medicine?*

Side effects and interactions or their signs can be highlighted; ways of dealing with unwanted effects can be outlined. Supplementary questions: *How will you know if the medicine is or isn't working? What should you do if the medicine doesn't work? What precautions have you been told to take while on this medicine? What side effects did your doctor tell you to watch for? What should you do if this effect does occur?* Allow CMI sections on advice and precautions, overdose and unwanted effects to be highlighted. Allow discussion on the benefits and the need for treatment to be monitored (may not be covered in CMI).

### Useful questions for consumers with repeat prescriptions

*How are you currently taking this medicine?*

Consumer's answer can be checked against the label instructions.

*How is it working?*

Identify potential problems with the adequacy of therapy and give consumers an opportunity to raise questions they might have.

*What have you noticed that's different while taking this medicine?*

Identify side effects and interactions or highlight their signs; ways of dealing with unwanted effects can be outlined. This is important in achieving safe medicine use and to establish concordance and shared understanding. Appropriate sections in the CMI should be used to reinforce if necessary.

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