Submission

Mechanism to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)

About PSA

The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing Australia’s pharmacists working in all sectors and locations. There are over 27,000 registered pharmacists,¹ of which approximately 80% work in the community sector.

PSA’s core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists’ practice; and representing pharmacists’ role as frontline health professionals.

Purpose

This submission is provided by PSA in response to the public consultation paper issued by the Therapeutic Goods Administration (TGA) on Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI).

¹ Based on data published by the Pharmacy Board of Australia in April 2013.

PSA Your voice.
Responses to consultation questions

The following section includes PSA’s comments in response to the questions posed in the consultation paper.

What is the purpose and function of the PI and CMI?

The consultation paper states that the PI document is considered by the TGA as a risk minimisation tool. This is consistent with general comments from pharmacists regarding the content and language of Pis and CMIs. Nevertheless, both Pis and CMIs are important resources or tools used by pharmacists to support professional practice.

Product Information

Pharmacists may use a PI as one of several sources of information about a medicine. While information provided in a PI relating to the quality, safety and effectiveness of the medicine is important and useful, pharmacists are cognisant that Pis are limited to the parameters of a medicine’s registration as approved by the TGA. Therefore, it does not provide information about medicines which pharmacists could consider to be comprehensive for all situations. One example is off-label use i.e. when a medicine is prescribed or used for indications, purposes or doses outside of what has been approved by the regulator.

PSA also uses Pis as a source of medicine information to complement other sources when developing materials for pharmacists including education articles and modules, practice support and training resources, and reference texts. An example of a reference text produced by the PSA is the Australian Pharmaceutical Formulary and Handbook which the Pharmacy Board of Australia lists as a mandatory reference that pharmacists must have access to during clinical assessment, reviewing, dispensing and counselling processes.

Consumer Medicine Information

Pharmacists have a professional obligation to provide necessary and up-to-date information to enable consumers to make informed decisions about medicines. In this context, CMIs are regarded as a valuable tool for assisting the process of consumer medication counselling. A pharmacist’s duties extend to ensuring CMI content of specific relevance to an individual is brought to their attention and to also ensure consumers understand the information. As a tool used by pharmacists, CMI leaflets are designed to help increase consumer knowledge and can enhance therapeutic outcomes by facilitating the appropriate use of medicines and minimising where possible, the potential for adverse drug reactions due to inappropriate use.

PSA provides guidance to pharmacists on the use of CMIs as a tool to provide information about the medicine and advice which is tailored to the needs of consumers and/or carers. The PSA’s Guidelines for pharmacists, Consumer Medicine Information and the pharmacist, is provided as an attachment to this submission.

As stated in PSA’s guidelines, CMI leaflets may be offered to the consumer each time a product is dispensed, however, whether this is appropriate is a matter for professional judgement. Specific circumstances where a CMI should generally be provided include: when a medicine is first provided to the consumer; with each supply of medicine for which regular reinforcement of information may be required (e.g. the medication is cytotoxic); at regular intervals for medicines used for long term therapy; and when the pharmacist has received advice that a sponsor has made significant changes to the content of a CMI.
Is the purpose and function of the PI and CMI well understood by prescribers and consumers?

Through their daily interactions with consumers, pharmacists report an increasing awareness of consumers regarding the availability of CMls. However, based on pharmacists' experience, consumer understanding about CMls is highly variable, as is the desire to access information about their medicines through this format.

Pharmacists are not able to comment on how well prescribers understand the purpose and function of PI/CMI. Pharmacists will often receive requests from prescribers or nurses regarding information on specific medicines which may range from important clinical information (which may or may not be readily available in a PI) and how to achieve optimal therapeutic outcomes, through to the price or availability of a medicine.

Does the public understand the current mechanisms for reviewing and updating the PI?

Based on anecdotal feedback, pharmacists do not believe the general public is aware of the purpose or existence of Pis or that these documents can be accessed, for example, through the TGA web site. Further, we feel it is unlikely that the public would understand the current mechanisms for reviewing and updating the PI. It may be possible that they would accept any reviewing or updating occurs as part of a quality assurance process for which they do not wish to have a role.

We believe consumers may generally have a better understanding about CMls but may not appreciate the link between a PI and a CMI.

Are these mechanisms adequate or are there any other mechanisms that could be considered?

Clearly it is important that there is an ongoing process to consider information gathered through post-market monitoring and ensure Pis appropriately reflect any new critical information, particularly where it relates to safety aspects. It is PSA's view, however, that this tends to restrict the scope of any update to some form of response to a 'negative' outcome. For example, this may result in the inclusion of an additional warning statement targeting certain patient factors.

Ideally, if it was possible to incorporate new evidence-based information to support clinical best practice Pis would become far more useful for pharmacists and other health professionals. The need and desire for quality information to be included in Pis and CMls has been canvassed previously2 both from a consumer safety perspective as well as supporting best practice for health professionals to facilitate better therapeutic outcomes.

Another issue of concern which has been brought to PSA’s attention by member pharmacists previously is when there is an apparent conflict between a PI and Pharmaceutical Benefits Scheme (PBS) information. This has occurred where a PI stated two dosage forms of a particular medicine to be bioequivalent but under the PBS, bioequivalence was not flagged. While PSA understands there may be instances when a manufacturer may prefer to not supply bioequivalence data for PBS listing purposes, it can be frustrating for pharmacists to encounter conflicting information of this nature and be unable to provide a solution in response to a genuine consumer need.

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2 Stockigt JR. The quality of medication information in Australia: the need for more clinical expertise and accountability. MJA 2009; 190(3):110–1.
<table>
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<tr>
<th><strong>Should the TGA:</strong></th>
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<td>• consider publishing PI for OTC medicines in the PI/CMI search facility;</td>
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<tr>
<td>• consider requiring all S3 medicines to publish both the PI and CMI; and/or</td>
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<tr>
<td>• consider requiring CMI to be available to the public for all registered medicines?</td>
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The consultation paper states that around 20–25% of registered OTC medicines have a PI. In these instances PSA believes they should be made available through the PI/CMI search facility as a central source of this type of information, irrespective of whether or not they are arranged for publication elsewhere. It would be useful to provide an explanation for consumers on the reason for a PI having been issued for a particular OTC medicine (e.g. for S2 and unscheduled medicines where the TGA has determined a PI is necessary).

Pharmacist intervention and oversight is required for the provision of S3 medicines. Therefore PSA believes a PI and a CMI must be published for all S3 medicines.

For all registered medicines which require a PI, we believe a corresponding CMI must be made available through the PI/CMI search facility.

| **Is the current format for presenting information in PI and CMI relevant and useful to the end user?** |

Research has shown that consumers appreciate receiving written or verbal information about medicines they are taking and there are benefits in providing information, in particular, written medicine information.\(^3\)\(^,\)\(^4\)\(^,\)\(^5\) Consumers rated accurate side-effect information as the most important element, however, they considered current CMI leaflets to be technical and long.\(^6\) These barriers have been identified on many occasions previously and continue to be regarded as contributing factors which hinder uptake and use of CMIs.

Consumers also welcomed the concept of tailored information,\(^7\) and this is consistent with the pharmacist’s role in providing individualised information to better meet the consumer’s needs.

From the perspective of pharmacists using PIs as a medicine information source, the ordering of clinically relevant information can impact on their useability. The consultation paper provides information on the proposed alterations to the PI format which, PSA has noted, would bring Australian PIs in line with current international practice. We are happy to support this proposal.

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Are there other options for ensuring easier access to the most important information in the PI other than re-formatting?

PSA certainly welcomes clearer linkages between complementary information sources, for example, between PIs and AusPARs.

Is there consensus on what is understood by maintaining the currency of the PI and CMI?

PSA would strongly recommend that key issues are summarised and communicated to consumers and health professionals from time to time about steps being taken by the TGA and key outcomes from consultations. PSA is happy to assist in disseminating these types of information generally to our member pharmacists.

Attachment:

*Guidelines for pharmacists: Consumer Medicine Information and the pharmacist.* (Pharmaceutical Society of Australia; 2007)

Submitted by:

Pharmaceutical Society of Australia
PO Box 42, Deakin West ACT 2600
Tel: 02 6283 4777
www.psa.org.au

Contacts:

Liesel Wett, Chief Executive Officer

Kay Sorimachi, Director Policy and Regulatory Affairs
kay.sorimachi@psa.org.au

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This document is intended to assist pharmacists to understand their legal and professional obligations in relation to the provision of Consumer Medicine Information (CMI).

These guidelines do not set a mandatory standard. In some circumstances, consumer characteristics or cultural, linguistic or environmental factors may influence the application of these guidelines in different (e.g., community, aged care, outpatient) settings. Additional guidance is available for pharmacists in institutional settings.

Guidelines developed by the Australian Pharmaceutical Advisory Council (APAC) provide operational standards for both continuity of care between the hospital-community interface, and community medication management and address the place of CMI in the counselling process.

A. Background

In Australia, sponsors of Prescription Only Medicines and Pharmacist Only Medicines have an obligation to provide written information about their products for consumers in accordance with requirements set out in the Therapeutic Goods Regulations 1990. The term “CMI” applies only to information that is prepared by the sponsor of a medicine in accordance with this regulatory requirement.

CMI is brand specific information and must be consistent with the approved Product Information (PI). CMI leaflets must be written in a manner that will be easily understood by consumers. They are made available as package inserts, pads of leaflets or electronically through internet web sites or integrated with dispensing software.

Research has shown that consumers appreciate receiving written or verbal information about medicines they are taking and there are benefits in providing information, in particular, written medicine information. It has also been reported that consumer factors such as disease state, health locus of control, coping style, health literacy levels and occupation influence the consumer’s interest in reading and seeking written medicines information and therefore, pharmacists have a role in tailoring the counselling they provide to better meet the consumer’s needs.

The Medicines Information to Consumers (MIC) program was launched through the Third Community Pharmacy Agreement (CPA) to encourage pharmacists to use CMI to promote the quality use of medicines and assist consumers to make informed decisions about their medicines. Under the Fourth CPA, payments to community pharmacies are made through the dispensing fee on claimable prescriptions.

B. Privacy and confidentiality

As with any other communication about medicines, confidentiality should be maintained in relation to the consumer’s medicine and health information. This extends to ensuring details of the medicine for which a consumer receives a CMI are kept confidential. Information contained in a CMI leaflet is intended for the person taking that medicine. Therefore, a CMI leaflet should not be shown to any person for whom a medicine is not intended, unless that person has been authorised by the consumer to receive the medicine and/or CMI leaflet on their behalf, or unless there are compelling grounds and the pharmacist in his/her judgment believes it is appropriate.

When a person is acting as an authorised agent for a consumer, it is appropriate to provide the CMI leaflet to the agent with the necessary details or explanations in relation to the optimal use of the medicine.

C. Legal responsibilities

Currently there is no legislation or regulation which specifically requires a pharmacist to supply a CMI leaflet to a consumer. However, pharmacists have a professional obligation to provide all necessary and up to date information to enable consumers to make informed decisions about their medicines. CMI should be regarded as a valuable tool for assisting that process.

A pharmacist’s duties extend to ensuring CMI content of specific relevance to an individual is brought to their attention. Pharmacists should also ensure consumers understand the information. Pharmacists should not delegate medication counselling tasks to non-pharmacists.

On occasions it will be useful to supplement a CMI leaflet with other forms of written medicines and health information (e.g. Pharmacy Self Care Fact Cards) to assist the consumer’s understanding of their condition or medication management issues. Pharmacists must use their professional judgment.
and discretion in each situation to ensure that they are providing balanced information to the consumer.

D. Documentation

Appropriate and accurate records assist medication management and provide evidence of pharmacists’ professional services. Adequate documentation is an important component of risk management and quality consumer care. It may also be used for verification of claims for remuneration of counselling services.

Pharmacists are encouraged to use reliable systems for documenting actions taken in relation to CMI leaflets. As a minimum, pharmacists should record when a CMI leaflet was provided as part of the counselling process or when an offer to provide a CMI leaflet was declined by the consumer or their agent. Where the pharmacy dispensing software does not support this type of record, pharmacists are encouraged to approach the software vendors about the development of this type of functionality.

E. Counselling with CMI

CMI leaflets are a useful resource for pharmacists when informing consumers about their medicines. CMI leaflets do not replace counselling by pharmacists, nor do they reduce the pharmacist’s duty to counsel consumers about medicines. CMI leaflets should be seen as an important component of consumer medication counselling.

While it is not suggested that every aspect of a CMI leaflet needs discussion with the consumer, during counselling pharmacists may:

- highlight parts which are particularly relevant to that consumer;
- use the CMI leaflet in an interactive manner and encourage the consumer to read and seek clarification as necessary; or
- provide further relevant information (eg. about the disease or the approved PI).

Pharmacists may annotate the CMI leaflet with additional information appropriate for the consumer. Any annotations made should be clearly identified and signed by the pharmacist who makes those additions. CMI leaflets must not otherwise be altered or abbreviated in any way by the pharmacist as they are official product documents. Alterations and abbreviations of a CMI leaflet could expose pharmacists to legal action under product liability laws.

1. Provision of CMI

CMI leaflets are a tool to help increase consumer knowledge and can enhance therapeutic outcomes by facilitating the appropriate use of medicines and minimising where possible, the potential for adverse drug reactions due to inappropriate use.

CMI leaflets may be offered to the consumer each time a product is dispensed. Whether this is appropriate is a matter for professional judgment. Pharmacists should endeavour to distribute the most recent or current version of the CMI leaflet.

Specific circumstances where CMI should generally be provided include:

- when a medicine is first provided to the consumer;
- when brand substitution occurs and it is deemed appropriate;
- the dosage form has been changed (eg. from injection to tablet);
- with each supply of medicine for which regular reinforcement of information may be required eg. the medication is cytotoxic, teratogenic, or there are major contraindications to the use of a medicine;
- at the request of the consumer;
- when the consumer has special needs;
- at regular intervals for medicines used for long term therapy (eg. every six months, or on dispensing the last repeat of a prescription with five repeats);
- when the pharmacist has received advice that a sponsor has made significant changes to the CMI.

Pharmacists are strongly advised against withholding CMI. Some prescribers may indicate their wish to have a CMI leaflet withheld from the consumer. Pharmacists are reminded that consumers have the right to information about their medicine and should endeavour to communicate to the prescriber that a CMI leaflet cannot be withheld for this reason. It is particularly important in such instances for pharmacists to provide thorough counselling to address any particular concerns that may stem from the prescriber’s original request to withhold the CMI leaflet.

Pharmacists should not issue alternative forms of medicine information for consumers which have not been prepared by the relevant product sponsor, in place of the official CMI leaflet. Alterations and abbreviations of a CMI leaflet could expose pharmacists to legal action under product liability laws.

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* If a situation arises where in the pharmacist’s opinion the consumer’s physical or mental health may be harmed by information contained in a CMI leaflet, the pharmacist should consider discussing with the prescriber the possible risks within the overall clinical context. If a pharmacist subsequently determines that withholding the CMI leaflet is in the consumer’s best interests, they should not proceed with this course of action until they have consulted their insurer on the presenting circumstances.
In order to avoid or minimise confusion, pharmacists should provide as much useful information as possible to consumers regarding brand names and active ingredient names. This is particularly important where a person may be on multiple medications, medicines with more than one active ingredient or medicines with long or complex active ingredient names.

2. Non-approved and investigational uses of medicines

A medicine may be prescribed for conditions other than those mentioned in the CMI leaflet. This may not be an unusual scenario particularly where specialist prescribers are involved.

In these circumstances, pharmacists should:
clarify, if necessary, the use of the medicine with the consumer and/or prescriber;
assess the relevance of the CMI for the particular consumer’s needs and make a professional judgment to either provide additional resources or information from other sources (where appropriate and available) or refer the consumer back to the prescriber for additional information; and
counsel the consumer in the normal way with particular emphasis on the reason(s) the medicine is being used for their particular condition.

References
6. Advice received from the Pharmaceutical Defence Limited (dated 22 November 2006).

Endorsed by National Council January 2007
(Currently under review)