Initial Discussion Paper: Improving access to prescription medicines information

April 2005

Therapeutic Goods Administration
# TABLE OF CONTENTS

Glossary of terms and acronyms used.............................................................3

Introduction ......................................................................................................4

Chapter 1: Product Information ....................................................................7

Chapter 2: Consumer Medicine Information ................................................9

Chapter 3: Issues ......................................................................................14

Chapter 4: Objectives ................................................................................20

Chapter 5: Options for consideration...........................................................23

Chapter 6: Implementation ........................................................................28

Attachment A: Medsafe’s Requirements ........................................................29
**GLOSSARY OF TERMS AND ACRONYMS USED**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>APAC</td>
<td>Australian Pharmaceutical Advisory Council</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
<tr>
<td>CMI</td>
<td>Consumer Medicine Information</td>
</tr>
<tr>
<td>DSEB</td>
<td>Drug Safety and Evaluation Branch of the TGA</td>
</tr>
<tr>
<td>EDWG</td>
<td>Electronic Distribution Working Group</td>
</tr>
<tr>
<td>MIC</td>
<td>Medicines Information for Consumers program</td>
</tr>
<tr>
<td>NPS</td>
<td>National Prescribing Service Limited</td>
</tr>
<tr>
<td>PHARM</td>
<td>Pharmaceutical Health and Rational Use of Medicines Committee</td>
</tr>
<tr>
<td>PI</td>
<td>Product Information</td>
</tr>
<tr>
<td>PSA</td>
<td>Pharmaceutical Society of Australia</td>
</tr>
<tr>
<td>QARG</td>
<td>Quality Assurance Reference Group</td>
</tr>
<tr>
<td>QUM</td>
<td>Quality Use of Medicines</td>
</tr>
<tr>
<td>RACGP</td>
<td>Royal Australian College of General Practitioners</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>TG Act</td>
<td><em>Therapeutic Goods Act 1989</em></td>
</tr>
<tr>
<td>TG Regulations</td>
<td><em>Therapeutic Goods Regulations 1990</em></td>
</tr>
</tbody>
</table>
INTRODUCTION

Purpose of this Discussion Paper

The purpose of this initial Discussion Paper is to provide a basis for early discussions with stakeholders about the most appropriate means for improving consumer and professional access to web based copies of up-to-date Consumer Medicine Information (CMI) and Product Information (PI).

The Discussion Paper:

- provides background information about the means by which the Therapeutic Goods Administration (TGA) currently regulates CMI and PI;
- provides summary information about some of the ways in which consumers and professionals currently access up-to-date CMI and PI;
- identifies some of the concerns raised with the TGA regarding access to up-to-date CMI and PI; and
- identifies some possible options to address the issues raised.

It should be noted that this Discussion Paper is an initial Discussion Paper only, the main purpose of which is to enable the TGA to:

- better identify key stakeholders;
- gain a better understanding of the existing mechanisms for providing consumers and health professionals with access to up-to-date CMI and PI for all prescription medicines (including a better understanding of existing web-based databases and CMI and PI distribution networks);
- identify the strengths and weaknesses of existing mechanisms for consumers and health professionals to access CMI and PI;
- hear the views of stakeholders regarding whether the TGA should have an increased role in either strengthening existing web-based CMI and PI services or providing additional routes by which people can access CMI and PI electronically; and
- receive early feedback from stakeholders about the options proposed in this Discussion Paper and the advantages and disadvantages of each (including feedback from stakeholders about any other options that may also assist in increasing or improving the avenues through which consumers and professionals can access up-to-date, electronic CMI and PI for all prescription medicines).
Consultation on this Discussion Paper

The TGA is keen to consult widely on the issues detailed above and has engaged the services of mpconsulting to undertake such consultations and report to the TGA.

This Discussion Paper is available from the TGA website (www.tga.gov.au).

mpconsulting will be holding public forums in Sydney and Melbourne (please refer to the TGA website for dates, times and venues for the forums). If you would like to attend these forums could you please confirm your attendance by emailing Andrea Matthews (Principal, mpconsulting) at andrea@mpconsulting.com.au. In addition mpconsulting will also be undertaking some one on one consultations with key stakeholders.

Stakeholders may also wish to make written submissions. Written submissions may be forwarded to:

Andrea Matthews  
Principal  
mpconsulting  
PO Box 9606, DEAKIN ACT 2600  
Email: andrea@mpconsulting.com.au

The closing date for submissions is 27 June 2005.

Next steps

As noted above, through these early consultations the TGA hopes to gain a better understanding of the existing mechanisms for consumers and health professionals to access CMI and PI and to receive feedback about whether the TGA has a role to play in either improving existing mechanisms, or increasing avenues, through which people can access CMI and PI.

Following these initial consultations, mpconsulting will prepare a more detailed Discussion Paper for further consultation. It is anticipated that this more detailed Discussion Paper will be available in late August 2005. As with this initial Discussion Paper, the second Discussion Paper will also be available on the TGA website and direct mailed to key stakeholders. Public forums will be held to discuss the issues further (details of which will be included on the TGA website).
**Important note**

It is important to note that improving access to CMI and PI goes well beyond merely improving web-based access to these documents. However, the TGA also recognises that broader issues such as provision of CMI by health professionals and the appropriate content of CMI are issues that are currently being addressed by other policy bodies including, for example, the CMI Working Party of the Australian Pharmaceutical Advisory Council and the Quality Assurance Reference Group. The TGA is concerned to ensure that any initiative implemented by the TGA complements rather than duplicates or displaces the important and ongoing work of these other bodies.

The TGA also recognises that there are many organisations that currently provide electronic access to CMI and PI and the TGA is concerned to ensure that any additional initiatives identified through this process do not displace or adversely affect these existing services.
CHAPTER 1: PRODUCT INFORMATION

What is Product Information?

Product Information (PI) is a document that contains information sufficient to ensure safe and effective use of a medicine under nearly all circumstances. It presents a scientific, objective account of the medicine’s usefulness and limitations as shown by the data supporting the application for registration of the medicine with the TGA.

What information is included in a PI?

The TGA’s *Australian Guidelines for the Registration of Drugs*, describe the information that must be included in PI. The Guidelines provide that the PI should contain information under the following headings:

- name of the medicine;
- description;
- pharmacology;
- clinical trials;
- indications;
- contraindications;
- precautions;
- adverse effects;
- dosage and administration;
- overdosage;
- presentation and storage conditions;
- name and address of the sponsor;
- poison schedule of the medicine; and
- date of approval.

The Guidelines also describe further information about the types of information to be included in the PI under each of these headings.

Who ensures that the PI includes the required information?

It is a condition of registration under section 28 of the *Therapeutic Goods Act 1989* (the TG Act) that a PI be provided for each registered product (predominantly prescription medicines).

Applications to register a medicine in Australia must be accompanied by a copy of a draft PI.

If the TGA is satisfied that the PI meets the TGA’s requirements, the TGA approves the PI.
Who is responsible for ensuring that the PI is up to date?

The sponsor is responsible for ensuring that the PI is kept up to date. Following registration of the therapeutic good, the PI must not be changed without TGA approval (subject to certain exceptions such as in the case of safety-related changes or certain editorial changes which must be notified to the TGA).

Who has access to PI?

Generally speaking PI are accessible to health professionals through prescribing software or other subscription based services. For example, the website of the Royal Australian College of General Practitioners includes a searchable listing of PI that requires a member logon. Other providers of PI to health professionals include, for example, MIMS and the Australian Prescription Products Guide.

On the basis of research undertaken to inform this Discussion Paper, there does not appear to be any website that includes a comprehensive database of PI that is freely available to consumers.

For your consideration

As noted in the Introduction to this Discussion Paper the TGA is keen to better identify the organisations involved in the distribution of CMI and PI and identify whether there is any merit in the TGA supplementing existing services.

Your feedback on this issue would be appreciated.
CHAPTER 2: CONSUMER MEDICINE INFORMATION

What is Consumer Medicine Information?

Consumer Medicine Information (CMI) is a leaflet that contains information about a medicine that is written specifically for consumers. A CMI is also known as Patient Information.

CMI are based on PI and are drafted in language that is readily understood by consumers.

Other information sheets are sometimes provided to patients by pharmacists. These are not CMI and are not prepared by sponsors to the standard of CMI (this is discussed further in the following Chapter).

What information is included in a CMI?

A CMI includes:

• the name of the medicine;
• the active ingredients as well as the inactive ingredients;
• the dosage of the medicine;
• what the medicine is used for and how it works;
• any warnings and precautions, such as when the medicine should not be taken;
• any interaction the medicine might have with food or other medicines;
• how to use the medicine properly;
• side effects;
• what to do in the case of an overdose;
• how to store the medicine properly;
• the sponsor’s name and address; and
• the date the CMI was last updated.

CMI are prepared by the sponsor of the product and are not assessed by the TGA (except to the extent of ensuring their existence and compliance with the regulatory requirements). However, the TGA requires that CMI be consistent with the PI (as approved by the TGA) and that the CMI not be promotional.

To ensure that CMI are written in a manner that is easily understood by the consumer, a Quality Assurance Reference Group (QARG) was established by the Pharmaceutical Health and Rational Use of Medicines Committee (PHARM). The Reference Group operates with oversight by the Australian Pharmaceutical Advisory Council and includes representative consumers, doctors, nurses, pharmacists, sponsors, CMI writers and an expert in communications.

QARG randomly select CMI to assess the content and quality of the CMI including whether the information is consistent with the PI. QARG also
examines whether the CMI has been written in accordance with Government Usability Guidelines.

How do consumers currently access CMI?

The TGA Regulations require that CMI must be made available to consumers either in the primary pack in which the therapeutic goods are supplied or in another manner that will enable the information to be given to the person to whom the goods are administered or otherwise dispensed.

**Package inserts**

A number of sponsors include the CMI as a package insert in the medicine. The advantage of this is that it attempts to ensure that the consumer receives the CMI. The major disadvantage is that if any changes to the CMI are necessary it may be necessary to recall the product in order to change the CMI. For this reason, a number of sponsors are phasing out the use of package inserts for provision of the CMI.

**Provision of CMI by a doctor**

Doctors generally access CMI through software packages (or hard copy compilations) provided by a range of vendors. The compilations include CMI for many of the medicines prescribed by doctors.

**Provision of CMI by a pharmacist**

Like doctors, pharmacists also access CMI through software packages provided by software vendors.

In December 2002 the Medicines Information for Consumers (MIC) program was launched (through the Third Community Pharmacy Agreement between the Australian Government and the Pharmacy Guild of Australia). This initiative provides eligible pharmacists with ongoing incentive payments for providing CMI, at the rate of 10 cents per subsidised prescription (in addition to a readiness payment of $3000 per pharmacy paid in 2001 to help meet set up costs associated with the provision of CMI).

Pharmacists are asked to provide a signed certification statement to the Health Insurance Commission every two months verifying that they have provided CMI in accordance with professional standards and guidelines developed by the Pharmaceutical Society of Australia (PSA).

In accordance with these professional standards and guidelines, CMI should generally be provided:

- when a medicine is first provided to a consumer;
• on provision of a medicine where a significant change to the CMI has been notified by the sponsor or where the dosage form has been changed;

• with each supply of medicine for which there are valid reasons for regular reinforcement of information. For example where the patient has special needs or where there are major contraindications for use of the medicine;

• when the patient requests the information; and

• at regular intervals for medicines used for long term therapy.

Internet

Many CMI are also available on the internet including, for example:

• on some sponsors websites. A number of pharmaceutical companies with Australian based websites provide copies of CMI for their products (as provided in Australia) on those websites;

• through a range of different on-distributors. For example:

  ➢ the website of the Royal Australian College of General Practitioners (RACGP) includes a “Medicines Information” page which consists of a searchable listing of CMI. The CMI on the RACGP website are publicly available for viewing and downloading;

  ➢ the Better Health Channel website (established in 1999 by the Victorian Government to provide the community with access to online health related information) includes a page entitled “Medicines Guide” which is a directory containing a substantial list of common prescription medicines, with links to the product CMI;

  ➢ “myDr” website is a health care website designed to provide Australian consumers with health information. myDr is a project of the MIMS Consumer Health Group, and is effectively an extension of the health information that MIMS has been providing health professionals for a number of years. The myDr website includes a searchable database of online copies of CMI; and

  ➢ National Prescribing Service Limited (NPS). NPS is funded by the Commonwealth Government and is incorporated as a company limited by guarantee with a membership of peak health, medical and consumer organisations. NPS provides a range of services including a searchable database of CMI.
For your consideration

Please note that the above is by no means an exhaustive list of on-distributors and is indicative only of the types of websites that include CMI. Through initial consultations on this Discussion Paper, the TGA hopes to gain greater insight into the existing services available.

Medicines Line

Medicines Line is a service provided by the NPS and operated by the Mater Pharmacy Services (Mater Health Services, South Brisbane) and the PSA.

Medicines Line is a phone number that consumers can call and request, among other things, copies of CMI.

Medicines Line is managed by a committee comprising representatives of NPS, the Consumers’ Health Forum, the Consumers’ Sub-committee of PHARM, the Australian Medical Association (General Practice Division), the PSA, Mater Pharmacy Services, the RACGP and Medicines Australia.

How do on-distributors of CMI access up to date versions of CMI?

As noted above there are a range of different distributors of CMI including

- pharmaceutical companies (sponsors) who may provide their CMI on their own websites;

- software vendors who may access CMI from sponsors and include CMI in software packages for distribution to health professionals; or

- providers of web based health information who may also access CMI from sponsors or other on-distributors for inclusion on their websites.

While the ultimate source of CMI is the sponsor (and a number of on-distributors seek CMI directly from each of the companies), one service utilised by a number of on-distributors is healthlinks.net.

Healthlinks.net – Data Warehouse

Healthlinks.net Secure Data Warehouse (the Data Warehouse) is a central repository of sponsors’ CMI and PI. The service was developed at the request of pharmaceutical companies who were concerned about the currency of databases that on-distribute their documents. By accessing the data through the Data Warehouse, the on-distributors and other organisations requiring access to the CMI or PI have the authorised current version.

Currently 17 pharmaceutical companies subscribe to the Data Warehouse and approximately 790 CMI and 730 PI are available on the Data Warehouse.
While the pharmaceutical companies pay a fee for the Data Warehouse service, those on-distributors who access the CMI and PI from the Data Warehouse do so without charge. Access to the Data Warehouse is subject to the agreement of the pharmaceutical companies.

All parties work within two legal agreements, one that exists between the on-distributor and the pharmaceutical company and the other between the pharmaceutical company and healthlinks.net.

**Healthlinks – eCMI**

eCMI is another service managed by healthlinks.net. eCMI is a system for electronic distribution of CMI to retail and hospital pharmacy dispensing software vendors.

eCMI are distributed to all users free of charge and the cost of distributing CMI electronically is borne by the pharmaceutical companies. Pricing is determined by the Electronic Distribution Working Group (EDWG) and is based on API and AHI sales results including factors such as: number of drugs participating, volume of product sold, value of products sold and orphaned products.

38 companies distribute CMI to software vendors through eCMI (over 1200 CMI are available through eCMI). Based on industry data this represents over 85% of currently available eCMI.

The key difference between the Data Warehouse and eCMI is the users or primary clientele. The focus of the Data Warehouse is on ensuring that on-distributors (be they medical publishers, medical software developers, libraries, government departments or professional associations) have access to up-to-date CMI and PI. By contrast the focus of eCMI is providing up to date CMI specifically to software vendors who include electronic CMI in dispensing and other software provided to pharmacists and other health professionals.
CHAPTER 3: ISSUES

Following is a summary of some of the issues that have been identified by, or raised with, the TGA. Your advice on these issues is sought.

- Increasing the avenues available to consumers to access CMI

As detailed in the previous Chapter, the TGA requires that CMI must be made available to consumers either in the primary pack in which the therapeutic goods are supplied or in another manner that will enable the information to be given to the person to whom the goods are administered or otherwise dispensed.

Theoretically this means that consumers have access to CMI with any prescription medicine dispensed.

However, this is not always the case. As noted above, pharmaceutical companies are steadily moving away from the practice of including CMI in the primary pack (due to the difficulties associated with keeping the information up to date).

If a CMI is not in the primary pack then it should be provided at the point of dispensing of the product. While pharmaceutical companies provide CMI for their products to software vendors (either directly or indirectly) for inclusion with prescribing or dispensing software, research suggests that CMI are often not provided to consumers by health professionals. This may be for a range of reasons including time constraints and other conflicting priorities.

Research undertaken as part of an evaluation of the Medicines Information for Consumers (MIC) program noted that:

- the average number of CMI printed each day by pharmacists was estimated at 14, with this ranging from an estimated 6 in non-MIC participating pharmacists to 26 in pharmacies that have a PBS script volume of 200 or more each day; and

- using the estimates provided by pharmacists in the qualitative research in combination with the volume of PBS scripts provided, it was deduced that CMI are provided with 12% of all claimable scripts each day (as reported by pharmacists)\(^1\).

The TGA recognises that:

- there may be circumstances where a health professional uses their professional judgement to decide not to provide a CMI with a medicine. In the evaluation of the MIC program, it was consistently noted by pharmacists that the ability to use this professional judgement was of

---

paramount importance in order to achieve the desired health outcomes; and

- there are likely to be further increases in the number of CMI being provided to consumers as pharmacists become more familiar with the MIC program and the PSA professional standards and guidelines in relation to CMI and as consumers also become more aware of CMI and increasingly request CMI.

However, the TGA is also interested in exploring additional avenues for making CMI available to consumers in the event that they do not receive a CMI along with the prescribing or dispensing of the medicine or they do not retain the CMI but seek the information contained in the CMI at a later date.

There are also a range of circumstances where carers may seek information about a medicine on behalf of a consumer including when advice from a health professional is not readily available.

- **Not all sponsors make electronic copies of CMI available publicly**

The TGA estimates that:

- the total number of prescription medicines ranges that are required to be accompanied by a CMI is 2800;

- the total number of products (including products with different dosage forms) is approximately 6600; and

- there are 141 sponsors of such products.

The TGA does not require that the CMI be available to the public in electronic form and it is therefore not possible to authoritatively state the number of medicines for which electronic CMI exist (or are distributed).

However, the following anecdotal information is available:

- the healthlinks.net Data Warehouse holds approximately 790 CMI (and 730 PI). The total number of pharmaceutical companies utilising the Data Warehouse is 17. Approximately 23 on-distributors use CMI from the Data Warehouse. This includes publishers, libraries and government bodies;

- 38 companies distribute CMI to software vendors through eCMI and over 1200 CMI are available through eCMI. Industry data suggests that this represents over 85% of currently available eCMI;

- the Australian Prescription Products Guide is reported to include nearly 2000 CMI (and PI for more than 3,900 prescription and non-prescription products); and
• the Measurement of the Quality Use of Medicines Component of Australia’s National Medicines Policy (Second Report of the National Indicators) reported that in 2002 CMI were available for over 1900 products. Of these, CMI were electronically available for 1026 products.

It does not appear that there is any single web-based source of all CMI that is available free of charge to consumers. Those websites that provide CMI free of charge to consumers (such as myDr, the Better Health Channel and the website of the Royal Australian College of General Practitioners) do not include all CMI.

This may be because certain pharmaceutical companies choose not to provide their CMI (either directly or indirectly) to these on-distributors or because the pharmaceutical company does not distribute electronic copies of CMI at all.

For your consideration
Through these initial consultations the TGA is keen to gain more detailed information about the number of CMI (and PI) that are electronically available.

• Limited certainty regarding the currency of web-based CMI

The TGA requires that CMI are up to date and remain consistent with the PI. There are a number of circumstances in which the information in the CMI may need to be amended including, for example, because there has been a change to:

• the sponsor or the sponsor’s address; or
• the therapeutic indications or the contraindications.

One of the issues surrounding the web-based provision of CMI is ensuring that the CMI available on the web are current.

It appears that different on-distributors have different policies regarding how often they update CMI. While a pharmaceutical company may provide an updated CMI to an on-distributor, this does not necessarily mean that the on-distributor’s database will immediately be updated. Some update monthly, others less often. While the TGA does not wish to influence the policies of individual companies regarding updates, the TGA is interested in exploring whether there is a need for a website that is known to contain (or have links to) the most up-to-date CMI at any point in time.

For your consideration
Through these initial consultations the TGA hopes to gain a better understanding of the means utilised by on-distributors to ensure the availability of up-to-date CMI and PI.
• **Increasing the availability of PI to consumers and their carers**

As noted in the previous Chapter, PI are not widely available to consumers and are generally available to health professionals through subscription based services.

The evaluation of the MIC program noted that “Research indicates that consumers want more and better access to information about medicines than they receive as part of the traditional care offered by health professionals. Individual consumers require and desire different amounts of information about medicines and they also seek variable levels of involvement in shared care and decision-making processes”.²

The report also noted that during the qualitative component of the evaluation, mention was made by both pharmacists and consumers that occasionally the information provided within a CMI was insufficient to meet all of a consumer’s information requirements or that in the absence of being provided a CMI for medication a consumer will seek information elsewhere. The source considered to be most common for supplementary information was the internet.

If consumers (or their carers) seek more information on the internet, then it is desirable for them to have free access to PI from a reliable and trusted source rather than being forced to rely on information that may be unreliable or slanted in content.

On the other hand some would argue that it is not appropriate that PI be available to consumers because PI are documents directed at health practitioners and are not aimed at consumers. It is argued that in the absence of counselling, the information included in PI could easily be misused or taken out of context by consumers.

The TGA is also aware that the rationale for requiring CMI to be provided with medicines was based on the need for consumers to have information about the medicines that they are taking and that such information be provided in an easily understood way. It was not intended that PI be denied to those consumers who require more information and have the capacity to understand the more detailed information included in the PI.

• **Increasing the availability of PI to health professionals**

As noted in the previous Chapter, there are a range of different electronic providers of PI to health professionals.

---

For example:

- the Australian Prescription Products Guide includes PI for more than 3,900 prescription and non-prescription products; and

- MIMS provide electronic services to health professionals including PI.

While many health professionals have access to PI through subscription based services there are a number of circumstances in which health professionals will not have access to such services and will require access to up-to-date PI. For example:

- a number of medical practitioners (particularly specialists) do not use prescribing software and instead use manual scripts. While such professionals may have hard copy collations of PI, such collations may be out of date, may not include all PI and may include only abridged versions of some PI;

- medical practitioners who do not often write scripts (for example, surgeons) may not have electronic access to an up-to-date subscription service;

- health professionals working in large organisations, after hours or from home may not have access to subscription based services; and

- subscription based services are not always available 24 hours a day, 7 days a week and may have downtimes including when systems are being updated.

In each of these cases it may be valuable for health professionals to be able to access up-to-date PI from an alternative source that is available free of charge.

- **The TGA website contains very limited information on medicines**

As the public becomes more aware of the role of the TGA in the regulation of medicines, the TGA website is increasingly being used by consumers to access information about medicines.

However, the TGA website currently contains very little information about medicines that are included on the Australian Register of Therapeutic Goods (ARTG) with only summary information available such as the ARTG number, label name, sponsor, type of therapeutic good and product ID.

The TGA does not publish CMI or PI on its website. One of the suggestions that has been made to the TGA is that the TGA could potentially provide an authoritative, reliable, up-to-date source of CMI (and PI).
• **Minimising reliance on information sheets that are not CMI**

Information sheets are sometimes provided to patients by pharmacists and others. These are not CMI and are not prepared by sponsors to the standards of CMI. The information on these short documents is not always reliable and the TGA considers that the use of such information sheets should be discouraged particularly as alternate reliable sources of information are available in the form of CMI.

• **Consumer access to information from a trusted source.**

On the one hand it could be argued that the TGA could potentially provide a “trusted source” of CMI and PI for consumers.

However, it could equally be argued that there are already a number of trusted sources of CMI (that are better known to consumers than the TGA) and better able to provide comprehensive health information. It may therefore be useful to explore how such existing services could be strengthened so as to include all CMI and PI.

This is another key issue for discussion during consultations.
CHAPTER 4: OBJECTIVES

What are the objectives sought to be achieved?

In examining the options for increasing the availability of web-based CMI and PI, the TGA is seeking to:

- **increase the channels through which consumers can access up-to-date CMI.** Recognising that not all consumers receive a CMI as a package insert or from a health practitioner, the TGA is interested in exploring additional options for making CMI available to consumers. This objective is consistent with the findings of the evaluation of the MIC program that noted that “the majority of stakeholders felt that the ideal solution would be a multi-pronged approach with provision of a CMI occurring at the time a prescription was given (by the GP or doctor), at the time of medication dispensing (by a pharmacist) and additionally be available for access via the internet”\(^3\);

- **increase the availability of PI to health professionals and to those consumers (and their carers) who require more information than that offered by the CMI;**

- **ensure that there is a comprehensive source of up-to-date CMI and PI available on the web.** One of the issues noted in the previous Chapter is that different on-distributors of CMI and PI have different policies regarding updating the documents on websites. There is therefore limited certainty for health professionals and consumers that they are accessing current versions of CMI and PI. While the TGA recognises that it cannot compel on-distributors to maintain up-to-date versions of CMI or PI (nor have any influence over the sites that people access to download such documents), the TGA is interested in exploring whether it is possible to establish a reliable source of up-to-date information;

- **examine the options for including all CMI and PI on a single trusted website.** While there are a number of websites currently publishing CMI, the TGA does not believe that any one site includes all CMI. This is because not all sponsors provide CMI to the same on-distributors and also because not all sponsors distribute electronic copies of CMI. Similarly there does not appear to be any website than contains all PI and is accessible to the public;

- **ensure co-ordination with other initiatives.** In examining options for achieving the objectives detailed above, the TGA is concerned to ensure that any options examined by the TGA are consistent with existing government policies and enhance rather than detract from the valuable work being undertaken by other organisations in the context of CMI. For

---

example, the work of the following committees and Working Groups is relevant:

- the CMI Working Party is a Working Party of the Australian Pharmaceutical Advisory Council (APAC). The role of the Working Party is to: canvass options to ensure effective quality assurance processes for CMI; consider issues of CMI currency, accuracy, access/availability and regulation; consider the MIC evaluation outcomes and activities of NMP partners to inform the development of an action plan; and present an action plan to APAC.

- the Electronic Distribution Working Group (EDWG) comprises stakeholders from various industry forums including the Pharmacy Guild, the Pharmaceutical Society of Australia, Royal Australian College of General Practitioners, the Australian Self Medication Industry, Consumer Health Forum, healthlinks.net and representation from Hospital Pharmacy. EDWG was established to provide an industry forum to discuss means for improving electronic distribution of CMI.

- the PHARM Committee is a multidisciplinary Committee that provides expert advice to the Minister for Health and Ageing and the Department of Health and Ageing on the Quality Use of Medicines (QUM) Strategy. PHARM’s terms of reference include: the provision of advice on quality use of medicines to Government and other bodies; the promotion and review of the implementation of quality use of medicines strategies; prioritising and encouraging quality use of medicines activities in collaboration with health professionals, industry, consumers and Government; recommending proposals for funding under the Quality Use of Medicines Evaluation Program (QUMEP); evaluating the outcomes of completed QUMEP funded activities; and consideration of quality use of medicines matters referred by other relevant committees including the Pharmaceutical Benefits Advisory Committee and APAC.

The TGA is keen to consult with each of these Groups in the context of identifying a preferred option for achieving the objectives detailed above.

- **consider the New Zealand experience.** In New Zealand, pharmaceutical companies are required to prepare data sheets for all prescription medicines and restricted (pharmacist only) medicines. In addition, sponsors may publish CMI (as a package insert) provided the CMI is consistent with New Zealand Regulatory Guidelines for Medicines Volume 4. The Medsafe website provides a searchable database of all data sheets and CMIs that are provided electronically by sponsors, noting that Medsafe does not evaluate or approve CMI and that not all CMI are on the site. Further information regarding Medsafe requirements and publication of data sheets and CMI is included at Attachment A.
• **identify any opportunities for co-ordination with New Zealand in the context of the proposed trans-Tasman arrangements.** As stakeholders would be aware, there is soon to be established a trans-Tasman Agency for the regulation of therapeutic goods. One of the issues for consideration is the extent to which any initiative identified though consideration of improving access to CMI and PI in Australia may be of relevance in the context of the trans-Tasman reforms. The TGA will be consulting closely with New Zealand as issues are identified and any options explored.
CHAPTER 5: OPTIONS FOR CONSIDERATION

The following five options have been identified. The TGA seeks the advice of stakeholders regarding:

- the advantages and disadvantages of each of the options;
- the preferred options; and
- any other options that should be considered.

Option 1: Retain the status quo

Explanation

This option would mean relying on existing avenues for health professionals and consumers to access CMI and PI.

Advantages

- No increase in cost to the TGA or to sponsors.

Disadvantages

- No single comprehensive source of CMI or PI that is accessible to the public.
- No certainty that there is at least one site that is known to contain all up-to-date CMI and PI (as at any point in time).
- The objectives detailed in the previous Chapter would not be met.

Option 2: TGA explores means to assist in the strengthening of any existing databases

Explanation

As detailed in the previous Chapters, one of the main purposes of the initial consultations on this Discussion Paper is to improve the TGA’s understanding of the operation of existing services providing electronic CMI and PI to consumers and health professionals. Through this process, it may be possible to identify means by which to improve existing services so that they contain all CMI and PI. The TGA may or may not be able to play a role in such strengthening.

Advantages

- By relying on existing services this reduces any duplication (and costs associated with such duplication).
Consideration would need to be given to how any existing providers ensure that they have up-to-date versions of CMI and PI available on the web particularly where urgent safety related changes have been made by the sponsor.

Consumers already have a level of knowledge about existing services.

Some of the existing services can provide additional health information and advice to consumers beyond CMI and PI. Consumers could therefore access more comprehensive information from such a source than from the TGA.

Disadvantages

Existing providers may have difficulty providing all CMI and PI. While the TGA could potentially compel sponsors to provide electronic copies of CMI and PI to the TGA (or compel sponsors to post CMI and PI on their own websites) the TGA has no power to compel sponsors to provide electronic copies of PI and CMI to an external (in some cases, commercial) provider of services. Further, this would also advantage one provider as compared to another and may create distortions in the market place. As detailed previously, the TGA does not wish to interfere with existing services but merely identify means by which access to CMI and PI could be improved.

Option 3: TGA provides a link on the TGA website to an existing database of CMI and PI

Explanation

This option builds on Option 2. The TGA website could provide a link to one or more websites that contain CMI. For example, Better Health Channel, NPS or myDr (or one or more of the many other providers of web-based CMI information). This way the CMI (and PI) would also be available through the TGA website.

Advantages

No increase in cost to TGA or to sponsors.

No duplication.

Consumers who use the TGA website could access CMI through the TGA website.
Disadvantages

- There would need to be a process for selecting the organisation or organisations to which the TGA provides links (noting that this may provide some marketing advantage for the organisation selected).

- There may be legal issues if the TGA provides links to an external provider. However, these could to some extent be overcome through the inclusion of a disclaimer as follows:

  “This website contains links to other websites which are external to the Australian Government Department of Health and Ageing. The Australian Government Department of Health and Ageing takes reasonable care in selecting linking websites. It is the responsibility of the user to make their own decisions about the accuracy, currency, reliability and correctness of information contained in linked external websites.

  Linkage to external websites should not be taken to be an endorsement or a recommendation of any third party products or services offered by virtue of any information, material or content linked from or to this website. Users of links provided by this website are responsible for being aware of which organisation is hosting the website they visit.

  Views or recommendations provided in linked websites do not necessarily reflect those of the Commonwealth.”

- The TGA has no certainty that the CMI and PI included on the linked websites are updated regularly.

- The websites referenced by the TGA are unlikely to include all CMI and PI and the TGA could not compel all companies to provide such documents to any particular on-distributor (as noted in relation to Option 2).

- There does not appear to be an existing website that provides access to PI free of charge (although this will need to be explored further during consultations).

- The TGA has no jurisdiction over on-distributors and could not enforce any requirements for inclusion of all CMI and PI on the selected website; any requirements relating to how often the information on the website is updated; or any limitations on the promotional or other material that was included on the site.

Option 4: The TGA provides links to sponsor websites

Explanation

The TGA could require sponsors to maintain CMI and PI on their websites and provide links to the TGA for inclusion on the TGA website.
The TGA website would include a list of trade names and active ingredients that could be searched by a person accessing the TGA site. A link could then be provided to the relevant sponsor’s website and that website could include a pdf version of the CMI and PI.

This could be achieved on a voluntary basis with the co-operation of industry or through an amendment to the therapeutic goods legislation to require sponsors to maintain up-to-date copies of CMI and PI on their website and provide links to the TGA for inclusion on the TGA website.

Advantages

- Many sponsors already utilise the web for electronic ordering and distribution. While they may not have websites that are accessed publicly they are likely to have the capacity to provide CMI and PI via the web.

- The sponsors are the source of the CMI and PI and are responsible for keeping the documents up-to-date. Sponsors would be able to update their websites immediately following any change to the CMI and PI ensuring that the latest information is publicly available. There would be no time delay in the most up-to-date version of the CMI and PI being available because such availability would not depend on providers of subscription services or other on-distributors updating their websites.

- This would not replace any existing websites or services available to health professionals and consumers. It is expected that, where available, health professionals would continue to use their existing subscription services which are likely to be more user friendly and better directed to the needs of health professionals than the TGA website. However, the CMI and PI would be freely available to those health professionals that do not, or cannot, access subscription services.

- Consumers and health professionals could not only access the PI and CMI through the TGA website but also directly through the sponsor’s website. A general search of the web would be likely to reveal the CMI and PI.

- All CMI and PI would be available on a single website.

Disadvantages

- Some cost to the TGA (and therefore flow on costs to industry as a result of the TGA being a fully cost recovered organisation).

- There would be costs to those sponsors that do not currently hold CMI and PI on their websites or do not have local websites.

- Compliance costs would be likely to vary between the 141 sponsors of products requiring a PI and CMI. Some of these sponsors are small
companies supplying only 1 product, others are large companies supplying in excess of 400 products to the Australian market. Further consultation would need to be undertaken with sponsors to determine the number of sponsors that do not have local websites and the likely compliance costs for all sponsors.

- There may also be issues in terms of dead links that may discourage consumers from using the TGA website as a source of information.

**Option 5: TGA includes all CMI and PI directly on the TGA website**

**Explanation**

The TGA could include copies of all CMI and PI on the TGA website.

The TGA could enter an agreement with industry (on a voluntary basis) or make amendments to the therapeutic goods legislation to require that sponsors provide up-to-date CMI and PI to the TGA for inclusion on the TGA website. Sponsors could provide the CMI and PI either directly to the TGA or indirectly (for example, through healthlinks.net).

**Advantages**

- There would be a website that includes all CMI and PI and the website would be hosted by a trusted source. This may or may not be able to be achieved through voluntary agreement with industry.

- This is consistent with the approach adopted by Medsafe (NZ).

**Disadvantages**

- The costs to the TGA (and therefore flow on costs to industry as a result of the TGA being a fully cost recovered organisation) would be greater under this option than any other option. There would need to be a contact person within the TGA to whom sponsors would provide revised CMI and PI and every time a CMI or PI was revised this would require an update to the TGA website.

- There may be issues of liability for the TGA (for example, in the event that the information provided by sponsors is incorrect). The CMI and PI would need to be accompanied by statements clarifying that:
  
  - any queries relating to information contained in the CMI or PI should be directed to the pharmaceutical company named as the sponsor; and
  
  - TGA does not evaluate or approve CMI and is not responsible for the information contained in a CMI.
CHAPTER 6: IMPLEMENTATION

In the context of considering the options detailed above, the TGA also seeks advice from stakeholders regarding:

- whether the TGA website should include (by whichever means detailed above) CMI only or CMI and PI. Please refer discussion of this issue in Chapter 3;

- whether any of the options could be implemented on a voluntary or mandatory basis. For example, in relation to Option 4 the TGA could legislate to require sponsors to keep CMI and PI on their website and provide links to the TGA. The advantage of legislating the requirement is that it increases the likelihood of compliance by all 141 sponsors and provides a level playing field for all sponsors;

- any timeframes for implementation of the options. For example, if the TGA was to require that sponsors provide the TGA with electronic CMI and/or PI for inclusion on the TGA website (either directly or indirectly), what lead times would be required by industry in order to comply? Consideration will also need to be given to any transitional arrangements. For example, it may be possible to require that CMI and PI for all new products be available from a certain date with products that are already on the ARTG being introduced onto the website over a three year transition period;

- implications in relation to the proposed trans-Tasman arrangements. For example, consideration could be given to aligning the implementation of any of the options with the implementation of the trans-Tasman arrangements;

- if the TGA website (or any other website) is to include a searchable database of all CMI and PI should this initiative be accompanied by an education campaign so that consumers are aware that this facility exists? If so, who is best placed to undertake such an education initiative? Consideration may also need to be given to whether any education needs to accompany the availability of PI to reinforce the message that any decisions that a consumer makes based on the information included in the PI should be made in consultation with a health professional; and

- the means by which to ensure that CMI and PI are not associated with promotional material (or linked to the treatment of a specific disease) on the websites of sponsors (recognising the mechanisms potentially available through the Therapeutic Goods Advertising Code).
MEDSAFE’S REQUIREMENTS

In New Zealand, pharmaceutical companies are required to prepare data sheets for all prescription medicines and restricted (pharmacist only) medicines. Medsafe approves each data sheet on the basis of the company declaring that the data sheet conforms with the specified requirements and accurately reflects the product approved for distribution in New Zealand. Data sheets are updated as required to include newly approved dose forms, strengths or indications, or to update warnings, adverse effects, contraindications etc. as new safety information becomes available.

Data sheets are not required for related products, but if a product is marketed under two or more names, separate data sheets are required for each name of the product concerned.

Preparation of data sheets must be in accordance with the “New Zealand Guidelines for Medicines, Volume 1”. These Guidelines describe the requirements for applications and notifications under New Zealand legislation and include the information that must be included in data sheets.

The Guidelines provide that data sheets should contain information under the following headings:

- Name of the medicine;
- Presentation (includes dose form and strength, and flavour if applicable);
- Uses - Actions, Pharmacokinetics, Indications;
- Dosage and administration;
- Contraindications;
- Warnings and precautions;
- Adverse effects;
- Interactions;
- Overdosage;
- Pharmaceutical precautions;
- Medicine classification;
- Package quantities;
- Further information;
- Name and address; and
- Date of preparation.

The Guidelines also provide additional information under each of the headings as guidance on what should be included in data sheets submitted for approval, as well as detailed advice on preparation of data sheets, such as formatting, style and language. There are also requirements for including additional safety information relating to specific medicines and therapeutic groups.
Medsafe’s requirements for product inserts (including consumer information)

Applicants must indicate when a product is to be marketed with an enclosed product information leaflet, and must declare that the information in the leaflet is consistent with the approved data sheet. The leaflets are neither evaluated of approved – the onus is on the applicant to ensure and confirm to Medsafe that the information is consistent with the approved data sheet.

The New Zealand Guidelines also allow for Consumer Medicine Information to be included with the packaging of approved products. Whilst producing CMI is not mandatory, sponsors are encouraged to do so. Where a brand of medicine has more than one medicine classification depending on indications, strength etc, a separate CMI must be produced for each classification.

If CMI is to be included with the packaging of an approved product it must be written in accordance with the “New Zealand Regulatory Guidelines for Medicines Volume 4”. CMIs are not included in product applications, but are provided separately to the CMI Coordinator at Medsafe.

The sponsor is responsible for self-assessing CMI against the requirements of Volume 4 of the Guidelines – there is no approval or evaluation process undertaken by Medsafe. For Prescription and Restricted medicines, the CMI must be consistent with the information contained in the approved data sheet.

The Guidelines provide that data sheets should contain information under the following headings:

- Product identification details;
- What the medicine is used for and how it works;
- Advice before using the medicine;
- How to use the medicine properly;
- Side Effects;
- In case of overdose;
- Storage conditions;
- List of other ingredients;
- If you want to know more;
- Pharmaceutical Company; and
- Date on which the CMI was last revised.

The Guidelines also provide additional information under each of the headings as guidance on what details be included in CMIs, as well as detailed advice on preparation of CMIs, such as formatting, style and language.
Information available on the Medsafe website

The Medsafe website provides searchable databases of all data sheets and CMIs that are provided electronically by sponsors. The relevant pages of the Medsafe site note that:

- any queries relating to information contained in a data sheet should be directed to the pharmaceutical company named as the sponsor in the data sheet;

- where copies of data sheets are not currently available on the site, the site advises people to contact the pharmaceutical company directly;

- Medsafe does not evaluate or approve CMIs, therefore Medsafe is not responsible for the information contained in a CMI; and

- if a CMI for a product is not available it may not have been produced by the relevant and that a doctor or pharmacist should be able to provide the information.