Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

Second Discussion Paper:

Improving access to Consumer Medicines Information (CMI) and Product Information (PI)

January 2007

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GLOSSARY OF TERMS AND ACRONYMS USED

APAC	Australian Pharmaceutical Advisory Council
ACOM	Australian Catalogue of Medicines
ARTG	Australian Register of Therapeutic Goods
CMI	Consumer Medicine Information
DSEB	Drug Safety and Evaluation Branch of the TGA
EDWG	Electronic Distribution Working Group
JAEG	Joint Agency Establishment Group
MIC	Medicines Information for Consumers program
NPS	National Prescribing Service Limited
PHARM	Pharmaceutical Health and Rational Use of Medicines Committee
PI	Product Information
PSA	Pharmaceutical Society of Australia
QARG	Quality Assurance Reference Group
QUM	Quality Use of Medicines
RACGP	Royal Australian College of General Practitioners
TGA	Therapeutic Goods Administration
TG Act	*Therapeutic Goods Act 1989*
TG Regulations	*Therapeutic Goods Regulations 1990*

INTRODUCTION

Background

In April 2005, the TGA released a Discussion Paper on 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:

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

Following the release of the Initial Discussion Paper the TGA held forums in Sydney and Melbourne to discuss the issues raised in the Initial Discussion Paper and to seek stakeholder views on options for improving consumer and professional access to web based copies of up-to-date CMI and PI.

Written submissions were also received from a wide range of stakeholders.

Purpose of this Second Discussion Paper

As a result of the very valuable feedback provided on the Initial Discussion Paper, the TGA is now able to provide more detail about each of the options discussed and report on the outcomes of the consultations.

The purpose of this Second Discussion Paper is to seek stakeholder views on some revised options including the TGA's preferred option. As the feedback from this consultation will also flow through into the development of practices for the Australia New Zealand Therapeutic Products Authority (ANZTPA) and joint regulatory scheme, feedback is sought from both New Zealand and Australian stakeholders.

Stakeholders may wish to make written submissions to:

Dr John Donohoe
Drug Safety and Evaluation Branch
Therapeutic Good Administration
PO Box 100, WODEN, ACT 2606

The closing date for submissions is 30 March 2007.

SUMMARY OF OUTCOMES OF INITIAL CONSULTATIONS

The Initial Discussion Paper proposed the following key objectives:

- increasing the channels through which consumers can access up-to-date CMI;
- increasing the availability of PI to health professionals and to those consumers (and their carers) who require more information than that offered by the CMI;
- ensuring that there is a comprehensive source of up-to-date CMI and PI available on the web;
- examining the options for including all CMI and PI on a single trusted website;
- ensuring co-ordination with other initiatives;
- considering the New Zealand experience; and
- identifying any opportunities for co-ordination with New Zealand in the context of the proposed trans-Tasman arrangements.

Overall stakeholders strongly supported these objectives including improving the availability of both CMI and PI. The TGA is also committed to increasing web-based access to all CMI and PI.

Stakeholders consistently noted that web-based provision of information should not replace the fundamental and significant role of doctors and pharmacists in the provision of CMI. Further information regarding stakeholder views on the objectives of the process is included in Chapter 1 of this Discussion Paper.

The Initial Discussion Paper proposed five options for achieving the objectives detailed above:

Option 1: Retain the status quo;
Option 2: Strengthen existing databases (that currently contain some CMI and PI);
Option 3: Provide a link on the TGA website to existing databases (this could be implemented in conjunction with Option 2);
Option 4: TGA provides links to sponsors websites which would be required to include CMI and PI; and
Option 5: TGA includes all CMI and PI directly on the TGA website.

Overall stakeholders did not support Option 1 (retention of the status quo) because it would not achieve the objectives detailed above. Similarly Option

2 (strengthening existing databases) was not strongly supported because it was not clear how existing databases could be strengthened so as to ensure that there was a single source of all CMI and PI.

Stakeholders noted that while Options 3 and 4 would be likely to be cost effective, there were challenges in ensuring that at least one site contained all CMI and PI, noting the inherent difficulty of requiring sponsors to provide all CMI and PI to one commercial provider.

The majority of stakeholders seemed to support Option 5 (the TGA including all CMI and PI directly on the TGA website) as this was generally considered to be the most effective way to ensure that there was a single, trusted, electronic source of all CMI and PI.

In supporting Option 5, stakeholders made a number of important points:

- to be of any real benefit, any central repository must:
  - be up to date;
  - contain PI and CMI for all prescription medicines and from all sponsors; and
  - be easy for consumers to find, access and operate.
- the TGA should not "reinvent the wheel" and if the TGA were to develop a centralised database of all CMI and PI then the TGA should investigate means to utilise existing resources such as the Healthlinks Data Warehouse;
- costs should be kept to a minimum. In particular, it was noted that many sponsors have already committed to the provision of CMI via Healthlinks and it would appear unfair if they were also forced to commit to other means of distribution;
- the initiative would need to be well planned, resourced and properly implemented; and
- the implementation of any option should be accompanied by an education campaign to increase consumer awareness of CMI.

Further detail regarding stakeholder views on the options is included in Chapter 2 of this Discussion Paper.

The TGA has considered these views in detail and agrees with many of the concerns expressed in relation to the options. In summary, the TGA considers that Options 1-3 do not achieve the desired objectives and that in order for up-to-date copies of all CMI and PI to be available on the web then this must be organised by industry (Option 4) or by the TGA (Option 5).

The TGA is, however, concerned that Option 5 would appear to be the most costly option and that if this option were to be adopted it would require the commitment of considerable resources by the TGA. In turn, this would lead to increased costs to industry as a result of the TGA's policy of cost recovery.

The TGA considers that an alternative option may also be possible whereby sponsors provide the TGA with links to CMI and PI that are on the web (either on the sponsor's website or on the website of a third party distributor). In either case, the sponsor would be ultimately responsible for ensuring that all CMI and PI are available on the web, that these are up to date and that the TGA has links to these CMI and PI.

This option would be less costly than Option 5 but would still ensure that all CMI and PI can be accessed through the TGA website. This is therefore the preferred option of the TGA at this time. The costs and benefits of this option (along with Option 5) are discussed in more detail in Chapter 2 and the TGA is keen to receive comments from all stakeholders regarding these costs and benefits.

CHAPTER 1: STAKEHOLDER VIEWS ON OBJECTIVES AND SCOPE OF REVIEW

A. Objectives

As detailed in the summary of outcomes of consultations, the Initial Discussion Paper identified 7 key objectives that essentially defined the scope of the review and the outcomes sought by the TGA.

Stakeholders provided a range of comments on these objectives and also made suggestions regarding other issues or objectives that should be borne in mind as well as suggestions regarding the scope of the review.

Increasing the channels through which consumers can access up-to-date CMI

Stakeholders overwhelmingly noted that the primary source of CMI should be health practitioners (particularly pharmacists who should provide CMI at the point of dispensing of medicines). However, stakeholders also noted that only a small number of consumers are currently receiving CMI from their health practitioner.

It was therefore acknowledged that it would be valuable to increase the channels through which consumers can access CMI.

Increasing the availability of PI to health professionals and consumers

A range of views were expressed regarding whether PI should be freely available to consumers.

- A majority of stakeholders supported the availability of PI noting that:
    - consumers are free to search the internet and access drug information that is not Australian specific;
    - it would make sense to include Australian PI in any database; and
    - PI could be accessible via a separate pathway to the CMI and could include a notice to consumers about the purpose of PI. Consumers wanting access to PI could, for example, tick a box acknowledging that they have read the CMI, were wanting further information and that they would consult with their health care professional if they have queries from the PI. It was suggested that the advantage of this approach is that it is not onerous for the consumer but also reinforces the position of the healthcare professional in medication management.

- Other stakeholders noted that the PI is developed for health professionals and that there may be some risks associated with the provision of PI to consumers in the absence of medical advice. For example, in their submission MIMS noted that they initially published both the CMI and PI on the myDr website. However they chose to voluntarily withdraw the PI as they were concerned about the impact of consumers reading the full PI without the overlay of professional counseling.

The TGA considers that PI should be made available to the public for the following reasons:

- CMI are designed around a reading age of 12 and many consumers expect more information;

- not all medically qualified professionals have subscriptions to PI services and the TGA considers that it is imperative that all health professionals have unfettered access to PI (without the need to wait to obtain a password or pay for a subscription); and

- other countries including Europe, the U.S. and New Zealand already have PI on the web and as such consumers are currently able to access these PI. The TGA considers that it is preferable to have Australian PI available rather than consumers being forced to rely on European or U.S. PI particularly given the difference in medications (and use) in the different countries.

Ensuring there is a comprehensive source of up-to-date CMI and PI available on the web

Availability of CMI

One of the purposes of the Initial Discussion Paper was to identify the information that is currently available to consumers via the website.

The consultations confirmed that there is no single source of <u>all</u> CMI that is available to consumers.

Of the 2800 medicines that the TGA estimate require CMI:

- the MIMS database is reported to hold 1624 CMI;

- the Australian Prescription Products Guide is reported to hold nearly 2000 CMI; and

- Healthlinks.net is reported to hold approximately 1260 CMI. Healthlinks.net has advised that of the top 100 PBS generic medicines, healthlinks.net holds electronic CMI for 99% of these medicines.

While there is no single web-based source of all CMI, there are a number of websites that contain a large number of CMI that are freely accessible to consumers. These include, for example:

- myDr (reported to contain approximately 1800 CMI);

- the National Prescribing Service Limited (NPS). The NPS also hosts a Medicines Line that consumers can call for more information. The website of the NPS notes that if a CMI is unavailable on their website a consumer can call the Medicines Line and the CMI will be sourced for them;

- Australian Prescription Products Guide (APPGuide) online;

- RACGP online;

- the Better Health Channel (supported by the Victorian Government). The Better Health Channel website contains a "Medicines Guide" that is reported to contain over 750 CMI; and

- the websites of a number of pharmaceutical companies that each contain the CMI for the products produced by that particular company.

In terms of the extent to which the existing information is utilised, the following anecdotal information was provided by stakeholders:

- RACGP advised that over a 12 month period to 24 May 2005, the CMI section of the website had 77,124 visitors and 94,275 files were downloaded; and

- MIMS Australia advised that myDr is updated weekly and that myDr currently has 155,000 unique visitors per month. The medication search is the 4th most popular part of the site with 18,000 visits per month.

Availability of PI

In relation to PI:

- Healthlinks.net has advised that approximately 730 PI (provided by approximately 17 companies) 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;

- the Australian Prescription Products Guide is reported to include PI for more than 3,900 prescription and non-prescription products. PI are only available to subscribers ($200per annum);

- the RACGP website contains PI but these are only accessible by members. The RACGP advised that over a 12 month period to 24 May 2005, the PI section of the website had 42 visitors and 58 files were downloaded (available via member log on); and

- some pharmaceutical companies currently post the PI for their products on their website (for example, Roche).

It would appear that there is no single publicly available, non-subscription service providing PI for a range of products across different companies.

Currency of PI and CMI

A critical issue for the TGA (should the establishment of a comprehensive source of CMI and PI be pursued) is ensuring that the CMI and PI on the website (or websites) is up to date.

There are clearly two main advantages of providing information over the web – ease of access for stakeholders (both consumers and health professionals) and improved potential for keeping the information up-to-date. A key driver for this initiative is to establish a source of up-to-date information that can be relied upon to include all safety-related updates.

One of the objectives of this second round of consultations is to seek the advice of stakeholders regarding the timeframes within which changes can be made to CMI and PI that are posted on any comprehensive web-based source of all CMI and PI (whether this is hosted by industry or the TGA).

Ensuring co-ordination with other initiatives

A number of stakeholders noted that the TGA should ensure that any initiatives are consistent with:

the Quality Use of Medicines Objectives; and

the work being undertaken on the Australian Catalogue of Medicines (ACOM). The Catalogue will enable the transmission of consistent product details between health care providers. Each medicine will have its own unique identifying code (known as a Global Trade Item Number or GTIN), which will ensure that the many health systems being used by doctors, pharmacists and hospitals refer to the same medicine, improving the accuracy of medicines information communicated between the various systems and reducing the risk of adverse events

The TGA considers that wider availability of CMI and PI will be a useful adjunct to the ACOM initiative. It also supports the central goal of the National Strategy for Quality Use of Medicines which is to make the best possible use of medicines to improve health outcomes for all Australians.

Considering the New Zealand experience and identifying any opportunities for co-ordination with New Zealand in the context of the proposed trans-Tasman arrangements

A number of stakeholders noted that any discussion of options for improving access to CMI and PI in Australia should be undertaken in the context of the establishment of the ANZTPA and joint regulatory scheme and should involve New Zealand.

The TGA agrees that this issue should be considered in the context of the Joint Agency arrangements. As noted in the introduction, it is intended that the feedback from this consultation will also flow into the development of practices for the Joint Agency. Feedback is being sought from both New Zealand and Australian stakeholders.

B. Other issues raised regarding scope and objectives

Application of any initiatives to Schedule 3 medicines

Some stakeholders noted that the regulatory controls for Schedule 3 medicines, including content and availability requirements, are exactly the same as for prescription medicines. They therefore considered that distribution and access to Schedule 3 medicines must be taken into account in any system that is established for prescription medicines.

The option of extending the initiative to Schedule 3 medicines was not canvassed in the original Discussion Paper and therefore many interested stakeholders did not comment on this issue.

It is not currently proposed that Schedule 3 medicines be included in this initiative. However, the experience of this project may be utilised should any similar project be pursued in the future for over-the-counter medicines.

CHAPTER 2: STAKEHOLDER AND TGA VIEWS ON OPTIONS PROPOSED IN INITIAL DISCUSSION PAPER

As detailed in the Summary, five options were proposed in the Initial Discussion Paper.

Option 1: Retain the status quo;

Option 2: Strengthen existing databases (that currently contain some CMI and PI);

Option 3: Provide a link on the TGA website to existing databases (this could be implemented in conjunction with Option 2);

Option 4: TGA provides links to sponsors websites which would be required to include CMI and PI; and

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

This Chapter describes in more detail, stakeholder response to the options.

A. 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.

Outcomes of consultations

On the whole, stakeholders did not support Option 1 largely because it would not provide a single comprehensive source of CMI or PI that is accessible to the public.

TGA view

The TGA does not consider that Option 1 achieves the objectives detailed in the Initial Discussion Paper and as such does not support this option. The TGA considers that:

- the status quo does not ensure that health care professionals have unfettered access to PI (as, in most cases, access depends on subscription to a particular service);

- the status quo does not enable consumers to readily access additional information if they require more information than that provided in the CMI;

- there is no single source of **all** CMI and PI; and

- in the absence of subscribing to a service, consumers and health care professionals could not be confident that any CMI or PI that they access are the up-to-date versions of the documents. While the TGA acknowledges that the content of websites can not be controlled, the TGA considers that it would be desirable for there to be at least one source of information that health care professionals and consumers know to be authoritative, up-to-date and reliable.

The TGA agrees with stakeholders that internet access to CMI and PI should not replace the fundamental and significant role of doctors and pharmacists in the provision of CMI and that measures need to be taken to increase the provision of CMI by pharmacists. However, the TGA considers that increased availability of CMI and PI will assist those consumers who are not provided with CMI and/or those who require additional information.

B. Option 2 – Strengthen existing databases

Explanation

In the Initial Discussion Paper the TGA did not identify any specific means by which to strengthen existing databases and it was noted that one of the main purposes of the initial consultations was to improve the TGA's understanding of the operation of existing services providing electronic CMI and PI to consumers and health professionals.

Outcomes of consultations

On the whole stakeholders:

- considered that the TGA should not attempt to "reinvent the wheel" and that where existing resources exist these should be used to form the basis of any centralised database of CMI and PI;

- acknowledged that none of the existing services (in their current form) meet the key objective of providing a centralised up-to-date database of all CMI and PI;

- acknowledged that 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; and

- noted that without an integrated search facility, users would still need to undertake several separate searches on each of the existing websites.

One means that was identified for strengthening existing services was for the TGA to include on the ARTG details regarding when CMI and PI have been updated.

It was suggested that the TGA could include a simple list of all PIs and CMIs, the date they were approved and the date of any revision in the ARTG. Providers of CMI and PI could then access the site (as part of normal processes) to determine whether there had been any changes to PI or CMI. It was suggested that it would then be a simple procedure for data providers to find out whether changes have been made and contact sponsors to ensure that their own database is up to date. It was noted that this would be a resource that data providers could access as a guide to up-to-date CMI and PI.

TGA view

The TGA agrees that any "reinvention of the wheel" should be avoided. However, the TGA does not consider that it would be possible to strengthen any of the existing services such that they would contain all CMI and PI as this would require the TGA to mandate that sponsors provide all CMI and/or PI to one or more data warehouses or distributors. This presents difficulties in terms of competition.

Even if issues of competition could be overcome, and the TGA mandated that sponsors provide an electronic copy of PI and CMI to at least one in a list of "approved" data warehouses or distributors, this would still pose problems in terms of consumers not being able to search one website and be assured of finding the appropriate CMI or PI.

There could also be potential problems in terms of any conditions that the "approved" providers may place on membership (or access) and also no guarantees regarding the continuity of the service provision. For example, it would not be clear what would happen if one of the "approved" commercial providers goes out of business.

Regarding the suggestion that the TGA could include a list of all PIs and CMIs and the date of any revisions (that could be accessed by providers of web-based services), the TGA is concerned that this still does not ensure that there is a source of CMI and PI that is known to be up-to-date. The TGA would have no guarantee that providers of services access this list or how often they revise the PI and CMI on their websites. Essentially this would result in the status quo being maintained.

C. Option 3: Link on TGA website to existing database

Explanation

In the Initial Discussion Paper it was suggested that 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).

Outcomes of consultations

Stakeholders generally agreed with the advantages and disadvantages of this option, as outlined in the Initial Discussion Paper. That is, while it would avoid duplication and would enable consumers to access information through the TGA website, there would be similar difficulties to those identified in relation to Option 2.

It was noted that:

- 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;
- the websites referenced by the TGA are unlikely to include all CMI and PI; and
- the TGA could not compel all companies to provide the PI and CMI to any particular on-distributor.

TGA view

As for Option 2, if this option were to be pursued, then in order to address the problems that are inherent in the status quo, there would need to be a means for:

- ensuring that at least one of the existing services is expanded to include all PI (or that all PI were somehow accessible across the services); and
- ensuring that the CMI and PI are updated regularly.

The TGA does not consider that this is a viable option largely because 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.

In summary, the TGA does not consider that Options 1-3 are viable or assist in achieving the desired objectives. Further, most stakeholders also seem to be suggesting that these options are unsatisfactory because of issues around comprehensiveness, timeliness and difficulties in administration.

D. 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.

Outcomes of consultations

This option was not supported by stakeholders. It was noted that:

- sponsors would need to have a website established and would need the capability to include CMI and PI and this would impose costs on sponsors. It was noted that the additional work generated by having to include and maintain CMI and PI on their websites may be an issue for companies with large volumes of documents and also small companies with limited resources;

- documents may have inconsistent format and presentation (noting that they may not all be formatted to enable easy downloading and printing to any type of computer/printer);

- assuming there is no centralised search function, it may be difficult for consumers to find information about a medicine when a sponsor may not be known to a consumer or professional;

- deadlinks may discourage consumers who use the website; and

- the TGA has limited control over the content on the sponsors' websites and there is potential for sponsors to use the link for marketing purposes.

In the Initial Discussion Paper it was suggested that this could be achieved on a voluntary basis with the co-operation of industry. Stakeholders did not consider that this would be viable and noted that if this option were adopted, there would need to be 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.

TGA view

Given the difficulties that are inherent in Options 1 to 3, it would appear that if there is to be a comprehensive, easily accessible database of all CMI and PI then it would appear that this needs to be organised either through industry (Option 4) or by the TGA (Option 5).

The TGA acknowledges the difficulties that have been noted above and seeks the advice of stakeholders on a possible alternative model whereby:

- the TGA mandates that each sponsor must maintain a web-based version of each CMI and PI and that each sponsor must provide to the TGA the link to each CMI and PI;

- each sponsor may choose whether to maintain the electronic version of the CMI or PI on their own website or on the website of a third party service provider. In either case, the sponsor must be able to meet legislated requirements for the CMI and PI to be available on the web (through a link on the TGA website) and for the CMI and PI to be up-to-date. This would ultimately be the sponsor's responsibility even if the actual process of updating was outsourced by the sponsor to a third party provider; and

- in terms of consistent format and presentation, the TGA would still be approving the PI and the onus would continue to be on the sponsor to have appropriate CMI documents. If more details about presentation and specifications were needed, these could be prescribed.

It would appear that this approach:

- ensures that all CMI and PI are accessible through a central website (the TGA website). The concern that it may be difficult for consumers to find information, when a sponsor may not be known to a consumer or professional, would be overcome because the TGA website could include a simple search function. This could be on the name of the medicine or the ARTG number which is on the packaging of the medicine. The major concern about Option 4 - concern that consumers may not view the information on sponsor's websites as reliable - may be overcome as the information would be obtained through the TGA website;

- provides flexibility for sponsors. Sponsors can either establish their own website or they can utilise an existing database service. This has the potential to minimise costs and would mean very little additional impost for those sponsors that already subscribe to, for example, the healthlinks.net Data Warehouse;

- minimises the costs to the TGA - costs that will ultimately be borne by sponsors through the TGA's policy of cost recovery. Costs would be expected to be relatively low as the TGA would simply be providing an alphabetical listing of medicines, a simple search facility and links to the CMI and PI for each product listed on the TGA website. In addition to IT costs, the TGA estimates that a full time administrative officer would be required to support the initiative. The TGA estimates that the total costs to the TGA would be unlikely to exceed $200,000 per annum. This would be cost recovered from industry;

- has the most potential for ensuring that the CMI and PI are up-to-date. The TGA would mandate that the CMI and PI be updated within a certain number of days. For those sponsors that use a third party service provider, the sponsor would need to ensure that the contract with the service provider ensures updates occur within the mandated timeframe;

- has many of the advantages of Option 5. For example, it provides a single trusted source for all PI and CMI and it enables users to search by product rather than by sponsor which may not be known;

- would continue to pose potential difficulties in terms of any "deadlinks". However, the sponsor would be responsible for informing the TGA of any changes to the location of the CMI or PI; and

- could overcome the concern regarding links to advertising or promotional material by ensuring that the link is directly to the CMI or PI and not to the home page of a sponsor. Consideration could also be given to any changes that might be needed to the Therapeutic Goods Advertising Code 2005 in order to support this initiative.

Subject to the further advice of stakeholders regarding the viability of this alternative option (and the identification of any further advantages and disadvantages), the TGA prefers this option.

E. 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 an existing third-party service provider such as the healthlinks.net Data Warehouse).

Outcomes of consultations

This option was the preferred option of the majority of stakeholders. The key arguments in support of this Option were as follows:

- it provides a single trusted source for all PI and CMI;

- it enables users to search by product rather than by sponsor which may not be known;

- it is consistent with the approach taken by Medsafe and is therefore more readily harmonized with NZ when the Joint Agency comes into effect;

- it provides good exposure to consumers and professionals regarding the role and function of the TGA; and

- it would align with the TGA's efforts to become more transparent.

In supporting this Option stakeholders cautioned that;

- it should not detract from the services offered by other organisations;

- the TGA would need to mandate the provision of PI and CMI within a certain timeframe; and

- this would impose additional costs to industry and it is "imperative that the costs be contained". It was noted that a TGA website should not penalise companies who have contributed to the healthlinks.net Data Warehouse or impose additional costs or processes in order to populate and maintain currency and accuracy of the TGA website.

In terms of implementation, stakeholders noted that:

- the TGA could contract out the creation and maintenance of the database resulting in potential competitive cost reductions;

- sponsors could have the website of the central repository on the packaging of the medicines to increase stakeholder awareness of the availability of medicines information;

- issues of liability could be overcome by an overarching statement on the web stating that any queries should be directed to the sponsor and that the TGA is not responsible for the CMI content; and

- there would need to be a contact person within the TGA (or a contracted organisation) to whom sponsors would provide revised CMI and PI.

TGA views

The TGA considers that this approach meets the desired objectives and that it has some appeal. However, the TGA does not prefer this option for the following reasons:

- if the TGA takes on responsibility for ensuring that correct and up-to-date CMI and PI are posted on the TGA web, then it will be imperative that the TGA is properly resourced in order to fulfill this responsibility. In particular, document control will be a major issue given the number of changes to PI and CMI each year. For example, during 2005, the TGA

received a total of 844 submissions involving changes to PI or new PI. This total comprises:

- new chemical entities – 24
- extensions of indications – 38
- major variations – 34
- new generic – 78
- safety related notifications – 478
- other changes to PI – 192

If the TGA were to post all CMI and PI directly on the TGA website then the TGA would be responsible for document control and for ensuring that any changes are posted on the website as quickly as possible. Processing of approximately 844 PI changes per year would demand considerable resources. By contrast, the alternative option detailed under Option 4 does not require the TGA to "handle" these changes. Rather the sponsor would be responsible for ensuring that any changes are made and that the most up-to-date PI and CMI are posted on the web as quickly as possible.

- this is the most expensive, resource intensive option. In addition to IT costs, the TGA estimates that this initiative would need to be supported by 3 full-time TGA officers. The TGA estimates that the total recurring costs to the TGA would be approximately $500,000 per annum. This would be cost recovered from industry. Even if the TGA were to outsource the management of the TGA database of PI and CMI to a third party, this would incur costs that would be passed on to sponsors under TGA's cost recovery policy; and

- potential litigation continues to be of concern to the TGA. While Medsafe in New Zealand adopts this approach, the TGA notes that there is a very different legal environment in Australia and that there is a real risk to the TGA of litigation in the event that there are any problems, errors or delays in the posting of CMI and PI on the TGA website. The TGA considers that it is appropriate that ultimate responsibility for the accuracy of the CMI and PI rests with the sponsors (as it always has).

The TGA seeks the further advice of stakeholders regarding this option and its advantages, disadvantages and cost implications compared to Option 4 (as amended and further developed).

CHAPTER 3: IMPLEMENTATION ISSUES

At this stage the TGA considers that the preferred option would best be developed in the context of the ANZTPA and joint regulatory scheme.

Regardless of whether Option 4 (as revised) or Option 5 is adopted, further consideration will need to be given to the following implementation issues:

- legislative amendments. Either option may require legislative changes. As part of the implementation of the ANZTPA and joint regulatory scheme , Rules will be developed to define the requirements relating to CMI and PI. These Rules could reflect the preferred option;

- timeframes for implementation. Stakeholder advice is sought on the timeframes that would be required for implementation. For example, advice is sought regarding the time that sponsors expect that it would take between the legislation taking effect and all sponsors being required to have the CMI and PI available on the web. While the TGA expects that the timeframes would differ between Option 4 and Option 5, the TGA considers that if Option 4 was adopted it would not be unreasonable for all sponsors to have electronic CMI and PI available on a website within 12 months; and

- education. As suggested by stakeholders, any new initiative will need to be supported by an education campaign for consumers and health care professionals.

ATTACHMENT A

BACKGROUND INFORMATION ABOUT PI AND CMI

A. 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.

PI should contain the following information:

- 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.

PI are approved by the TGA and must be provided for each registered product (predominantly prescription medicines).

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).

Generally speaking PI is 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.

B. Consumer Medicine Information

Consumer Medicine Information (CMI) is a leaflet that contains information about a medicine that is written specifically for consumers. CMI are based on PI and are drafted in language that is readily understood by consumers.

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.

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.

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.

Healthlinks.net – Data Warehouse

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 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.

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.