

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

SECOND DISCUSSION PAPER:

IMPROVING ACCESS TO CONSUMER MEDICINES INFORMATION (CMI) AND PRODUCT INFORMATION (PI)

PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

The RMI acknowledges that while the Discussion Paper was initiated by the TGA, feedback provided will also flow through into the development of practices for the Australia New Zealand Therapeutic Products Authority (ANZTPA). Our submission, therefore, is written in the context of an operational ANZTPA.

This submission focuses on providing feedback on the revised options – Options 4 and 5.

OPTION 4: THE ANZTPA PROVIDES LINKS TO SPONSOR WEBSITES

Explanation: The ANZTPA could require sponsors to maintain CMI and PI on their websites and provide links to the ANZTPA for inclusion on the ANZTPA website. The ANZTPA website would include a list of trade names and active ingredients that could be searched by a person accessing the ANZTPA 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.

Option 4 is the preferred option of the TGA but not the majority of stakeholders. Under the ANZTPA the TGA will no longer exist and it is, therefore, premature for the TGA to be making decisions about the preferred option without reference to Medsafe's position. At the very least, any preferred option should be that nominated by the Joint Agency Establishment Group (JAEG).

A major concern about Option 4, noted in submissions on the First Discussion paper, was that consumers may not view information on the sponsor's websites as reliable. The TGA suggests (p.18) that this "...may be overcome as the information would be obtained through the TGA website". No information to support this view is given. By comparison, the Ministry of Health,

September 2006 *Direct-to-Consumer Advertising of Prescription Medicines in New Zealand: Summary of Submissions* noted (p.6) "A number of respondents supported the provision of independent information, and a range of options for doing this were suggested". Thus, the concern remains that some consumers may not view the information on a sponsor's website as reliable. Further, the accessing of a sponsor's website via the regulator's website may cause some consumers to question the relationship between regulator and industry.

It is stated (p.19) that Option 4 "has the most potential for ensuring that CMI and PI are up-to-date". It is somewhat disconcerting that the regulator, who approves the PI, would not be able to update their website as quickly as a third party distributor or meet their own mandated timelines for the updating of CMI and PI.

OPTION 5 : ANZTPA INCLUDES ALL CMI AND PI DIRECTLY ON THE ANZTPA WEBSITE

Explanation: The ANZTPA could include copies of all CMI and PI on the ANZTPA website. The ANZTPA could enter an agreement with industry (on a voluntary basis) or make amendments to legislation to require that sponsors provide up-to-date CMI and PI to the ANZTPA for inclusion on the ANZTPA website. Sponsors could provide the CMI and PI either directly to the ANZTPA or indirectly (for example, through an existing third-party service provider such as the healthlinks.net Data Warehouse).

Option 5 was the preferred option of the majority of stakeholders. Presumably, the stakeholders who responded to the first discussion paper in support of Option 5 included consumers (including health professionals and patients/carers), and sponsors. If so, it would be disappointing for the regulator to ignore the views of both the consumers and the providers of CMI and PI by pursuing their own preferred option. If Option 5 is not considered by the regulator to be a true candidate for adoption, one questions the validity of the consultation process and the value of including this option in the Discussion Papers.

Further, an important factor for success or failure of a scheme is "buy-in" by the stakeholders. Option 5 has the support of the majority of the stakeholders. Option 4 does not.

The RMI considers that the key arguments in support of Option 5 are:

- it provides a single trusted source for all PI and CMI
- it is consistent with the approach taken by Medsafe which has successfully met the needs of regulator, sponsors and consumers, including health professionals
- it is a free, non-subscription, publicly available source for all PI and CMI which overcomes existing barriers to access to this information in Australia and will continue to provide the level of access New Zealanders expect as standard
- as the regulator approves all PI and changes to PI, except for self-assessable changes which are instead notified to the regulator, the ANZTPA has access to the most up-to date PI.
- Similarly, the regulator assesses the CMI for compliance with regulatory requirements and has ready access to up-to-date CMI
- if adopted by the TGA, Option 5 will be more readily harmonised with New Zealand when the ANZTPA comes into effect
- Option 5 meets the key objectives proposed in the TGA's initial Discussion Paper on Improving Access to CMI and PI

The TGA puts forward a number of reasons that Option 5 is not their preferred option:

- "...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....."
- "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/ANZTPA 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".

The RMI does not agree with the TGA's concerns about the workload and need for the regulator to "handle" these changes thus requiring considerable resources.

The RMI proposes the following straightforward system which is not resource intensive and will ensure PI and CMI changes are posted on the web in a timely manner:

- 1) When a self-assessable, safety related notification (SRN) is submitted to the regulator, the sponsor submits an electronic copy, in PDF, of the updated PI and any affected CMI at the same time. The regulator then uploads onto the website the PI and CMI, the content of which are the responsibility of the sponsor.

If the updates electronic PI/CMI updates are not included with the SRN, the notification is not effective.

- 2) When a new product licence application, or a variation to a product licence, is submitted to the regulator for approval, the sponsor also submits the PI for approval and a copy of any CMI. After the PI is approved, the sponsor submits in electronic form a PDF of the approved PI and the CMI as the final step before the regulator approves the licence application or variation. The electronic copies can then be simply uploaded by the regulator onto the website.

Thus, all the work ensuring the accuracy of the PI and CMI is performed by the sponsor, who takes responsibility for the accuracy. The regulator's responsibility is limited to ensuring that the PI/CMI are uploaded onto the website within any mandated timeframe. With 844 applications per year (PI), that averages only about 17.5/week (for 48 weeks of the year) or approximately 3.5 /day to be uploaded onto the website.

- "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....."

The RMI strongly rejects the TGA's assertion that this is the most expensive, resource intensive option. Although the TGA estimates the costs at \$500,000 and a resourcing requirement of 3 full-time officers, it provides no supporting data to validate these estimates. In New Zealand, Medsafe currently operates a system essentially identical to that proposed by the RMI earlier in this

submission. This system is managed from within the current Medsafe fee structure and from within current staffing levels. One could be cynical and question if the cost would be as high if the TGA/ANZTPA did not operate a full cost recovery model.

The provision of CMI and PI has a significant public good component and as such the associated costs should be covered through general taxation – i.e. from the Government(s) - and not from industry. Thus, the RMI rejects the TGA's or, in the future, the ANZTPA's assertion that costs associated with improving access to CMI and PI be cost recovered from industry.

Finally, the TGA puts forward the following reason for not supporting Option 5:

- “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 RMI questions the reality of the TGA's concerns, especially in a trans-Tasman setting under the ANZTPA. Currently in Australia, there are a number of websites providing CMI and PI including the National Prescribing Service which is funded by the Commonwealth Government. Why, therefore, should the potential for litigation be any greater for the TGA/ANZTPA than for these sites.

The RMI believes that the concerns held by the TGA can be overcome by:

- a) sponsors having responsibility for the accuracy of the PI and CMI which is provided in PDF format to the regulator for uploading on to the website
- b) including a disclaimer on the website stating that the regulator is not responsible for the accuracy of PI and CMI
- c) under the ANZTPA, having the website hosted in New Zealand, rather than Australia, with access via a link to the ANZTPA New Zealand office and the CMI/PI database.

ADDITIONAL POINTS FOR CONSIDERATION

- In the transition period, following the introduction of the ANZTPA, it is important that CMI and PI currently available on the Medsafe website remains accessible to New Zealand consumers for products which do not have a full ANZTPA product licence.
- The RMI believes that the inclusion of CMI in packs should be optional – i.e. at the discretion of individual companies.

CONCLUSION

Previous consultation has shown that Option 5 has the greatest stakeholder support.

Option 5 meets the key objectives for improving access to CMI and PI outlined in the Discussion Paper.

The RMI strongly recommends the adoption of Option 5 - the regulator includes all CMI and PI on the regulator's website.

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