



Mental Health Council of Australia Submission to:

**Panel to Review the Transparency of the
Therapeutic Goods Administration
February 2011**

Introduction

The Mental Health Council of Australia (MHCA) is the peak, national non-government organisation representing and promoting the interests of the Australian mental health sector, committed to achieving better mental health for all Australians. The membership of the MHCA includes national organisations of mental health service consumers, carers, special needs groups, clinical service providers, community and private mental health service providers, national research institutions and state/territory peak bodies.

The MHCA welcomes the opportunity to provide comments to the Panel to Review the Transparency of the Therapeutic Goods Administration (TGA) and commends TGA efforts to improve transparency of regulatory processes.

The MHCA is committed to ensuring that people living with mental illness and their carers have access to the best possible treatment options, including choosing medicines where it is an appropriate treatment choice and using medicines in ways that are safe and effective. Access to prescription medicines plays a major role in the lives of mental health consumers and carers with prescriptions relating to the nervous system, such as antidepressants, anti-anxiety drugs and antipsychotics, accounting for twenty percent of those written by GPs.¹

Accessing safe and effective medicines to treat mental illness

The 2006 MHCA *Report of the National Stakeholder Workshop on Mental Health and the Quality Use of Medicines* summarised a range of barriers and potential solutions to consumers and carers accessing and benefiting from medicines for the treatment of mental illness.

Significant barriers continue to include:

- Negative community attitudes about mental illness and treatment medications, and the influence of these attitudes on mental health consumers, their family, friends, carers and even some health professionals.
- Significant fear around medicines used in the treatment of mental illness, for example, some consumers and carers are concerned about addiction, and changes to their personality or lifestyle.

¹ Australian Institute of Health and Welfare (2009). *Australia's Health 2008*. Canberra:AIHW

- Consumers and carers are not fully informed of the importance of the medications they are taking, nor are they fully informed of the health risks associated with inappropriate use of these medicines.
- Requests by consumers and carers to try alternative medicines due to unwanted side effects are often dismissed or trivialised.
- Gaps in information support for mental health consumers and carers from medical professionals such as GPs, pharmacists and discharge planners exist, including minimal counselling and not providing Consumer Medicine Information (CMI) when writing or filling a prescription.
- CMI are too long and difficult to read, and not relevant to mental health consumer and carer needs.

All of these impact heavily on a consumer's ability to make informed decisions about their medicines use and contribute to the lack of information carers have available to assist them in their caring role.

Several strategies were identified in the report to improve access to information about medicines use, including:

- Improving information around medicines to consumers, carers and professions in such areas as:
 - ✓ The development of easily accessible CMI in a variety of formats. Unfortunately CMI is not well known among mental health consumers and carers
 - ✓ The development and maintenance of a central repository of information, including education materials, clinical evidence and practice guidelines etc. on specific mental health medicines for use by professionals and consumers. The MHCA has previously called for the development of such a resource through its own website, and is currently working towards publishing an information portal that connects consumers and carers with trusted information about medicines (including the TGA)
 - ✓ Overhauling the TGA website to make it more intuitive and easy-to-use for consumers and carers. Recent changes have vastly improved the website but it can still be difficult for consumers and carers unfamiliar with the TGA to find their way around the site or even to know what useful information is housed on the site
 - ✓ Providing information about where consumers and carers can get further help, information and support about their medicines
- Improving behaviours around prescribing by providing consumer and carer input into training of professionals about medicines
- Undertaking better post-market monitoring including investigation of serious health events around medicines use, and then publishing the results of these investigations in a format that is easy to understand
- Providing a stronger role for the provision of input from consumers and carers on the type of information they need, how it should be disseminated etc
- Providing more information or evidence of differing side effect profiles of medicines for different population groups including women, children and older people
- Collection of national data on access to medicines and health outcomes to improve therapies. This data could then be provided to prescribers to improve therapies, as with other drugs this kind of feedback led to changes in prescribing patterns and treatment outcomes in a number of other disease areas.

Other issues

The mechanism for consumer and carer reporting of adverse medicines events is not well known both broadly in the community and especially among mental health consumers and carers. The TGA needs to better promote the mechanism and value of these reports, as well as how consumers and carers can access the adverse drug reactions unit and its surveillance reports. Explanatory notes on how to interpret surveillance reports would be highly valued by consumers and carers.

These notes, CMI, and other information about medicines need to be available in a variety of formats and through a number of sources. Many consumers and carers in rural areas do not have internet access and, if they do, often have only dial up or public library-based access. Some consumers and carers prefer to access medicines information through health professionals and take away hard copies for later referral. Reputable telephone advice lines (such as MedicinesLine) are also a valued information source.

Medicines alerts are rarely communicated to consumers, carers and their representative organisations. Medicines Safety Updates etc are regularly communicated by the TGA to health professionals and while this may change individual prescribing habits and provide a prompt for a medicine review for clients taking the medicine, it does not filter down to everyone taking a medicine of concern. The TGA needs to make sure that any relevant peak body, for example the MHCA in the case of mental illness-related medicines alerts, is also receiving information about the alert so that it can communicate this to stakeholders. The TGA needs to remember that few non-government peak bodies have staff cognisant with TGA processes, including alerts, nor do they necessarily have the resources to translate complex medicines information.

The MHCA highly values the TGA and industry negotiating the release of Australian Public Assessment Reports (AusPAR) on the evaluation of prescription medicines. These are an excellent step towards greater transparency of decisions by the TGA and brings Australia a little closer to what is published by international regulatory agencies. However, these documents are not written for consumers and their carers and a consumer/ carer summary of the AusPARs would make this evaluation information more readily available to those using a medicine on a daily basis or waiting for it to proceed into the Australian market.

This would be an ideal role for a consumer/carers liaison-type position, section or advisory group within TGA and could assist TGA in the production of regulatory information specifically aimed at consumers and carers.

Conclusion

The MHCA commends the TGA for examining methods to improve transparency of regulatory processes and looks forward to further work in this area.

The TGA needs to be open to the input of stakeholders, particularly consumers and carers, to ensure it is catering to their information needs. Mechanisms for stakeholder input beyond invitations to respond to a review should be examined.

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