APPENDIX 4

Review to improve the transparency of the Therapeutic Goods Administration

Final Report–June 2011

Executive Summary & Recommendations

The *Therapeutic Goods Act 1989* states as its principal object 'to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods' that are used in Australia or exported from Australia. This system is achieved through the operation of the Therapeutic Goods Administration (TGA), a Division of the Department of Health and Ageing.

A perception has arisen in the community that the TGA does not provide the public with sufficient information about its activities and about the therapeutic goods that it regulates. This perception led the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, to establish a panel of consumer, health practitioners and therapeutic goods industry representatives to review and report on the transparency of the TGA.

In the performance of its task, the Panel consulted widely with persons and organisations affected by the TGA's activities. It also took into account the requirements of the Australian Government's Declaration of Open Government which determines a whole of government context directing agencies towards enhanced transparency and a consumer focus in their activities. Coincident with this, the Panel noted that action has been taken by a number of the overseas regulators that have functions equivalent with those of the TGA to increase the transparency of their activities.

In the course of the Review it became apparent to the Panel that the TGA had done much in recent years to increase knowledge by stakeholders of the role and the functions that it performs. However, it was also apparent that the expectations of the public are not being met and there is more that the TGA can do. In this Report the Panel proposes means by which the TGA can provide greater transparency in the understanding by the public of its role and functions and can better inform stakeholders on the issues that are of concern to them.

The Panel considers that it is necessary for the TGA to recognise that it serves multiple stakeholders and that it must adapt its communication strategies accordingly. Consumers and health practitioners have as much interest in therapeutic goods as the industry that produces and markets those goods. It is important that the TGA

recognise this when formulating the communications strategy that is recommended by the Panel.

The Panel considers that the TGA should adopt a pro-active stance to the many issues relating to therapeutic goods that are of concern to the public that it serves. It should move away from the conservative approach that has characterised its actions in the past and recognise that it has a duty to collaborate with stakeholders to create a culture in which the community has confidence in the therapeutic goods the TGA regulates.

The Panel recognises that the TGA provides a service to the community by the timely registration, listing and inclusion of suitable products onto the Australian Register of Therapeutic Goods (ARTG). The TGA also has an ongoing responsibility to conduct post-marketing surveillance on these products and to inform the community about new information that changes their risk-benefit ratio. Post-marketing surveillance includes monitoring the promotion of therapeutic goods and taking timely and effective action when promotion is in breach of the Therapeutic Goods Advertising Code 2007 or when self-regulation fails.

The Panel observes that, in order to maintain confidence in the regulatory system and ensure that products beneficial to the Australian community continue to be made available by sponsors, the performance of the TGA's regulatory functions must be objective, consistent and timely. It is also essential that the TGA's independence from sponsors and fairness in decision-making be reinforced by openness in its dealings.

The Panel believes that the adoption of the following recommendations will assist both the government and the TGA by increasing the community's trust in therapeutic goods regulation and by showing that it is possible to balance legislative obligations with the need to provide more and better information to the Australian community.

Recommendations

Raise Stakeholder Involvement in the TGA

Recommendation 1

The TGA establish an Australian Therapeutic Goods Advisory Council, with membership representative of major stakeholder groups, to enable more effective stakeholder input into future directions and program implementation. The Council will have an oversight role in the implementation, ongoing monitoring, and evaluation of the recommendations of this review.

Recommendation 2

The TGA define, adopt and publish consultation principles to guide regulatory transparency and accountability.

Recommendation 3

The TGA develop and implement a comprehensive communication strategy to inform and educate. A dedicated communications team should be established within TGA to implement that strategy.

Recommendation 4

The TGA work transparently with other key providers of information to enhance the information available to the public (community and stakeholders), consistent with the principles of the quality use of medicines.

Recommendation 5

The TGA develop a plan to ensure information on the key public access portal, the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences

Recommendation 6

The TGA provide user-friendly information on the risk based framework under which it operates, including detailed explanations of how this operates for different classes of therapeutic goods. As a priority, the differences between registered and listed therapeutic goods, and their processes of evaluation, should be explained.

Recommendation 7

The TGA implement mechanisms to educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market.

Recommendation 8

The TGA provide clear information on the role of its statutory advisory committees, and adopt a consistent and transparent approach to the publication of information from those committees.

Recommendation 9

The TGA improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints.

Recommendation 10

The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency. This may be achieved in conjunction with the proposed Australian Therapeutic Goods Advisory Council.

Market Authorisation Process

Recommendation 11

The TGA develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for each therapeutic product type. The policy should take into account the practices followed by comparable international regulators.

Recommendation 12

The TGA explore mechanisms for providing explanations on its various regulatory processes, and adopt publication principles on the outcomes of application assessments using as an exemplar the Australian Public Assessment Reports (AusPAR).

Recommendation 13

The TGA assess and report on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application.

Recommendation 14

The TGA work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods.

Post Market (Monitoring & Compliance)

Recommendation 15

The TGA conduct, and report on, a feasibility study into the development of an early post marketing risk communication scheme for therapeutic goods, with consideration of international models.

Recommendation 16

The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely communication of alerts and recalls, to health practitioners and to consumers.

Recommendation 17

The TGA explore mechanisms to maintain the currency of Consumer Medicines Information (CMI) and Approved Product Information (PI).

Recommendation 18

The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.

Recommendation 19

The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system.

Recommendation 20

The TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods.

Recommendation 21

The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation.