



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

Review to improve the transparency of  
the Therapeutic Goods Administration

Final Report

June 2011

Historical document

ISBN: 978-1-74241-523-9  
Online ISBN: 978-1-74241-524-6  
Publications Approval Number-D0482

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Historical document

## FOREWORD

The Review Panel began its work on 7 December 2010. The Panel comprised persons representing a range of interests and holding a diversity of views. It is pleasing therefore that the recommendations of the Review are unanimous.

The Report reflects seven months of consultation and deliberation by the Panel. It makes 21 recommendations which the Panel believes will enable the TGA to better communicate its regulatory processes and decision to the community. The Panel anticipates that some recommendations will have an immediate impact, while others will take time to implement.

The Panel recognises that the effective implementation of its recommendations will, in some cases, be dependent upon the availability of resources over and above those presently available to the TGA. It does not seem likely that the proposals could be implemented within the TGA's present budget without a reduction in the functions presently being performed. The Panel is strongly of the view that the work of the TGA should not be diminished in any way. Accordingly, if the government is to accept and give effect to the Panel's recommendations, it will be necessary for resources additional to those currently available to be found.

The Panel has indicated where it considers that urgent attention needs to be given to changes in TGA's procedures. However, it recognises that implementing some recommendations will only be able to be done over a longer term. The Panel suggests that, on receipt of this Report, the government request the TGA to develop and cost an implementation plan for the recommendations. The Australian Therapeutic Goods Advisory Council that the Panel recommends should be appointed, should be involved in the finalising and monitoring of this plan.

On 20 June 2011 it was announced that the Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic goods. The announcement said that the creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries.

Over time, the joint arrangements will be administered by a single regulatory agency, the Australia New Zealand Therapeutic Products Agency, which will absorb the current regulators - Australia's Therapeutic Goods Administration and New Zealand's Medsafe.

This announcement was made too late for the Panel to take it into account in the preparation of its Report. However the Panel believes that the implementation of its recommendations will not be affected by these new arrangements.

I acknowledge the Panel's commitment to this Review and the important contributions of the many people who took the time to provide insight into their expectations of the TGA.

The unstinting commitment and contribution of the Review Secretariat to the management of the Review, the content of the Report and the completion by the required date deserves particular commendation.

Professor Dennis Pearce AO  
Chair, Transparency Review Panel

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## EXECUTIVE SUMMARY

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.

## CHAPTER 1: INTRODUCTION TO THE REVIEW

### Transparency Review

On 16 November 2010, the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, announced a review to improve the transparency of the Therapeutic Goods Administration (TGA). The Parliamentary Secretary advised that a review panel of consumer, health practitioners and therapeutic goods industry representatives was being established under the Chairmanship of Emeritus Professor Dennis Pearce AO. The 13 member Review Panel was asked to comprehensively review the way in which the TGA communicates its regulatory processes and decisions, and to report against the Terms of Reference as set out later in this chapter.

The Parliamentary Secretary noted that the Review is consistent with the Government's policy of reducing unnecessary regulatory burden, and its increased transparency agenda, particularly its changes to the *Freedom of Information Act 1982* (FOI Act) to improve public access to decision-making.

In announcing the Review, the Parliamentary Secretary indicated that consumers, health practitioners, the therapeutic goods industry and the public would have an opportunity to provide input to the Review. The methods used for obtaining input were to be determined by the Panel.

### Objective of the Review

The objective of the Review is to make recommendations to assist the Government and the TGA to adopt more effective practices to ensure the public is better informed about the TGA's regulatory processes, and the benefits and risks of therapeutic goods. (The reference to the 'public' includes organisations engaged in the therapeutic goods industry.)

### Terms of Reference

The Review Panel was asked to consider and report on:

1. the current arrangements for disclosure of information or advice in relation to all therapeutic goods currently on the market in Australia, or previously approved for marketing in Australia;
2. opportunities for increased provision of public information on therapeutic goods currently on the market in Australia, or previously approved for marketing in Australia;
3. opportunities for improved public understanding of the procedures for ongoing monitoring of products already on the market, and the evaluation, assessment and testing of new products;
4. the timeliness of the provision to the public of information regarding the evaluation, assessment and testing of new products;
5. any constraints on the release of further information, including possible implications for public health or safety, which might influence future arrangements;
6. arrangements for the public disclosure of information utilised by other comparable international regulators; and

7. opportunities to improve public access to information through enhancements to web-based and other information dissemination mechanisms.

Following a roundtable discussion on advertising of therapeutic goods held at Parliament House on 24 November 2010, the Parliamentary Secretary requested that the Review Panel Terms of Reference include consideration of:

8. the need to improve public awareness of, and access to, information on the arrangements for regulation of therapeutic goods advertising.

Following the release on 25 May 2011 of the *Final Report of the management of adverse events associated with Panvax and Fluvax* (the Horvath Report), the Parliamentary Secretary requested that the Review Panel Terms of Reference include consideration of:

9. Recommendation 6 in the Horvath Report which reads: Improvements to the transparency of TGA's vaccine safety monitoring processes should be considered by the independent Transparency Review of the TGA being chaired by Professor Dennis Pearce.

The Panel was initially required to report by 29 April 2011 but that date was extended to 30 June when the size of the task, and the extent of the public interest in the Review, became apparent.

### **The Review Panel**

The Panel for the Review was chaired by Professor Dennis Pearce AO. Professor Pearce is a former Commonwealth Ombudsman, former Chair of the Australian Press Council and is Special Counsel, DLA Piper Lawyers. He has conducted numerous reviews for both the Australian and ACT governments.

The Panel of thirteen members broadly represented the main stakeholder groups of: consumers (four representatives); health practitioners (three representatives); the rural health sector (one representative) and the therapeutic goods industry (five representatives). The five representatives of the therapeutic goods industry represent the following sectors: prescription medicines; generic prescription medicines; over-the-counter medicines - e.g. pain relief, cold and flu preparations; complementary medicines - also known as 'traditional' or 'alternative' medicines, including vitamin, mineral, herbal, aromatherapy and homeopathic products; and medical devices - e.g. bandages and dressings, replacement hips, heart valves etc.

The members of the Panel were:

John Aloizos	Australian Medical Association
Carol Bennett	Consumers Health Forum of Australia
Karen Carey	Consumers Health Forum of Australia
Elizabeth de Somer	Medicines Australia
Ken Harvey	Choice
Clifford Hughes	New South Wales Clinical Excellence Commission
Kate Lynch,	Generic Medicines Industry Association
Alison Marcus	Consumers Health Forum of Australia
Andrew McLachlan	National Medicines Policy Committee
Steven Scarff	Australian Self Medication Industry
Janie Smith	National Rural Health Alliance (until 15 May 2011)
Kristy Tomas	Complementary Healthcare Council of Australia (until 13 May 2011)
Wendy Morrow	Complementary Healthcare Council of Australia (from 16 June 2011)
Anne Trimmer	Medical Technology Association of Australia

Secretariat support to the Review was provided by the TGA.

### **Context for the Review**

The context in which the Review was undertaken was provided by a number of matters. Of particular significance were:

- Australia's National Medicines Policy (NMP) agreed by the Commonwealth, State and Territory Governments in 2000;
- the Government's policy of greater openness in government decision-making and provision of increased access to government information;
- the global nature of the therapeutic goods industry, and the actions of the primary regulators that have roles akin to that of the TGA; and
- the funding and placement in government of the TGA.

#### *(a) Australia's National Medicines Policy*

The NMP notes that the partners to the Policy 'must be engaged in a cooperative endeavour to bring about better health outcomes for all Australians, focussing especially on people's access to, and wise use of, medicines.'<sup>1</sup>

The central objectives of the Policy are stated to be:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

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<sup>1</sup> The NMP notes that the term 'medicine' is intended to include prescription and non-prescription medicines as well as complementary health care products. The Panel interprets the principles set out in the Policy to be applicable also to medical devices.

The TGA has a critical role to play in giving effect to these objectives.

Other statements in the NMP that have relevance to the role of the TGA and that are pertinent to the transparency of its activities, include:

- consumers and health practitioners should have timely access to accurate information and education about medicines and their use;
- issues relating to use of medicines should be reported accurately and responsibly by the media;
- to the extent possible, partners must recognise the primary position of the consumer;
- regulatory agencies should promote quality use of medicines by encouraging use of modern communication principles in provision of Consumer Medicines Information (CMI), label information, etc; and
- governments should do likewise by coordinating and funding efforts to promote quality use of medicines, including public information campaigns.

*(b) Government's Openness Policy*

On 1 July 2010, the Government made the following statement:

**Declaration of Open Government**

The Australian Government now declares that, in order to promote greater participation in Australia's democracy, it is committed to open government based on a culture of engagement, built on better access to, and use of, government held information, and sustained by the innovative use of technology.

Citizen collaboration in policy and service delivery design will enhance the processes of government, and improve the outcomes sought. Collaboration with citizens is to be enabled and encouraged. Agencies are to reduce barriers to online engagement, undertake social networking, crowd sourcing and online collaboration projects and support online engagement by employees, in accordance with the Australian Public Service Commission Guidelines.

The possibilities for open government depend on the innovative use of new internet-based technologies. Agencies are to develop policies that support employee initiated, innovative Government 2.0-based proposals.

The Australian Government's support for openness and transparency in Government has three key principles:

- **Informing:** strengthening citizen's rights of access to information, establishing a pro-disclosure culture across Australian Government agencies, including through online innovation, and making government information more accessible and usable;
- **Engaging:** collaborating with citizens on policy and service delivery to enhance the processes of government and improve the outcomes sought; and
- **Participating:** making government more consultative and participative.

This commitment applies to the actions of TGA, and provides a basis for the adoption of a culture of openness in its decision-making.

*(c) Global regulation of therapeutic goods*

The principal regulators that perform functions similar to TGA, and against which TGA benchmarks its activities are the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA); the European Medicines Agency (EMA); the United States Food and Drug Administration (FDA); and Health Canada. The activities of these bodies are discussed in greater detail in Appendix 4. However, it is significant as part of the context to the Review that the world-wide trend towards greater openness in governmental decision-making has resulted in these bodies reviewing, or indicating an intention to review, the transparency of their decision-making. Australia cannot afford to be left behind in this worldwide approach to the regulation of therapeutic goods.

*(d) Funding and placement in government of the TGA*

Any consideration of the issues relating to the operation of the TGA must take account of the fact that the TGA is entirely funded on a cost recovery basis by the therapeutic goods industry<sup>2</sup>. No government funding is provided for the TGA's functions. Notwithstanding the source of its funding, the Panel observes that the TGA is obliged to serve multiple stakeholders and has to adjust its actions accordingly, albeit against a position where the industry must bear the cost of those actions.

It is also of significance to the Review that the TGA is a Division of the Commonwealth Department of Health and Ageing (DoHA). This means that its activities are governed by the general requirements of the *Public Service Act 1999*, and other legislation applicable to the Australian Public Service (APS).

## **Transparency**

The Panel's Terms of Reference do not define what is meant by 'transparency'. To enable it to perform the task allotted to it, the Panel has drawn on the Government's Declaration of Open Government set out above. It has adopted as its approach the general principle that transparency in its activities requires the TGA to act in a way best designed to promote accountability to citizens and provide information about what it is doing.

To this end, TGA is required to establish a pro-disclosure culture that will give the public confidence in the performance of its regulatory role. It should communicate openly with stakeholders and should, where possible, make the information it holds accessible and usable. TGA should solicit public feedback on a regular basis to identify information of greatest use to stakeholders, improve its communication, and offer stakeholders increased opportunities to participate in policymaking and to provide the benefits of their collective expertise and information.

## **TGA's Recognition of its Role and Responsibilities**

The Panel is aware of the considerable efforts made by TGA in recent years to improve its operation against the criteria for transparency and open government laid down by the Government. A description of the TGA's role and current activities is set out in Appendix 3. It can be seen from this summary that the TGA has done much in recent years to publicise its actions, and to consult with stakeholders about its role and functions. However, the TGA itself acknowledges that more can be done. It is against this background that the

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<sup>2</sup> The Government approach to cost recovery is set out in the Department of Finance and Administration 'Cost Recovery Guidelines' July 2005.

Panel has assessed the present transparency of the TGA, and made recommendations for its improvement.

### **Previous Reviews**

In carrying out its Review, the Panel has been aware of the existence of other previous reviews which have considered or current reviews which are considering, issues relevant to those being considered in this Review. A selection of the reviews that have considered issues relevant to this inquiry are:

- Health Technology Assessment Review<sup>3</sup> (2010)
- Required Advisory Statements for Medicine Labels<sup>4</sup> (2011)
- Improved Advertising Arrangement for Therapeutic Goods<sup>5</sup> (2010)
- Reforms in the Medical Devices Regulatory Framework<sup>6</sup>(2010)
- *Final Report of the Review of the management of adverse events associated with Panvax and Fluvax* (the Horvath Report)<sup>7</sup> (2011)
- Review of uniform recall procedures of therapeutic goods (not a formal review but part of the 2011 work plan of the National Co-ordinating Committee on Therapeutic Goods)

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<sup>3</sup> Available on the Department of Health and Ageing website

<sup>4</sup> Available on the TGA website

<sup>5</sup> Available on the TGA website

<sup>6</sup> Available on the TGA website

<sup>7</sup> Available on the Department of Health and Ageing website

## CHAPTER 2: REVIEW METHODOLOGY

The Review adopted a strong focus on communication, consultation and engagement, and sought input through submissions and conducting public meetings.

The public consultation phase of the Review encouraged individuals and organisations to put their views forward through written submissions, and /or attendance at either a public meeting, or a meeting organised for a specialist group, e.g. with officials of state and territory health departments, or other regulatory bodies.

The Panel decided that all submissions to the Review, notes of the public meetings, and summaries of the Panel meetings would be published on the TGA website so that progress on the Review could be monitored by interested parties.

It should be noted that the obligations under the *Privacy Act 1988* prevented the disclosure of personal information about individuals who had not consented to such disclosure. For that reason, parts of submissions were blacked out or omitted where the redacted material would enable the identification of individuals other than persons who had lodged submissions to the Review.

The names of submitters do appear. When the Panel called for submissions the TGA website stated: "Please note that any comment or submissions you provide will be made available to the public." The Privacy Act permits publication where a person consents to the disclosure, such as in these circumstances.

### Call for Submissions

The Review Panel called for written submissions by:

- notices on the TGA and DoHA websites on 22 December 2010;
- advertisements in national, state and territory newspapers on 15 January 2011;
- a letter from the Chair to a large number of stakeholder organisations, and to other persons identified by Panel members, on 18 January 2011;
- a press release by Professor Pearce; and
- Panel members advertising the opportunity to make a submission through their own networks.

The written submission period was set from 22 December 2010 to 11 February 2011, however submissions were accepted until 11 March 2011. A total of 118 submissions were received from a broad spectrum of stakeholders.

### Consultations

The Panel conducted public consultations in Sydney, Melbourne, and Perth in late February and early March 2011. A fourth meeting scheduled for Albury was cancelled due to a lack of registrations.

Meeting details and an invitation to register for one of the public meetings were provided on the TGA website on 3 February 2011, advertised in *The Sydney Morning Herald* on

12 February 2011, and *The West Australian*, *The Border Mail* and *The Age* on 19 February 2011. (Meeting advertisements are at Appendix 8). In addition to this Panel members actively marketed the public meetings through their networks.

Eighty-one people representing consumers, therapeutic goods industry, health practitioners, media and regulatory consultants attended the three public meetings. The meetings were chaired by Professor Pearce, and attended by at least one Panel member.

A similar format was used for each meeting. After introductions by Professor Pearce, a representative from the TGA gave a short presentation on the TGA, before Panel members led a number of focussed discussion groups. Each stakeholder group addressed specific questions (see Appendix 9), and allowed participants the opportunity to raise other issues relating to transparency and the Review. At the end of the group session, each Panel member who led a group reported back to the whole group.

A one-on-one meeting with a Panel member was offered to those who were unable to attend the public meetings.

Two consultative meetings with representatives from State and Territory health departments were hosted in Perth on 4 March 2011, and in Melbourne on 30 March 2011. All States and Territories were represented and contributed at these meetings.

The Chair met with officers of the Australian Practitioners and Veterinary Medicines Authority (APVMA), Australian Competition and Consumer Commission (ACCC), and the National Rural Health Alliance (NRHA) and held telephone discussions with CRANaplus and the UK MHRA.

Meetings of the Panel were held on:

- Tuesday 7 December 2010
- Thursday 10 February 2011
- Wednesday 23 March 2011
- Wednesday 13 April 2011
- Thursday 9 June 2011
- Thursday 23 June 2011
- Tuesday 20 June 2011

The 119 public submissions to the Review were received from 108 stakeholders representing 6 main stakeholder groups:

• Consumers and consumer representatives:	39
• Health practitioners and associations:	21
• Therapeutic goods industry & representative bodies:	23
• Regulatory consultants:	3
• Government organisations:	10
• Bodies or individuals associated with the TGA:	7
• Other:	5

In addition, the three public meetings were attended by 81 people from 5 main stakeholder groups:

- Consumers and consumer representatives: 19
- Health practitioners and associations: 7
- Therapeutic goods industry & representative bodies: 49
- Regulatory consultants: 2
- Government organisations: 4

### **Report Structure**

In its consideration of the information obtained from the consultations, the Panel broadly grouped the issues raised under each of the Terms of Reference. This allowed them to identify the issues which, though important, were not related to transparency and could not be considered under the Terms of Reference.

Through this process, the commonality of topics across different Terms of Reference became clear, and the Panel agreed that the development of specific recommendations under each of the Terms of Reference could lead to a fragmentation in the way single issues were addressed by the TGA during implementation. For example, issues relating to the TGA website were identified against Terms of Reference 1, 2, 3, 4, 7 and 8.

During 2010, the TGA's operational structure was reorganised to include a Market Authorisation Group (pre-market issues) and a Monitoring and Compliance Group (post-market issues). In the interests of developing cohesive recommendations which could be implemented effectively, the Panel considered that it would be best to adopt an organisational grouping to the operational recommendations. A third group of recommendations would address the critical area of TGA's profile in the community.

For this reason, the report provides a succinct analysis against the Terms of Reference in Chapter 3. It is followed by the main discussion of issues, and the resulting Recommendations are grouped according to Market Authorisation; Monitoring and Compliance; and Profile in the Community.

## CHAPTER 3: SUMMARY OF ISSUES RAISED AGAINST THE TERMS OF REFERENCE

This chapter draws together the range of issues provided to the Review Panel on each of the Terms of Reference.

The Panel recognises that some of the content in this chapter reflects misunderstanding about the TGA's role, the regulatory processes that are currently in place, and the level of information that is publicly available regarding therapeutic goods. However, the Panel decided that, while the statements might be inaccurate, they are an accurate reflection of the level of public and industry understanding, and should be included in this summary. They were considered by the Panel, along with all the issues raised against the Review's Terms of Reference.

The fact that such misunderstandings exist also serves to demonstrate the complexities of the systems currently in place regarding the regulation of therapeutic goods, the difficulties key stakeholders have finding information contained in the TGA's databases and on its website, and the importance of providing effective information to the public.

### **(1) The current arrangements for disclosure of information or advice in relation to all therapeutic goods currently on the market in Australia, or previously approved for marketing in Australia;**

A consistent theme identified in the responses to the Review was that the TGA could significantly improve its current arrangements for disclosing information and advice on therapeutic goods that are currently available, or have been approved for the Australian market.

The consultations highlighted a lack of community knowledge about the TGA's role to safeguard public health by regulating therapeutic goods available on the Australian market. Among those who had heard of the TGA, some were unaware of the range of assessment and monitoring activities undertaken by the organisation, or how it went about those regulatory functions and processes. Stakeholders want the regulatory processes for each category of therapeutic goods to be explicit and open to scrutiny.

Some submissions see public education on therapeutic goods as a role for the TGA, and expressed concern that there is a perceived gap in services. It was also suggested that the TGA may not have the capacity to respond flexibly to this educative role due to perceived limitations of the organisation's funding mechanism, which is 100% cost recovery from industry.

Regulatory processes are complex. Some industry submissions indicated a need for greater predictability in the processes, particularly in the outcomes and timeframes for the evaluation of applications for therapeutic goods other than prescription medicines. It was claimed that often the timeframes are not disclosed and/or are vague, and that the reasons for a decision are not always provided.

Industry is seeking not just quantitative information about the volume of assessments but also qualitative information on the common reasons for delays in assessments of applications. It was suggested that such data could be used by sponsors for educative purposes, and would assist in improving the quality of applications.

Sponsors also spoke of the difficulties they experience with the TGA's 'help' systems. There are numerous 'help line' numbers available to sponsors, but these are not as useful as they could be as there is a perception that the advice received from the TGA can be inconsistent and unreliable, and it is not always evident that it is accurately referenced to published information.

A number of submissions raised the scarcity of information on the outcomes of statutory advisory committee deliberations. Currently where applications by sponsors are considered by a statutory advisory committee, the committee's recommendations are provided to a sponsor within a week of its meeting. However, some stakeholders requested that the recommendations be made more widely available.

The TGA recently changed the process for the publication of recommendations from the Advisory Committee on Prescription Medicines, which has resulted in the public summary of recommendations being included in the prescription medicine Australian Public Assessment Report (AusPAR). This change has concerned some of the respondents to the consultation, who stated that they wanted a return to the timely publication of all advisory committee recommendations.

This is countered by others, who are satisfied with the approach by the prescription medicines sector to include statutory advisory committee recommendations in the AusPAR Public Summary of the TGA decision making process. Furthermore, industry respondents advised caution against publishing the advisory committee discussions in full, due to the commercially sensitive nature of some of the information discussed. Regardless of differing views, all respondents were seeking consistency in the TGA's approach.

There were calls for the TGA to improve the way it conducts its consultative processes, including policy reviews. Some stakeholder groups believed that their input to proposed changes in TGA processes appeared not to have been taken into account. Consultative processes are seen as ambiguous, with vague timeframes, and with no public advice provided on the progress of consideration of issues after the consultation period. Those who have been involved with these processes considered that, regardless of commitments made at the beginning of a consultation, not all submissions were published, summaries were generally not publicly available, and justification of the decision was not provided. (A comparison was made with this Review for which all submissions have been posted on the Review website.)

A view was put that a high level advisory committee with representation of all major stakeholder groups, should be created to promote a greater cross-sectoral focus, and provide advice to the TGA on strategic planning, performance and service standards.

Throughout the consultations, the TGA's website was criticised for being complex and hard to search. Users find it difficult to establish the currency of documents, and whether the version they have accessed is the most recent. In many cases, stakeholders claim that public documents have not been updated to reflect changes. The type of information

contained on the website is considered by many to be too technical, not targeted to specific audiences, and generally not appropriate or useful for either consumers or health practitioners.

Many of those who responded said that the TGA would benefit from having a well-designed communication strategy. They considered that part of this strategy would be to move from an out-sourced media consultant, to resourcing an in-house communication team to handle media enquiries and provide timely responses to media issues relating to therapeutic goods, including alerts and warnings.

## **(2) Opportunities for increased provision of public information on therapeutic goods currently on the market in Australia, or previously approved for marketing in Australia;**

The Panel heard that there was frustration resulting from difficulties in accessing information on therapeutic goods that are currently on the market in Australia, or have been approved for the Australian market. Submissions identified a number of opportunities where the TGA could increase its provision of public information, including:

- improved searchability of the Australian Register of Therapeutic Goods (ARTG);
- access to educative information about the TGA's regulatory processes and post market surveillance reporting;
- improved access to clinical data that was considered by the TGA as part of the assessment process of all products;
- access to consumer information for all therapeutic goods, not just for prescription medicines;
- harmonisation between Australian Medicines Terminology (AMT) and electronic identifiers;
- clarification on the labelling requirements for therapeutic goods;
- responsiveness to matters of public interest relating to therapeutic goods raised in the media, or flowing from actions of other regulators; and
- the introduction of an on-line system for sponsors to track (all) applications.

Industry submissions raised concern about the length of time taken for the assessment of some applications, and the lack of information available to sponsors on the status of an application in the assessment process. They would like to have greater certainty about the timing and conduct of assessment processes. A number of industry submissions suggested that the TGA introduce an on-line system where sponsors could track the progress of their applications.

Some submissions expressed dissatisfaction with the functionality of the ARTG. The database was criticised for being complex, difficult to interrogate, and not providing the capacity to search a product's history or any changes that may have occurred to a product. In its current format, the ARTG does not provide a history or archive of listings.

Providing a link between the database and the Government Notices Gazette (where information on therapeutic goods removed from the ARTG is published) was highlighted as an opportunity to improve publicly available information on the de-registration of therapeutic goods. A number of contributors suggested that, rather than simply providing the link to the Gazette, the information contained in the notice should also be publicly

accessible on the TGA website. This would assist consumers and health practitioners to quickly obtain information on products that have been deregistered or withdrawn from the Australian market.

Stakeholders are looking for a product's history to be available and remain on the TGA's website, even after it is no longer available on the Australian market. This would provide the public, particularly health practitioners, with the current status of a therapeutic good, including information about its withdrawal or recall.

The consultations highlighted the need for the TGA to provide the public with clear information on all of its regulatory processes, and more specifically the assessment and post market surveillance of all therapeutic goods.

It was not apparent, or readily understood that the TGA assesses each therapeutic good based on the level of risk associated with its use. The risk category then determines the type of assessment and evaluation undertaken by the TGA. Consequently, there was a misconception that all products included on the ARTG have been pre-evaluated, and are known to be effective and safe.

For example, there was confusion about the difference between higher risk registered (AUST R) and lower risk listed (AUST L) medicines. Most consumers were unaware that only registered medicines are rigorously evaluated for quality, safety and efficacy prior to market entry. Listed products have a limited evaluation. Sponsors certify that their products only contain pre-approved, relatively safe, stable ingredients, and they hold evidence to support the claims made.

Stakeholders commented that there was very little information available about the TGA's post market surveillance activities and commented on the lack of public reporting. They held the view that the TGA's sanctions and penalties appeared ineffective, and were rarely applied. To increase public confidence in the TGA's post market regulatory role, it was suggested that the TGA educate the public on the post market surveillance processes. It should also publish decisions of the outcomes of reviews, and provide summaries of common issues which would assist industry, eg. recent audit outcomes.

While the TGA's publication of the AusPARs for prescription medicines has been welcomed, there are calls to extend the availability of this type of information to other therapeutic goods. Some stakeholders requested that the TGA publish more detailed information from applications, including clinical evaluations used to support the assessment of higher risk medical devices, and for other classes of therapeutic goods.

However, some sectors of the industry raised concerns that making this information publicly available would possibly notify competitors of commercial decisions, eg. to withdraw an application during the assessment process, and identify commercially sensitive material.

Stakeholders would like to see the limitations of Consumer Medicines Information (CMI) and Approved Product Information (PI) better publicised, including increasing the public's awareness that both the CMI and the PI are written by the sponsor at the time of product approval. There is a view that neither is updated nor are they required to be updated when any new evidence becomes available about the product.

A number of respondents proposed that the TGA could provide points of contact to external groups, such as the Australian Medicines Handbook Pty Ltd (AMH), Therapeutic Guidelines Ltd (THL) and the NPS Better choices, Better health (NPS), who can assist in providing further, or more up to date, information. Another suggestion is to encourage clinicians to provide any concerns they may have, regarding errors and limitations in the CMI and PI, to the TGA. This would prompt a review of the material.

Consumers and health practitioners expressed a need for specific information about medical devices to be publicly available. This is seen to be particularly relevant for high risk devices, and would allow both consumers and health practitioners to make informed decisions about a product's suitability. They proposed that, where this information is published, a link to the sponsor's website could also be provided. Stakeholders are seeking information in a similar format to the consumer and practitioner information currently available for prescription medicines.

As part of the increased public information relating to therapeutic goods, health practitioners want to see the TGA actively engaged in adopting AMT, and other appropriate electronic identifiers to ensure that its electronic systems are harmonised with those of the National E-Health Transition Authority's (NEHTA) standards.

Consultations indicated that there is a level of uncertainty in the community about who is responsible for, and what the TGA's role is, in the regulation and monitoring of therapeutic goods labelling. Despite the published requirements for labelling of medicines and medical devices, both consumers and health practitioners expressed their concerns regarding the adequacy of controls over labelling. A notable concern was the placement of pharmacy labels over manufacturers' labels, thereby covering mandatory information including important dosage and active ingredient information.

Another concern with labelling was the lack of compulsory disclosure of a product's complete ingredients, including whether it may contain nanoparticles. This is considered to be important safety information for people with allergies and intolerances, and for those who are concerned about the possible health risks of new ingredients or formulations. Currently, information about non-active ingredients for therapeutic goods is difficult to obtain or not available; and some submissions suggested that the therapeutic goods industry adopt a similar system to that used in food labelling.

Many of those who responded criticised a perceived lack of responsiveness by the TGA on matters of public interest regarding therapeutic goods. They perceived that the TGA provided slow and inadequate responses to media enquiries, and questioned the lack of a 'public face' in the debate over the regulation of certain therapeutic goods. Stakeholders requested that the TGA adopt a policy of providing timely public comment and media responses, and suggested the TGA be proactive as well as reactive when developing a communication strategy.

**(3) Opportunities for improved public understanding of the procedures for ongoing monitoring of products already on the market, and the evaluation, assessment and testing of new products;**

The majority of those who responded to the Review expressed a desire to see the TGA take advantage of new communication technology, and create opportunities that will improve the public's understanding of the TGA's regulatory processes including the assessment of new products and the monitoring of products already approved for the Australian market.

The Panel heard that stakeholders would welcome the TGA adopting the EMA's policy of publicly accounting for all therapeutic goods applications that are approved, withdrawn, and rejected by the organisation. There are differing views on this proposal, especially regarding timing and level of information that should be released by the TGA. However, there is an appreciation that this is already happening for prescription medicines through the AusPAR processes.

Industry is looking for information on the common reasons for delays in the assessment of applications, problems in applications, and data relating to manufacturing performance including de-identified trends in Good Manufacturing Practice (GMP) audits. It is proposed that this type of information could be incorporated by industry into its education and continuous improvement programs.

There were requests by stakeholders for internal checklists, used by TGA assessors and auditors, to be made publicly available. The provision of these documents would assist all stakeholders understand the TGA's monitoring, evaluation and assessment practices. It may also assist applicants in ensuring that their documentation is complete prior to submitting an application for assessment. Many highlighted the public's inability to establish the currency and version of guideline documents, and suggested that the TGA regularly update and publish all its guideline documents for all processes. Others suggested the TGA develop an index of all the guideline documents, to ensure that the current version is being used by everyone.

The obligation imposed on the TGA by the FOI Act was noted as being relevant to these suggestions.

A number of those who responded thought the TGA's regulatory system could be improved if consumers were provided with the opportunity of having greater involvement in the TGA's advisory processes for the evaluation, assessment and testing of new products, and the ongoing monitoring of products already on the market.

It was suggested that the TGA develop a new 'early post-marketing system' for any recently registered medicine that requires a risk management plan. A number of stakeholders suggested that the TGA consider the use of a similar concept to the UK black triangle (◻) scheme. The adoption of a symbol could act as a valuable alert for health practitioners and consumers to be aware that a product has only recently been registered for the Australian market.

It was noted that the TGA does not regularly provide key performance data to the public. Stakeholders want greater visibility of the volume and variety of work completed across the different regulatory areas of the TGA. Industry requested that the data that is

currently supplied in confidence to members of the TGA Industry Consultative Committee (TICC) be made more widely available.

There were frequent calls by participants for the TGA to improve the adverse event/incident reporting systems for therapeutic goods. Of particular concern to stakeholders was that clinicians may report, in the first instance, to the company or to a State or Territory government maintained event/incident reporting system, rather than to the TGA. Participants identified a number of opportunities to improve the system, including: the development of a national adverse event database available on-line; linking the TGA's reporting of adverse events/incidents into the other state-based reporting systems; education for consumers, clinicians and retailers on reporting incidents, and how to follow-up on reported events; and communication to the public about the rationale for the actions taken.

Respondents highlighted the need to improve the reporting of sanctions and penalties of post market surveillance activities, as the information available is limited and difficult to find. From the public's viewpoint, it would appear that the TGA rarely imposes sanctions and penalties on those who are not complying with the Act. A suggestion is the adoption of a similar reporting method to that of the United States FDA, where audit reports and warning letters are published. It was also acknowledged that there may be many reasons for product withdrawal which are not a result of post market surveillance.

At the consultations, a number of stakeholders requested that the TGA develop a national medical device register, which would include public access to post-market surveillance data before long term trial evidence is available. While some stakeholders wanted to see the development of a new register, others wanted the TGA to aggregate all of the current device registers.

#### **4) The timeliness of the provision to the public of information regarding the evaluation, assessment and testing of new products;**

Many of those who contributed to the consultation process said they were dissatisfied with the time taken by the TGA to provide the public with information on the evaluation, assessment and testing of new therapeutic goods. For many others, the slow response times to advertising complaints were a key concern.

In the consultations, it was suggested that there could be benefits to patient safety in providing advance notice of investigations prior to a potential recall, to those organisations that a product recall or withdrawal is likely to affect, for example the N.S, State and Territory health departments, industry associations, and practitioner organisations. This would also entail a clear and timely process to advise these groups on the outcome of the investigation, especially if the concerns are not proven.

It was also suggested that the TGA should develop an appropriate and effective public warning system to indicate when a product is being investigated, and provide the public with notification of the outcome. However, contrary to this suggestion, some stakeholders are concerned that the introduction of such a system could cause unnecessary alarm to consumers.

There was an element of frustration expressed over the length of time taken for the TGA to publish alerts for the notification of product recalls and withdrawals. There is an expectation by consumers and health practitioners of much faster alerts from the TGA. Stakeholders would like to see consumer notification of recalls of therapeutic goods, and the provision of a historic list of recalls on the TGA website.

Stakeholder responses also indicated that the TGA provides insufficient information on its appeal processes, decisions and sanctions. It was a source of frustration to many stakeholders that, in many areas, information on what decisions have been taken, and the rationale for these decisions, was difficult for the public to establish.

There was also a community expectation that the TGA should be providing timely comment on concerns about product safety raised with, or by, an overseas regulator. Stakeholders want to know if the product is on the Australian market, and what action the TGA is taking to assess the situation. There could be benefit in having a link on the TGA website to relevant pages on other regulator websites.

#### **5) Any constraints on the release of further information, including possible implications for public health or safety, which might influence future arrangements;**

The consultations highlighted the sensitivities and constraints about the release of further information. The Panel heard arguments for and against methods and timing of the release of information the TGA holds.

There were conflicting views as to what is commercial-in-confidence, and what implications the release of this type of information may have on the TGA's regulatory processes. Some stakeholders suggested that confidentiality be granted by exception, whereas others argued that the release of commercially sensitive information could advantage a sponsor's competitors.

Some stakeholders have indicated that what is commercial-in-confidence will vary with the type of therapeutic good. Not all therapeutic goods have the benefit of patent protection. Sponsors of products without such protection may seek to protect their intellectual property by keeping information about the product out of the public arena. Publication of the full application to the TGA may therefore devalue the sponsor's asset. Stakeholders urged the TGA to consider these issues when developing disclosure policies.

Further to this, stakeholders highlighted the impact on competition within the industry if details of withdrawn or rejected applications are published. It is acknowledged that the release of this information is already occurring for prescription medicines through the AustralAR processes.

Stakeholders did not think that the technical nature of the majority of information should be seen as a constraint on its release. It was suggested that the information could be modified for certain audiences. A good example of this is the consumer summaries that are provided as part of the European Public Assessment Reports (EPAR).

Some who responded wanted to see the publication of clinical trial and clinical evaluation data, which is not currently made available. There was agreement that the disclosure of this type of information would have commercial implications for some sectors of the

therapeutic goods industry. The provision of clinical trial summary data is already occurring for prescription medicines through the AusPAR. Some industry sectors are concerned that there are currently no mechanisms for data protection for generic, over-the-counter (OTC), and complementary medicines and, therefore, there could be a competition issue regarding the publishing of clinical trial data.

Stakeholders were aware that the TGA has international obligations about sharing information, and they would like the TGA to be more transparent about the types of information that are shared by TGA through international agreements.

#### **(6) Arrangements for the public disclosure of information utilised by other comparable international regulators;**

A summary of the arrangements for the public disclosure of information by comparable regulators in other jurisdictions, including the recent overseas trends, and the promotion and facilitation of the harmonisation of regulatory controls for therapeutic products is provided in Appendix 4 of the Review Report.

At the consultations, stakeholders acknowledged that they would like to see the TGA adopt some of the recent initiatives in public disclosure that have been implemented by the MHRA; the EMA; and the FDA. Some of these include

- the provision of increased information on how to complain - FDA;
- new work on the release of information, and the publication of all clinical trial data used in decision making - EMA; and
- the publication of adverse reaction data on its website, and the black triangle scheme - MHRA.

It was suggested by some stakeholders that the TGA should accept a product's overseas approval by a comparable international regulator without further examination. It was also suggested that the TGA should disclose information as to why it had assessed the product differently to its international counterparts.

There was also interest in knowing how the TGA compares to other international regulators in regard to staffing and financial resources, and whether there are other regulators that have the same cost recovery mechanisms in place. Stakeholders wanted the level of resourcing allocated by the TGA for communication activities relative to that of comparable agencies, including international regulators, to be considered.

#### **(7) Opportunities to improve public access to information through enhancements to web-based and other information dissemination mechanisms;**

The Panel received and heard many suggestions on ways the TGA could enhance its mechanisms for disseminating information and increasing public knowledge of the existence and role of the TGA, and opportunities for public and consumer interaction. At one consultation, the TGA was described as 'faceless'. There was unanimity throughout the consultation that the TGA's website needs to be restructured, and the other methods used

by the TGA for providing information must be improved. This was a shared view from all sectors involved in the consultations.<sup>8</sup>

Those who responded are seeking a restructured website that includes:

- separate entry points for different stakeholder groups;
- improved functionality in accordance with an agreed communication strategy;
- better integration of relevant and appropriate material; and
- enhanced access to information about the TGA, incorporating organisation structure charts with names and photos, and videos about assessment processes undertaken by the TGA.

It is widely agreed that the TGA could be better at targeting the distribution of all its information. There are concerns that information is not reaching its intended audiences, and it was suggested that the TGA not just limit its communication to the internet but also increase its targeted use of printed information including brochures and leaflets (with text and/or pictographs), and in accessible formats for people with disabilities. It was proposed that the provision of information 'kiosks' in pharmacies would improve consumers' access to further information on relevant therapeutic goods.

A number of submissions suggested the TGA provide general information to pharmacists, pharmacy assistants, health stores, practitioners and other retailers on the provision of point of purchase information, including, but not limited to, the CMI in hard copy and on the internet.

Health departments and hospitals are seeking increased engagement with the TGA. These organisations are particularly interested in the TGA providing prompt advice of product approvals and effectiveness data as new approvals and their effectiveness may have an influence on budgetary demands.

Additionally, in order to properly advise and inform patients, medical and health practitioners are looking for timely advice on therapeutic goods, especially the distribution of information regarding adverse drug reactions, adverse events with medical devices, and emergency product recalls. It was agreed that access to this type of information would be greatly improved if the TGA was more proactive in its communication with stakeholders.

Consumers and health practitioners consider the TGA needs to create information linkages with key groups, especially those who are involved at critical intervention points in the supply chain including, for medicines: the prescribing process prescriber, dispensers, the NPS health departments, and practitioner organisations; and, for medical devices: the surgeon and the relevant medical bodies such as the colleges and associations. The creation of these linkages would be particularly advantageous for disseminating information regarding alerts and withdrawals.

Many of those who responded held the view that the TGA needs to raise its profile and promote its identity to the wider community by providing information and education materials about what the TGA does, what processes it uses, the rating of products

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<sup>8</sup> It should be noted that these comments were made prior to the changes made to the website on 4 May 2011.

according to level of risk, and how stakeholders can be involved in these processes. This could be done through the mass media and participation at conferences where the audience are TGA's stakeholders, as well as working constructively with other government and non-government health care and promotion organisations.

Comments pointed to a lack of knowledge of the existence and role of the TGA, the difficulty in finding information on the TGA website, and the need to improve its layout and search functions. In particular, some people who use the public access entry to the ARTG consider that information on medical devices is particularly difficult to obtain. While devices are categorised on the database, some suggested that it seemed necessary to have specific knowledge of the device, such as the sponsor's name, including a trading name, to find a specific listing.

### **(8) The need to improve public awareness of, and access to, information on the arrangements for regulation of therapeutic goods advertising;**

Overall, there was a sense by stakeholders that breaches of the Therapeutic Goods Advertising Code cannot be effectively pursued. Throughout the consultation process, the Panel heard that stakeholders find the therapeutic goods advertising complaints system frustrating. There are calls for the TGA to improve the provision of information on the regulation of therapeutic goods advertising: concerns that there is no clear path to make certain complaints; that complaints are often referred to other bodies (whereupon nothing further is heard); and that available sanctions appear ineffective.

Stakeholders are seeking clarity from the TGA on the:

- entry points for those wanting to make a complaint;
- process on how to make a complaint, and
- decision making process for resolution of the complaint.

They highlighted the difficulties of knowing who they should complain to about various types of promotion, and questioned whether they should be approaching the TGA, the Therapeutic Goods Advertising Complaints Resolution Panel (CRP), ACCC or industry self-regulatory bodies.

Those contributing said the system could be improved if protocols were adopted, whereby complainants were provided with an acknowledgement of a complaint when it is received by a designated one-stop-shop, and provided with feedback at appropriate intervals as to where the complaint had been sent, and what had happened to it.

Stakeholders would generally like to see the publication of all advertising complaint decisions, the remedial actions taken, advice about whether compliance was achieved, and the time involved. It was suggested that this data be made publicly available on-line, so that those seeking information can conduct a search by a company's name.

However, others said that there needed to be a balance between consumer and industry interests. Industry did not want to see information relating to the lodging of complaints being made publicly available. The basis for their concern was that a complaint may be vexatious, unfounded, or lodged by a competitor for a commercial advantage.

Stakeholders were also seeking an outline of historical data on complaints processes that would be publicly available, and which could act as a deterrent to on-going/serial non-compliance by individual advertisers. This would possibly include the:

- number of recent complaints received over the last (two) years;
- nature of the complaint;
- time taken to conclude of the matter;
- the finding in relation to the complaint;
- sanctions imposed and their compliance; and
- follow-up measures that may have been taken, if necessary.

**(9) Recommendation 6 of the Horvath Review – Improvements to the transparency of the TGA’s vaccine safety monitoring processes should be considered by the independent Transparency review of the TGA being chaired by Professor Dennis Pearce.**

[This term of reference was directed to the Panel after it had completed its public consultations, and receipt of submissions had closed. However, the establishment of the Horvath Review was known when this Review was set up and some submissions were made to the Panel based on the circumstances that had led to the Horvath Review. The report of the Horvath Review also referred to submissions that it had received. The following sets out statements from these sources that are relevant to this term of reference.]

The Horvath Review noted the complexity of the current reporting system for adverse events following immunisation, the need for clarity on the reporting pathway, and improved information flows between the TGA and the jurisdictions.

While the TGA has the legislated responsibility to monitor the safety of vaccines, many other bodies also have a role to play. The Horvath Review found that roles and responsibilities with regard to surveillance and vaccine safety were not well understood, and there was ambiguity between the many organisations, committees and individuals that have a role in identifying, investigating and acting upon safety signals related to the use of vaccines in Australia.

The Horvath Review heard that jurisdictions would like to see greater clarity of the processes within the TGA, and of the interrelationships between the TGA as the regulator, DoHA, and other bodies with roles in the National Immunisation Program.

Some submissions to both reviews called for improvements to be made to the system to make it more robust, and timely in its response to adverse events. It was suggested that the TGA provide information on how the safety system operates. Some stakeholders wanted to know what constitutes a trigger for the TGA to commence an investigation into an event.

Submissions to this Review thought the system could be improved by the regular provision by TGA of information to keep health practitioners, consumers and the media informed of the TGA’s management of adverse events. Health practitioners and consumers said that they were not sufficiently informed of the events surrounding the suspension of a product and the subsequent investigation.

A number of stakeholders want to see Australia adopt the same policy as some overseas countries, where the data base containing information relating to adverse events are available to the public. However, others recognise that the TGA needs to demonstrate caution on how this information is managed, and there needs to be a balance between the benefits and risks of the actions taken given that the association between a product and an adverse event may not be causal.

The wider recommendations of the Horvath Review for greater oversight and transparency of adverse event and adverse reaction details following immunisation are consistent with the broader requests for transparency of all adverse reactions to therapeutic goods. The development of a vaccine specific advisory committee to monitor and review this information would further facilitate this initiative.

Historical document

## CHAPTER 4: DISCUSSION AND RECOMMENDATIONS

### Raise Stakeholder Involvement in the TGA

#### Advisory Council

##### Issue:

- The creation of a high level advisory council with representation of all stakeholders.

##### Discussion

The consultations highlighted the need for the TGA to establish a mechanism to improve communications between the TGA and its key stakeholders. The Panel considered that consumers provide valuable insight into the users' perspective about the work of the regulator.

The Panel agreed that there is merit in the TGA establishing an overarching advisory council with a similar composition to that of the Transparency Review Panel, that is, to have approximately 15 members representing consumers, health practitioners, and the therapeutic goods industry. It was seen as a possible method of bridging the perceived gap between the TGA and end users.

The terms of reference for the council would need to be developed by the TGA and stakeholders. It is envisaged that the council would provide strategic advice on planning, performance and service standards, benchmarking, cost recovery, quality improvement, resource requirements and options, and management initiatives. It would have a key role in advising the TGA on stakeholder engagement, and on reviews of its regulatory and process changes: see Recommendation 2.

A council of this type would meet twice a year, and could receive reports from a number of the committees that the TGA supports, including the National Coordinating Committee on Therapeutic Goods (NCC TG), and the Therapeutic Goods Committee (TGC).

*"We have also heard a proposal from a public consultation meeting that a permanent independent advisory committee of similar constitution to the Transparency Review Panel be set up to advise TGA and to consider matters of concern raised by stakeholders .... this proposal has merit" - Medtronic*

The panel discussed whether the Therapeutic Industry Consultative Committee (TICC) should continue if the proposed council is established, and if its membership would adequately represent industry's needs. The Panel recognised that, if the council is established, the TGA will need to consider whether TICC should continue to have a role in the consultative process.

*"The Terms of Reference for such a committee needs to be carefully developed and should also include the capacity to provide a forum for any stakeholders to submit issues of concern for consideration and appropriate consultation with the TGA" -Regulatory Solutions Pty Ltd*

The Panel considered that it would be preferable for council members to be appointed by the Minister responsible for the TGA, to provide a further mechanism to ensure equitable representation across stakeholder groups.

### **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.

### **Consultation**

#### **Issue:**

- Improve how the TGA conducts its consultative processes to overcome:
  - a sense that input to TGA consultations from stakeholders has previously been overlooked; and
  - a perception that current consultative processes are ambiguous, with vague timeframes and no public advice provided on the progress of consideration of issues after the consultation period.

### **Discussion**

Submissions to the review provided evidence of significant stakeholder frustration with the TGA's conduct of its regulatory review and consultation processes. This was a common view across the range of stakeholders who made submissions to the Panel.

The Panel considered that the most effective way for the TGA to address this issue is to develop and adopt principles to guide the conduct of the many reviews and consultation processes it undertakes. Stakeholders considered it should include: adequate and appropriate background information; realistic pre-published timeframes; clear submission and decision-making processes; publication of all submissions (as for this Review); publication of the rationale for accepted and rejected suggestions; an implementation plan which gives reasons for prioritisation of actions; and the proposed method of evaluation of the implementation.

*"The TGA needs to implement as a matter of urgency the Australian Government's requirements on Best Practice Consultation (Appendix C Best Practice Regulation Handbook<sup>9</sup>). This will provide the TGA with a structure and processes to improve transparency with regard to its stakeholder consultation and decision making." – ACCORD*

The Panel considered that the adoption of consultation principles will provide a level of clarity and certainty to the conduct of consultations on specific issues.

It is also of the view that the conduct of biannual public fora held by the TGA for the general public (consumers, health practitioners and industry) could provide valuable input to the TGA on the issues of concern to stakeholders, particularly consumers. It would provide insight into the areas they see as risks and benefits, which may be very different from the perspectives held either by industry or by the regulator. These fora

<sup>9</sup> <http://www.finance.gov.au/obpr/proposal/handbook/appendix-C-best-practice-consultation.html>

should be held on a rotating basis in states and territories to provide national coverage over time.

## **Recommendation 2**

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

## **Communication**

### **Issues:**

- The TGA would benefit from having a publicly available communication strategy directed by an in-house communication team to handle media enquiries and provide timely responses to media issues relating to therapeutic goods.
- Many members of the public are unaware of the TGA's role, or the range of assessment and monitoring activities undertaken by the organisation and how it conducts those regulatory functions and processes.
- Other organisations (government and private) are active providers of health information, including about therapeutic goods and their safe use.

### **Discussion**

The regulation of therapeutic goods has not been quarantined from the demand for immediate and accessible information. The consultations have shown that the TGA and its work cannot be considered well known by the Australian community. The role of the FDA, the United States regulator, seems better known in Australia, and its information is as likely to be relied upon as that from the TGA.

A recent survey for the Consumers Health Forum of Australia (CHF) showed that "Although the overall awareness of the TGA appears high (over 60 per cent) among the general population, this drops down significantly among people with lower levels of education (approximately 40 per cent), indicating a need for awareness campaigns to be targeted at particular population groups."<sup>10</sup>

To guide the TGA on meeting community expectations about information and communication, and to raise its profile within the community, stakeholders suggested that the TGA develop a publicly available communication strategy. The Panel agrees that effective communication is central to the transparency of the TGA, as it significantly influences the safe use of therapeutic goods.

*"It would appear that, until recently, informing the public has not been a central activity of the TGA, whereas consumers now experience and expect a greater degree of interactivity from government agencies, many of which hold consultation forums, information sessions or conduct outreach activities."* – Commonwealth Ombudsman

There is some debate on how much information should be included in a communication strategy. The strategy needs to provide the TGA with guidance on how to promptly and accurately address the community's information requirements in a manner that does not cause alarm. The Panel agreed that a publicly available communication strategy would enhance the TGA's capabilities to respond appropriately to issues relating to therapeutic goods, and to build community knowledge of its work. It must be explicit in how, what

<sup>10</sup> <http://www.tga.gov.au/pdf/submissions/review-tga-transparency-1101-submission-chfa.pdf>

and when the TGA communicates, and ensure that there is a much higher level of media engagement.

The communication strategy should also provide the TGA with the autonomy to respond promptly to media enquiries, and encourage it to have a public face in the debate over the regulation of therapeutic goods. If the TGA were to adopt this role it may counter the argument that the TGA is currently reactive as opposed to proactive when dealing with the media.

The strategy should meet a wide spectrum of needs and publicly identify that the TGA is communicating to a diverse audience, including groups with specific needs (eg. Aboriginal and Torres Strait Islander peoples, Aboriginal Medical Services, migrant and refugee organisations, people with disabilities, and those for whom English is a second language). It should recognise that stakeholders are seeking varying degrees of information on therapeutic goods and their regulation, including educational and guidance materials. The strategy should ensure the provision of appropriate information sharing strategies, and point of use information available on-line, printed and face-to-face.

*"... we are aware that many people cannot readily access self service information over the internet and would encourage government agencies to consider a diversity of ways in which to provide information to the public" – Commonwealth Ombudsman*

The Panel suggests that the TGA undertake a consultative process with stakeholders, in the first instance, when considering the development and implementation of a strategy. It was also recognised that for a strategy of this type to be effective, it needs ongoing evaluation against its objectives. It should also be built into the TGA's key performance indicators to ensure that appropriate communication with stakeholders is integral to the work of regulation.

As part of the development of a communication strategy, the Panel thought it would be appropriate for the TGA to look toward similar regulators, both in Australia and overseas and consider this information in developing and implementing the strategy.

To be successful, the Panel considers the TGA would need to increase its in-house communications and media capacity. It should have a dedicated media section that deals with media inquiries about regulatory issues, and is able to respond pro-actively to issues of public concern rather than reacting. It should be able to comment promptly on reports of concerns that have arisen overseas in relation to particular products.

The Panel noted the experience of the MHRA in the United Kingdom. A separate media office from that of the Department of Health has facilitated fast and confident handling of medicines and medical device issues, and is considered by the MHRA to have built public confidence in the work of the regulator.

The Panel appreciated that it has not been a traditional role of public servants to deal directly with the media. However, the Panel believed that, in regard to technical matters, expert commentary is likely to prevent misunderstandings and misrepresentation by the media. The Panel also noted that the overseas regulators equivalent to the TGA are recognising that the public's need for accurate information is best met by permitting

professionals with appropriate media training, to speak directly on public health issues and concerns.

*“As specialist journalists working in the medical sector we have often found it a struggle to engage with the agency. Understanding the complexities of drug and device regulation are challenges enough, but without help from the TGA itself that task can become near impossible.” – Australian Doctor*

The Panel recommends that the key elements of the communication strategy include identification of:

- key target audiences – public, consumers, health practitioners, industry, media, government and non-government organisations, advocacy and representative groups;
- information needs of each audience – on the TGA role, and how it undertakes that role; its performance; its business processes; information and educational materials for the safe use of products;
- critical intervention points (timing) for each audience – including information provision at point of purchase and point of use for consumers, at point of prescribing or dispensing for health practitioners, early warning systems and alerts;
- dissemination opportunities – using targeted and mass media pathways;
- information products for each dissemination pathway; and
- funding for information dissemination – including in-house communication capacity.

The strategy should also be used to develop a level of consistency in the information provided about differing types of therapeutic goods, including on the various ‘help lines’. In particular, it should address the need identified by consumers and health practitioners for information about medical devices that is consistent with that provided about prescription medicines through Aus’ARs, CMIIs and PIs.

*“There is arguably an increased need for information about medical devices, as they cannot be ceased in the way that medications can be when a problem occurs. Consumers need access to high quality, independent information before a device is implanted, and consider that the TGA should play a role in the provision of this information.” - CHF*

The Panel recognised that TGA does not work alone in the provision of information and education about therapeutic goods. In particular, the NPS was established to enable people to make better decisions about medicines and medical tests, leading to better health and economic outcomes. The NPS works with health professionals to keep them up to date with the latest evidence, and it provides individuals with the tools and knowledge to make better decisions.<sup>11</sup> In addition, patient and consumer organisations are active in this area, and, for health professionals, medical reference sources such as MIMS, Therapeutic Guidelines Limited (TGL) and AMH have specific roles. The role of the Pharmaceutical Benefits Scheme (PBS) in making necessary medicines more affordable to the public through cost-effectiveness evaluation also needs to be taken into account.

The Panel considered that delivery of consistent messages is an important part of encouraging the quality use of medicines.

<sup>11</sup> [http://www.nps.org.au/about\\_us](http://www.nps.org.au/about_us)

*“The TGA is the authoritative agency for assessing information on safety and efficacy of medicines. Communication of that assessment is an important second step. Poor direct availability of information from the TGA as well as an absence of relationships with other channels of distribution such as NPS creates an access barrier to comprehensive information.” – NPS*

The Panel also noted that (in contrast with the NPS) the TGA does not receive any government budgetary support for its public information and education role. This factor alone makes it desirable that the TGA work strategically with other key providers of information, particularly the NPS. The Panel considered that there would be merit in the establishment of a formal cooperative agreement with the NPS to work jointly in the delivery of information and education materials about therapeutic goods and their regulation.

The Panel recognised the work of the NPS in providing consumers with a valuable source of information about medicines. It considered that, as a priority, the TGA should explore with the NPS the possibility of extending its work in the area of medical devices and complementary medicines, as there are fewer existing resources to assist consumers in their decision making about these products.

Further possibilities for increased collaboration were identified with:

- State and Territory health departments to improve the two way exchange of information, particularly for timely alerts and warnings, and for better communication about adverse events;
- the Australian Quarantine and Inspection Service (AQIS) about the separate requirements for the import of a product, and the options for streamlining the processes;
- bodies that maintain medical device registers, such as the National Joint Replacement Registry and immunisation registers;
- health practitioners associations in relation to the specific needs of patients of their members, and ways to address those needs;
- consumer groups and specific health groups to actively engage in addressing emerging issues for them, which can range from access to emerging therapeutic options, to interactions between the prescription and complementary medicines, or unsubstantiated therapeutic claims (advertising);
- industry to develop a greater partnership in the regulatory process, and particularly the consultative processes on changes to requirements;
- the health media who ask for greater access to the TGA for informed comment and engagement, when appropriate, about public safety issues; and
- the ACCC in relation to the enforcement of sanctions for deceptive advertising.

### **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.

## TGA Website

### Issues:

- The TGA's website is criticised for being complex, not targeted to specific audiences, and hard to search. The currency and version of a document is difficult to establish, and it may not be evident that a document reflects the current situation.
- To provide the public, particularly health practitioners, with the current status of a therapeutic good a product's history should continue to be available on the TGA website, even after it is no longer available on the Australian market.
- Linkages should be provided from the TGA website to other sources of information on therapeutic goods.

### Discussion

Throughout the consultation phase of the Review, stakeholders were advised that the TGA was in the process of improving its public access website to make it less complex and more accessible. The impetus for the redesign was a June 2009 stakeholder satisfaction survey, where the results showed public dissatisfaction with the website in its then current form, and most of those who contributed to the Review concurred with the 2009 survey results. The remit for the redesigned website was that it had to be user friendly, and provide information in an intelligible tiered structure.

The TGA advised the Panel that the redesign needed to comply with the mandatory requirements of the Australian Government's *Web Guide* which dictates, among other things, the design of Government websites.

The Panel noted that many of the concerns that were raised by stakeholders regarding the TGA website, have now been addressed with the redesigned TGA website launched on 4 May 2011. The redeveloped site is easier to navigate, and provides entry points for consumers, health practitioners and industry.

Earlier in the Review period the TGA had also improved access to the ARTG by enabling more efficient search capacity for products recently added to the database, and the capacity to search by nominated active ingredient – two issues noted in a large number of submissions.

*"Where goods are registered by the TGA they should be listed on a database that is searchable by consumers with cross linking by manufacturer, and all ingredients. Ingredients should similarly be linked to suitable pharmacological evidence databases."* – David Brookman (medical practitioner)

However, the Panel agreed that stakeholders would benefit from the TGA making further improvements to the website that would encompass improved functionality. The site should provide the public with more information on TGA's regulatory processes, and historical information on therapeutic goods that are currently and/or previously available on the Australian market.

To access additional post market information, an important inclusion on the TGA's website would be good directions and linkages to other organisations that have a direct interest in

particular types of therapeutic goods (medicines, vaccines, devices), such as the NPS and the Australian Commission on Safety and Quality in Health Care (ACSQHC). These bodies could meet the need of website users for additional and impartial information, and possibly advice.

TGA notices published in the *Government Notices Gazette* should also be published on the TGA website.

The website should also include material relating to the type of information exchanged through agreements with other regulators in Australia and overseas.

The Panel discussed a request to enhance the TGA's website with an organisational structure chart that included names and photos of key personnel. The names of the Office heads, and where the positions sit within the organisation, is currently included on the website. However, it was noted that it was not usual government practice to identify public servants personally in this way.

The submissions identified the problem that stakeholders found it difficult to determine the currency of documents on the website, and to determine whether the information is the most current available. Some inconsistencies in information on different parts of the site were also noted. The Panel considers that this has the potential to undermine the credibility of all information on the site and must be addressed through the adoption and use of version control systems.

Discussion of the website also encompassed the range of electronic notifications that are, or could potentially be used by the TGA. While the further development of these are a part of a comprehensive communication strategy, the website is a key delivery portal for a range of audiences and a focus on currency, timeliness, and accuracy is essential for credibility and to build public confidence.

*"... some sort of early alerting/notification service regarding new medicines (and also new indications) is needed. This could be a service through the ARTG" - AMH*

### **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.

### **Information on Therapeutic Goods Regulation**

#### **Issues:**

- The lack of knowledge and, therefore, understanding of the TGA's risk-based approach to the evaluation of therapeutic goods.
- The confusion about the difference between registered (AUST R) and listed (AUST L) products.

### **Discussion**

The submissions to the Review highlighted a general lack of understanding of TGA's risk-based approach to the assessment of therapeutic goods for use by the Australian community. They showed that for most consumers, and for some health practitioners, the

differing levels of evaluation, based on the risk profile of the product, are not understood. In particular, it is not understood that low risk products (including a range of medical devices and complementary medicines) are not individually assessed, but are listed on the ARTG on the basis of the availability of specified information held by the sponsor.

Low risk complementary medicines and medical devices are not evaluated by the TGA and complementary medicines are not evaluated for efficacy by the TGA, prior to release. The sponsor of the product is required under the Therapeutic Goods Act (s26(6) and s26(7)) to hold appropriate evidence for all claims made, and must supply this evidence to the TGA on request (for example: post-market evaluation). Informed decision-making, by both consumers and health practitioners, requires an understanding of both the risks and benefits of a product, and an awareness that the risk/benefit assessment may change in the light of new knowledge.

The Panel agreed with a number of submissions which put the view that while the public do not understand the regulatory system, there is perceived to be a community expectation that products on the Australian market have been assessed and are effective as well as safe. The Panel also agreed that consideration needs to be given to how to make the public aware of the varying levels of evidence used in an evaluation, including clinical trials data and the weightings given to different types of evidence.

The Panel agreed that the complex system of risk assessment and product evaluation must be explained meaningfully for a variety of audiences, with widely different levels of health literacy. It needs to be explained that no therapeutic good is risk free, and that risk is not an absolute concept - it is an assessment of the potential of a product to do harm to those it is intended to help, or to others (such as children) who may come in contact with it, regardless of whether the harm results from following or disregarding the directions for use.

Listed products are required to be made according to GMP, and to contain ingredients that have been assessed as safe for use. Individual products are not assessed by the TGA for their safety, or their manufacturing quality, prior to being released onto the market by sponsors.

The Panel considered that this lack of understanding of the overall system results in the commonly raised concern in the submissions that the regulatory distinction between AUST R and AUST L products, as approved by the TGA, is not understood. For example, submissions noted the lack of awareness of AUST R and AUST L numbers and, therefore, little awareness that only AUST R products have been assessed for quality, safety, and efficacy, whereas AUST L products may not be assessed but must meet requirements for safety and quality. A number of submissions considered that all products should be assessed for efficacy.

*"... many healthcare professionals are not familiar with the differences between a registered and a listed drug. Whilst MIMS can assist to some extent with this issue by making the TGA assessment more obvious to its customers, we believe that the TGA needs to address this issue in the transparency review to ensure that both health professionals and consumers are aware of the limits of assessment with listed products." - MIMS*

Stakeholders, including Panel members, have raised the risk based approach to regulation as a transparency issue. Many noted that the products which are not assessed for efficacy by the TGA prior to release to consumers are not necessarily seen as medical products. Their use may be influenced by many different sources of advice, including personal reading, advice from health practitioners, staff of pharmacies and health product retailers.

Many low risk medical devices are included on the ARTG, as well as listed complementary medicines. The Panel acknowledges that there are a number of evidence based complementary medicines and low risk medical devices. The current regulatory system makes it difficult for these products to be distinguished. A number of submissions considered that all products should be assessed for efficacy.

A concern was expressed in the submissions that people using complementary medicines do not recognise the importance of drawing this use to the attention of their health practitioner, as the potential for adverse interactions or other risks is not recognised.

Concerns were also expressed over the lack of community understanding about homeopathic products, and their frequent availability in pharmacies. The view was put that consumers should be made aware of the lack of modern scientific evidence for these products, and that because of this, there may be serious questions about some advertising practices used.

Submissions not only supported public education campaigns about registered and listed products, but also called for some closely targeted campaigns. For example, submissions pointed to the need for the TGA to work with pharmacy associations to ensure that pharmacists and their staff are well aware of the differences between registered and listed products. They should be able to explain that difference effectively to consumers to assist them to make informed decisions.

The Panel considered that the TGA should develop and implement information and education mechanisms. It also suggested that cooperation with agencies, such as the NPS, would enhance the consistency and spread of information provided for the public. Liaison with groups such as health practitioner associations could be valuable in providing appropriate targeted information to practitioners and their associates.

*"... the TGA develop initiatives to improve consumer understanding of how medicines are regulated in Australia, including the difference between AUST R and AUST L numbers." – recommendation of the CHF*

#### **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.

## Statutory Advisory Committees

### Issue:

- The work of the TGA's statutory advisory committees is valued, and a range of stakeholders would welcome greater access to their considerations and decisions.

### Discussion:

The amount and type of information that is made publicly available by the TGA's statutory advisory committees is seen by stakeholders as inconsistent. The Panel was made aware that there is an apparent lack of timely (publicly available) information on the TGA's statutory advisory committees' recommendations, and little transparency of their deliberations. Currently, the TGC is the only TGA committee to publish its minutes, and unlike other similar committees, the TGA's statutory advisory committees do not publish their meeting agendas.

A number of submissions identified the need to consider publication of declarations of conflicts of interest for members of statutory and expert advisory committees.

*"Members of advisory groups and committees should be publicly disclosed on the website. Their declarations about conflicts of interest should be published. Details of meetings and meeting agendas should be published."* – Melissa Sweet (health journalist)

As with other parts of the regulatory process, the Panel would like to see the TGA adopt broadly consistent processes and publication formats by the TGA's statutory advisory committees, especially relating to the coverage and timing of publication of the committees' considerations and advice. However, the Panel appreciated that consideration would need to be given to the constraints imposed by the relevant legislation, and that handling of commercially sensitive material may need to be different for the different types of therapeutic goods. These matters would in turn influence the content of, and the timing of making, the committee's recommendations publicly available.

*"It is recommended that ... the findings and recommendations of the TGA Advisory Committees be made available to medical specialists."* – Medical Oncology Group of Australia

## 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.

## Regulation of Advertising

### Issues:

- The lack of transparency about the regulation of advertising of therapeutic goods causes confusion.
- The existing system for complaining about advertising is described as complex, confusing, slow and ineffective.

### Discussion:

In late December 2010, and subsequent to a 2010 consultation on advertising by the TGA, the Parliamentary Secretary asked the Panel to include consideration of "the need to

improve public awareness of, and access to, information on the arrangements for the regulation of therapeutic goods advertising”.

The advertising issue relates primarily to therapeutic goods that are: classified under the TGA's risk framework as low risk; and are advertised directly to consumers.

Submissions to the Review illustrated frustrations about the fact that the legislation is complex, and the complaint process is not transparent. Complainants reported that they find it difficult to know who to complain to, and they receive little feedback on the progress and outcome of their complaint.

*“... lack of consistency between advertising approvals and complaints resolution panel determinations - we believe, that a strong improvement in transparency and communication between these two authorities, combined with an appropriate similar skill set relevant to CM and its regulation could help resolve current issues and inconsistencies.” - PharmaCare*

The Panel noted that the TGA website information regarding advertising, and the links it provides, are not easy to follow and that the advertising of therapeutic goods to consumers and health practitioners is controlled by a complex mix of measures. There are statutory measures administered by the TGA, in conjunction with a separate Complaints Resolution Panel, together with industry self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations. It also noted that the Complaints Resolution Panel may refer a complaint back to TGA for follow-up action, and that the TGA has recently indicated it will publish orders made under regulation 9 of the Therapeutic Goods Regulations 1999. However, there was a strong view in some submissions that there is insufficient enforcement power available, action is rarely taken and that rulings can easily be circumvented.

The overall view was put that this means that many breaches of the Therapeutic Goods Advertising Code are not, indeed cannot, be effectively pursued, and that there is little scope for the tracking of the full range of individual actions taken against any one company, as there is no publicly available mechanism to track this information. The Panel agreed that this topic is characterised by: a lack of clarity in the legislation; confusion about the range of responsible bodies; the complaints processes to be followed; and the outcomes of those complaints.

It also noted that the issues of transparency of information about regulation, processes and outcomes were themes throughout this Review, and were being addressed through a number of recommendations. However, it also considered that while the topic of regulation of advertising has been the subject of a number of other reviews and consultative processes, the lack of transparency about the legislation and the regulatory processes warranted a recommendation in its own right by this Panel.

### **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.

## Key Performance Indicators

### Issue:

- The TGA does not currently publish qualitative and quantitative information about the work it does.

### Discussion

As a division of the Department of Health and Ageing, information relating to the performance of the TGA is included in the Department's Annual Report. This, in effect, is the sole source of information about the TGA's operations. Performance data provided to industry representatives to the TICC is neither made widely available to the industry (sponsors), nor published.

*"... information on key strategic directions and the TGA's performance against effectiveness indicators, currently in the Departmental Annual Report should have a higher public profile."*  
- Regulatory Solutions

*"TGA ought to release raw data on their key performance indicators (e.g. approval times) as opposed to averages."* - ASMI

Stakeholders considered that this lack of transparency also applies to the range of regulatory actions and decisions made by the TGA, as well as to information on its post-market monitoring activities. They wanted feedback to all stakeholders on the volume of work undertaken, the timeframes set and performance against them, the common problems identified (e.g. in applications, audits, advertising), reports on compliance action and sanctions imposed, and tribunal and court decisions.

Industry in particular asked for increased visibility of the work undertaken in the different regulated areas, which could be seen as providing a form of accountability to the industry for the fees and charges they pay.

*"There is no legitimate reason for the TGA to withhold information from the public on its actual performance in processing OTC and complementary medicines."* - Archer Emery & Associates

The Panel noted that stakeholder requests are similar to those raised in the FDA's transparency initiative and the recent release of performance information in FDA-TRACK<sup>12</sup>, and its May 2011 action to make the outcomes of enforcement and compliance activities accessible on-line.

*"This [FDA-TRACK] website enables all interested external and internal visitors to view FDA's performance data at the program office level and gain a better understanding of the breadth of FDA's core responsibilities, as well as see progress on important projects and programs."*  
FDA<sup>13</sup>

The Panel considered that there are multiple and compelling reasons for releasing a greater range of performance information publicly. The most compelling reason is that

<sup>12</sup> See Appendix 4

<sup>13</sup> <http://www.fda.gov/AboutFDA/Transparency/track/ucm195010.htm>

building understanding of the organisation will add to its credibility. It is essential, to this end, that it be made clear what the TGA does, and why and how long it takes to do it. The Panel considered this to be an integral part of achieving greater openness about the TGA.

### **Recommendation 10**

The TGA, in conjunction with 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**

#### **Disclosure of Commercial Information**

##### **Issue:**

- The TGA has not published a policy on the disclosure of commercially sensitive materials.

##### **Discussion**

In a discussion about commercially sensitive material, the Panel heard that transparency is a tool in a quality framework. It is important for the TGA to develop a policy that:

- enables sponsors to have a high degree of certainty about what is recognised by the TGA as commercially sensitive information;
- is broadly consistent while recognising that there are different product types;
- includes guidance on the timing of the release of information; and
- is consistent with overseas regulatory practice.

*"It would be useful if some direction could be included on the TGA website indicating the kind of information that is deemed to be commercial-in-confidence. In the interests of transparency, TGA would hope that the amount of information that could be classified in this way would be kept to an absolute minimum." – TGA*

It was suggested that if information is deemed to be in the public's interest, it should be in the public domain. However, this gives rise to the question of how this is to be done, and who should determine its sensitivity. Industry Panel members are concerned about releasing information that is currently treated as commercial in confidence.

Concern was also expressed that the impact of the release of confidential information will be different for different types of therapeutic goods, and that these differences would need to be considered in the development of any disclosure policy.

*"The CHC does not support disclosure of product information in relation to ingredients/formulas as this encroaches on commercial-in-confidence details. The complementary medicine industry already struggles with the lack of exclusivity/data protection available impacting on competitiveness and innovation in the market. The CHC believes publicly disclosing additional product information would **not** benefit consumers but lessen the forces of competition." – Complementary Healthcare Council of Australia*

In determining whether information relating to a product should be released by the TGA, it is relevant to take into account whether that information is publicly available from other comparable international regulators.

The EMA, FDA and MHRA all have policies in place on the handling of commercially sensitive materials, and the Panel suggested that the TGA should look to its overseas counterparts for guidance in developing a policy.

*“Examine existing arrangements for provision of information and comparable international regulatory models” – Medicines Australia*

### **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.

### **Regulatory Processes**

#### **Issue:**

- The TGA’s regulatory processes are generally unknown, or if they are known, they are not well understood.

#### **Discussion**

The perception of the TGA being impenetrable is reinforced by the lack of public knowledge of its regulatory processes.

*“TGA materials aimed at consumers and busy general practitioners that explain different aspects of the regulatory system - including the exceptions - would be useful ...” – Commonwealth Ombudsman*

The Panel thought that stakeholders would benefit from the publication of the rationale for recommendations made by the TGA’s statutory committees, and the final decisions on applications, including withdrawals and rejections.

The introduction of the AusPAR for prescription medicines at the end of 2009 was widely welcomed, and many stakeholders would like to see them introduced for other therapeutic goods. This would allow the public to see the steps in the evaluation process that has led the TGA to approve, or not approve all types of therapeutic goods.

*“The introduction of the AusPARs is indeed a major step forward and TGA staff must be congratulated for the efforts they place into their production.” – Dr Agnes Vitry*

Industry stakeholders identified a concern about the TGA’s published guidelines and an inconsistency of the TGA’s application of these guidelines in the delivery of services to industry.

The Prescription Medicines Business Process Reforms (BPR) aims to simplify the initial submission processes, aims to allow for interaction between sponsors and the TGA at known intervals, and should provide greater certainty for industry about the timing and conduct of the process. The Panel heard that there is support for the underlying objectives

of the BPR, and consideration should be given to applying these principles to other categories of therapeutic goods.

### **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).

#### **On-line Tracking**

##### **Issue:**

- There is a lack of information available to sponsors on the status of an application in the assessment process.

##### **Discussion**

The Panel heard there were concerns about the length of time taken for the assessment of some applications, and the way in which the TGA seeks information and engages with a sponsor during an assessment.

*“TGA should provide information to industry on the progress with a assessment of product applications, for example, by providing a tracking mechanism to communicate where an application is up to in the registration process. An applicant is then better placed to understand when approval might be granted and the product might come to market.” - Medical Technology Association of Australia*

Industry stakeholders suggested that the system could be improved if the TGA developed an on-line system for sponsors to monitor the progress of the assessment of their applications, as they currently find it difficult to know the application’s status. Other stakeholders, including researchers, would like to see this taken a step further, whereby the TGA provides open access to data, enabling the identification of all products currently undergoing assessment.

The Panel did not consider there was merit in the submission regarding open access, and noted that it is not aware of this practice being adopted by comparable overseas regulators. It did, however, agree there would be benefits in the implementation of an on-line tracking system for sponsors only.

*“Improvement in the visibility of the evaluation and registration approval process so that sponsors/manufacturers are able to have a clearer indication of how their submission is progressing through the approval process (eg. via tracking on the web using unique locumment ID). This would assist in monitoring the likely timeframe for a decision/outcome.” - Australian Red Cross Blood Service*

*“Ensure consistency of practices and sharing of information across the various Offices and Evaluation Units of the TGA” - Pfizer*

### **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.

## Labelling

### Issues:

- The community wants to know who is responsible for the regulation and monitoring of therapeutic goods labelling, and the TGA's role in the process.
- There are concerns regarding the inadequacy of controls over labelling.
- There are no requirements for a product to completely list its contents, including whether it contains nanoparticles.

### Discussion

The approval of product labels is part of the approval process for therapeutic goods. The Panel shared stakeholders' concerns that poor labelling practices can be a safety issue for consumers.

The Panel heard that there are three areas of particular concern with regard to labelling:

- the inaccessibility of mandatory information on the therapeutic goods;
- the inconsistency of the positioning and font size for important information; and
- the lack of information about non-active ingredients.

With medicines, in particular, consumers and health practitioners both expressed considerable frustration that the manufacturer's label, which contains dosage and active ingredient information is frequently obscured by the pharmacist's label with precedence given to the prescriber's dosage instructions and pharmacy marketing information. However, it should be noted that the TGA has no control over this practice.

The Panel noted the level of frustration expressed by stakeholders in locating the AUST R or AUST L number on many products. The inclusion of these numbers in a minimum font size is mandatory but the precise location on the label is not.

There was also concern about dispensing errors caused by products being allowed to have similar names, and it was suggested that the TGA adopt a similar system to the FDA where the Office of Generic Drugs encourages manufacturers to use TALLman lettering labels to visually differentiate medicines.

The Panel noted calls for a consistent approach by the TGA to the approval of product names to ensure certainty for industry and safety for consumers.

The Panel noted that the TGA has commenced work in partnership with the ACSQHC to address labelling issues.

*"The naming of products is well documented as a high risk area when discussing medication safety. We would like to suggest that the TGA take greater responsibility in risk assessing the naming of medicines in order to minimise the already complicated picture of Look Alike Sound Alike Drugs (LASA)."* – NSW Therapeutic Advisory Group

In the current system, information about non-active ingredients for therapeutic goods is difficult to obtain, or not available. It was suggested that the adoption, by the therapeutic goods industry, of a similar system to that used in food labelling would greatly assist consumers. A further improvement to labelling would be the inclusion of information on

non-active ingredients on the label of therapeutic goods, particularly products that contain potential allergens or modified ingredients.

#### **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)**

##### **Early Post Marketing Risk Communication Scheme**

###### **Issue:**

- Health practitioners and consumers would like to see the adoption of some sort of early post marketing system to increase their awareness that a product has only recently been registered for the Australian market.

###### **Discussion**

In its submission, the TGA's Advisory Committee on the Safety of Medicines (ACSOM) drew the Panel's attention to the lack of public awareness of the uncertainties of medicine safety in the early post registration period for medicines requiring a risk management plan. ACSOM proposed that a new risk communication scheme be introduced to alert consumers and health practitioners to the level of risk in the early post-market period. The scheme would be similar to the United Kingdom's black triangle (▼) alert system (discussed in Appendix 4: 'Trends in public disclosure by comparable overseas regulators').

*"Health professionals would be particularly encouraged to report adverse events that appeared to be related to drugs with the early postmarketing symbol." - ACSOM*

It would also signal that the TGA practises important post-market surveillance and would encourage public understanding of safety profiles.

*"[there should be] Provision of information on post-market surveillance on newly introduced therapeutic items, especially recently developed medicines and vaccines which have undergone limited clinical trialling in Australia and/or overseas." - ANF*

While Panel members agreed with the concept of an 'early post marketing risk communication scheme', some members are opposed to the use of the United Kingdom's black triangle as they interpreted it as being 'sinister', and not as a cautionary symbol to raise awareness of a product's recent approval. However, the symbol (or a variant) is used, or is to be introduced, in other European countries.

Discussion with the MHRA indicated the scheme had been in force in the UK for many years. It was considered to be well accepted by the public, and by industry. It played a useful role in identifying problems in the products that had not emerged in pre-market trials. While there may not be a direct correlation, the Panel was advised that approximately eighty percent of adverse incident reports related to medicines to which the black triangle scheme applied.

The aim of the proposed scheme is to directly link risk communication to the public with the TGA's requirement for risk management plans. It would indicate to the public which products are associated with a particular uncertainty or risk. The scheme would be applied according to a set of criteria, including timeframes. A product would graduate from the scheme when its safety profile had been sufficiently well established. The scheme would need to be accompanied by an education campaign for health practitioners and consumers.

The Panel considers that a scheme of this kind could assist in linking health practitioners into post-market surveillance activities.

### **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.

### **Safety Information – Alerts and Recalls**

#### **Issue:**

- Stakeholders want to be sufficiently informed of the event, concerning the investigation, suspension or cancellation of a product.

#### **Discussion**

Currently, there appears to be insufficient information from the TGA on the events concerning the investigation, suspension or cancellation of a product.

The Panel's deliberations on the issue of alerts and warnings also highlighted the community's expectation that the TGA comment when issues about the safety, quality and efficacy of a product included on the ARTG are the subject of media debate.

Although health practitioners would like to receive timely advice of problematic therapeutic goods, the Panel noted that the TGA must currently wait until its investigation is complete before issuing advice.

It was suggested that the TGA consider developing an appropriate and effective warning system to alert stakeholders that a product is under investigation and, further to this provide a public notification of the investigation's outcome. However, the Panel agreed with the concerns raised by some stakeholders that the introduction of such a system could cause unnecessary alarm to consumers.

The Panel agreed that the distribution of therapeutic goods safety information needs to be built into the TGA communication strategy, with the aim of:

- improving the dissemination of important information on therapeutic goods;
- providing links on the TGA website to appropriate agencies, State and Territory health departments and Coroners;
- reducing the length of time taken for the TGA to publish alerts for the notification of product recalls and withdrawals;
- notification of recalls to all stakeholders;
- making up-to-date information on the subsequent status of the product available and easy to find; and

- providing a historical list of recalls on the TGA website, including the publication of voluntary recalls.

*“Public information about adverse events must not be limited to passive measures such as inclusion of the information on a website; there must be a hierarchy of proactive strategies for informing health professionals and the public of adverse events, with the level of the response proportionate to the severity of the adverse events and the potential risk to public health and safety.” - CHF*

The Panel considers that the process for distributing alerts should be reviewed to ensure it is as effective as possible. Currently the flow of information may be slow to reach health practitioners through jurisdictional and practitioner association channels, and subsequently to consumers. Health administrators and practitioners noted that this problem is not unique to the TGA, as they also encounter difficulties in ensuring that timely advice is received throughout their networks.

### **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.

### **Consumer Medicines Information and Approved Product Information**

#### **Issue:**

- Stakeholders want to see the limitations of the CMI and the PI publicised.

#### **Discussion**

CMIs and PIs regarding approved prescription medicines have been published by the TGA since November 2009.

While this information is welcomed by consumers and health practitioners, there was much comment in the consultations about the fact that these documents are provided by the sponsor and written at a point in time related to the approval. There was a strong view in the submissions that CMIs and PIs are not updated on a regular cycle. A concern was expressed that consumers may be provided with out-of-date advice about their medication, and have no way to easily check whether it is up-to-date.

*“find a suitable way to ensure that, for product information for drugs where the patent has expired and the information is old, the PI is updated and reviewed regularly.” - MIMS*

Some contributors also considered that there is a need for the TGA to educate and encourage clinicians to advise the TGA of their concerns if they discover errors in a PI or CMI. They should also be advised that the TGA can initiate a review of the material at anytime if it becomes aware of new information, and it is already a requirement that sponsors inform the TGA when significant new safety information becomes available.

*“A mechanism [should be] developed whereby expert clinicians who discover sections of PI or CMI which are at odds with modern clinical practice and advice can make a brief submission to the TGA ...” - Endocrine Society of Australia*

The Panel considered that the TGA, in the first instance, needs to explore a mechanism to maintain the currency of CMI and PI, including consideration of links to other information providers eg., AMH and TGL. It also strongly supported the need to provide similar information for all therapeutic product types, for the use of consumers and health practitioners.

It should be acknowledged that some members of the Panel would have preferred to see the recommendation provide 'that the TGA **implement** mechanisms' rather than 'explore'. However, it was agreed that the stakeholders affected by this recommendation will need to be appropriately consulted, and the practicalities of such a measure will also need to be investigated prior to implementation.

### **Recommendation 17**

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

### **Outcomes of Investigations and Compliance Actions**

#### **Issue:**

- There is very little information available about the TGA's post market surveillance activities, and there is a lack of public reporting on the outcomes of investigations and compliance actions.

#### **Discussion**

There is a public perception that the TGA's investigations and compliance actions are ineffectual and rarely applied.

*"The TGA ought to produce timely statements regarding regulatory activities ..." - ASMI*

The point was made that knowledge of the surveillance work undertaken by the TGA, and the outcomes achieved, are central to public confidence in the quality, safety and efficacy of therapeutic goods on the Australian market.

Consideration was given by the Panel to the trends in disclosure of post-market activities by overseas regulators. The Panel noted that, as part of the FDA's transparency initiative, it has made information on its inspections and court actions more accessible on-line. The FDA is proposing to increase the public's access further, by the end of 2011, to provide more information on its enforcement and compliance activities.

The Panel debated this, and agreed that if the TGA educated the public on its post market surveillance processes, published decisions including penalties and sanctions, and provided summaries of common opportunities for improvement from recent audit outcomes, it would increase the public's confidence in the TGA's post market regulatory role.

*"Cancer Council WA recommends the conclusions of the TGA's post-market safety investigations are made publicly available." - Cancer Council WA*

### Recommendation 18

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

### Adverse Events Reporting

#### Issues:

- The current reporting system for adverse events is complex.
- Timely advice and the distribution of information regarding adverse drug reactions appear to be lacking.
- The regular provision of information to keep health practitioners, consumers and the media informed of the TGA's management of adverse events is needed.
- The lack of transparency regarding information on adverse events including events following immunisation.

#### Discussion

During the consultation phase of the Review, the method for reporting an adverse event was an issue that was frequently raised by consumers and health practitioners. The confusion for consumers is caused by the numerous different reporting methods – to their doctor or pharmacist, to the Adverse Medicines Events Line, relevant State or Territory reporting systems, or directly to the TGA. The Panel heard that this confusion carries through into the health sector with some health administrators and health practitioners noting that they may report to a company (sponsor) in the first instance or through their state health department instead of to the TGA.

The Panel noted the submission from the CHF: *“That a rigorous post-market surveillance system is developed and promoted, ideally with data-linked, real time monitoring systems involving the Commonwealth, State and Territory authorities and including reporting by clinicians, sponsors and consumers”<sup>14</sup>.*

*“Informing the community of how the safety system operates and makes decisions would improve confidence in the system when specific events occur” – Review of the management of adverse events associated with Panvax and Fluvax*

The Panel considered that part of the TGA's role for overseeing product safety includes the provision of information to keep health practitioners, consumers and the media informed of the TGA's management of adverse events.

The Panel considered that there needs to be education for consumers, clinicians and retailers on the method for reporting incidents, and how reported events can be followed up. There also needs to be communication to the public about the rationale for the actions taken in response to an incident.

*“Implementation of mechanisms to enable greater engagement with TGA of both health professionals and consumers of health and aged care services in order to greatly improved information flow on issues relating to medicines and other therapeutic products (for example, adverse reactions to medicines or deficits in medical devices).” - ANF*

<sup>14</sup> CHF, 2011 ‘Submission to the Review to Improve Transparency of the Therapeutic Goods Administration’, March 2011

The Panel acknowledges that the TGA needs to exercise appropriate judgement in response to adverse event reports in the public interest.

Another concern is that it does not seem possible for the public to trace the number of events reported relating to a specific product. Stakeholders asked for a publicly accessible national adverse event database, with online interrogation capacity. The MHRA publishes a monthly summary of tabulated data relating to adverse event notifications on its website.

Stakeholders drew the Panel's attention to some of the adverse events (incident) systems currently in use by overseas regulators. The Western Australian Department of Health suggested the FDA's co-sponsorship of the USA's Vaccine Adverse Event Reporting System, and its facilitation of public availability could provide a transparent model for vaccines.

The Horvath Review also highlighted the lack of knowledge of how to make an adverse event report, and the lack of understanding of the significance of these reports.

The Panel considered that the TGA may want to adopt an approach for the collation of adverse events data that is consistent with overseas practice (MHRA, FDA and Health Canada). The database should cover events from all therapeutic product types, including events following immunisations, and provide details of all reported adverse events. Some of the Panel would also like to see the inclusion of events relating to complementary medicines and non-marketed medicines in the interest of patient information and safety. It was also suggested that the database could link in with other jurisdictions and the NPS. The aim of implementing such a system is improved integration between jurisdictional, national and overseas reporting systems.

*"Wider access to this information could help to raise awareness of the importance of spontaneous reporting to [TGA] and be of interest and value to health professionals, researchers and providers of medicines information." - ACSOM*

#### **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.

## CHAPTER 5: RELATED ISSUES THAT AROSE IN THE CONSULTATIONS

During the consultations, and in some of the submissions made to the Review, stakeholders drew the Panel's attention to a number of issues regarding the TGA or therapeutic goods that are not directly related to 'transparency'. When the Panel considered these issues, it determined that they were outside the scope of the Terms of Reference for the Review, and in some cases were policy matters for consideration by government. However, the Panel agreed that these matters are important, and decided that each issue should be noted and/or drawn to the attention of either the TGA, or the most appropriate government agency.

**It should not be taken that the Panel agrees with, or recommends, any of the views that are set out in this chapter. However, as they were strongly put, the Panel does not consider that they should pass without being noted.**

### Independence of the TGA and its place within government

For many stakeholders, the way the TGA operates is seen as a consequence of its role. Submissions identified a perception that the TGA is a regulator working within the realities, and the constraints, of its location within the DoHA bureaucracy. It was suggested by a number of stakeholders that the TGA should be established as a statutory body in its own right, under the Government's health portfolio. Other Australian regulatory bodies with comparable functions, such as the APVMA, the National Health and Medical Research Council (NHMRC) and the Private Health Insurance Administration Council (PHIAC) are statutory bodies. However, the TGA is a Division of DoHA, and not an independent agency.

The role of the TGA was compared by a stakeholder to that of the Australian Institute of Health and Welfare (AIHW), a portfolio agency with responsibility for health and welfare statistics and information, but the TGA does not have the same level of independence. It was suggested that if the therapeutic goods regulator were to operate as a portfolio agency, the benefits, in terms of transparency, would include:

- requiring the TGA to actively engage with all stakeholders in its own capacity;
- providing a greater focus on stakeholders, and on the TGA's role in the public health arena; and
- enabling the TGA to better focus on the matters for which it is accountable.

Central to this discussion was the impact of the TGA's current funding structure of 100% cost recovery from industry.<sup>15</sup> Some consumers perceived that the funding structure limits the TGA's capacity to provide public education and information. Industry stakeholders understand, and in some cases are supportive of, consumers' requests for the TGA to improve public education. However, they are also conscious that the TGA's legislated funding structure does not necessarily provide for the level of engagement the community is seeking.

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<sup>15</sup> The Panel noted that equivalent figures for comparable overseas regulators were U.S. FDA (26%), EMA (80%), Health Canada (80%) and U.K. MHRA (80%)

In recognition of the possible limitations imposed by the current funding structure, a number of consumers, and their representatives, suggested that it would be more appropriate for the public information and education functions expected of the TGA to be provided through a direct annual budget allocation by the Government, rather than through cost recovery from industry.

It was pointed out that, although full-cost recovery from industry may appeal to Governments, the consumer paid regardless. Either the cost of regulation was passed on by industry through higher priced products or, if the Government paid, through increased taxation. It was suggested that the latter was more equitable.

### **Concerns over complementary medicines and homeopathic products**

The assessment by the TGA of complementary medicines (such as vitamin and mineral supplements, herbal medicines and especially homeopathic products) was raised as an important issue, in both the consultations and the submissions. Contributors were concerned that the recognition of these products by the TGA, and the AUST L number on the label, provided the public with a perception that the claims made for these products had validity.

At both the consultative sessions and in submissions, it was asserted that many therapeutic claims, or claims regarding efficacy and safety made for complementary medicines, cannot be supported from the limited scientific evidence available, while information about possible adverse effects, especially their interaction with conventional medicines, is often lacking. However, complementary medicines are not permitted to state any interactions with conventional medicines in any material that could be considered advertising.

It was accepted that the majority of complementary medicines are low-risk products, but low-risk does not mean no-risk. Submissions claimed that many complementary medicines are heavily promoted as 'natural' or 'natural alternatives', with the implication that they are harmless. It was said that this can result in consumers not advising their medical practitioner or pharmacist about their use, and that health practitioners often do not ask about them.

Some submissions sought not just greater transparency on what an AUST L number means with respect to the TGA's risk-based assessment of safety, quality and efficacy. They asked for changes in labelling and legislation. Some suggested that all labels, promotion and ARTG Public Summary documents of AUST L products should contain the warning, 'These products have not been evaluated for efficacy by Australian health authorities'. Other submissions sought changes to the evidence-based requirements for listed medicines, to more clearly distinguish evidence-based complementary medicines from those that were not. Some submissions requested universal evaluation of all therapeutic goods for efficacy, arguing that there was no such thing as complementary medicines, only medicines with evidence of efficacy and those that lacked evidence. In particular, many submissions strongly put the view that the listing of homeopathic products by the TGA be ceased, as it is perceived to provide an unwarranted or inappropriate endorsement of the products that may be no better than a placebo.

These submissions were clearly outside the scope of the Review but, as they were pressed very strongly, the Panel considers that they should be recorded.

### **Radiopharmaceuticals**

One submission highlighted the difficulties of ensuring access to safe and effective radiopharmaceuticals, and the disincentive to register these products for use in Australia. This issue is, in part, due to the low volume of radiopharmaceuticals required for Australia's relatively small population, and an increasing disinclination by pharmaceutical manufacturers and sponsors to go through the registration process. While it was noted in the submission that these issues are outside the scope of the Review, the stakeholder wanted to make the Panel aware of their concerns. It was also noted in the submission that limited availability was provided through the Special Access Scheme, rather than through the more usual market method.

In addition, the submission raised the pricing of radiopharmaceuticals, and the level of Medicare fees, as a barrier to patient access.

### **Cost of medicines**

The issue of cost effectiveness and pricing of products was raised in another submission, but it also recognised that it was not a matter for the TGA. The submission suggested that the TGA could improve public awareness, and address the current perception of tardiness, by clarifying the delineation between the TGA approval and the PBS listing.

### **Extemporaneous Compounding**

State and Territory health officials raised the practice of compounding as an area for improvement. While they supported its use in the hospital setting, especially for children, they wanted consumers to be aware of the safety concerns. These submissions expressed concern that there was a lack of transparency surrounding potential breaches of GMP. The Panel has noted advice from the TGA that the NCCTG is currently developing advice on this topic.

### **Public availability of submissions for rescheduling of medicines**

One practitioner group was interested in the Advisory Committee on Medicines Scheduling (ACMS) a committee under the auspice of DoHA, making more information publicly available. Its submission acknowledged that the TGA published pre-meeting information in the *Government Notices Gazette* about the medicines that are being considered. However, the group regarded this as inadequate, as the *Gazette* only gives minimal information. The submission requested that the ACMS provide the reasons for a proposed change in the scheduling of a medicine. It was noted that the public may be impacted by the outcomes of an ACMS meeting, and may not be able to access this information to make a submission, or to provide an appropriate response, for the Committee's consideration.

### **Medical devices and the risks of magnetic resonance imaging**

A submission raised that risks of magnetic resonance imaging (MRI) exposure for patients who have certain types of medical implants, and the importance of screening potential MRI patients for potentially hazardous implants. It drew the Panel's attention to

difficulties and frustrations that radiologists have in assessing the risk from an identified implant, as the product documentation is rarely available from either the patient, or the treating practitioner.

The submission suggested the TGA require that the documentation for all implants include information on their MRI safety status. Further, the MRI compatibility information should be publicly available from the manufacturer (manufacturer's or sponsor's website or call centre). It also suggested that the TGA provide a database of registered implants, including their MRI compatibility.

### **Consistency of Consumer Medicines Information**

Consumers are concerned about the inconsistency of the information provided in the CMI for equivalent medicines, and want to see the TGA standardise them. In particular, they are seeking the same consumer information for a generic medicine product as is provided for the originator product.

### **Maintenance of medical equipment**

At one consultation, stakeholders sought greater transparency regarding the requirements for maintenance of medical equipment, such as diathermy machines. There is a concern that hospital maintenance workers are conducting repairs of fragile and complex equipment, or maintenance contracts are awarded to people who are not the original manufacturer and may not have the knowledge required to adequately maintain equipment to ensure safety.

### **International alignment of standards with the therapeutic goods regulatory framework**

Standards Australia raised the need to ensure that the standards referred to within the therapeutic goods regulatory framework are suited for the purpose, and are internationally aligned where appropriate. They considered that medical devices, and other therapeutic goods, present a significant risk to consumers and the industry, and emphasised that the Australian standards that exist in this domain must be properly maintained. They indicated willingness to work with the industry and the TGA to maintain current standards.

## APPENDIX 1 - ACRONYMS

ACCC	Australian Competition and Consumer Commission
ACCM	Advisory Committee on Complementary Medicines
ACMD	Advisory Committee on Medical Devices
ACMS	Advisory Committee on Medicines Scheduling
ACNM	Advisory Committee on Non-prescription Medicines
ACSOM	Advisory Committee on the Safety of Medicines
ACSQHC	Australian Commission on Safety and Quality in Health Care
AMA	Australian Medical Association
ADR	Adverse Drug Reaction
ADER	Adverse drug event reporting
ADRS	Adverse drug reactions system
AMH	Australian Medicines Handbook
AMT	Australian Medicines Terminology
ANF	Australian Nursing Federation
APS	Australian Public Service
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ASMI	Australian Self Medication Industry (Association)
AusPAR	Australian Public Assessment Report (for Prescription Medicines)
AUST L	Australian Listed
AUST R	Australian Registered
ARTG	Australian Register of Therapeutic Goods
BP	British Pharmacopoeia
BPR	Business process reforms of prescription medicines (by TGA)
CHC	Complementary Healthcare Council of Australia
CHF	Consumers Health Forum of Australia
CHM	Commission on Human Medicines (United Kingdom)
CM	Complementary medicines
CMi	Consumer Medicines Information
CPP	Certificates of Pharmaceutical Product
CRP	Complaints Resolution Panel
DoHA	Department of Health and Ageing (Australia)
EMA	European Medicines Agency
EPAR	European Public Assessment Report
FDA	Food and Drug Administration (United States of America)
GMiA	Generic Medicines Industry Association

GMP	Good Manufacturing Practice
GPRD	General Practice Research Database (United Kingdom)
HPFB	Health Products and Food Branch (Canada)
ICT	information and communication technology
IMS	information management services
IVD	<i>in vitro</i> device
IVDD	<i>in vitro</i> diagnostic device
MA	Medicines Australia
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MATA	Medical Technology Association of Australia
NCCTG	National Coordinating Committee on Therapeutic Goods
NEHTA	National E-health Transition Authority
NHMRC	National Health and Medical Research Council
NHS	National Health Service (United Kingdom)
NMP	National Medicines Policy Commission
NPS	National Prescribing Service – known as ‘NPS Better choices, Better health’
NRHA	National Rural Health Alliance
NSWCEC	New South Wales Clinical Excellence Commission
NRAS	National Registration and Accreditation Scheme
OTC	over the counter medicine
PBS	Pharmaceutical Benefits Scheme
PHIAC	Private Health Insurance Administration Council
PI	Approved Product Information
RMP	Risk Management Plan
s	section (legislation)
SOP	Standard Operating Procedures
TGA	Therapeutic Goods Administration
TGC	Therapeutic Goods Committee
TGL	Therapeutic Guidelines Ltd
TICC	TGA Industry Consultative Committee
WHO	World Health Organization

## APPENDIX 2 - GLOSSARY

(as agreed by the Panel for the purposes of the Report)

**Australian Register of Therapeutic Goods** - a computer database of therapeutic goods approved for marketing in Australia.

**Australian Listed** - a listed therapeutic product on the Australian Register of Therapeutic Goods.

**Australian Public Assessment Report (AusPAR) for Prescription Medicines** - provides information about the evaluation of a prescription medicine, and the considerations that led the TGA to approve or not approve an application.

**Australian Registered** - a registered therapeutic product on the Australian Register of Therapeutic Goods.

**Bioequivalence** - a term used when comparing the bioavailability of a medicine when administered as two or more pharmaceutical products, typically a brand name product and a generic product. Before a generic product can be approved for marketing in Australia, the manufacturer must prove that it has the same strength as the brand name product, and achieves the same rate and extent of drug absorption based on concentrations of drug in the systematic circulation. If a generic product is established as **bioequivalent** then it has the same rate and extent of drug absorption, and therefore provides equivalent pharmacological effects to the original product.

**Biologicals** - a term used to describe therapeutic products based on human (or mammalian) cellular, protein and tissue materials.

**Complementary medicines** - medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homeopathic medicines and certain aromatherapy products.

**Compounding** - the extemporaneous preparation of pharmaceutical products by a pharmacist for individual patient use.

**Consumer Medicines Information** - written medicines information for consumers, setting out the safe and effective use of a prescription or pharmacist-only medicine. CMI is based on information in the Approved Product Information.

**Consumers** - includes users of therapeutic goods and their carers.

**FOI Act** - means *Freedom of Information Act 1982*

**Government 2.0** - an Australian Government initiative about the use of technology to encourage a more open and transparent form of government, where the public has a greater role in forming policy and has improved access to government information.

**Health Practitioner** – includes the range of health care service providers, such as medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists, osteopaths, herbalists, homeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine, or podiatrists registered under a law of a State or Territory.

**Homeopathy** – Medicinal products made in the homeopathic tradition.

**Horvath Review** – *Final Report on the management of adverse events associated with Panvax and Fluvax* (25 May 2011)

**Industry** – a term used to describe therapeutic goods manufacturing and distribution companies, and their representative organisations.

**Medical Device** - any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.

**National Immunisation Program** – refers to the [National Immunisation Program Schedule](#) which includes vaccines against a total of 16 diseases, and which is implemented by the Immunise Australia Program.

**National Medicines Policy** – Australia's National Medicines Policy aims to improve positive health outcomes for all Australians through their access to and wise use of medicines. It is based on four central objectives.

**NPS Better choices, Better health** - an independent, not-for-profit organisation, funded by the Australian Government Department of Health and Ageing, to support the best use of medicines and pathology tests to improve health and well-being.

**Pharmacovigilance** – the science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other drug-related problem.

**Product** – in the context of this document, the term 'product' refers to all types of therapeutic goods, including medicines (prescription, OTC and complementary) and devices.

**(Approved) Product Information** – a summary for health professionals of the scientific and clinical information relevant to the safe and effective use of a prescription or pharmacist-only medicine. The approved product information is written by the sponsor of the product, and approved by the TGA.

**Quality Use of Medicines** – One of the four central objectives of the National Medicines Policy: The quality use of medicine ensures that medicines are used most effectively to achieve better quality of life and longer lives. This can include providing access to appropriate medicines, and ensuring that these medicines are being used correctly, as well as access to alternate and complementary therapies.

**Radiopharmaceuticals** - radioactive substances used in nuclear medicine for the diagnosis or treatment of disease.

**Risk Management Plan** (for therapeutic goods) – a plan to identify the known and potential risks associated with a therapeutic good, and determine an approach to clarifying the medicine's safety profile and minimising possible harm to patients in clinical practice.

**Special Access Scheme** – a legislated arrangement administered by the TGA which provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

**Sponsor** - in relation to therapeutic goods, means:

- a. a person who exports, or arranges the exportation of, the goods from Australia; or
- b. a person who imports, or arranges the importation of, the goods into Australia; or
- c. a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

- d. exports, imports or manufactures the goods; or
- e. arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

**TALLman Lettering** – a safe labelling strategy which combines of lower and upper case letters to highlight the differences between look-alike drug names. For example, fluOXETine and fluVOXAMine, helping to make these medicines more easily distinguishable.

**Therapeutic goods** - goods:

- a. that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
  - i. for therapeutic use; or
  - ii. for use as an ingredient or component in the manufacture of therapeutic goods; or
  - iii. for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- b. included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and

includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- c. goods declared not to be therapeutic goods under an order in force under section 7; or
- d. goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or
- e. goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the Food Standards Australia New Zealand Act 1991); or
- f. goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

**Therapeutic use** - use in or in connection with:

- a. preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- b. influencing, inhibiting or modifying a physiological process in persons; or
- c. testing the susceptibility of persons to a disease or ailment; or
- d. influencing, controlling or preventing conception in persons; or
- e. testing for pregnancy in persons; or
- f. the replacement or modification of parts of the anatomy in persons.

## APPENDIX 3 - BACKGROUND: THERAPEUTIC GOODS ADMINISTRATION<sup>16</sup>

### Establishment and role

The Australian community expects that medicines and medical devices in the marketplace are safe, of high quality, that they work (are efficacious), and are of a standard at least equal to that of comparable countries.

The *Therapeutic Goods Act 1989* commenced operation on 15 February 1991. Section 4 states as the Objects of the Act:

1. The objects of this Act are to do the following, so far as the Constitution permits:
  - a. 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:
    - i. used in Australia, whether produced in Australia or elsewhere; or
    - ii. exported from Australia;
  - b. to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.
- 1A The reference in paragraph (1)(a) to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.
2. This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.

To give effect to these objects, the Act provides a national framework for the regulation of therapeutic goods in Australia. This framework is administered by the Therapeutic Goods Administration (TGA) which is a division of the Department of Health and Ageing (the Department). The TGA is responsible through the Secretary of the Department to the Australian Government for the administration of the legislation.

A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use.

Therapeutic use means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury;
- influencing, inhibiting or modifying a physiological process;
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacing or modifying parts of the anatomy.

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<sup>16</sup> This outline of the TGA's activities is based on information provided by the TGA.

There are five sectors within the therapeutic goods industry:

- Prescription medicines
- Generic prescription medicines
- Over-the-counter medicines – e.g. pain relief, cold and flu preparations
- Complementary medicines - also known as 'traditional' or 'alternative' medicines, including vitamin, mineral, herbal, aromatherapy and homeopathic products
- Medical devices – which covers a wide range of products such as replacements hips, heart valves, bandages and dressings, hospital beds.

The TGA regulates therapeutic goods through:

- pre-market assessment;
- post-market monitoring and enforcement of standards;
- licensing of Australian manufacturers; and
- verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

The TGA's operations are fully cost-recovered. It derives all of its income from the fees and charges it levies on the therapeutic goods industry. The budget for 2010-11 is \$110.5M.

In undertaking its regulatory role, the TGA adopts a risk management approach by:

- identifying, assessing and evaluating the risks posed by therapeutic products;
- applying any measures necessary for managing the risks posed; and
- monitoring and reviewing risks over time.

This risk management approach means that differing standards are adopted in the assessment and management of therapeutic goods according to the perceived risk to the public of their use. So a medicine that has been used for many years, e.g. paracetamol, will not be subjected to the same degree of checking as a newly devised drug. Likewise, surgical dressings will not be examined and tested in the same way as an implant.

Under this risk management approach, 'registered' products are pre-evaluated for quality, safety and efficacy while 'listed' products are only reviewed for safety and quality. The latter must only contain pre-approved listable ingredients and be manufactured under GMP requirements. Listed products may also undergo post-market evaluation.

### **TGA Facts and Figures**

The TGA currently employs approximately 580 staff. This includes around 400 scientists.

In 2009-10 the TGA:

- completed 1720 evaluations for prescription medicines;
- approved 5,341 registrations of medical devices;
- approved 99 conformity assessments;
- finalised 1,835 Over-The-Counter medicine applications;
- received 163 new export listing applications; 91 variation applications; 11 self-assessable notifications; 1,690 Certificates of Pharmaceutical Product (CPP) applications; and 285 blood permits;
- tested 960 samples and products;
- approved 15,733 Special Access Scheme medicines;

- approved 2,991 Special Access Scheme medical devices;
- conducted 333 Australian and 136 overseas audits of therapeutic goods manufacturers;
- approved 3,213 manufacturing applications;
- considered 156 complaints relating primarily to advertising;
- reported on 1,938 medical device investigations;
- made 40 medicine, 1,107 human blood and 353 medical device recalls; and
- maintained the Australian Register of Therapeutic Goods (ARTG), which currently has over 62,600 entries with approximately 9,000 new entries added in the period, and around 4,700 entries cancelled.

The TGA is primarily located in Symonston in the ACT, but it also has staff located in Melbourne, Sydney, Adelaide and Brisbane.

### **TGA Reform Program**

In February 2009, the Australian Government agreed to implement a three-year program of administrative, structural and legislative reforms within the TGA aimed at enhancing the processes and practices of regulatory decision making for therapeutic goods. The reforms are intended to strengthen the risk management approach to ensuring public health and safety.

The reforms are designed to improve the TGA's capacity to deliver appropriate, consistent, effective, efficient, timely and transparent regulation of therapeutic products to meet the challenges of a modern regulatory environment. This requires in particular:

- matching the TGA's resources to risks associated with regulatory processes;
- enhancing the robustness of regulatory decision making and recordkeeping across the organisation;
- improving business processes to achieve greater efficiency and predictability for industry; and
- providing an overall shift in organisational culture towards greater consistency, transparency and efficiency.

#### **Achievements to date reported to the Panel include:**

- new administrative arrangements to align TGA into 3 streams
  1. market authorisation
  2. monitoring and compliance
  3. regulatory support
- transition to a reformed business process for the evaluation of prescription medicine
- commencing publication of Australian Public Assessment Reports on TGA decisions whether or not to approve an application for a prescription medicine
- progressive publication of Product Information and Consumer Medicine Information on the TGA website
- changes to therapeutic goods legislation to enable improved information disclosure and improved public reporting of outcomes of expert committees
- publication of orders made by the TGA relating to advertising complaints which are referred to the TGA by the Complaints Resolution Panel
- enhanced information management and decision support systems for effective operation of the regulatory framework, including a review of existing IT systems and an upgrading of the website;
- commencing consultation over potential reforms to advertising and medical device regulatory frameworks

## What legislation governs the TGA?

The TGA administers the *Therapeutic Goods Act 1989* (the Act) and the associated *Therapeutic Goods Regulations 1990*. The Act is made up of 69 sections (over 400 pages). The TGA is also responsible for the *Therapeutic Goods (Charges) Act 1989*.

The Act regulates supply, importation and export of goods in Australia. Only goods entered on the Australian Register of Therapeutic Goods (ARTG) can be marketed in Australia.

In addition, there are provisions allowing access to medicines and medical devices not on the ARTG. The Special Access Scheme allows those who are very ill to access products not on the ARTG which they or their doctors believe will assist them. There are also exemptions for personal importation, experimental uses and for doctors wishing to import and supply a product for a particular patient. These exemptions are not intended to facilitate the commercial supply of goods.

As a Division of the Department, the TGA is regulated by a large number of other Acts. This particularly includes the *Financial Management and Accountability Act 1997* and the *Public Service Act 1997*. In addition, the following Acts have some bearing on the transparency of the TGA decision-making:

- *Administrative Appeals Tribunal Act 1975*;
- *Administrative Decisions (Judicial Review) Act 1997*;
- *Ombudsman Act 1976*;
- *Freedom of Information Act 1982*;
- *Privacy Act 1988*;
- *Archives Act 1983*;
- *Electronic Transmissions Act 1997*;
- *Crimes Act 1914*;
- *Criminal Code Act 1995*;
- *Evidence Act 1995*;
- *Copyright Act 1968*;
- *Trademarks Act 1995*; and
- *Patents Act 1990*.

The Act contains provisions regarding the release of information (s 61).

## Decision making

The Minister for Health and Ageing (the Minister) and those delegated by the Minister have the authority to make decisions under the Acts administered by the TGA.

Delegates are supported in their decision making by a range of guidance material which has its basis in the relevant legislative and regulatory requirements, and generally steps through the application, evaluation and decision making processes. Guidance documents include Standard Operating Procedures (SOP). In accordance with the requirements of the *Freedom of Information Act 1982*, these documents are publicly available.

## TGA Advisory Committees

The assessment of evidence relating to applications is assisted by external evaluators and experts, through the advisory committee structure.

The TGA supports a range of external committees (both statutory and non-statutory) that provide advice to the TGA on matters related to the regulation of therapeutic goods.

Six committees are established under the Act and the Regulations. They are:

- Advisory Committee on Complementary Medicines (ACCM);
- Advisory Committee on Medical Devices (ACMD);
- Advisory Committee on Non-prescription Medicines (ACNM);
- Advisory Committee on Prescription Medicines (ACPM);
- Advisory Committee on the Safety of Medicines (ACSOM); and
- Therapeutic Goods Committee (TGC).

Recent changes to regulations have provided for the establishment of a seventh committee to support the regulation of biologicals. The TGA has commenced work to establish this committee.

The Regulations outline the functions, the required number of members, the expertise required of members, and the terms of membership, for each Committee.

In some cases, the legislation specifies what steps the Minister must take in appointing members to committee positions.

Recruitment for Committee vacancies, requiring ministerial appointment, is undertaken by:

- open invitation via the TGA website and/or other media seeking nominations of suitably qualified applicants, and
- written invitation to relevant professional colleges and peak bodies seeking nominees.

## What information is currently available to the public?

The TGA maintains a website that makes substantial information available about its operations. There are over 3,800 individual files on the website, with many files containing hundreds of pages of information.

In the 2009-10 financial year there were over 47 million visits to the TGA website.

The TGA launched a re-developed website on 4 May 2011. The website has been re-developed to provide better content, tailored to stakeholders, and to put processes in place that will allow stakeholders to more easily locate and understand the information the TGA is publishing. The TGA also publishes some material in the *Commonwealth of Australia Gazette* when it is required in legislation.

In addition to descriptive information, the website provides access to the Australian Register of Therapeutic Goods (ARTG). Therapeutic goods are divided broadly into two classes: medicines and medical devices. Before they may be supplied in or exported from

Australia, medicines must be entered as either registered or listed medicines, and medical devices (unless exempted) must be included, on the ARTG.

In November 2009 the TGA commenced publishing on the website Consumer Medicines Information (CMI) and Approved Product Information (PI) documents prepared by the sponsoring pharmaceutical companies. CMI contains information for the patient on the safe and effective use of a medicine. The PI document provides health professionals with a summary of the essential scientific information to allow the safe and effective use of a medicine. As at May 2011 approximately 76% of prescription medicines on the ARTG have PI published and 57% have CMI on the TGA website.

As a condition of registration, certain medicines, mainly those prescribed by an approved prescriber, are required to have a PI document which provides information relating to the safe and effective use of the medicine, including the medicine's usefulness and limitations. PI documents are written by the product sponsor and agreed with the TGA as part of the approval process before it can be made available in Australia.

In October 2009, the TGA commenced publishing Australian Public Assessment Reports for Prescription Medicine (AusPAR) containing information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve an application.

Where an application for approval of a prescription medicine has been approved, the AusPAR will generally be published within a month after the TGA has registered the product on the ARTG. This allows time for the AusPAR to be prepared and the company to review the proposed AusPAR. For applications that are rejected the AusPAR is not published until a 90 day appeal period is complete. No AusPAR is published if an application is withdrawn by the sponsor during the assessment process.

From 1 November 2010, orders made under regulation 9 of the Therapeutic Goods Regulations relating to advertising complaints which are referred to the TGA by the Complaints Resolution Panel have been published.

*Medicines Safety Update* is the drug safety bulletin of the TGA. This publication replaced the *Australian Adverse Drug Reaction Bulletin* at the beginning of 2010. *Medicines Safety Update* is published every 2 months in print in *Australian Prescriber* (which is distributed free-of-charge to over 50,000 subscribers by the NPS Better choices, Better health) and on the websites of the TGA and *Australian Prescriber*.

The *Update* is written by professional staff of the TGA. Topics are selected from issues identified from the TGA's post market medicines safety monitoring activities. It is written primarily for a health professional audience, although it is freely available for any reader. The publication aims to provide practical information and advice about avoiding known safety issues observed in adverse reaction reports to the TGA, as well as to inform readers of new safety issues that have been investigated by the TGA.

Media inquiries to the TGA are handled by its contracted media relations agency, McNiece Communications, which is an experienced media consultancy. In carrying out its media liaison role, it liaises with senior TGA officers regarding technical or scientific information to answer enquiries. Around 300 media inquiries were handled in 2009-10.

Additionally, the TGA responds to around 18,000 telephone calls annually to its 16 publicly advertised phone lines. This is in addition to responding to faxes received at 14 separate fax numbers and emails to 19 separate email addresses which are publicly advertised.

The TGA actively participates in conferences and seminars where it presents information on its processes. In addition, the TGA consults with stakeholders through the TGA-Industry Consultative Committee (TICC) which now includes consumer as well as industry representatives. Information on the TGA is also included as part of the Department of Health and Ageing's Annual Report.

### **Creation of an Australia New Zealand Therapeutic Products Agency (ANZTPA)**

On 20 June 2011 it was announced that the Australian and New Zealand Governments have agreed to proceed with a joint scheme for regulation of therapeutic goods (i.e. medicines, medical devices, etc).

The announcement said that the creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging economic integration and benefitting industry in both countries.

Over time, the joint arrangements will be administered by a single regulatory agency, the Australia New Zealand Therapeutic Products Agency, which will absorb the current regulators - Australia's Therapeutic Goods Administration and New Zealand's Medsafe.

## APPENDIX 4 - TRENDS IN PUBLIC DISCLOSURE BY COMPARABLE INTERNATIONAL REGULATORS

The Review was asked to consider “Arrangements for public disclosure of information utilised by comparable overseas regulators”. This Appendix outlines recent initiatives in public disclosure by the United Kingdom’s Medicines and Healthcare Products Regulatory Agency (MHRA); the European Medicines Agency (EMA); the United States of America’s Food and Drug Administration (FDA); and Health Canada.

### United Kingdom: Medicines and Healthcare Products Regulatory Agency

The Medicines and Healthcare Products Regulatory Agency (MHRA) was set up in April 2003 from a merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. The MHRA is an executive agency of the Department of Health.<sup>17</sup> The MHRA regulates the sale or supply of medicines (including prescription, over-the-counter, herbal, and homeopathic products), medical devices, advanced therapy medicinal products and blood and blood products for human use.

The MHRA’s main activities are similar to the TGA’s. The MHRA:

- assesses the safety, quality and efficacy of medicines and the performance of medical devices for sale or supply;
- operates post-market surveillance systems, including manufacturing audits;
- monitors and ensures compliance by manufacturers and others with legislation and takes enforcement action if appropriate;
- takes action to safeguard public health, such as issuing warnings and, removing or restricting the sale of products; and
- provides the public and health professions with authoritative information to enable informed dialogue on treatment choices.

The MHRA also performs some functions that are not of a kind presently undertaken by the TGA. It regulates clinical trials of medicines and medical devices; promotes good practice in the safe use of medicines and medical devices; and manages the General Practice Research Database (GPRD) and the British Pharmacopoeia (BP).

### MHRA Communication Strategy

The MHRA states that, since 2005, it has been working to develop an agency-wide communication strategy to underpin its mission of enhancing and safeguarding health by ensuring that high quality, timely and accurate information is widely available to inform decisions about the use of medicines and medical devices. Its initial strategic priorities have been to:

- improve the flow of information to healthcare practitioners;
- improve its media profile;
- improve internal communications;
- improve public engagement in the Agency’s work; and

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<sup>17</sup> <http://www.mhra.gov.uk/Aboutus/Whoweare/index.htm>

- promote more informed debate on the benefit and risk issues underpinning the work of the MHRA.<sup>18</sup>

In the period since 2005, the MHRA has allocated significant resources to work with:

- the public, including children and young people, and patient groups (in relation to clinical trials for example); and
- specific health care practitioners, such as hospital and community pharmacists.

The 2009/10 MHRA Annual Report and Accounts indicates the means that are used by it to involve stakeholders at an early stage of policy development in order to help shape policy in a manner which meets their perceived needs. By way of example, there have been discussion groups with patients, the public, healthcare practitioners and with children and young people to explore the possibility of making certain medicines for life-threatening and debilitating conditions available to patients earlier, and before a full licence is granted.

Legislative changes similar to Australian Freedom of Information legislation have facilitated greater public access to information, including that held by the MHRA. Industry's concerns about the protection of genuine commercial secrets/information led to a number of regulatory agencies agreeing in 2004 to a Memorandum of Understanding on Disclosure, and to publication in 2008 of the Guidance on Disclosure of Types of Human and Veterinary Medicines Information held by the Human and Veterinary Regulatory Authorities<sup>19</sup>. This document is a guide to the Access to Information legislation as applicable to the medicines industry. This legislation recognises that industry has particular sensitivities about the disclosure of information related to their commercial interests.

The Guidance identifies broad types of information (e.g. formulas, processes, unpublished aspects of intellectual property) that regulatory bodies may disclose on request, after checking if disclosure is in the public interest. While each request for information is treated on its own merits, the Guidance says that the checking process relating to public interest includes timely consultation with third parties who may have supplied the information, particularly commercially sensitive information. The Guidance notes that commercial sensitivity (particularly market sensitivity) may decrease with time and for this reason, the sensitivity of the information at the time of the request is the consideration.

However, the MHRA adopts the general approach that information should not be released until a decision has been made on the matter to which it relates. There is no disclosure of the making of applications.

### **MHRA Public Information**

The MHRA has implemented a proactive approach to the provision of public information which includes:

- collaboration with key stakeholders in developing risk communication campaigns, such as *Get Real, Get a Prescription* – a campaign about buying medicines online

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<sup>18</sup> MHRA Communications Strategy Summer 2005-April 2007

<sup>19</sup> <http://www.mhra.gov.uk/NewsCentre/CON2033022>

through unregistered pharmacies which involved cinema and TV advertising as well as more traditional publishing methods;

- providing adverse reaction data via the website;
- the establishment of a media office; and
- publication of Drug Safety Update Bulletins, and information card/ brochures for patients.

The MHRA has its own communication team. The team comprises 34 officers and looks after all information communicated both internally and externally. It handles 20,000 calls each year and 500 emails per week.

Four of the communication team constitute a dedicated press office. The office provides appropriately skilled persons to deal with media inquiries on a 24 hour basis every day. Technical officers within the Agency have been trained to deal with media inquiries and give interviews.

The MHRA press function was formerly provided by the Central Department of which the MHRA is a part. However, the MHRA says that the establishment of its own office has allowed greater use of the media for delivering positive messages rather than only being responsive to media requests or stories. It says that 50% of media stores are now proactive. The MHRA, while acknowledging that it is necessary to keep the Minister informed of what it is saying, the MHRA commented that it considers that having its own press office has improved its relationship with the Minister's office. It also asserts that the discipline flowing from being responsible for the conduct of its dealings with the press has resulted in a greater strategic thinking about its regulatory role.

The MHRA has a well publicised adverse event reporting scheme, the Black Triangle Scheme. The inverted Black Triangle symbol (▼) appears next to the name of a relevant product which contains an active ingredient which has been newly licensed for use in the United Kingdom (UK) and for which there is relatively limited information about its safety from clinical trials. Such pre-market trials generally involve only small numbers of eligible patients who take the medicine for a relatively short period of time which means that patients taking part in the trials may not be fully representative of those who will use the medicine when it is marketed.

New medicines are intensively monitored to ensure that any new safety hazards are identified promptly. The Commission on Human Medicines (CHM) and the MHRA encourages the reporting of all suspected reactions to newer drugs and vaccines, which are denoted by the black triangle (▼). This symbol appears next to the name of a relevant product in:

- the British National Formulary;
- the British National Formulary for Children;
- the Nurse Prescribers' Formulary;
- the Monthly Index of Medical Specialities;
- the Association of the British Pharmaceutical Industry Medicines Compendium;
- and
- [Drug Safety Update](#).

It also must appear on any advertising material.

The MHRA says that the Scheme is working well in that it highlights those drugs which are not regarded as dangerous but which have a priority for monitoring. There have been no complaints from industry about the operation of the Scheme. In the MHRA's view the Scheme has encouraged a greater engagement with new drugs by health practitioners and the public user. Around 80% of adverse drug reaction reports relate to black triangle medicines.

The MHRA has an adverse events reporting scheme. It attracts some 25,000 reports each year. Ten per cent of reports are patient generated, the rest coming from health practitioners, hospitals, etc. Reports can be made by going to the MHRA website and this has become the method used most frequently.

Adverse drug reaction data is provided via the MHRA website with a view to the public being able to find up-to-date information about medicine safety and draw informed conclusions. Adverse event reports are published monthly. It is the MHRA's view that this has not caused problems in the community and has encouraged reporting of adverse events.

In addition, in March 2011 the MHRA added a new section to its website which collates information about company-led drug recalls. The Agency had not previously communicated such information and did not issue Full Distribution Drug Alerts for these cases. Company-led recalls are usually cases with a known and limited distribution and it is seen as beneficial not to contact large numbers of unaffected individuals. The MHRA decided to publish limited information about these recalls on its website to allow anyone to seek more information from the company concerned if they wish and to provide a central resource for all such information. Company-led recalls are only published in one section of the website and do not result in a MHRA Drug Alert, MHRA email alert, Drug Safety Update notice or an alert to primary care trusts<sup>20</sup>.

### **Regulation of Homeopathic Products**

In January 2011 the MHRA commenced an informal consultation on the labelling of homeopathic products as part of its overall review of the *Medicines Act 1968*. In its introduction, the MHRA set out some provisional ideas and pointed out that regulation of homeopathic products are included in the European Union Directive on Pharmaceuticals and is a treaty obligation on the UK. It also noted that the greatest threat posed by homeopathy is that it may be advocated for the treatment or prevention of serious conditions. In recent years, homeopathic products being promoted for the prevention of malaria and the treatment of cancer have been removed from the UK market.

The MHRA paper<sup>21</sup> has proposed a number of changes to its labelling requirements to ensure these deliver clarity as to the status of the products and their composition. The paper also noted that its approach is driven solely by consideration of risk-benefit and the protection of public health.

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<sup>20</sup> <http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/DrugAlerts/Company-ledrecalls/index.htm>

<sup>21</sup>

<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/Othermedicinesconsultations/CON105929>

## European Union: European Medicines Agency

The European Medicines Agency (EMA) is a decentralised body of the European Union. Its main responsibility is the protection and promotion of public and animal health through the evaluation and supervision of medicines for human and veterinary use, including complementary and homeopathic medicines. In carrying out its role the EMA evaluates applications for European marketing of human and veterinary medicines; monitors the safety of medicines and takes appropriate action if adverse drug reaction reports suggest that the benefit-risk balance of a medicine has changed since its approval. The EMA also plays a role in stimulating innovation and research in the pharmaceutical sector.<sup>22</sup>

All EMA activities are conducted on a cost recovery basis except for those concerned with public health issues, including pharmacovigilance. These are funded through the European Union's contribution of around 20% of the Agency's annual budget<sup>23</sup>.

The EMA's committees are responsible for issuing opinions on the safety and efficacy of medicines, including for example marketing authorisation applications by pharmaceutical companies. These opinions are used by the European Commission as the basis of its legally-binding decisions. Through the EMA a single marketing authorisation is issued for all European Union countries, as well as Iceland, Liechtenstein and Norway. The centralised procedure for marketing is compulsory for the following groups of human medicines:

- human medicines for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, and viral diseases;
- medicines derived from biotechnology processes, such as genetic engineering;
- advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and
- officially designated 'orphan medicines' (medicines used for rare human diseases).

Each member state has its own procedures for the authorisation, within their own territory, of medicines that fall outside the scope of the centralised procedure.

The EMA does not have any role in relation to medical devices. This is discussed in the section European Assessment of Medical Devices.

On 26 January 2011, the EMA released its "Road map to 2015"<sup>24</sup> which proposes three priority areas for future action:

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<sup>22</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home\\_Page.jsp&murl=&mid=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&murl=&mid=22)

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/general/general\\_content\\_000130.jsp&murl=menus/about\\_us/about\\_us.jsp&mid=WC0b01ac0580029336](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&murl=menus/about_us/about_us.jsp&mid=WC0b01ac0580029336) Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of [medications](#), [biological products](#), herbal and [traditional medicines](#) with a view to:

- identifying new information about hazards associated with medicines; and
- preventing harm to patients.

<sup>24</sup> [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2011/01/WC500101373.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/01/WC500101373.pdf)

- addressing public health needs, for example by stimulating medicines development in areas of unmet need;
- facilitating access to medicines including by addressing the high-attrition rate during the medicines development process, and reinforcing the benefit/risk-balance assessment model; and
- optimising the safe and rational use of medicines by strengthening the evidence base in the post-authorisation phase to enable better regulatory decision making.

The expected outcomes of this program include enhancing patient safety by avoiding unnecessary risks as a result of the use of medicines; becoming a reference point for information on medicines evaluated by the Agency; and improving the decision-making process by taking due account of patient experience. In line with this approach, the EMA has already undertaken public consultation on a policy on access to safety data contained in EudraVigilance (adverse drug reaction) reports, but has not yet announced its policy.

The Panel has been told that the EMA is also moving towards the introduction of a scheme equivalent to the MHRA black triangle scheme.

The Agency says that openness and transparency have been adopted as fundamental values in the Agency's regulatory framework. These values are intended to allow stakeholders to understand the rationale for the Agency's scientific decision-making, and provide the basis on which patients and healthcare practitioners can have confidence in the EMA's decisions and information.

Over the last five years the EMA has concentrated on developing its patient and consumer focus. The work has included:

- a redesigned website to improve access to their information;
- the inclusion of patient organisations in their activities;
- redesigning patient leaflets (proposed by sponsors and approved by the EMA); and
- amending legislation to allow patients to be involved as individuals in the product approval process.

A Patient Working Group has been established which meets quarterly to provide advice to the Agency on specific projects, such as design of package information, patient focus in guideline documents and establishing a clinical trial with a patient focus.

The Agency's new pharmacovigilance policy has introduced 'public hearings' to their product approval processes. In addition, patients and members of the public are gradually being included on all scientific committees. Conflict of interest declarations for all committee members and staff are completed annually and published on the Agency's website.

### **EMA Public Information**

As part of the EMA's response to increasing public demand for more openness and transparency the EMA released its "Policy on access to documents (related to medicinal products for human and veterinary use)"<sup>25</sup> on 29 November 2010. Under the Policy it will give wider access to documents held by the Agency while it ensures that personal data and

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<sup>25</sup> [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2010/11/WC500099473.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf)

commercial in confidence information remain adequately protected. The EMA emphasises that the timing of release of information is significant in managing the competing interests.

As a general rule, the EMA will only release documents once a procedure concerning a medicine has been finalised in order that the decision-making process is protected. All applications are accounted for in terms of 'approved' or 'negative' outcomes, while for 'withdrawn' applications, the sponsor's letter of withdrawal is published as the explanation. European Public Assessment Reports (EPARs) can be searched by negative as well as positive outcomes and contain the reasons for the decisions.

The new policy gives access to all business-related documents unless there is a need to respect arrangements with other regulators or international organisations, or to protect the privacy and integrity of an individual. This includes the release of material submitted as part of marketing authorisation application, such as clinical trial reports. The EMA has produced general guidance on the types of documents it holds, whether they can be made available and whether they have to be redacted.

The decision whether to release a document or parts thereof may depend on the outcome of the balance between public and private interests. For instance, in case of a document containing information of commercial interest, the Agency has indicated it will consider the balance between the right of the applicant to gain access to documents and the interest of industry to have commercial confidential information duly protected.

The Agency has said it will ensure protection of commercial interest in accordance with the notion of commercial confidential information. In view of the lack of a legal definition, for the purpose of this policy 'commercial confidential information' is taken to mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. Implementation of the policy on access to documents will be a two stage process with the first phase focusing on reactive disclosure in response to written requests. In phase two, the EMA will gradually establish an electronic register of the documents held by the Agency which can be disclosed.

As part of their communication strategy, the EMA routinely issues a press release for each product approval, and a monthly report on changes and variations to product approvals.

As a further initiative to increase the transparency of medical research, the EMA recently launched its 'EU Clinical Trials Register' which for the first time gives the public access to information on interventional clinical trials in medicines authorised in the 27 Member States and also Iceland, Liechtenstein and Norway.

### **Europe: Assessment of Medical Devices**

At present Europe has no equivalent of the Australian Register of Therapeutic Goods. Regulatory directives about medical devices for the 27 member states of the European Union are developed by the European Commission, and each Member State is required to transpose the directive(s) into national law – resulting in a common regulatory framework across the Union, but administered individually at the national level.

The current medical devices regulatory framework in Europe requires, at the national level, each Member State to either establish or appoint an existing government agency to act as the *Competent Authority* for implementation of the regulatory framework, including designation of assessment bodies for the purpose of assessing the conformity assessment procedures applied by manufacturers to their products.

These assessment bodies are referred to as *Notified Bodies*, and may be designated for the assessment of some or all categories of medical devices, and for some or all conformity assessment procedures applicable to those devices.

Generally the *Competent Authority* acts as both the *Regulatory Authority* and *Designating Authority* for all devices in the jurisdiction, but this is not always the case. In many jurisdictions, a single authority is responsible for the regulation of medical devices, active implantable medical devices and in-vitro diagnostic devices. However in others, these device categories may be separated over two, or in some instances, three separate *Competent Authorities*.

As a consequence, across the 27 member States, there are 34 separate organizations for medical devices, which may perform all or only part of the work of implementation of the legislative requirements to implement the regulatory framework; conduct of regulatory activities such as post-market vigilance; and assessment and appointment of *Notified Bodies*.

Once a manufacturer, and their product(s) have been assessed by a *Notified Body* and appropriate certification has been issued, the manufacturer is able to affix the mark CE to the product and place the product on the market in that member state.

The European Commission is considering revisions to improve and strengthen the legal framework for medical devices, and to meet the growing expectations of European citizens. Experience has indicated that the current system does not always offer a uniform level of protection of public health in the European Union, with new and emerging technologies presenting challenges to the current framework. In addition, the Commission is considering ways in which the European industry can remain competitive in a globalized medical devices market.

In 2008, the European Commission consulted stakeholders on the revision of the legal framework for medical devices. At the time of writing this report, no advice has been provided on future directions in this work.

### **United States of America: Food and Drug Administration**

The Food and Drug Administration (FDA) is an agency within the United States of America (USA) [Department of Health and Human Services](#). The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of a much broader range of products than are assessed by the TGA. The range covers human drugs (including complementary medicines and homeopathic drugs), biological products, medical devices, food products, cosmetics, dietary supplements, veterinary drugs and products that emit radiation. It also regulates the manufacture, marketing, and distribution of tobacco products. The FDA receives approximately 26% of its income through cost recovery from industry.

The FDA's mandate says that it also has responsibility for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health.

### Transparency Initiative

In June 2009, as a result of a memorandum on Transparency and Open Government issued by President Obama, the FDA established an internal task force to develop recommendations for enhancing the transparency of the FDA's operations and decision-making processes. It had the aim of making the Agency's actions, decisions and underlying processes more transparent to the public, while still meeting the goal of appropriately protecting confidential information. It was noted that meeting this aim was likely to reduce the need for requests by the public under the USA's Freedom of Information Act.

The FDA has advanced its initiative in 3 phases:

- I. **FDA Basics:** The aim was to provide the public with basic information about the FDA and how it does its work. A new web-based resource, *FDA Basics*<sup>26</sup> was launched in January 2010. It includes questions and answers about the FDA; nine short videos that explain Agency activities; and conversations with fourteen FDA officials about the work of their offices within the FDA. Feedback to the site is being used to update and add to the resource.
- II. **Public Disclosure:** The aim was to proactively disclose information the FDA has in its possession, and to make information about the FDA's activities and decision-making more transparent, useful and understandable to the public, while protecting confidentiality of trade secrets and individually identifiable patient information. The information that was not then available to the public was inventoried and consideration given to whether the public health would benefit from its disclosure. In May 2010, the FDA released a draft report<sup>27</sup> containing 21 proposals for public comment on the proposals and on the priorities for implementation.

The final report has not yet been made available. However, in May 2011, as part of phase II activities, the FDA took the initiative to make enforcement and compliance activities accessible online, including making the final inspection classification public. In taking this initiative the FDA noted that access to this information will provide the public and regulated industry with more information about company practices that may jeopardise public health, as well as about companies that have had satisfactory FDA inspections; information about recall and enforcement activities that will help consumers make decisions about products; and information about inspection results, which can be expected to create greater incentive to bring practice into compliance with the law. The FDA has plans to extend the available information by the end of 2011.

- III. **Transparency to Regulated Industry:** The aim of this phase is to address ways the FDA can be more transparent to the regulated industry as a means of fostering a more

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<sup>26</sup> <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm2021108.htm>

<sup>27</sup> <http://www.fda.gov/AboutFDA/Transparency/PublicDisclosure/default.htm>

efficient and cost-effective regulatory process. In January 2011, the FDA released the report<sup>28</sup> of this phase which identified 19 steps the FDA is taking. These steps can be broadly grouped under the headings of:

- *Better Communication* - 6 actions relating to improving communication to industry about FDA policies and procedures, strategic priorities, organisational structure and leadership, improving response times to web-based requests;
- *A More Transparent Review Process* – 4 actions which are intended to improve transparency during the product applications review process development of additional guidance re meetings with sponsors, the types of notifications it provides to industry, expectations about the use of secure email and details of the information flow about a sponsor's application;
- *Guidance and Regulations* – 2 actions focus on greater transparency in the guidance development process including identification of best practice, and participation in guidance development and 2 actions in the regulations development process to contact affected parties when significant new obligations are to be imposed and improving the accuracy of timetables in the FDA's published regulatory agenda; and
- *Communications with Importers* – 5 actions address issues for the importing community to improve the flow of information and clarify procedures.

The report also contained five additional proposals for comment by the regulated industry. These covered the proposed publication of timelines for guidance development processes; posting on the website any presentations given by staff to external audiences; information to submitters about appeal processes; procedures relating to electronic submission of documents by importers; and initiating planning for an additional web resource for importers. The FDA allowed a 60 day period for public comment, and is now assessing the input and preparing recommendations for future action.

In releasing the draft "Strategic Priorities 2011-2015" in September 2010, the Commissioner of Food and Drugs, Margaret A Hamburg underlined the importance of not only giving partners and stakeholders insights into the Agency's work, but also promoting public participation by increasing the opportunities for input and feedback, as a means of harnessing ideas from inside and outside the Agency.

### **FDA Public Information**

In advancing its Transparency initiative, the FDA has given significant attention to the way in which stakeholders can access the volume of information available through its website. In the first instance, as noted above, FDA **Basics** was launched to explain what the agency does and how regulated products are approved for sale.

This was followed in January 2011 by the next stage of the website redevelopment, **FDA Basics for Industry**.<sup>29</sup> This addresses basic questions for industry about regulated products and provides a web-based navigation guide for manufacturers. It includes easier access to frequently requested material, such as guidance documents, information about the review process and about registration and listing information.

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<sup>28</sup> <http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/default.htm>

<sup>29</sup> <http://www.fda.gov/AboutFDA/Transparency/TransparencytoRegulatedIndustry/default.htm>

In addition, **FDA-TRACK** has been introduced as the new Agency wide performance monitoring system for the over 100 FDA program offices. Performance measures are reported on monthly, enabling external and internal users to monitor performance, especially on important projects and programs. Its name stands for Transparency; Results; Accountability; Credibility; and Knowledge. Each FDA office is progressively adding its performance measures and reports against them.

These three information sources now provide access into the FDA for all stakeholders and build on the pre-existing services, such as the 'FDA For You' sections (for consumers, industry and health practitioners) which provide information and advice appropriate to each audience.

The FDA has different systems for complaints and adverse event reporting, depending on the nature and severity of the issue. *Consumer Complaint Reporting* is used for therapeutic goods complaints such as adverse events after taking dietary supplements, and problems with prescription and over-the-counter medications. *MedWatch* is for reporting serious adverse events, product quality problems, product use error and problems with a different manufacturer of the same medicine (i.e. not getting the same result from a generic as from a brand name drug, or from another generic). *Emergencies* can be reported to a 24-hour emergency line or to a local area FDA Consumer Complaint Coordinator.

A separate system, the *Vaccine Adverse Event Reporting System*, is jointly sponsored by the FDA and the Centres for Disease Control and Prevention. It provides a nationwide mechanism by which adverse events can be reported, analysed and made available to the public. It is also used to provide vaccine safety information suitable for parents, carers, health practitioners, vaccine manufacturers and state vaccine programs.

In its May 2010 draft report "*Transparency Initiative: Draft Proposals For Public Comment Regarding Disclosure Policies*" the Transparency Task Force said the FDA had adopted the following definition of trade secret:

A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

It noted that trade secrets include such things as a company's manufacturing processes and precise product formulations. The Task Force put the view that trade secrets have limited value for public disclosure, and that the value for public disclosure of other types of data, such as clinical trial results and adverse event reports, is significantly greater.

The draft report indicated that data relating to manufacturing methods and processes, which is the direct result of innovative efforts, deserves protection because keeping trade secret information confidential maintains investment in new product development and thus is important to fostering innovation.

As a result, it proposed that trade secrets should remain confidential. Where such trade secrets exist in the documents proposed for public disclosure in the draft report, the Task Force supported their redaction from the documents before the documents are disclosed.

FDA's current practice is to treat a substantial amount of the information that is submitted to FDA by companies and that does not fall under FDA's definition of trade secrets as confidential commercial information that is not publicly disclosed.

The Task Force examined the categories of information currently withheld as confidential commercial information. In some cases, the Task Force found that some firms are already disclosing certain information FDA currently treats as confidential commercial information. In those cases, the Task Force concluded that there may be little public benefit to withholding the information.

In other cases, the Task Force weighed the interests of the public in disclosure and the competitive interests that may be affected by disclosure of the information currently considered confidential commercial information. As noted earlier, the outcomes of the FDA's consultations on this document have not yet been made available.

### **Health Canada**

The Food and Drugs legislation and regulations authorise Health Canada to regulate the safety, efficacy and quality of therapeutic products. The Agency works in a similar fashion to the TGA in evaluating and monitoring the safety, efficacy and quality of human and veterinary drugs, medical devices, natural health products and other therapeutic products available to Canadians.

Responsibility for this process rests with Health Canada's Health Products and Food Branch (HPFB) which is also similar to that of the TGA, although it also has responsibility for the safety and quality of food. However, the size of the two organisations is significantly different with the HPFB with more than 2,200 staff in comparison to around 580 TGA staff.

The HPFB processes are summarised in the three following components:

- Pre-market review. Before a therapeutic product is authorised for sale in Canada, the manufacturer must provide HPFB with scientific evidence of its safety, efficacy and quality, as defined by regulations. The evidence is then reviewed to determine whether the risks associated with the product are acceptable in light of its potential benefits. If they are, and if the product has been proven to be effective under specified conditions, it is approved for sale in Canada.
- Post-market surveillance, inspection and investigation. Once therapeutic products reach the market, the Branch monitors them for safety, efficacy and quality. Reports of suspected problems are received from manufacturers, health care practitioners and consumers, and the Branch evaluates them and takes appropriate action if a serious health risk is identified. Such actions can range from issuing warnings to the public and the health care community to removing a product from the market. Among its other functions, the Branch also conducts inspections, investigates products, and licenses laboratories and manufacturing facilities. It uses formal risk management principles and scientific methods to arrive at its decisions, with a view to optimising public safety, product availability and product quality.

- Working with others: The Branch has developed strong partnerships with other levels of government, academia and stakeholders to ensure that their perspectives are included in its assessment of the health benefits and risks of every therapeutic product it reviews. Participants in the regulatory process include patients and consumers, health care practitioners, research scientists, industry, academic institutions, pharmacies, hospitals, regulatory scientists and policy makers.<sup>30</sup>

In its 2007-12 Strategic Plan, the HPFB set the goal to “remain a modern and responsive regulator”<sup>31</sup>, including adopting a lifecycle approach to regulating health products; establishing strategic partnerships to fulfil its mandate; and better integrating transparency, openness and accountability into its day-to-day work. It says that the work will include, inter alia, improving processes around compliance and enforcement activities; increasing public input into the review of regulated products; and early, consistent engagement with stakeholders and the public in decision-making processes.

Central to this latter point is the continued implementation of its Public Involvement Framework which requires a structured process for engagement with the public at differing levels. A previous Public Advisory Committee was disbanded in 2007 in favour of using a wider variety of involvement methods to inform and involve the stakeholders. Some of these are inclusion of patients on expert advisory committees, and seeking input through public forums, public meetings, and workshops.

The Canada Vigilance Adverse Reaction Online Database contains information about suspected adverse reactions to health products drawn from adverse reaction reports submitted to Health Canada. These reports are made by consumers and health practitioners, who submit reports voluntarily, as well as by manufacturers and distributors, who are required under legislation to submit reports. Information concerning vaccines used for immunization is provided in the Vaccine Safety section of the Public Health Agency of Canada Website<sup>32</sup>.

Health Canada has implemented a cost recovery framework in which around 80% of costs are fully recovered from industry. Costs are recovered for four specific fee categories. The system uses a cost sharing formula based on the relative level of benefit received by the fee paying industry in relation to the public benefit derived from the activity.

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<sup>30</sup> [http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic\\_acces-therapeutique-eng.php#8.2](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php#8.2)

<sup>31</sup> Health Canada, Health Products and Food Branch “2001-12 Strategic Plan’ p. 3

<sup>32</sup> <http://www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php>

## APPENDIX 5 - PUBLIC SUBMISSIONS TO THE TGA TRANSPARENCY REVIEW

The Transparency Review Panel received a total of 118 written comments or submissions from individuals and organisations from 22 December 2010 to 11 February 2011 (the closing date for public submissions). All submissions were made available on the TGA website.

### A

- [Consultation submission: Accord Australia \(pdf,268kb\)](#)
- [Consultation submission: Advisory Committee on Prescription Medicines \(ACPM\) \(pdf,538kb\)\\*](#)
- [Consultation submission: Advisory Committee on the Safety of Medicines \(ACSOM\) \(pdf,58kb\)](#)
- [Consultation submission: Amway of Australia \(pdf,18kb\)](#)
- [Consultation submission: Andrewartha, Shane \(pdf,40kb\)](#)
- [Consultation submission: Archer Emery & Associates \(pdf,47kb\)](#)
- [Consultation submission: ARCS Australia Ltd \(pdf,1.1Mb\)\\*](#)
- [Consultation submission: Arola, Travis, KTI Biologicals Inc \(pdf,71kb\)](#)
- [Consultation submission: Arthritis Australia \(pdf,1.7Mb\)\\*](#)
- [Consultation submission: Asthma Australia \(pdf,213kb\)](#)
- [Consultation submission: Australasian Tissue & Biotherapeutics Forum \(pdf,161kb\)](#)
- [Consultation submission: Australian & New Zealand Association of Physicians in Nuclear Medicine \(ANZAPNM\) \(pdf,58kb\)](#)
- [Consultation submission: Australian Commission on Safety & Quality \(pdf,48kb\)](#)
- [Consultation submission: Australian Customs & Border Protection Services \(pdf,53kb\)](#)
- [Consultation submission: Australian Dental Industry Association \(ADIA\) \(pdf,197kb\)](#)
- [Consultation submission: Australian Dental Industry Association \(ADIA\) \(pdf,57kb\)](#)
- [Consultation submission: Australian Doctor \(pdf,22kb\)](#)
- [Consultation submission: Australian Health Practitioner Regulation Agency \(pdf,1.1Mb\)](#)
- [Consultation submission: Australian Medicines Handbook \(pdf,193kb\)](#)
- [Consultation submission: Australian Nursing Federation \(pdf,149kb\)](#)
- [Consultation submission: Australian Orthopaedic Association \(pdf,181kb\)](#)
- [Consultation submission: Australian Pesticides and Veterinary Medicines Authority \(APVMA\) \(pdf,26kb\)](#)
  - [Discussion on 29 March 2011: Australian Pesticides and Veterinary Medicines Authority \(APVMA\) \(pdf,25kb\)](#)
- [Consultation submission: Australian Rheumatology Association \(pdf,260kb\)](#)
- [Consultation submission: Australian Red Cross Blood Service \(pdf,42kb\)](#)
- [Consultation submission: Australian Self Medication Industry \(ASMI\) \(pdf,88kb\)](#)
- [Consultation submission: Australian Self Medication Industry \(ASMI\) \(pdf,91kb\)](#)
- [Consultation submission: Australian Skeptics \(Victorian Branch\) \(pdf,164kb\)](#)

- [Consultation submission: Australian Society of Anaesthetists \(pdf,134kb\)](#)

## B

- [Consultation submission: Baxter Healthcare \(pdf,24kb\)](#)
- [Consultation submission: Breast Cancer Network Australia \(pdf,52kb\)](#)
- [Consultation submission: Brookman, David \(pdf,200kb\)](#)
- [Consultation submission: Butler, Shane \(pdf,28kb\)](#)

## C

- [Consultation submission: Cancer Council WA \(pdf,85kb\)](#)
- [Consultation submission: Care Pharmaceuticals \(pdf,2.5Mb\)\\*](#)
- [Consultation submission: Carers Australia WA \(pdf,61kb\)](#)
- [Consultation submission: Carroll, Peter \(pdf,47kb\)](#)
- [Consultation submission: Clark, John \(pdf,31kb\)](#)
- [Consultation submission: Cohen, Steve \(pdf,35kb\)](#)
- [Consultation submission: Coleman, Keith \(pdf,10kb\)](#)
- [Consultation submission: Collins, Michael \(pdf,40kb\)](#)
- [Consultation submission: Commonwealth Ombudsman, NSW \(pdf,94kb\)](#)
- [Consultation submission: Complementary Healthcare Council of Australia \(CHC\) \(pdf,90kb\)](#)
- [Consultation submission: Consumers Health Forum of Australia \(CHF\) \(pdf,1.2Mb\)\\*](#)
- [Consultation submission: Consumers Health Forum of Australia \(CHF\) \(pdf,79kb\)](#)
- [Consultation submission: Council of Australian Therapeutic Advisory Groups \(pdf,36kb\)](#)
- [Consultation submission: CRANAplus \(pdf,11kb\)](#)
- [Consultation submission: Cranwick, Dr Noel \(pdf,35kb\)](#)
- [Consultation submission: Crossing, Sally, Cancer Voices NSW \(pdf,108kb\)](#)

## D

- [Consultation submission: Department of Health, Government of WA \(pdf,111kb\)](#)
- [Consultation submission: Department of Health, Victoria \(pdf,150kb\)](#)
- [Consultation submission: Direct Selling Association of Australia \(pdf,138kb\)](#)
- [Consultation submission: Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee \(pdf,138kb\)](#)
- [Consultation submission: Dunlop, Dr Rachel \(pdf,179kb\)](#)

## E

- [Consultation submission: Endocrine Society of Australia \(pdf,288kb\)](#)

## F

- [Consultation submission: Friends of the Earth \(pdf,737kb\)\\*](#)
- [Consultation submission: Friends of the Earth \(pdf,110kb\)](#)

## H

- [Consultation submission: Hanigan, Graeme \(pdf,464kb\)](#)
- [Consultation submission: Heywood, Jennifer \(pdf,70kb\)](#)
- [Consultation submission: Holley, Associate Professor Loraine \(pdf,17kb\)](#)

## I

- [Consultation submission: IVD Australia \(pdf,732kb\)\\*](#)

## J

- [Consultation submission: Jansons, Sergei \(pdf,27kb\)](#)
- [Consultation submission: Jarman, Julie \(pdf,10kb\)](#)
- [Consultation submission: Johnson & Johnson Family of Companies \(pdf,210kb\)](#)

## K

- [Consultation submission: Kelly, David \(pdf,70kb\)](#)
- [Consultation submission: Kertz, John \(pdf,261 kb\)](#)

## L

- [Consultation submission: Love, Professor Bruce \(pdf,39kb\)](#)
- [Consultation submission: Lucire, Dr Yolande \(pdf,96kb\)](#)
- [Consultation submission: Lucire, Dr Yolande \(pdf,54kb\)](#)
- [Consultation submission: Lucire, Dr Yolande \(pdf,26kb\)](#)
- [Consultation submission: Lurton, Robert \(pdf,25kb\)](#)

## M

- [Consultation submission: McDonald, Professor Peter \(pdf,28kb\)](#)
- [Consultation submission: McLeod, Mr Ken \(pdf,83kb\)](#)
- [Consultation submission: McNeil, Helen \(pdf,19kb\)](#)
- [Consultation submission: Maiwald, Matthias \(pdf,925kb\)\\*](#)
- [Consultation submission: Marcus, Alison \(pdf,16kb\)](#)
- [Consultation submission: Marron, Loretta \(pdf,394kb\)](#)
- [Consultation submission: Medical Oncology Group of Australia Incorporated \(pdf,189kb\)](#)
- [Consultation submission: Medical Technology of Australia \(MTAA\) \(pdf,152kb\)](#)
- [Consultation submission: Medical Technology of Australia \(MTAA\) \(pdf,171kb\)](#)
- [Consultation submission: Medication Services QLD \(pdf,326kb\)](#)
- [Consultation submission: Medicines Australia \(pdf,70kb\)](#)
- [Consultation submission: Medicines Australia \(pdf,78kb\)](#)
- [Consultation submission: Medtronic \(pdf,46kb\)](#)
- [Consultation submission: Mental Health Council of Australia \(pdf,115kb\)](#)
- [Consultation submission: Mills, Bayani \(pdf,27kb\)](#)
- [Consultation submission: MIMS \(pdf,92kb\)](#)
- [Consultation submission: Mordi Skeptics \(pdf,183kb\)](#)

**N**

- [Consultation submission: National Prescribing Service \(NPS\) \(pdf,4.1Mb\)\\*](#)
- [Consultation submission: Newsome, Brad \(pdf,67kb\)](#)
- [Consultation submission: NSW Therapeutic Advisory Group Inc. \(pdf,48kb\)](#)

**O**

- [Consultation submission: Optometry Board of Australia \(pdf,27kb\)](#)

**P**

- [Consultation submission: Pfizer Australia Pty Ltd \(pdf,47kb\)](#)
- [Consultation submission: Pharmacare \(pdf,328kb\)](#)
- [Consultation submission: Pharmaceutical Society of Australia \(pdf,155kb\)](#)
- [Consultation submission: The Pharmacy Guild of Australia \(pdf,158kb\)](#)
- [Consultation submission: Public Health Association of Australia \(pdf,576kb\)\\*](#)

**R**

- [Consultation submission: Ratnayeke, Mr Mani \(pdf,17kb\)](#)
- [Consultation submission: Real Health Care Reform Pty Ltd \(pdf,125kb\)](#)
- [Consultation submission: Real Health Care Reform Pty Ltd \(pdf,47kb\)](#)
- [Consultation submission: Regulatory Solutions \(pdf,77kb\)](#)
- [Consultation submission: Reilly, Wesley \(pdf,15kb\)](#)
- [Consultation submission: Robertson, Geraldine \(pdf,62kb\)](#)
- [Consultation submission: Lock, Dr Chris \(pdf,17kb\)](#)
- [Consultation submission: Royal Australian and New Zealand College of Psychiatrists \(RANZCP\) \(pdf,118kb\)](#)
- [Consultation submission: Royal Australian and New Zealand College of Radiologists \(pdf,22kb\)](#)
- [Consultation submission: Royal College of Pathologists of Australasia \(pdf,50kb\)](#)

**S**

- [Consultation submission: Sanofi Aventis \(pdf,64kb\)](#)
- [Consultation submission: Smallwood, Robert \(pdf,93kb\)](#)
- [Consultation submission: Standards Australia \(pdf,34kb\)](#)
- [Consultation submission: Stenning, Gordon \(pdf,66kb\)](#)
- [Consultation submission: Sweet, Graham \(pdf,71kb\)](#)
- [Consultation submission: Sweet, Melissa \(pdf,261kb\)](#)

**T**

- [Consultation submission: Therapeutic Guidelines Limited \(pdf,122kb\)](#)
- [Consultation submission: Thornton, Dr Helen \(pdf,28kb\)](#)
- [Consultation submission: Tivendale, Charles \(pdf,32kb\)](#)

**V**

- [Consultation submission: Verberne, Daniel \(pdf,27kb\)](#)
- [Consultation submission: Vitry, Dr Agnes \(pdf,95kb\)](#)

**W**

- [Consultation submission: Williams, Mrs M \(pdf,80kb\)](#)

\*Large file warning: Attempting to open large files over the Internet within the browser window may cause problems. It is strongly recommended you [download this document to your own computer](#) and open from there.

Historical document

## APPENDIX 6 - COPY: ADVERTISEMENT FOR NATIONAL DAILY PAPERS

Saturday 15 January 2011

### Review to improve transparency of the Therapeutic Goods Administration (TGA)

The Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, has initiated a comprehensive review of the way the TGA communicates its regulatory processes and decisions.

A Review Panel of consumer, health professional and therapeutic goods industry representatives is being chaired by Professor Dennis Pearce AO.

The Panel is to report at the end of April 2011 on:

- opportunities to provide more information about products on the market;
- how the public can improve its understanding of the ways new products are assessed and products on the market are monitored;
- the timing for making information available about new products;
- the type of information and how it is made public by comparable overseas regulators;
- constraints (or barriers) to the release of further information, such as implications for public health and safety;
- how the material can be published - e.g. use of the internet and other publication methods; and
- opportunities for the public to access more information about the advertising of therapeutic goods.

For more information visit the TGA website: [Call for input: Review to improve transparency of the Therapeutic Goods Administration \(TGA\)](#)

If you would like to make a comment or a submission you can either:

email it to the Review Secretariat at [transreviewpanel@tga.gov.au](mailto:transreviewpanel@tga.gov.au)

or mail it to:

Transparency Review Secretariat  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

Submissions must reach the Secretariat no later than Friday 11 February 2011. Please note that any comment or submissions you provide will be made available to the public.

## APPENDIX 7 – LETTER OF INVITATION TO STAKEHOLDERS



### **Panel to Review the Transparency of the Therapeutic Goods Administration**

Dear Sir/Madam

As the Chair of the Panel to Review the Transparency of the Therapeutic Goods Administration (TGA), I am writing to invite you to make a submission to the Review.

The Review was announced by the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP on 16 November 2010. The purpose of the Review is to improve the TGA's transparency. In particular, it will focus on the way the TGA communicates its regulatory processes and decisions.

The purpose of the project is to improve public knowledge of the TGA's regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions.

The Review Panel includes consumer, health professional and therapeutic goods industry representatives and I have been asked to report by the end of April 2011.

The Panel has been asked to report on:

- opportunities to provide more information about products on the market;
- how the public can improve its understanding of the ways new products are assessed and products on the market are monitored;
- the timing for making information available about new products;
- the type of information and how it is made public by comparable overseas regulators;
- constraints (or barriers) to the release of further information, such as implications for public health and safety;
- how the material can be published – e.g. use of the internet and other publication methods; and
- opportunities for the public to access more information about the advertising of therapeutic goods.

For the full Terms of Reference, membership of the Panel and to read comments already provided to the Panel by some individuals and organisations please visit the TGA website at <http://www.tga.gov.au/consult/tga-transparency-Review.htm>.

In particular, the Panel would like to hear from consumers about:

- instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- the type of information that could have helped you;
- the way you would like to access that information – e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;
- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful; and
- what other information you use.

If you are a health professional the Panel would like your comments on:

- information provided by the TGA on the safety, quality and efficacy of medicines and the safety, quality and performance of medical devices included on the Australian Register of Therapeutic Goods (ARTG) including:
  - Australian Public Assessment Reports for prescription medicines;
  - Approved Product Information;
  - Consumer Medicine Information;
  - Public summary documents on the ARTG;
  - TGA Advisories and Medicines Safety Updates; and
- any problems that you have encountered in regard to the transparency of TGA processes and decision-making.

If you participate in the production or marketing of therapeutic goods, please provide comment on:

- what ways you think the TGA could provide greater assistance to you in the evaluation and registration, listing or marketing processes; and
- any issues that you have encountered in regard to the transparency of TGA processes and decision-making.

If you work in the media, we would appreciate your comments on the timeliness, quality and utility of information provided in response to enquiries and/or Freedom of Information requests.

You are invited to comment on any matters relevant to the Terms of Reference.

Please note that all submissions will be made available on the TGA website.

To make a comment or a submission you can either email it to the Review Secretariat at [TransReviewPanel@tga.gov.au](mailto:TransReviewPanel@tga.gov.au) **OR** mail it to:

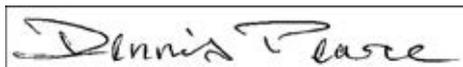
Transparency Review Secretariat  
Therapeutic Goods Administration  
P O Box 100  
WODEN ACT 2606

Submissions must reach the Secretariat no later than **Friday 11 February 2011**.

The Panel will hold a limited number of public meetings in late February and March 2011 and details about these will be provided on the TGA website on Thursday 3 February 2011.

I look forward to receiving your views.

Yours sincerely



Dennis Pearce AO  
18 January 2011

## APPENDIX 8 – PUBLIC MEETING ADVERTISEMENTS



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**The Panel to Review the Transparency of the  
Therapeutic Goods Administration invites you to a  
Public Meeting with Panel Members  
Monday 28 February 2011,  
The Chifley, 648 Dean Street, Albury 9.30am-1.00pm**

The Review Panel would like to hear from **consumers, healthcare professionals and industry stakeholders:**

- about instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- what type of information could have helped you;
- the way you would like to access that information - e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;
- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful?
- what other information you use?

The aim of the review is to improve public knowledge of regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions.

### **About the Therapeutic Goods Administration**

The Therapeutic Goods Administration (TGA) is responsible for assuring the quality, safety and efficacy of therapeutic goods including:

- prescription and over-the-counter medicines (such as pain relievers and cough and cold preparations);
- complementary medicines (including vitamin and mineral supplements, and herbal medicines); as well as
- medical devices (including blood pressure measuring devices, orthopaedic joint replacements, heart valves and diagnostic imaging equipment, such as CT scanners.

**To attend: email [transreviewpanel@tga.gov.au](mailto:transreviewpanel@tga.gov.au) giving your name and contact details (email and phone number) OR call telephoning Anne Cianci on 02 6232 8427**



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**The Panel to Review the Transparency of the  
Therapeutic Goods Administration invites you  
to a Public Meeting with Panel Members**

**Tuesday, 01 March 2011,  
Intercontinental, Melbourne The Rialto, 495 Collins Street, Melbourne  
9.30am-1.00pm**

The Review Panel would like to hear from **consumers, healthcare professionals and industry stakeholders:**

- about instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- what type of information could have helped you?
- the way you would like to access that information - e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;
- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful?
- what other information you use?

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**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**The Panel to Review the Transparency of the  
Therapeutic Goods Administration invites you to a  
Public Meeting with Panel Members  
Wednesday 23 February 2011,  
1.00pm-4.00pm  
The Sebel, 350 Church Street, Parramatta**

The Review Panel would like to hear from **consumers, healthcare professionals and industry stakeholders:**

- about instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- what type of information could have helped you?
- the way you would like to access that information - e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;
- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful?
- what other information you use?

The aim of the review is to improve public knowledge of regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions.

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**To attend: email [transreviewpanel@tga.gov.au](mailto:transreviewpanel@tga.gov.au) giving your name and contact details (email and phone number) OR call telephoning Anne Cianci on 02 6232 8427**



**Australian Government**

**Department of Health and Ageing  
Therapeutic Goods Administration**

**The Panel to Review the Transparency  
of the Therapeutic Goods Administration  
invites you to a Public Meeting with Panel Members  
Friday, 04 March 2011,  
The Rydges, Cnr King & Hay Streets, Perth  
9.30am-1.00pm**

The Review Panel would like to hear from **consumers, healthcar  
professionals and industry stakeholders:**

- about instances where it could have been useful for you to have had access to better information about your medicine, supplement or device;
- what type of information could have helped you?
- the way you would like to access that information - e.g. on the internet or other electronic media; through your doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device;
- whether you have ever looked for information provided by the TGA and, if so, where did you find it and was it helpful?
- what other information you use?

The aim of the review is to improve public knowledge of regulatory decision-making and to enhance public understanding of the benefits and risks of therapeutic goods so that the Australian community can understand how the TGA operates and the reasons for its key decisions.

**About the Therapeutic Goods Administration**

The Therapeutic Goods Administration (TGA) is responsible for assuring the quality, safety and efficacy of therapeutic goods including:

- prescription and over-the-counter medicines (such as pain relievers and cough and cold preparations);
- complementary medicines (including vitamin and mineral supplements, and herbal medicines); as well as
- medical devices (including blood pressure measuring devices, orthopaedic joint replacements, heart valves and diagnostic imaging equipment, such as CT scanners.

**To attend: email [transreviewpanel@tga.gov.au](mailto:transreviewpanel@tga.gov.au) giving your name and contact details (email and phone number) OR call telephoning Anne Cianci on 02 6232 8427**

## APPENDIX 9 – GROUP DISCUSSION QUESTIONS

### Consumers:

- What type of information should TGA provide about medicines, supplements and devices?
- How adequate is the information provided by the TGA on the safety, quality and efficacy of medicines and the safety, quality and performance of medical devices included on the Australian Register of Therapeutic Goods (ARTG)?
- How easy is it to access this information?
- In what way should that information be provided to consumers – e.g. on the internet or other electronic media; through a doctor, pharmacist or health professional; in a brochure or handout about a specific medicine or a therapeutic device?
- How should information provided by TGA best be updated and who should be responsible for this?
- There is limited capacity for manufacturers of therapeutic goods to advertise their availability to the general public. The TGA has a role in ensuring that advertisements are truthful. Are you aware of seeing any advertisements for therapeutic goods (e.g. on TV, in magazines etc)?
- Do you know how to make a complaint about an advertisement for a therapeutic good? Have you ever done so; and if yes, comment on your experience with the process?
- What other issues relevant to the interests of consumers and falling within the terms of reference should be considered by the review Panel?

### Health practitioners:

- How adequate is the information provided by the TGA on the safety, quality and efficacy of medicines and the safety, quality and performance of medical devices included on the Australian Register of Therapeutic Goods (ARTG)?
- Consider in particular the information provided in:
  - Australian Public Assessment Reports for prescription medicines;
  - Approved Product Information;
  - Consumer Medicine Information;
  - Public summary documents on the ARTG;
  - TGA Advisories and Medicines Safety Updates.
- How easy is it to access this information?

- Have you encountered problems in regard to the transparency of TGA processes and decision-making?
- What can be done to make the advertising processes relating to therapeutic goods more transparent?
- What other issues relevant to the interests of health professionals and falling within the terms of reference should be considered by the review Panel?

**Producers and marketers of therapeutic goods:**

- In what ways could TGA provide greater assistance in the evaluation and registration, listing or marketing processes?
- Consider in particular:
  - the adequacy of guidelines; and
  - the provision of information relating to the making, withdrawal or refusal of applications (either to applicants or publicly or both).
- What information additional to that presently made publicly available by TGA could be released without raising confidentiality issues?
- Any issues that you have encountered in regard to the transparency of TGA processes and decision-making?
- The scope and significance to your activities of commercial in confidence limitations on access to information?
- What can be done to make the advertising processes relating to therapeutic goods more transparent?
- What other issues relevant to the interests of producers and marketers and falling within the terms of reference should be considered by the Review Panel?

**Media representatives:**

- The timeliness, quality and utility of information provided in response to enquiries and/or Freedom of Information requests?
- What are your information needs?
- Are there ways the TGA could meet your needs more effectively, and if so, how?
- What can be done to make the advertising processes relating to therapeutic goods more transparent?

Historical document

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6232 8605  
[www.tga.gov.au](http://www.tga.gov.au)