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Performance Audit

Therapeutic Goods Regulation: Complementary Medicines

Department of Health and Ageing

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
30 August 2011

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken an independent performance audit in the Department of Health and Ageing with the authority contained in the *Auditor-General Act 1997*. Pursuant to *Senate Standing Order 166* relating to the presentation of documents when the senate is not sitting, I present the report of this audit and the accompanying brochure to the Parliament. The report is titled *Therapeutic Goods Regulation: Complementary Medicines.*

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely

Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Contents

Tables

Figures

Abbreviations and glossary

ACCM	Advisory Committee on Complementary Medicines. Advises and makes recommendations to the TGA on the inclusion, variation or retention of a complementary medicine in the ARTG. Successor committee to CMEC.
The Act	The *Therapeutics Goods Act 1989*.
The Advertising Code	The Therapeutic Goods Advertising Code 2007.
AGC	Audit Governance Committee. See p. 176.
ANZTPA	The proposed Australia New Zealand Therapeutics Products Authority. See p. 40 *et seq*.
ARGCM	Australian Regulatory Guidelines for Complementary Medicines. See p. 49.
ARTG	Australian Register of Therapeutic Goods. See p. 37 *et seq*.
ASMI	Australian Self-Medication Industry.
AUST L	This notation on a medicine package, followed by a number, indicates that the medicine is a product *listed* on the ARTG. See p. 71.
AUST R	This notation on a medicine package, followed by a number, indicates that the medicine is a product *registered* on the ARTG. See p. 68.
CM	Complementary Medicine
CAM	Complementary and Alternative Medicine. In Australia, the term 'Complementary Medicine' is equivalent and preferred.
CHC	Complementary Healthcare Council.
CHF	Consumers' Health Forum.
CMEC	Complementary Medicines Evaluation Committee. Now defunct, succeeded by ACCM.

CMIRG	Complementary Medicines Implementation Reference Group. A group established by the TGA to provide advice on and oversee the implementation of the government response to the report of the Expert Committee on Complementary Medicines in the Australian Health System. See p. 53 *et seq*. and p. 147 *et seq*.
CRP	Complaints Resolution Panel.
DoHA	Department of Health and Ageing.
eBS	TGA's Electronic Business Services. See p. 184.
ELF 3	Electronic Listing Facility, Version 3. TGA computer system used for managing the listing of medicines on the ARTG. See p. 68.
Expert Committee	The Expert Committee on Complementary Medicines in the Health System, established in 2003. See p. 36.
GMP	Good Manufacturing Practice. See. p. 163.
ISO	International Organisation for Standardisation. See p. 185.
JCPAA	Joint Committee of Public Accounts and Audit.
LIMS	Laboratory Information Management System. See p. 180.
MHRA	Medicines and Healthcare Products Regulatory Agency. United Kingdom government agency with responsibilities in that jurisdiction equivalent to those of the TGA in Australia.
NHP	Natural Health Product (term used in Canada). See Appendix 2.
NMP	National Medicines Policy.
NICM	National Institute of Complementary Medicine.
OCM	Office of Complementary Medicines. OCM is the Office (as branches are known in the TGA) responsible for complementary medicines regulation.
OICG	Office of Complementary Medicines–Industry Consultative Group. This consultative group meets five times a year.

OMQ	Office of Manufacturing Quality. Within the TGA, the OMQ is responsible for ensuring manufacturers of medicines and medical devices meet appropriate standards of quality.
OTC medicines	Over-the-counter medicines. Medicines for self-treatment including cough and cold remedies, anti-fungal treatments, sunscreens, non-prescription analgesics such as aspirin and paracetamol.
PIC/S	Pharmaceutical Inspection Convention/Pharmaceutical Inspection Cooperation Scheme. See pp. 163–8.
RCU	Regulatory Compliance Unit. The TGA's RCU is responsible for on-going surveillance, enforcement and related activities, including investigations into illegal and counterfeit therapeutic goods.
The Regulations	Therapeutic Goods Regulations 1990.
Regulation 9 Order	The TGA may issue a Regulation 9 Order (under the Regulations) to initiate action by non-compliant advertisers. See p. 121.
TGA	Therapeutic Goods Administration, part of DoHA.
TGACC	Therapeutic Goods Advertising Code Council.
TICC	Therapeutic Goods Administration–Industry Consultative Committee. This consultative committee meets twice a year.
WHO	World Health Organization, Geneva.

Summary and Recommendations

Summary

Introduction

1. Some two-thirds of all Australians use complementary medicines—also known as 'traditional' or 'alternative' medicines—including vitamins, minerals, herbal, aromatherapy and homoeopathic products.[1] Popular examples of complementary medicines in Australia include fish oil, St John's Wort and glucosamine. These and many other complementary medicines are generally available for self-medication by consumers. There are about 10 000 such medicines available on the Australian market.[2] Consumption has continued to rise in recent years and, together with increasing exports of Australian-manufactured complementary medicines, market growth has been estimated at between three and twelve per cent a year. Sales of complementary medicines in Australia were estimated at $1.2 billion a year in 2010. Similar growth has been observed across other industrialised countries and the global market has been estimated at $US 83 billion annually.

2. Growth in the use of complementary medicines has been attributed to concerns about adverse effects from conventional drugs and the desire to pursue alternative treatments. These medicines are also widely considered to offer a gentler means of managing chronic conditions associated with greater life expectancy.[3] However, there are potential risks as well as benefits in the use of all medicines, including complementary medicines, and this is recognised in Australia's National Medicines Policy (NMP).

3. The community expects medicines on the Australian market to be safe, of good quality, effective and to be available promptly. The Commonwealth

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1 National Institute of Complementary Medicines, 'Facts and Statistics', January 2009, available from <www.nicm.edu.au/content/view/65/36/> [accessed 4 August 2011].

2 Of the 10 000 complementary medicines, only about 200 are in the higher risk 'registered' category; the remainder are in the lower-risk 'listed' category. There are about 3000 sponsors of complementary medicines, including both listed and registered medicines. The sponsor is, generally, the manufacturer, importer or exporter of the medicine.

3 *WHO Traditional Medicine Strategy 2002–2005*, Geneva, 2002, p. 2, available from <www.who.int/medicines/publications/traditionalpolicy/en/> [accessed 4 August 2011]. Similarly, the National Prescribing Service Limited has reported that many Australian consumers see their complementary medicine use as natural and 'part of a holistic view of health'. The research also revealed that many users associated 'natural' with complementary medicines being harmless and unlikely to cause any adverse effects.

regulates complementary medicines, along with other therapeutic goods (medicines and medical devices) through the *Therapeutic Goods Act 1989* (the Act). The object of the Act is to provide for a system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods. The Minister for Health and Ageing has responsibility for the Act and the Therapeutic Goods Administration (TGA), part of the Department of Health and Ageing (DoHA), has the regulatory role.[4]

4. The TGA has operated over the last two decades with an evolving regulatory framework. The Act has been amended frequently since it came into effect and the regulation of complementary medicines has changed, generally to provide easier market access for the low-risk category of these products. An important development in this respect was the introduction, in 2001, of a system of self-assessment for certifying that low-risk complementary medicines satisfy the regulatory requirements that allow them onto the Australian market. Consistent with the view that such complementary medicines are low-risk, this mechanism provides only limited assurance to the public about the characteristics of these medicines.[5]

5. The TGA's regulation of complementary medicines attracted attention in 2003 when it recalled more than 1600 products manufactured by Pan Pharmaceuticals, then Australia's largest contract manufacturer of complementary medicines. The Government subsequently appointed the Expert Committee on Complementary Medicines in the Health System (the Expert Committee) to review the regulation of these medicines. The ANAO also undertook a performance audit of the TGA in 2004, focusing on the regulation of non-prescription medicines (which includes complementary medicines). The review and the audit report generated a number of recommendations for change, almost all of which were accepted.

6. A substantial change to the governance of therapeutic goods regulation was planned for mid-2006 with a project to introduce a joint regulatory agency

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[4] In addition, the Australian Competition and Consumer Commission (ACCC) is reported as having applied the provisions of the *Competition and Consumer Act 2010* relating to misleading and deceptive conduct to claims relating to a complementary medicine (*The Australian* newspaper, 25 June 2011).

[5] Reported risks associated with listed complementary medicines are: delay in seeking treatment for serious conditions; unexpected side-effects; adverse interactions between the complementary medicine and prescription medicines; and the costs to consumers of purchasing products which, in some cases, are not effective in treating the conditions they claim to treat. See <www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Complementary_therapies_safety_and_legal_issues?open> [accessed 4 August 2011].

for therapeutic products in both Australia and New Zealand. After extensive preparation, the project was suspended in mid-2007 when the New Zealand Government announced it was not proceeding with the legislation. Regulation of complementary medicines was the stumbling block to implementing the joint scheme at this time. This initiative has recently been revived by the prime ministers of Australia and New Zealand.[6]

7. The regulation of complementary medicines came to public attention in Australia when DoHA reported in late 2010 that, based on 2009–10 data, as many as 90 per cent of products reviewed were found to be non-compliant with regulatory requirements, despite the system of self-assessment by sponsors. Among the medicines the TGA reviewed, 31 were selected at random, for which the following compliance issues were recorded (with a number of products recording multiple breaches):

- 20 medicines had labelling issues such as non-compliance with labelling requirements and/or breaches which may mislead consumers.
- 12 included incomplete and/or inappropriate information on the Australian Register of Therapeutic Goods (ARTG).
- 22 were found to have manufacturing and/or quality issues.
- 14 did not have adequate evidence to substantiate claims made about the medicines.

8. A significant number of products subsequently required removal from the ARTG. This information was contained in DoHA's incoming government brief, which was released to the public in late 2010.[7] The information in the brief attracted significant interest and debate on the topic has persisted.

Audit objective and scope

9. The objective of this audit is to examine the effectiveness of the TGA's administration of complementary medicines regulation in Australia. The

[6] See <www.tga.gov.au/about/international-anztpa-factsheet.htm> [accessed 4 August 2011]. A contentious factor leading to the suspension was concern about the possible adverse effect of the new arrangements on Maori traditional medicines. The New Zealand Government is introducing a separate scheme to regulate complementary medicines in the New Zealand market.

[7] DoHA, Incoming Government Briefing—Volume 1, item D27. See: <www.health.gov.au/internet/main/publishing.nsf/Content/min-briefs> [accessed 5 August 2011].

primary focus is on listed complementary medicines, which comprise about 98 per cent of these medicines.

10. The scope of the audit encompassed the TGA's administration of complementary medicines regulation, including the systems and processes that the TGA employs to: develop guidance documentation; list complementary medicines; undertake post-market review of products; regulate advertising; and collect evidence of the efficacy of listed complementary medicines.

11. The last performance audit of the TGA was ANAO Audit Report No. 18 2004–05, *Regulation of Non-prescription Medicinal Products,* which took place after the major recall of Pan Pharmaceutical products. That audit focused substantially on the regulation of manufacturing practice by the suppliers of non-prescription medicines. The current audit also follows up the implementation of the recommendations of the 2004 audit.

Overall conclusion

12. The system for the regulation of complementary medicines in Australia was designed to have a 'light touch',[8] due to the relatively low risk ascribed to the proper use of the majority of complementary medicines. The regulatory system has been further amended since its inception, twenty years ago, to ensure that market access for these products is not impeded unnecessarily. Because market access has been made easy, quick and low cost, an important safeguard to the integrity of the regulatory system is that easy entry be balanced by an effective post-market monitoring of compliance with regulatory requirements that is commensurate with the relatively low risk profile of these products.

13. The results of TGA post-market monitoring in recent years have shown that non-compliance by sponsors of complementary medicines with regulatory requirements has been consistently high. In 2006, on the basis of a random sample, the TGA found a non-compliance rate of 75 per cent. DoHA has recently reported non-compliance as high as 90 per cent for the products reviewed. While the recent data is based on small sample sizes, making it difficult to gauge the magnitude of non-compliance with any precision, TGA figures nevertheless show that a high level of non-compliance has endured for

[8] TGA, advice to the Secretary, DoHA, 'Medium Term TGA Direction', January 2010.

some years and that a substantial proportion of the cases of non-compliance are categorised as 'moderate' or 'significant'.[9] The TGA has expressed concern that this situation presents potential risks to the public, the industry and confidence in the regulatory system.[10] In this context, the available evidence indicates that the regulation of complementary medicines in Australia has been of limited effectiveness. The administration of the regulatory framework could be strengthened by the TGA making changes to improve the integrity of the self-assessment process for pre-market listing, using a risk-based approach to better target its post-market reviews, and improving the transparency of information available to consumers, health professionals and industry.

14. Listing new medicines was intended to be based largely on self-assessment by the sponsor of the medicine. However, risks arise in the operation of this self-assessment model because it permits inappropriate or misleading claims and indications to be made by sponsors through the deliberate or inadvertent entry of information in the 'free-text' field of the TGA's online Electronic Listing Facility (ELF).[11] Given the importance of self-assessment to listing new medicines, placing restrictions on the ability of sponsors to enter free text in ELF would mitigate the risks, while maintaining the promptness and ease of listing. The TGA is currently progressing work on a 'coded indications' project to this end and the ANAO has recommended that this project be finalised as soon as practicable.

15. At present, the TGA does not use in any systematic way the knowledge it gains from post-market reviews of complementary medicines listed on the ARTG to identify and target consistent non-compliance with the regulatory framework. There is a significant opportunity for the TGA to cost-effectively strengthen its post-market review activities. Improved analysis of existing information could inform a more targeted and risk-based approach to monitoring non-compliance. In particular, the ANAO recommends that the TGA use its random sampling review of listed medicines to develop risk profiles against the most significant characteristics of listed medicines and the

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9 See Table 4.3, Chapter 4.

10 DoHA, Incoming Government Briefing—Volume 1, item D27. See: <www.health.gov.au/internet/main/publishing.nsf/Content/min-briefs> [accessed 5 August 2011].

11 'Indications' means the specific therapeutic purposes of the medicine. The term 'claims' is generally taken as having a broader meaning, and includes statements made about the product in advertisements.

less compliant sponsors and manufacturers.[12] These profiles would inform the TGA's targeted review strategy and enable it to direct efforts into improving compliance on a risk basis, whether through providing information or education to sponsors or, where necessary, through regulatory action. Against the background of 3000 sponsors and 10 000 listed medicines, a risk-based approach to compliance monitoring has the benefit of directing limited resources to those products presenting the greatest risk of non-compliance. The TGA could also benefit from developing a more active, but targeted, approach to monitoring compliance with advertising requirements, with options to be considered in the context of developing the risk profiles.

16. The Government's recent review of the transparency of the regulatory framework was prompted by concern about the lack of information made available by the TGA about its regulatory processes and decisions. That review examined what information should be made more public and made recommendations about how that information could be better conveyed.[13] The ANAO has concluded that transparency could be strengthened significantly by making information available in a timely manner to the Australian public for each listed complementary medicine, stating whether it has been subject to post-market review, when, and the outcome of that review. The options for doing so include the provision of information on the TGA website, such as by adding fields to the publicly-viewable elements of the ARTG.[14]

17. The most challenging aspect of regulating complementary medicines, which also affects the transparency of the system as a whole, is the public availability of evidence relating to their efficacy. It has been government policy since March 2005 that the TGA collect a summary of evidence from sponsors, an item which sponsors were required to hold when listing their medicine. The TGA developed an understanding that the requirement would be legislated in

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[12] In the context of its regulation of accredited residential aged care providers, DoHA has recently developed a *Service Providers of Concern* list, which the department has identified as representing a high risk of non-compliance. Similarly, the Aged Care Standards and Accreditation Agency Ltd maintains a 'Homes of Interest' list.

[13] The Transparency Review of the TGA, chaired by Professor Dennis Pearce AO, was announced on 16 November 2010 by the Parliamentary Secretary for Health and Ageing. The review, which was completed in July 2011, ran concurrently with the present performance audit. At the time this audit was being finalised the Government was considering the Review's recommendations. The report of the Review is available from <www.tga.gov.au/newsroom/review-tga-transparency-1101.htm> [accessed 4 August 2011].

[14] This was originally suggested by the Expert Committee on Complementary Medicines in the Health System in its 2003 report.

the context of the ANZTPA project but implementation faltered after the suspension of that project. In the course of the audit, the TGA advised that it had taken steps in May 2011 to restart implementation of this policy.

18. In summary, the regulatory framework for complementary medicines is important for consumers, health professionals and industry, and is now operating in the context of a growing domestic and international market with numerous sponsors and listed medicines. The effectiveness of the TGA's administration of the framework would be improved by limiting the capacity which currently exists for sponsors to enter inappropriate claims as part of the pre-market listing process, adopting a risk-based approach to compliance monitoring and by implementing the existing government policy that the TGA collect a summary of evidence of efficacy for each listed complementary medicine. The public release of those summaries would have the further benefit of improving transparency by making relevant information available to consumers and health professionals about the effectiveness of complementary medicines. The ANAO has made five recommendations aimed at strengthening the integrity and transparency of the framework within existing policy settings, in large measure by refining the TGA's existing systems and processes and better targeting the utilisation of resources.

Key findings

Guidance documentation (Chapter 2)

19. The TGA uses a range of guidance documents to help regulate complementary medicines. These documents provide essential information to sponsors about how to engage with the regulatory system. Their currency and completeness are important to effective regulation. In each of the cases examined by the audit, the review of guidance documentation for complementary medicines has taken and continues to take a long time. While the subject matter is complex and necessarily must draw on particular expertise, excessive delay creates uncertainty for industry, has implications for consumers and carries risks for the authority and perceived regulatory integrity of DoHA and the TGA.

20. The TGA's Office of Complementary Medicines (OCM), which has day-to-day responsibility for the regulation of complementary medicines, has identified outdated guidance documents as a potential contributing factor for poor regulatory compliance. It has been aware that regulatory compliance has

been poor since at least 2007. This makes it all the more urgent that work on finalising guidance documentation be completed expeditiously.

21. The OCM has also identified 'Sponsors that intentionally use delaying or obstructive tactics' as a factor in poor regulatory compliance. While it is very difficult to determine how often such behaviour occurs, to the extent that it does, outdated or unfinalised guidance documents can potentially enhance the opportunity for such 'tactics' to be deployed successfully.

22. The TGA has clearly set out to achieve a consensus among stakeholders over its guidelines. While this is a desirable goal, in practice the regulation of complementary medicines has attracted polarised opinions at times. In these circumstances, there may be only marginal benefit in artificially drawing out the processes.

Pre-market assessment of products (Chapter 3)

23. The pre-market assessment process for listed products has a light touch, as was intended. There is little to inhibit a sponsor from having a new medicine listed, whether or not they understand the regulatory requirements, or even where they do not have full regard to these requirements. Self-certification is the primary test at this point. There are limits to what the TGA can do, within the existing legal framework, to gain any greater assurance about claims made for a product until after that product has been listed.

24. When the regulatory system was put in place there may have been little understanding of the likely level of non-compliance of complementary medicines with the regulatory framework. This was likely to have been the case in 2001 when the amendments were made that introduced self-assessment by sponsors. Even in 2005, the then Government's perception was that 'the results of the TGA's limited audits may not justify a conclusion that there is widespread non-compliance with the Guidelines.'[15]

25. In April 2010, post-market compliance review work by the TGA revealed a high level of non-compliance by complementary medicines, with only three products in a random sample of 31 being found to be wholly compliant with regulatory requirements. Later in the year (December 2010),

[15] *Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*, Attachment 2, p. 12, available from <www.tga.gov.au/pdf/archive/committees-eccmhs-response-050309.pdf> [accessed 4 August 2011].

DoHA published on its website its incoming government brief, including an item on compliance of complementary medicines. This reported that 'based on 2009–10 data, as many as 90 per cent of products reviewed are found to be non-compliant with regulatory requirements, with a significant number of products requiring removal from the ARTG.' These findings attracted public comment which has persisted.[16]

26. Working within the current framework, there are opportunities for improvement in several areas. In particular, the TGA has advised the ANAO that the greatest opportunity for improving pre-market assessment of listed products lies in restricting or removing the free text field in the ELF system as a means of limiting the use of inappropriate claims or indications for products listed on the ARTG. A change to the pre-market self-assessment rules would involve a policy change—a matter for ministers and DoHA advice.

27. While it is difficult for the regulator to assess whether apparent failure to understand the rules and guidance documents is genuine, this is not a reason to reduce the effort to ensure that guidance is clear, comprehensive and current. The ANAO suggests that additional effort could be worthwhile to keep systematic records of sponsor errors made at data entry (including repeated attempts to submit an application for the same product with slightly different supporting data) and apparent failure to understand the rules on the part of sponsors. This data could indicate where greater clarity or educational effort might be warranted. It would also form a basis for assessing risk in new applications. Such assessments could then form an additional guide for targeted post-market review of new and existing listed products associated with sponsors with a poor record.

28. The TGA has agreed to consider enhancements to its IT systems to capture further information about application validation errors as this information is not currently recorded.

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[16] See the *Sydney Morning Herald*, 29 and 31 December 2010; the *Sunday Canberra Times*, 6 February 2011; ABC Radio National, the *Health Report*, 16 and 24 May 2011, available from <www.abc.net.au/rn/healthreport/index/> [accessed 4 August 2011]; various reports on 'Croakey: the Crikey Health Blog' available from <blogs.crikey.com.au/croakey/> [accessed 4 August 2011] and the *6 minutes.com.au* website, available from <www.6minutes.com.au/news/complementary-medicines-fail-audits> [accessed 4 August 2011]. It should also be noted that, on 13 May 2011, the TGA published, for the first time, data on its post-market review compliance review work. This is available from <www.tga.gov.au/industry/cm-post-listing-compliance-reviews.htm> [accessed 4 August 2011]. This information was the basis of subsequent press articles.

Post-market review of products (Chapter 4)

29. Under the current legislation, post-market review is the key element in effective regulation of listed complementary medicines. This is because listing is based substantially on self-assessment.

30. Currently, the TGA provides the public with no information about the outcomes of its post-market review of complementary medicines. The public release of such information, which could be readily achieved by introducing a publicly-viewable part of the ARTG, would contribute to informing consumers and would enhance transparency of the regulatory system. This matter has received separate attention, concurrent with this audit, through the work of the Transparency Review and the working group on complementary medicines.

31. The TGA has concluded and reported that the levels of non-compliance observed during its post-market review are very high—'up to 90 per cent reviewed'. It has then gone on to conclude that this presents potential risks to the public, the complementary medicines industry and to confidence in the regulatory system. These results were based partly on a targeted sample, which could be expected to show a higher-than-average rate of non-compliance. Nevertheless, on the data available it is apparent that, on the occasions it has been measured, non-compliance has been high for at least the last five years.[17]

32. Further work on the actual state of compliance by careful and thorough examination of a random sample of listed complementary medicines could establish with greater confidence the likely level of non-compliance. If done thoroughly, this could also provide insight into those characteristics, if any, which correlate with non-compliance and provide a basis for further, targeted review.

33. There is benefit in the TGA evaluating the merits of using sponsor behaviour as a basis for targeting its compliance reviews. This could be done without necessarily forming an adverse view of sponsor intent. The ANAO proposes that the TGA consider developing a system of risk profiling for sponsors to inform a program of targeted compliance reviews. A risk-based

[17] Use of figures drawn from the TGA's post-market random reviews requires some caution as they are based on small samples and include a substantial component of minor non-compliance. It would be unfair to characterise all the compliance failure in the same way. However, it also appears likely that there is a substantial proportion—between a quarter and a half—where the OCM considers that the compliance failure is in the categories 'moderate' or 'serious'.

approach would enable the TGA to direct appropriate efforts into improving compliance on a risk basis, whether through providing information or education to sponsors or, where necessary, through regulatory action.

34. In addition, there would be merit in adopting a targeted approach to identifying complementary medicines which are most likely to be non-compliant with the regulatory requirements. The ELF system currently randomly selects newly-listed products for review, and the systematic analysis of the results of those reviews could provide a cost-effective basis for a more targeted approach.

Regulating the advertising of complementary medicines (Chapter 5)

35. Dealing with complaints about the advertising of therapeutic goods to consumers is an important aspect of administering the advertising regulations. It is also an increasing part of the workload for the Complaints Resolution Panel (CRP) and the TGA.

36. Within the three-tiered system of controls for regulating the advertising of therapeutic goods, the TGA carries primary responsibility for effective management of the system as a whole. The TGA is also authorised to receive and investigate advertising complaints.

37. An Internet search by the ANAO for advertisements of therapeutic goods containing claims that are not permitted by the regulations identified numerous instances which included these claims, and the TGA's own search identified the use of prohibited terms including 'cancer'. There would be benefit in the TGA developing a more active, but targeted, approach to monitoring compliance, to be considered in the context of the proposal for the list of sponsors discussed earlier. A targeted, risk-based approach would help provide the TGA with greater assurance while limiting the resource requirements.

38. While the TGA does conduct some complaint handling practices in line with better practice principles, an analysis of complaint investigations also identified that the TGA does not have timeframes for completing investigations of advertising breaches; and that more detailed performance information could be collected and used by the TGA to gauge its performance and effectiveness in this area.

39. The ANAO has recommended the development of a standard operating procedure that specifies timeframes for completing investigations of

advertising breaches; and the reporting on progress and trends to the TGA executive.

Providing evidence of efficacy (Chapter 6)

40. Obtaining evidence of the efficacy of listed complementary medicines has been a difficult issue. The ANAO understands that there is no substantial precedent for collecting this information from sponsors in any other jurisdiction. Nevertheless, the TGA has not identified any policy or practical impediments to implementing government policy, announced in March 2005, to collect a summary of evidence.

41. The TGA developed an understanding that the requirement would be legislated, would involve collecting the evidence summary before or at listing, and that legislation would be introduced as part of the ANZTPA project. Thus, when the project was suspended, the proposed means for implementing the recommendation was no longer available. However, it is open to the TGA to collect the necessary material at some point after the listing of the medicine has taken place.

42. As the audit was being concluded, the TGA provided evidence that options for addressing the issues raised in the remaining recommendations of the Expert Committee were being considered as part of reviews on transparency and on complementary medicines reform. The reviews were initiated or endorsed by the Parliamentary Secretary.

43. It would enhance transparency and help inform both consumers and healthcare professionals if the TGA were to place the summary of evidence it collects from sponsors, as received, on its website—with a clear indication of whether it had been assessed or evaluated by the TGA. DoHA-sponsored research conducted by the National Prescribing Service (NPS) has shown the need for improving the availability of information about complementary medicines and, hence, awareness for Australian health professionals and consumers. The NPS concluded that strategies to improve decisions by consumers about complementary medicines should focus on enhancing the information resources preferred by consumers, including the Internet.[18,19]

[18] NPS, Review of the Quality of Complementary Medicines Information Resources: Summary Report. National Prescribing Service, Sydney, March 2009, p. 5.

[19] NPS, Information Use and Needs of Complementary Medicines Users, December 2008, p. 61.

44. The publication of summaries of evidence on the TGA website would enable potential consumers of the listed item or their advisers to access this information, should they wish, and form a view about the merits of that summary of evidence when considering whether to purchase and use the medicine.

Previous ANAO and Parliamentary inquiry recommendations (Appendix 1)

45. The last ANAO performance audit on regulation of therapeutic goods was tabled in December 2004, ANAO Audit Report No.18 2004–05, *Regulation of Non-prescription Medicinal Products*. This audit took place after the major recall of Pan Pharmaceutical products. The audit focused substantially on the regulation of manufacturing practice by the suppliers of non-prescription medicines.

46. As part of the current audit, the ANAO examined DoHA's progress with the recommendations of the 2004 performance audit and the additional recommendations of the subsequent inquiry by the Joint Committee of Public Accounts and Audit (JCPAA). The assessment of the implementation of the 32 recommendations from these two previous reports on the operation of the TGA found that the work was nearly complete:

- 29 recommendations are implemented;
- two recommendations are substantially implemented; and
- one recommendation is partially implemented.

Agency response

47. The Department of Health and Ageing provided the following response to the report:

> The Department of Health and Ageing thanks the Australian National Audit Office (ANAO) for its report regarding the regulation of complementary medicines in Australia.
>
> The Department has accepted all recommendations and has commenced work on developing a plan to implement all of the findings.
>
> The recommendations are consistent with other work affecting complementary medicines regulation, including the recent reviews on Transparency, Advertising and Complementary medicines reform and the broader reform of the TGA under the TGA 21 project. The recommendations will be implemented in concert with recommendations arising from these other reviews, to the extent that their recommendations are accepted by the Government.

Recommendations

Recommendation No. 1

Para. 2.62

To achieve timely completion of key guidance material for complementary medicines, the ANAO recommends that DoHA:

(a) provides a target date for the completion and publication of each key guidance document; and

(b) provides regular progress reports on the development of key guidance documents, on the TGA website, to keep industry, health professionals and consumers informed.

DoHA response: Agree

Recommendation No. 2

Para. 3.74

To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG), the ANAO recommends that DoHA seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.

DoHA response: Agree

Recommendation No. 3

Para. 4.66

The ANAO recommends that the TGA makes information available in a timely manner to the Australian public, for each listed complementary medicine, stating whether it has been subject to post-market review by the TGA, when it was reviewed, and the outcome of that review.

DoHA response: Agree

Recommendation No. 4

Para. 4.98

To improve compliance with the regulatory framework, the ANAO recommends that the TGA:

(a) use its random sampling review of listed medicines to develop risk profiles of sponsors and the most significant characteristics of medicines; and

(b) use the profiles to inform its program of post-market reviews.

DoHA response: Agree

Recommendation No. 5

Para. 5.95

The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches. In developing the procedure the TGA should incorporate:

(a) appropriate timeframes for completing the investigations; and

(b) the provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.

DoHA response: Agree

Audit Findings

1. Regulating Complementary Medicines

This chapter provides an overview of how the Department of Health and Ageing, through the Therapeutic Goods Administration, regulates complementary medicines, a major category of therapeutic goods in Australia. It also introduces the audit, including the audit objective, scope and approach.

Regulating complementary medicines: an overview

1.1 The community expects the medicines and related products available on the Australian market to be safe, of good quality, and to be effective in treating the condition they purport to address. They also expect that new medicines and products will become available promptly to patients and consumers. The Commonwealth regulates therapeutic goods in Australia with a view to satisfying these expectations.[20]

1.2 Therapeutic goods are products for human use in preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury. They include medicines and medical devices, including blood components, for supply in Australia and their export.[21] The primary legislation which authorises and requires regulation of therapeutic goods—prescription medicines, medical devices and complementary medicines—is the *Therapeutic Goods Act 1989* (the Act) which took effect on 15 February 1991.[22] The object of the Act is to provide for a system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.[23] The Minister for Health and Ageing has responsibility for the Act and the Therapeutic Goods

[20] See TGA, Consumer Information & Education, available from <www.tga.gov.au/consumers/information.htm> [accessed 4 August 2011].

[21] Technically, medicines are defined in the Act as therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and any other therapeutic goods declared by the [Health] Secretary, by a notice published in the Gazette, not to be medical devices.

[22] The Act is supported by the *Therapeutic Goods (Charges) Act 1989,* the *Therapeutic Goods (Charges) Regulations 1990,* the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, available from <www.comlaw.gov.au/> [accessed 4 August 2011]. See also the links at <www.tga.gov.au/industry/legislation.htm#acts> [accessed 4 August 2011].

[23] *Therapeutic Goods Act 1989*, s. 4(1)(a), available from <www.comlaw.gov.au/> [accessed 4 August 2011].

Administration (TGA)—part of the Department of Health and Ageing (DoHA)—has the regulatory role.

1.3 Generally, the therapeutic goods whose supply is regulated by the TGA fall into three categories:

- *medical devices*—medical devices are items used on humans for therapeutic benefit and which generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body;[24]
- *registered medicines*—registered medicines are those assessed as having a higher level of risk. The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data. They include all prescription medicines, most 'over-the-counter' medicines[25] and a small number of complementary medicines; and
- *listed medicines*—listed medicines are considered to have a lower level of risk. They have established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. This category includes about 98 per cent of complementary medicines.

1.4 This chapter explains the background to complementary medicines regulation in Australia and introduces the subsequent chapters. It addresses:

- the growing use and manufacture of complementary medicines;
- why complementary medicines have come to be regulated;
- how the regulation of complementary medicines has developed into its current form over the last 15 years or so; and
- the role of the TGA and the events which have shaped its approach to implementing the regulation of complementary medicines.

[24] Medical devices range from a bandage that a person would put on a scratch to high-risk products such as pacemakers that are implanted in the body.

[25] Products in this category are considered to be lower risk than prescription medicines. However, they still require a high level of scrutiny, for example, to ensure adequate labelling for appropriate use. Examples of products in this category are mild analgesics, cough/cold preparations, and anti-fungal creams.

Table 1.1

Complementary medicines

What are complementary medicines?
In Australia, medicinal products containing herbs, vitamins, minerals, and nutritional supplements, homoeopathic medicines and certain aromatherapy products are referred to as 'complementary medicines'. Complementary medicines comprise traditional medicines, including traditional Chinese medicines, Ayurvedic medicines and Australian Indigenous medicines. Other terms sometimes used to describe complementary medicines include 'alternative medicines', 'natural medicines' and 'holistic medicines'. Complementary medicines are generally available for use in self-medication by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. While the majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, many are indicated for maintaining health and wellbeing, or the promotion or enhancement of health.

Source: TGA, <www.tga.gov.au/industry/cm-basics-regulation-overview.htm> [accessed 2 August 2011].

The growing use of complementary medicines

1.5 Complementary medicines (often referred to overseas as 'Complementary and Alternative Medicines' or 'CAM') are widely used in both developing and industrialised countries, and the global market for these products has expanded substantially over the last decade. This rise in use can be attributed to a range of factors. The World Health Organization (WHO) has noted that, in many industrialised countries, popular use of complementary medicines is fuelled by concern about the adverse affects of conventional drugs. The WHO went on to comment that 'longer life expectancy has brought with it increased risks of developing chronic, debilitating diseases such as heart diseases, cancer, diabetes and mental disorders. For many patients, CAM appears to offer gentler means of managing such diseases.'[26] In 2008, the WHO estimated the global market for traditional medicines at $US 83 billion annually, with an 'exponential' rate of increase.[27]

[26] *WHO Traditional Medicine Strategy 2002–2005*, Geneva, 2002, p. 2, available from <www.who.int/medicines/publications/traditionalpolicy/en/> [accessed 4 August 2011].

[27] WHO, *The World Medicines Situation 2011—Traditional Medicines: Global Situation, Issues and Challenges*, Geneva, 2011.

1.6 In 1996, surveys in Victoria and South Australia found about 50 per cent of people had recently used alternative medicines.[28] By early 2009, the National Institute of Complementary Medicine's (NICM) figures indicated that two-thirds of Australians use these medicines each year.[29] Health professionals may be contributing to the increased usage in Australia. Research undertaken by the National Prescribing Service (NPS) in 2007 showed about 90 per cent of general practitioners had recommended at least one complementary medicine in the last 12 months and almost all surveyed community pharmacists had recommended some kind of complementary medicine over that period.[30]

1.7 In terms of market value, one source estimates that, in 2003, the annual retail turnover of complementary medicines in Australia was $800 million, with an additional 20 per cent of Australian output being exported.[31] By March 2011, the Department of Innovation, Industry, Science and Research (DIISR) estimated the value of sales in Australia to be $1.2 billion a year.[32] NICM's estimate of market growth is between three and 12 per cent a year.

1.8 Complementary medicines have value not only to consumers but also to the industry that produces them, both for domestic and export consumption. Production of complementary medicines in Australia is becoming a substantial industry. NICM estimates from January 2009 valued

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28 Minister for Health and Family Services, Media release, MW79/96, 16 October 1996, available from <www.health.gov.au/internet/main/publishing.nsf/Content/health-archive-mediarel-1996-mw7996.htm> [accessed 4 August 2011]. In 2000, a similar proportion was reported in the report of the Expert Committee on Complementary Medicines in the Health System (the Expert Committee), *Complementary Medicines in the Australian Health System*, (Report to the Parliamentary Secretary to the Minister for Health and Ageing), September 2003, p. 36, available from <www.tga.gov.au/archive/committees-eccmhs-report-031031.htm> [accessed 4 August 2011]. A further study reported that in 2004, some 52.2 per cent of the population in South Australia used complementary medicines. (MacLennan, A. H., Myers, S. P., and Taylor, A. W., 'The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004', *Medical Journal of Australia,* 2006, 184 (1), pp. 27–31, available from <www.mja.com.au/public/issues/184_01_020106/mac10324_fm.html> [accessed 4 August 2011].)

29 NICM, 'Facts and Statistics', January 2009, available from <www.nicm.edu.au/content/view/65/36/> [accessed 4 August 2011].

30 NPS, *Complementary Medicines—Information Use and Needs of Health Professionals: General Practitioners and Pharmacists*, December 2008, updated April 2009, pp. 6–7, available from <www.nps.org.au/research_and_evaluation/current_research/complementary_medicines/cms_health_professionals_research/complementary_medicines_health_professionals_research> [accessed 4 August 2011].

31 Expert Committee, op. cit., p. 37.

32 See DDIISR, Australian Pharmaceuticals Industry Data Card 2010, available from <www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Documents/Australian_Pharmaceuticals_Industry_Data_Card.pdf> [accessed 4 August 2011].

the Australian industry at $1.5 billion to $2.5 billion.[33] In 2009–10 the Australian pharmaceuticals industry as a whole had a turnover of approximately $22 billion, with exports of over $4.1 billion.[34] Thus, the production of complementary medicines comprises a growing part of the local medicines industry.[35]

Why complementary medicines are regulated

1.9 According to the WHO, in recent years there has been, internationally, a public demand for increased accountability in the complementary medicines marketplace: 'Consumers want to know that their products meet acceptable criteria to be considered both safe and effective.'[36] This, according to the WHO, has led to an increased interest among health authorities in the research, regulation, international trade and marketing of traditional medicines.

1.10 There are potential risks as well as benefits in the use of all medicines, including complementary medicines.[37] This is explicitly recognised in Australia's National Medicines Policy (NMP) which, since 2000, has provided overarching guidance on all aspects of the management of medicines in Australia, including complementary medicines.[38]

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33 NICM, 'Facts and Statistics', op. cit.

34 See DIISR, op. cit. IBISworld reports that Australia's Pharmaceutical Product Manufacturing industry has overtaken road vehicle manufacturing as the nation's largest high-tech manufacturing exporter. It estimates that pharmaceutical exports in 2010–11 will reach $4.3 billion, which is 45.4 per cent of industry revenue, up from 37.9 per cent a decade ago. See *IBISworld Industry Insight*, October 2010, available from <www.ibisworld.com.au/newsletter/issues/au/10oct/news.aspx> [accessed 4 August 2011].

35 NICM also estimates that almost four times more in out-of-pocket expenses is spent on complementary medicines than on pharmaceuticals (the cost to the consumer of most pharmaceuticals in Australia being subsidised by the Pharmaceutical Benefits Scheme).

36 WHO, *The World Medicines Situation 2011—Traditional Medicines: Global Situation, Issues and Challenges*, Geneva, 2011.

37 A recent Australian paper drawing attention to these risks is Lim, A., Cranswick, N., and South, M. 'Adverse events associated with the use of complementary and alternative medicine in children', *Archives of Disease in Childhood*, December 2010. The authors found, over a two-year period, '39 reports of adverse events associated with CAM [Complementary and Alternative Medicine] use, including four reported deaths. Reports highlighted several areas of concern, including the risks associated with failure to use conventional medicine, the risks related to medication changes made by CAM practitioners and the significant dangers of dietary restriction. The reported deaths were associated with a failure to use conventional medicine in favour of a CAM therapy.' The study, which focuses on paediatric medicine, is available from <adc.bmj.com/content/early/2010/11/24/adc.2010.183152.full%20> [accessed 4 August 2011].

38 DoHA 1999, National Medicines Policy, p. 2, available from <www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm> [accessed 4 August 2011].

1.11 The NMP states that the quality, safety and efficacy of medicines available in Australia should be equal to that of comparable countries. To this end, 'the level of regulation should be consistent with the potential benefits and risks for the community' based on appropriate risk-assessment processes. The NMP identifies the TGA as having primary responsibility for regulatory arrangements, but recognises that co-operation is necessary with state and territory governments, industry, health practitioners and consumers.

1.12 The chairman of the Expert Committee on Complementary Medicines in the Health System stated in his preface to the Committee's report, *Complementary Medicines in the Australian Health System* (September 2003), that 'One of the key prerequisites of ethical behaviour of every healthcare provider is to do no harm.'[39] He identified three types of harm associated with complementary health care as potentially taking the form of:

- direct harm, which results in adverse patient outcome. This can occur, for example, when a complementary medicine interacts adversely with a prescription medicine;
- indirect harm, which results from a delay of appropriate treatment or from unreasonable expectations that discourage patients and their families from accepting and dealing effectively with their medical condition; and
- economic harm, as a result of expenditure on harmless, but inefficacious treatment or products.[40]

1.13 An important risk associated with complementary medicines is the belief that, because they are 'natural' they must be safe.[41] Relevantly to Australia, the WHO has noted:

> The idea that just because traditional medicine products come from natural sources they are completely safe is dangerously false. Not everything that is natural is safe; traditional medicine products must be used judiciously and as indicated, just like any other medication, and with awareness of potential

[39] Expert Committee, op. cit., p. 8.

[40] The material referred to appears in a policy paper by the then New South Wales Medical Board (from 1 July 2010, replaced by the Medical Council of New South Wales), available from <www.mcnsw.org.au/page/resources/policies/> [accessed 4 August 2010].

[41] See, for example, the Victorian Government's Better Health Channel advice, available from <www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Complementary_medicines_tell_your_doctor?open> [accessed 4 August 2011].

herb–herb and herb–drug interactions. The risks are relatively small when traditional medicines are used correctly, but they are still there, and consumer understanding is generally low. For example, a cross-sectional population survey conducted in Australia found that less than half (46.6%) of traditional, herbal medicine users were even aware that there could be potential risks associated with product use.[42]

The development of complementary medicines regulation

1.14 Many countries have not systematically regulated complementary medicines. Some countries, for example, treat them as foods; others treat them as dietary supplements. The WHO noted in its *Traditional Medicine Strategy 2002–2005* that relatively few countries had a developed policy on traditional medicine and/or complementary and alternative medicine. However, a more recent WHO publication shows that the number of WHO member states reporting having regulations or laws governing herbal medicines has risen from 14 before 1986 to 110 in 2007.[43,44] A summary of activity in selected overseas jurisdictions is provided in Appendix 2 (p. 191).

Development of the framework in Australia

1.15 Until the 1980s certain sorts of therapeutic goods were unregulated in Australia. This was the case with most therapeutic devices and with complementary medicines for which there were increasing concerns about quality, safety and the 'extravagant therapeutic claims' that were being made.[45]

1.16 National regulation of complementary medicines commenced with the *Therapeutic Goods Act 1989*. Section 9A of the Act requires the Secretary of DoHA to maintain a register of therapeutic goods. This is the Australian Register of Therapeutic Goods (ARTG), which is at the heart of therapeutic goods regulation in Australia (see the box below).

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42 WHO, *The World Medicines Situation 2011—Traditional Medicines: Global Situation, Issues and Challenges*, Geneva, 2011, p. 8.

43 ibid., p. 4.

44 The international situation is difficult to gauge: the WHO notes that: 'The variety of levels to which traditional medicines are integrated into the pharmaceutical culture of each individual country serves to highlight the vastly different cultural understanding and priorities between countries.' See WHO, *The World Medicines Situation 2011—Traditional Medicines: Global Situation, Issues and Challenges*, Geneva, 2011, p. 5, available from <www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch18_wTraditionalMed.pdf> [accessed 4 August 2011].

45 McEwen, J. 2007, *A History of Therapeutic Goods Regulation in Australia*, p. 137.

1.17 A therapeutic good must be on the ARTG before it can be imported into, supplied in Australia or exported, unless it is in a special category of exempt or excluded goods. The importer or manufacturer of the goods (under the Act, the 'sponsor') is responsible for applying to the TGA to have their goods included in the ARTG. The sponsor of a therapeutic good included in the ARTG must be an Australian resident and/or doing business in Australia.

Table 1.2

The Australian Register of Therapeutic Goods

Elements of the Australian Register of Therapeutic Goods
The ARTG is established under the Act. The Secretary of DoHA is required to maintain the ARTG, comprising three parts: (1) *registered medicines*. These are higher-risk items whose efficacy must be demonstrated before they can be registered. The Act requires them to be evaluated for quality, safety and efficacy before they can be registered. They must display an 'AUST R' number on their label as proof of registration; (2) *listed medicines.* These can be listed unless they fail to comply with quality and safety criteria. They are not evaluated for efficacy. They are generally lower-risk items, usually self-selected by consumers for self-treatment. They must display an 'AUST L' number on their label as proof of listing. Medicines for export only are listed on the ARTG; and (3) *medical devices*. These include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, in vitro diagnostic devices, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves. Medicines included in the ARTG are divided into three broad categories: (1) *prescription medicines.* These are medicines available only upon prescription by a qualified health practitioner, usually for a serious illness. They must be registered on the ARTG, will usually contain an active ingredient which is a 'scheduled' substance (that is, included in the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*)[46] and their use may involve risks; (2) *over-the-counter (OTC) medicines.* These items, also registered on the ARTG, include mild analgesics, cough and cold preparations and anti-fungal creams. OTC medicines generally have active ingredients less potent than those used in prescription medicines; and (3) *complementary medicines* (sometimes called 'complementary and alternative medicines', 'CAM'). Most complementary medicines are listed on the ARTG and include vitamins, minerals, Chinese traditional medicines, herbal, aromatherapy and homeopathic products.

Source: Therapeutic Goods Act 1991.

[46] The SUSMP is maintained by DoHA, supported by the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS). See the information available at <www.tga.gov.au/about/committees-acmcs.htm> [accessed 4 August 2011].

1.18 Under the regulatory regime established by the Act in 1991, products representing a lower level of risk to the public were subject to a lower level of regulation. A new mode of entry into the ARTG was created for most complementary medicines: they are recorded as *listed medicines*. In contrast, registered medicines, because of their ingredients, the manner of their presentation or intended use, are considered to pose a higher potential risk to the public.

1.19 Growing interest in complementary medicines was recognised in October 1996, when the then Minister for Health and Family Services held the *Alternative Medicines Summit* in Canberra, aimed at improving access to alternative medicines. Changing the approval process for complementary medicines was on the government agenda from 1997 'with a view to ensuring any inappropriate existing impediments are removed.'[47]

1.20 In January 2001, the TGA described the listing process by which most complementary medicines gained access to the ARTG as 'a streamlined, less expensive, market entry process ... These lower-risk products are individually assessed, but not evaluated, by the TGA before they are released onto the market.' This arrangement, in the TGA's view, allowed for timely market access 'but with a level of pre-market evaluation of the components of each medicine that delivers an assurance of safe, quality products.'[48] Nevertheless, concerns that the listing system did not fully meet the needs of industry for streamlined market access for their listed products led to further changes.

1.21 Current arrangements for listing medicines on the ARTG are governed by amendments introduced by the *Therapeutic Goods Amendment Act 2001*:

> The amendments in this Bill provide for a medicine to be listed in the Register following self-assessment by the applicant, provided the requirements of section 26A are met.[49]

1.22 Section 26A, under which complementary medicines are listed, requires that the Secretary must list the medicine provided that a specified range of

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47 See *TGA News*, No. 23, April 1997, p. 2, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews23.pdf> [accessed 14 December 2010].

48 TGA, *Additional Submission to Productivity Commission Regarding the Regulation of Complementary Medicines*, 30 January 2001, available from <www.pc.gov.au/__data/assets/pdf_file/0005/39290/sub102.pdf> [accessed 4 August 2011].

49 Therapeutic Goods Amendment Bill (No. 4) 2000, Second Reading Speech, Thursday, 7 December 2000, available from <parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansards/2000-12-07/0038/hansard_frag.pdf;fileType=application%2Fpdf> [accessed 4 August 2011].

conditions are met (such as that the medicine has not previously had its registration or listing cancelled) and the applicant makes certain certifications (for example, that the product complies with quality requirements and contains only active ingredients from a defined list). The sponsor must also pay relevant fees before listing can take place.

The Therapeutic Goods Administration

1.23 The Therapeutic Goods Administration (TGA) is responsible, within DoHA, for the administration of the Act. This work makes it an adviser to government and a major regulator of industry in Australia. Under the Act, the TGA must make decisions whether to permit or reject market authorisation of—in effect, the right to sell—therapeutic goods imported, exported, manufactured and supplied in Australia. In addition, it monitors those products to ensure that standards are maintained. This monitoring includes inspecting factories both in Australia and overseas to ensure that the factory adheres to Good Manufacturing Practice (GMP). The Act also regulates the advertising of therapeutic goods, which is managed partly through a co-regulation arrangement with industry.

1.24 Within the TGA, specific responsibility for complementary medicines falls to the Office of Complementary Medicines (OCM), created in 1999.

1.25 Two major events have influenced the direction of the TGA in recent years: the suspended project to establish a single regulatory scheme and organisation for therapeutic products in both Australia and New Zealand (the Australia–New Zealand Therapeutic Products Authority, ANZTPA) and the Pan Pharmaceuticals matter.

1.26 From December 2003, work was underway to form the Australia–New Zealand Therapeutic Products Authority (ANZTPA), a single agency to perform the TGA's functions for both Australia and New Zealand. The project was suspended when, in mid-July 2007, the New Zealand State Services Minister announced that the then New Zealand Government was not proceeding with the legislation. This was attributed to it having insufficient

parliamentary support to pass such legislation.[50] The most contentious factor leading to the suspension was concern about the possible adverse effect of the new arrangements on complementary medicines in New Zealand, including Maori traditional medicines.[51]

1.27 The ANZTPA project was expected to yield the secondary benefits of reviewing and enhancing the existing regulatory scheme and the TGA's operations. After the project's suspension, that work became the basis of moves by the TGA to take advantage of the several years of preparation for the intended joint organisation to improve the regulatory arrangements in Australia.[52]

1.28 There have been several other major reviews pressing for reform of the TGA and its work. The most prominent, relevant to complementary medicines, has been the work of the Expert Committee on Complementary Medicines in the Health System (the Expert Committee), which reported in September 2003. That report, *Complementary Medicines in the Australian Health System,* was commissioned largely in response to public concern about the trust that could be placed in complementary medicines after the Pan Pharmaceuticals recall in April 2003 and the suspension of that company's manufacturing licence.[53]

1.29 In 2005, the Government accepted 35 of the 49 recommendations made by the Expert Committee and accepted another recommendation in principle.

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[50] DoHA, Establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA), Project Closure and Review Report, 19 September 2007, p. 6. See also <www.anztpa.org/index.htm> [accessed 4 August 2011]. On 20 June 2011, the Australian and New Zealand prime ministers announced their agreement to proceed with the ANZTPA scheme. On 16 June 2011, New Zealand announced it has developed a standalone framework for domestic regulation of low risk complementary medicines. A review of this proposed scheme for natural health products in five years' time will consider whether or not to maintain a separate scheme for certain natural health products in New Zealand. See the information available from <www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr11-dept-dept200611.htm> [accessed 4 August 2011].

[51] One commentator observed 'The most contentious aspect of the ANZTPA initiative has been its potential impact on the regulation of CAM products ... CAM products are currently subject to minimal regulation in New Zealand.' See von Tigerstrom, B. 2007, op. cit. The announcement that the project had re-commenced in June 2011 identified that 'Regulation of complementary medicines was the stumbling block to implementing the joint scheme when it was first agreed.' On 16 June 2011, New Zealand announced that it had developed a standalone framework for domestic regulation of low risk complementary medicines.

[52] DoHA, Australian therapeutic products regulatory framework: A Way Forward for the TGA, Project Business Case, 13 September 2007.

[53] Expert Committee on Complementary Medicines in the Health System, *Complementary Medicines in the Australian Health System*, Report to the Parliamentary Secretary to the Minister for Health and Ageing, September 2003, p. 35, available from <www.tga.gov.au/archive/committees-eccmhs-report-031031.htm> [accessed 4 August 2011].

It did not accept the one recommendation about the amount of research funding available for complementary medicine research in Australia. The remaining 12 recommendations, most of which were outside the direct responsibility of the Australian Government, were supported or noted.[54]

1.30 The Government gave the TGA responsibility for coordinating the implementation of its response. Many recommendations became substantially integrated with the ANZTPA proposal. Following suspension of that initiative in 2007, the TGA noted that work done for that proposal would facilitate implementation of some of the Expert Committee's recommendations.[55]

1.31 TGA management subsequently sought to take advantage of the momentum and positive approach to change that had developed for the ANZTPA project. This commenced with a business case in September 2007. Since that time a range of legislative changes has been made supporting regulatory reform.[56]

1.32 The ANAO performance audit of the regulation of non-prescription medicinal products (December 2004) also followed the Pan Pharmaceuticals recall and licence suspension. That audit examined non-prescription medicines, which includes both over-the-counter (OTC) and complementary medicines. The audit identified opportunities for improvement at most points in the process, and made 26 recommendations, all of which were agreed by DoHA. Their implementation is discussed at Appendix 1.

1.33 More recently, the TGA has undertaken its own internal structural review, known as the 'TGA 21' project. Work undertaken in preparation for the creation of ANZTPA identified for the TGA the diverse and, at times, inconsistent business practices that had developed across the organisation. TGA 21 establishes two distinct streams of activity around its core regulatory functions: (i) product approval and (ii) monitoring of products in the marketplace.

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[54] See the Australian Government response to the recommendations of the Expert Committee on Complementary Medicines in the Health System, March 2005, available from <www.tga.gov.au/archive/committees-eccmhs-response-050309.htm> [accessed a August 2011].

[55] DoHA, Australian therapeutic products regulatory framework: A Way Forward for the TGA, Project Business Case, 13 September 2007.

[56] The TGA's regulatory reform agenda is explained on its web site on the page 'Regulatory Reform', available from <www.tga.gov.au/industry/reforms.htm> [accessed 4 August 2011].

1.34 Other reviews affecting the TGA's administration have been underway recently. Three whose outcome will be relevant to the current audit are:

- *a review of advertising*. Before this audit commenced, the TGA invited comments from interested parties on some proposed changes to the regulation of therapeutic goods advertisements;[57]
- *a transparency review.* In November 2010, the Parliamentary Secretary for Health and Ageing announced a comprehensive review of the way in which the TGA communicates its regulatory processes and decisions. The review was in response to community concern about the lack of information made available by the TGA and considered what information should be made more public, and how that information could be better conveyed. The review was to focus on improving the TGA's transparency. The report of the Review was under consideration by the Government as the present audit was being finalised;[58] and
- *a working group on complementary medicines.* During the course of the audit, the Parliamentary Secretary agreed to the establishment of a working group to review the regulation of complementary medicines in Australia.[59]

The TGA's administrative framework for regulating complementary medicines

1.35 DoHA has a framework, through the TGA, to regulate the supply of complementary medicines in Australia in accordance with the Act. That framework has three operational elements:

- the licensing and audit of manufacturers;
- pre-market assessment of products (that is, before they can be entered onto the Australian Register of Therapeutic Goods (ARTG) and, hence, before they can lawfully be supplied); and

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[57] TGA consultation, *Improving advertising arrangements for therapeutic goods*, available from <www.tga.gov.au/newsroom/consult-advertising-arrangements-101028.htm> [accessed 4 August 2011].

[58] TGA, *Transparency review of the TGA*, available from <www.tga.gov.au/newsroom/review-tga-transparency-1101.htm> [accessed 4 August 2011].

[59] TGA, Minute to Parliamentary Secretary, 'Reforming the Regulation of Complementary Medicines', 9 December 2010. See also TGA evidence to Senate Estimates, Hansard, 31 May 2011, Community Affairs Legislation Committee, p. 56; available from <www.aph.gov.au/hansard/senate/commttee/s83.pdf> [accessed 4 August 2011].

- post-market regulation (that is, regulation of items which the TGA has already placed on the ARTG and which are, therefore, permitted to be available on the Australian market, and regulation of importation and supply of items which are not approved by the TGA and are not generally permitted to be on the market).[60]

1.36 This structure has been in place for some years and is described in documents publicly available on DoHA's TGA website.[61]

1.37 The framework is supported by extensive guidance, documentation and standards which the TGA has developed to help sponsors of complementary medicines meet their legislative obligations. The *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) forms the principal component. The TGA also provides items such as Compositional Guidelines (to clarify the specific form or type of substances that the TGA approves for use in listed medicines where there is no other approved standard available),[62] *Enforcement Guidelines* (to describe and explain the Act's enforcement provisions) and *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (to help sponsors determine the appropriate evidence to support indications and claims made for listable medicines). The TGA makes all these documents publicly available.[63]

Costs of regulating complementary medicines

1.38 The TGA is required to recover 100 per cent of its costs through fees and charges imposed on industry. Its revenue was $101.3 million for 2009–10. Within its overall budget, the cost for regulating complementary medicines is derived using activity-based costing. In 2009–10 the cost of regulating complementary medicines was $9.4 million, or around 9.3 per cent of the overall TGA budget. The average staffing level at the OCM is 23.4 in 2011.

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60 Much of the enforcement and surveillance work undertaken by the post-market areas of the TGA actually relates to the importation and supply of unapproved products.

61 TGA, *The regulation of complementary medicines in Australia—an overview*, April 2007, available from <www.tga.gov.au/industry/cm-basics-regulation-overview.htm> [accessed 4 August 2011].

62 The TGA does not develop Compositional Guidelines for all listable substances: this occurs only where there is no relevant standard for the substance in the British Pharmacopoeia, European Pharmacopoeia, or United States Pharmacopoeia.

63 Standards, guidelines and other publications relating to complementary medicines and their regulation are available from <www.tga.gov.au/industry/cm-sgp.htm> [accessed 4 August 2011]. In this context, 'indications' means the specific therapeutic purposes of the medicine. The term 'claims' is generally taken as having a broader meaning, and includes statements made about the product in advertisements.

1.39 From the perspective of the complementary medicines industry, regulation is not solely a cost burden. Industry derives a benefit both from domestic consumer confidence in its products and from its capacity to market those products elsewhere to the extent that being able to say that their products satisfy the Australian regulators provides assurance to prospective consumers in overseas markets.[64]

Previous relevant ANAO performance audits

1.40 The ANAO has undertaken several performance audits of therapeutic goods regulation since the TGA was formed in 1991:

- Audit Report No.8 1996–97, *Drug Evaluation by the Therapeutic Goods Administration*, tabled in October 1996. This audit focused on prescription drugs. It made 14 recommendations.
- Audit Report No.2 2000–01, *Drug Evaluation by the Therapeutic Goods Administration—Follow-up Audit*. This follow-up audit reviewed progress with implementation of the recommendations of the previous audit and made a further three recommendations.
- Audit Report No.18 2004–05, *Regulation of Non-prescription Medicinal Products*. This audit took place after the major recall of Pan Pharmaceutical products. The audit focused on the regulation of manufacturing practice by the suppliers of non-prescription medicines. The audit made 26 recommendations, all of which were agreed by DoHA. Their implementation is discussed at Appendix 1.

[64] The TGA advised the Productivity Commission's 2002 inquiry into cost recovery by Commonwealth Agencies, p. II: 'The TGA's high standing internationally also provides Australian industry with a substantial benefit when marketing overseas. The fact that a therapeutic good is on the [ARTG] is of great commercial benefit.' A more recent view is: 'Many industry representatives interviewed believed that the high standard of the Australian regulatory system represents a competitive advantage, both globally and in the local market. It is also of great benefit to consumers as it underpins their confidence in purchasing and using Australian made products.' Queensland Government, Dept. of State Development, Trade and Innovation, Final Report, *Natural Ingredients Supply Analysis for Complementary and Alternative Medicines*, 5 January 2006; available from <www.dtrdi.qld.gov.au/dsdweb/v3/documents/objdirctrled/nonsecure/pdf/18460.pdf> [accessed 4 August 2011].

The audit

Audit objective and scope

1.41 The objective of this audit is to examine the effectiveness of the TGA's administration of complementary medicines regulation in Australia. The primary focus is on listed complementary medicines.

Audit criteria

1.42 The audit criteria were to assess whether:

- DoHA manages the evaluation of applications to approve new complementary medicines for supply in Australia effectively;
- DoHA's monitoring of complementary medicines available for supply in Australia is effective; and
- other key aspects of therapeutic goods regulation are managed effectively for complementary medicines, including the implementation of recommendations of earlier audits and reviews.

Audit approach

1.43 Fieldwork for the audit was conducted primarily at the TGA premises in Symonston, ACT. The audit team received presentations on the operation of the various parts of the TGA and subsequently interviewed TGA staff at Symonston, where it examined and took copies of TGA records. It spoke to representatives of industry and consumer representative groups in Sydney and Canberra, and visited the premises of the Complaints Resolution Panel in North Sydney to discuss the Panel's work with its secretariat. The audit team also examined a copy of the ARTG, using specialised auditing software.

1.44 The audit was conducted in accordance with ANAO auditing standards at a cost of $457 500.

Report structure

1.45 In the light of the TGA's operational framework for regulation of complementary medicines, the remaining chapters are structured as follows:

(2) *Guidance documentation.* This chapter discusses the development and maintenance of guidance documents used by the TGA to regulate complementary medicines.

(3) *Pre-market assessment of products.* This chapter discusses the TGA's assessment of complementary medicines before they are allowed onto the Australian market.

(4) *Post-market review of products.* This chapter shows how DoHA has been regulating complementary medicines after they have entered the market and what the results have been.

(5) *Regulating the advertising of complementary medicines.* This chapter considers how effectively the TGA regulates the advertising of complementary medicines. While the focus of this chapter is on complementary medicines, other therapeutic goods are considered where there is a direct relationship to the systems or processes designed to manage therapeutic goods advertising as a whole.

(6) *Providing evidence of efficacy*. This chapter examines moves to strengthen the requirements for providing evidence of the efficacy of complementary medicines since the Expert Committee's report in 2003.

2. Guidance Documentation

This chapter discusses the development and maintenance of guidance documents used by the TGA to regulate complementary medicines.

The importance of guidance documentation

2.1 Effective management of a regulatory program requires that guidance material reflects government policy, is current and comprehensive. This helps regulated entities to understand what is required or expected of them and the consequences of not meeting those requirements or expectations. It thereby helps them to achieve compliance, lessens the later burden on the regulator and, most important, reduces the risk of non-compliant products reaching the market, where consumers would bear the risks of that non-compliance.[65]

2.2 In considering the status of guidance documentation for complementary medicines it must be noted that there was, at the outset, little guidance from experience elsewhere. Therefore the task of developing the documentation was more challenging than if there were others whose experience could be drawn upon. On the other hand, the TGA has been regulating complementary medicines since the Act came into effect in 1990 and has had the benefit of a number of reviews, particularly the one conducted by the Expert Committee in 2003.

2.3 The following discussion considers the currency of the following three guidance documents:

- *The Australian Regulatory Guidelines for Complementary Medicines* (ARGCM);
- *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims*; and
- *Draft Evidence Guideline for Listed Medicines Indicated for Weight Loss*.

[65] ANAO, *Administering Regulation: Better Practice Guide*, March 2007, p. 6.

The Australian Regulatory Guidelines for Complementary Medicines

2.4 The TGA developed the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) to:

- provide information to help sponsors of complementary medicines to meet their obligations under therapeutic goods legislation;
- help ensure that applications to the TGA relating to complementary medicines uniformly meet all the essential regulatory requirements so that applications may be processed successfully within minimum timeframes; and
- enhance the clarity and transparency of processes leading to the Registration and Listing of complementary medicines in the Australian Register of Therapeutic Goods (ARTG).[66]

2.5 The content of the ARGCM is intended to reflect the current Australian requirements for the regulation of complementary medicines.

2.6 The TGA began developing the ARGCM from 2001, in consultation with the two main industry representative bodies which have a relevant interest.[67] After extensive consultation the document was made available in 2004. The Expert Committee, in its report on complementary medicines in the healthcare system, noted that this was underway and made no specific recommendations about the guidelines. At that time, the ARGCM was expected to provide a basis for developing new guidelines for complementary medicines under the then proposed Australian–New Zealand regulatory scheme (ANZTPA).

The ARGCM has been due for updating since 2008

2.7 A meeting of the Office of Complementary Medicines–Industry Consultative Group (OICG) in April 2007 identified updating the ARGCM (then dated March 2006) as a topic for the future.[68] By 2008, the OCM regarded

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66 The ARGCM is available from <www.tga.gov.au/industry/cm-argcm.htm> [accessed 4 August 2011].

67 These are the Complementary Healthcare Council of Australia (CHC) and the Australian Self-Medication Industry (ASMI).

68 OICG 15, Item 13.1, 20 April 2007. Most parts of the ARGCM were, as of February 2011, dated June or September 2005. The appendix on the ELF was the most current component, dated June 2009. Part II, on listed complementary medicines, was dated March 2006.

it as due for review and updating.[69] Since then there has been both further legislative and administrative change likely to have a bearing on its content.[70]

2.8 The OCM has recently identified updating the ARGCM as directly relevant to improving the regulatory compliance of listed products as it will 'provide clarity to sponsors to enable them to understand the regulatory requirements for listed medicines'.[71] The TGA has also advised that this is one of its actions to improve compliance (a matter that is discussed in a later chapter).[72]

2.9 Specifically, the OCM advised the ANAO that:

> In May 2010, the OCM requested feedback from the OCM–Industry Consultative Group (OICG) on the areas identified by the OCM as needing updating and on industry priorities for other sections needing review.
>
> The OCM proposes that the project will be conducted in the following three phases:
>
> - Correcting typographical and administrative issues including updating broken web links (completed March 2011).[73]
> - Update the ARGCM to reflect current legislative framework and processes. These updates will be published by the end of August 2011.
> - Develop and implement improvement processes which will occur after 1 May 2011.
>
> The OCM has allocated resources to manage the first two phases of the ARGCM review. A draft project plan ... was originally developed in July 2010 and is currently being updated to reflect this staged approach. An updated version of the ARGCM, incorporating the first two phases, is proposed to be published on the TGA website by May 2011 following public consultation.[74]

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69 At an OICG meeting, a TGA officer stated that it was 'now recognised as due for review and updating'. (Outcome Note, Twenty-Fourth Meeting of the OICG, 12 December 2008, Item 7.1. p. 6).

70 An example is the newly-introduced capacity to suspend a product from the ARTG rather than cancelling it in certain circumstances. A catalogue of recent reform is set out on the TGA website, available from <www.tga.gov.au/industry/reforms.htm> [accessed 4 August 2011].

71 TGA, OCM advice, November 2010.

72 TGA, OCM advice of November 2010 and 22 December 2010.

73 Phase I updates were published on 1 March 2011 ('Version 4.0') correcting typographical errors and broken website links. The new edition is available from <www.tga.gov.au/industry/cm-argcm.htm#argcmp1> [accessed 4 August 2011]. Phase II updates were then being consolidated.

74 TGA, OCM advice, 2 December 2010.

2.10 The OCM expects the third phase of the review to entail a complete review and improvement of the document. Given that OCM regards updating the ARGCM as likely to contribute to improved compliance, the high level of non-compliance recently reported by the TGA (discussed in Chapter 4) implies that it is desirable that this updating be completed promptly.

2.11 A project plan for updating the ARGCM exists (dated November 2010), but remains in draft format.[75]

Review of the 'Guidelines for Levels and Kinds of Evidence to Support Indications and Claims'

2.12 The TGA developed the *Guidelines for levels and kinds of evidence to support indications and claims* (the Guidelines) in consultation with its former Complementary Medicines Evaluation Committee (CMEC) and industry.[76] These guidelines are important as they give sponsors direction on the type and level of evidence the TGA considers is necessary to support the indications and claims sponsors make for their listed medicines. According to the Expert Committee, the Guidelines were developed from a National Health and Medical Research Council (NHMRC) document on levels of evidence and 'adapted to suit the challenges of making evidence-based claims for complementary medicines.'[77]

2.13 The edition of the Guidelines dated October 2001 remains the latest available, and is accessible on the TGA website. The Expert Committee found in 2003 that it provided a sufficient framework to assess the efficacy of listed complementary medicines.[78]

Expert Committee proposed the Guidelines become regulations

2.14 The Expert Committee noted that when a sponsor submits an application to the TGA to list a medicine on the ARTG, they must certify, among other things, that they hold evidence to support the indications and claims made for that medicine. However, the type and level of evidence

[75] Copy provided by the TGA on 2 December 2010.

[76] The 'Proposed Approach of the CMEC to Standards for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods' was released in 1999 for a trial period.

[77] Expert Committee, Report, p. 85. See <www.tga.gov.au/archive/committees-eccmhs-report-031031.htm> [accessed 4 August 2011].

[78] Expert Committee, Report, p. 84.

required is not specified in the law. This means that a sponsor may base their certification on whatever evidence they believe appropriate. The Committee recommended:

> The *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* should be prescribed in the Therapeutic Goods Regulations 1990 as the requirement for the level and kind of evidence to support the indications and claims for Listed complementary medicines [Recommendation 4].[79]

2.15 In the committee's view, this would provide an equitable and enforceable base for the type and level of evidence considered the minimum necessary to adequately support indications and claims for listed medicines. In other words, the committee found that the content of the Guidelines was satisfactory but that they needed to be mandatory—not optional—to achieve greater consistency and equity in the regulation of complementary medicines.

The Government agreed to make the Guidelines into regulations

2.16 In March 2005, in its published deliberations on its response to the Expert Committee's report, the then Government considered a range of options to implement this recommendation. It then opted for 'Mandatory compliance with the TGA Guidelines, together with mandatory submission by the sponsor of a brief summary of the evidence held to support the claims, as proposed by recommendations 4 and 5 of the Expert Committee.'

2.17 The Government response noted that, as the Guidelines had been formulated to represent the minimum level and type of evidence which would be acceptable, the only sponsors who would be disadvantaged and face additional costs would be any who had made incorrect certifications and did not, in fact, hold evidence which meets the Guidelines. These sponsors would then face the choice of obtaining the necessary evidence, modifying the claims made for the products, or withdrawing the products from the market.[80]

2.18 On this basis, the Government agreed to the recommendation and stated that it 'would establish enforceable standards of evidence to support claims for Listed complementary medicines' and the TGA would consult with the NHMRC to encourage greater consistency in the type of evidence to

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[79] Expert Committee, Report, p. 85.

[80] *Australian Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*, March 2005, Attachment 2, p. 15, available from <www.tga.gov.au/archive/committees-eccmhs-response-050309.htm> [accessed 4 August 2011].

support therapeutic claims.[81] The Government noted the Guidelines were scheduled for review, in consultation with stakeholders, to enhance applicability to all 'modalities' of complementary medicines.

The TGA established CMIRG to track progress

2.19 In 2005, following the Government response to the report of the Expert Committee, the TGA appointed another external committee, the Complementary Medicines Implementation Reference Group (CMIRG), to oversee implementation of the Expert Committee's recommendations and report progress.[82] CMIRG was involved in the preparation of several reports on progress, published on the TGA website.[83]

2.20 In late 2005, the OCM expected to commence the review of the Guidelines in early 2006 with a view to their being completed by June of that year. An industry representative asked, at the November 2005 TGA–Industry Consultative Committee (TICC), whether the Guidelines would be compliant with NHMRC evidence guidelines.[84] The National Manager, TGA, advised that NHMRC Guidelines would be considered when reviewing TGA's Guidelines.

2.21 The (then) Complementary Medicines Evaluation Committee was briefed on the matter by a TGA officer:

> The TGA officer pointed out the concerns raised by the Expert Committee regarding the lack of legal underpinning for the levels of evidence required for claims made for low risk (Class I) or Listed medicines. Because of this, some sponsors had decided not to adhere to the guidelines because they were merely guidelines.
>
> The TGA officer noted that the move to the joint agency has provided an opportunity to review the Guidelines and, in the review process, to indicate to

[81] *Australian Government Response, op. cit.*, p. 1. The TGA provided evidence that those discussions with the NHMRC took place on 9 May 2007.

[82] The TGA website provides information about CMIRG, available from <www.tga.gov.au/archive/committees-eccmhs-progress.htm#cmirg> [accessed 4 August 2011]. CMIRG was chaired by the person who had chaired the Expert Committee. CMIRG's terms of reference were to: provide advice on the development of a plan and timetable for implementing the Government Response to the recommendations of the Expert Committee; monitor progress on the implementation of the Government Response; and assist in the development of a report reviewing progress 12 months after commencement of the implementation plan. OCM advised (15 December 2010) that CMIRG met eight times: first on 13 July 2005 and last on 17 November 2008.

[83] The progress reports are available from <www.tga.gov.au/archive/committees-eccmhs-progress.htm> [accessed 21 June 2011].

[84] TGA, Minutes, 18th TGA–Industry Consultative Committee meeting, Thursday 24 November 2005.

stakeholders that they will have legal underpinning. In the new joint agency, the Guidelines themselves are proposed to become a Managing Director's Order (MDO) much like the Therapeutics Goods Orders (TGOs).[85]

2.22 The review of the Guidelines did not start in early 2006, as the OCM had expected. In October 2006, the TGA reported:

> The TGA is planning to undertake a review of the *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* during 2006–07 so that the Guidelines can be incorporated into the legally enforceable legislation for the proposed joint regulatory scheme, in line with the Government's response to recommendation 4. The review of the Guidelines includes liaison with the [NHMRC] to ensure greater consistency between the Guidelines and the NHMRC's levels of scientific evidence while at the same time continuing to also recognise evidence based on traditional use for certain complementary medicines as outlined in the Government's response to [Expert Committee] recommendation 8.[86]

2.23 In January 2007, the OCM reported that the review had commenced during December [2006] with a request for a meeting with the NHMRC.[87] However, the review stalled following the suspension, a few months later, of the ANZTPA project.[88]

2.24 In May 2008, one of the two major industry representative bodies put its view to government that this recommendation and other unimplemented Expert Committee recommendations, should be 'fast-tracked' for implementation.[89]

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85 Complementary Medicines Evaluation Committee, Ratified Minutes Fifty-sixth Meeting, 21 April 2006. available from <www.tga.gov.au/archive/committees-cmec.htm> and <www.tga.gov.au/about/committees-accm.htm> [accessed 4 August 2011]. CMEC was replaced by the Advisory Committee on Complementary Medicines (ACCM) in January 2010. ACCM's role is to advise and make recommendations to the TGA on the inclusion, variation or retention of complementary medicines in the ARTG.

86 TGA, Implementation of the Government Response to the Recommendations of the Expert Committee on Complementary Medicine in the Health System, Progress Report, October 2006, available from <www.tga.gov.au/pdf/archive/committees-eccmhs-progress-0610.pdf> [accessed 4 August 2011].

87 TGA, OCM, Strategic Business Update, Complementary Medicines Program, (Report to TICC on the activities of the Complementary Medicines Program for the second quarter 2006–07).

88 This was the view of ASMI in *Strengthening Regulatory Controls for Listing of Complementary Medicines* (Submission to the Parliamentary Secretary to the Minister for Health and Ageing), May 2008, p. 7, available from <www.asmi.com.au/documents/Industry/Submission%20to%20Jan%20McLucas%20Re%20Comp%20Med%20regulatory%20reform%20May08.pdf> [accessed 4 August 2011].

89 ASMI, op. cit., p. 4.

2.25 The momentum continued until at least July 2008, when the TGA undertook a round of consultation on the reforms to be carried forward after the suspension of ANZTPA. At a presentation on regulatory reform for complementary medicines, the then head of the OCM noted that a significant future direction was the proposal to provide legal underpinning for the Guidelines. The record of the consultations shows:

> Participants noted the proposal to provide legal underpinning to the 'levels of evidence' guideline. Progress has been made in reviewing the existing *Guidelines for the Levels and Kinds of Evidence Required to Support Indications and Claims* for listed complementary medicines to allow this to occur. Proposed changes to the evidentiary requirements for Listed medicines will be subject to stakeholder consultation.

2.26 The expectation at the time was 'that the legislative changes required to underpin the levels and kind of evidence to support indications and claims for listed complementary medicines will be introduced into the autumn 2009 sitting of the Australian Parliament.'[90]

2.27 Consistent with this, the DoHA *Regulatory Plan 2008–09* sets out implementation of this recommendation with an expected date of June 2009. This item in the plan, prepared in July 2008, notes that the TGA had reviewed the existing guidelines and consulted stakeholders, as part of the ANZTPA process. Consultation with key Australian stakeholders was continuing. At that time, the ANZTPA proposal had been postponed indefinitely, and the Government had indicated that it would move to introduce these regulatory requirements within existing Australian legislation.[91]

2.28 In early 2009, the former chair of CMIRG (and of the Expert Committee) wrote that he expected the legislative changes to make the Guidelines into regulation would be introduced into the Parliament in 2009.[92]

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[90] Formerly available from <www.tga.gov.au/regreform/cm.htm#pres> [accessed 11 February 2011] and, for the paper on regulatory reform, <www.tga.gov.au/regreform/080730prescm.pdf> [accessed 11 February 2011]. This page of the TGA website stated that it was last updated on 2 September 2008. This is not accessible on the revamped TGA website from 4 May 2011.

[91] DoHA, *Regulatory Plan 2008–09*, available from <www.health.gov.au/internet/main/publishing.nsf/Content/Regulatory+Plan+2008-09> [accessed 4 August 2011]. A similar intention had appeared in the previous year's regulatory plan, but with an implementation date of June 2008.

[92] Bollen, Michael D and Whicker, Susan D. 'Complementary Medicines Regulatory Reform', *Australian Health Review*, vol. 33, no. 2, May 2009, pp. 288–94. See: <www.publish.csiro.au/?act=view_file&file_id=AH090288.pdf> [accessed 4 August 2011].

Progress stalled by late 2009

2.29 CMIRG had ceased operation after its last meeting in November 2008. The OCM subsequently arranged for a final 'close-out' report on the Expert Committee recommendations to be prepared in late 2009.[93] This is, in effect, the last formal document recording what had become of the recommendations the Government had agreed to. It is not publicly available.

2.30 On Recommendation 4, the close-out report records the following status and comments as at December 2009:

> **Underway**
>
> Based on experience since the Guidelines were first introduced in 2001, including the learnings from the development of the Guidelines for Levels and Kinds of Evidence for Listed Medicines with Indications for Weight Loss, the broader Guidelines will be reviewed to provide greater clarity. The review will consider ways to encourage industry to use the guidelines to improve their capacity to evaluate the quality of evidence used in making claims.

2.31 The original recommendation had been accepted by the then Government. There is no evidence of any relevant change in policy settings since that time. But the intent expressed in the close-out report is to *encourage* compliance rather than requiring it, whereas the very reason for giving the guidelines the force of regulation was that industry was electing to disregard them. It is not clear when or how the adopted policy was set aside, or the basis for doing so.

2.32 As at August 2011, the status of the proposal, over seven years after the Expert Committee made its recommendation and six years after the Government agreed to it, is that the policy position has been reversed without further reference to government and there has been no change to practice.[94]

2.33 The close-out report does not explain how the TGA (or DoHA more broadly) has reached that position on the matter. That is, it does not identify what constraints, pressures or difficulties inhibited progress over the years and led it to this position, in which it appears to have ceased progressing implementation. The TGA advised:

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[93] TGA, Office of Complementary Medicines, Internal Report, 'Complementary Medicines Implementation Reference Group: Final Report', December 2009.

[94] On the basis of the briefing given to CMEC in 2006 it is apparent that the recommendation could have been implemented by means of a Therapeutic Goods Order (TGO).

> The TGA acknowledges that the CMIRG close out report dated December 2009 does not address progress with implementing the [Expert Committee] Recommendation 4. The reason for this is not apparent to current TGA staff.[95]

2.34 The matter is not mentioned in the DoHA *Regulatory Plan 2009–10*.[96]

2.35 As this audit was being concluded, the TGA provided evidence that it had sought the approval of the Parliamentary Secretary to proceed with implementing the remaining recommendations of the Expert Committee. This would include the recommendation to prescribe the Guidelines in the Regulations. The working group advising the TGA on reform of the regulation of complementary medicines supports the inclusion in the Regulations.[97]

Industry is progressing a review of the Guidelines

2.36 Aside from progress with implementation of the Expert Committee recommendation, as agreed by government, the question also arises about progress made with reviewing the Guidelines themselves.

2.37 Industry representatives have taken the initiative in revising the Guidelines. In May 2010, a report to the OICG advised that the two main industry representative organisations were 'developing a proposal for the Levels of Evidence Guidelines, based upon an industry driven review by 15–20 experts.'[98] The two organisations provided the July meeting of the same group with an update on the plan for:

> the industry associations' review of the Levels of Evidence Guidelines. The working group is currently developing Terms of Reference and this review document will be forwarded to OCM prior to being discussed at OICG. Members will be updated as the project progresses.[99]

2.38 The TGA advised that the industry associations' intention was raised again at the February 2011 TGA–Industry Consultative Committee bilateral meeting. It added that:

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95 TGA advice of 20 May 2011.

96 DoHA, Regulatory Plan 2009–10, available from <www.health.gov.au/internet/main/publishing.nsf/Content/Regulatory+Plan+2009-10> [accessed 4 August 2011].

97 TGA, minute of 26 May 2011.

98 The two organisations are CHC and ASMI. Outcome Note, OICG 30, 14 May 2010.

99 Outcome Note, OICG 31, 16 July 2010, Item 11.1, p. 5.

> At that time, the National Manager indicated that the TGA would undertake its own review and the industry could submit their comments as part of the consultation process. The OCM is unaware of the current status of the review being undertaken by industry.[100]

2.39 It is appropriate that industry representatives should have input into this review, given that industry will be required to meet the Guidelines and can be expected to command much expertise in this field.

2.40 The TGA also advised that it 'has indicated to the industry associations that the work of the industry group will hopefully be able to inform the work undertaken by TGA on this issue.' The TGA has also stated that it envisages that the NHMRC and broader stakeholders will be consulted.

The delay in settling the future of the Guidelines: consequences

2.41 The delays in settling the future of the Guidelines may detract from the objective of the Government's *National Medicines Policy* (NMP). In particular, one of the NMP goals is the 'quality use of medicines'. According to the NMP, this requires that 'consumers and health practitioners should have timely access to accurate information and education about medicines and their use.' The former chair of the Expert Committee stated, two years ago:

> The delay in addressing the issues around evidence impacts heavily on the quality of and access to information necessary to support consumers and health professionals in the quality use of complementary medicines.[101]

2.42 The TGA advised that:

> The TGA undertook a review of the evidence guidelines for listed medicines as part of the acceptance of the [Expert Committee] recommendations. However, finalisation of this review has not occurred, as it has been recognised that work done on the draft Evidence Guidelines for Listed Medicines Indicated for Weight Loss would provide valuable input to the broader Evidence Guidelines for Listed Medicines. It is envisaged that consultation with the NHMRC would form part of this finalisation, with particular regard to the current review of the NHMRC evidence guidelines, along with broader consultation with other stakeholders.[102]

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[100] TGA advice of 20 May 2011.

[101] Bollen, Michael D and Whicker, Susan D. op. cit. pp. 288–94.

[102] TGA advice of 20 May 2011.

2.43 This additional set of evidence guidelines, concerned with listed medicines indicated for weight loss, is considered below.

Draft Evidence Guidelines for Listed Medicines Indicated for Weight Loss

2.44 The OCM has been working for several years on the draft *Evidence Guidelines for Listed Medicines Indicated for Weight Loss*. It is developing these to help sponsors of listed complementary medicines work out the level and kind of evidence to provide in support of indications and claims for weight loss.

2.45 The OCM has stated that products with indications for weight loss are, among listed medicines, a special case, and warrant special guidelines:

> indications for weight loss are not as precise as with many other indications in that they refer to a complex condition with many different aspects. For example, it is a continuous variable in that there is a continuum from underweight, through normal, overweight and obese. Also, there are a lot of terms that can be used to imply weight loss, such as 'essential for the body to metabolise fat' and 'has impact on cellulite'. In addition, given that the claim of weight loss is relatively modern, there is an ongoing challenge in defining the relevance of traditional evidence in supporting such claims.[103]

Preparation of the first draft and consultation

2.46 A consultant prepared the first draft of these guidelines in November 2007. By January 2009, the TGA had not released any guidelines and attracted press criticism because the process had, to that point, taken 14 months. The press suggested that both consumer groups and 'sections of the complementary medicines industry' were concerned about the delay.[104]

2.47 At that time, the TGA acknowledged that the guidelines had taken longer than expected (though it did not explain why) but said that the document prepared in November 2007 was the first step and not the penultimate step. Moreover, if there were no pressing matters of public safety, the TGA thought it better that it did things properly rather than quickly. It released a consultation draft of the guidelines the following month.[105,106]

[103] TGA, OCM advice of 9 December 2010.

[104] *The Australian* newspaper, 23 January 2009, p. 3, article, 'Anger at delay on fat guideline'.

[105] TGA Briefing Note for the Parliamentary Secretary, 21 January 2009.

Consultation closed on 3 April 2009, having attracted 26 submissions.[107] The TGA found that, when these were collated and summarised, it had received diverse and polarised views.[108]

Focused consultation

2.48 In September 2009, the TGA advised the minister that:

> The submissions have been considered and, where appropriate, suggestions have been incorporated into a revised draft. During this process, the document has been significantly modified.
>
> All those who submitted comments on the draft guideline will be provided with a copy of the revised draft and invited to participate in a focused consultation to be held on 26 October 2009. During this focused consultation, participants will have the opportunity to comment on pre-identified elements of the guidance document. Subsequent to this, the guidance document will be refined and a proposed implementation plan will be constructed.[109]

2.49 In an attempt to build consensus, the TGA invited respondents to the initial draft to a workshop in Canberra. The TGA advised the ANAO that the focused workshop was held in October 2009 'to explore key issues raised during the online consultation' that had taken place since the draft had been released.[110] The OCM recorded the major outcomes of the October meeting:

> (1) [the] document was considered useful and valuable; (2) minor adjustments are to be made to the main body and the expansion of the last section were recommended; and (3) a graded implementation strategy was recommended.[111]

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[106] TGA, *Draft Guideline for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss*, Consultation paper, available from <www.tga.gov.au/archive/consult-cm-weightloss-090206.htm> [accessed 4 August 2011].

[107] There were six responses from individuals, five from regulators or government groups, three from consumer groups, six from the complementary medicines industry, three from industry peak bodies and three from professional groups (TGA, minute to the National Manager from the Head, OCM, 'Evidence Guidelines for Listed Medicines Indicated for Weight Loss', August 2009,).

[108] TGA, minute, *Evidence Guidelines for Listed Medicines Indicated for Weight Loss*, October 2010.

[109] DoHA, TGA parliamentary question time brief, 'Crackdown on Weight Loss Programs', Background section, September 2009.

[110] TGA, OCM email advice of 9 December 2010.

[111] TGA, OCM, Weekly Issues Summary, 23 March 2010.

Consequential delays

2.50 The OCM postponed action on other regulatory matters with a view to resolving these guidelines first. For example, in early 2010, it recorded that the Complaints Resolution Panel (CRP), which considers certain advertising complaints (see Chapter 5) had referred a number of complaints to the TGA about products making weight loss claims. The complaints related to the evidence available to support the claims for the products, and the CRP did not feel it had the expertise to appropriately make a determination.

2.51 The OCM recorded that progress with the matters that had been referred by the CRP 'has been put on hold pending finalisation of the Evidence Guidelines for Listed Medicines indicated for weight loss.'[112]

Progress stalled after the workshop

2.52 During the course of 2010, the OCM records several relevant internal meetings but without a specific further outcome. As of 2 August 2010, the OCM recorded that there was now a 'need to develop a way forward'.[113]

2.53 In November 2010, the OCM prepared a minute in which it advised that there were 'approximately 350 products listed in the ARTG making some form of claim or indication related to weight loss.' It wrote:

> It is unlikely that sponsors of products currently indicated for weight loss hold evidence that will fully comply with the scientific evidence requirements of the Guidelines. As such, implementation of the Guidelines is likely to result in the loss of most, if not all, Listed weight loss products from the market.
>
> However, the TGA is obligated to ensure that therapeutic goods that are safe, efficacious and of acceptable quality are available to the Australian population. Unsubstantiated claims made by Listed weight loss products are a frequent source of consumer complaints received by the TGA and have the potential to cause significant financial harm to consumers.[114,115]

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[112] TGA, OCM, Weekly Issues Summary, 23 March 2010.

[113] TGA, OCM Weekly Issues Summary, 24 August 2010.

[114] This is consistent with views put in the NHMRC *Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults*, 'Part 10—Weight-loss supplements and Alternative Treatments', available from <www.health.gov.au/internet/main/publishing.nsf/Content/obesityguidelines-guidelines-adults.htm> [accessed 4 August 2011]. These guidelines recommended: 'It is important to advise patients about the lack of evidence for the use of alternative, over-the-counter weight-loss medications and, in some cases, the possible dangers of their use.' The guidelines were last updated in March 2004. Although then expected to be revised in 2006, a revision is now expected to be complete in 2012 (see: <www.nhmrc.gov.au/nics/programs/obesityguidelines.htm> [accessed 12 May 2011]).

2.54 Here the OCM identifies the financial risk to consumers as a consideration. This is consistent with one of the forms of harm identified by the Chair of the Expert Committee in 2003 (para. 1.12 above). Two years earlier, the only risk it overtly considered was that there were no pressing matters of public safety (para. 2.47, above).

A completion date remains uncertain

2.55 The OCM advised in December 2010 that 'the development of these guidelines is still ongoing and there is no current date for completion':

> The work that has gone into the development of these guidelines has identified a need to re-examine how we consider evidence for claims for Listed Medicines. This has been communicated and discussed with consumers and peak industry bodies. [An industry body] has agreed that action needs to be taken with the involvement of consumers and other industry bodies.[116]

2.56 The TGA was invited to elaborate on the implications of 're-examining how the TGA considers evidence for claims.' It advised that:

> TGA agrees that the levels of evidence should be consistent across all sectors but recognises that providing useful explanations to guide and assist understanding of levels of evidence relevant to particular stakeholder groups may vary to reflect the paradigm in which they operate.[117]

2.57 The former chair of the Expert Committee pointed out, in 2009, that the delay in addressing questions of evidence has:

> impacted on the development of more appropriate study designs necessary to support therapeutic claims for specific product areas such as those promoted for weight loss, which has enabled the market to be inundated with a vast range of products with an equally vast range of combinations of active ingredients supported by the limited evidence as defined under the regulatory role definition of traditional use ...[118]

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[115] The TGA confirmed that the NHMRC's Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults were considered when the draft weight loss guidelines were being developed. It should be noted that in relation to efficacy of pharmacotherapies, the NHMRC document relates to products that are indicated for obesity, a claim not permitted for listed medicines. The TGA advised that it envisages consulting the NHMRC again before finalising its evidence guidelines. The TGA also would not seek to be inconsistent with NHMRC clinical guidelines but does wish to have a guideline to support the Complementary Medicines industry in terms relevant to it.

[116] TGA, OCM email advice of 9 December 2010.

[117] TGA advice of 20 May 2011.

[118] Bollen, Michael D and Whicker, Susan D., op. cit., pp. 288–94.

Developing guidance documentation

2.58 A range of guidance documents is used by the TGA to help regulate complementary medicines. These documents provided essential information to sponsors about how to engage with the regulatory system. Their currency and completeness are important to effective regulation. In each of the cases examined above, review of this documentation has taken and continues to take a long time.[119] The subject matter is complex and necessarily must draw on particular expertise. However, excessive delay in finalising important documentation of this sort can:

- result in uncertainty for industry about the rules it must work with and how these might change. Industry needs to make judgments about bringing products to market and withdrawing others. Continuing uncertainty imposes additional costs as it tries to make these judgements;
- have implications for consumers. For example, if some weight-loss products are withdrawn from the market because their sponsor cannot demonstrate their efficacy, consumers may have wasted their resources purchasing ineffective products; and
- weaken the authority and perceived regulatory integrity of the TGA.

2.59 The OCM, with day-to-day responsibility for regulation of complementary medicines, has itself identified outdated guidance documents as a potential contributing factor for poor regulatory compliance. It has been aware that regulatory compliance has been poor since at least 2007. This makes it all the more important that guidance documentation be kept current.

2.60 The OCM has also identified 'Sponsors that intentionally use delaying or obstructive tactics' as a factor in poor regulatory compliance. While it is difficult to determine how often such behaviour occurs, to the extent that it does, outdated or unfinalised guidance documents can potentially enhance the opportunity for such 'tactics' to be deployed successfully.

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[119] OICG deliberations indicate that guidance documents other than those mentioned here may also be in need of review or finalisation. For example, in late 2010, OCM asked OICG to review three guidance documents developed in 2006 and 2007 by OCM and OICG for use as adjunct guidelines to the ARGCM: *Guidance on Standardisation of Herbal-derived Ingredients*; *The Use of Modified Unprocessed Herbals and Biological Materials in Complementary Medicines*; and *Guidance on Equivalence of Herbal Extracts*. OICG was asked to advise the OCM if they are still considered relevant. In February 2011, the OCM finalised and published the last-mentioned on its website, see the information available from <www.tga.gov.au/industry/cm-herbal-extracts.htm> [accessed 4 August 2011].

2.61 The TGA has clearly set out to achieve a consensus among stakeholders over its guidelines. While this is a desirable goal, in practice the regulation of complementary medicines has attracted polarised opinions at times. In these circumstances, there may be only marginal benefit in artificially drawing out processes.

Recommendation No.1

2.62 To achieve timely completion of key guidance material for complementary medicines, the ANAO recommends that DoHA:

(a) provides a target date for the completion and publication of each key guidance document; and

(b) provides regular progress reports on the development of key guidance documents, on the TGA website, to keep industry, health professionals and consumers informed.

Agency response

2.63 DoHA agreed to the recommendation.

2.64 The ANAO proposes that this recommendation be considered in the context of the TGA ensuring that adequate formal guidance is in place to ensure compliance with best practice administrative standards, including for project management and record keeping.

3. Pre-market Assessment of Products

This chapter discusses the TGA's assessment of complementary medicines before they are allowed onto the Australian market.

Pre-market assessment is based on risk of use

3.1 The TGA's pre-market assessment of a complementary medicine is based on the risk of its use. That risk is assessed by taking into account factors such as the toxicity of its ingredients, the form of dosage, the likelihood and significance of side effects and of adverse effects from prolonged use or inappropriate self-medication.

3.2 Particular complexity is introduced to regulating complementary medicines such as those derived from plants because their character can vary or be affected by factors including the following:

- *the species or variety of plant used*—closely related plants may vary greatly in the amount of active ingredients they contain;
- *source*—the same plant grown in different areas of the world may exhibit different therapeutic properties;
- *part of the plant used*—for example, the content of leaves, stems and roots may vary and need to be considered separately;
- *manufacturing process*—the manufacturing process may interact with the active ingredients. For example, the type of solvent used to extract the desired ingredients may affect the final product; and
- *contamination*—the same herb from different sources may exhibit different levels of contamination.

3.3 In practice, the Therapeutic Goods Act divides all medicines into two categories:

- *higher risk*—which includes all prescription and over-the-counter medicines and relatively few complementary medicines; and
- *lower risk*—which includes most complementary medicines.

Changes to regulation of complementary medicines in 2001

3.4 The mechanism that governs the regulation of listed complementary medicines was introduced by amendments to the Therapeutic Goods Act in

September 2001. The amendments provided for the introduction of a 'redeveloped and refined system for electronically listing medicines' on the ARTG.[120] In particular, the new system was to provide for listable medicines to be marketed more quickly through the electronic lodgement of applications.[121]

3.5 The timeframe for entry of low-risk medicines in the ARTG in 1994–95 had been around five months.[122] Following the introduction of the original electronic lodgement facility (ELF) in mid-1996, processing times came down to an average of less than ten days by 1997–98 and ten days or less for 93 per cent of applications by 2000.[123] This was a period during which the numbers of applications a year had roughly doubled.[124]

3.6 The Government moved to further expedite the process with the changes that took effect in 2001, having stated that:

> There have been concerns that the current listing system, whilst an improvement over the previous paper-based system, does not fully meet the needs of industry for streamlined market access for their listed medicines.[125]

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120 Second Reading speech, Therapeutic Goods Amendment Bill (No. 4) 2000, Senate Hansard, 7 December 2000, p. 21031, available from <www.aph.gov.au/hansard/senate/dailys/ds071200.pdf> [accessed 4 August 2011].

121 The new model for listing was developed by the Listed Medicinal Products Project Advisory Committee from late 1998 to mid-2000. See TGA News Issue 36 (October 2001), formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews36.pdf> [accessed 7 April 2011].

122 TGA News Issue 22 (October 1996)—Legislation update, formerly available from <www.tga.gov.au/docs/html/tganews/news22/legis.htm> [accessed 11 February 2011].

123 TGA, Submission to the Productivity Commission Review of Cost Recovery by Commonwealth Agencies, 4 December 2000, p. 9, available from <www.pc.gov.au/__data/assets/pdf_file/0004/39226/sub089.pdf> [accessed 4 August 2011]. Later, the TGA advised the Productivity Commission that, before the ELF system had been introduced, the turnaround time for applications was 'of the order of' 70 days. After the ELF system most applications were 'turned around' in about 10 days, except where serious regulatory problems were identified. See: TGA, Additional Submission to the Productivity Commission Review of Cost Recovery by Commonwealth Agencies, 30 January 2001, p. 5, available from <www.pc.gov.au/__data/assets/pdf_file/0005/39290/sub102.pdf> [accessed 4 August 2011].See also the transcript of evidence by the then National Manager, TGA, 7 December 2000, available from <www.pc.gov.au/__data/assets/pdf_file/0015/37131/canberra001207.pdf> [accessed 4 August 2011].

124 TGA, Submission to the Productivity Commission Review of Cost Recovery by Commonwealth Agencies, 4 December 2000, pp. 9 and 15, available from <www.pc.gov.au/__data/assets/pdf_file/0004/39226/sub089.pdf> [accessed 4 August 2011]. The chart provided in the TGA submission indicates that the average processing time dropped to well under 10 days for the 1997–98 financial year and remained at that level for the following two financial years.

125 Second Reading speech, Therapeutic Goods Amendment Bill (No. 4) 2000, Senate Hansard, 7 December 2000, pp. 21029–30.

3.7 A consequence of these changes to the Act is that the TGA has limited pre-market opportunity to assess listed medicines. This was intended:

> The electronic listing of medicines under section 26A relies heavily on information provided by applicants and is predicated on self-assessment, rather than the TGA checking every detail to establish whether the medicine meets statutory requirements for listing in the listing process.[126]

3.8 Therefore it needs to be borne in mind that the structure of the regulatory framework for listed complementary medicines places emphasis on self-assessment by sponsors in getting their product listed, with the TGA assuming greater post-market monitoring responsibilities.[127]

The Expert Committee found the arrangements appropriate

3.9 In 2003, the then Government appointed the Expert Committee to conduct a major review of complementary medicines in the Australian health system.[128] The Expert Committee reported later that year and concluded that, ideally, all listed medicines should be assessed for efficacy by the TGA before their supply. On the face of it, this approach would run contrary to the self-assessment system then only recently introduced. However, the Expert Committee also found that 'the current system of control is practical and generally commensurate with the risk and benefit of the products'. Moreover, it found that the TGA's two-tiered, risk-based regulatory system should be maintained, but with some enhancements.'[129] The system was 'generally considered sufficient and relevant to meet appropriate standards of quality, safety and efficacy for Registered and Listed complementary medicines.'[130]

3.10 The ANAO considered how each of the two tiers or categories of medicines is assessed before they are allowed onto the Australian market, looking particularly at the higher-volume lower-risk category.

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[126] Therapeutic Goods Amendment Bill (No. 4) 2000, Explanatory Memorandum, Notes on Clauses, Item 6.

[127] Second Reading speech, Therapeutic Goods Amendment Bill (No. 4) 2000, Senate Hansard, 7 December 2000, pp. 21029–30.

[128] The Expert Committee's membership and terms of reference are set out on the TGA's website, and are available from <www.tga.gov.au/archive/committees-eccmhs.htm> [accessed 4 August 2011].

[129] Expert Committee, Report, Finding 2.1.2, p. 82. The enhancements referred to included, in particular, improving consumer awareness that listed medicines have not been evaluated for efficacy before supply. These matters are taken up at para. 4.49 et seq. and in Chapter 6.

[130] The Expert Committee recommended some changes, such as that sponsors be required to submit a summary of evidence held by the sponsor that supports the efficacy of listed and grandfathered registered medicines on the ARTG. This is considered in Chapter 6.

3.11 The TGA has used an electronic listing facility ('ELF') since the mid-1990s. This was released in its current form (known as 'ELF 3') in 2003. This system greatly facilitates the listing of (lower-risk) medicines. A discussion of the processes involved follows, including the use of the ELF 3 system.

3.12 This chapter concludes with an analysis of a range of matters identified in the course of the audit which may warrant attention, to improve the integrity of pre-market processing.

Higher-risk (registered) complementary medicines

3.13 Under the Act, the TGA must evaluate each higher-risk medicine individually for quality, safety and efficacy and, if satisfied, *register* it on the ARTG. A consumer can identify a registered medicine (whether it is a prescription-only, an over-the-counter or a complementary medicine) by a notation on the label 'AUST R' followed by a unique identification number.

3.14 There is no mark on the product label to show the consumer explicitly that the TGA has evaluated the product; however, this can be deduced by those who are aware that registered products must have been evaluated to have attracted the AUST R notation.[131]

3.15 Only a small proportion of complementary medicines are registered medicines, comprising around 200 products.[132] The TGA receives correspondingly few applications to register new complementary medicines (see Table 3.1). Many of these are multivitamins and minerals.

[131] TGA, 'Buying medicines—What's on the label for me?', available from <www.tga.gov.au/consumers/information-medicines-label.htm> [accessed 4 August 2011]; and TGA, Office of Medicines Safety Monitoring, 'AUST R and AUST L numbers—why are they important?', *Australian Prescriber*, No. 3, 2010, available from <www.australianprescriber.com/magazine/33/3/80/3> [accessed 4 August 2011].

[132] As at 3 May 2011, there were 208 registered complementary medicines on the ARTG (TGA advice).

Table 3.1

New registered complementary medicines, by half-year

	2007–08		2008–09		2009–10	
	1st half	*2nd half*	*1st half*	*2nd half*	*1st half*	*2nd half*
Applications received	7	3	4	0	2	3
Approved	0	1	2	0	1	1
Rejected	0	1	1	0	0	0
Withdrawn by sponsor	3	0	1	0	1	1
Lapsed	0	1	0	0	0	0

Applications on-hand as at 30 June 2010: 9

Note: The presentation of the data in this and subsequent tables (by half-year) reflects standard TGA practice.

Sources: TGA presentation, 'Regulation of Complementary Medicines in Australia', 1 September 2010, and TGA – Industry Consultative Committee, agenda paper 2.5, meeting of 24 September 2010.

Lower-risk (listed) complementary medicines

3.16 The majority of complementary medicines—about 11 000—are considered to be lower-risk and are *listed* (as contrasted with *registered*) on the ARTG.[133] Whereas the Act requires the DoHA Secretary to evaluate medicines intended for registration on the ARTG for quality, safety and efficacy before allowing them onto the Australian market, it does not require the evaluation of listed medicines individually before they are made available. The amendments made to the Act in 2001 were intended to facilitate the prompt availability of new medicines to the market by relying on self-assessment by sponsors:

> A new refined listing system has been developed, which seeks to assure the safety and quality of, and maintain consumer confidence in, listed medicines that may be supplied in Australia, whilst facilitating quicker market access by applicants.[134]

3.17 Under the amendments the Secretary must list a medicine provided the application contains certain certifications provided by the sponsor and fees

[133] As at 3 May 2011, there were 10 813 listed complementary medicines on the ARTG (TGA advice).

[134] Therapeutic Goods Amendment Bill (No. 4) 2000, Second Reading speech, Senate Hansard, 7 December 2000, p. 21031.

have been paid. There is minimal scope for the TGA to perform any substantial pre-market assessment.

3.18 Listed medicines may contain only certain ingredients and may carry indications only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions. This is intended to minimise the risk of consumers self-medicating for a condition that requires medical supervision.

How assurance is obtained

3.19 Even though the TGA has no opportunity to evaluate listed medicines individually before allowing them onto the market, to meet the objects of the Act, there must still be a system of controls on the quality, safety and efficacy of these medicines. In the first instance this comes from the sponsor: the TGA obtains assurance about safety, quality and efficacy of listed medicines through the sponsor's self-assessment in the application process.

3.20 Specifically, assurance about:

- *quality*—flows primarily from the sponsor's self-certification that the medicine is manufactured to specified quality standards by a licensed manufacturer adhering to Good Manufacturing Principles. This is important because, as noted earlier (para. 3.2), some complementary medicines, particularly herbal products, can vary greatly in their constituents and content of active ingredients;[135]
- *safety*—flows from the sponsor's self-certification that the ingredients comprise only substances already assessed by the TGA as being of low risk and that the medicine is safe for the purpose for which it is to be used;[136] and

[135] The Therapeutic Goods Act defines the quality standards applicable to all therapeutic goods through pharmacopoeial monographs or standards supplemented by Therapeutic Goods Orders (TGOs). For regulatory purposes, the British Pharmacopoeia (BP) was, until 1 July 2009, the source of official standards. The Act has been amended to recognise the European Pharmacopoeia (Ph Eur) and United States Pharmacopeia-National Formulary (USP) as additional standards. Where there are no applicable monographs the sponsor must develop a compositional guideline, which the TGA will consider. See, for example: TGA, *The regulation of complementary medicines in Australia—an overview*, available from <www.tga.gov.au/industry/cm-basics-regulation-overview.htm> [accessed 4 August 2011].

[136] Where a risk is identified with the use of a particular substance (for example, use by particular groups, such as children, or in its interactions with other medicines), restrictions may be imposed (such as the use of label advisory information) to manage the risk, but the substance may still be eligible, with restrictions, to be a listed medicine on the ARTG.

- *efficacy*—flows from the sponsor's self-assessment that the indications and claims they make about the medicine are supported by evidence which, as the Act requires, the sponsor holds. Under current practice, the sponsor does not have to say what this evidence is, nor provide a copy of it to the TGA. However, the evidence sponsors hold must be sufficient to substantiate that the indications and claims are true, valid and not misleading.

3.21 By its nature, this process seeks to balance the level of assurance obtained with the perceived risk of use of the medicine. On the basis that listed complementary medicines are seen as low-risk, the mechanism provides the TGA, and, by implication, the Australian public, with only limited assurance about the characteristics of the medicine.

3.22 Once a sponsor has applied to list a medicine, has paid any fees[137] and certified that the product meets all legal requirements then the Act (s. 26A) requires the Secretary to list the medicine in the ARTG.[138] The sponsor may then lawfully supply that medicine in Australia. There is no opportunity for the TGA to delay this event, for example, by seeking to verify any claim the sponsor makes. In this way, the mechanism in the Act enables prompt listing.

3.23 When the TGA lists a medicine on the ARTG, it immediately attributes it a unique identifier in the form 'AUST L' followed by a specified number. The sponsor must reproduce this on the product label. All that can be deduced from the 'AUST L' on the label is that the sponsor has satisfied pre-market assurance requirements for safety, quality and efficacy of the medicine through the self-certification process mentioned above.[139]

The TGA evaluates the safety of ingredient substances

3.24 The TGA assesses the safety of substances used in listed complementary medicines through an evaluation to ensure that such

[137] The application fee for listing a medicine as at 1 July 2011 was $680, with an annual charge of $860. Application fees are set out on the TGA website, and are available from <www.tga.gov.au/about/fees-110701.htm> [accessed 4 August 2011].

[138] The provision of the Act under which medicines are listed is s. 26A. See the ARGCM, Part II, available from <www.tga.gov.au/pdf/cm-argcm-p2.pdf> [accessed 4 August 2011].

[139] The 'AUST R' and 'AUST L' notations on labels have an important role in the recall of a medicine, should it occur, as they uniquely identify the product. This is explained in an article in the *Australian Prescriber*, 'Medicines Safety Update' Volume 1, Number No. 3; 2010, June 2010, available from <www.australianprescriber.com/magazine/33/3/80/3> [accessed 4 August 2011].

substances are low risk. The guidelines explain that, once the TGA has established that a substance is of low risk, many of these substances need no further controls on their use in listed medicines.[140]

3.25 The TGA regularly receives applications for new listable substances from sponsors. For each, it prepares an evaluation report on the substance's safety, based on the information available, including data the sponsor supplies. The TGA's internal performance report on applications for new listable substances shows it had received 21 applications from 2007–08 to 2010–11 (see Table 3.2). Six applications were on hand at the end of December 2010.

Table 3.2

Applications to the TGA for new listable substances, by half-year

	2007–08		2008–09		2009–10		2010–11
	1st half	*2nd half*	*1st half*	*2nd half*	*1st half*	*2nd half*	*1st half*
Applications received	2	5	7	4	3	0	0
Approved	0	2	5	1	7	4	1
Rejected	0	0	0	0	0	0	0
Withdrawn by sponsor	1	1	1	0	1	0	0
Lapsed	1	5	0	0	0	1	1

Sources: DoHA, TGA Half-Yearly Performance Report, July–December 2009, Report 8: *Registration and listing of complementary medicines*; TGA presentation, 'Regulation of Complementary Medicines in Australia', 1 September 2010; TGA – Industry Consultative Committee (TICC), agenda paper 2.5, meeting of 24 September 2010; TICC paper for March 2011.

3.26 The TGA publishes notices for new listable substances on its website once they have been registered in the Federal Register of Legislative Instruments.[141] However, it does not report on the time taken from application to outcome for considering new listable substances. The TGA advised that, in the period 1 July 2009 to 30 June 2010, the average time taken from date of receipt until publication of the listing notice was 26 months.[142] Given that the length of this period affects how long a new product takes to become available,

[140] ARGCM, Part III, s. 5.1, available at <www.tga.gov.au/pdf/cm-argcm-p3.pdf> [accessed 4 August 2010].

[141] TGA confirmed that notices for new listable substances are published on the TGA website once they have been registered in the Federal Register of Legislative Instruments (FRLI). Information on this is available from <www.tga.gov.au/industry/legislation-listing.htm> [accessed 4 August 2011].

[142] TGA advice, 1 June 2011.

and one of the objects of the Act is timely availability of therapeutic goods, it would aid accountability and transparency if the TGA were to report this data publicly as a matter of course.

Self-certification, facilitated by ELF, expedites availability

3.27 The changes brought about by the *Therapeutic Goods Amendment Act 2001*, which placed the onus on sponsors to self-certify their products, were supported by an updated version of ELF. These changes further expedited the listing process, as was intended. In particular, the TGA's adoption of its web browser-based version 3 of the ELF system ('ELF 3') in September 2003 supported low-cost and streamlined electronic application and validation. ELF 3 allows sponsors (or their agents) to use the Internet to create draft applications; to submit them for processing; to view previously submitted material; and to apply to vary current listings.[143]

3.28 TGA officers have described the ELF mechanism as providing 'instant authority for the listed medicine to be supplied in or exported from Australia'.[144] The target timeframe for processing applications is two days, once payment is received. The time from lodgement to payment may vary (depending on the method of payment the sponsor chooses) but the TGA generally meets that target.[145] In a straightforward case, the time that elapses between a sponsor completing an application and listing is less than 24 hours.[146] The OCM then writes to the sponsor setting out the general and any specific conditions-of-listing that apply to the product.[147]

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[143] The TGA helped sponsors adjust to the new environment by 'providing sponsors of listed medicines a three-month period in which they could update, re-validate and re-certify information relating to their currently-listed medicines on the ARTG free of charge ... to ensure that the information recorded on the ARTG is true, correct and fully compliant with all legislative requirements.' *TGA News Issue 42*, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews42.pdf> [accessed 7 April 2011]. The TGA was not able to advise how many sponsors took advantage of this concession.

[144] TGA, OCM, 'Complementary Medicines in Australia', presentation, September 2008.

[145] The two-day time is exclusive of finance processing, as the time taken to apply the payment to an application varies depending on payment method (credit card, cheque, online). The two days refers to the time taken for the application to be processed once it is released from the finance side of the system.

[146] TGA advice at the presentation on Complementary Medicines to the ANAO, 1 September 2010.

[147] The term 'conditions-of-listing' refers to conditions imposed under the Act and which may relate, among other things, to the manufacture of the goods, their use or supply, the keeping of records relating to the goods, standards applicable to them, testing, labelling and adverse reactions. See ARGCM, Part II, Section 10.1, available from <www.tga.gov.au/pdf/cm-argcm-p2.pdf> [accessed 4 August 2011].

3.29 Table 3.3 sets out the numbers of new listed medicines and variation transactions over recent years.

Table 3.3

New listed medicines and variations, by financial year

	2005–06	2006–07	2007–08	2008–09	2009–10
New listed medicines	2331	2243	1935	1664	1970
Variations and notifications	1418	1317	2108	2085	1970

Source: TGA presentation, 'Regulation of Complementary Medicines in Australia', 1 September 2010.

3.30 When a sponsor submits an application for listing, that is the point when they must make the certifications that give the assurances required by the TGA (para. 3.19, above). This certification occurs in the course of entering the application data into ELF 3. More specifically, to achieve a successful listing, the sponsor must certify, among other items, that the product:

- is eligible for listing;
- is safe for its intended purpose;
- conforms to every applicable standard;
- has been manufactured, at each step in the process, by the holder of a licence to carry out that step;
- complies with applicable quality and safety criteria; and
- that they, the sponsor, hold adequate evidence to support all the claims they make about their product.[148]

3.31 Appropriately, the ELF 3 system applies built-in validation rules to the data entered by a sponsor. It checks, for example, that all the ingredients the sponsor lists in the application are permitted in listed medicines, and that the manufacturers the sponsor refers to in the application are among those known by the TGA to have a valid licence for such manufacture. These automated processes are an efficient way of testing that information the sponsor provides is consistent with what the TGA regards as acceptable.

[148] This is set out in detail in the ARGCM, Part II, s. 4.1.7, available from <www.tga.gov.au/pdf/cm-argcm-p2.pdf> [accessed 4 August 2011].

The ELF system tests for inappropriate claims

3.32 Listed complementary medicines, consistent with being considered 'low risk', may only carry indications and claims for the symptomatic relief of conditions (other than serious disease, disorders, or conditions), health maintenance, health enhancement and risk reduction. For example, a claim that a listed product will control a serious disease is not permitted.

3.33 The online application form on ELF 3 has pre-specified or coded indications from which the sponsor can select. It also has a free-text field available to users in which they can state indications and claims for their product. If the sponsor elects to use the free-text field there is a risk that they may make claims or provide indications that the TGA assesses as extravagant or inappropriate for a listed medicine.

3.34 The TGA has built into ELF 3 a capacity to scan the free-text field and product names, which may also imply inappropriate claims. The scan will detect certain restricted or prohibited terms entered by the sponsor. This is to provide some assurance that the sponsor makes claims or indications consistent with the product's status as a listed medicine.

3.35 The scan compares the entered text with a list of words the TGA has compiled and which it suspects are likely to be used to make inappropriate claims. If the system detects such a word then the TGA can examine the particular case and take the matter up with the sponsor as necessary.[149] This is an efficient means of detecting the use of restricted or prohibited terms that the TGA has pre-specified.

3.36 Once an application has satisfied all the validation checks which ELF 3 applies, the sponsor has submitted the application and has paid any relevant fees, the system automatically generates an AUST L number and adds the new medicine to the ARTG.[150] The system also emails the sponsor to notify them of the AUST L number, that processing is complete, and to advise whether the product has been selected for later, post-market random review.[151] In effect, the ELF 3 computer system has made the decision to add the item to the ARTG, in

[149] If ELF 3 detects a prohibited term, it will not validate the application. If it detects a restricted term, a message to the applicant will appear after validation. (TGA advice, 1 June 2011.)

[150] Once the validated application has been submitted, fourteen days are allowed for the relevant fees to be paid, after which, if they have not, the application will be rejected automatically.

[151] ELF 3 automatically selects products for random review at this stage in processing. This review process is part of post-market monitoring, discussed later.

accordance with the rules the TGA has specified and embodied into the tests performed by the system.

The ELF 3 system has been authorised to make its automated decisions

3.37 Section 7C of the Act allows the DoHA Secretary to arrange for computer programs to make decisions. Under the Act, those decisions are then taken to be decisions of the Secretary. The Government introduced this provision in 2009, explaining in Parliament that:

> Since 2003 the TGA has operated an electronic system to permit sponsors to list low-risk medicines containing pre-approved ingredients on the ARTG without prior scrutiny by the TGA ...
>
> The proposed new section 7C regularises this process by providing for computer programs to make decisions that could be made by the Secretary ...[152]

3.38 Thus, from 28 August 2009, there has been within the Act a capacity for the Secretary (or a delegate) to authorise computer-based decision-making, such as that now carried out by ELF 3, by making an arrangement to authorise the computer program to add items to the ARTG as listed products.[153]

3.39 During the course of the audit, on 24 February 2011, authorisations came into effect for all TGA computer systems used for decision making.[154] This has provided assurance that ELF 3 and other, similar TGA computer-based decision-making processes have a sound legal basis.

Educating and assisting the sponsor

3.40 For sponsors to use the ELF 3 facility effectively it is important that they are aware both of the legislative requirements for listing complementary medicines and how the system works at a practical level.[155] When the Act was changed in 2001 to enable sponsors to self-assess their products' compliance, it

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[152] Senate *Hansard*, Second Reading Speech, Therapeutic Goods Amendment (2009 Measures No. 1) Bill 2009, 15 June 2009, p. 3113.

[153] TGA, Strategic Business Outlook: Complementary Medicines Program (first half of 2009–10), p. 4.

[154] The TGA provided a copy of the instrument of authorisation, dated 24 February 2011. This includes the TGA's system for automatically including low-risk medical devices on the ARTG, 'DEAL', the *Devices Electronic Application Lodgement* system.

[155] The TGA provides an ELF3 user guide, available from <www.tga.gov.au/industry/ebs-elf-userguide.htm> [accessed 21 June 2011]. ELF 3 is a component of the TGA's eBusiness Services System (eBS).

stated that 'This shift in responsibilities emphasises the accountability of sponsors to provide correct information in applications to list medicines.'[156]

3.41 Appropriately, the TGA provides users with the guidance documentation which explains the regulatory requirements (discussed in Chapter 2). The documentation also includes an ELF User Guide, which has detailed, practical instructions for creating and submitting listed medicine applications.

3.42 The OCM has also engaged regularly with industry representative bodies about the guidance it provides and how it can best enable sponsors to submit applications efficiently and effectively.[157] It has expressed its intention to continue to 'Work with peak industry bodies so that they may better assist their members to understand the regulatory system, particularly in relation to how ELF works and what it can and cannot do.'[158]

3.43 There is also evidence that, where it has introduced new processes, the OCM has recognised these would require some education and time for sponsors to adjust. There is also evidence that the OCM has discussed these with industry representative bodies before introducing the changes.[159]

Four matters in pre-market assessment that would benefit from consideration

3.44 The ANAO identified the following aspects of pre-market assessment operations—as they are currently carried out—whose consideration could improve their integrity:

(1) indications and claims in older products have not been checked;

(2) arrangements for scanning free-text indications are not robust or comprehensive and require manual backup;

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[156] Therapeutic Goods Amendment Bill (No. 4) 2000, Explanatory Memorandum, Outline.

[157] This is evident from records of OCM – Industry Consultative Group (OICG) meetings over the years and presentations by the OCM on its processes.

[158] TGA, OCM presentation, 'The Electronic Listing Facility for Complementary Medicines', November 2010, p. 14; and TGA minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010.

[159] See, for example, 'Proposed Changes to the Random Review Process of Listed Medicines', paper distributed to OICG members for information at OICG meeting 11, 18 September 2006.

(3) the coded indications project—which could address both these issues by eliminating the free-text field—has been proceeding very slowly; and

(4) some sponsors may, on occasions, be entering incorrect information into the ARTG intentionally.

Indications in older products have not been checked

3.45 Although the ELF validation check is a quick and efficient means of detecting restricted or prohibited words in indications, its effectiveness is limited in several ways. The first limitation is the existence of a corpus of older products that have not been checked by this mechanism.

3.46 When ELF 3 came into operation in 2003, there was already a large number of complementary medicines listed on the ARTG. The TGA did not check these at the time to detect any use of restricted or prohibited words in indications. The TGA confirmed that only where some change to the listing requires a variation or 'grouping' transaction[160] will ELF 3 scan the record of an already-listed product to detect such items. If no changes have been made to a product since the implementation of ELF 3 then, under current procedures, there is no opportunity for the words to be detected by the system. The TGA does no manual checking of these cases.

3.47 The TGA also discovers, from time to time, the need to add to its restricted or prohibited terms list. For example, the term 'OCP' (Oral Contraceptive Pill), was added in February 2008. However, when the TGA does add a new term it does not search the database to detect any previous use of that term to verify that it has not been used inappropriately on an earlier occasion.

3.48 Thus it remains possible that listed items which were on the ARTG in 2003 (and items added since then but before the OCM added a new restricted or prohibited term to the list) contain indications or claims which are not permitted. There is also a potential inconsistency in treatment between products already listed and whose indications and claims have not been checked and new products, whose sponsors cannot make the same claims because of the current, improved checking process.

[160] Grouping is where the goods are intended to replace the currently supplied goods. The current AUST L is maintained. An application fee is payable.

3.49 To check the possibility of prohibited words existing in indications and claims for older items, the ANAO tested a limited sample of ARTG records. The test was for the presence of a small selection of prohibited words (drawn from the TGA's list). It detected instances—which it referred to the TGA for consideration and advice. The TGA's OCM advised that:

> A number of products included in [the ANAO's] list do appear to have potential compliance issues. The OCM will prioritise these products based on the risk and will conduct a targeted review if necessary. Appropriate regulatory action will be taken if required.[161]

3.50 The OCM also advised that all the matters identified by ANAO testing related to products using the free-text field for indications. The TGA has been progressing a project (discussed below) that would remove the free-text field altogether by requiring sponsors to select only from coded indications when applying to list a new medicine. This would reduce the opportunity for inappropriate claims to be made.

3.51 In the light of the ANAO's testing, the TGA also found that it had set up incorrectly one of the validation rules in ELF 3 (relating to Crohn's disease indications). The TGA advised that it had corrected the rule in the system.[162]

The scanning arrangements are limited and require manual backup

3.52 The second limitation on the effectiveness of the ELF validation check is that the comparison undertaken in the scanning check is inherently simple: it depends on a perfect match between the string of characters comprising a restricted or prohibited term and the words used in the application.[163] The TGA acknowledges that, although it is theoretically possible for it to amend the prohibited word list in ELF to include variations, such as plurals and alternate spellings, it would be challenging to devise a list that would be comprehensive enough to identify all possibilities.[164]

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[161] TGA advice, 22 December 2010.

[162] TGA advice, 22 December 2010.

[163] It is possible, for example, for the user, deliberately or accidentally, to enter a prohibited word into the system but with a minor misspelling that will avoid detection while still conveying the same meaning as if it had been written correctly. They could use a zero symbol in place of the letter 'O' or the numeral '1' or exclamation mark in place of an 'i' or lower-case 'L'—for example, 'MAG!C'. Similarly, plurals or other forms of words may pass validation unless specifically included in the list. For example, OCM advises that 'cataracts' will pass validation whereas 'cataract' will not.

[164] TGA advice, 22 December 2010.

3.53 The TGA has formed the view that some sponsors are unwilling or unable to adhere to the regulatory framework[165] and sometimes intentionally enter information incorrectly into the ARTG.[166] It has not provided an estimate of the frequency of such behaviour. Any change to the restricted words list receives close attention from industry and it seems likely that sponsors are aware which terms will fail the ELF 3 validation test.[167] In these circumstances, it may be relatively easy to evade the validation check by using a form of words unlikely to be identified in that process. This does not mean this feature of ELF 3 is of no value; rather, there is a risk that its value will have declined over time if it is possible for sponsors to devise ways of working around the test.

3.54 To address this problem, the OCM established new procedures in 2008 to check entries manually, including free text indications for new listings and groupings.[168] However, it is not planning to examine the existing records:

> Given that there are more than 10,000 products that were listed on the ARTG prior to this time, to retrospectively identify and review the indications for these products manually would be challenging in a practical sense.[169]

3.55 Examining the existing records would run the risk of consuming resources currently deployed on other processing work. It may be possible to devise a risk-based approach that takes account of both new and existing listed products so as to undertake manual checking in the most cost-effective way. On the other hand, the ANAO understands that the rate of turnover of complementary medicines on the ARTG may limit the cost-effectiveness of this strategy. On balance, the better approach to ensuring the integrity of claims and indications may be to accelerate the coded indications project so as to limit the inclusion of inappropriate claims and indications in the first place.

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[165] TGA, Senate Estimates Brief, 'Complementary Medicines—Compliance Issues', 12 October 2010.

[166] TGA, OCM minute to the National Manager, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', OCM, April 2010. Also, OCM Presentation to the ANAO, 'The Electronic Listing Facility for Complementary Medicines,' 15 November 2010.

[167] See, for example, the record of OICG 32, 1 October 2010, (p. 7), at which an unidentified member of the group expressed concern that OCM may, without notification, have prohibited a term that was previously 'available for use'.

[168] TGA, OCM, Standard Operating Procedure 'Reviewing new Listings and Conditions of Listing letters'.

[169] TGA advice, 22 December 2010.

The coded indications project has been proceeding very slowly

3.56 Coded indications have existed in ELF 3 since its release in 2003. They comprise a list of pre-specified indications from which a sponsor can select appropriate ones when applying to list a new medicine. However, as noted above, sponsors have hitherto had access to a 'free-text box' as well as coded indications for their products. This free-text box allows sponsors to enter whatever text they choose (including multiple indications) at the risk of the TGA detecting any unacceptable material. Under the coded indications proposal, the TGA would remove the free-text option and require sponsors to select only from the standard list. To achieve this, the TGA would need to revise the list of coded indications already in use and make it sufficiently comprehensive.

3.57 Discussion about the TGA restricting indications to only coded indications goes back some years and was considered as part of the ANZTPA project. Under that project, the existing ELF 3 coded indications were investigated for use in conjunction with low-risk complementary medicines.[170] After the postponement of ANZTPA, the review of these coded indications continued with the OICG.

3.58 At an OICG meeting in December 2006 an OCM agenda paper drew OICG members' attention to a high level of non-compliance, which the OCM attributed to sponsors including 'extensive claims/indications and advertising puffery' in the free text area of the online application.[171] The meeting record also shows that, when discussing the agenda item 'Random reviews of listed medicines: Recurring deficiencies' it had discussed the intention that 'Custom indications will be removed in the future, and replaced by new coded indications.'[172]

3.59 In May 2008, the TGA proposed a range of regulatory reforms, with the then Parliamentary Secretary seeking to carry forward the momentum from the suspended ANZTPA project. One element in these proposals was to 'mandate the use of coded indications when entering the therapeutic

[170] Listed complementary medicines were to be called 'Class 1' medicines under the ANZTPA proposal. This is explained on the ANZTPA website, which now comprises information regarded as historical. See: <www.anztpa.gov.au/cm/fs-cm.htm> [accessed 4 August 2011].

[171] OICG 13, Information Paper, Item 5.1, *Random review of listed medicines: Recurring deficiencies*, 1 December 2006.

[172] OICG 13, Draft Outcome Note, 1 December 2006.

purpose(s) for the medicine in an application to include a listed medicine on the ARTG.'[173] DoHA advanced this proposal to the point of including it explicitly (and in the same terms) in its *Annual Regulatory Plan 2008–09*. This placed it among activities planned in the then current financial year, 2008–09, with an expected timetable date of June 2009.[174] The Regulatory Plan states that it was last updated on 26 August 2008, with corrections made on 19 November 2008. However, the OICG meeting of December 2008 noted 'no significant progress had been made since [a report was] last tabled at OICG.' The meeting recognised the importance of establishing a set of coded indications but 'Members registered disappointment at the lack of progress.'[175]

3.60 Since then, the OCM has reported to the TGA – Industry Consultative Committee (TICC) that 'in partnership with the OICG, the OCM and committee members continued to work on the coded (standard) indications as a way of facilitating the use of the [ELF].'[176] By early December 2009, the OCM reported that its officers had completed a preliminary plan, which was to be revised following internal consideration later that month. At that point, it had incorporated all existing coded indications in a new framework.[177]

3.61 In April 2010, an internal analysis of regulatory compliance of recently-listed complementary medicines revealed high levels of non-compliance.[178] In a subsequent analysis of the regulatory issues identified by post-market reviews the OCM nominated coded indications as a way of inhibiting the use of inappropriate terms and claims in free-text indications. The high level of non-compliance then observed provided a substantial reason to progress the coded indications project.[179]

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[173] TGA, Minute, *Proposed Options for Therapeutic Goods Regulatory Reform*, 30 April 2008.

[174] DoHA, *Annual Regulatory Plan 2008–09*, p. 12. See: <www.health.gov.au/internet/main/publishing.nsf/Content/Regulatory+Plan+2008-09> [accessed 4 August 2011].

[175] Outcome Note, Twenty-Fourth Meeting of the OICG, 12 December 2008, p. 7.

[176] TGA, 'Strategic Business Outlook—Complementary Medicines Program' (TICC agenda paper 2.5), reports on activities of the Complementary Medicines Program for first and second halves of 2009–10.

[177] TGA, OCM Weekly Issues Summary, various editions.

[178] TGA, minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010. This is discussed further in Chapter 4.

[179] TGA, minute, 'Re: Listed Complementary Medicines—current trends and regulatory directions', July 2010.

3.62 In November 2010, the OCM advised that 'progress is being made in an iterative manner in conjunction with the OICG':[180]

> The current project aims to reclassify and expand existing standard ('coded') indications to enable modification or removal of the free text box in ELF. Reclassifications will utilise the existing ICD-10 framework to maximise the capacity of the system to cater for new standard indications.[181] The classification would permit sponsors to search standard indications by ICD-10 code, body system or indication type to facilitate easy retrieval. The OCM is working closely with the OICG to progress this project. A draft list of updated indications has been created and the OCM internal project working group is refining the draft list.
>
> As you would appreciate this project is very resource intensive, will require extensive consultation, modifications to the ELF and potential changes to the regulatory framework. The OCM is committed to progressing and completing this project, however a definite time frame has not been set for complete implementation.[182]

3.63 It also stated that the coded indications project is 'still in the initial stages of development'.

3.64 When the coded indications project is more advanced and it is possible to restrict new listed products to only coded indications, the question will arise of whether the public interest and equitable treatment will require the same discipline to be imposed on existing products as well as new ones.[183]

Poor understanding of the regulatory system

3.65 The TGA has identified 'poor understanding by sponsors and their agents of the regulatory system and legislative requirements' as being among the challenges of managing listing operations.[184] This poor understanding is evident to OCM staff from their regular interaction with sponsors.

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[180] TGA, OCM advice of November 2010.

[181] 'ICD-10' refers to the system for International Classification of Diseases. The latest in the series, ICD-10, was endorsed by the forty-third World Health Assembly in May 1990 and came into use from 1994.

[182] TGA, OCM advice of 2 December 2010.

[183] This may not be necessary if the rate of turnover of listed products is sufficiently high.

[184] TGA, OCM presentation, 'The Electronic Listing Facility for Complementary Medicines,' 15 November 2010, p. 12.

3.66 An additional complexity is that OCM staff have also developed a perception that sponsors are intentionally entering incorrect information into the ARTG and using the ELF system 'as a de facto regulatory consultant to see what is possible to List, whether it is actually eligible or not'.[185] In other words, there is a suspicion that some sponsors are gaming the system—testing its limits to see what it will let them enter, without proper regard for the rules.

3.67 The TGA has expressed similar concerns previously and it seems likely that similar practices have endured for some years. For example, in 2006, the OCM drew the attention of industry representative bodies to its concern:

> that a significant proportion of sponsors/agents are not taking their responsibilities seriously and repeatedly submitting inadequate labels/evidence expecting the reviewers to identify and inform them of corrective actions. This has resulted in the slowing down of the review process.[186]

3.68 The OCM was concerned that the 'information provided by the sponsors in relation to the label and product specifications [were] only draft documents'. OCM staff then provided advice to sponsors on the deficiencies of their applications. The OCM believed that, had those products subsequently been selected for post-market review without the advice of 'de facto consultants' from OCM, then 'most of the products would not have been ready for market supply.'[187]

3.69 More recently, the OCM has attributed low regulatory compliance to 'information incorrectly entered into the ARTG, both intentional and unintentional' and sponsors 'that intentionally use delaying or obstructive tactics.' In particular, it refers to sponsors 'Displaying apparent willingness to cooperate while providing unreasonable/illogical arguments or proposing unsatisfactory solutions to identified problems, often in a bid to "buy time" in the marketplace.'[188]

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185 TGA, op. cit., p. 13.

186 TGA, 'Proposed Changes to the Random Review Process of Listed Medicines', Item 12.1, OICG 11, 18 September 2006

187 Ibid.

188 TGA, minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010.

Strengthening pre-market assessment

3.70 The pre-market assessment process for listed products has a light touch, as was intended. There is little to inhibit a sponsor from having a new medicine listed, whether or not they understand regulatory requirements, or even if they do not have full regard to these requirements. Self-certification is the primary test at this point. There are limits to what the TGA can do, within the existing legal framework, to gain any greater assurance about claims made for a product until after the product has been listed.

3.71 When the regulatory system was put in place there may have been little understanding of the level of non-compliance among listed medicines. This was likely to have been the case in 2001 when the amendments were made that introduced self-assessment by sponsors. Even in 2005, the then Government's perception was that 'the results of the TGA's limited audits may not justify a conclusion that there is widespread non-compliance with the Guidelines.'[189]

3.72 In April 2010, post-market review work by the TGA revealed a high level of complementary medicine non-compliance, with only three products in a random sample of 31 being found wholly compliant. Later in the year (December 2010), DoHA published on its website its incoming government brief, including an item on compliance of complementary medicines. This reported that 'Based on 2009–10 data, as many as 90 per cent of products reviewed are found to be non-compliant with regulatory requirements, with a significant number of products requiring removal from the ARTG.' This attracted public comment which has persisted.[190]

3.73 Now that the TGA has become aware that it has substantial non-compliance, any proposal to change the pre-market self-assessment rules would involve a policy change—a matter for ministers and DoHA advice.

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[189] *Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*, Attachment 2, p. 12, available from <www.tga.gov.au/pdf/archive/committees-eccmhs-response-050309.pdf> [accessed 4 August 2011].

[190] See the *Sydney Morning Herald*, 29 and 31 December 2010; the *Sunday Canberra Times*, 6 February 2011; ABC Radio National, the *Health Report*, 16 and 24 May 2011, available from <www.abc.net.au/rn/healthreport/index/> [accessed 4 August 2011]; various reports on 'Croakey: the Crikey Health Blog' available from <blogs.crikey.com.au/croakey/> [accessed 4 August 2011] and the *6 minutes.com.au* website, available from <www.6minutes.com.au/news/complementary-medicines-fail-audits> [accessed 4 August 2011]. It should also be noted that, on 13 May 2011, the TGA published, for the first time, data on its post-market review compliance review work. This is available from <www.tga.gov.au/industry/cm-post-listing-compliance-reviews.htm> [accessed 4 August 2011]. This information was the basis of subsequent press articles.

Nevertheless, working within the current framework, there are opportunities for improvement in several areas, as suggested by the foregoing analysis. In particular, the TGA has advised the ANAO that the greatest opportunity for improving pre-market assessment of listed products lies in restricting or removing the free text field in the ELF system as a means of limiting the use of inappropriate claims or indications for products listed on the ARTG.

Recommendation No.2

3.74 To improve the integrity of the self-assessment process for listing complementary medicines on the Australian Register of Therapeutic Goods (ARTG), the ANAO recommends that DoHA seeks to finalise work on the 'coded indications' project so as to limit the use of inappropriate claims and indications on the ARTG.

Agency response

3.75 DoHA agreed to the recommendation.

3.76 While it is difficult for the regulator to assess whether apparent failure by sponsors to understand the rules and guidance documents is genuine, this is not a reason to reduce the effort to ensure that guidance is clear, comprehensive and current. The ANAO suggests that additional effort could be worthwhile to keep systematic records of sponsor errors made at data entry (including repeated attempts to submit an application for the same product with slightly different supporting data) and apparent failure to understand the rules on the part of sponsors. This data could indicate where greater clarity or educational effort might be warranted. It would also form a basis for assessing risk in new applications. That could then form an additional guide for targeted post-market review of new and existing listed products associated with sponsors with a poor record.

3.77 The TGA has advised that it will consider making enhancements to its IT systems to capture further information about application validation errors as this information is not currently recorded.

4. Post-market Review of Products

This chapter shows how DoHA has been regulating complementary medicines after they have entered the market and what the results have been.

The TGA focuses on post-market review

4.1 Because it is quick and easy to list new complementary medicines the TGA must take particular care in its post-market review of those products. The then Government recognised this when it introduced the *Therapeutic Goods Amendment Act 2001*:

> Under the changes introduced by the Bill sponsors of listable medicines will have greater responsibilities in relation to pre-market assessment of the medicines they wish to list on the Register and the Therapeutic Goods Administration (TGA) will assume greater post-market monitoring responsibilities in relation to these medicines.[191]

4.2 In turn, the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM) reflects this by stressing the importance of post-market monitoring:

> In facilitating early market access [for listed medicines], there is reliance on a comprehensive risk-based system for the post market monitoring of Listed complementary medicines.[192]

4.3 This approach has sometimes given rise to concerns about the limited pre-market assurance the TGA receives. Members of the former Complementary Medicines Evaluation Committee (CMEC) expressed concern in 2006 both about the process and about the evidentiary basis of claims and indications for listed medicines:

> Some Members expressed concern over the high level of trust afforded to sponsors when 'self-certifying' as part of the [ELF] system. Members also expressed concern over the limited degree of review of the efficacy data itself. TGA officers clarified that while the data to support efficacy itself are seldom reviewed, scrutiny of summaries of the evidence held by sponsors, provided following a random or targeted review, ensures the consistency or appropriateness of the data in supporting the claims being made for products.

[191] Therapeutic Goods Amendment Bill (No. 4) 2000, Explanatory Memorandum, Outline.

[192] TGA, ARGCM v4.0, March 2011, Part II, s. 8.1, p. 60.

If this is found to be inadequate, then a follow-up stage is initiated and a more detailed investigation ensues.[193]

4.4 In other words, because of the relative ease, speed and low cost with which products can be listed, the TGA must place considerable reliance on post-market monitoring to achieve its regulatory objectives. The ARGCM states that the TGA conducts that monitoring to:

- provide assurance of the safety of complementary medicines through a risk-based program of post market monitoring and surveillance;
- provide consumer confidence in the safety and quality of complementary medicines; and
- ensure industry compliance with regulatory standards and guidelines for complementary medicines.[194]

TGA compliance strategies

4.5 The TGA states that it employs a range of compliance strategies. These strategies are:

- random and targeted desk-based audits of listed medicines;
- monitoring of suspected adverse reactions;
- targeted and random laboratory testing of products and ingredients;
- targeted and random surveillance in the market place;
- an effective, responsive and timely recalls procedure;
- audit of Good Manufacturing Practice; and
- controls on the advertising of therapeutic goods.

4.6 Ideally, compliance strategies can be directly related to specific risks identified in a risk analysis. This can provide assurance that an agency is directing its efforts to control those risks and give confidence in the regulatory system. Although the TGA approach is said to be risk-based (see para. 4.2, above) the ARGCM, recently updated, does not explain the basis for the TGA's

[193] TGA, Complementary Medicines Evaluation Committee, Ratified Minutes Fifty-sixth Meeting, 21 April 2006, p. 26. Note: the TGA has omitted this text from the version of the minutes provided publicly by the TGA, entitled 'Extracted ratified minutes' available from <www.tga.gov.au/archive/committees-cmec-resolutions-56.htm> [accessed 4 August 2011]. The ANAO takes the view that this practice serves no useful administrative purpose and is equivalent to maintaining 'two sets of books'.

[194] TGA, ARGCM, Part II, s. 8.1, p. 60.

choice of strategies nor how that choice relates to the known risks of regulating listed medicines.

4.7 The ANAO examined a selection of these strategies, in particular the use of random and targeted desk-based audits. The TGA's obtaining assurance of Good Manufacturing Practice (a primary topic of the last ANAO audit of the TGA) is considered in Appendix 1. Controls over advertising are considered in Chapter 5.

4.8 This chapter examines the TGA's post-market review of complementary medicines and also the results of that review work, considering:

- *random and targeted reviews*—the purpose and the benefits of each technique;
- *a range of matters that may warrant attention*—questions identified in the ANAO's field work which could be considered in any move to improve the integrity of the post-market regulatory process; and
- *the outcomes of TGA post-market reviews*—the actual results of OCM random and targeted reviews.

Random and targeted reviews

4.9 Every regulator who finds that it is not practicable or cost-effective to review every regulated product in detail must choose how best to select a sample for review. Targeted and random sampling each have value as techniques for the regulator.

The purpose of random reviews

4.10 The very existence of a random review can act as a general deterrent to non-compliance. This will work better provided the schedule of random review is sufficiently frequent that the risk of a review (or, at least, the perceived risk) promotes compliance among the regulated parties.

4.11 A random sample also promotes fairness in that every product has an equal chance of being selected. In the case of listed medicines, this means that each sponsor faces the possibility of being involved in a product review, in proportion to the number of new products that sponsor lists.

4.12 The results of testing a random sample also provide a basis for drawing statistically valid conclusions, within confidence limits, about the characteristics of the population as a whole, such as its level of compliance.

Further, such testing can identify emerging topics and highlight characteristics that can help build profiles of non-compliance risk. That information can then inform and provide a sound basis for targeted reviews.

4.13 On the other hand, random review, which is inherently not risk-based, can be resource-intensive. In comparison, a targeted review, being based on some foreknowledge of the risks, will tend to identify a higher proportion of cases of non-compliance for the effort put into reviewing.[195] Generally, a combination of random review (for general deterrence, to check general compliance and, most particularly, to develop risk profiles) and targeted review (to pursue high-risk types of case identified in random reviews and other sources) can provide a balanced review effort.

OCM random review of listed medicines in practice

4.14 The changes introduced in 2001 to make the listing process quick and easy for complementary medicines were to be facilitated by a new version of the Electronic Listing Facility (ELF 3).[196] In addition, as sponsors were, thereafter, to assume greater responsibility for pre-market assessment of products, this would free TGA resources for a greater focus on post-market review:

> The TGA resource currently employed to review newly listed medicines for eligibility for listing will be re-deployed to conduct more detailed and rigorous reviews of listed medicines, on both random and targeted bases. These deskbased full reviews of listed medicines will form one plank of a raft of enhanced post-market monitoring activities in relation to listed medicines.[197]

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[195] In its 2003 report, the Expert Committee made no comment on the design of the TGA's system of random and targeted reviews. However, it did recommend that 'The TGA substantially increase random and targeted assessment of the evidence to support the indications and claims held by sponsors for Listed medicines (Recommendation 6).'

[196] TGA, *TGA News*, Issue 34, February 2001, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews34.pdf> [accessed 7 April 2011]. This has not been accessible on the revamped TGA website from 4 May 2011.

[197] TGA, *TGA News*, Issue 34, February 2001, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews34.pdf> [accessed 7 April 2011]. This has not been accessible on the revamped TGA website from 4 May 2011.

4.15 In practice, although ELF 3 had been piloted in October–December 2000, it was not operational until September 2003.[198] Between September 2001 (when s. 26A of the Act was introduced) and the commencement of ELF 3 in September 2003, the TGA received applications for listed complementary medicines on 'floppy disc'. TGA evaluators performed a manual desk-based assessment of the information before the listing details were electronically transferred to the ARTG. During this period, TGA evaluators randomly selected approximately 10 per cent of new listings for a more detailed review. This included review of the label and product specifications, though not evidence for efficacy.

4.16 In September 2003, the manual desk-based pre-listing assessment and upload to the ARTG was replaced by ELF 3. This system was designed to automatically select a certain proportion of new listings for random review. However, it was mid-2004 when the OCM began randomly selecting and reviewing listed medicines for post-market review. It explained that this was done by 'reviewing medicine labels, product specifications and the evidence held by the sponsor in support of claims/indications made in relation to the medicine.'[199]

4.17 When ELF 3 selects products at the time of listing for later random review it also generates a notice to the sponsor, who should then be able to prepare for the review, which is generally scheduled to take place six months after listing.[200]

TGA developed a rigorous approach to sampling for random review

4.18 The TGA's documented approach to risk management states that it developed a sampling method for the desk-top review of randomly selected listed products. The sampling model was developed with the assistance of the Australian Bureau of Statistics, an aspect specifically identified by the then

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198 The TGA advised in its *TGA News Issue 36* that the forecast release date of the new ELF 3 had been extended, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews36.pdf> [accessed 7 April 2011]. In *TGA News Issue 42* (November 2003) it announced that ELF 3 had commenced on 15 September 2003, formerly available from <www.tga.gov.au/docs/pdf/tganws/tganews42.pdf> [accessed 7 April 2011]. These editions have not been accessible on the revamped TGA website from 4 May 2011.

199 TGA, OCM, *Proposed Changes to the Random Review Process of Listed Medicines*, agenda paper for Item 12.1, OICG 11, 18 September 2006. More detail on the matters the TGA examines during its desk-based reviews is set out in the ARTG, Part II,Section 8, p. 60 et seq. The algorithm for random selection is built-in to the system.

200 Some products are not placed on the market until some time after they have been listed.

Government as part of the means of obtaining assurance that sponsor certifications are correct under the new listing process introduced by the changes to the legislation in 2001.[201]

4.19 The sampling model is based on the TGA's expectation at the time it was devised that about 10 per cent of cases would have deficiencies, together with a management requirement for 95 per cent confidence of precision within plus-or-minus 4 per cent.[202]

> Based on an average of 700 applications for listing per quarter this means that approximately 172 applications for listing are subject to a Level 1 Review per quarter (688 per year). Of these, a number of samples are required to submit additional information for Level 2 Review. Of these, some are also required to submit additional information for a Level 3 Review.[203]

4.20 The clear intent of such an approach is to be able to use a random sample to test, with the specified degree of confidence, the level of compliance across the population of newly listed medicines generally.

4.21 The TGA advised that, initially, the proportion of newly listed medicines to be selected by ELF 3 for random post-listing compliance review was 15 per cent.[204] In late 2003, the Expert Committee had recommended 'increased random and targeted auditing of sponsors of Listed complementary medicines to ensure that evidence of efficacy is held.'[205] The Expert Committee's discussion did not indicate what it considered were appropriate proportions of newly listed medicines for review or how TGA resources should be divided between targeted and random review.

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[201] Hansard, House of Representatives, 8 March 2001, p. 25429, speech, Minister for Employment Services, available from <www.aph.gov.au/hansard/reps/dailys/dr080301.pdf> [accessed 4 August 2011].

[202] TGA, *The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods*, Version 2.0, May 2011, p. 32, available from <www.tga.gov.au/pdf/basics-regulation-risk-management.pdf> [accessed 4 August 2011]. At the commencement of the audit the ANAO confirmed with the TGA that this document—then Version 1—represented current thinking (TGA advice of 13 September 2010). The TGA has advised that the estimate set out in this document that 10 per cent of cases would have errors originated from discussions with a senior ABS consultant at the time.

[203] The different levels of review are explained in the ARGCM, Part II, Section 8.2.1 (pp. 61–2). Level 1 is the primary level of review, which may, in a proportion of cases be followed by the more detailed Level 2 targeted review and in some cases a more exhaustive Level 3 targeted review. However, a Level 3 targeted review may take place without a Level 1 or Level 2 review preceding it.

[204] TGA advice of 17 May 2011.

[205] Expert Committee, Report, p. 85.

4.22 The TGA advised that, subsequently, it increased the target for random review to 20 per cent in the 2005–06 reporting period and 22 per cent in 2006–07 and 2007–08.[206] This was changed for the 2008–09 reporting period to a target of 600 random and targeted desk-based reviews of new and existing listed complementary medicines, an arrangement that remains current:[207] 'The OCM is expected to select a total 600 listed medicines for desk-based audit annually, which is equivalent to 150 per quarter or 50 reviews per month.'[208]

Random sampling currently falls short of the approach intended

4.23 Although 600 reviews is fewer than the 688 specified in the original approach, this reduction may not substantially compromise the intended confidence interval if this many *random* reviews were carried out. However, this number also includes a substantial proportion of *targeted* reviews.[209] Targeted reviews examine cases which have already come to attention for some reason (such as a complaint or international alert—see para. 4.26 below). It is not statistically valid to draw conclusions about compliance in the whole population of new listings from the results of *targeted* reviews.

4.24 The TGA explained the change in its review strategy as follows:

> During the second half of 2008–09, broader issues relating to the safety and quality of Listed Complementary medicines became a major focus of the OCM's Post Market Review Section. Reflecting issues in the market place, targeted reviews increased significantly. While documentation to confirm the reasons for changing the reporting requirement from "22% random reviews" to "600 audits" cannot be readily located, the TGA understands that the need to address emerging safety/quality issues in a timely manner explains why this requirement was amended.[210]

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206 TGA advice of 17 May 2011.

207 TGA advice of 20 May 2011.

208 TGA, OCM, *Review Process for Listed Complementary Medicines—random and targeted*, 27 August 2010.

209 The TGA confirmed that this is the case (advice of 17 May 2011).

210 TGA advice of 17 May 2011. The TGA further advised that the rate for random review of new listings dropped to only five per cent during 2009–10 as the OCM carried out major projects (targeted reviews) relating to the safety and quality of listed complementary medicines. These targeted reviews included medicines at risk of contamination with aristolochic acids; medicines containing *Ephedra* spp. and Levodopa; and an investigation into the quality of *Ginkgo biloba* leaf extracts used in complementary medicines (TGA advice, 20 May 2011).

4.25 As explained in the discussion above (paras. 4.10 – 4.13), with constrained resources it may well be appropriate for the TGA to vary the effort put into random versus targeted reviews from time to time. The strategy should reflect management priorities, whether that is to test current overall compliance rates or to target high risk cases with a view to increasing compliance. With the high rate of non-compliance observed in recent years (discussed later) targeted reviews could take priority. However, the TGA should be aware that reduced random sampling also affects the confidence intervals and reduces the precision with which it can estimate overall compliance and tune its targeted review strategy.

OCM targeted reviews

4.26 Targeted reviews take place when information comes to the OCM's attention that causes it to suspect that a problem may exist with a medicine. This information may derive from any of these sources:

1. an OCM safety, quality or regulatory investigation;
2. referral by internal TGA stakeholders (including OCM manual screening of newly-listed products);[211]
3. alerts generated by international regulatory agencies;
4. complaints from external stakeholders;[212] or
5. emerging issues identified from random or targeted reviews.[213]

Risk profiles enable regulators to target effectively

4.27 Generally, regulators develop risk profiles based on what they learn from other sources, including random review programs.[214] Given that the TGA has stated that targeted reviews may derive from 'emerging issues identified from the random review process' (see para. 4.26, above) it would be reasonable for the TGA to use its random reviews of compliance of listed medicines to develop risk profiles for targeted reviews.

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[211] TGA advice of 17 May 2011.

[212] These could be state or Commonwealth government bodies, health care practitioners, industry members or consumers.

[213] TGA, OCM, *Review Process for Listed Complementary Medicines—random and targeted*, 27 August 2010, section 3, p. 2.

[214] See, for example, OECD, *Information Note: Compliance Risk Management—Use of Random Audit Programs*, September 2004, p. 15 et seq., available from <www.oecd.org/dataoecd/44/34/33818547.pdf> [accessed 4 August 2011].

4.28 There is a range of characteristics upon which the OCM could develop risk profiles, including the ingredients, claims, indications, and condition(s) addressed. In addition, since all medicines included on the ARTG are linked to recognised sponsors, it should be possible to identify consistently non-compliant sponsors or manufacturers. Persistent errors by such parties could form a sound basis for targeted review of other products associated with the same parties, products which the TGA would have good reason to review without necessarily forming an adverse view of sponsors' intent.

4.29 The TGA is aware that behaviour varies markedly among sponsors. It has said that 'a percentage of the complementary medicine industry is consistently non-compliant with regulatory requirements', a group it refers to as 'repeat offenders'.[215] One of three main barriers to compliance (in its view) is:

> Unwillingness to adhere to the rigorous nature of the regulatory framework. A small group of sponsors have a tendency for recurring problems within the stated requirements of the Australian regulatory framework for complementary medicines. The identification of advertising issues and the use of obstructive or delaying tactics during reviews are particularly present in this group.[216]

4.30 The OCM has advised that:

> Issues that are identified in one or more reviews may indicate a widespread issue and may be sufficient to result in further reviews of other medicines. The issues may be in relation to misleading claims entering the market for particular ingredients or a particular problem with goods associated with a type of condition. OCM Officers within the [Listing Compliance Section of OCM] use their judgment to make the decision to initiate (or not initiate) new reviews based on information from other random or target reviews, taking into account matters such as the seriousness of the issue, the number of other medicines on the Register that may be affected, the effectiveness/relevance of pursuing a particular issue, and availability of resources.[217]

[215] TGA, Senate estimates brief, 12 October 2010.

[216] TGA, OCM minute, 'Re: Listed Complementary Medicines—current trends and regulatory directions', July 2010.

[217] TGA, OCM advice of 2 December 2010.

4.31 Thus, within OCM, risk assessment is left to the judgement of the officers within the Listing Compliance Section, rather than being incorporated into a formal risk profiling procedure.

Four matters in post-market review that would benefit from consideration

4.32 The ANAO identified the following aspects of the TGA's post-market review process—as they are currently carried out—which could improve the integrity and effectiveness of these operations:

(1) the TGA does not maintain a risk-based profile of sponsors;

(2) the TGA does not routinely gather products from the field for post-market review;

(3) the TGA does not report its review activity or outcomes; and

(4) regulatory action by the TGA takes a long time.

The TGA does not maintain a risk-based profile of sponsors

4.33 Keeping records of repeated instances of non-compliance can help to identify those who are unaware of the rules and require education and guidance, as well as those who may be deliberately non-compliant. For example, in the context of its regulation of accredited residential aged care providers, DoHA has recently developed a *Service Providers of Concern* list, which the department has identified as representing a high risk of non-compliance.[218] DoHA's guidance material notes that 'Identification on the list does not necessarily indicate that significant non-compliance has been identified. Rather, it may indicate emerging risks of significant non-compliance.'

4.34 Although the TGA states that it is dealing with consistent non-compliance by some sponsors,[219] it does not use the knowledge it gains from post-market reviews to target the products listed by these sponsors in any systematic way. When asked whether they agreed that it would be useful to record, by sponsor, which were regular offenders (even if only to identify which might most need more education or guidance), the TGA advised:

[218] Similarly, the Aged Care Standards and Accreditation Agency Ltd. maintains a 'Homes of Interest' list.

[219] TGA, Senate Estimates brief, 'Complementary Medicines—Compliance Issues', 12 October 2010.

> To reiterate, the OCM does not keep a database or list of sponsors that are non-compliant. The TGA is proposing a strategy to address levels of compliance as a whole. This may include working with consumers and peak industry bodies to identify barriers.[220]

4.35 Industry representatives have stated publicly that they would welcome sanctions on 'repeat offenders' but, as is clear from the above advice, the OCM does not keep records of who they are.[221] That is, even though the OCM states that it is aware of repeated non-compliance by some sponsors, it advised that it does not keep a database or list of sponsors that are non-compliant. Nor does it consolidate information about companies that are regularly non-compliant. 'All information held is product specific.'[222] All medicines on the ARTG, including listed medicines, are linked to recognised sponsors so the TGA holds the information it would need to formulate a list.

4.36 When the OCM has referred in briefing material to 'consistently non-compliant sponsors', it states that that perception is based not on data generated during reviews but is an impression received over the course of monitoring the regulatory compliance of listed complementary medicines. Moreover, the OCM does not initiate reviews focusing on a particular sponsor.

4.37 In discussing its approach to compliance, the OCM explained it in terms of its focus on making lawful regulatory decisions based on material findings of fact surrounding compliance of a particular medicine with the law:

> The previous compliance performance of a Sponsor is irrelevant when considering the facts surrounding whether an individual medicine complies with the requirements of the legislation.[223]

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[220] TGA, OCM advice of 8 December 2010. In explaining the strategy referred to here, the TGA has subsequently advised that it has been working with a range of stakeholders to address levels of compliance with listed complementary medicines. Further, it has established a working group of relevant stakeholders to review the regulatory framework for complementary medicines. It first met on 12 April 2011.

[221] Complementary Healthcare Council of Australia, Media Release, 28 September 2010, 'CHC rejects claims that the CM market is "unpoliced" or that criticism of the TGA is "widespread"', available from <www.chc.org.au/News/MediaRelease/?page=1> [accessed 4 August 2011]. Specifically, the CHC stated: 'The CHC agrees that a revised structure of sanctions, especially for repeat offenders, should be high on the agenda so as to provide major incentive to those repeat offenders to adhere to relevant Industry Codes of Conduct and Practice and commercial best practice.'

[222] TGA, OCM advice of 8 December 2010.

[223] TGA, OCM advice of 8 December 2010.

4.38 On the face of it, there is a risk that the OCM approach conflates two distinct stages in a compliance program:

(1) first, the need to identify which products to review and the conduct of that review, and

(2) second, in the light of the results of that review, the need, in some cases to take regulatory action where the TGA has identified non-compliance.

4.39 Targeted reviews initiated by a notice (issued under section 31 of the Act) can take place at the delegate's discretion and do not constitute regulatory action. This is the first stage identified above, which may or may not lead to compliance action, depending on what the review reveals. This is also the stage at which the TGA could usefully take account of previous behaviour when deciding where to direct its review effort. This is a separate matter from taking action in the light of non-compliance in an individual case, where previous compliance performance is clearly irrelevant to considering the facts and the making of a fair decision.

4.40 Generally, a regulated entity's compliance history should influence the design of a regulator's response, with a view to the entity either returning to compliance or, if the public interest requires it, exiting the market.[224] If the TGA does not focus on persistently non-compliant sponsors—when it has a clear impression that a small group persistently do not comply—it is not making full use of information to hand and declining an opportunity to control the risk of non-compliant products continuing to enter and remain on the market and the consequences of that to consumers of those products.

4.41 The ANAO proposes that the TGA consider developing a risk-based profile of sponsors to inform its program of targeted compliance reviews. This would enable it to direct appropriate efforts into improving compliance on a risk basis, whether through providing information or education to sponsors or, where necessary, through regulatory action.

The TGA does not routinely gather products from the field for post-market review

4.42 Where a regulator requires corrective action on the part of a regulated entity, follow-up review by the regulator helps to ensure that the required

[224] ANAO Better Practice Guide, *Administering Regulation*, March 2007, p. 63.

action has taken place and that regulatory objectives are met. A lack of follow-up may encourage regulated entities to disregard the regulator's requirements and detract from the effectiveness of the regulatory regime.

4.43 Desk-top review may provide a level of assurance about corrective actions that sponsors promise to undertake in response to matters identified in a listing compliance review. However, as a technique, it is also dependent on the way in which sponsors choose to respond to the TGA. Gathering products from the field would provide greater assurance when the TGA is seeking to verify that corrective actions have, in fact, taken place.

4.44 The TGA does not routinely obtain samples of listed products from the field (for example, by purchasing them at a retail outlet—a health food shop or a pharmacy) for examination and review.[225] Where it is following up corrective action, after a review, it relies on the sponsor providing a satisfactory response to the OCM: in effect, a further self-certification. It advises that it 'may choose to follow up cases where significant safety and/or quality issues have been identified'.[226]

4.45 The TGA has stated that 'Most sponsors of Listed medicines take appropriate corrective actions when compliance issues are brought to their attention, without the need for regulatory action by the TGA.'[227] This is the view of an experienced TGA officer.[228]

4.46 The TGA's current practice—not verifying independently that corrective action has been taken—introduces an additional risk in the regulation of listed medicines. This risk is greater in circumstances where the regulator holds reasonable doubts about the consistency or integrity of sponsor behaviour.

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[225] The TGA advised (17 May 2011) that it usually utilises the powers of the Act under s. 31 to obtain documents and samples. However, samples from the market may be used for testing in substance-targeted testing programs.

[226] TGA, OCM advice, November 2010. The TGA advised (17 May 2011) that, while it does not routinely obtain samples of products 'from the field' for review, it will do so on a case-by-case basis. When undertaking a compliance review, documents and samples are generally requested from the sponsor under s. 31 of the Act. In some circumstances, the Office of Laboratory and Scientific Services may be requested by OCM to purchase samples from the marketplace for testing or may choose to conduct a testing review based on market samples. The outcomes from testing may be reviewed by the OCM for compliance at a later date, after the testing has been performed.

[227] TGA Senate Estimates Brief, 12 October 2010.

[228] TGA advice of 17 May 2011.

There are other reasons for reviewing products from the field

4.47 The OCM has stated that a contributing factor for compliance failure is sponsor 'failure to update the ARTG when product alterations are implemented.'[229] This provides two further reasons for the TGA to go beyond its desk-based review strategy and to review listed products gathered from the field:

- first, one way of detecting such alterations is field-testing; and
- second, if random field-testing were carried out, even at a low but consistent level, it could provide a general deterrence—to encourage sponsors to update the ARTG when products are altered.

4.48 The ANAO suggests that the TGA consider developing a program of obtaining samples of complementary products from the field with a view to testing them for regulatory compliance. This could be done with both a random and a targeted component, for the reasons set out above.

The TGA does not publicise its review activity or outcomes

4.49 The TGA has advised the Senate that numerous stakeholders, including healthcare professionals, other government agencies, in Australia and overseas, and manufacturers and sponsors of therapeutic goods may be relevant 'customers' of its regulatory activities. However, as the Commonwealth regulator of therapeutic goods under the Act, 'first and foremost the Australian public is the TGA's prime consideration and customer.'[230]

4.50 A regulator can provide greater assurance to the public where it provides information publicly about the outcomes of its review activities. In the case of the TGA, this approach could inform the public about the aspects that have been reviewed, when the review took place, what the specific findings were, and help them to make choices about products. It could also be helpful by showing what has *not* been tested.

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[229] TGA minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010.

[230] Senate Community Affairs Committee, Answers to Estimates Questions on Notice, Health and Ageing Portfolio, Supplementary Budget Estimates 2010–11, 20 October 2010, Question E10-025, available from <www.aph.gov.au/Senate/committee/clac_ctte/estimates/sup_1011/doha/doha_025.pdf> [accessed 3 May 2011].

4.51 The TGA provides the Australian public with no information about which listed complementary medicines it has reviewed nor the outcomes of those reviews. Further, after a review it is not generally possible for the public to find out from, for example, the TGA website, which products have been reviewed, or even if they have satisfied all the requirements. Only where a product contains an ingredient (or contaminant) which makes it inherently risky to the consumer (in which case it may have caused an adverse reaction and be subject to a recall) does the result of TGA evaluation of a listed item become apparent.

4.52 A survey of complementary medicine use in South Australia in 2004 found that 'half the population thought that [complementary and alternative medicines] were independently tested by the TGA before being allowed to be sold.'[231] Similarly, when the National Prescribing Service researched the information use and needs of complementary medicines users it found that:

> More than half of respondents (52%) thought that CMs were independently tested by a government agency such as the TGA. Of those who thought they were tested, one quarter thought they were tested for quality, three-quarters thought they were tested for safety, and one-third thought they were tested for efficacy or for what they claim to do.[232]

The AUST L number is not understood

4.53 Generally, the only information available to the consumer about the TGA's involvement with any particular listed product is the AUST L number on the product container. This may not be noticed by the consumer as the print is small, a matter that has attracted adverse comment from the former chair of the Expert Committee.[233] There is evidence to confirm the Australian public is generally unaware of the AUST L numbers. An anonymous, self-administered survey completed by randomly selected pharmacy customers at 60 community pharmacy locations between August 2008 and February 2009 showed that

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[231] MacLennan, A. H., Myers, S. P., and Taylor, A. W., 'The continuing use of complementary and alternative medicine in South Australia: costs and beliefs in 2004', *Medical Journal of Australia,* 2006, 184 (1), pp. 27–31, available from <www.mja.com.au/public/issues/184_01_020106/mac10324_fm.html> [accessed 5 August 2011].

[232] NPS, *Information Use and Needs of Complementary Medicines Users*, December 2008, available from <www.nps.org.au/research_and_evaluation/current_research/complementary_medicines/cms_users_research/complementary_medicines_consumer_research> [accessed 5 August 2011]. Significantly, this research, funded by DoHA, was undertaken in response to Recommendation 25 of the Expert Committee.

[233] Bollen, Michael D and Whicker, Susan D., op. cit., pp. 288–94.

88 per cent of surveyed consumers had never noticed the term 'AUST L'.[234] Among those in the survey who did notice the AUST L:

> 33% thought it meant the product was tested by a government agency for safety, 26% thought it was tested by a government agency for quality, and 24% thought it denoted an Australian made product, 15% thought it was tested by a government agency for effectiveness and 13% stated they did not know what it meant.

4.54 As discussed in Chapter 3, the presence of the AUST L number shows that the product has been listed on the ARTG, which is achieved by sponsor certification and payment of fees. Thus every listed product bears an AUST L number, whether or not it has been reviewed, post-market, by the TGA. In contrast, registered medicines, which bear an AUST R number, will have been evaluated in every case for safety, quality and efficacy before being entered onto the ARTG.

4.55 The Expert Committee, in 2003, concluded that 'consumers may not be aware that Listed medicines have not been evaluated by the national regulator for efficacy before their supply. The committee considered there is an ethical responsibility on government to ensure that consumers are informed about this difference between Listed and Registered complementary medicines.'[235]

The TGA does not explain the AUST L number clearly

4.56 When, in 2006, DoHA was asked 'Do you think that the public understand that when they see a TGA AUST-L label that it does not mean that the highest levels of evidence have been used by the TGA to verify the drugs efficacy?' the TGA is reported to have advised:

> The TGA has a number of information resources for consumers including the pamphlet *Buying medicines—What's on the label for me?* to explain the risk-based regulatory system including the difference between AUST R and AUST L medicines. In addition, there is a large volume of information on the TGA website.[236]

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[234] L. Braun et al., 'Adverse reactions to complementary medicines: the Australian pharmacy experience', *International Journal of Pharmacy Practice*, 18: 242–4. The work on which these results draw was funded by the DoHA as part of the Fourth Community Pharmacy Agreement.

[235] Expert Committee, Report, p. 16.

[236] DoHA, Media Unit, Answers By Federal Health Department to Background Briefing Questions, undated, ABC Radio, *Background Briefing*, broadcast 15 October 2006, available from <www.abc.net.au/rn/backgroundbriefing/documents/health_department_response.pdf> [accessed 5 August 2011.]

4.57 The advice provided in the location referred to reads as follows:

> *What do the Aust R and Aust L numbers mean?*
>
> They show that the medicines are accepted by the Therapeutic Goods Administration for supply in Australia and are included in the Register. The number is printed on the outer packaging so that it can be seen easily.
>
> AUST R medicines are assessed for safety, quality and effectiveness. They include all prescription only medicines ...
>
> AUST L medicines are much lower risk self-medication products. They are used for minor health problems and are reviewed for safety and quality. ... [237]

4.58 There is no explanation of what is meant by 'assessed' and 'reviewed' or how they may differ, nor of why AUST L products are reviewed for safety and quality but, unlike AUST R products, apparently not for effectiveness.[238] Internal TGA documentation shows that its officers had formed the view in 2008 that 'Consumers currently are of the belief that the TGA fully assess and test every medicine'.[239]

4.59 There is also information elsewhere on the TGA's website. An article under the heading *AUST R and AUST L numbers—why are they important?* includes the following statement:

> Where the medicine label does not include an AUST L or AUST R number the TGA has not evaluated the quality, safety or efficacy of the product and therefore the safety of the product is unknown.[240]

4.60 This is strictly correct but not a helpful or complete explanation. This is because products bearing AUST L may also not have been evaluated by the TGA and, even where they are, are not evaluated for efficacy.

4.61 The explanation that the TGA provides on its website page 'You and Your Healthcare Products' as part of its 'Information for consumers' is equally

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[237] See <www.tga.gov.au/consumers/information-medicines-label.htm> [accessed 12 August 2011].

[238] It is possible to find elsewhere on the TGA's site, mention of the fact that AUST L products are 'not assessed individually for efficacy' in 'The regulation of complementary medicines in Australia—an overview' (See: <www.tga.gov.au/industry/cm-basics-regulation-overview.htm> [accessed 5 August 2011].)

[239] TGA, internal paper, Discussion Framework—Therapeutic Goods Listing, March 2008.

[240] TGA, Medicines Safety Update No. 3, 2010, available from <www.tga.gov.au/hp/msu-2010-03.htm> [accessed 12 August 2011]. It should be noted that the AUST R and AUST L numbers, by uniquely identifying the product, have an important role in the recall of a medicine, regardless of whether their significance is understood by the consumer.

incomplete and, hence, potentially unhelpful to the consumer about the degree of testing of AUST L products:

> An AUST R number shows that a product has been assessed for safety, quality and effectiveness. AUST L numbers are given to lower risk products used for minor health complaints or health maintenance.[241]

4.62 The evidence shows that the public is generally unaware of the significance of the AUST L number or, in some cases, wrongly concludes that it shows that the TGA has tested the product. The TGA's own explanations are incomplete, even when directed at the public. Moreover, the public, the TGA's prime customer, has no way of establishing whether a listed product has been tested by the TGA, or what the outcome of testing has been.

4.63 When asked in 2011 whether it considered that there is a good understanding among the general public of the difference between AUST R and AUST L products, the TGA responded: 'The TGA has received some feedback to suggest a level of confusion within the general public of the difference between AUST R (Registered) and AUST L (Listed) products.'[242]

4.64 In response to a further question on what the TGA is doing to educate the public about the difference between AUST R and AUST L it responded saying that it was:

> progressing an internet site redevelopment to implement a user-centred website that provides consistent, accurate and appropriate information from the TGA in a manner that is easy to locate, access and understand.

4.65 A redeveloped TGA website appeared on 4 May 2011. However, the above material about the meaning of AUST L, which was on the old TGA website, remains on the redeveloped one.

Recommendation No.3

4.66 The ANAO recommends that the TGA makes information available in a timely manner to the Australian public, for each listed complementary

[241] Formerly available at <www.tga.gov.au/meds/healthcare.htm> [accessed 11 April 2011].

[242] Answer to a question from Senator Siewart (question No. 9, Outcome 1) to DoHA at the 2010–11 Additional Estimates hearing, 23 February 2011. Answer provided 3 May 2011. See: <www.aph.gov.au/Senate/committee/clac_ctte/estimates/add_1011/doha/009.pdf> [accessed 5 August 2011].

medicine, stating whether it has been subject to post-market review by the TGA, when it was reviewed, and the outcome of that review.

Agency response

4.67 DoHA agreed to the recommendation.

4.68 An option for implementing this recommendation would be placing information on the TGA website, such as by adding fields to the publicly-viewable elements of the ARTG.

Regulatory action by the TGA takes a long time

4.69 Generally, the quicker that regulatory decisions are made—particularly a decision to remove a product from the market—the lower the risks borne by the consumer. On the other hand, regulatory decisions need to be lawful, fair, based on the facts and taken in a measured way. Haste may place a burden of risk on the regulated party, such as undue compliance costs or loss of market share.

4.70 Ideally, the regulator should have in mind a target time for making such decisions. That target should balance the interests involved. If the target and actual time taken are reported publicly this will enhance the accountability of the regulator.

4.71 Consultancy advice received by DoHA in 2008 about TGA decision-making observed that the TGA often seeks industry action where the TGA would otherwise need to exercise formal regulatory powers:

> The OCM stated that they do not make very many cancellation decisions, where a complementary medicine is cancelled from the Register. It is more likely the Sponsor would cancel the complementary medicines themselves. If there is to be a cancellation the OCM will send out a proposal to cancel letter to accord the Sponsor natural justice.[243]

4.72 To gauge the time TGA regulatory decisions on listed medicines take, the ANAO sought advice from OCM on its recent regulatory action. The OCM provided a list of cases where regulatory action had taken place (or was underway) for the period 1 January to 1 November 2010. This identified just over a dozen cases where a medicine had been cancelled from the ARTG. This was more often as a result of a sponsor's decision than OCM action.

[243] Consultancy advice to the Secretary, DoHA, 2008, para. 10.22, p. 25, and para. 21.5, p. 59.

4.73 In the sample of cases provided to the ANAO:

- there were five cases where a targeted review had led the TGA to issue a cancellation notice under s. 30 of the Act (and where dates were available for both the commencement of the review and the date of issue of the cancellation notice). The mean time taken was 180 days;
- three other items had their review 'created' in October 2009 but the status was described as 'pending' in two cases and 'undecided' in the other (in November 2010); and
- in eight other cases the sponsor had cancelled the listing, following receipt of a 'proposal to cancel notice' from the TGA. The mean time that had elapsed between the 'creation' of the review and receipt of a response from the sponsor was 200 days.[244]

4.74 During the period between starting the review and cancellation of the product from the ARTG, that product remains on the register and, hence, may be marketed in Australia. Unless the product is found to have a direct health risk, it is not recalled even when cancelled.

4.75 In the small sample examined above, the mean time taken from the commencement of a review to either a cancellation notice or a proposal to cancel notice is over six months. Where the sponsor made the decision it generally took a little longer. The TGA does not have any target timeframe for the making of this type of regulatory decision. It does not report publicly on its performance in making them or in relation to sponsor withdrawal of items from the register after review action has commenced. It would aid transparency of the regulatory process if it were to do so.

4.76 The ANAO suggests that the TGA reviews these arrangements with a view to (i) identifying opportunities to expedite this process while observing the requirements of administrative law for natural justice and fair decision-making and (ii) setting some targets and reporting publicly against them.

The outcomes of TGA post-market reviews

4.77 As noted earlier (para. 3.72), DoHA reported in late 2010 that, based on 2009–10 data, as many as 90 per cent of products reviewed are found to be

[244] One item was omitted from the calculation of this mean as the stated dates were anomalous: the date of review creation post-dated that of receipt of the sponsor's response to the proposal-to-cancel notice.

non-compliant with regulatory requirements, with a significant number of products requiring removal from the ARTG. However, by the TGA's own assessment, non-compliance has been high for some years. When the OCM conducted its analysis in April 2010 and found about 10 per cent of medicines were compliant with 'reviewed requirements', it noted that this is a finding 'which the OCM believes is reasonably consistent with findings over previous years.'[245] This section examines these findings and the reasons advanced by the TGA for this state of affairs.

The TGA found 75 per cent non-compliance in 2006

4.78 In May 2006, the TGA–Industry Consultative Committee (TICC) was updated by the head of the OCM on then recent activity, including:

> Random and targeted (Post-market) sampling targets and results, noting sample sizes had increased to 20% over the quarter (target 24%). [OCM head] advised that whilst deficiency rates were high, many of these were relatively minor labelling matters and few incidents ultimately involved suspension, cancellation or recall and these rates were expected to fall with further education of industry.

4.79 Later in the year, the TGA provided less sanguine advice to the OICG on the state of non-compliance among listed medicines. It had completed random reviews of 237 products among which 178 (75 per cent) attracted a deficiency notice or a proposal to cancel the listing.[246]

4.80 The OICG sought a breakdown of the types and frequency of recurring deficiencies, which the OCM provided to its next meeting (1 December 2006) From a sample of '50 recent deficiency notices sent by the OCM' the paper categorised problems into three types, each comprising about one-third of the identified problems: problems with labels, problems with product specifications and problems with evidence (see Table 4.1).[247]

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[245] TGA, OCM Minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010.

[246] On the available figures, the ANAO estimates that the TGA could be 95 per cent confident that the deficiency rate for the entire population was 75 per cent plus or minus 5.5 per cent.

[247] TGA, *Random Review of listed medicines: Recurring deficiencies*, agenda paper 5.1, circulated by the TGA at OICG 13, 1 December 2006.

Table 4.1

Excerpt from paper circulated at OICG meeting 12, 30 October 2006

Random Review of Listed Medicines—Recurrent Deficiencies
Problems with the submitted evidence:
• When evidence is based on tradition of use, it is not reflected on the label.
• Not all of the claims/indications are covered by the evidence provided.
• The RDD [Recommended Daily Dose] for the ingredients are lower than that in the evidence.
• Clinically proven claims when no trial [was] conducted or when it was only a pilot scale study.
• Evidence is solely based on animal/in vitro studies.
• The number of subjects used in the study is too small.
• Different plant species or plant parts.
• Evidence relates to another (more serious form of) disorder.
• Study carried out in a different target population.
• The effect/outcome is not statistically significant (P >0.05).
• The effect/outcome observed is not clinically significant.
• Evidence relies on biological plausibility, [for example,] linking thermogenic property of a substance to weight loss.
• Breaches of the advertising code.
• Evidence of uncertain quality (obscure texts, Internet sites etc).

Source: TGA record of its advice to OICG meeting 12, 30 October 2006, Item 9.1.

4.81 The OCM stated at the time that it issued deficiency notices (or took other regulatory action) only for 'significant' problems. That is, where the deficiencies included non-compliance with the applicable standard, inconsistency with the formulation or inadequate evidence to support claims/indications.'

4.82 The TGA recommendation to the OICG was that 'Members are asked to note the recurring deficiencies.' Apart from drawing this to the attention of industry representatives at this meeting, TGA reported that it then commenced work internally to develop options to address the issue, including consideration of work on evidence levels and requirements.[248]

[248] TGA advice of 20 May 2011.

Non-compliance rates have remained high

4.83 In a brief drafted in April 2009, the OCM stated that:

> In a 10 month period from July 08 to April 09, 70% of post market reviews identified issues regarding inappropriate claims and/or breaches to the Therapeutic Goods Advertising Code. Significant resources are diverted, in pursuing these matters, from other issues such as manufacture, quality or packaging.[249]

4.84 In September 2009, the head of OCM advised the TGA–Industry Consultative Committee (TICC) that 'There is currently a high failure rate for targeted and random reviews. The TGA is currently analysing the causes and possible solutions.'[250] At the subsequent TICC meeting (March 2010), the TGA advised the committee that: 'Post-market reviews, both random and targeted, still have a high failure rate, and the TGA is working to address this' though the nature of that work was not recorded.

4.85 In April 2010, in response to a request from senior management, the OCM reported internally on its analysis of non-compliance. The scope of this analysis was listed medicines with concluded reviews over the period 1 July 2009 to 30 March 2010.[251] In that period, the TGA had completed 264 reviews and investigations of listed complementary medicines, of which 110 were desktop-based compliance reviews. Among these 110, the TGA found 98 medicines (approximately 90 per cent) had at least one compliance issue (Table 4.2, below). Of the 98 non-compliant products:

- forty-one were cancelled from the ARTG; and
- fifty-seven were remedied and remained in the ARTG.[252]

4.86 Other relevant activities among the 264 reviews closed included 22 medicines cancelled by the sponsor upon receiving the TGA's request for information. As the OCM advised, 'In some cases the sponsor chose to remove

[249] TGA, draft minute to Parliamentary Secretary, 'Indications for Listed Medicines', dated 23 April 2009. The TGA advises that it cannot confirm the accuracy of the data cited. (Advice of 17 May 2011.)

[250] TGA, Minutes, TICC, September 2009.

[251] A desktop compliance review is concluded if all non-compliance issues have been corrected or the medicine is cancelled from the ARTG.

[252] TGA advice of 17 May 2011.

the medicines rather than address the issues. In other cases, sponsors cancel medicines for reasons of discontinuation or reformulation of the goods.'[253]

Table 4.2

Desk-top compliance reviews of listed complementary medicines completed from 1 July 2009 to 31 March 2010

Type of review:	Random	Targeted	Total
No. of desktop compliance reviews completed	31	79	**110**
No. of products where full compliance was found against the regulatory requirements reviewed	3	9	**12**
No. of products that required corrective action and the sponsor corrected deficiencies	25	32	**57**
No. of products that required corrective action and the TGA cancelled the medicine at the sponsor's request	2	25	**27**
No. of products that the TGA cancelled as a result of regulatory breaches	1	13	**14**

Source: TGA advice, 17 May 2011.

4.87 The TGA has reported the overall result as revealing 'as many as 90 per cent of products reviewed are found to be non-compliant'.[254] It must be borne in mind that the analysis includes the results of both random reviews (31 cases) and targeted reviews (79 cases). Targeted reviews are likely to reveal a higher number of compliance failures than random reviews. Therefore no statistically valid, general conclusion can be drawn about the state of compliance among newly-listed medicines at that time from the results of the 110 reviews as a whole. The random reviews alone can provide some general insight, though the small sample size (31) limits the confidence with which conclusions can be

[253] Of the 264 reviews closed, 110 had a regulatory outcome as reported and further analysed in Table 4.2. A further 85 were investigations/other work in relation to individual medicines; 23 were investigations of classes of medicines without an ARTG number; 22 were cancelled by the sponsor after a s. 31 notice (a notice under the Act seeking information) and 18 reviews were ceased (for example, because the goods were not manufactured). TGA, OCM minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010. On the question of the 22 medicines cancelled by sponsors, the TGA advised that it does not routinely continue compliance reviews of a medicine, if that medicine is cancelled upon request by the sponsor after a s. 31 notice is issued. It is possible that a portion of these cancelled medicines may be non-compliant. Without the review data it is difficult to comment whether the actual non-compliance levels would be worse than that reported.

[254] DoHA, Incoming Government Briefing—Volume 1, item D27. See: <www.health.gov.au/internet/main/publishing.nsf/Content/min-briefs> [accessed 5 August 2011].

drawn. The OCM found three wholly compliant cases among the 31 randomly-sampled cases.

4.88 In the light of its analysis of the level of non-compliance among listed complementary medicines the TGA formed the view that 'compliance issues may present potential risks to public health and the risk of loss of confidence in both the regulatory system and the complementary medicines industry.'[255]

4.89 Later analysis of post-market random reviews in the period July – December 2010 showed similar levels of non-compliance (full compliance observed in four out of 32 cases reviewed) though the nature of the non-compliance observed was generally judged less significant (figures for both periods are set out in Table 4.3). These results, aggregated, show that 24 out of 63 randomly-reviewed items are either moderately or serious non-compliant.[256]

4.90 Further work on the actual state of compliance by careful and thorough examination of a random sample of listed complementary medicines could establish with greater confidence the likely general level of non-compliance. This could also provide insight into those characteristics, if any, which correlate with non-compliance and provide a basis for further, targeted review.

[255] TGA, Senate estimates brief, October 2010.

[256] This would allow a conclusion (with 95% confidence) that between one quarter and one-half of all such medicines are moderately or seriously non-compliant.

Table 4.3

Results of post-market random reviews in two recent periods

Review period	July 2009 – March 2010	July – Dec. 2010	Total
No. of random desktop compliance reviews completed	31	32	63
No. of products where full compliance was found against the regulatory requirements reviewed	3	4	7
No. of products where at least one non-compliance issue is identified	28	28	56
No. of products that had minor non-compliance issues	9	23	32
No. of products that had moderate non-compliance issues	11	5	16
No. of products that had significant non-compliance issues	8	0	8

Source: TGA Advice, 17 May 2011.

The TGA has identified reasons for low compliance

4.91 The OCM analysis of the low compliance rate among listed complementary medicines in April 2010 also included a list of 'reasons and contributing factors' (See Table 4.4.).

4.92 The most substantial post-market control available to the OCM to enforce regulatory compliance is its capacity to suspend an item from the ARTG or cancel it. It has not yet used the former and the TGA has cast doubt on the effectiveness of the latter as a control. This is because the cost incurred by a sponsor to re-list a medicine (albeit in a slightly different form) is very low: it is physically very easy and quick, and application and variation fees are small. That is, if the TGA were to cancel a non-compliant product the sponsor would be aware that they can easily and promptly re-list it at low cost.[257]

[257] To meet the requirements of s. 26A(1)(e) of the Act, the same product cannot be re-listed after cancellation. However, introducing minor changes that form the basis of a claim that it is a new product may enable the product to satisfy this provision.

Table 4.4

OCM summary of reasons for compliance failure

Potential contributing factors
Poor understanding by sponsors/agents of the regulatory system and legislative requirements: • Difficulty understanding and applying the variety of applicable legislation and other documents. In addition, some guidance documents are lengthy and outdated. • A proportion of the sponsors do not appear to understand their legal responsibilities, especially regarding the implications of self-certification at time of listing.
Aggressive marketing strategies by sponsors that frequently result in issues with advertising, evidence, and overall presentation.
Sponsors that intentionally use delaying or obstructive tactics: • Repeat offenders, problems only addressed when identified by TGA. • Displaying apparent willingness to cooperate while providing unreasonable/illogical arguments or proposing unsatisfactory solutions to identified problems, often in a bid to 'buy time' in the marketplace. • Awareness that the system allows for repeated cancellation and re-listing of products which provides for avoidance of addressing problems identified in reviews. • Awareness that the TGA rarely prosecutes or applies civil penalties.
Sponsors frequently misunderstand that ELF validation is not equivalent to approval by the TGA and is not confirmation of eligibility for listing.
Lack of awareness by sponsors of the manufacturing requirements and the complete formulation of their medicines, particularly when Proprietary Ingredients are included.
Lack of clarity in relation to regulatory requirements, for example, what indications are acceptable for listed medicines and what constitutes a reference to a serious condition.
Information incorrectly entered into the ARTG, both intentional and unintentional, and failure to update the ARTG when product alterations are implemented.
Sponsors or manufacturers initiating modifications to labelling and manufacturing standards without seeking consent to supply non-conforming goods from the delegate of the Secretary.
Lack of understanding of matters of critical significance in relation to evidence (e.g. minimum dose), or inability to implement the guidance provided in relation to evidence.
English language as a barrier for some sponsors.

Source: TGA, OCM Minute, 'Re: Request for analysis of non-compliance issues for listed complementary medicines', April 2010.

4.93 In a subsequent minute the OCM summarised the array of causes in Table 4.4 in three main 'barriers' to compliance:

- Challenges in navigating and understanding the scope of requirements;
- Unwillingness to adhere to the rigorous nature of the regulatory framework; and
- The impact of OCM operational challenges upon the level of compliance monitoring.[258]

4.94 The OCM proposed to take action to address these, comprising improving sponsor compliance resources (to improve sponsor understanding of the regulations, including continuing work on updating guidelines); strengthening regulatory monitoring (by increasing resources devoted to product review); and increased regulatory consequences for non-compliance. The last of these involves invoking a new capacity, available since August 2009, to suspend items from the ARTG rather than cancel them. It was thought that this less heavy-handed intermediate course of action would be a useful regulatory tool to help encourage compliance. The TGA has not yet used this capacity but advised it intends to use it later in 2011.

4.95 Other, later advice about corrective action focuses on the 'TGA working with key stakeholders to improve compliance and manage potential risks through consultation and education.'[259] Although these proposed courses of action address the problem of educating and guiding sponsors in need of such help and the need for the TGA to work harder at detecting non-compliance, none seems to address the most difficult problem set out in the OCM list of reasons for compliance failure—unwillingness to adhere to the framework.

4.96 The challenges reportedly faced by some sponsors in complying with the regulatory framework raise again the issue of developing risk-based profiles, as discussed earlier in this chapter (para. 4.41). There is benefit in the TGA evaluating the merits of using sponsor behaviour as a basis for targeting reviews. As discussed earlier, this could be done without necessarily forming an adverse view of sponsor intent.

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[258] TGA, OCM, Minute, 'Re: Listed Complementary Medicines—current trends and regulatory directions', July 2010.

[259] See, for example, Senate Estimates brief, 12 October 2010.

4.97 In addition, there would be merit in adopting a targeted approach to identifying those complementary medicines which are most likely to be non-compliant with the regulatory requirements. The ELF system currently randomly selects newly-listed products for review, and more systematic analysis of the results of those reviews could provide a cost-effective basis for a more targeted approach.

Recommendation No.4

4.98 To improve compliance with the regulatory framework, the ANAO recommends that the TGA:

(a) use its random sampling review of listed medicines to develop risk profiles of sponsors and the most significant characteristics of medicines; and

(b) use the profiles to inform its program of post-market reviews.

Agency response

4.99 DoHA agreed to the recommendation.

5. Regulating the Advertising of Complementary Medicines

This chapter considers how effectively the TGA regulates the advertising of complementary medicines. While the focus of this chapter is on complementary medicines, other therapeutic goods are considered where there is a direct relationship to systems or processes designed to manage therapeutic goods advertising as a whole.

Why the advertising of therapeutic goods is regulated

5.1 In Australia, the advertising of medicines has long been a focus of government interest. As early as 1907, a Commonwealth Government-commissioned report recommended that there should be:

> No advertisement or announcement … of any proprietary or secret cure be permitted in any newspaper, journal, serial … and that it should not be lawful to transmit by mail any books, magazines … or other publications … [which] contain announcements [of] … any cure or cure system.[260]

5.2 The reasons for government interest were that if there were not adequate controls on the advertising of medicines, as well as their production and sale, the public could be exposed to risks such as misleading claims about their effectiveness.[261]

5.3 This interest continues in the modern era. In 1989, when the Australian Government introduced the Therapeutic Goods Bill, the Bill's Explanatory Memorandum stated that 'therapeutic goods' are considered to include goods which are likely to be taken to be for therapeutic use because of the way they are presented or advertised.[262]

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[260] Parliament of Australia, *Report of the Royal Commission on Secret Drugs, Cures and Foods*, vol 1, 1907, pp. 428–9.

[261] Senator the Hon Jan McLucas, Parliamentary Secretary to the Minister for Health and Ageing, *Regulating Secret Cures: Regulatory Issues in Relation to Therapeutic Goods and Nanotechnology*, Speech delivered at the Menzies Centre for Health Policy: Minter Ellison Health Conundrum Series, 6 May 2008, p. 2.

[262] Therapeutic Goods Bill 1989, *Explanatory Memorandum*, p. 2.

Current policy and legislative framework

5.4 The National Medicines Policy (NMP), in place since 1999, includes an objective to ensure the 'quality use of medicines' by the Australian public.[263] This policy states that 'industry and health practitioners should contribute [to the policy] through appropriate information, education and promotion activities'.[264]

5.5 Consistent with the NMP, the Government regulates the advertising of therapeutic goods to ensure it 'promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer'.[265] In October 2010, the Government stated that:

> A system of advertising regulation for therapeutic goods should contribute to the quality use of medicines by ensuring that healthcare professionals and consumers receive accurate information about the quality, safety and efficacy of medicines. It is particularly important that consumers receive accurate information about the benefits and risks of those goods that they can safely access without the intervention of a healthcare professional.[266]

5.6 The policy position is reflected in the *Therapeutics Goods Act 1989* (the Act), which includes an objective 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'.[267]

How the legislative framework works

5.7 The regulatory framework for advertising therapeutic goods is complex, having a three-tiered system of controls, including legislation, co-regulation and self-regulation by the therapeutic goods industry. The TGA has overall responsibility for administering the framework and its legislative underpinnings, which comprise:

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263 DoHA, *The National Medicines Policy Document: Objects of the Policy*, 10 November 2008, <www.health.gov.au/internet/main/publishing.nsf/content/national-medicines-policydoc~national-medicines-policy-2> [accessed 8 August 2011].

264 DoHA, *The National Medicines Policy Document: Quality Use of Medicines*, <www.health.gov.au/internet/main/publishing.nsf/Content/national-medicines-policydoc~national-medicines-policy-5> [accessed 8 August 2011].

265 Therapeutic Goods Advertising Code 2007, para 1(1).

266 TGA, *Advertising Therapeutic Goods in Australia: Consultation Paper*, June 2010, p. 1. <www.tga.gov.au/pdf/consult/consult-advertising-arrangements-101028.pdf> [accessed 8 August 2011].

267 *Therapeutic Goods Act 1989*, s. 4.

- the *Therapeutic Goods Act 1989* (the Act);
- the Therapeutic Goods Regulations 1990 (the Regulations); and
- the Therapeutic Goods Advertising Code 2007 (the Advertising Code).

5.8 The major components are summarised in Table 5.1.

Table 5.1

Major components of advertising regulations

The Therapeutic Goods Act
• Advertising is defined in the Act as 'any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods'. • The Act contains general offences relating to the registration and listing of therapeutic goods, such as a person committing an offence if they advertise an indication, for which they have not received pre-approval from the TGA. • Chapter 5 of the Act, 'Advertising, counterfeit therapeutic goods and product tampering', includes definitions of terms used in the advertising regulations, specifies restricted and prohibited representations that advertisers must abide by (for example, references to serious diseases identified in the Code), and specific offences relating to advertising therapeutic goods. • Provides that the Minister may, by legislative instrument, introduce a therapeutic goods advertising code. • Provides for the Governor-General to make regulations, which may prescribe requirements for the advertising of therapeutic goods.
The Therapeutic Goods Regulations
• Specify which advertisements require approval (for example, the advertising of designated therapeutic goods in 'specified media'). • State the conditions against which the approval of an advertisement must be assessed. • Specify the power of the Secretary of DoHA to approve, or refuse to approve, certain advertisements. Currently this power is delegated to the industry bodies, the ASMI and the CHC. • Establish the Complaints Resolution Panel, including its membership and functions. • Specifies the powers of the Secretary of DoHA to issue written orders to companies ordering them to comply with determinations made by the Complaints Resolution Panel. This includes ordering the withdrawal and retraction of advertisements that are in breach of the advertising regulations. • Establish the Therapeutic Goods Advertising Code Council, and specify its membership and functions (such as providing advice to the Minister on changes to the Code).

The Therapeutic Goods Advertising Code

- The objective of the Code is to 'ensure that the marketing and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer'.
- Contains principles of advertising therapeutic goods that must be upheld by companies.
- Places prohibitions on when certain representations ('restricted', 'prohibited' and 'permissible') can and cannot be made (for example, prohibited representations of diseases such as cancer).
- Specifies minimum requirements of what must be contained in an advertisement of a therapeutic good.
- Specifies appeals and complaints mechanisms (for example, as specified in the Regulations).
- Sets out what therapeutic goods may be advertised to minors (persons under the age of 18). For example, certain goods including tampons, acne preparations and sunscreens.

Source: ANAO analysis.

Managing the advertising regulations

5.9 As specified in the Act, the Regulations and the Code, key bodies are designated different responsibilities. The system of co-regulation involves:

- peak industry representative bodies assessing certain therapeutic goods advertising for pre-approval;[268]
- the Therapeutics Goods Advertising Code Council (TGACC) advising the minister on the effectiveness of the Advertising Code; and
- the TGA and the Complaints Resolution Panel (CRP) investigating complaints about alleged breaches of the advertising regulations.[269]

5.10 The system of self-regulation involves peak industry bodies managing industry association codes of conduct containing principles their members must uphold.[270] The industry bodies also manage complaints about advertising to healthcare professionals where that advertising is alleged to have breached the code.

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[268] TGA, *Regulation of Advertising Therapeutic Goods in Australia*, May 2011, p. 2. <www.tga.gov.au/pdf/advertising-regulation.pdf> [accessed 8 August 2011]. These bodies are the Australian Self-Medication Industry (ASMI) and the Complementary Healthcare Council (CHC).

[269] The CRP handles complaints involving non-prescription advertising that is required to be pre-approved. For example, advertising that appears in mainstream print and broadcast media (and includes Internet advertising which is exempt from pre-approval).

[270] The Government has stated that 'it supports the self-regulation of industry conduct, including for promotional activities undertaken by therapeutic goods companies'. DoHA, *Position Paper on the Promotion of Therapeutic Goods*, June 2010, p. 1.

Advertising complaints

5.11 Dealing with complaints about the way therapeutic goods are advertised to consumers is a major component of administering the advertising regulations. Over the last four calendar years (2007 to 2010) the CRP has reported receiving 289, 270, 335 and 295 complaints respectively.[271] This volume of complaints can affect the TGA when the CRP recommends that it take regulatory action where advertisers fail to comply with CRP determinations (see para. 5.16 below).

5.12 There are several mechanisms to address complaints alleging breaches of the advertising requirements for complementary medicines (Table 5.2).

Table 5.2

Responsibilities of complaint handling bodies

Type of Therapeutic Good	Complaints about advertising to consumers	Complaints about advertising to healthcare professionals
Prescription medicines	The TGA. It is illegal to advertise prescription medicines direct to consumers.	Medicines Australia Code of Conduct Committee. Complaints about non-members of Medicines Australia may be referred to the TGA.
Non-prescription medicines (including complementary medicines)	The CRP (for advertisements where prior approval is required); and industry associations (for other advertisements).[272] The TGA if advertiser is a non-member, a retailer or a distributor.	Industry associations (ASMI and CHC). The TGA if advertiser is a non-member of the ASMI and the CHC, a retail outlet, a distributor or a practitioner.
Medical devices	The Complaints Resolution Panel (for broadcast media, mainstream print media, billboards, cinema films). The TGA.	The TGA.

Source: TGA, Regulation of Advertising of Therapeutic Goods in Australia, May 2011, pp.3–4.

The Complaints Resolution Panel

5.13 The CRP, a central component of the co-regulatory scheme, receives, considers and determines the validity of complaints about the advertising of non-prescription medicines in mainstream print and broadcast media

[271] Complaints Resolution Panel, <www.tgacrp.com.au/> [accessed 12 August 2011].

[272] Since 1999–2000 contracts have been in place between DoHA and CHC/ASMI for self-regulatory advertising complaint functions, including for their assessment approval of certain advertisements.

(including the Internet).[273] The CRP is managed by a small secretariat based in Sydney. Since 1998, an industry body under contract to the TGA has provided secretariat support to the CRP and to the Therapeutic Goods Advertising Code Council (TGACC).[274,275]

Complaints handled by the TGA

5.14 The TGA, as well as the CRP, is authorised to receive and investigate advertising complaints. In general, the TGA can investigate breaches of advertising regulations—whether or not they are subject to a complaint—in all types of media.[276]

5.15 Operationally, the TGA currently investigates the complaints involving advertisers who are not members of an industry body, are retailers, distributers or practitioners, or advertising that appears on the Internet.[277,278] During 2009–10, the TGA investigated and finalised 228 complaints across a range of product types,[279] compared to 260 in 2008–09.[280]

5.16 A substantial component of the TGA's work on advertising breaches is referred from the CRP. When CRP determinations are not complied with (or not acknowledged) by advertisers, it may recommend that the TGA take regulatory action (a 'Regulation 9 Order'). The TGA issues Regulation 9 Orders to initiate action by non-compliant advertisers including a withdrawal, or to publish a retraction or correction to an advertisement.

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273 TGA, *Overview of the Regulation of Advertising Therapeutic Goods in Australia: Briefing Paper for Chief Regulatory Officer and Principal Legal Adviser*, p. 2.

274 TGA, *Minute to the Parliamentary Secretary re: CRP Contract*, 18 September 2009, p. 1.

275 Both the CRP and the TGACC websites are managed by the ASMI secretariat services. See: <www.tgacrp.com.au/index.cfm>; and <www.tgacc.com.au> [accessed 8 August 2011].

276 TGA advice to the ANAO, 13 January 2011.

277 Due to the large volume of complaints that are currently being referred to the CRP, the TGA will investigate Internet advertising complaints only if they are submitted directly to it (and not the CRP). (TGA advice to the ANAO, 29 October 2010.) There is no prearranged split between the CRP and TGA to undertake Internet advertising complaint investigations. (TGA advice to the ANAO, 17 November 2010.)

278 TGA advice to the ANAO, 13 January 2011. This advice includes an explanation of the different types of advertising breaches that the TGA is legislatively authorised to investigate. This is qualified by the statement that the TGA's scope is 'subject to the limitations set out in specific advertising provisions'. As discussed later in this chapter, the TGA may benefit from having a standard operating procedure that clarifies the limitations for TGA staff.

279 TGA, *Advertising Matter by Category, Product Type and Referral 2009–10*, p. 1.

280 TGA, *Advertising Matter by Category, Product Type and Referral 2008–09*, p. 1

Current review of the advertising arrangements

5.17 In recent years, the community, health professionals and industry have expressed concerns that the regulatory framework for advertising therapeutic goods is not operating as effectively as it could. The concerns include:

- a lack of transparency of follow-up action by the TGA when it takes regulatory action arising from matters dealt with by the CRP;
- complainants not being told of the outcome of their complaints; and
- the ineffectiveness of sanctions available in the legislation governing the advertising of therapeutic goods.[281]

5.18 These concerns led the Government to review the advertising arrangements overall.[282] In June 2010, DoHA released two papers for public comment, prepared by two of its divisions, relating to the regulation of advertising therapeutic goods.[283]

5.19 DoHA also outlined in its *Annual Regulatory Plan 2010–11* and *Annual Regulatory Plan 2009–10* that it expected to implement legislative changes to the Act and the Regulations by July 2011. The changes were proposed to improve the existing arrangements for the advertising of therapeutic products.[284,285]

5.20 The ANAO examined the TGA's performance in carrying out its direct responsibilities in regulating the advertising of complementary medicines.[286] The remainder of this chapter considers the following matters:

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[281] TGA, *Senate Estimates Brief: Advertising–Current Process and Source of Criticism*, October 2010.

[282] The TGA states that 'the purpose of seeking comment on these proposals [outlined in the consultation paper] is to improve the rules governing the advertising of therapeutic goods. Improved arrangements for the regulation of therapeutic goods advertising forms part of the regulatory reform program currently being implemented to improve, clarify and strengthen the framework for the regulation of therapeutic goods in Australia'. See: <www.tga.gov.au/newsroom/consult-advertising-arrangements-101028.htm> [accessed 8 August 2011].

[283] The Regulatory Policy and Governance Division of DoHA developed and released the *Position Paper on the Promotion of Therapeutic Goods*. The TGA released *Advertising Therapeutic Goods in Australia: Consultation Paper*.

[284] DoHA, *Annual Regulatory Plan 2010–11*, February 2011, p. 28. <www.health.gov.au/internet/main/publishing.nsf/Content/Regulatory-Plan-2010-11> [accessed 8 August 2011].

[285] DoHA, *Annual Regulatory Plan 2009–10*, September 2009, p. 18. <www.health.gov.au/internet/main/publishing.nsf/Content/Regulatory+Plan+2009-10> [accessed 8 August 2011].

[286] While the focus of the following analysis is on complementary medicines, other therapeutic goods are considered where this cannot be avoided.

(1) the strategy and processes adopted to detect non-compliance with the advertising requirements; and

(2) the extent to which complaint investigations are conducted in line with key elements of better practice principles.

Detecting and addressing non-compliance

5.21 The TGA is authorised to receive and investigate therapeutic goods advertising complaints. Monitoring and addressing non-compliant behaviour provides assurance to the Australian public and its stakeholders that mandated advertising requirements are being met.[287] The ANAO examined:

(1) whether the TGA is effectively using a compliance program, and whether risk analysis and a graduated response are employed to address non-compliant behaviour; and

(2) whether the TGA offers advice and education to advertisers, so that they better understand their regulatory obligations.

Whether the TGA effectively uses a compliance program

5.22 To examine the TGA's current approach to managing non-compliant advertisers, the ANAO reviewed a sample of completed TGA investigations into advertising complaints.[288] The ANAO considered whether the TGA uses a risk-based compliance strategy for assessing adherence to the advertising regulations. This analysis is informed by key components of an effective compliance strategy, which include:

- use of risk analysis to gauge the seriousness of advertising breaches;
- use of a graduated response to encourage compliance;
- addressing non-compliance using proactive and reactive approaches; and
- use of performance information to measure non-compliance.

[287] ANAO Better Practice Guide, *Administering Regulation,* March 2007, p. 51.

[288] Paras. 5.57–5.58 below discuss the method used by the ANAO to select TGA complaint investigations.

Using risk analysis to gauge the seriousness of advertising breaches

5.23 An effective way to plan a compliance program is through the analysis of the seriousness of the risks posed by non-compliant behaviour. Risks to consumers can be mitigated when breaches are dealt with efficiently and non-compliance is controlled.[289] To provide context, Table 5.3 provides examples from the Act and the Code of what advertisers must *not* do.

Table 5.3

Breaches under therapeutic goods regulations

Examples of what advertisers of therapeutic goods must not do
• Advertise an indication for a therapeutic good that was not a TGA-approved indication. • Be likely to arouse unwarranted and unrealistic expectations of product effectiveness. • Be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases. • Mislead, or be likely to mislead, directly or by implication or through emphasis, comparisons, contrasts or omissions. • Contain any claim, statement or implication that a product is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure. • Contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side-effects.

Source: ANAO analysis. See: *Therapeutic Goods Act 1989*, s. 22(5) and s. 41ML (for medical devices). Therapeutic Goods Advertising Code 2007, para. 4(2)(a)-(c) and paras (g) and (i).

5.24 To identify the seriousness of risks posed by breaches, a systematic approach would seek to understand whether advertisers are using campaigns across different media and/or across different states. This is an aspect which complainants may not have identified.

5.25 A systematic approach to assessing risk would also take account of how long breaches had occurred, and the scale of the breach, which can range from a minor administrative breach (for example, a failure to publish an approval number in an advertisement) to more serious breaches (such as a listed medicine advertisement making claims that a serious medical condition can be cured (using a prohibited representation)).

5.26 The benefit of applying risk ratings that identify the seriousness of different types of breaches are that they can provide:

[289] ANAO Better Practice Guide, *Administering Regulation*, March 2007, p. 63.

(a) an insight for the TGA to determine how quickly to respond to non-compliant behaviour; and

(b) a justification and basis for determining what sanctions should be applied in response to the non-compliant behaviour.

5.27 The TGA's risk management policy broadly identifies that post-market activities may include a 're-evaluation' of the risks posed by a particular product, which may include the advertising of the product.[290] However, the TGA is not applying a systematic risk-based approach (such as risk ratings) to identify and address advertising breaches.

5.28 The TGA also does not analyse instances of non-compliance to identify repeat offenders, except through staff experience and recollection. Nor does it gather data on the size and scale of breaches. For example, the scope of TGA investigations is often limited to the breaches identified by complainants.

5.29 The TGA has not documented its current approach to its compliance program. A documented approach would allow the TGA to clearly define: the types of activities that will take place to identify and address non-compliant behaviour; the designated staff that will undertake compliance activities and how frequently these activities will occur; and how the activities will be reported to senior management and stakeholders.[291]

5.30 For the reasons outlined above, the ANAO suggests the TGA apply risk ratings to the different types of advertising breaches that it identifies. This analysis could also be used to improve case management practices, such as the prioritisation of investigations (further discussed at paragraphs 5.66 – 5.71 below). The information collected could also be used to improve the detail provided in performance reports.

The TGA's use of a graduated response to non-compliance

5.31 Many government agencies use a graduated response, incorporating elements of the Ayres and Braithwaite enforcement pyramid, to address non-compliant behaviour (Figure 5.1). A graduated response to non-compliant behaviour can be tailored to the seriousness of the risks of the non-compliance.

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[290] TGA, *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods*, May 2011, p. 31, available from <www.tga.gov.au/pdf/basics-regulation-risk-management.pdf> [accessed 8 August 2011].

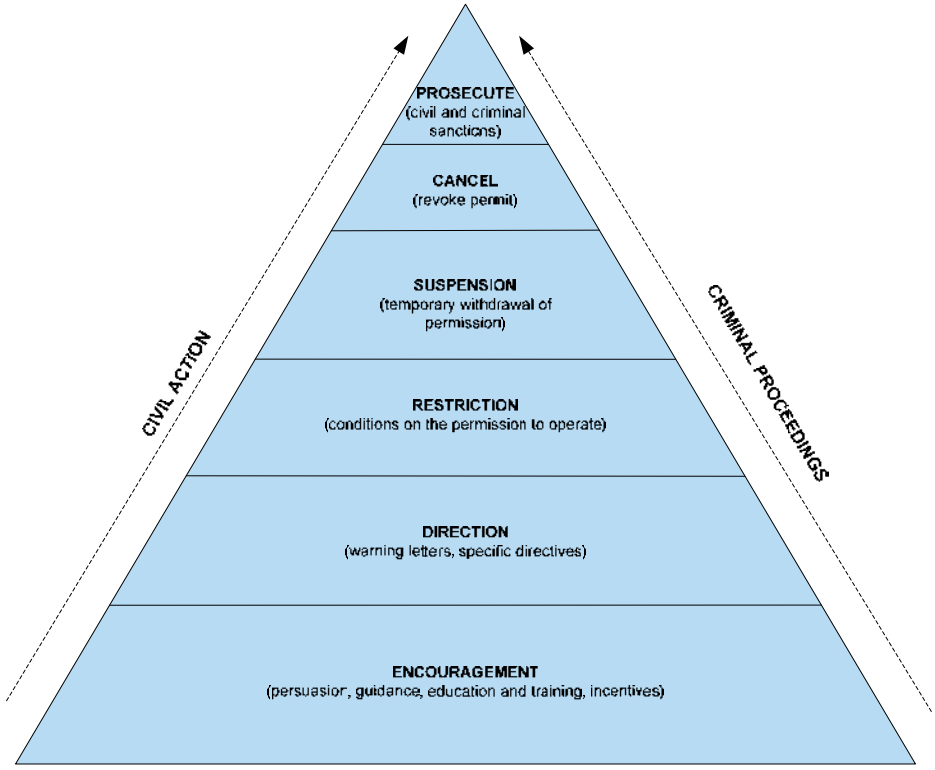
[291] ANAO Better Practice Guide, *Administering Regulation:*, March 2007, p. 52.

It helps stakeholders understand the seriousness with which an agency views breaches against the regulations it administers.[292]

5.32 A graduated response allows a regulator, such as the TGA, to escalate its response to non-compliance based on whether companies have responded to the TGA's directives or not. This is also an efficient and effective control because the threat of escalation may be sufficient to induce compliance at a lower cost than if more punitive sanctions (such as court action) are employed.

Figure 5.1

A graduated response to non-compliance



Source: ANAO, Based on the enforcement pyramid in Ian Ayres and John Braithwaite, *Responsive Regulation: transcending the Deregulation Debate*, Oxford University Press, 1992, p.35.

5.33 The TGA's current approach to non-compliance is graduated and employs a variety of mechanisms. They include, in ascending order:

[292] ANAO Better Practice Guide, *Administering Regulation:*, March 2007, p. 64.

- providing educational opportunities for stakeholders involved in the advertising of therapeutic goods;
- issuing warning letters to non-compliant advertisers;
- issuing Regulation 9 Orders seeking adherence to the regulations;
- cancelling the product from the ARTG; and
- threatening to refer matters of non-compliance to the Commonwealth Director of Public Prosecutions for consideration of prosecution action.

5.34 The effectiveness of a graduated response may be limited by the sanctions available towards the top of the compliance pyramid.[293] This is evident in the TGA's use of warning letters to non-compliant advertisers that their conduct breaches regulations. Mostly, the TGA uses either 'soft' or 'heavy' warning letters before issuing Regulation 9 Orders.

5.35 In a selection of cases examined by the ANAO, where multiple warning letters were issued, an average of over 183 calendar days (approximately six months) passed before the advertisers' non-compliance was voluntarily rectified (Table 5.4). This does not include the time the non-compliant advertising had been operating before the TGA commenced action. An analysis of the TGA's complaint investigations shows that, in some cases, over a period of many months, non-compliant advertising continued to breach regulations.

Table 5.4

Non-compliance times involving the use of multiple warning letters

Case and number of warning letters issued	Start date	Finish date	Total calendar days of identified non-compliance
Case 1 (3 warning letters)	15/11/2007	9/5/2008	174
Case 2 (3 warning letters)	22/2/2008	6/6/2008	104
Case 3 (2 warning letters)	30/1/2007	2/4/2008	422
Case 4 (2 warning letters)	22/5/2009	12/1/2010	230
Case 5 (2 warning letters)	18/5/2009	6/8/2009	78
Case 6 (2 warning letters)	24/10/2008	22/1/2009	88
Mean calendar days of identified non-compliance:			**183**

Source: ANAO analysis.

[293] TGA, *Options for the Future Regulation of the Advertising of Therapeutic Goods*, 23 Feb. 2009, p. 3.

Addressing non-compliant behaviour using proactive and reactive approaches

5.36 Balancing when it is appropriate to pursue non-compliant behaviour either proactively or reactively allows an agency to move between a flexible and targeted response.[294]

5.37 A reactive approach is flexible because it allows for an agency to react to a sudden change or awareness of non-compliance. Monitoring and addressing non-compliance through complaints is essentially a reactive activity. A proactive approach entails the systematic monitoring of compliance targeted towards the highest regulatory risks. It can involve the active surveying of advertising within the therapeutic goods market.

5.38 The TGA's current approach to monitoring non-compliant behaviour is wholly reactive. It has said that 'consumers must complain in order to get action, this is a reactive, rather than [a] proactive, approach'.[295] This means that consumers may be subject to non-compliant advertising until someone complains and the TGA acts. The TGA recognises its current approach can be improved by proactively monitoring compliance.[296]

5.39 During the audit the ANAO tested a 'proactive' approach to identify non-compliant advertising. The Internet was searched for therapeutic goods advertising using the term 'TGA approved' and 'safe' (both of which are not permitted by the regulations). The search identified many thousands of instances which included these claims and three egregious examples were provided to the TGA. The TGA identified other breaches in these examples (such as the use of the prohibited term 'cancer').[297]

5.40 In response to the ANAO's advice, the TGA stated that it planned to send warning letters to the advertisers of the products. As at 20 June 2011, two of the breaches were not rectified on the websites identified by the ANAO.

5.41 There would be benefit in the TGA developing a more active, but targeted, approach to monitoring compliance, to be considered in the context of the proposal for the list of sponsors discussed earlier (see paras 4.40 – 4.41).

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294 ANAO, *Administering Regulation: ANAO Better Practice Guide*, March 2007, p. 56.

295 TGA, *Options for the Future Regulation of the Advertising of Therapeutic Goods*, February 2009, p. 44.

296 TGA, *Notes from OPR Planning Meeting 15 November 2010–Advertising*, November 2010, p. 2.

297 TGA advice to the ANAO, 29 October 2010.

A targeted, risk-based approach would help provide the TGA with greater assurance while limiting resource requirements.

Using performance information to measure non-compliant behaviour

5.42 The Advertising Unit currently produces ad hoc performance reports using a stand-alone database. This can produce limited material, including:

- the numbers and product types relating to complaints received during a given timeframe;
- the numbers and product types relating to complaints referred internally within the TGA for follow-up action or to other agencies; and
- the numbers of items of advice that the TGA Advertising Unit have provided in response to external requests for information.

5.43 While the information in the database is useful, it is not aligned with better practice principles. For example, it provides only brief details of the actions taken by the TGA, which can be identified only by examining each entry.[298] The database cannot produce information on the numbers and types of different regulatory breaches that were affirmed, time taken to resolve complaints, and the volume of complaints against specific companies.[299]

5.44 Because the TGA produces limited performance information, it is unable to analyse the advertising breaches it identifies. It may benefit from using such information to assess whether the regulatory mechanisms to control advertising compliance require strengthening and to target repeat offenders.

5.45 The TGA provides no periodic performance reports to its executive on its monitoring of advertising compliance. No reports were provided during 2008–09 and 2009–10.[300] Such reports would help the TGA to understand the volume and range of breaches, and trends in non-compliance.[301]

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[298] TGA advice to the ANAO, 13 January 2011.

[299] In August 2010, the TGA introduced a 'correspondence sheet' that can be scrutinised to assess the volume and types of breaches of individual companies. However, this information is yet to be formally incorporated into performance reports. (TGA advice to the ANAO, 13 January 2011 and 18 May 2011.)

[300] TGA advice to the ANAO, 13 January 2011 and 18 May 2011.

[301] The TGA is currently reviewing its performance reporting arrangements across the TGA, this also includes reporting on advertising matters. TGA advice to the ANAO, 17 May 2011.

5.46 The average time taken to issue Regulation 9 Orders, from when the TGA receives a CRP recommendation, is eight-and-a-half weeks.[302] This does not mean matters will then be resolved. It may take another three weeks before the TGA contacts companies who do not respond to the orders (allowing for natural justice).[303] If this is not successful, the TGA may consider cancelling the relevant product. However, no cancellations of any products preceding the issuing of a Regulation 9 Order took place during 2008–09 or 2009–10.[304]

5.47 The TGA does not measure the proportion of cases where it decides not to act on CRP recommendations. The TGA estimates that it does not act in about half the cases for complementary medicines, for a range of reasons:[305]

- the advertiser has complied with the sanctions requested by the CRP, but did not advise the CRP of this in writing;
- a company refuses to publish or broadcast a retraction in print media, on the television or the radio, but the advertisement may have been broadcast some time ago and a retraction would not achieve the remedial action sought;
- the sponsor may have cancelled the product from the ARTG and stopped all advertising but not advised the CRP; and
- the advertiser may have provided additional evidence to the TGA that they did not make available to the CRP to substantiate their claims.[306]

5.48 The TGA's Advertising Unit is not aware of having successfully used the full range of sanctions, such as seeking a prosecution for breaches:[307]

> Due to the very low financial penalties currently available (a maximum of $6600 for individuals and $33 000 for corporations) for advertising offences in the Act and other investigative priorities for the TGA, it is not cost-effective for

[302] TGA, *Responses re Publication of Reg 9 Orders sc 0910*, p. 1. The average is based on the length of time between the date of a CRP Recommendation to the Secretary and the date the Regulation 9(1) Order was signed by the Delegate. The average is based on 36 Regulation 9(1) Orders identified by the TGA, consecutively, before September 2010. (TGA advice to the ANAO, 17 May 2011.)

[303] TGA, *Responses re Publication of Reg 9 Orders sc 0910*, p. 1.

[304] TGA advice to the ANAO, 17 May 2011.

[305] TGA, *Responses re Publication of Reg 9 Orders sc 0910*, p. 1.

[306] TGA advice to the ANAO, 17 May 2011.

[307] TGA advice to the ANAO, 13 January 2011.

> the TGA to initiate a formal investigation of an advertising breach with a view to preparing a brief of evidence for consideration of prosecution by the Director of Prosecutions …
>
> It has never been cost-effective for the TGA to initiate a formal investigation of an advertising breach with a view to preparing a brief of evidence. [308]

5.49 The size of penalties attached to criminal offences may also mean that it is seen as not in the public interest to proceed.[309] This view is consistent with legal advice provided to the Advertising Unit about specific breaches.[310]

5.50 The TGA has also observed that 'prosecution is currently the only available option where administrative requests fail to achieve compliance'.[311] There have never been any cases that have been referred for prosecution action and accepted. As a consequence, the prospect of using prosecution action against non-compliant behaviour, and as a deterrent, seems limited.

Educational opportunities for advertisers

5.51 Education forms an early and cost-effective way to instruct and ensure that stakeholders understand how best to meet their regulatory obligations. Educational opportunities for stakeholders can take different forms, including formal guidance documents, training seminars and courses, fact sheets and information provided on websites.

5.52 Currently, the TGA provides education to advertisers on the requirements of the advertising regulations. It does this through public seminars,[312] information published on websites (TGA, CRP, and the TGACC) and by providing guidelines and fact sheets.[313] However, because there are

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308 TGA, *Senate Estimates Brief: Advertising–Current Process and Source of Criticism*, October 2010, p. 2.

309 TGA advice to the ANAO, 13 January 2011. Before the CDPP may decide to initiate prosecution action for an advertising breach it must consider the allegations against the public interest criteria set out in the *Prosecution Policy of the Commonwealth*.

310 TGA, *Legal advice: Advertisements for Therapeutic Goods*, October 2010, p. 1.

311 TGA, *Senate Estimates Brief: Advertising–Current Process and Source of Criticism*, October 2010, p. 2.

312 The TGA presents advertising seminars a number of times each year in several capital cities. It encourages company representatives involved in advertising therapeutic goods to attend.

313 Examples available on the TGA's website include: *Guidelines for Brand Advertising of Substances Included in Schedule 3 of the Poisons Standard* (November 2000); *Guidelines for Levels and Kinds of Evidence to Support Indications and Claims* (October 2001); and *Advertising and Supply of Therapeutic Goods to Healthcare Professionals: Schedule 1 to the Therapeutic Goods Regulations* (June 2010).

diverse guidelines across three organisations (without one clear and targeted guide to advertising requirements overall) there is some risk of confusion.

5.53 Many stakeholders are also critical of the TGA's approach in this area, and have stated that a preferred option would be to rationalise the information sources on advertising. This could involve, for example, combining all CRP, TGACC and TGA advertising material into a single Internet site.[314]

5.54 There are other barriers for stakeholders trying to access educational material. For example, from November 2010 until August 2011, the TGACC website, under the heading 'Guide to the Advertising of Non-prescription Medicines to Consumers' stated that 'This page is currently offline until further notice'.[315]

5.55 Educational materials can include the use of guidelines for stakeholders to understand their obligations under the regulations. In recent years the TGA and the CRP have identified many breaches of the advertising regulations relating to weight-loss products. Since 2007, the TGA has worked on the development of *Guidelines for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss*.[316,317] Because industry has long been aware that the TGA has agreed to develop special guidelines for weight loss products, there has been an opportunity for sponsors to defend their actions in advertisements by pointing to a lack of these guidelines. This is illustrated by one significant case, involving breaches of the advertising regulations over four years. Table 5.5 below summarises the key developments in that case.

[314] TGA, *Summary of Issues Raised in Public Submissions on the Consultation paper on Therapeutic Goods* Advertising, September 2010, p.23; p. 2.

[315] See <www.tgacc.com.au/glossaryList.cfm> [accessed 8 August 2011].

[316] TGA, *Minute: Evidence Guidelines for Listed Medicines Indicated for Weight Loss*, October 2010, p. 1.

[317] The TGA's development of the guidelines is further discussed in Chapter 2. Chapter 3 considers the process of listing products on the ARTG.

Table 5.5

Case study of a 'weight loss' product

Chronology of events 2007 to 2011
• Between 2007 and 2008, the CRP received four complaints about a sponsor's weight loss product. • The CRP found the advertising claims were incorrect, lacked balance, were unverified, aroused unwarranted expectations of product effectiveness and misled consumers. • Sanctions imposed by the CRP included: the withdrawal of the advertisement and representations; and not using inappropriate representations until the sponsor satisfied the CRP that it would not result in a contravention of the Therapeutic Goods Act, the Therapeutic Goods Regulations or the Advertising Code. • In February 2008, following the adverse determinations, the sponsor initiated a Ministerial review (the appeal of an initial decision under Regulation 48). This resulted in the TGA upholding the CRP's determinations. • In September 2008, the CRP referred the determination of the fourth complaint with adverse findings to the TGA, recommending that regulatory action be initiated, because of a failure by the sponsor to comply with the determination. • The TGA agreed to accept additional evidence from the sponsor. • In early 2009, the further data was reviewed and deemed not sufficient to affect the TGA's and CRP's findings. • In February 2010, the TGA wrote to the sponsor stating that its failure to comply with the CRP's findings and the TGA's reviews will not be pursued in light of the lack of the TGA finalising its weight loss guidelines. • In March 2010, the sponsor wrote to the TGA stating that it would cease using promotional claims that have been determined to be in breach of the Advertising Code, and that the supply of its weight loss product will be discontinued after its remaining stock runs out. • In October 2010 the TGA, at a meeting with the sponsor, agreed to consider additional statistical data about the product. • The sponsor also stated that it believed that the lack of published regulatory guidance on listing weight loss products was the key factor in the misalignment between sponsors and regulators. • At June 2011, the *Guidelines for Levels and Kinds of Evidence for Listed Medicines with Indications and Claims for Weight Loss* remained in draft form and were not finalised.

Source: ANAO analysis of a TGA complaint investigation company file.

5.56 This case prompted a senior TGA officer to observe that the outcome was driven by the company's marketing approach, rather than by effective and efficient regulation by the TGA.[318]

The effectiveness of the TGA's advertising complaints handling system

5.57 The ANAO assessed the TGA's advertising complaints handling system by considering the extent to which it is managed in line with better practice.[319] This focused on the processes supporting the life cycle of complaints handling: accessibility of the complaints system; acknowledgment of complaints, assessment and prioritisation, planning investigations, transparency, responsiveness and timeliness.

5.58 The ANAO reviewed a sample of 20 completed TGA investigations into advertising complaints by examining 'company files' randomly selected from 214 files created in 2008 and 2009. It also assessed five company files nominated by the TGA as having attracted the largest volume of complaints.

The general conduct of TGA complaint investigations

Accessibility

5.59 For a complaints system to be functional, it should be easily accessible. Otherwise, complainants may be unclear where to direct their complaint, and may 'forum-hop', leading to multiple agencies having to manage a single complaint.

5.60 The methods for complainants to submit their allegations include:

- accessing the TGA's website—which lists four postal mailing addresses for the organisations that handle different complaints;
- using a general TGA email address (or contacting the TGA by phone or fax);
- using an online complaint submission form, accessed through the CRP's website (known as the 'Central Complaints Mail Box'); and

[318] TGA, Internal email correspondence, 13 April 2010.

[319] The ANAO's analysis was informed by the Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, and ANAO Better Practice Guide, *Administering Regulation*, March 2007, p. 32.

- posting mail to the CRP directly.

5.61 While there may be satisfactory coverage of the means by which complainants can submit complaints, a problem remains that 'multiple entry points for the lodgement of complaints is confusing for consumers'.[320]

5.62 A more efficient approach would be (in the case of the TGA website) to have access to complaints information from its home page, rather than consumers having to navigate several levels of menus.[321] TGA stakeholders have also suggested that all advertising information, including on how to make complaints, could also be rationalised into a single Internet site.[322]

Acknowledging complaints

5.63 Acknowledging complaints quickly reassures complainants that their complaint is receiving attention. It also helps to manage a complainant's expectations by outlining the complaint investigation process and by advising how long it takes to finalise.[323]

5.64 Analysis of completed complaint investigations showed that the time taken by the TGA to acknowledge complaints varies:[324]

- one calendar day was the fastest acknowledgement, whereas 58 calendar days was the longest; and
- the average acknowledgement time was 12 days.

5.65 Reasons for the disparity among response times were not apparent from examining the company files.[325] Some files (three cases) also did not contain evidence of whether complainants had been acknowledged by the TGA, while in another six cases the CRP received the initial complaint.[326]

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[320] TGA, *Options for the Future Regulation of the Advertising of Therapeutic Goods*, 23 February 2009, p. 44.

[321] Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 12.

[322] TGA, *Summary of Issues Raised in Public Submissions on the Consultation Paper on Therapeutic Goods* Advertising, September 2010, p. 2.

[323] Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 21.

[324] This was based on an examination of 12 complaints received by the TGA.

[325] The different response times may reflect changing work practices with time. The TGA's Advertising Unit currently aims to acknowledge complaints within two working days. (TGA advice, 20 May 2011.)

[326] One complaint examined was also received anonymously.

Assessment and prioritisation

5.66 Assessing the priority of each complaint can promote effective complaint handling. This is because, before an investigation takes place, an agency can determine the resources it will need to handle the complaint, and the potential risks posed by the alleged breaches. Under a risk-based approach, an agency may choose to pursue matters of substance over minor technical breaches and therefore direct resources to the more serious breaches.

5.67 The TGA does not assess or prioritise its complaint investigations. Current practice is to process cases by the date of receipt. However, the TGA has prioritised cases where there is strong media or stakeholder interest.[327] Special handling of complaints that may draw media attention is in line with the better practice principle that a sensitive matter may call for such handling. However, there are other bases for allocating priority. A complaint unit has an obligation to deal efficiently with all complaints and excessive attention to high-profile cases has equity implications.[328]

5.68 One prominent stakeholder has also stated that advertising complaint investigations should be prioritised on the basis of substantive breaches of the Advertising Code rather than minor technical issues such as the incorrect positioning of an advertising approval number on a label.[329]

5.69 'Triaging' of complaints is another way to improve the efficiency of complaint handling. This approach has the potential to benefit an agency such as the TGA that receives many similar complaints about regulatory breaches or complaints about products across a variety of different media.

5.70 An example of where the TGA has successfully 'triaged' multiple breaches of the advertising regulations, is in the advertising of medical services using substances listed in Schedule 4 of the *Standard for the Uniform Scheduling of Medicines and Poisons*.[330] These products include injectable dermal fillers such

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[327] ANAO analysis identified one example where a series of emails indicate that the processing of a complaint was re-prioritised, relating to a CRP determination.

[328] Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 22.

[329] CHC, *CHC Submission–Advertising Therapeutic Goods in Australia: Consultation Paper*, p. 2. <www.tga.gov.au/pdf/submissions/consult-advertising-arrangements-101028-submission-chc.pdf> [accessed 8 August 2011.

[330] The advertising to consumers of Schedule 3, 4 or 8 products is unlawful as it constitutes an offence under s.42DL(1)(f) of the *Therapeutic Goods Act 1989* (apart from the limited exceptions relating to some Schedule 3 products, which are not applicable to this situation). See: <www.tga.gov.au/industry/advertising-schedule4-substances.htm> [accessed 8 August 2011].

as Botox and collagen.[331] This was achieved by the TGA consulting with Internet search engine companies about content on their websites and seeking the removal of identified breaches.[332]

5.71 While there are some examples of the TGA using prioritisation and 'triaging' techniques to manage its case load, it may benefit the TGA to consider options for further assessing, prioritising and, where practicable, triaging its complaint investigation case work.

Planning

5.72 Planning an investigation into a complaint before it begins is important for non-routine cases. A plan can help to focus the attention of an investigator so that the scope of a complaint is fully understood. It can also allow supervisors and others to review the path of the investigation, and suggest changes where necessary.[333]

5.73 Currently, the TGA does not prepare investigation plans. An analysis of completed complaint investigations found that more complex cases take longer to finalise (which is to be expected). This is particularly relevant when the TGA takes action against non-compliant companies.

5.74 In cases that span long periods, or that are complex, a plan may help to provide a structure to those conducting the investigation. A plan can also assist to determine the best way forward, to conclude the case. They can also help to manage cases during staff turnover, particularly if a handover of the case is required.

Internal coordination

5.75 Effective planning can benefit from integrating the management of complaints across an agency as-a-whole.[334] Within the TGA's operations, this relates to how it deals with complaints that are not related to advertising but are related to other breaches of the therapeutic goods regulations.

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331 TGA, *Advertising Medical Services that Include Schedule 4 Substances*, 8 September 2008, p. 1, available from <www.tga.gov.au/industry/advertising-schedule4-substances.htm> [accessed 8 August 2011].

332 TGA, *Legal advice: Advertisements for Therapeutic Goods*, October 2010, p. 2; TGA advice, 13 January 2011.

333 Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 23.

334 Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 15.

5.76 An analysis of the Advertising Unit's management of complaint investigations shows that many cases are referred by it, for follow-up action, to other areas of the TGA, including the OCM and the Regulatory Compliance Unit (RCU).

5.77 An analysis of a selected sample of referrals to the RCU from the Advertising Unit (five referrals) showed that the RCU can provide summary information about the outcome of the action they took.[335] This analysis shows that, in some instances, the complaints referral process has positively influenced improvements in the regulation of complementary medicines. Several referrals from the Advertising Unit to the OCM led to the post-market monitoring and review of complementary medicines with inappropriate claims that the medicines could control blood glucose levels.[336]

5.78 A factor that has made it difficult for the TGA to track the referral of complaints to different sections internally is the way in which they have been tracked and recorded. An example of a referral of a complaint investigation to the OCM highlights the need for good recordkeeping and tracking:

> A recorded outcome of this matter could not be identified within electronic files … The addressee of the Minute is no longer employed by the TGA but was contacted and recalls that it may have been referred to another officer who was then within the Section [the OCM] but has also since left the TGA … It is probable that, as the medicines were not included on the ARTG, and because the Regulatory Compliance Unit were aware of the issue, no further action was taken by the OCM.[337]

5.79 The OCM informed the ANAO that limitations in the OCM's ability to track referrals from the Advertising Unit have been reduced through the introduction, in 2009, of an electronic tracking system. In comparison to the OCM, the RCU has, since January 1996, used an electronic tracking system.[338]

Transparency

5.80 Conducting complaint handling investigations transparently allows each complainant to understand whether their concerns have been resolved, for example, by informing complainants of the outcome of an investigation.

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335 TGA advice to the ANAO, 1 December 2010.

336 TGA advice to the ANAO, 10 December 2010.

337 TGA advice to the ANAO, 10 December 2010.

338 TGA advice to the ANAO, 17 May 2011.

5.81 The TGA's current practice is not to notify complainants of the outcome of its investigations. The TGA's current policy states that:

> The Advertising Unit does not advise complainants of the outcome where advertising complaints are lodged directly with the TGA. Where the complainant formally asks to be advised the generic response is that the information cannot be provided as it is considered to be 'commercial-in-confidence'.[339]

5.82 It was apparent during the audit that this practice continues.[340]

5.83 TGA internal legal advice has cautioned against deciding not to disclose information for 'commercial-in-confidence' reasons:

> It is not accurate to say that there are privacy and confidentiality provisions that apply to *all requests for information* regarding regulatory investigations. It depends on the particular investigation.
>
> Where the TGA has conducted its own investigation [or launched an investigation as a result of CRP recommendations] it can release under s. 61(5A) [of the Therapeutic Goods Act] the outcome of the investigation and the resulting regulatory action. An outcome where no regulatory action is taken could also be released under s61(5A), subject to the requirements of the Privacy Act'.[341]

5.84 There is a contrast between the TGA's current practice of not disclosing investigation outcomes and that of the CRP. The CRP publishes on its website the outcomes of all its determinations. This provides complainants with an opportunity to access information about CRP findings, the advertising regulations found to have been breached, and CRP determinations. The TGA could improve its openness if it were to adopt practices similar to those of the CRP.

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339 TGA, *TRIM Document: R10/267667 Re: No formal advice of outcome from advertising complaints lodged with TGA*, 8 September 2010, p. 1.

340 One response provided by the TGA to a complainant states that 'any further action taken by the TGA in regard to this matter will be considered commercial-in-confidence. Therefore, we are unable to advise you any further in relation to the investigation or any outcomes'. Another complaint investigation identifies that a complainant received little feedback about the progress of a TGA's investigation four months after the initial complaint had been made.

341 TGA, *Minute in relation to points made by Dr Ken Harvey*, 1 April 2010, p. 1.

5.85 A similar concern is the lack of transparency about the outcome of recommendations from the CRP to the TGA.[342] In response to these and other criticisms, the TGA has changed some of its practices.[343] On 5 November 2010 it stated publicly its intention to publish Regulation 9 Orders 'issued by the TGA for determinations finalised by the Panel [the CRP] after 1 November 2010'.[344]

5.86 The TGA does not currently have a communications strategy in place for complaints handling[345] (or a communications strategy across the TGA more generally)[346] but further measures were expected to be put in place to improve the openness of the TGA.[347]

Responsiveness and timeliness

5.87 The timely resolution of alleged breaches of the regulations can help to uphold the integrity of the Government's regulatory approach to the advertising of therapeutic goods. Managing complaints in a timely and responsive way is also an important principle of an efficient and effective complaints handling system.[348] The timeliness of resolving complaint investigations is indicative of whether the TGA is efficiently managing the volume of complaints it receives.

5.88 Conversely, delays in resolving complaints can also be indicative of the limits imposed by the regulations. This was evident in the assessment that the sanctions available to the TGA under the advertising regulations may be deficient.[349] (This issue is discussed further in paras. 5.48 to 5.50, above.)

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342 TGA, *Summary of Issues Raised in Public Submissions on the Consultation paper on Therapeutic Goods* Advertising, September 2010, p. 23.

343 TGA, *Senate Estimates Brief: Advertising–Current Process and Source of Criticism*, October 2010, p. 1.

344 TGA, *Advertising Complaint Investigations*, 5 November 2010, p.1, available from <www.tga.gov.au/industry/advertising-complaint-investigations.htm> [accessed 8 August 2011]. Two Regulation 9 decisions, both dated 3 August 2011, had been published on the TGA website as of 8 August 2011 (see <www.tga.gov.au/industry/advertising-reg9.htm> [accessed 8 August 2011].

345 TGA, *Summary of Issues Raised in Public Submissions on the Consultation paper on Therapeutic Goods* Advertising, September 2010, p. 23.

346 TGA, *Minute: A Proactive Communications Strategy for the TGA*, December 2010.

347 TGA, *Advertising Complaint Investigations*, 5 November 2010, p. 1, available from <www.tga.gov.au/industry/advertising-complaint-investigations.htm> [accessed 8 August 2011].

348 Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, pp. 13–14.

349 A TGA Senate Estimates Brief states that 'the Government is aware that the current legislation is deficient in terms of an effective range of sanctions to deal with advertising (and other regulatory) breach legislation.' *TGA Senate Estimates Brief: Advertising Current Sources of Criticism*, October 2010, p. 1.

5.89 Timeliness—at each stage of the process and overall—is relatively easy to measure.[350] However, no timeliness standards have been set for advertising complaint investigations.

5.90 CRP statistics show that it takes a long time to complete complaint investigations and resolve complaints. In 2010, the average time taken from complaint receipt to a determination of the CRP was 149 calendar days (about 5 months). In earlier years for which data is available the average over the year has ranged from 113 to 153 calendar days (for 2009 and 2008 respectively).

5.91 During 2009–10 the TGA received a total of 228 complaints, a decrease of 12 per cent compared to 2008–09.[351] Unlike the CRP, the TGA does not measure the time it takes to complete investigations. The ANAO analysed examples of investigations conducted during 2008 to 2010. Lengthy timeframes for resolving advertising complaint investigations were evident:

- four investigations took over a year to finalise;
- the most lengthy investigation identified by the ANAO took 571 calendar days (about 1.5 years), while the shortest took 12 days;[352] and
- the average time taken to complete 22 complaint investigations was 182 calendar days (6 months).[353, 354]

5.92 The TGA has no timeliness standards for managing and completing advertising complaint investigations. The lack of these standards, coupled with the lack of performance information, means that the TGA cannot properly gauge its performance. The development of timeliness standards would enable the TGA to measure its performance. Such information could also be employed to establish benchmarks for improvement.

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350 Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, p. 28.

351 TGA, *Advertising Matters by Category, Product Type and Referral: 2009–10* and *2008–09* November 2010, p. 1.

352 ANAO analysis of TGA complaint investigation company files.

353 ANAO analysis. The average was determined using complaint investigations sourced from 22 of the 25 company files reviewed by the ANAO. Three of the 25 files were excluded because the complaint investigations were referred by the TGA's Advertising Unit to the TGA's Regulatory Compliance Unit.

354 The TGA states that timeframes for the completion of investigations can vary for a number of reasons. For example: advice from clinical, laboratory, medical device or legal sections within the TGA may need to be sought before an investigation can be finalised; the level of cooperation from advertisers may vary; and staffing levels within the TGA's advertising unit may change. The route of a complaint (if it was referred from another agency or the CRP), may also dramatically influence the processing time for a complaint. (TGA advice to the ANAO, 20 May 2011.)

5.93 The TGA also does not have a standard operating procedure to guide staff on either the conduct of TGA advertising complaint investigations, or on managing referrals of recommendations from the CRP to the Secretary.[355,356] Without formalised guidance there is a risk that investigation processes may not be undertaken consistently.[357] This risk is heightened by the fact that the Advertising Unit is small and staff turnover could lead to a loss of expertise.

5.94 The TGA would benefit from developing a standard operating procedure incorporating timeliness standards to guide staff on appropriate timeframes for completing complaint investigations. As discussed earlier (para. 5.45), regular performance reports to the TGA executive could provide information on progress with investigations, and trends in non-compliance.

Recommendation No.5

5.95 The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches. In developing the procedure the TGA should incorporate:

(a) appropriate timeframes for completing the investigations; and

(b) the provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.

Agency response

5.96 DoHA agreed to the recommendation.

[355] TGA, *Responses re Publication of Reg 9 Orders sc 0910*, p.2.

[356] The TGA states that although there are no SOPs, the Advertising Unit has a series of template letters that cover most scenarios for complaint investigations. TGA, Advice to the ANAO, 13 January 2011.

[357] Commonwealth Ombudsman, *Better Practice Guide to Complaint Handling*, April 2009, pp. 14–15.

6. Providing Evidence of Efficacy

This chapter examines moves to strengthen the requirements for providing evidence of the efficacy of complementary medicines since the Expert Committee's report in 2003.

The relationship between claims and efficacy

6.1 The question of evidence of efficacy has been an enduring and challenging theme in the regulation of complementary medicines both in Australia and overseas.[358] Consumers and health professionals may reasonably ask whether a medicine works—whether it delivers the benefits promised in the claims made about it by its sponsor and what evidence exists to show that these claims are true.

6.2 Claims about a complementary medicine are also strongly related to its market success. The TGA explained in December 2000 the essential link between the therapeutic claims made about a medicine, its subsequent success as marketed product and the product being accepted by the TGA:

> The therapeutic promise the company is making carries with it, if you like, a government endorsement that that has been verified and, I think in terms of marketing, I think that is a significant benefit that is bestowed on the industry and certainly in the area of exports a number of companies have said to me the very best advertising they can have for their product for overseas markets, particularly in the region, is the fact that the Therapeutic Goods Administration has approved it, and it carries with it one of the highest quality regulator stamps in the world.[359]

6.3 The TGA went on to say that 'Industry could just as well position most of these goods as foods and pay no fees in Australia, but industry chooses the

[358] See WHO, *The World Medicines Situation 2011—Traditional Medicines: Global Situation, Issues and Challenges*, Geneva, 2011, p. 7.

[359] Productivity Commission, Inquiry into Cost Recovery, oral evidence given by the then National Manager, TGA, Canberra, 7 December 2000, available from <www.pc.gov.au/__data/assets/pdf_file/0015/37131/canberra001207.pdf> [accessed 13 May 2011].

therapeutic route most of the time because making a therapeutic claim confers such a strong market benefit.'[360]

Development of the requirement to provide evidence

6.4 When it began to regulate complementary medicines, the TGA did not require evidence to support manufacturers' claims for complementary medicines provided the products were not for the treatment of serious illnesses. However, the position changed in 1999 because of 'a concern that multiple and at times improbable claims were being made about products.'[361]

6.5 This did not lead to an expectation that a medicine would be listed only if its efficacy could be demonstrated. A difficulty in requiring a thorough evaluation (including clinical trials) before listing, is that many listed ingredients are traditional and there is little scope for them to be patented. This opens opportunities for competitors and thereby limits the scope for the sponsor to obtain benefit from marketing their product. In turn, this limits any incentive to invest in obtaining the evidence of efficacy.

6.6 The WHO recognises that the methods of research and evaluation of the efficacy of herbal medicines (encompassing many complementary medicines) are more complex than for conventional pharmaceuticals. This is because:

> A single medicinal plant may contain hundreds of natural constituents, and a mixed herbal medicinal product may contain several times that number. If every active ingredient were to be isolated from every herb, the time and resources required would be tremendous. Such an analysis may actually be impossible in practice, particularly in the case of mixed herbal medicines.[362]

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[360] TGA, *Submission to Productivity Commission Review of Cost Recovery By Commonwealth Agencies,* 4 December 2000, p. 26, available from <www.pc.gov.au/__data/assets/pdf_file/0004/39226/sub089.pdf> [accessed 13 May 2011]. The then National Manager explained in his oral evidence to the Inquiry (op. cit, p. 787): 'A lot of these products are able to be sold as foods, and hence if they wish to market them as foods they're able to do that at no regulatory cost. If they choose to market them as medicines because they want to make a therapeutic promise about the product, the TGA enables them to do that and for that we, I think, have a set of fees and charges which are remarkably low.'

[361] John McEwen (Principal Medical Adviser, Therapeutic Goods Administration), 'What does TGA approval of medicines mean?', *Australian Prescriber*, 2004, vol. 27, pp. 156–8.

[362] World Health Organization, *National policy on traditional medicine and regulation of herbal medicines*, (Report of a WHO global survey), Geneva, May 2005 p. iii, available from <apps.who.int/medicinedocs/pdf/s7916e/s7916e.pdf> [accessed 5 April 2011].

6.7 The concerns held in 1999 led to the introduction, in April of that year, of a requirement that:

> sponsors of AUST L products must hold evidence to substantiate their claims. This evidence may be called for and evaluated by the TGA, should a concern or complaint arise at any time during the life of a product. If the evidence is inadequate, the TGA may cancel the listing for the product.[363]

6.8 Thus the requirement in the Act became, as it remains now, that the sponsor must, at the time of listing, certify that that they hold the evidence to support indications and claims made in relation to the listable product. The indications or claims are not subject to pre-market evaluation at the time of listing. However, the evidence held by sponsors must be sufficient to substantiate that the indications and claims are true, valid and not misleading.

6.9 In 2000, the TGA, comparing the Canadian experience with that in Australia, put the view that the Australian approach was a 'logical and effective' system:

> allowing these products to make limited therapeutic claims from the outset, rather than remaining in a fixed position of requiring full evaluation before any claim of a therapeutic nature can be made, which has proved untenable.[364]

The Expert Committee and consumer information needs

6.10 In 2003, the Expert Committee formed the view:

> Consumers should be better informed about the regulatory framework for medicines, the differences in the processes for assessing the efficacy of Listed and Registered complementary medicines, and the levels of evidence for the efficacy of Listed complementary medicines.[365]

6.11 It went on to recommend that DoHA commission a study to determine, among other things, the complementary medicines information and skills needs of healthcare professionals and consumers. The National Prescribing Service (NPS) was funded by DoHA to undertake the study. The NPS research has shown the need to improve the availability of information about complementary medicines and the level of awareness for Australian health

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[363] John McEwen, ibid.

[364] TGA, *Submission to the Productivity Commission Review of Cost Recovery by Commonwealth Agencies* (Submission 89), 4 December 2000, p. 35, loc. cit.

[365] Expert Committee, Report, p. 117.

professionals and consumers. The NPS concluded that strategies to improve decisions by consumers about complementary medicines should focus on enhancing the information resources preferred by consumers, including the Internet.[366]

Changes to evidence requirements proposed by the Expert Committee

6.12 As discussed in Chapter 2, the Expert Committee found that the TGA's *Guidelines for levels and kinds of evidence to support indications and claims* provided a sufficient framework to assess the efficacy of listed complementary medicines. The Expert Committee recommended not only that these guidelines be made mandatory, but it also proposed that 'Sponsors of Listed medicines should submit to the TGA a summary of the evidence they hold to support the efficacy of their products' (Recommendation 5).[367]

6.13 The Committee added:

> The requirement to submit a summary of the evidence on which efficacy of their product is based should also be applied to Listed complementary medicines already on the ARTG and to 'grandfathered' Registered complementary medicines.[368]

6.14 The Expert Committee formed the view that the marketing of products that do not have evidence of efficacy was unethical. Therefore, adherence to the levels of evidence framework provided by the Guidelines to support the efficacy of complementary medicines was important to the credibility and viability of the industry. The Expert Committee's recommendation would assist sponsors to focus on their obligation to hold evidence to support the efficacy of their listed complementary medicines.

6.15 The Expert Committee envisaged that these summaries of evidence would be assessed randomly by the TGA as part of the requirement to include the sponsor's product on the ARTG, as routine assessment (that is, assessing all of them) could prove to be a major task.

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[366] NPS, Review of the Quality of Complementary Medicines Information Resources: Summary Report. National Prescribing Service, Sydney, March 2009, p. 5; NPS, Information Use and Needs of Complementary Medicines Users, December 2008, p. 61; and Tudball J., Williamson M., and Toms M., 'Complementary medicines and consumer information: what do they need, where do they go and what is the point?' National Medicines Symposium, 14–16 May 2008, Canberra.

[367] Expert Committee, Report, 2003, Recommendation 5.

[368] Expert Committee, Report, p. 86.

6.16 In other words, the Expert Committee recognised that the task of assessing the evidence supporting every one of the numerous listed products would be substantial and might not be practicable. However, it also recommended an increase in the random and targeted auditing of listed products, including evidence holdings. This should help to ensure compliance.

6.17 The Australian Government, after consulting widely on the Expert Committee's recommendations, accepted this recommendation and set this out in its formal response in March 2005. The remainder of this chapter seeks to assess the TGA's progress with its implementation of that recommendation.

Implementation of the requirement to supply evidence

6.18 The Government response to the Expert Committee not only accepted the recommendation that evidence summaries be collected by the TGA from sponsors but gave it prominence.[369] The response noted that the TGA had undertaken only a limited number of targeted audits of the information actually held by sponsors: 'In most cases, the TGA has found the information held by the sponsor to be inadequate to support the claims being made.'[370] The Government response stated explicitly that it would require all sponsors to submit a summary of the evidence they hold to the TGA.[371]

6.19 At that time, the proposed joint agency with New Zealand, ANZTPA, was still expected to be implemented soon thereafter and the response to the recommendation noted this:

> Implementation will involve consultation with affected stakeholders in Australia and New Zealand. This requirement would be introduced under arrangements for the trans-Tasman therapeutic products regulatory agency.

Initial reporting on implementation of the Expert Committee's recommendations

6.20 The TGA finalised an implementation plan for the Expert Committee's recommendations in October 2005. It also established the Complementary

[369] The proposed course of action was specifically mentioned in the Parliamentary Secretary's foreword to the response and in the executive summary.

[370] *Australian Government response to the recommendations of the Expert Committee on Complementary Medicines in the Health System*, March 2005, p. 12, available from <www.tga.gov.au/archive/committees-eccmhs-response-050309.htm> [accessed 8 August 2011].

[371] Op. cit. p. 1.

Medicines Implementation Reference Group (CMIRG) to provide advice on and to oversee the implementation of the government response. That group was first convened in July 2005 with members drawn primarily from Australia but with New Zealand representation.

6.21 The TGA subsequently provided two progress reports on implementation in February and October 2006. These are both publicly available on the TGA website.[372]

The first update

6.22 The first update states that an audit of progress had been conducted to gain a clear indication of progress to date. That report provides no specific advice on progress with Recommendation 5, but that recommendation appears to be encompassed by the comment that 'preliminary work for many recommendations has begun' and that full implementation would be dependent on the ANZTPA scheme coming into effect.

The second update

6.23 The second update, eight months later, explicitly states that:

> Sponsors of Listed medicines ... will be required to submit a summary of the evidence supporting the claims made for their products at the time of listing their products once the proposed joint regulatory scheme comes into effect (Recommendation 5).

6.24 In other words, the TGA proposed to implement the requirement through legislation as part of the ANZTPA project. The timeline in the progress report shows that the TGA expected Recommendation 5 to be implemented by late 2007.

Further, unpublished updates

6.25 The TGA prepared two further updates, dated June and December 2007, but these were not made public, possibly because of the change caused by the suspension of the ANZTPA proposal in mid-2007.

6.26 In October 2008, the TGA stated that 'It is expected that a further report will be issued following the next meeting of the [Complementary Medicines Implementation Reference Group (CMIRG)] in November 2008.'[373] That

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[372] See <www.tga.gov.au/archive/committees-eccmhs-progress.htm> [accessed 8 August 2011].

[373] *Therapeutic Goods Administration submission to Professor Dennis Pearce AO*, October 2008, p. 6.

meeting took place on 17 November 2008 but no further report was forthcoming.[374]

6.27 The TGA advised its Parliamentary Secretary in January 2009 that:

> A re-convened CMIRG is likely to focus on issues relating to efficacy of Complementary Medicines including the current lack of scientific evidence of efficacy of many complementary medicines. Addressing this issue in the short term, especially given the resourcing required to do so may not be a priority in the current fiscal environment.[375]

6.28 CMIRG did not meet again.[376]

Current status of the provision of evidence

6.29 In November 2010, DoHA provided a copy of a final report from CMIRG, dated December 2009. This was not prepared by CMIRG but by a consultant. The OCM had arranged for a final 'close-out' report for CMIRG's work to be prepared by the consultant in late 2009.[377] Unlike the Expert Committee report, original government response and two subsequent updates which are available on the TGA website, this final report on progress is labelled as 'intended for internal TGA use only' and has not been made public.[378] The OCM advised that:

> This was an internal document and not a meeting report and so it was not considered appropriate to post it as a CMIRG report at that time. We recognise that this close out report is now dated and are in the process of making it current and clearly identifying that it is an internally generated document.[379]

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374 DoHA email advice of 15 December 2010.

375 DoHA, minute of 21 January 2009.

376 TGA advice, 15 December 2010. Also the minutes, 26th TGA–Industry Consultative Committee (TICC) meeting, 30 March 2010, show that 'ASMI asked whether the Complementary Medicines Implementation Reference Group (CMIRG) had been disbanded. [An OCM officer] confirmed that this had occurred.'

377 The ANAO understands that CMIRG itself has neither seen nor cleared it. The OCM provided a copy to the ANAO.

378 TGA, Office of Complementary Medicines, Internal Report, 'Complementary Medicines Implementation Reference Group: Final Report', December 2009.

379 TGA, OCM advice, 15 December 2010.

6.30 The 'close-out' report shows that Recommendation 5 is 'Completed' and states:

> Recommendation 5 which sought to require sponsors to submit a summary of the evidence held to support the efficacy of their Listed and "Grandfathered" registered products. The Listing form has been changed since the Expert Committee's recommendation so that sponsors are required to state (via a tick box) that they hold evidence to support the efficacy of their product/ingredient at the time of Listing. The evidence supporting "Grandfathered" products is being assessed in line with evaluations of new products or applications for variation. These provisions are in line with the risk-based regulatory system and the Government's commitment to reduce regulatory burden.[380]

6.31 On face value, this appears to represent a change from the government position of requiring the supply of a summary of evidence for both listed and grandfathered registered products, for the following reasons:

- first, to require the sponsor simply to 'tick a box' to state that they hold evidence for a listed product does not satisfy the policy requirement that they provide a summary of that evidence to the TGA; and
- second, considering the evidence for grandfathered registered products only when the sponsor seeks a variation would be a substantial change from the government policy position as stated in 2005, which clearly envisaged that the TGA actively seek a summary of evidence from sponsors for these products.

6.32 When it made its recommendation, the Expert Committee clearly understood that sponsors were already required to certify that they held evidence to support the indications and claims in the ARTG.[381] The fact that, since 2003, sponsors have been required to tick a box to provide this certification does not represent any advance in the direction of requiring them to provide a summary of evidence to the TGA. The 'tick box' was simply a new means for collecting the certification previously required in any case.

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[380] TGA, Office of Complementary Medicines, Internal Report, 'Complementary Medicines Implementation Reference Group: Final Report', December 2009.

[381] 'When a sponsor submits an application to the TGA to include a medicine in the ARTG as a Listed medicine, ... the sponsor also certifies that they hold evidence to support the indications and claims in the ARTG.' Expert Committee, Report, p. 85.

6.33 The TGA subsequently advised:

> The 'tick box' mentioned in the CMIRG report dated December 2009 refers to the Statutory Declaration required by [the Act] which includes the requirement that the applicant must certify, at the time of listing, that the applicant holds information or evidence to support any claim relating to the medicine. This 'tick box' was included in the ELF system when it was first launched in September 2003 and it was not linked to the [Expert Committee's] recommendation.'[382]

6.34 On the question of the current status of the recommendation, the TGA has further advised that:

> It appears that the CMIRG 'close out' report in relation to recommendation 5 is not accurate. This document will be corrected to reflect that this item remains 'uncompleted'.[383]

6.35 Thus, the Australian Government's decision to implement the recommendation remains unactioned since March 2005.

Work underway on efficacy

6.36 When the OCM's advice was sought about what work it had underway to address the problems identified in relation to the efficacy of listed complementary medicines, it provided the list set out in Table 6.1. This list does not include progressing the implementation of this recommendation.

[382] TGA, OCM advice of 16 December 2010.

[383] TGA, OCM advice of 16 December 2010.

Table 6.1

Mechanisms to address problems of efficacy in listed complementary medicines

Items the OCM has been investigating over the last few years
• The Coded Indications project. • The establishment of monographs for complementary medicine substances, similar to those used by Health Canada's Natural Health Products Directorate (NHPD). The OCM has been collaborating with the NHPD over recent years in relation to monographs and precleared information. As part of this [work] with Canada, Australia also co-hosted two working groups in Sydney of the International Regulatory Cooperation for Herbal Medicine (IRCH) in March 2010 on Monographs and Precleared Information, and Evidence to support Safety and Health Claims. In addition to Canada and Australia, this working group included representatives from Singapore, Hong Kong (China), Malaysia, [the] United States of America and Brazil. • New suspension provisions were introduced in September 2009—the OCM is currently working to implement utilisation of suspension provisions. • Facilitating the ability for companies to use the registration pathway rather than Listing where appropriate. • Need to review the *Levels of Evidence Guidelines*, including review of acceptable claims for Listed Medicines. • Update of the *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM)—this is currently underway. • TGA-wide openness and transparency initiative—this includes the TGA Intranet website redevelopment project which will involve review of existing information on the website and more innovative ways of presenting information to stakeholders. • Continued focused training sessions aimed at industry members on regulatory requirements. • Exploring the roles of caveats and disclaimers on labels with regards to claims and evidence recognising the number of products on the market.

Source: TGA, OCM advice of 22 December 2010.

Whether progress with implementation is possible

6.37 After the suspension of the ANZTPA project, the TGA considered in detail how to build on the extensive work that had been done for that project so that reform of the regulatory framework could continue. This included consideration of those recommendations of the Expert Committee which had been agreed by government but which had become dependent on the

ANZTPA implementation. It concluded that 'new solutions may need to be examined in the short to medium term, in order to effect the changes required in the Government Response to the Expert Committee.'[384] The OCM was identified as the branch with primary responsibility.[385]

6.38 The ANAO sought the OCM's advice on whether Recommendation 5 could now be progressed, independently of the suspended ANZTPA proposal (see para. 6.19). The OCM stated that, under the Act, the TGA:

> does not have an ability to require an applicant to submit a summary of evidence, either before or at the time of listing. The TGA does have the ability under the Act to request information and evidence supporting efficacy of listed medicines after the medicines are listed in the ARTG. Evidence review is conducted on a number of selected listed medicines post ARTG listing.[386]

6.39 This advice appears to assume that, if the TGA were to seek a summary of evidence from sponsors, it might be expected to do this *before* the medicine is listed on the ARTG. However, under the Act, it has no capacity to do this before listing, as listing proceeds largely on a self-certification basis, as explained in Chapter 3. Nevertheless, this advice also shows that this may not be a substantial impediment to progressing the Expert Committee's recommendation. This is because the TGA has the power to seek the evidence *after* listing the product on the ARTG.

6.40 This is foreshadowed in the legislative amendment that set these arrangements in place in 2001:

> once an application has been submitted by an applicant using the electronic lodgement facility ... any requests for information about the goods will be made after entry of the goods on the Register, as part of the post-market monitoring.[387]

6.41 The Expert Committee's original recommendation does not concern itself with timing of the submission of evidence summaries—whether this should be done before or after listing—but simply proposes that sponsors

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[384] DoHA, *Australian therapeutic products regulatory framework: A Way Forward for TGA*, 13 September 2007, pp. 38–9.

[385] Ibid. p. 52.

[386] TGA, OCM advice of 16 December 2010.

[387] Therapeutic Goods Amendment Bill (No. 4) 2000, Explanatory Memorandum, Item 9.

submit that summary.[388] Moreover, to implement that part of the Expert Committee recommendation relating to grandfathered registered complementary medicines, summaries of evidence must be obtained *after* listing as these items are already on the ARTG.

6.42 Once the ANZTPA project was suspended, and the intended mechanism to implement the Expert Committee's recommendation was no longer available, it has effectively been assumed that no other course of action was available. This is despite the intention set out in the TGA's consideration of how to build on the work done in preparation for ANZTPA (see para. 6.37 above).

Impetus for action

6.43 The Australian Government's response of March 2005 acknowledged that 'the results of the TGA's limited audits may not justify a conclusion that there is a widespread non-compliance with the Guidelines …'.[389] Even so, the response adopted the mandatory submission of a summary of evidence, over other options. These deliberations included no discussion of timing of the submission of the evidence.[390] It has come to light since the time of the government response that non-compliance is high (see Chapter 4). This makes the case stronger to implement the government commitment.

6.44 The Government response also noted that the costs to industry would not be high, as sponsors are required to certify that they hold the evidence to support their claims anyway. Thus there would be little regulatory burden on industry. On this basis, the comments made in the close-out report about the TGA's action on the recommendation being consistent with reduced regulatory burden, does not explain the lack of progress implementing the policy.

6.45 As already noted, it appears that mandatory submission could be implemented, consistent with this policy, with no impediment to prompt

[388] It seems that the question of the timing of seeking the summary of evidence is introduced into the picture not by the original recommendation nor the government response but by the TGA's progress report of October 2006. This states that 'Sponsors of Listed medicines … will be required to submit a summary of evidence supporting the claims made for their products *at the time of listing their products* once the joint regulatory scheme comes into effect' [Emphasis added]. This involves a choice by the TGA to require the summary at that point (which would require a change in the law) and to depend on the ANZTPA proposal and associated legislation going ahead, which it did not.

[389] *Australian Government Response to the Recommendations of the Expert Committee on Complementary Medicines in the Health System*, March 2005, p. 12, loc. cit.

[390] Australian Government Response, op. cit., pp. 13–18.

listing, but with a need for sponsors to provide the evidence summary thereafter.

6.46 In response to why it had not progressed the policy, the OCM advised:

> A number of challenges have emerged with the implementation of recommendation 5 of the [Expert Committee] report, which recommended that sponsors supply a summary of evidence for all Listed medicines. Assessing the evidence supplied for every new Listed complementary medicine on the Australian Register for Therapeutic Goods (ARTG), would not be practical from a resource perspective. The major constraints are the need to devote resources to specifically manage the large administrative burden, and the lack of clinical expertise in the Office. In order to ensure fairness, the same oversight would need to be applied to the over 10,000 Listed complementary medicines already on the ARTG.[391]

6.47 This discussion does not so much address the recommendation—which is simply that the TGA collect a summary of the evidence from the sponsor—as discuss a more onerous proposition: to assess or evaluate the evidence in each case. As noted earlier, (para. 6.16 above) the Expert Committee had recognised that assessing evidence for all items would be impracticable and had envisaged (and suggested) increased random sampling as a compliance measure. The resource implications of implementing the policy to collect evidence summaries are not as great as those that would be required if the TGA were to assess the evidence in every case.

6.48 The OCM further advised that:

> In addition to the question of resources, the challenge of assessing evidence supporting claims supplied from a number of different paradigms (e.g. clinical trials, traditional usage) also exists. This situation presents a problem for both the TGA and sponsors in that there is a lack of clarity in current guidelines in exactly what is required and what should be assessed. This is a challenge faced by all foreign regulators who regulate these types of products. In Australia, the development of specific guidelines for Listed Medicines making claims for Weight Loss represents an attempt to provide enhanced clarity to sponsors. Australia is the first jurisdiction in the developed world to try and address these issues through the creation of specific evidence guidelines for complementary medicines. This has meant that there has been no precedent or experience to learn from.

[391] TGA, OCM advice of 23 December 2010.

> As you are aware we have introduced processes to screen new Listed medicines with a focus on the claims being made, as well as increased attention to projects such as the Coded Indication initiative.[392]

6.49 This returns to the question of the problem of assessing evidence (discussed earlier in relation to the guidelines on evidence) where the challenges are undoubtedly substantial. However, resolving this question should not be an impediment to implementing Recommendation 5 as that requires only that the TGA collect a summary of evidence already held by sponsors.

TGA proposal to collect evidence of efficacy

6.50 Obtaining evidence of efficacy of listed complementary medicines has been a difficult issue. The ANAO is not aware of any substantial precedent for collecting this information from sponsors in any other jurisdiction. Nevertheless, a review of the TGA's advice suggests that no policy or practical impediments have arisen to implementing the Government's policy to collect a summary of evidence, since that policy was announced in March 2005.

6.51 The TGA developed an understanding that the requirement would be legislated, would involve collecting the evidence summary before or at listing, and that legislation would be introduced as part of the ANZTPA project. Thus, when the project was suspended, the proposed means for implementing the recommendation was no longer available. However, as discussed above, on the face of it, it seems practicable to proceed using existing powers which enable the TGA to collect the necessary material at some point after listing has taken place.

6.52 As the audit was being concluded, the TGA provided evidence that options for addressing the issues raised in the remaining recommendations of the Expert Committee were being considered as part of reviews on transparency and on complementary medicines reform. The reviews were initiated or endorsed by the Parliamentary Secretary.

6.53 It would enhance transparency and help inform both consumers and healthcare professionals if the TGA were to place the summary of evidence it collects from sponsors, as received, on its website—with a clear indication of whether it had been assessed or evaluated by the TGA. DoHA-sponsored

[392] TGA, OCM advice of 23 December 2010.

research conducting by the National Prescribing Service (NPS) has shown the need for improving complementary medicines information availability and awareness for Australian health professionals and consumers, and the NPS concluded that strategies to improve decisions by consumers about complementary medicines should focus on enhancing information resources preferred by consumers, including the Internet.[393,394]

6.54 The publication of summaries of evidence on the TGA website would enable potential consumers of the listed item or their advisers to access this information, should they wish, and form a view about the merits of that summary of evidence when considering whether to purchase and use the medicine.

Ian McPhee
Auditor-General

Canberra ACT
30 August 2011

[393] NPS, Review of the Quality of Complementary Medicines Information Resources: Summary Report. National Prescribing Service, Sydney, March 2009, p. 5.

[394] NPS, Information Use and Needs of Complementary Medicines Users, December 2008, p. 61.

Appendices

Appendix 1: Previous ANAO and Parliamentary inquiry recommendations

This appendix assesses DoHA's progress implementing the 32 recommendations from the previous performance audit and subsequent JCPAA inquiry.

Previous ANAO audit and JCPAA inquiry

1. The last ANAO performance audit on regulation of therapeutic goods was tabled in December 2004, Audit Report No. 18 2004–05, *Regulation of Non-prescription Medicinal Products*. This audit took place after the major recall of Pan Pharmaceutical products. The audit focused substantially on the regulation of manufacturing practice by the suppliers of non-prescription medicines.

2. As part of the current audit, the ANAO examined DoHA's progress with the recommendations of the 2004 performance audit and the additional recommendations of the subsequent inquiry by the Joint Committee of Public Accounts and Audit (JCPAA).[395] This appendix assesses progress with the 32 recommendations from the audit and the inquiry into the operation of the TGA.

3. Much of the previous audit was concerned with the manufacture of medicinal products and the TGA's audit of manufacturing practice. Therefore, to provide adequate context for the discussion and analysis of that progress, this appendix also provides brief introductory background on Good Manufacturing Practice (GMP), and how it relates to the TGA's regulatory practices.

4. The 2004 audit was entitled *Regulation of Non-prescription Medicinal Products*. The term 'non-prescription medicines' incorporates over-the-counter medicines, such as registered medicines that are authorised to be sold by pharmacists without a prescription and complementary medicines, such as herbal supplements and vitamins.

5. GMP audits conducted by the TGA were a major theme of the ANAO performance audit report. The ANAO made 26 recommendations, most of which related to GMP audits. Those recommendations focus on the

[395] JCPAA, *Report 404: Review of the Auditor-General's Reports 2003–2004 Third and Fourth Quarters; and First and Second Quarters of 2004–2005* (October 2005).

procedures and tools used to support GMP audits, consistent application of regulatory activities, recording of decisions, and audit outcomes. In 2005, the JCPAA held an inquiry to review the ANAO findings and made six recommendations, also primarily relating to GMP audits.

6. Table 6.2 summarises the status of DoHA's implementation of the recommendations, as at June 2011. Each was assessed as one of the following: fully, substantially, partially or not implemented.

Table 6.2 Implementation of ANAO and JCPAA recommendations

Recommendation	Status of implementation—May 2011	Recommendation	Status of implementation—May 2011
ANAO Rec. 1	Implemented	ANAO Rec. 16	Implemented
ANAO Rec. 2	Implemented	ANAO Rec. 17	Implemented
ANAO Rec. 3	Implemented	ANAO Rec. 18 and JCPAA Rec. 39	Implemented
ANAO Rec. 4	Implemented	ANAO Rec. 19	Implemented
ANAO Rec. 5	Implemented	ANAO Rec. 20.	Substantially implemented
ANAO Rec. 6	Implemented	ANAO Rec. 21.	Implemented
ANAO Rec. 7	Implemented	ANAO Rec. 22.	Substantially implemented
ANAO Rec. 8	Implemented	ANAO Rec. 23.	Implemented
ANAO Rec. 9	Implemented	ANAO Rec. 24. and JCPAA Rec. 40.	Implemented
ANAO Rec. 10	Implemented	ANAO Rec. 25. and JCPAA Rec. 41	Implemented
ANAO Rec. 11	Implemented	ANAO Rec. 26.	Partially implemented
ANAO Rec. 12	Implemented	JCPAA Rec. 37.	Implemented
ANAO Rec. 13	Implemented	JCPAA Rec. 38.	Implemented
ANAO Rec. 14	Implemented	JCPAA Rec. 42	Implemented
ANAO Rec. 15	Implemented		

Source: Source: ANAO analysis.

7. An analysis of the measures put in place to implement the recommendations is provided below. In summary, the analysis shows that:

- 29 recommendations are implemented;

- two recommendations are substantially implemented; and
- one recommendation is partially implemented.

The principles of 'Good Manufacturing Practice'

8. Good Manufacturing Practice (GMP) is a set of manufacturing principles and procedures which, when applied by manufacturers, helps to ensure a high level of quality of manufacture of therapeutic products.

9. The definition of 'manufacture' within the context of GMP is to produce therapeutic goods and to engage in any part of the process in the production of the goods, such as bringing the goods to their final state, engaging in the assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods, or of any component or ingredient of the goods as part of that process.[396] Within this definition, GMP applies to manufacturers of finished medicinal products, the raw materials that constitute them, and those involved in packaging a product.

Australian requirements

10. The Act requires manufacturers of therapeutic goods in Australia to hold a licence. It also allows the minister, from time to time, to determine written principles to be observed in the manufacture of therapeutic goods for humans.[397] In practice, to obtain a licence, a manufacturer must demonstrate compliance with requirements defined in principles called 'Good Manufacturing Practice'.

11. In 2002, the Australian Government announced that the principles of GMP would be aligned to standards established by an international body, the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Cooperation Scheme (jointly referred to as 'PIC/S'). The TGA

[396] TGA, *Good Manufacturing Practice for Therapeutic Goods*, 31 July 2009, available from <www.tga.gov.au/industry/manuf-gmp-tg.htm> [accessed 8 August 2011].

[397] Therapeutic Goods Act 1989, s. 36(1).

is currently one of 39 international regulatory authorities participating in the PIC/S.[398]

12. Since 2002, the Australian GMP requirements have been realigned with amendments to the PIC/S (in 2002, 2007 and 2009). Most recently, on 29 July 2009, a further amendment took place whereby a one year transition period was applied, ending on 1 July 2010, after which point the 2002 medicinal products and 1994 sunscreens codes were revoked.[399]

13. The PIC/S GMP standards seek to 'further facilitate the removal of barriers to trade in medicinal products, to promote uniformity in licensing decisions and to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products'.[400]

14. GMP applies to both Australian and overseas manufacturers. Recognised compliance with GMP obtained through successfully completing a GMP audit. Once a therapeutic good is included on the ARTG, the manufacturer undergoes periodic audits against GMP requirements to ensure they maintain compliance. Failure to do so can result in removal of the product from the ARTG or other regulatory action. The Act provides for criminal offences and civil penalties for breach of manufacturing principles.

15. The TGA's Office of Manufacturing Quality (OMQ) is responsible for conducting GMP audits. When it is satisfied that GMP requirements are met, a delegate of the Secretary, DoHA, issues GMP licences for Australian therapeutic goods manufacturers or GMP clearances to an overseas manufacturer. Currently, Australia recognises GMP clearances issued by foreign regulators. This is based on the adoption of PIC/S by those regulators, and associated agreements and memoranda of understanding between Australia and the respective countries.

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398 Pharmaceutical Inspection Co-operation Scheme, *Welcome to the PIC/S Website*, available from <www.picscheme.org/> [accessed 8 August 2011].

399 Before July 2009, Australia had its own Codes of GMP for manufacture of medicinal products and sunscreens: the *Australian Code of Good Manufacturing Practice for Medicinal Products* (16 August 2002) and the *Australian Code of Good Manufacturing Practice for Sunscreen Products* (1994).

400 PIC/S, *Guide to Good Manufacturing Practice for Medicinal Products*: *PE 009-9 (Intro)*, 2009, available from <www.picscheme.org/publication.php?id=4> [accessed 8 August 2011].

16. The Act requires overseas manufacturers that supply therapeutic goods to Australia to meet at least an equivalent standard of GMP as Australian manufacturers. To avoid the need for an international on-site audit by the TGA, sponsors may submit an acceptable form of evidence of the standard of manufacture for assessment (GMP clearance) before or when applications are lodged for listing/registration of medicines.[401]

Assessment of the implementation of recommendations

Original recommendation 1: The ANAO recommends that DoHA develop and publish suitable performance indicators and targets for the processes associated with the licensing and certification of non-prescription medicine manufacturers. The targets should be reflected in the TGA's customer service charter, and in decision-making and audit processes.

17. DoHA has implemented this recommendation. Performance indicators for the processes associated with the licensing and certification of non-prescription medicine manufacturers is published in DoHA annual reports.[402] There is also an identifiable relationship between portfolio budget statements, in which the targets are set, and the reporting of whether the targets are met, in annual reports.[403]

18. The TGA also produces internal half-yearly performance reports. These provide performance information on the activities of the OMQ such as on outcomes for licenses; certification; clearances; and clearances by region.[404] This information can be used to assess the TGA's performance in completing key tasks in the licensing and certification of medicines.

19. The TGA's *Customer Service Charter* (July 2006 and October 2010) generally reflect the goal to 'meet performance times and standards

[401] Available from <www.tga.gov.au/industry/manuf-medicines-audit.htm> [accessed 8 August 2011]. The basis for a GMP Clearance assessment is a Mutual Recognition Agreement (MRA) Regulator's GMP certificate, or equivalent evidence from a non-MRA country such as the United States. See *Guidance on the GMP Clearance of Overseas Medicine Manufacturers*, 16th Edition, March 2008, p. 8, available from <www.tga.gov.au/industry/manuf-overseas-medicines-gmp-clearance.htm> [accessed 8 August 2011].

[402] These relate to the percentage of licensing and surveillance audits performed within target timeframes for Australian and overseas manufacturers. DoHA, *Annual Report 2008–09*, p. 54; and DoHA, *Annual Report 2009–10*, p. 75.

[403] DoHA, *2009–10 Health and Ageing Portfolio Budget Statements*, pp. 81–2.

[404] TGA, *TGA Half-Yearly Performance Reports: July to December 2009*; see reports 12 and 13.

that have been agreed with consumer and industry bodies (these are set out in the TGA Group of Regulators Business Plan)'.[405] The TGA's *Business Plan 2008–09*, *Business Plan 2009–10* and *Operational Manufacturing Plan 2010–11* also include performance indicators and targets that relate to the licensing and certification of medicine manufacturers.[406]

20. A requirement of the recommendation is that targets are also reflected in decision-making and audit processes. OMQ advised in February 2011 that:

> Defined measures and targets for the conduct of audits are to be published in the TGA Business Plan and in the Overseas GMP Guidelines. This is consistent with the statement in the Customer Service Charter. OMQ has provided input to the TGA Business Plan through the OMQ Operational Plan. The latest version of the Overseas GMP Guidelines has been out for comment and is not yet a released document.[407]

21. Following the advice above, the TGA, in May 2011, incorporated its licensing and certification performance targets into the policy documents *Australian Regulatory Guidelines Good Manufacturing Practice (GMP) Clearance for Overseas Manufacturers* and *Standard Operating Procedure: Audit Scheduling*.[408,409]

22. This indicates that the recommendation is implemented because performance indicators and targets are fully integrated into policy documents (which define decision-making and audit processes).

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[405] TGA, *Therapeutic Goods Administration Customer Service Charter*, October 2010, available from <www.tga.gov.au/about/tga-customer-service-charter.htm> [accessed 8 August 2011].

[406] TGA, *Business Plan 2009–10*, p. 15; *Operational Manufacturing Plan 2010–10*, p. 17.

[407] TGA advice, 8 February 2011.

[408] TGA, *Australian Regulatory Guidelines Good Manufacturing Practice (GMP) Clearance for Overseas Manufacturers*, 17th Edition, Version 1.0, May 2011; TGA, *Standard Operating Procedure: Audit Scheduling–B4.01*, 13 May 2011, p. 2.

[409] TGA advice, 20 May 2011.

Original recommendation 2: The ANAO recommends that DoHA, taking into account any international agreements, develop a strategic management plan to monitor the regulatory equivalence of countries with which it has GMP agreements, including:

- standards and procedures to be monitored;
- performance measures and targets to be monitored;
- the currency of the agreements;
- resources required to monitor equivalence, including management arrangements; and
- reporting arrangements.

23. DoHA has implemented this recommendation. There is evidence that a *Strategic Plan for Managing International Agreements for the Therapeutic Goods Administration* (August 2010) has been implemented. The strategic plan incorporates two elements of the recommendation, an attachment that details the currency of international agreements; and annual reporting arrangements activity (such as the currency of the agreements and performance measures) to take place from the end of the 2010 calendar year.[410]

24. In May 2011, the TGA also implemented standard operating procedures that align with its strategic plan, and incorporate performance measures and monitoring arrangements for its international agreements.[411] These provide guidance to staff on establishing international agreements, information exchanges under international agreements and maintenance of equivalence of international agreements.[412]

Original recommendation 3: The ANAO recommends that DoHA strengthen the management and accountability for, the process for assigning GMP audit frequency by:

- articulating the rationale for audit frequencies, based upon systematic risk analysis, and undertaking regular evaluation of their appropriateness;

[410] TGA, *Strategic Plan for Managing International Agreements for the Therapeutic Goods Administration*, August 2010, p. 8.

[411] TGA advice to the ANAO, 20 May 2011.

[412] TGA, *Standard Operating Procedure: Establishing International Agreements*, May 2011; TGA, *Standard Operating Procedure: Information Exchange Under International Agreements*, May 2011; TGA, *Standard Operating Procedure: Maintenance of Equivalence of International Agreements*, May 2011.

- ensuring that reasons for use of discretion in setting audit frequency are documented;
- maintaining reliable records of risk ratings, and supporting information; and
- recording the degree of acceptable compliance.

25. DoHA has implemented this recommendation. Management of, and accountability for, the process for assigning GMP audit frequency has been strengthened by implementing the policy documents: *Audit Frequency Matrix – Product and Process Risk Dimension* (August 2010); and *OMQ Review of the Audit Frequency Matrix* (September 2010). These documents explain the rationale behind the audit frequency matrix (which uses two variables, *product risk* and *manufacturer compliance*).[413]

26. When GMP audits take place the reasons for the use of discretion in assigning re-audit frequency are required to be documented;[414] and a Manufacturers' Information System has been implemented to record risk and compliance ratings.[415]

Original recommendation 4: The ANAO recommends that DoHA:

- establish systems for the collection of management and performance information to enable it to assess performance in the execution of the GMP audit program; and
- assess the impact on TGA's regulation of manufacturers, including the risk of undetected non-compliance, from failure to achieve a GMP audit program consistent with risk profiling.

27. DoHA has implemented this recommendation. There is evidence that the OMQ has a system that is designed to collect management and performance information to enable the department to assess its performance in the execution of the GMP audit program.[416]

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413 TGA, *OMQ Review of the Audit Frequency Matrix*, September 2010, p. 3.

414 TGA, *OMQ Standard Operating Procedure No.B7.04 Medicine Programs Specific Requirements*, November 2006; and DoHA, *Internal Audit Report No.13 2009–10: Follow-up Audit of the ANAO's Recommendation in its Report on the TGA's GMP Audit Practices*, para. 3.3.10, p. 22.

415 DoHA. *Internal Audit Report No.13 2009–10: Follow-up Audit of the ANAO's Recommendation in its Report on the TGA's GMP Audit Practices*, para. 3.3.11, pp. 22–3.

416 TGA, *Review of TGA Reporting Processes*, 1 November 2010, pp. 6–7.

28. A Manufacturers' Information System is used to collect information about audit scheduling and associated audit results. The performance information is then used to determine whether targets in the *Operational Plan Manufacturing Quality* are met.[417] This information is also presented in DoHA's annual report.[418]

29. The TGA currently has a sound process to assess overdue audits. An assessment of the risks posed by overdue audits is designed to take place through identification and analysis of risks of undetected non-compliance.[419]

Original recommendation 5: The ANAO recommends that DoHA establish contingency plans, consistent with the TGA's regulatory responsibilities, to address the risk of delays in the execution of the overseas GMP audit program.

30. DoHA has implemented this recommendation. On 16 May 2011, the TGA revised two standard operating procedures to incorporate contingency plans designed to address the risk to overdue re-audits. For example, the standard operating procedure *Contingency Plans for Overdue Re-Audits* requires TGA staff to 'record the reasons for the delay and relevant information in the Overdue Reaudit Contingency Plan'.[420]

31. The contingency plan standard operating procedure also lists options to address the risk of delays in the overseas GMP audit program, such as:

- manufacturers providing an extension of clearance for selected products where the interruption of supply would have an impact on public health;
- overseas manufacturers requesting that a sponsor investigate whether a manufacturer would be eligible for a compliance verification assessment;

[417] TGA, *Business Plan 2009–10*, p. 15; *Operational Manufacturing Plan 2010–11*, p. 15.

[418] DoHA, *Annual Report 2009–10*, p. 75.

[419] TGA, *OMQ Standard Operating Procedure: No.B4.10 Risk Assessment*, June 2010.

[420] TGA, *Standard Operating Procedure: No.B4.11 Contingency Plans for Overdue Re-Audits*, May 2011, p.1.

- the Product Regulator, requiring that sponsors undertake batch release testing, if the delay is due to an action or inaction of the manufacturer;
- the Office of Laboratories and Scientific Services performing batch testing, if the delay is due to an action or inaction of the TGA;
- the Product Regulator, applying restrictions on supply across the product range, especially higher risk products; and
- suspending or revoking a licence, clearance or certificate if there is sufficient evidence to undertake the regulatory action.[421]

32. The above directives provide Audit Managers with guidance on what to do in the event of a delay of an overseas audit, and constitute specific contingency plans to address the risks that may arise.

Original recommendation 6: The ANAO recommends that DoHA assess the cost-benefit of unannounced GMP audits, and their role and contribution in the regulatory oversight strategy. The assessment could also address the broader lessons for the future from the targeting of non-prescription medicine manufacturers in 2003.

33. DoHA has implemented this recommendation. In response to the recommendation the department assessed the cost-benefit of unannounced audits in October 2010.[422] This analysis explains the role of unannounced audits and their contribution to regulatory oversight. There is also an analysis and assessment of the financial costs surrounding this activity:

> Many of the costs and benefits relating to the conduct of unannounced audits are not capable of quantitative measurement. As a result, expert opinion from experienced audit staff was used to weighup the relative value or merits of conducting unannounced audits … there may be some additional financial costs associated with unannounced audits (duration, re-visit, efficiency) and some impact on the audit schedule (re-visits, two auditors per site). These costs may reduce if

[421] TGA, *Standard Operating Procedure: No.B4.11 Contingency Plans for Overdue Re-Audits*, May 2011, p. 4.

[422] TGA, *OMQ: Cost-benefit Assessment of Conducting Unannounced Audits*, October 2010.

unannounced audits became more common and less confronting for manufacturers.[423]

34. The TGA came to the view that there would be a benefit in conducting more announced audits, providing a clear strategy is developed and communicated with its stakeholders before making such a decision. The TGA also states that 'a transparent and targeted approach, with clear objectives, would reduce associated risks (costs)'.[424]

35. Taking into account the information provided in the TGA's assessment of the cost-benefit of conducting announced audits, Recommendation 6 is implemented.

Original recommendation 7: The ANAO recommends that DoHA establish greater structure around administrative procedures, and develop support tools around planning of GMP audits and collection of evidence to facilitate consistency and adequacy of coverage in the conduct and reporting of audits of non-prescription medicine manufacturers.

36. DoHA has implemented this recommendation. Within the TGA, the OMQ has established a comprehensive range of support tools, such as a Manufacturers' Information System. This is used to plan audits, collect evidence and to facilitate consistency in TGA practices.

37. OMQ standard operating procedures also cover the aspects of conducting audits that include: audit scheduling; planning and undertaking audits; audit review and completion; and review panel.[425] Guidance material is also available to staff that covers the conduct of an audit, audit reporting, findings, follow-up and close-out.[426]

Original recommendation 8: The ANAO recommends that DoHA provide guidance to auditors and manufacturers on the deficiencies considered critical for OTC medicine manufacturers and for complementary medicine manufacturers. The department should also monitor the consistent application of such guidance by GMP auditors and Review Panels.

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[423] TGA, *OMQ: Cost-benefit Assessment of Conducting Unannounced Audits*, October 2010, pp. 6–8.

[424] TGA, *OMQ: Cost-benefit Assessment of Conducting Unannounced Audits*, October 2010, p. 9.

[425] TGA standard operating procedures: *B4.01 Audit Scheduling*; *B4.02 Planning and Undertaking Audits*; *B4.03 Audit Review and Completion*; and *B4.07 Review Panel*, June 2010.

[426] TGA, *G004 Conduct of an Audit–Auditor Training Manual*, April 2009; and *G002 Audit Reporting: Findings, Follow-up and Close-out*, Issue 3, July 2010.

38. DoHA has implemented this recommendation. The TGA now provides guidance to its auditors on the deficiencies considered critical for OTC medicines manufacturers, though policy documents such as the *Auditor Training Manual*,[427] the *Audit Reporting Manual*;[428] and a standard operating procedure *Audit Review and Completion*.[429] Guidance is also provided to manufacturers through public information such as *Audit of Medicine Manufacturers*,[430] *Risk Based Approach to Audit Frequency*,[431] and *Australian Code of Good Manufacturing Practice—Current Status*.[432]

39. To monitor and review the consistent application of the guidance documents outlined above, the TGA has an OMQ Audit Governance Committee. The committee's role is to formulate, review and advise on the policy objectives, scope, implementation, management, resourcing and improvement of the manufacturing audit and clearance programs.

Original recommendation 9: The ANAO recommends that, to improve transparency and to assist its clients in their compliance, DoHA:

- improve the information available to non-prescription medicine manufacturers and sponsors on the GMP audit process; and
- develop, and make transparent to its clients, procedures for the handling and resolution of complaints, appeals and disputes regarding audit findings.

40. DoHA has implemented this recommendation. There is general information about GMP audits processes available to manufacturers and sponsors of therapeutic products on the TGA's website.[433] Information about the procedures for the handling and resolution of complaints, appeals and disputes regarding audit findings is also

[427] TGA, *G004 Conduct of an Audit–Auditor Training Manual*, Issue 2, April 2009.

[428] TGA, *G002 Audit Reporting: Findings, Follow-up and Close-out*, Issue 3, July 2010.

[429] TGA, *Standard Operating Procedure: B4.03 Audit Review and Completion*, June 2010.

[430] TGA, *Audit of Medicine Manufacturers*, 30 November 2010, available from <www.tga.gov.au/industry/manuf-medicines-audit.htm> [accessed 8 August 2011].

[431] TGA, *Risk Based Approach to Audit Frequency*, 30 November 2010, available from <www.tga.gov.au/industry/manuf-audit-frequency.htm> [accessed 8 August 2011].

[432] TGA, *Australian Code of Good Manufacturing Practice–Current Status*, 31 July 2009, available from <www.tga.gov.au/industry/manuf-cgmp-status.htm> [accessed 8 August 2011].

[433] TGA, *Manufacturing Therapeutic Goods*, available from <www.tga.gov.au/industry/manuf.htm> [accessed 8 August 2011].

available, set out in the *Office of Manufacturing Quality Complaints Process*.[434]

Original recommendation 10: The ANAO recommends that DoHA strengthen GMP audit close-out procedures by:

- establishing clear guidance, including examples and standards, on the assessment and acceptance of evidence of corrective action by manufacturers;
- subjecting close-out to appropriate review; and
- maintaining relevant and reliable management information to facilitate monitoring of close-out, and allocation of audit resources.

41. DoHA has implemented this recommendation. It has established clear guidance for the assessment and acceptance of evidence of corrective action by manufacturers. For example, the document *Audit Reporting: Findings, Follow-up and Close-out* provides advice to TGA staff on corrective actions and collecting objective evidence.[435] A standard operating procedure is also in place that outlines the processes for completing audits.[436] This also provides process guidance for subjecting an audit to close-out and appropriate review.[437]

42. The TGA uses a Manufacturers' Information System to facilitate monitoring the close-out of an audit, and the allocation of audit resources. This system also has the ability to record audit work flow, findings and ratings.

Original recommendation 11: The ANAO recommends that DoHA:

- establish a suitable range of expertise on TGA Review Panels to address regulatory issues, consistent with procedural requirements; and
- ensure that Review Panels are constituted in accordance with SOPs.

43. DoHA has implemented this recommendation. TGA standard operating procedures specify that review panels should comprise:

[434] TGA, *OMQ Complaint Process*, 10 May 2010, available from <www.tga.gov.au/industry/manuf-complaint-process.htm> [accessed 8 August 2011].

[435] TGA, *G002 Audit Reporting: Findings, Follow-up and Close-out*, Issue 3, July 2010.

[436] TGA, *Standard Operating Procedure: B4.03 Audit Review and Completion*, June 2010.

[437] TGA, *Standard Operating Procedure: B4.03 Audit Review and Completion*, June 2010, pp. 3–4 and p. 6.

- an independent chair who is an Audit Manager or Technical Manager;
- at least two other members, including the chair, that are either an OMQ Audit Manager (who is not responsible for an audit); an Executive Level 2 auditor; an OMQ Quality Systems Manager; a TGA Technical Specialist; or a representative from a TGA Product Regulator.[438]

44. During March 2010 to May 2011 the TGA established review panels in accordance with its *Review Panel* standard operating procedure.[439] For example, the Review Panels had independent chairs (either an audit manager or technical manager); and included at least two other members that fulfilled the requirements of the standard operating procedure.

Original recommendation 12: The ANAO recommends that DoHA establish, and promulgate, TGA procedures for the:

- imposition and management of short-term reporting enforcement action;
- consistent application of licence restrictions; and
- imposition of restrictions on overseas manufacturers audited and certified by the TGA. Relevant matters include the roles and responsibilities of officials, key steps, complaints mechanism and time-lines.

45. DoHA has implemented this recommendation. The TGA has documented procedures for staff to follow when managing short-term enforcement action. The procedures are set out in: the Audit Reporting: Findings, Follow-up and Close-out guidance document;[440] and Standard Operating Procedure: B4.03 Audit Review and Completion.[441]

[438] TGA, *Standard Operating Procedure: B4.07 Review Panel*, June 2010, pp. 2–3.

[439] During March 2010 to May 2011 the TGA advised that all but one of the Review Panels complied with its standard operating procedure. (TGA advice of 17 May 2011.)

[440] TGA, *G002 Audit Reporting: Findings, Follow-up and Close-out*, p. 13.

[441] TGA, *Standard Operating Procedure: B4.03 Audit Review and Completion*, June 2010.

46. The TGA, through its OMQ, has a suite of standard operating procedures to direct staff on how to grant, and manage, variations to licenses.[442]

47. The TGA also provides information publicly which addresses the arrangements that apply to an audit of an overseas manufacturer. This is contained in the Guidance on the GMP Clearance of Overseas Medicine Manufacturers.[443] As identified above, standard operating procedures have also been developed to provide guidance to staff.

Original recommendation 13: The ANAO recommends that DoHA arrange independent assessment of recent key enforcement actions, to draw lessons for the future when making decisions potentially affecting public health and safety.

48. DoHA has implemented this recommendation. It commissioned a consultancy review of TGA operations in response to the 2004 audit report. This was completed in June 2005 and 'assessed recent regulatory actions to enforce compliance to draw lessons for the future that will assist TGA decision-making affecting public health and safety'.[444]

49. The findings of the consultancy review presented recommendations for the TGA to implement enhancements to:

- standard operating procedures used by the TGA's Manufacturer Assessment Section (now the OMQ);[445]
- processes surrounding the identification of non-compliance; and
- variations to license conditions, suspensions and revocations.[446]

50. These suggested enhancements were subsequently incorporated into the standard operating procedures OMQ currently uses.[447] For the

[442] For example the TGA has the following standard operating procedures: B2.03–Granting Licences/Certifications; B4.07 Review Panel; B5.00 Licence Certificate Management Overview; B5.01 Licence Suspension or Revocation; B5.02 Variation to Licence and or Certificate; B5.03 Transfer of Licence; and B5.04 Certificate Revocation Clearance Cancellation.

[443] TGA, *Guidance on the GMP Clearance of Overseas Medicine Manufacturers*, March 2008, loc. cit.

[444] TGA, *Deloitte-Therapeutic Goods Administration Consultancy Findings*, June 2005, p. 4.

[445] Ibid., p. 13.

[446] Ibid., Attachment B, pp. 8–11.

reasons outlined above, it is apparent that DoHA has implemented recommendation 13.

Original recommendation 14: The ANAO recommends that DoHA establish procedures to guide and prepare staff and management should there be difficulty in gaining access to premises to conduct a GMP audit.

51. DoHA has implemented this recommendation. The Act provides the power for authorised TGA staff to enter premises during audits.[448] When TGA staff attempt to use the powers granted to them, and are denied access to premises, they are required to follow a standard operating procedure that details the appropriate actions.[449]

Original recommendation 15: The ANAO recommends that DoHA strengthen the TGA's management and monitoring of enforcement action by establishing:

- timeliness standards for key decision steps in the enforcement process, and monitoring performance against the standards; and
- monitoring and reporting procedures for the implementation of Review Panel recommendations and other enforcement action.

52. DoHA has implemented this recommendation. The TGA has in place a timeliness standard that requires critical deficiencies and non-conformities to be given priority and review, and are to be referred to the Review Panel 'as soon as possible'.[450,451]

53. Timeliness standards for key decisions in enforcement are monitored through a 'weekly incident score sheet' and 'monthly summary of regulatory actions'. These describe regulatory actions and are reviewed by audit managers. Oversight of the implementation of Review Panel

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447 The TGA advised that OMQ procedures have been amended to incorporate enforcement actions. There is evidence that this is the case. The OMQ document *G002 Audit Reporting: Findings, Follow-up and Close-out* (July 2010) contains available enforcement actions.

448 See, for example, s. 40(1) and s. 40(4)(b)(i) of the Act.

449 TGA, *Standard Operating Procedure: Planning and Undertaking Audits*, June 2010.

450 Audit reports where critical deficiencies/non-conformances were identified at audit are to be given priority for preparation and review, and referred to a Review Panel 'as soon as possible'. TGA, *Standard Operating Procedure: Audit Review and Completion*, June 2010, p. 2.

451 A review panel is established to review when decisions made regarding audits where a critical deficiency has been found, or the compliance rating has been determined to be unacceptable, are independent of the conduct of the audit. TGA, *Standard Operating Procedure: Review Panel*, June 2010, p. 1.

recommendations is a function of the OMQ Audit Governance Committee (AGC).

54. Among its roles, the AGC is expected to monitor the implementation of regulatory actions. The TGA advised that the OMQ AGC is required to:

> Formulate, review and advise on the policy, objectives, scope, implementation, management, resourcing and improvement of the manufacturing audit and clearance programs through the QMS including … monitoring the implementation of regulatory actions.[452]

55. The AGC also reviews Review Panel recommendations through monthly reports which, since March 2010, are provided to the AGC to monitor the performance of the audit program.[453]

56. DoHA has implemented recommendation 15. There are timeliness standards for key decision steps in the enforcement processes and mechanisms for monitoring these standards. A standard operating procedure is also in place for the AGC to maintain oversight over Review Panel recommendations.

Original recommendation 16: The ANAO recommends that DoHA enhance management procedures for GMP compliance ratings to enable review and analysis over time, and to identify issues needing correction, by:

- assessing and recording initial compliance ratings; and
- documenting reasons for ratings and subjecting them to appropriate review.

57. DoHA has implemented this recommendation. This has occurred through the introduction of guidance documents, standard operating procedures and a Manufacturers' Information System that are expected to be followed and used by TGA OMQ staff.

58. The TGA provides the guidance document *Audit Reporting: Findings, Follow-up and Close-out* to its staff. This is designed to 'provide [staff] with a standard against which audit reports are evaluated'.[454] There are standard operating procedures for compliance rating rationales, the

[452] TGA advice to the ANAO, 20 May 2011. TGA, *Standard Operating Procedure: No.B1.03 Role and Authority Descriptions*, September 2010, p.17.

[453] TGA advice to the ANAO, 20 May 2011.

[454] TGA, *G002 Audit Reporting: Findings, Follow-up and Close-out*, Issues 3, July 2010, p. 2.

audit review record and the deviation required to justify change in a compliance rating.[455] Procedures also specify that the review of audit reports, provisional compliance ratings and close-out action should take place.[456]

Original recommendation 17: The ANAO recommends that DoHA inform manufacturers of their compliance rating, to assist manufacturers in improving [their] quality management, and to reinforce findings presented in Deficiency Reports.

59. DoHA has implemented this recommendation. Standard operating procedures specify that the TGA should provide manufacturers with completed audit reports. They also require manufacturers to be informed of impositions or changes to a 'site authorisation' or new conditions.[457]

60. To help manufacturers to understand their compliance ratings, the TGA publishes information on its website that summarise the classification of compliance ratings.[458]

Original recommendation 18: The ANAO recommends that DoHA increase testing when there is increased risk exposure arising from limitations in the manufacturer audit program and where there is a reasonable expectation it will assist in monitoring compliance. The overall strategy for priority testing should reflect this increased use, as well as the requirement for the Manufacturer Regulator to advise the laboratory when limitations arise.

Original JCPAA recommendation 39: The Committee recommends that the TGA increase its post-market laboratory testing for non-prescription medicinal products from overseas manufacturers, particularly with an emphasis on products from manufacturers who have not been subject to certification or audit in the past 18 months.

61. The DoHA has implemented ANAO recommendations 18 (ANAO) and 39 (JCPAA).These recommendations were made when the TGA faced a backlog in its overseas manufacturer GMP compliance audit program.

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455 TGA, *B4.02 Standard Operating Procedure: Planning and Undertaking Audits*, June 2010.

456 TGA, *B4.03 Standard Operating Procedure: Audit Review and Completion*, June 2010.

457 TGA, *B4.02 Standard Operating Procedure: Planning and Undertaking Audits*, June 2010; and TGA, *FB4.03 Audit Close-out Letter*, April 2010.

458 TGA, *Risk Based Approach to Audit Frequency*, 30 November 2010, available from <www.tga.gov.au/industry/manuf-audit-frequency.htm> [accessed 8 August 2011].

When the TGA agreed to the recommendation, there were few alternatives to manage the risks to consumers of a delayed audit program.[459] DoHA states that, since 2005, compliance verification processes have been established to provide alternatives to conducting overseas audits. A standard operating procedure specifies what TGA staff should do where an overseas re-audit is overdue.[460]

62. In cases where overseas audits are overdue, the procedure is to identify audits that cannot be completed within the scheduled time and to formally assess the risk of the manufacturer's continued operation, through development of an overdue re-audit contingency plan. If the risks are unacceptable, the TGA may consider testing selected products produced by the manufacturer.[461]

63. DoHA advises that the circumstances underpinning these ANAO and the JCPAA recommendations have changed. This is because:

- delays in conducting overdue audits have reduced dramatically;
- the TGA now has more GMP auditors at its disposal;
- the TGA audit program has a greater focus on overseas manufacturers and a 'real-time manufacturers profile' has been established; and
- the TGA has established international agreements with other therapeutics goods regulatory agencies, and now has better access to information such as results of GMP audits conducted by these regulators.[462]

64. The changed circumstances and improvements to the TGA processes mean that the concerns underpinning both the ANAO and JCPAA recommendations have been addressed or are no longer relevant.

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459 DoHA, *Review of TGA's Post-Market Monitoring and Review Process: Laboratory Testing*, Audit Report 4 of 2010–11, August 2010, p. 31.

460 TGA, *Standard Operating Procedure: No.B4.11 Contingency Plans for Overdue Re-Audits*, May 2011.

461 Ibid.

462 DoHA, *Review of TGA's Post-Market Monitoring and Review Process: Laboratory Testing*, Audit Report 4 of 2010–11, August 2010, p. 31.

Original recommendation 19: The ANAO recommends that DoHA develop performance indicators and targets for the timeliness of TGA laboratory testing.

65. DoHA has implemented this recommendation. The TGA's Office of Laboratory and Scientific Services now uses a Laboratory Information Management System (LIMS) to capture and record performance information. Recently the TGA rated the LIMS as one of the most effective performance recording and reporting information systems used within the TGA.[463]

66. The TGA has established performance indicators for the timeframes for the completion of laboratory testing, which are between respective regulating sections within the TGA in Memorandums of Understanding. These are reported on in half-yearly performance reports.[464]

Original recommendation 20: The ANAO recommends that reports be provided to the TGA's Product Regulator on the effectiveness of recall-related corrective actions implemented by manufacturers.

67. DoHA has substantially implemented this recommendation. The ANAO identified in its 2004 audit report that 'formal feedback to the Product Regulator [the OCM] only occurs if the audit identified unsatisfactory corrective action'. In February 2011 the TGA maintained this practice.[465] However, in April 2011, the TGA amended its standard operating procedure *Planning and Undertaking Audits*, so that 'if a recall follow-up [is] requested a [recall follow-up record] form be completed and sent to the TGA Recalls Unit, the relevant Product Regulator, and the Head of the Office of Product Review.[466]

68. Recommendation 20 is substantially implemented because a standard operating procedure is in place. It specifies that reports should be

[463] TGA, *Review of TGA Reporting Processes: Strengths, Weaknesses and Improvements*, September 2010, p. 11.

[464] TGA, *TGA Half-Yearly Performance Reports: July to December 2009*, Reports 14 and 15.

[465] TGA advice to the ANAO, 8 February 2011. The practice is specified in TGA, *Standard Operating Procedure B4.03 Audit Review and Completion*, June 2010.

[466] TGA advice to the ANAO, 20 May 2011. TGA, *Standard Operating Procedure: No.B4.02 Initial Audit or Re-Audit*, April 2011, p.6; and TGA, *Form No.FB4.02.e Recall Follow-up Record*, April 2011, p.1.

provided to the Product Regulator, not only in cases where this action is ineffective, but in all cases of recall action.

69. The TGA states that it has not been able to identify any recent examples where feedback was provided to the Product Regulator (in cases involving ineffective recalls). The TGA was also unable to provide any examples of reports relating to the effectiveness of recall related corrective actions.[467]

70. The ANAO notes that the implementation of the standard operating procedure by the TGA is relatively recent (April 2011). Recommendation 20 can be considered implemented when the TGA can demonstrate that its working practices have aligned with the revised standard operating procedure and reports have been provided to the Product Regulator.

Original recommendation 21: The ANAO recommends that DoHA conduct, and disseminate to relevant stakeholders, regular trend analysis of recalls information, in order to assist in identifying systematic issues.

71. DoHA has implemented this recommendation. In response to the ANAO's 2004 audit report, the TGA's Recall's Unit introduced a recalls database.[468] This allows for the recording and reporting of activities associated with recalls, such as the breakdown of:

- medicines recalls (by product types);
- medical device recalls (including the separation of devices and in vitro diagnostic devices, and by class of medical device); and
- blood recalls (by type fault).[469]

72. During 2010, Quarterly Trends Analysis Reports were produced from the database and distributed to heads of the Offices of Devices, Blood and Tissues; Prescription Medicines; and Non-Prescription Medicines.[470]

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[467] TGA advice to the ANAO, 8 February 2011.

[468] The database was introduced in January 2006.

[469] TGA, *Presentation to the ANAO: Recalls of Therapeutic Goods*, 17 September 2010, slide 21.

[470] TGA, *Minute: Recalls Unit Trends Analysis Report*, 30 June 2010.

Original recommendation 22: The ANAO recommends that DoHA review and enhance the TGA's risk management framework for non-prescription medicinal products. The revised framework should, inter alia:

- be systematic, structured and integrated with the TGA's overall risk management strategies;
- allocate resources to various risk treatments;
- identify any necessary differences in risk treatments between Australian and overseas manufacturers, and their impact;
- provide information necessary to support effective management of risk and monitoring of treatments;
- ensure new or targeted strategies are based upon structured risk assessments, and evaluate their outcomes for lessons learned for future management of compliance; and
- identify the impact of slippage on planned risk treatments.

73. DoHA has substantially implemented this recommendation. The TGA sets out its approach to risk management in regulating all therapeutic goods (registered and listed medicines, and medical devices) in a paper published in May 2011 and available on its website.[471] The paper considers each type of therapeutic good in turn.

74. The previous version of *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods* (Version 1, July 2004) was published before the ANAO made this recommendation. While there have been some minor amendments to the original document, its content remains substantially the same.

75. The TGA advised that although the July 2004 version is a high-level document and needed to be updated to reflect structural changes in the TGA, its content still reflects its approach to managing risk.[472,473]

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[471] *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods*, Version 2, May 2011, loc. cit.

[472] TGA advice to the ANAO, 13 September 2010.

[473] The TGA has also published a *Risk Management Framework* document. The primary objective of this is to provide guidance and instruction on 'how' business risks are to be managed. However it does not provide information on 'what' the risks are. This document also states that an associated plan and risk related document is *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods July 2004*.

76. Notably, the TGA's risk management paper references a superseded Australian Standard.[474] Since 1999 the AS/NZS 4360:1999 *Risk Management—Principles and Guidelines* has been superseded twice (in 2004 and 2009). While the content of the material referenced may have altered slightly since 1999, it is important that the TGA's approach to managing risk is updated to reflect current best practice.

77. An analysis of TGA risk registers for the OCM and OMQ shows that the TGA is meeting some of the requirements of recommendation 22. For example, the registers identify 'risk events' and identify what activities will take place to control these risks.

78. Recommendation 22 will be implemented when the TGA reviews and enhances its risk management framework for non-prescription medicines.

Original recommendation 23: The ANAO recommends that DoHA strengthen the capture, recording, management and use of information to support regulation of non-prescription medicines by:

- holding key information collected from its regulatory processes on management information systems;
- maintaining the reliability and completeness of data holdings; and
- enabling better integration and sharing of information between the different areas of the TGA involved in regulatory functions.

79. DoHA has implemented this recommendation. Since 2004 the TGA has improved and introduced ICT systems to store, track and analyse major steps in its regulatory processes.

80. In October 2008 the TGA updated its Manufacturers' Information System. The system is a component of the TGA's Online Services Internet site (Electronic Business Services (eBS)).[475] One of the functions of eBS is to contain information about the work flow of non-prescription medicine applications for listing in the ARTG and the TGA's post-market activities.

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[474] *The Therapeutic Goods Administration's Risk Management Approach to the Regulation of Therapeutic Goods*, Version 2, May 2011, p. 8.

[475] TGA, *TGA eBusiness Services Overview*, June 2009, [accessed 8 March 2011].

81. In 2006 the TGA improved its records management capability (previously serviced centrally by DoHA) by establishing a Records Management Section. The TRIM records management system has also been introduced across the TGA, to be used as the primary repository for electronic records.[476]

Original recommendation 24: The ANAO recommends that DoHA strengthen its documentation procedures to ensure key regulatory decisions taken by the TGA are fully documented, and that files are appropriately maintained.

Original JCPAA recommendation 40: the Committee recommends that the Therapeutic Goods Administration urgently review its information management systems, including documentation of key decisions and correct electronic and hard copy filing of relevant documents. The importance of maintaining accurate and up-to-date records should also be communicated to all TGA staff.

82. DoHA has implemented both recommendations. In 2005, DoHA engaged a consultant to review implementation of the recommendations.[477] The review found the TGA had developed a records management strategy and was planning to introduce an electronic document management system, which it has now done ('TRIM').

83. The TGA also has policy documents in place which direct staff on appropriate document handling procedures. A standard operating procedure *File Maintenance* is a directive that covers general file maintenance (but does not relate to 'documenting key regulatory decisions').

84. In 2009 the TGA commenced legal awareness training for its staff. The training is designed to cover:

- the roles and responsibilities of decision-making;
- good decision-making practices; and
- writing statements of reason.[478]

[476] TGA, *Record Keeping: Four Activities Under TGA 21*, 6 July 2010, p. 1.

[477] TGA, *Deloitte Consultancy Findings*, June 2005.

[478] TGA Intranet, *TGA Legal Awareness Training Program*, 26 August 2010.

85. A key activity under *TGA 21* is for the TGA Principle Legal Advisor and Director of Information Management to identify how TRIM can be used effectively to ensure that key regulatory decisions are fully documented.[479]

86. An example of where the TGA has implemented procedures to ensure that key decisions are recorded is in the use of 'key decision checklists' for decision-making delegates.[480] The OMQ also requires TGA auditors to document findings and actions carried out during GMP audits.

Original recommendation 25: The ANAO recommends that DoHA review and improve the TGA's quality assurance program to improve the quality, consistency and reliability of its GMP audits.

Original JCPAA recommendation 41: The Committee recommends that the Therapeutic Goods Administration continue with its re-accreditation process for ISO 9000 and National Association of Testing Authorities standards. When the TGA achieves these standards this information should be promulgated to manufacturers and other industry bodies.

87. DoHA has implemented these recommendations. The TGA's OMQ uses an uncertified Quality Management System (QMS). The QMS has been peer-reviewed by Health Canada and includes a suite of guidance material, manuals, standard operating procedures and forms to support the conduct of GMP audits. A Quality Manager is also tasked to manage the QMS, and reports directly to the Head of OMQ.

88. While it appears that the TGA has implemented recommendation 25, when analysed in conjunction with the JPCAA's recommendation 41, the TGA has not continued and finalised its re-accreditation with ISO 9000 and National Association of Testing Authorities standards.

89. In September 2010, the TGA advised that it had decided not to apply for certification to the International Organisation for Standardisation (ISO) protocol on quality management *ISO 9000*.[481] In May 2011, it clarified its rationale for this decision:

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[479] TGA, *Record Keeping: Four Activities under TGA 21*, 6 July 2010, p. 1.

[480] For example, TGA, *Standard Operating Procedure: FB2.04.h – s.38(2) Special Circumstances Delegate Checklist*; TGA, *Standard Operating Procedure: FB4.04.a – s.38 Grant of Licence Delegate Checklist*; TGA, *Standard Operating Procedure: FB5.04.b s.41 Revoke of Suspend a Licence*.

[481] TGA advice to the ANAO, 29 September 2010.

> The [TGA] has sought an alternative to the JCPAA recommendation … by complying with ISO Guide 62 – *General Requirements for Bodies Operating Assessment and Certification/Registration of Quality* Systems … The [OMQ] has sought and achieved an independent "certification" to an equivalent standard with Regulatory relevance … In doing so the OMQ has satisfied the intent of the JCPAA recommendation to improve its quality assurance program … It should be noted that the process of recognition as a Registrar by Health Canada is a regulatory equivalent to the accreditation of a certification body in the non-regulatory domain.[482]

90. While the thrust of the JCPAA's recommendation, to improve the quality assurance program was realised, it appears that the JCPAA was not informed of this outcome. Such a decision should have been clearly articulated to the JCPAA, to provide assurance that the intent of their recommendation had been realised. The ANAO notes the TGA's omission and suggests that in the future the TGA should directly inform the JCPAA of its rationale for any decision to diverge from its recommendations.

91. The ANAO concludes that recommendation 25 and JCPAA recommendation 41 have been implemented.

Original recommendation 26: The ANAO recommends that DoHA implement a performance management system that defines key outcomes, key performance indicators and targets for the regulation of non-prescription medicinal products.

92. DoHA has partially implemented this recommendation. The TGA does produce performance information relating to non-prescription medicines. However, the TGA is aware it has disparate reporting regimes and varying degrees of rigor applied to performance reporting.

93. Performance information and reporting is a recurring theme in ANAO reports on the TGA:

- In 1996 the ANAO recommended (no. 12) that the TGA strengthen its public reporting to better meet the information needs of Parliament and consumers in the interest of enhanced accountability;

[482] TGA advice to the ANAO, 20 May 2011.

- In 2000 the ANAO found that the TGA does not have adequate performance indicators relating to the efficiency of drug evaluation. The absence of adequate performance indicators of the efficiency of processing limits the ability of industry, the Parliament and other stakeholders to understand variations in TGA's processing performance.[483] Two recommendations in the report also relate to the TGA's performance information and reporting processes.[484]
- In 2004 three recommendations were agreed to by the TGA, also relating to improving its performance reporting arrangements.[485]

94. Currently, the TGA is undertaking work to improve its capture and reporting of performance information. This is taking place through a Performance Measures Steering Committee. The steering committee was formed on 14 September 2010 and its terms of reference are to create, and implement, revised performance measures that assess the TGA's effectiveness and operational efficiency.[486]

95. The TGA has also recently reviewed its performance reporting processes.[487] The review identified that although effective performance reporting systems such as the Laboratory Information Management System, used by the Office of Laboratory and Scientific Services, should remain in place, improvements can be made to performance reporting, such as establishing:

- a specialised area/unit tasked with business performance reporting and that individual office reporting activities (as they now exist) be systematically relocated to this unit; and

[483] ANAO, *Drug Evaluation by the Therapeutic Goods Administration Follow-up Audit*, Audit Report No.2 of 2000–2001, p.18.

[484] Ibid. See recommendations 1 and 3.

[485] ANAO, *Regulation of Non-prescription Medicinal Products*, Audit Report No.18, 2004–2005. See recommendations 4, 19 and 26.

[486] TGA, *TGA Executive Committee Meeting: Agenda Item No.9.2*, 15 November 2010, p.1.

[487] TGA, *Review of TGA Reporting Processes: Strengths, Weaknesses and Improvements*, November 2010.

- a uniform approach to quality assurance of the reporting mechanism, the rigour of which could withstand independent audit.[488]

96. As identified above, the TGA has identified that it needs to establish a performance reporting framework that efficiently harnesses useful information that can be used for performance reports. When the TGA establishes a robust performance reporting framework then the full implementation of recommendation 26 will be achieved.

Original JCPAA recommendation 37: The Committee recommends that the TGA provide this Committee with a copy of the audit frequency matrix, and any other documentation linked to determination of audits (such as procedures for undertaking an unannounced audit), when it is completed.

97. DoHA has implemented this recommendation. It relates directly to the ANAO's recommendations 3 (audit frequency) and 6 (unannounced audits) examined above.

98. An executive minute from the Secretary of DoHA to the Minister for Health and Ageing states that a draft copy of the audit frequency matrix standard operating procedure was provided to the JCPAA.[489] The minute also states that a completed copy would be provided to the JCPAA once it was finalised. However, the TGA advised the ANAO that 'the document was not finalised in that form but was superseded by other documents as part of a revised OQM Quality Management System'.

99. While the relevant documents pertaining to the recommendation were not provided to the JCPAA, recommendation 37 is considered implemented as the thrust of its intent has been addressed by the OMQ currently having a Quality Management System, which contains guidance material and procedures for planning and executing audits.

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[488] Ibid. p. 12.

[489] The Hon Tony Abbott MP, Minister for Health and Ageing, *Letter to Tony Smith MP, Chair of the JCPAA*, 4 May 2006, p. 2, available from <www.aph.gov.au/house/committee/jcpaa/auditor_generals/exminhealth2.pdf> [accessed 4 May 2011].

Original JCPAA recommendation 38: The Committee recommends that the Therapeutic Goods Administration document its procedures for implementation of enforcement action against manufacturers. This should include:

- a clear definition of different enforcement actions, the circumstances in which they are applied, and manufacturers' rights of submission or appeal;
- stipulation of management authorisation for enforcement actions;
- a definition of timelines for short-term reporting and TGA assessment of manufacturer reports; and
- a requirement that all manufacturers subject to an enforcement action will undergo a follow-up audit within three to six months of the initial action.

100. DoHA has implemented this recommendation. There is evidence that the TGA has a Quality Management System containing guidance material and procedures for regulatory action. Some examples of the documentation available are standard operating procedures contained in the OMQ's *Branch Manual*; and guidance documents, such as, *Regulatory Audit by OMQ*;[490] *Audit Reporting, Findings, Follow-up and Close-out*; and *Guidance on the GMP Clearance*.[491] The *Conduct of an On-site Audit GMP/QMS Audit* (Auditor Training Manual) also contains relevant material.[492] Manufacturers are also advised of the OMQ's complaints process through the TGA's website.[493] The TGA is also piloting an electronic audit feedback form for its stakeholders.[494]

101. Upon examination of the current OMQ Quality Management System procedures and other information outlined above, the TGA has documented the required information.

[490] TGA, *Regulatory Audits by OMQ*, September 2010.

[491] TGA, *Audit Reporting: Findings, Follow-up and Closeout*, Issues 3, July 2010.

[492] TGA, *Conduct of an On-site GMP/QMS Audit*, April 2009.

[493] TGA, *Office of Manufacturing Complaint Process*, 10 May 2010, available from <www.tga.gov.au/industry/manuf-complaint-process.htm> [accessed 8 August 2011].

[494] TGA, *Audit Feedback Forms: Pilot*, 7 May 2010, available from <www.tga.gov.au/manuf/audit-feedback.htm> [accessed 9 March 2011].

Original JCPAA recommendation 42: The Committee recommends that the Therapeutic Goods Administration report to the Committee on the establishment and operation of the Trans-Tasman Therapeutic Products Agency, with regard to how the new agency will continue to regulate non-prescription medicinal products in accordance with the 26 ANAO recommendations. The TGA should also report on any changes to its governance and reporting arrangements. These reports should be forwarded to the Committee in February and July 2006.

102. DoHA has implemented this recommendation. On two occasions the Minster for Health and Ageing wrote to the JCPAA outlining:

- the progress on the proposed establishment of the Australia New Zealand Therapeutics Products Authority (ANZTPA);
- the regulation of non-prescription medicines in the joint regulatory scheme; and
- changes to the TGA's governance and reporting arrangements.[495]

103. It is important to note that in July 2007 the New Zealand Government announced that it would not proceed with the proposed ANZTPA scheme. The negotiations between countries were postponed for several years.[496] On 20 June 2011, the Australian and New Zealand prime ministers announced their agreement to proceed with the ANZTPA scheme.[497]

104. The formal correspondence from the Minister for Health and Ageing to the JCPAA, outlined above, satisfies the requirements of recommendation 4.

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[495] The Hon Tony Abbott MP, Minister for Health and Ageing, *Letter to Tony Smith MP, Chair of the JCPAA*, 9 March 2006, available from <www.aph.gov.au/house/committee/jcpaa/auditor_generals/exminhealth.pdf>; and the Hon Tony Abbott MP, Minister for Health and Ageing, *Letter to Tony Smith MP, Chair of the JCPAA*, 18 July 2006, available from <www.aph.gov.au/house/committee/jcpaa/auditor_generals/exminhealth3.pdf> [accessed 8 August 2011].

[496] TGA, *Australia New Zealand Therapeutics Product Authority*, 14 December 2007, available from <www.tga.gov.au/about/international-anztpa.htm> [accessed 8 August 2011].

[497] See <www.health.gov.au/internet/main/publishing.nsf/Content/mr-yr11-dept-dept200611.htm> [accessed 8 August 2011].

Appendix 2: Regulating complementary medicines overseas

This appendix briefly summarises activity in Canada and across the European Union and provides sources for further information.

Canada:

All natural health products (NHPs) sold in Canada are subject to the Natural Health Products Regulations, which came into force on 1 January 2004.

NHPs are defined as vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, and other products like amino acids and essential fatty acids.

<www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php>

Europe:

All medicinal products, including herbal medicinal products, need a marketing authorisation to be placed on the EU market.

In March 2004, the Herbal Directive (Directive 2004/24/EC) was adopted to facilitate this marketing authorisation process. It provided a transitional period of seven years to register traditional herbal medicinal products that were already on the market at that time. This transitional period ended on 30 April 2011.

<www.ec.europa.eu/health/human-use/herbal-medicines/index_en.htm>

Other regions:

Information on regulation in some other regions is provided in the WHO Report of a Global Survey on National Policy on Traditional Medicine and Regulation of Herbal Medicines.

<apps.who.int/medicinedocs/en/d/Js7916e>

Information provided by the TGA, May 2011.

Index

F

G

H

I

L

M

N

O

P

Q

R

S

T

V

W

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