Australian Government

TGA reforms:

A blueprint for TGA's future

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Introduction

The Therapeutic Goods Administration (TGA) was established to safeguard and enhance the health of the Australian community through effective and timely regulation of therapeutic goods. It does this through the application of the *Therapeutic Goods Act 1989* (the Act). The TGA is a Division of the Commonwealth Department of Health and Ageing.

The TGA applies risk-based regulatory processes to therapeutic goods before they are marketed and monitors products once they are on the market. Additionally, it assesses the suitability of medicines and medical devices for export from Australia.

It also regulates manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality. It has a team of inspectors that audit manufacturing facilities around the world to ensure that products supplied in Australia are of high quality.

The TGA works with consumers, health professionals, industry and its international counterparts in order to effectively regulate increasingly complex medicines and medical devices resulting from rapid scientific and medical developments.

In order to ensure that the TGA continues to fulfil its public health role and is able to meet community expectations within a complex therapeutics regulatory environment, several major reviews have been undertaken across various therapeutic regulatory areas. These have included:

- the review to improve transparency of the Therapeutic Goods Administration;
- the Working Group on Promotion of Therapeutic Products;
- public consultations on the regulatory framework for advertising therapeutic goods;
- the Auditor-General's report on Therapeutic Goods Regulation: Complementary Medicines;
- an informal working group examining the regulation of complementary medicines and reasons for low compliance rates;
- public consultations on the medical devices regulatory framework; and
- the Health Technology Assessment Review.

The reviews were undertaken as part of the commitment to open government.

In response to the various reviews, the Government has drawn this work together into a comprehensive package of reforms to be progressed in stages. The reforms will enhance the TGA's current processes to ensure that the regulatory framework within which it operates remains able to adapt with flexibility to new scientific

developments and emerging community expectations. They will improve the Australian community's understanding of the TGA's regulatory processes and decisions and enhance public trust in the safety and quality of therapeutic goods.

These reforms will also ensure that the TGA is better aligned to the central principles of the National Medicines Policy, by effectively implementing plans to inform the community of its role in providing timely access to the therapeutic goods that Australians need, and that they meet appropriate standards of quality, safety and efficacy.

These reforms are grouped under the following themes to ensure the Government can effectively monitor progress and achievements:

- communications and stakeholder engagement;
- advertising of therapeutic products;
- complementary medicines;
- medical devices; and
- promotion of therapeutic products.

In providing its response the Government has indicated where implementation can begin immediately and where further consultation needs to be undertaken. In respect to responses that require further work, the Government will provide a concrete plan of action in the first half of 2012.

Communication and stakeholder engagement

Current arrangements for communication and stakeholder engagement

The TGA has a number of mechanisms in place to provide information on the regulation of therapeutic goods to consumers, health professionals and industry.

The Australian Register of Therapeutic Goods (ARTG) includes details of all therapeutic goods authorised by the TGA for use in Australia. This online database is accessible through the TGA website.

The TGA website has specific information portals for consumers, health practitioners and the therapeutic goods industry. This website provides a wide range of information about the role of the TGA, its regulatory processes and decisions.

Publications available from this site include Australian Public Assessment Reports (AusPAR) for prescription medicines. An AusPAR provides information about the evaluation of a prescription medicine, and the considerations that have led the TGA to approve or not approve an application to bring it to market.

Communication with stakeholders is currently undertaken by the TGA through a range of committees dedicated to specific areas of regulation, with membership drawn mainly from subject matter experts (health practitioners and researchers),

consumers, and in some cases, therapeutic goods industry association representatives.

The TGA also conducts regular consultations on options to change existing regulation and procedures in response to emerging community and industry concerns, and in response to medical and technological advances.

Current issues

In recent years there has been a growing awareness that:

- the TGA's role as a regulator is not well known or understood by the Australian community;
- the information provided by the TGA has been primarily directed to the therapeutic goods industry, rather than being targeted to assist consumers in their healthcare decision making;
- there is a need to bolster confidence in the TGA as the regulator through proactive and targeted communication with all stakeholders, and consumers in particular, about its role and regulatory decisions; and
- the community increasingly expects access to detailed information about the work of the TGA and in particular, about its evaluation of therapeutic goods.

What the Government will do

In response to these concerns, and consistent with the Government's commitment to openness and transparency, the TGA will adopt a strong focus on improving its communication and engagement with the community.

The Government will work to adopt the recommendations of the recent review to improve the transparency of the Therapeutic Goods Administration (the Transparency Review) and has asked the TGA to progressively implement them over the next four years.

Over the next 12 to 18 months the TGA will give priority to actively engaging with the community and providing improved information and education materials.

The TGA will also establish an Australian Therapeutic Goods Advisory Council. Representation on this Council will come from across the stakeholder base to encourage wider input into the work of the TGA, including the implementation of the Transparency Review's recommendations. Stakeholders will also be able to provide direct feedback and comment to the TGA through attendance and participation in biannual public fora.

The Government will ensure that the TGA focuses on the information needs of the community and other stakeholders to ensure that the right information is presented in a way that meets the varying needs of all stakeholders. This will include working with stakeholders to develop consultation principles to deliver transparent stakeholder engagement in regulatory policy making on emerging issues, and to promote accountability to the public.

Central to effective communication is the implementation of a communication strategy to inform and educate stakeholders. Of critical importance in this strategy, is the development of information products that inform consumers, health professionals and the regulated industry about emerging health issues pertinent to the work of the regulator. The TGA will work with key health information providers to explain:

- the risk based framework that the TGA uses for its assessments of different types of therapeutic goods;
- that listed medicines and some medical devices (low risk products) are not required under legislation to be evaluated for effectiveness by the TGA before being made available in Australia;
- the purpose and appropriate use of published material such as Product Information and Consumer Medicines Information documents; and
- the role of its statutory advisory committees and the adoption of a consistent approach to the publication of information from those committees.

The TGA website will be continuously improved and updated to ensure that it provides high quality information in a variety of formats.

In response to issues raised in the reviews, improvements will be made to the information base about complementary medicines, through redeveloped key guidance documents (made available according to a published timetable) and better access to information about regulatory decisions.

The TGA will develop and publish a policy on the disclosure of commercial in confidence information broadly consistent with international counterpart regulators; and will work with state and territory governments to improve the visible management of adverse event reporting.

These priority tasks are to address the most urgent community needs for information and education about the TGA and to ensure effective comment and feedback is provided to the TGA.

In addition to the priorities listed above, the TGA will work with stakeholders to progressively implement the remaining Transparency Review recommendations. Some recommendations will require further work for longer term implementation. Formal consultation and regulatory analysis processes will be undertaken in line with government policies.

The recommendations concerning the advertising of therapeutic goods and the associated complaint system will be addressed in the context of broader advertising reforms.

Advertising of therapeutic products

Current regulatory arrangements for advertising therapeutic goods

The advertising of therapeutic goods to consumers and health practitioners is controlled by a combination of statutory measures administered by the TGA and self-regulation through Codes of Practice administered by the relevant therapeutic goods industry associations. Advertising to consumers is permitted for the majority of medical devices and medicines available for over the counter sale, while advertising prescription-only and certain pharmacist-only medicines to the general public is prohibited.

Advertisements for therapeutic goods in Australia are subject to the requirements of the Act and Regulations, the *Competition and Consumer Act 2010* and other relevant laws. Advertisements directed to consumers must also comply with the Therapeutic Goods Advertising Code with certain advertisements directed at consumers requiring approval prior to broadcast or publication.

The responsible use of advertising provides one mechanism to enhance the health outcomes of Australians.

Current issues

Current calls for a more robust and effective system for the regulation of therapeutics advertising that ensures consumer confidence, and provides a level playing field for industry, have been noted by Government.

The regulatory framework for advertising therapeutic goods has been the subject of a number of reviews over the past decade. The current framework has more recently been the subject of public criticism around misleading advertising of therapeutic goods and the potential consequential risks to public health. This criticism has focused mainly on the scope of the pre-approval process, the timeliness of the complaints handling process and that the available sanctions and penalties do not provide sufficient deterrence.

In June 2010, the TGA released a consultation paper seeking feedback on options to enhance the operation and effectiveness of the therapeutic goods advertising regulatory scheme. In November 2010, the Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, chaired a meeting to discuss this feedback and ways to improve the regulation of therapeutic goods advertising. The meeting agreed that the TGA should develop options for improvements to the arrangements for the pre-approval of advertisements; the complaints resolution system; and sanctions and penalties for non-compliance with the advertising requirements.

Criticisms of therapeutic goods advertising included:

- concerns about unfounded efficacy claims used in advertisements. The current pre-approval system is limited in its ability to prevent consumers from being

exposed to advertisements for therapeutic goods that contain misleading claims related to the treatment of serious medical conditions, because only a sub-set of products are covered and only a sub-set of advertising media is covered by the current arrangements;

- a lack of clarity about complaints processes. Consumers view the advertising complaints system as cumbersome and slow, with multiple processing pathways, procedures and resolution bodies depending on the nature of the complaint; the type of therapeutic good; the advertising media involved; and the target audience for the advertisement; and
- a lack of incentive to comply with regulatory requirements. The currently available sanctions and penalties that can be imposed as a consequence of non-compliance with advertising requirements have been criticised for not providing a sufficient deterrent. These sanctions and enforcement strategies involve significantly lower pecuniary penalties compared to other comparative breaches of the Act.

What the Government will do

The TGA will work to improve current arrangements for the regulation of therapeutic goods advertising.

A central point for all complaints about advertising will be created at the TGA. Some complaints will be handled directly by the TGA. Specifically, complaints regarding efficacy or the intended purpose of therapeutic goods, or for advertisements which could pose a significant risk to public health will be dealt with directly by the TGA without reference to the Complaints Resolution Panel.

The TGA will develop options for consideration by Government in consultation with stakeholders on:

- broadening the current arrangements for pre-approval of advertisements to include medical devices and advertisements for therapeutic goods on pay TV. The requirements may also be modified to improve transparency by requiring more detailed monitoring and reporting; and
- developing a more effective approach to sanctions and penalties for breaches of advertising requirements to bring the current therapeutic goods advertising arrangements into line with other areas of government regulation, provide for civil penalty provisions (and infringement notices) that parallel the offences and provide for penalties set at a level which would act as a deterrent and better align the range of sanctions and penalties with other government agencies.

Complementary medicines

Current arrangements for complementary medicines regulation and listing

The TGA has a two-tiered regulatory framework for complementary medicines, based on risk. Low risk medicines containing pre-approved low risk ingredients with demonstrated safety and quality are listed on the ARTG. Evidence for efficacy for listed complementary medicines is not evaluated prior to entry, although sponsors are required to hold evidence to support their claims.

The TGA currently undertakes post-listing reviews of the evidence for a proportion of products listed each year through a targeted and random audit system. Higher risk complementary medicines must be registered on the ARTG, which involves individually evaluating the quality, safety and effectiveness of the product.

Applications for listed medicines are submitted through the TGA's Electronic Listing Facility. The Facility can detect and refuse to validate applications that are non-compliant with some, but not all, requirements. Following payment and subsequent inclusion of the listing on the ARTG, the medicine is eligible to be supplied into the Australian market.

Sponsors must, at the time of listing, certify that the medicine meets a range of requirements including the general requirements for the labelling of the product under the Act.

Current issues

The Auditor-General's report into complementary medicines regulation highlighted:

- a poor rate of compliance with the regulatory requirements;
- a lack of incentives for sponsors to comply with the legislation;
- a lack of clarity and understanding of the regulatory requirements; and
- community concern that the labels of complementary medicines fail to inform consumers that listed medicines have not been assessed against efficacy criteria.

The flow-on effect of non-compliance with the regulations is a reduction in community confidence in the existing regulatory framework and the TGA's oversight of therapeutic goods more generally.

Further, the lack of understanding within the community of the TGA's regulatory role in this area has led to misconceptions around the level of regulatory rigour that complementary medicine products undergo. There has been reported confusion surrounding the 'AUST L' number, which must be printed on the label of listed complementary medicines to demonstrate that they have been listed on the ARTG.

What the Government will do

To reduce the level of non-compliance by sponsors the TGA will (in consultation with stakeholders) update, and include in the regulations, the *Guidelines for the levels and kinds of evidence to support indications and claims.* The Electronic Listing Facility will also be amended to provide increased guidance and cautionary notes for sponsors about the potential consequences of providing misleading or unsubstantiated claims, and eliminate sponsors' access to free text.

The Government will examine the regulatory impact of options for enhancing sanctions and penalties for repeated breaches of the compliance requirements and the application, enforcement and publication of sanctions and penalties, including those relating to advertising breaches. These sanctions would include recalling products from the market that are removed from the ARTG as a result of regulatory action where circumstances warrant.

The TGA will work with stakeholders to develop options to improve labelling to help educate and assist consumers make informed decisions about the quality use of therapeutic goods.

Medical devices

Current regulatory arrangements of medical devices

The TGA regulates the quality, safety and performance of medical devices supplied in Australia, using a regulatory framework which allows inclusion of medical devices in the ARTG. The fundamental components of the framework set out requirements for safety and performance of a medical device and a classification system based on the risk the device presents to the patient, the user and the environment.

Medical devices are classified according to the intended purpose of the medical device and the degree of risk involved for the patient and user. The device classifications are determined through the *Therapeutic Goods (Medical Devices) Regulations 2002,* and take into account factors such as the degree of invasiveness in the human body, the duration and location of use and whether the device relies on a source of energy. The level of pre-market assessment of medical devices is commensurate with the risk classification. The lowest risk devices (Class I) including things like tongue depressors and bandages can be automatically included in the ARTG based on declarations given by the sponsor. The level of evidence required for higher risk devices increases with increasing risk classification.

The regulatory framework for medical devices includes provision for post-market monitoring by the TGA including checking evidence, conducting periodic inspections of a manufacturer's quality management systems and technical documentation (including documentation held by a sponsor), and imposing

specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices.

In addition to this, the TGA receives expert orthopaedic input on hip, knee and shoulder arthroplasty devices through the independent expert advisory committee, the Orthopaedic Expert Working Group (OEWG).

The National Joint Replacement Registry (NJRR), created through an arrangement with the Commonwealth Department of Health and Ageing, also provides post-market surveillance on joint replacement procedures carried out across Australia to ensure ongoing safety and efficacy of the medical devices implanted.

The Registry contains the most complete set of data relating to hip and knee replacement in Australia. The data is used to inform surgeons, other health care professionals, government bodies, including the TGA, orthopaedic device companies and the community.

Current issues

The current entry of products onto the ARTG allows for several devices from one sponsor to be included under a single device description. These individual devices may not appear distinctly on the ARTG. This makes it difficult to identify if a particular device is in fact listed on the ARTG or not, and makes it difficult to identify the products in the event of a recall of the device.

The Government recognises community concerns that have arisen with some joint replacement implants. This has led to calls to increase the pre-market scrutiny of these and other high risk prostheses.

In addition to this the Government is currently considering the Senate Community Affairs Reference Committee report, *Regulatory standards for the approval of medical devices in Australia,* (which was tabled on 22 November 2011) and will respond to the report in the first half of 2012.

What the Government will do

The Government will implement a number of reforms to the regulation of medical devices. The TGA has been asked to increase the rigour of pre-market regulatory assessment of higher risk medical devices, and to ensure an appropriate level of evidential review is undertaken to assure safety, quality and efficacy of these devices.

Following the HTA Review recommendations, a consultation paper, *Reforms in the Medical Devices Regulatory Framework*, was released in November 2010. In response to the comments received during the consultation process, the Government will reclassify the load bearing component of a hip, knee or shoulder joint replacement that functions in a similar way to the natural joint from Class IIb

(medium-high risk non-IVD medical devices) to Class III (high risk non-IVD medical devices).

The Government, in consultation with stakeholders, proposes to introduce two additional changes:

- the way in which a kind of medical device is included in the ARTG will be amended**.** Sponsors will be required to nominate product names under each ARTG entry for each kind of medical device, improving the ability of the TGA to facilitate the recall, if necessary, of medical devices. All ARTG entries for medical devices will need to include product name details related to the product; and
- the level of available product information on the TGA website relating to medical devices will be increased. This will improve the transparency of information about medical devices for consumers and health professionals.

The TGA will implement these proposals by amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002,* and will include an appropriate transition period.

Regulatory provisions relating to the use of third party assessment bodies and increasing premarket scrutiny of implantable medical devices are linked to recommendations of the recent Senate Community Affairs References Committee inquiry into 'The standards for the approval of medical devices in Australia' These remain under consideration and further consultation is planned.

Promotion of therapeutic products

Current arrangements for the promotion of therapeutic products

The professional relationship between health care practitioners and therapeutic goods companies is governed by industry and professional codes of conduct, not by government regulation.

A number of therapeutic goods industry associations have codes of conduct/practice which include guidelines on ethical and responsible business practices.

Current issues

From time to time, examples are highlighted of industry offering inducements to health professionals to promote products. This has the potential to influence clinical decisions on grounds other than the best interests of the patient. Strong and enforceable industry codes of conduct are effective in limiting unethical behaviour, but there needs to be consistency across industry codes in terms of their requirements, application, enforcement and penalties. This is currently lacking. There are also concerns that non-members of industry associations may not be bound by industry codes.

What the Government will do

The Government has been working with industry to address these issues and strengthen the self-regulatory framework. On 30 June 2010 the Government released a *Position Paper on Promotion of Therapeutic Goods* which proposed strengthening self-regulation and called on the therapeutic goods industry to develop common high-level principles as the basis for strengthening and aligning its codes of conduct. An industry-led working group was established and has developed a framework of high level principles, in consultation with healthcare professional and consumer representatives, to support consistent ethical standards.

The Government's preference is to maintain an emphasis on self-regulation and strongly supports industry's initiative to harmonise their codes of conduct to incorporate the working group's high level principles. The inclusion of these high-level principles into industry specific codes of conduct is a continuing process and the Government will consider the feasibility of establishing a committee to evaluate the work of industry bodies. Further changes will be considered if it is found that there is a need to provide greater encouragement to non-members of industry associations to nominate and sign up to an appropriate industry code, including the TGA seeking notification of a sponsor's nominated code of conduct at the point of including a product on the ARTG.

Resourcing

The Government's proposed reforms are fundamental to the appropriate operation of the regulatory frameworks that allow therapeutic goods to be supplied in the Australian marketplace and directly relate to that regulatory activity.

As has been the case since 1998, the full cost of regulating therapeutic goods will continue to be met by cost recovery from the regulated industry. This operates effectively under the Act through annual negotiations with relevant industry sectors.

In order to deliver the fundamental reforms, a modest increase in the TGA's fees and charges will be required. Any increases will be subject to the Australian Government's regulatory impact analysis requirements including the requirements for new or amended cost recovery activities as detailed in the *Australian Government Cost Recovery Guidelines*.

Reforms relating to the promotion of therapeutic goods sit outside the TGA and thus resourcing of that project will not be sought through cost recovery.

Implementation and governance of reforms

Plans for implementing the reform initiatives are currently being developed and will be made publicly available.

In addition to the usual governance processes applying to the TGA in its role as a Division of the Commonwealth Department of Health and Ageing, the Secretary of the Department of Health and Ageing has been asked by the Government to establish a high level steering committee to oversight all aspects of the implementation of these reforms. Progress on the reforms will also be reported to the newly formed Australian Therapeutic Goods Advisory Council and in biannual public consultative fora.

Correlation of recommendations

Appendix 1

Recommendations relating to:	Recommendation	Government response
Communication and stakeholder engagement	**Transparency Review - Rec 1** The TGA establish an Australian Therapeutic Goods Advisory Council, with membership representative of major stakeholder groups, to enable more effective stakeholder input into future directions and program implementation. The Council will have an oversight role in the implementation, ongoing monitoring, and evaluation of the recommendations of this review.	Agreed
	Transparency Review – Rec 2 The TGA define, adopt and publish consultation principles to guide regulatory transparency and accountability.	Agreed
	Transparency Review - Rec 3 The TGA develop and implement a comprehensive communication strategy to inform and educate. A dedicated communications team should be established within TGA to implement that strategy.	Agreed
	Transparency Review - Rec 4 The TGA work transparently with other key providers of information to enhance the information available to the public (community and stakeholders), consistent with the principles of the quality use of medicines.	Agreed
	Transparency Review - Rec 5 The TGA develop a plan to ensure information on the key public access portal, the TGA website, is current, accurate, relevant, timely and up to date, and meets the needs of its audiences.	Agreed

Recommendations relating to:	Recommendation	Government response
	Transparency Review - Rec 6 The TGA provide user-friendly information on the risk based framework under which it operates, including detailed explanations of how this operates for different classes of therapeutic goods. As a priority, the differences between registered and listed therapeutic goods, and their processes of evaluation, should be explained.	Agreed
	Transparency Review - Rec 7 The TGA implement mechanisms to educate and inform the public that listed medicines are not evaluated for effectiveness by the TGA prior to market.	Agreed
	Transparency Review - Rec 8 The TGA provide clear information on the role of its statutory advisory committees, and adopt a consistent and transparent approach to the publication of information from those committees.	Agreed
	Transparency Review - Rec 9 The TGA improve access and quality of information on the processes for regulation of advertising of therapeutic goods, including the complaint process and the outcomes of complaints.	Agreed
	Transparency Review - Rec 10 The TGA, in conjunction with key stakeholders, develop and publish agreed Key Performance Indicators to provide quantitative and qualitative information on the TGA's organisational effectiveness and operational efficiency. This may be achieved in conjunction with the proposed Australian Therapeutic Goods Advisory Council.	Agreed
	Transparency Review - Rec 11 The TGA develop and publish a policy on the disclosure of commercially confidential information, noting significant issues for	Agreed

Recommendations relating to:	Recommendation	Government response
	each therapeutic product type. The policy should take into account the practices followed by comparable international regulators.	
	Transparency Review - Rec 12 The TGA explore mechanisms for providing explanations on its various regulatory processes, and the TGA adopt publication principles on the outcomes of application assessments using as an exemplar the Australian Public Assessment Reports (AusPAR).	In-principle agreement with consultation to be undertaken with stakeholders to further develop options for consideration by the TGA.
	Transparency Review - Rec 13 The TGA assess and report on the feasibility of developing an on-line system for the submission and tracking of all applications for assessment, which enables the sponsor to ascertain the progress of an application.	Agreed with consultation to be undertaken with stakeholders to further develop options for consideration by the TGA.
	Transparency Review - Rec14 The TGA work with stakeholders to improve labelling and packaging requirements to educate and assist consumers and health practitioners to make informed decisions about the quality use of therapeutic goods.	The Government considers that there is capacity to improve labelling and packaging requirements and will further develop options in consultation with stakeholders.
	Transparency Review - Rec15 The TGA conduct, and report on, a feasibility study into the development of an early post-marketing risk communication scheme for therapeutic goods, with consideration of international models.	Agreed
	Transparency Review - Rec 16 The TGA actively promote the distribution of therapeutic goods safety information, and examine mechanisms for improving the timely	Agreed

Recommendations relating to:	Recommendation	Government response
	communication of alerts and recalls, to health practitioners and to consumers.	
	Transparency Review - Rec 17 The TGA explore mechanisms to maintain the currency of Consumer Medicines Information and Approved Product Information.	In-principle agreement with further consultation to be undertaken with stakeholders and development of options for consideration by the TGA.
	Transparency Review - Rec 18 The TGA progressively develop and implement a system to publish the outcomes of investigations and compliance actions taken.	Agreed
	Transparency Review - Rec 19 The TGA more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system.	Agreed
	Transparency Review - Rec 20 The TGA make its Adverse Events Database available to, and searchable by, the public in a manner that supports the quality use of therapeutic goods.	Agreed
	Transparency Review - Rec 21 The TGA work with State and Territory governments, stakeholders, and other relevant agencies, to improve the visible management of adverse event reporting in support of consumer safety and consistent with the findings of the Horvath Review into Immunisation.	Agreed

Recommendations relating to:	Recommendation	Government response
Complementary medicines	**The Auditor-General's report was tabled in Parliament on 30 August 2011**	
	Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 1 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	Agreed
	(b) provides regular progress reports on the development of key guidance documents on the TGA website, to keep industry, health professionals and consumers informed.	Agreed
	Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 2 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.	Agreed
	Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 3 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.	Agreed

Recommendations relating to:	Recommendation	Government response
	Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 4 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	Agreed
	(b) use the profiles to inform its program of post-market reviews.	Agreed
	Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines - Rec 5 The ANAO recommends that the TGA adopt a standard operating procedure for completing investigations of advertising breaches. In developing the procedure TGA should incorporate:	
	(a) appropriate timeframes for completing the investigations of advertising breaches; and	Agreed
	(b) the provision of regular reports to the TGA executive on progress with investigations and trends in non-compliance.	Agreed
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 1 Provide increased information:	

Recommendations relating to:	Recommendation	Government response
	(a) on product labels regarding regulatory assessment undertaken by TGA of complementary medicines; and	The Government considers that improvements in this area could increase public awareness of the regulation of complementary medicines and will work with stakeholders to develop options for consideration by Government.
	(b) on TGA website regarding regulatory assessment undertaken by TGA of complementary medicines.	Agreed
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 2a Modify Electronic Listing Facility system, to:	
	(a) include restriction or elimination of access by sponsors to 'free text'**.**	Agreed
	(b) Provide guidance and cautionary notes for sponsors using the Electronic Listing Facility, regarding the consequences of misleading and unsubstantiated claims.	Agreed
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 3 Update 'Guidelines for levels and kinds of evidence' and include 'Guidelines for levels and kinds of evidence' in regulation.	In-principle agreement with further consultation to be undertaken with stakeholders.
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 4 Review current 'coded indications' project based on the document	Agreed

Recommendations relating to:	Recommendation	Government response
	'Guidelines for levels and kinds of evidence' and either restrict or eliminate access by sponsors to 'free text' in the Electronic Listing Facility.	
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 5 Apply, enforce and publicise sanctions and penalties, including for advertising breaches, including recalling products from the market that are removed from the ARTG as a result of regulatory action, where circumstances warrant.	Agreed
	Informal Working Group Examining Complementary Medicines Regulation and Reasons for Low Compliance Rates - Rec 6 Enhance sanctions and penalties for repeated breaches of non-compliance (as well as strengthening sanctions and penalties for advertising).	Noted with further consultation with stakeholders to consider appropriate sanctions and penalties.
Medical devices	**Medical Device Reforms – Proposal 1** Reclassification of joint replacement implants.	Agreed
	Medical Device Reforms – Proposals 2A Use of third party assessment bodies for Australian manufacturers.	Noted. Linked to further recommendations in Senate Community Affairs References Committee inquiry into 'The regulatory standards for the approval of medical devices in Australia'.

Recommendations relating to:	Recommendation	Government response
	Medical Device Reforms – Proposal 2B Increasing pre-market scrutiny for implantable medical devices.	Noted. Linked to further recommendation in Senate Community Affairs References Committee inquiry into 'The regulatory standards for the approval of medical devices in Australia'.
	Medical Device Reforms – Proposals 2C Recognition of third party assessment bodies.	Noted. Linked to further recommendation in Senate Community Affairs References Committee inquiry into 'The regulatory standards for the approval of medical devices in Australia'.
	Medical Device Reforms – Proposal 3(i) Amend the way in which a kind of medical device is included in the ARTG.	The Government will look at options to improve the way medical devices are included on the ARTG in consultation with stakeholders.
	Medical Device Reforms – Proposal 3(ii) Enhance the ability to identify devices that have been approved by the TGA for supply in Australia by having the ARTG identifier on the label.	Not agreed. Proposal not supported as other reforms will achieve this objective.
	Medical Device Reforms – Proposal 4 Publication of device product information on the TGA website.	The Government will look at options for publication on the TGA website in consultation with stakeholders.

Recommendations relating to:	Recommendation	Government response
Advertising of therapeutic products	**Advertising consultation – Rec 1** Publish the report on advertising reform on the website, once finalised.	Agreed
	Advertising consultation – Rec 2 Reforms to advertising framework.	The TGA will further consult with stakeholders on appropriate reforms to the advertising framework.
	Advertising consultation – Rec 2a. Modify pre-approvals process to include medical devices and pay TV (advertising claims about the efficacy of a product to be assessed by the TGA).	In-principle agreement with further consultation to be undertaken with stakeholders and development of options for consideration by Government.
	Advertising consultation – Rec 2b. Establish a single entry point for all complaints, with some handled by TGA (complaints about the efficacy of a product to be assessed by the TGA).	Agreed
	Advertising consultation – Rec 2c. Develop a more effective approach to sanctions and penalties (including use of the infringement notice provisions).	The Government will look at options to introduce more effective approaches to sanctions and penalties in consultation with stakeholders.
Promotion of therapeutic products	**Working Group on Promotion of Therapeutic Products - Rec 1** The artificial difference in the Position Paper between 'high risk' and 'low risk' products be set aside, with application of a sector specific industry code to be determined by coverage of the relevant	Supported

Recommendations relating to:	Recommendation	Government response
	therapeutic sector to a specific product.	
	Working Group on Promotion of Therapeutic Products - Rec 2 Consistency of therapeutic sector industry codes of practice be facilitated by each therapeutic industry association, incorporating in its code the high level principles, operational coverage areas and governance provisions developed by the working group.	Supported
	Working Group on Promotion of Therapeutic Products - Rec 3 Each industry association must determine the steps required to be taken to implement the working group's recommendation 2, and the time by which these steps will be completed. Each industry association will advise the Government of the anticipated completion date for implementation.	Supported Noting that industry associations have indicated that the target timeline for completion of code revisions is 2014.
	Working Group on Promotion of Therapeutic Products - Rec 4 Information on therapeutic industry codes be made available to the public via the internet, with access to the complaints processes and links to each of the applicable codes. The industry associations will work with the Government to identify the most appropriate vehicle to make the information available.	Noted Improves access to information responds to consumer concerns and will strengthen self-regulation.

Recommendations relating to:	Recommendation	Government response
	Working Group on Promotion of Therapeutic Products - Rec 5 TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing on the ARTG.	Not supported as currently proposed. Departs from self-regulatory model. The Government's preference is to maintain the current self-regulatory focus. If after industry codes have been updated, further encouragement is required for non-members to nominate a code, the Government will consider further legislative measures including the TGA seeking this information
	Working Group on Promotion of Therapeutic Products - Rec 6 TGA provide on the ARTG public summary for each product, information on the nomination of an industry code, in a searchable format.	Noted Cannot be implemented separately to Recommendation 5.
	Working Group on Promotion of Therapeutic Products - Rec 7 Industry associations work with TGA to develop a process for notification to an association when an applicant nominates that association's code of practice.	Not supported as currently proposed. Departs from self-regulatory model as TGA is co-opted as an intermediary between industry associations and product sponsors.

Recommendations relating to:	Recommendation	Government response
	Working Group on Promotion of Therapeutic Products - Rec 8 Industry associations develop comprehensive training programs on the codes to ensure that non-members (as well as members) are educated on the requirements of the relevant code.	Supported
	Working Group on Promotion of Therapeutic Products - Rec 9 The effectiveness of voluntary registration be evaluated annually and that consideration be given to mandatory nomination of a code if voluntary registration proves ineffective to achieve the Government's objectives.	Noted Evaluation prior to 2014 may be premature given industry's advice on when their codes may be revised and operational. Further work with industry associations will be required to identify the most appropriate evaluation methodology.
	Working Group on Promotion of Therapeutic Products - Rec 10 AHPRA and AHMAC be encouraged to advocate changes to health professional codes to more closely reflect the mutuality of obligations between industry and healthcare professionals, to ensure ethical promotion of therapeutic products.	The Government will refer this matter to AHPRA and National Boards.
	Working Group on Promotion of Therapeutic Products - Rec 11 The healthcare professional colleges and associations actively pursue alignment of their professional codes and/or guidelines to be consistent with the principles and areas of operational coverage.	The Government will refer this matter to National Boards and professional colleges.

Recommendations relating to:	Recommendation	Government response
	Working Group on Promotion of Therapeutic Products - Rec 12 Education on relationships with the therapeutic industry be included in the training of healthcare professional students, in addition to education on the healthcare professional codes and guidelines.	The Government will refer this matter to healthcare professional associations and/or education bodies.
	Working Group on Promotion of Therapeutic Products - Rec 13 An educative complaints portal be established as a mechanism to assist channelling complaints to the appropriate industry association. The industry associations will work with the Government to identify the most appropriate vehicle for this purpose.	Noted Strengthens access to information, communication and universal adherence to consistent industry-wide codes. Further work by industry associations will be required to identify options, expectations regarding lines of responsibility and mechanisms for effective implementation.
	Working Group on Promotion of Therapeutic Products - Rec 14 Each industry association provides on its website, a link to the complaints mechanism for each other therapeutic industry sector.	Supported
	Working Group on Promotion of Therapeutic Products - Rec 15 The industry associations actively engage in the education on and dissemination of the outcomes of the deliberations of the working group, with assistance from the Government as appropriate.	Noted Further work by industry will be required to identify the need and scope for Government assistance and the capacity to fulfil within existing resources.

Recommendations relating to:	Recommendation	Government response
	Working Group on Promotion of Therapeutic Products - Rec 16 The establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group.	Noted Further work by industry will be required to identify mechanisms for evaluation.
	Working Group on Promotion of Therapeutic Products - Rec 17 The Government form a permanent advisory group, similar in composition to the working group, with responsibility for the oversight of implementation of the working group's recommendations, and with a mandate to regularly report to Government on the effectiveness of the implementation against the evaluation criteria set out above.	Noted Proposal for continuing involvement of government departs from a self-regulatory approach. Further work will be required to identify an appropriate role, membership and source of resourcing of such a group.
	Working Group on Promotion of Therapeutic Products - Rec 18 The Government review the National Medicines Policy (NMP) and consider replicating its policy coverage through the development of analogous policies for other therapeutic product sectors.	Not supported as currently proposed.