# Working Group on Promotion of Therapeutic Products

# Report to Parliamentary Secretary Catherine King

# 18 March 2011

## Contents

## Glossary of acronyms

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|---|---|
| **ACCC** | Australian Competition and Consumer Commission |
| **ADIA** | Australian Dental Industry Association |
| **AHPRA** | Australian Health Practitioners Registration Authority |
| **AHMAC** | Australian Health Ministers' Advisory Council |
| **ARTG** | Australian Register of Therapeutic Goods |
| **ASMI** | Australian Self Medication Industry |
| **CHC** | Complementary Healthcare Council |
| **FCPA** | Foreign Corrupt Practices Act of 1977 (US) |
| **GMiA** | Generic Medicines Industry Association |
| **IVDA** | IVD Australia |
| **MA** | Medicines Australia |
| **MTAA** | Medical Technology Association of Australia |
| **NMP** | National Medicines Policy |
| **TGA** | Therapeutic Goods Administration |
| **WHO** | World Health Organization |

## 1. Executive summary

The ethical promotion of therapeutic products is central to the trust-based framework within which healthcare professionals advise and treat patients. The therapeutic product industries necessarily work closely with healthcare professionals to develop evidence-based approaches to particular treatments, in the development of educational materials on the correct use of products, and to support hands-on learning in the correct use of certain products. However the fundamental trust, and the value of the relationship, can be undermined where the independence of decision-making by healthcare professionals may be seen to be compromised by inappropriate promotion which is not in the best interests of patients or consumers, and which can add to the cost of healthcare.

To deal with these concerns, in June 2010 the Australian Government released a Position Paper with the objective of ensuring that decisions on management (including treatment options) for health needs are based on sound clinical evidence, not driven by incentives or other influences. The Government was also concerned to ensure that self-regulatory therapeutic industry codes of conduct are effective in minimising the potential for any promotional activities to compromise the quality use of medicines and to increase cost pressures on the health system.

In Australia there are a number of industry associations which represent different therapeutic industry sectors. Many of the associations have codes of conduct which apply to members of the associations. However these codes do not have uniform coverage, nor are they enforceable to address the behaviour of non-members of the associations. The Position Paper sought mechanisms to ensure a level playing field across the therapeutic sectors, and between members and non-members of industry associations. It also noted the need to ensure the standards for conduct of health care professionals align with the standards expected of the therapeutic products industries.

The working group established to respond to the Position Paper has considered the public submissions received, the current coverage of the industry codes, and possible mechanisms to extend code compliance to non-members of associations.

The working group developed a high level statement of the principles to be incorporated in each therapeutic industry sector code, together with a statement of the obligations on companies operating in the industry covered by the code. The high level statement of principles provides that the Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties. In this context the quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumers' needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

Therapeutic industry sector codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant

community. The therapeutic industry sectors have committed to collaborating with relevant stakeholders in code creation, updating, education, monitoring and compliance.

The working group has recommended that each therapeutic industry sector code include provisions which address the following operational areas:

- Gifts and offers
- Industry-sponsored educational events
- Conduct of company representatives
- Consulting arrangements with healthcare professionals
- Shareholdings and/or other financial interests by healthcare professionals in therapeutic product companies and/or products
- Hospitality and entertainment
- Research and education grants
- Promotional claims/advertisements to healthcare professionals
- Surrogate medical writing ('ghost' writing)
- Sponsorship of third party educational conferences
- Celebrity endorsements
- Direct to consumer advertising
- Funding of patient groups
- Product samples
- Disease awareness campaigns
- Use of social media in promotions directed to healthcare professionals.

The working group has recommended that each therapeutic industry code include provisions which address governance areas for the effective implementation of the code by companies in each therapeutic industry sector:

- Education on the code's operation
- Monitoring of compliance with the code
- Enforcement of the code in response to a complaint or a breach
- Sanctions to support the enforcement.

The working group considered the requirements on companies within an industry sector which need to be incorporated in an industry code. The working group has recommended that each therapeutic industry code provide that sponsors of therapeutic products meet their obligations under the code by:

- Adhering to the ethical promotion of therapeutic products
- Providing products that conform to the highest relevant standards of safety, efficacy and quality as established by TGA
- Maintaining trust and confidence in the industry through transparency and accountability
- Respecting ethical requirements and codes of practice which apply to healthcare professionals
- Upholding not just the letter of the Code but also the spirit of the Code
- Having in place a comprehensive process to monitor behaviour and deal with complaints
- Remedying behaviour if found to be in breach of the Code
- Being entitled to fair and equitable treatment under the Code.

The working group addressed the need for adherence to industry codes by non-members as well as members by recommending that an applicant nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing/inclusion of a product on the ARTG.

The working group also considered the need for alignment of the codes which govern the behaviour of healthcare professionals with the industry codes, incorporating high level ethical principles and recognising the mutuality of these relationships. The working group has recommended ongoing engagement with the bodies responsible for the codes which govern healthcare professionals to encourage increased alignment of coverage of the codes

The working group sees merit in the establishment of an advisory body with stakeholder representation from industry, healthcare professional bodies and consumer interests to monitor the implementation of its recommendations. It also emphasises the need for education on ethical obligations, for both industry and healthcare professionals, including healthcare professional students. Education should be extended to members and non-members of industry associations.

## Recommendations

### Recommendation 1

The working group **recommends** that 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 therapeutic sector to a specific product.

### Recommendation 2

The working group **recommends** that 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 and detailed in Appendix B to this report.

### Recommendation 3

Each industry association must determine the steps required to be taken to implement 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. The indicative dates for completion are detailed in Appendix C to this report.

### Recommendation 4

The working group **recommends** that 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..

**Recommendation 5**

The working group **recommends** that 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.

**Recommendation 6**

The working group **recommends** that TGA provide on the ARTG public summary for each product, information on the nomination of an industry code, in a searchable format.

**Recommendation 7**

The working group **recommends** that the industry associations work with TGA to develop a process for notification to an association when an applicant nominates that association's code of practice.

**Recommendation 8**

The working group recommends that the 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.

**Recommendation 9**

The working group **recommends** that 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 as outlined in the Position Paper.

**Recommendation 10**

The working group **recommends** that 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.

**Recommendation 11**

The working group **recommends** that 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 outlined in Appendix B to this report.

**Recommendation 12**

The working group **recommends** that 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.

**Recommendation 13**

The working group **recommends** that an educative complaints portal be established as a mechanism to assist channeling complaints to the appropriate industry association. The industry associations will work with the Government to identify the most appropriate vehicle for this purpose.

**Recommendation 14**

The working group **recommends** that each industry association provide on its website a link to the complaints mechanism for each other therapeutic industry sector.

**Recommendation 15**

The working group **recommends** that 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.

**Recommendation 16**

The working group **recommends** the establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group. In particular the evaluation should address the evaluation criteria set out in Appendix C to this report.

**Recommendation 17**

The working group **recommends** that the Government form a permanent advisory group, similar in composition to the working group, with responsibility for the oversight of implementation of the recommendations and with a mandate to report to Government on a regular basis on the effectiveness of the implementation against the evaluation criteria set out above.

**Recommendation 18**

The working group **recommends** that the Government review the National Medicines Policy and consider replicating its policy coverage through the development of analogous policies for other therapeutic product sectors.

## 2. Position Paper on Promotion of Therapeutic Goods

On 30 June 2010 the then Parliamentary Secretary for Health, Mark Butler, issued a *Position Paper on the Promotion of Therapeutic Goods*[1]. The policy objective outlined in the Position Paper is that the Government aims to ensure that decisions on management (including treatment options) for health needs are based on sound clinical evidence, not driven by incentives or other influences. Further, the Government view is

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation%3A+Position+Paper+on+the+Promotion+of+Therapeutic+Goods

that self-regulatory therapeutic industry codes of conduct need to be effective in minimising the potential for any promotional activities to compromise the quality use of medicines and to increase cost pressures on the health system.

To address the issues outlined in the Position Paper, Mr Butler appointed Anne Trimmer, Chief Executive Officer of the Medical Technology Association of Australia, to chair a working group of industry, clinician and consumer representatives. The members of the working group are detailed in Appendix A. All key therapeutic industry associations are represented, as well as many of the peak healthcare professional bodies. In addition to the members of the working group, a wider group of interested healthcare professional and industry groups has been kept informed about the activities of the working group.

The re-elected Labor Government, under the direction of Parliamentary Secretary for Health Catherine King, endorsed the continuation of the work of the working group.

Prior to the release of the Position Paper, the Government had identified concerns about actual or perceived weaknesses in the current arrangements for self-regulation by therapeutic industry associations[2]. The issues included the need for high level principles underpinning sector specific codes and the structure of the complaints system. The working group was concerned about the inconsistency of provisions between existing codes, and between members and non-members of the industry associations.

The Position Paper outlined several objectives to be achieved from the deliberations of the working group. These included:

- The strengthening and standardisation of industry self-regulation through development of an industry framework for consistent industry-wide codes based on a common set of high level principles
- Mechanisms to ensure compliance by both members and non-members of industry associations with a relevant code of conduct
- Reciprocal arrangements with health care professionals to ensure consistent ethical standards for the interaction of health care professionals with the therapeutic goods industry.

The working group has addressed each of these objectives. The outcome of its deliberations is set out in detail in sections 5 to 8.

## 3. Therapeutic products industries and codes of practice

The therapeutic products industries are very diverse, ranging from research-based medicine, biotechnologies, medical devices, dental products and in-vitro diagnostics to complementary healthcare and pharmacy products. Therapeutic products are regulated using a risk based approach by the government regulator, the Therapeutic Goods Administration (TGA). Regulatory oversight includes a number of controls on the advertising of therapeutic products to consumers[3].

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2 http://www.health.gov.au/internet/ministers/publishing.nsf/Content/983FEEB3394F5CFECA2577520017090 6/$File/mb039.pdf

3 http://www.tga.gov.au/docs/html/advmed.htm

The promotion of therapeutic products to healthcare professionals and those with responsibility for purchasing decisions is largely[4] regulated by the industry, usually by means of codes of practice developed by the industry association representing a sector.

The therapeutic products industries strongly support self-regulation. It is evidence of a mature and responsible industry that it provides a framework for industry participants to guide ethical behaviour. Companies which are members of an industry association with a code are bound by it as a condition of membership and take their responsibilities seriously under the code. Non-member companies are not obligated, but are encouraged, to observe the code, as an industry standard. A breach of the code, if established by the complaints process, can result in significant financial penalties. In addition, in some cases the findings are made public on the association's website and in its Annual Report. The opprobrium that goes with such a finding can be damaging to a company's reputation.

The industry associations with well-developed code monitoring and enforcement provisions use independent stakeholder representatives with specific and defined experience to populate the committees which undertake those functions. While there is industry representation on both the monitoring and complaints committees, the industry representation is in the minority, with other stakeholders drawn from the relevant healthcare professionals, other users of the relevant therapeutic products, and consumers.

The coverage and content of the codes of practice are also influenced by other factors. In some cases the codes in Australia draw on international codes within the same industry. In other cases the codes reference, or are influenced by, the ethical principles of bodies such as the World Health Organization. In Australia the pharmaceutical industry is a partner in the National Medicines Policy which sets a framework for the quality use of medicine, which incorporates ethical promotion of medicines. Additionally the codes usually reflect applicable legislation such as the *Competition and Consumer Act* 2010 and the *Therapeutic Goods Act* 1989.

The ethical promotion of therapeutic products to healthcare professionals has become an area of significant focus in many jurisdictions in recent years. As part of the healthcare reforms introduced in the United States by President Barack Obama, legislation has mandated the federal introduction of so-called 'sunshine provisions' which require open disclosure by pharmaceutical and medical device companies of all financial relationships with healthcare professionals.

The Physician Payment Sunshine Act was included among the provisions of the Patient Protection and Affordable Care Act, 2010[5]. The law requires that payments of cash or in-kind transfers to physicians or teaching hospitals must be reported. The US Department of Health and Human Services is establishing a website where notification of payments will be publicly accessible. The payments include compensation; food, entertainment and gifts; travel; consulting fees, research funding or grants; education or

[4] http://www.tga.gov.au/advert/advpmhcp.htm

[5] Patient Protection and Affordable Care Act Pub.L. 111–148, 124 Stat. 119, H.R. 3590, enacted March 23, 2010.

conference funding; stocks or stock options; ownership or investment interest; royalties or licences; and charitable contributions.

The legislation contains significant financial penalties for companies which fail to report the required information on time. Implementation of the reporting requirements will be phased in over the next two years.

In both the United States and the United Kingdom, the government has implemented legislation to extend the reach of government oversight to the dealings of agents and distributors in third countries[6]. Australia also has laws which prohibit the provision of a benefit to a foreign public official with the intention of influencing that official[7]. The UK Bribery Act comes into effect in April 2011 and is wider in scope than the US Foreign Corrupt Practices Act (FCPA). It applies to any corporation or partnership (no matter where it is registered or carries on its activities), provided that at least some of its activities are carried on in the UK. The Act makes it an offence to receive as well as give a bribe. Bribery of private individuals and companies is criminalized and there is no need to prove corrupt intent. Unlike the FCPA there is no exemption for facilitation payments.

## 4. Submissions and consultations on Position Paper

In releasing the Position Paper the Government called for public submissions. A total of 37 submissions were received[8].

The submissions canvassed a number of themes:

- A concern that the Position Paper focuses on higher risk products, ignoring the fact that many problems arise in the promotion of 'lower risk' products
- A view that the Therapeutic Goods Act must provide, as a condition of product licence, that industry commits to transparent self-monitoring, independent monitoring, Code adherence, complaint resolution procedures and education on ethics
- A concern that all therapeutic goods suppliers be covered by a code and that non-members not 'free-load' on members of the industry associations which establish monitoring and complaints mechanisms at the cost of the members
- A proposal that one over-arching principles-based code of practice be established to apply to all therapeutic claims and promotional practices with either an expert committee or a statutory body to provide one monitoring process, one complaint (and appeal) process and one set of effective sanctions, funded by government
- A view that self-regulation is ineffective or of limited efficacy and that some form of government oversight is necessary. The contrary view was put by some industry associations that government regulation should be a last resort

[6] Foreign Corrupt Practices Act (US) 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq. (FCPA); Bribery Act 2010 (UK)

[7] *Criminal Code Act1995* Cth, Schedule Division 70

[8] http://www.health.gov.au/internet/main/publishing.nsf/Content/Consultation%3A+Position+Paper+on+the+Promotion+of+Therapeutic+Goods

- The need for promotion of therapeutic products to align with the WHO Ethical Criteria for Medicinal Drug Promotion
- The need to have reciprocal provisions in healthcare professional codes with an appropriate mechanism to ensure compliance.

The working group considered the submissions in its deliberations.

The Position Paper identified various agencies with which the working group should consult. These include the National Medicines Policy (NMP) Committee and the Australian Health Practitioner Regulation Authority (AHPRA). In addition the Chair of the working group has consulted with the Australian Competition and Consumer Commission (ACCC), given its oversight of industry codes of practice.

The NMP Committee considered the consistency of the report with the National Medicines Policy objectives and principles and provided comments which have been taken into account in the drafting of this report and its recommendations.

The NMP Committee agreed that medicines and other therapeutic products should be brought under the same policy framework as a reflection of the changing environment in relation to health technologies. However it considered that a separate, but aligned, policy should be developed to cover other therapeutic products which is consistent with, and adopts, the principles and objectives of the national Medicines Policy, as opposed to reviewing and extending the existing policy. The NMP Committee gave as its reasons for this approach the differences between medicines and other therapeutic products, particularly in relation to registration (related to safety and efficacy) and reimbursement (relating to cost-effectiveness), and the need to mitigate confusion.

In addition the NMP Committee believes that the NMP advisory structure provides a successful governance framework for the provision of advice on the future implementation of the policy and it was unclear to the Committee how governance arrangements would effectively operate if the policy was to be extended.

Comments by the ACCC on the implications for the industry associations of the application of industry codes to non-members are addressed in section 6.

The Chair of the working group consulted with TGA on mechanisms to enable nomination of an industry code by a non-member of an association. This issue is addressed in section 6.

## 5. Alignment and consistency of industry codes

Eight therapeutic industry associations participated on the working group:

- AusBiotech
- Australian Dental Industry Association (ADIA)
- Australian Self Medication Association (ASMI)
- Complementary Healthcare Council (CHC)
- IVD Australia (IVDA)
- Generic Medicines Industry Association (GMiA)
- Medical Technology Association of Australia (MTAA)

- Medicines Australia (MA).

The maturity and scope of the codes of practice of each of the associations varies considerably. Some are long-established and very comprehensive. Some have been in place for a long time but are less comprehensive. Some have been adopted more recently. Some associations have provisions that are more in the nature of statements of principle rather than fully-fledged codes. Links to each of the codes of practice as at 1 January 2011 can be found at Appendix D.

The working group developed a high level statement of the principles that should be incorporated in a therapeutic industry code, together with a statement of the obligations on companies operating in the industry covered by the code. These are collected in Appendix B.

The high level statement of principles is as follows:

*The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means:*

- *Selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;*
- *Choosing suitable therapeutic products if this is considered necessary; and*
- *Using therapeutic products safely and effectively.*

*Therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community.*

*Therapeutic products industry sectors will collaborate with relevant stakeholders in code creation, updating, education, monitoring and compliance.*

*A therapeutic industry code must include provisions addressing the following operational areas:*

- *Gifts and offers*
- *Industry-sponsored educational events*
- *Conduct of company representatives*
- *Consulting arrangements with healthcare professionals*
- *Shareholdings and/or other financial interests by healthcare professionals in therapeutic product companies and/or therapeutic products*
- *Hospitality and entertainment*
- *Research and education grants*
- *Promotional claims/advertisements to healthcare professionals*
- *Surrogate medical writing ('ghost' writing)*
- *Sponsorship of third party educational conferences*
- *Celebrity endorsements*
- *Direct to consumer advertising*
- *Funding of patient groups*

- *Product samples*
- *Disease awareness campaigns*
- *Use of social media in promotions directed to healthcare professionals.*

*A therapeutic industry code must include provisions addressing the following governance areas:*

- *Education on the code's operation*
- *Monitoring of compliance with the code*
- *Enforcement of the code in response to a complaint or a breach*
- *Sanctions to support the enforcement.*

For the purpose of its deliberations, the working group agreed that it would be useful to have definitions of 'promotion' and 'ethical promotion', taking into account the World Health Organization's statement on *Ethical Criteria for Medicinal Drug Promotion*[9]. These terms are used, or implied, in the obligations on companies.

*'Promotion' in relation to a therapeutic product, means any communication or activity by a sponsor to a healthcare professional that, directly or indirectly, encourages the use, acquisition or other supply of a therapeutic product, by purchase, sale or otherwise, or discourages such use, acquisition or supply of a therapeutic product.*

*'Ethical promotion' includes:*

- *Promotion only of therapeutic products that are legally available in Australia and then only where permitted under therapeutic goods legislation;*
- *Claims made that are reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They do not include misleading or unverifiable statements or omissions likely to induce unjustifiable use of product or give rise to undue risks;*
- *Comparison of products is factual, fair, and substantiated; and*
- *Promotional activities do not, directly or indirectly, involve misleading, deceptive, unfair or unconscionable conduct, or offer inappropriate inducements.*

The working group considered the requirements which companies within an industry sector must observe, to be incorporated in an industry code.

*A therapeutic industry code must provide that sponsors of therapeutic products will meet their obligations under the code by:*

- *Adhering to the ethical promotion of therapeutic products*
- *Providing products that conform to the highest relevant standards of safety, efficacy and quality as established by TGA*
- *Maintaining trust and confidence in the industry through transparency and accountability*
- *Respecting ethical requirements and codes of practice which apply to healthcare professionals*

[9] The definition draws on WHO Ethical Criteria for Medicinal Drug Promotion (with minor modifications), http://apps.who.int/medicinedocs/en/d/Jwhozip08e/

- *Upholding not just the letter of the Code but also the spirit of the Code*
- *Having in place a comprehensive process to monitor behaviour and deal with complaints*
- *Remedying behaviour if found to be in breach of the Code*
- *Being entitled to fair and equitable treatment under the Code.*

Given the diversity of codes and the level of maturity in implementing complaints and sanctions processes under the codes, the industry associations considered four options to address the Position Paper's objective of achieving consistency. These were:

- Option 1 – high level principles are embedded in each industry association code
- Option 2 – high level principles are embedded in each industry association code plus operational coverage relevant to industry sector (to be drafted by each association for inclusion in its code) plus governance provisions (at a minimum a code requires provisions dealing with monitoring, complaints, sanctions) and education of company personnel. ACCC guidelines on development of an industry code should be referenced to assist drafting
- Option 3 – high level principles in a model code with annexes with specific operational coverage which varies depending on the industry sector
- Option 4 – one code (containing industry-specific provisions) and one governance body for education, monitoring, complaints and sanctions with independent evaluation (served by industry-specific panels).

Having considered each of these options, the industry associations agreed on option 2 as the recommended option as providing a degree of flexibility and most likely to be able to be implemented within a short time frame. The industry associations also thought that option 3 might be achievable in a longer timeframe. Option 4 would require all industry associations to create and incorporate a common governance body. This was not regarded as feasible because it does not provide sufficient flexibility to differentiate between the therapeutic sectors and the business environment in which companies operate, however it would have the benefit of providing a single body responsible for education, monitoring complaints and evaluation.

The associations also agreed that option 1 does not provide sufficient direction to achieve alignment. This consensus was reached notwithstanding that the Position Paper had specified only that the associations have a consistent set of high level principles. When the industry associations considered the capacity to enforce the codes, it became apparent that high level principles would not of themselves provide sufficient substance against which to ensure consistency between the codes and enforceability between members and non-members.

The recommended option (option 2) has been accepted by the working group as a whole as a workable compromise to ensure sufficient information to enable an assessment of the effectiveness of the new arrangements when progress is evaluated (see further at section 9). In discussion with the ACCC, option 2 was also seen to address the minimum requirements for an effective industry code of practice. The ACCC publishes guidelines to assist industries to develop self-regulatory codes[10].

10 http://www.accc.gov.au/content/item.phtml?itemId=658186&nodeId=c84e7c9517b774a9d75a2dc613174209

The Position Paper referred to coverage by the industry codes of 'higher risk' products. This differentiation concerned the working group. The legislation that applies to therapeutic products does not differentiate along a clear-cut axis between 'lower risk' and 'higher risk'. Determining the coverage of products that are within, or outside, the application of the codes would become problematic. The solution recommended by the working group is to remove this notional differentiation and to rely on industry sector coverage, not product categorisation. The codes of practice operate on the basis of application to a particular sector of the therapeutic industries, and to the companies which operate within that sector. The solution is to have an applicant sign on to a code by relevance of its sector, not by product risk. Industry sectors involving promotion to healthcare professionals include sponsors of medicines (research-based, generic and over-the-counter), medical devices, biotechnology, in-vitro diagnostics, dental products, and complementary healthcare products.

The working group recognises that some companies have multiple internal business divisions with the result that a company may operate across more than one sector. In those cases the company would nominate the code which is relevant to that product division or sector (which is the way in which companies operate now with multiple business divisions and therefore different codes applying). The benefit for these multi-sector companies is that the codes with which they are complying will now be aligned and consistent, thereby addressing the challenge of complying with multiple conflicting code requirements.

The list of operational areas to be addressed in each code is not finite but represents common areas of industry activity. It therefore reflects the minimum areas of coverage. Each industry sector might also address additional areas of activity that are pertinent to that sector.

Option 2 mandates the inclusion of the list of requirements to address monitoring, enforcement and sanctions. The working group did not see it as its role to mandate the nature of the arrangements for monitoring or enforcement. These will be addressed by each industry association in its own code. The effectiveness of the arrangements will become one of the subject areas for evaluation. The working group has also identified the education of company personnel as a key requirement in embedding code compliance.

There are practical considerations in requiring each industry code of practice to provide for monitoring, enforcement and sanctions. The industry associations currently fund the monitoring of code compliance (at the cost of members, or paid for out of fines paid by a company in breach). For the smaller associations it may not be possible to establish a stand-alone monitoring or complaints mechanism. The industry associations have considered different models for the practical management of these requirements to ensure a robust monitoring and complaints system that does not disadvantage the members of an association. These include:

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&fn=Guidelines%20for%20developing%20effective%20voluntary%20industry%20codes%20of%20conduct.pdf

- Model 1 – an industry association may constitute its own monitoring and enforcement mechanism within the scope of mandated requirements[11]
- Model 2 – an industry association without existing monitoring and enforcement mechanisms to meet the mandated requirements, may nominate another association's mechanism on a fee for service or other cost recovery arrangement. This leaves in place those industry association arrangements which meet the mandated requirements
- Model 3 - an industry association without existing monitoring and enforcement mechanisms that meet the mandated requirements, may nominate an independent organisation to undertake monitoring and enforcement on its behalf. The processes of the independent organisation would be fee for service (cost-recovered) with terms of reference and membership that align with the mandated requirements.

The increased cost of administering a monitoring and complaints process which involves non-members might be met out of fines collected through the complaints and sanctions processes or through levy of a fee on non-members.

The industry associations also considered the issue of quantum of sanctions, recognising that the companies within the therapeutic industries vary widely in their size and capacity to meet a financial sanction for breach of a code. The working group considered that each code should have the level of sanction which would effectively deter non-compliance within that industry sector. The issue of equality of sanctions can be reviewed when the effectiveness of the reforms is evaluated to see if any disparity in sanction levels has caused unintended consequences.

A further important component of some of the existing industry codes of practice is the requirement for education of company personnel on the content of the codes. This is mandatory under some codes[12]. Industry associations will need to develop training arrangements to ensure that the code requirements are well-understood across the industries, particularly by the personnel of non-member companies which sign on to a code. The personnel within those companies may not have had any exposure to the requirements of codes of practice. This can be done by a variety of means. MTAA and MA, for example, provide online training programs on the code which can operate as part of a company training program.

**Recommendation 1**

The working group **recommends** that the artificial difference between 'high risk' and 'low risk' products in the Position Paper be set aside, with application of a sector specific industry code to be determined by coverage of the relevant therapeutic sector to a specific product.

**Recommendation 2**

The working group **recommends** that consistency of therapeutic sector industry codes of practice be facilitated by each therapeutic industry association incorporating in its

[11] At the time of this report, MA, MTAA, GMiA and ASMI have these arrangements in place
[12] See, for example, section 6 of the MA Code, section 7.2 of the MTAA Code

code the high level principles, operational coverage areas and governance provisions developed by the working group and detailed in Appendix B to this report.

## 6. Application of industry codes to non-members of industry associations

The Position Paper proposed a mechanism as part of the product registration process whereby an applicant for registration of a product on the ARTG would nominate the relevant industry sector code by which it would be bound. The Position Paper makes it clear that the intention is not to require applicants to become members of an industry association, but rather that a level playing field is created between members and non-members in that all will be required to operate within the terms of the nominated code of practice.

To ensure that there is no 'forum shopping' among applicants, a company would be required to sign on to the therapeutic industry code that aligns with a therapeutic sector with coverage of the product. As all codes will address the same operational areas, and have monitoring and enforcement requirements an applicant will not benefit from shopping around for a more lenient code.

The working group notes that the Government's intention is for the 'sign on' process to be voluntary in the first instance. If, on evaluation, there is limited voluntary sign on to a relevant code, the Government has indicated it will move to mandate the requirement by legislation. The working group is concerned that voluntary nomination may not be effective to achieve the Government's objectives and that code nomination should be made a mandatory part of product registration. There is a precedent for this approach, as the 'registration approval' letters issued by the TGA's Drug Safety and Evaluation Branch contain a condition that promotional material for prescription medicines must comply with the requirements of the Code of Conduct of Medicines Australia[13].

The process by which an applicant will nominate a relevant code of practice will need to be developed by the industry associations working with the TGA and then instituted by the TGA. There will also need to be a mechanism for the industry associations to be made aware when a non-member has nominated that association's code in order to enable effective monitoring of that company's activities.

There will need to be a process to capture non-member companies that have existing products registered on the ARTG. Companies' business divisions with existing products already registered on the ARTG could have a defined period in which they would be required to nominate which industry code of conduct to which they will adhere. The nomination should also be identifiable in the ARTG public summary document, in a searchable format so that compliance can be determined over time.

The Chair has had preliminary discussions with the TGA regarding processes that need to be in place to ensure that applicants:

- Are aware of the requirement to sign on to a relevant therapeutic industry code

[13] http://www.tga.gov.au/advert/advpmhcp.htm

- Understand which code is relevant to a particular product registration application
- Can access the codes
- Can nominate a code, as a condition of product licence.

The Chair consulted with the ACCC to identify the implications for the industry associations in extending code coverage to non-members of the associations. In certain circumstances the ACCC is able to grant immunity from legal action for conduct that might otherwise raise concerns under the competition provisions of the *Competition and Consumer Act* (CCA). One way that immunity may be obtained is by applying for authorisation from the ACCC. The ACCC may grant an authorisation when it is satisfied that the public benefit from the conduct outweighs any public detriment.

Not all of the therapeutic sector industry codes are authorised by the ACCC. The requirement for authorisation depends on whether the arrangements or conduct within the code give rise to a risk of breaching the competition provisions of the CCA. Applications for authorisation are assessed by the ACCC on a case-by-case basis.

There are implications for the industry associations in extending the codes to non-members of the associations, both for those which have authorised codes and for those which do not. The ACCC is able to grant authorisation, on application, to apply to non-members who may become parties to an arrangement such as a code of practice. However the parties for whom authorisation is given must be referred to in the application.

An industry association wishing to seek immunity on behalf of all current and future parties to a code must specify the extent of coverage at the time of lodging the application.

Each industry association code is at a different point of development. In addition some codes are authorised by the ACCC but others are not authorised. As a result the steps that each industry association must take to ensure that its code incorporates the requirements identified in this section will vary, as will the timing of final implementation of the principles and operational coverage.

Each industry association will need to take advice on the legal implications of compliance with the recommendations of this report, and whether or not authorisation or re-authorisation by the ACCC will be required, including re-authorisation to extend code coverage to non-members. Each industry association will need to estimate the time by when all necessary steps will have been taken. The timelines in Appendix C are indicative. Where ACCC authorisation or re-authorisation is required, the timeline might need to be extended to ensure the authorisation process is complete.

The ACCC has the authority to impose conditions on its authorisation, as it has in the case of the current authorisation of GMiA's Code and the previous Edition 15 of Medicines Australia's Code.

**Recommendation 3**

Each industry association must determine the steps required to be taken to implement 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. The indicative dates are detailed in Appendix C to this report.

**Recommendation 4**

The working group **recommends** that 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.

**Recommendation 5**

The working group **recommends** that 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.

**Recommendation 6**

The working group **recommends** that TGA provide on the ARTG public summary for each product, information on the nomination of an industry code, in a searchable format.

**Recommendation 7**

The working group **recommends** that the industry associations work with TGA to develop a process for notification to an association when an applicant nominates that association's code of practice.

**Recommendation 8**

The working group recommends that the 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.

**Recommendation 9**

The working group **recommends** that 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 as outlined in the Position Paper.

## 7. Alignment with healthcare professional codes

The Position Paper proposes that there be alignment between the industry codes and the codes that govern the behaviour of healthcare professionals. The stated rationale is that there are two parties to the relationship and that the ethical promotion of therapeutic products expected of industry should be mirrored or reflected in the healthcare professional codes.

With the introduction of AHPRA on 1 July 2010, there are now 10 national medical boards. These are:

- Chiropractic Board of Australia
- Dental Board of Australia
- Medical Board of Australia
- Nursing and Midwifery Board of Australia
- Optometry Board of Australia
- Osteopathy Board of Australia
- Pharmacy Board of Australia
- Physiotherapy Board of Australia
- Podiatry Board of Australia
- Psychology Board of Australia.

AHPRA has several functions, including supporting the National Boards in their primary role of protecting the public. In addition to managing the registration processes for health practitioners and students in Australia, AHPRA also manages investigations into the professional conduct and performance of health of registered health practitioners (except in NSW where this is done jointly by the Health Professional Councils Authority and the Health Care Complaints Commission).

Each National Board has published guidelines on good medical practice, including a code of practice. The codes of practice include a section which deals with conflicts of interest which, while not inconsistent with the industry codes, does not have the same level of detail. As an example, the Code of Practice of the Medical Board[14] sets out in section 8.11, the restrictions on behaviour that might constitute a conflict of interest:

- Acting in a patient's best interests when making referrals and when providing or arranging treatment or care
- Informing a patient when there is an interest that could affect, or could be perceived to affect, patient care
- Recognising that pharmaceutical and other medical marketing influences doctors, and being aware of ways in which the practice may be being influenced
- Recognising potential conflicts of interest in relation to medical devices and appropriately managing any conflict that arises in the practice
- Not asking for or accepting any inducement, gift or hospitality of more than trivial value, from companies that sell or market drugs or appliances that may affect, or be seen to affect, the way patients are prescribed for, treated or referred
- Not asking for or accepting fees for meeting sales representatives
- Not offering inducements to colleagues, or entering into arrangements that could be perceived to provide inducements
- Not allowing any financial or commercial interest in a hospital, other health care organisation, or company providing health care services or products to adversely affect the way in which patients are treated

The working group considered its preferred approach to addressing the objective in the Position Paper was to have the industry code coverage reflected in the healthcare professional codes and guidelines. The working group recognised that, notwithstanding that clinical bodies are represented on the working group, it is principally an industry-led body and therefore has limited capacity to influence the uptake by the National Boards of reciprocal provisions. The Chair of the working group will communicate the outcomes of

[14] http://www.medicalboard.gov.au/Codes-and-Guidelines.aspx

the group's deliberations to each National Board and to the key healthcare professional colleges and associations, as well as to AHPRA.

The working group is of the view that code coverage of healthcare professionals should extend to healthcare professional students and that education programs dealing with the relationships with industry be specifically directed to healthcare professional students.

Ultimately it will be for each National Board, healthcare professional college and association to determine whether it should amend its code or guidelines to provide consistency with the industry codes.

There are also many other professional bodies for unregistered healthcare practitioners many of which have their own professional guidelines and codes[15]. Currently the number and diversity of these bodies makes it challenging to ensure that all develop an understanding of the obligations on therapeutic industry companies and the corresponding obligations that they are under to align their guidelines and codes. The Australian Health Ministers Advisory Council (AHMAC) has released a proposal for a national scheme (including a code of conduct) to regulate herbalists, naturopaths, reiki therapists and other unregistered health practitioners[16]. The working group strongly supports the development of a code of practice for unregistered practitioners

**Recommendation 10**

The working group **recommends** that AHPRA and AHMAC be encouraged to advocate changes to the health professional codes to more closely reflect the mutuality of obligations between industry and healthcare professionals to ensure ethical promotion of therapeutic products.

**Recommendation 11**

The working group **recommends** that 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 outlined in Appendix B to this report.

**Recommendation 12**

The working group **recommends** that 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.

[15] http://www.tga.gov.au/advert/schedule1.htm#att2

[16] http://www.ahmac.gov.au/cms_documents/Options%20for%20Regulation%20of%20Unregistered%20Health%20Practitioners.doc

## 8. Improving transparency of industry codes for health professionals and consumers

Many of the submissions raised concerns about the absence of easy access to the complaints processes under the industry codes. Some of the industry associations provide information on their websites to assist consumers and healthcare professionals who might wish to bring a complaint. However this implies an understanding of which is the applicable code in order to go to the appropriate website.

The working group acknowledged that there is no readily available access point for consumers and healthcare professionals to obtain information. The working group recommended that the Government should work with the industry associations to provide a website portal to facilitate complaints, including links to the appropriate industry association website. This could be undertaken by TGA when putting in place a process for nomination of an industry code. The US FDA "Truthful Prescription Drug Advertising and Promotion (Bad Ad Program)" provides a useful example of an outreach program designed to educate healthcare providers about the role they can play in ensuring that the advertising and promotion of therapeutic goods is truthful and not misleading[17].

**Recommendation 13**

The working group **recommends** that an educative complaints portal be established as a mechanism to assist channeling complaints to the appropriate industry association. The industry associations will work with the Government to identify the most appropriate vehicle for this purpose.

**Recommendation 14**

The working group **recommends** that each industry association provide on its website a link to the complaints mechanism for each other therapeutic industry sector.

## 9. Communication of working group outcomes

The working group is of the view that there needs to be wide dissemination of the outcomes of its considerations. Industry and healthcare professionals alike need to be made better aware of the expectation that they act in accordance with codes of practice to ensure *"good health incorporating the quality use of therapeutic products … based on genuine consumer health needs and supported by the ethical conduct of all parties."*

The working group would welcome the Government's support for, and assistance with, mechanisms to communicate these messages. The National Prescribing Service website[18] and Australian Prescriber[19] are examples of possible communication portals.

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[17] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm

[18] http://www.nps.org.au/

[19] http://www.australianprescriber.com/

**Recommendation 15**

The working group **recommends** that 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.

## 10. Evaluation

The working group is of the view that there needs to be regular evaluation of the implementation of recommendations in response to the Position Paper. An annual review of progress against several criteria is recommended. The industry associations which do not yet have a developed code of practice have undertaken to commence work on code development. However it is likely to be late 2011 before all industry associations have codes of practice which incorporate all the recommendations from the working group.

As part of the assessment of the effectiveness of the implementation of the recommendations from the working group, the working group considers that in two years after the date of this report there should be an examination of the feasibility of adopting a model code with appendices to accommodate differences between the industry sectors.

The working group supports the establishment of an advisory body with similar composition to the working group, to undertake the ongoing assessment of effectiveness of the implementation of the recommendations of the working group and to report to Government on a regular basis.

The aim of the evaluation is to ensure that the codes of practice are effective and that the sanctions on code compliance are adhered with repeated code breaches dealt with appropriately. To evaluate and monitor the codes of practice the following processes and indicators are suggested.

Areas for evaluation include:

<u>Process</u>

- Completion of development of a code of practice in the therapeutic industry sectors which do not currently have a code or where the code requires amendment to incorporate the recommendations of the working group
- Establishment of code governance bodies with inclusion of relevant stakeholders
- Establishment of TGA's processes to enable subscription by an applicant for product registration to a relevant industry code of practice
- Establishment of a process to enable communication to an industry association that a company has subscribed to its code of practice
- Provision of education programs to ensure that all employees within a therapeutic industry sector (members and non-members of the associations) are able to receive at least basic training on the requirements of the code
- Implementation of monitoring programs that have been established, whether administered either by an association or by an agent on behalf of the association

- Implementation of a complaints processes that has been established, whether administered either by an association or by an agent on behalf of the association
- Provision of education programs for health professionals and consumers regarding code provisions and complaint procedures
- Publication of results of industry association monitoring and complaints in the public domain
- Adoption by the National Boards of amendments to guidelines and codes of conduct to reciprocate the restraints on behaviour under the industry codes.

Impact

- Effectiveness of TGA's processes to enable subscription by an applicant for product registration to a relevant industry code of practice
- Effectiveness of the communication by TGA to an industry association that a company has subscribed to its code of practice
- Extent to which non-members of associations have subscribed voluntarily to a relevant industry code of practice
- Knowledge and understanding of health professionals and consumers of code and complaint procedures
- Analysis of monitoring results
- Number of complaints submitted; by whom (including from the monitoring systems); the number upheld; and the timeliness of complaint procedures
- Compliance of members and non-members with code sanctions
- Analysis of sanction levels to ensure that sanctions are an effective deterrent.

Outcome

- The effectiveness of sanctions on code compliance and repeated code breaches by individual companies.

The indicators for effectiveness of the implementation of the recommendations of the working group are at Appendix C.

**Recommendation 16**

The working group **recommends** the establishment of a process to evaluate, on an ongoing basis, the implementation of the recommendations of the working group. In particular the evaluation should address the evaluation criteria set out in Appendix C.

**Recommendation 17**

The working group **recommends** that the Government form a permanent advisory group, similar in composition to the working group, with responsibility for the oversight of implementation of the recommendations and with a mandate to report to Government on a regular basis on the effectiveness of the implementation against the evaluation criteria set out in Appendix C.

## 11. Further areas for government consideration

The working group noted the importance of the National Medicines Policy as a framework document which informs many Government policies in the pharmaceutical sector. The working group believes that it is timely to review the National Medicines Policy with a view to replicating its policy coverage through the development of analogous policies for other therapeutic product areas. The four pillars of the National Medicines Policy are as relevant to the other therapeutic industry sectors as they are to medicines. However the fundamental differences in the way in which medicines are regulated and reimbursed militate against inclusion of other therapeutic sectors in the NMP. However there are good arguments to develop parallel policies for therapeutic goods not covered in the NMP.

**Recommendation 18**

The working group **recommends** that the Government review the National Medicines Policy and consider replicating its policy coverage although the development of analogous policies for other therapeutic product sectors.

## Appendix A
## Members of the working group

| | | |
|---|---|---|
| Anne Trimmer | Chair and Chief Executive Officer | Medical Technology Association of Australia |
| Carol Bennett | Chief Executive Officer | Consumers Health Forum of Australia |
| Anne Develin | National Manager, Regulatory Affairs | The Pharmacy Guild of Australia |
| Mark Feldschuh | President, Victorian Branch | The Pharmaceutical Society of Australia |
| Elizabeth Foley | ANF Federal Professional Officer | Australian Nursing Federation |
| Dr Peter Harman | Chief Executive Officer | IVD Australia |
| Dr Ken Harvey | Adjunct Senior Lecturer | School of Public Health, LaTrobe University |
| Dr Anna Lavelle | Chief Executive Officer | AusBiotech |
| Kate Lynch | Chief Executive Officer | Generic Medicines Industry Association |
| Dr Roderick McRae | Chairman of Council | Australian Medical Association |
| Dr Wendy Morrow | Executive Director | Complementary Healthcare Council |
| Mary Osborn | Senior Policy Officer | The Royal Australasian College of Physicians |
| Dr Deon Schoombie | Executive Director | Australian Self Medication Industry |
| Dr Brendan Shaw | Chief Executive | Medicines Australia |
| Troy Williams | Executive Director | Australian Dental Industry Association |

# Appendix B
# High level statement of principles and required code coverage

**High level statement of principles to be included in a therapeutic industry code**

The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products which is based on genuine consumer health needs and supported by the ethical conduct of all parties. The quality use of therapeutic products means:

- Selecting diagnostic and treatment options wisely based on the best available evidence and the consumer's needs;
- Choosing suitable therapeutic products if this is considered necessary; and
- Using therapeutic products safely and effectively.

Therapeutic industry codes have as their primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed through the eyes of the relevant community.

Therapeutic products industry sectors will collaborate with relevant stakeholders in code creation, updating, education, monitoring and compliance.

**Operational topics to be included in industry codes**

- Gifts and offers
- Industry-sponsored educational events
- Conduct of company representatives
- Consulting arrangements with healthcare professionals
- Shareholdings and/or other financial interests by healthcare professionals in therapeutic product companies
- Hospitality and entertainment
- Research and education grants
- Promotional claims/advertisements to healthcare professionals
- Surrogate medical writing ('ghost' writing)
- Sponsorship of third party educational conferences
- Celebrity endorsements
- Direct to consumer advertising
- Funding of patient groups
- Product samples
- Disease awareness campaigns
- Use of social media in promotions directed to healthcare professionals.

**Governance topics to be included in a therapeutic industry code**

- Education on the code's operation
- Monitoring of compliance with the code
- Enforcement of the code in response to a complaint or a breach

- Sanctions to support the enforcement.

**Obligations on companies to be included in a therapeutic industry code**

A therapeutic industry code must provide that sponsors of therapeutic products will meet their obligations under the code by:

- Adhering to the ethical promotion of therapeutic products
- Providing products that conform to the highest relevant standards of safety, efficacy and quality as established by TGA
- Maintaining trust and confidence in the industry through transparency and accountability
- Respecting ethical requirements and codes of practice which apply to healthcare professionals
- Upholding not just the letter of the Code but also the spirit of the Code
- Having in place a comprehensive process to monitor behaviour and deal with complaints
- Remedying behaviour if found to be in breach of the Code
- Being entitled to fair and equitable treatment under the Code.

## Appendix C
## Indicators for effectiveness of the implementation of the recommendations of the working group

| Evaluation process/ strategies | Indicators – outcomes and impact | By whom | Date of completion |
|---|---|---|---|
| To complete a code of practice in therapeutic industry sectors that in 2011 do not have a code or where the code requires amendment to incorporate the recommendations of the working group | All therapeutic industry sectors have a code of practice that includes all the recommendations from the 2011 Working Group on Promotion of Therapeutic Products | All therapeutic industry sectors | March 2012 or at the date of next authorisation review by ACCC, whichever is the later |
| To ensure that the composition of code governance bodies includes relevant stakeholders | All therapeutic industry sectors have code governance bodies that include relevant stakeholders | All therapeutic industry sectors | March 2012 or at the date of next authorisation review by ACCC, whichever is the later |
| To advocate for the establishment of TGA's processes to enable subscription by an applicant for product registration to a relevant industry code of practice | TGA's processes enable subscription by an applicant for product registration to a relevant code of practice | TGA | December 2011 |
| To establish process for communication to an industry association that a company has subscribed to its code of practice | Establishment of communication process that a company has subscribed to its code of practice | All therapeutic industry sectors<br>Government | December 2011 |
| To develop education programs for all employees within a | Number of evaluated and monitored learning programs developed for all | All therapeutic industry sectors | March 2012 |

| Evaluation process/ strategies | Indicators – outcomes and impact | By whom | Date of completion |
|---|---|---|---|
| therapeutic industry sector (members and non-members of the associations) to receive at least basic training on the requirements of the code | employees of the therapeutic industry sector on the requirements of the code | | |
| To establish monitoring programs administered either by an association or by an agent on behalf of the association | Establishment of monitoring program by each association or by an agent on behalf of the association | All therapeutic industry sectors | July 2012 |
| To establish a complaints processes, whether administered either by an association or by an agent on behalf of the association | Number of complaints reported in the annual report.<br>Demonstration on how the complaints were dealt with | All therapeutic industry sectors | July 2012 |
| To establish education programs for health professionals and consumers regarding code provisions and complaint procedures | Number of complaints received from health professionals regarding code provisions and complaint procedures | All therapeutic industry sectors | July 2012 |
| To publish results of industry association monitoring and complaints in the public domain | Number of complaints reported in the annual report.<br>Demonstration on how the complaints were dealt with | All therapeutic industry sectors | July 2012 |
| Encourage the National Boards to amend guidelines and codes of conduct to reciprocate the | Adoption by the National Boards of amendments to guidelines and codes of conduct with the reciprocation of | All therapeutic industry sectors | December 2013 |

| Evaluation process/ strategies | Indicators – outcomes and impact | By whom | Date of completion |
|---|---|---|---|
| restraints on behaviour under the industry codes | restraints on behaviour under the industry codes | | |
| **Impact** | | | |
| To compare the effectiveness of TGA's processes that enable subscription by an applicant for product registration to a relevant industry code of practice | The number of products registered by relevant industry code of practice to demonstrate an increase from 2013 | All therapeutic industry sectors | March 2014 |
| To increase the effectiveness of the communication to an industry association that a company has subscribed to its code of practice | A demonstrated increase in the number of subscriptions to an industry code of practice from 2013 | All therapeutic industry sectors | March 2014 |
| To increase the number of non-members of associations with voluntary subscription to a relevant industry code of practice | A demonstrated increase in the number of voluntary subscriptions by non-members of associations to their relevant industry code of practice from 2013 | All therapeutic industry sectors | March 2014 |
| To increase the knowledge and understanding of health professionals and consumers of code and complaint procedures | A demonstrated increase of knowledge and understanding of health professionals and consumers code of practice from 2013 | All therapeutic industry and health sectors | March 2014 |
| To collect, analyse and report on agreed information that demonstrates compliance with relevant industry code of | The publication of set of indicators that demonstrate compliance with relevant industry code of practice | All therapeutic industry sectors | March 2014 |

| Evaluation process/ strategies | Indicators – outcomes and impact | By whom | Date of completion |
|---|---|---|---|
| practice | | | |
| To collect, analyse and report on agreed information that demonstrates compliance with relevant industry complaints handling procedures | The publication of the number of complaints submitted; by whom (including from monitoring systems); the number upheld, the reasoning behind each determination and the timeliness of complaint procedures | All therapeutic industry sectors | March 2014 |
| To collect, analyse and report on agreed information that demonstrates compliance of members and non-members with code sanctions | The publication of set of indicators that demonstrates compliance of members and non-members with code sanctions | All therapeutic industry sectors | March 2014 |
| To collect, analyse and report on agreed information that demonstrates effective sanction levels across the association codes | The publication of set of indicators that demonstrates effective sanction levels across the association codes | All therapeutic industry sectors | March 2014 |

## Appendix D
## Therapeutic industry association
## Codes of Practice

AusBiotech

http://www.ausbiotech.org/UserFiles/File/Code-of-Conduct.pdf

Australian Dental Industry Association (ADIA)

Australian Self Medication Association (ASMI)

http://www.asmi.com.au/about/ASMI-Code-of-Practice.aspx

Complementary Healthcare Council (CHC)

http://www.chc.org.au/AboutUs/CodeofPractice/

IVD Australia (IVDA)

http://www.ivd.org.au/dmxreadyv2/cms/app_engine/assets/documents/policy/code%20of%20conduct/ivd%20australia%20code%20of%20conduct%20-%20011110.pdf

Generic Medicines Industry Association (GMiA)

http://www.gmia.com.au/assets/file/GMiA%20Code%202nd%20Edition%20Dec%202010.pdf

Medical Technology Association of Australia (MTAA)

http://mtaa.org.au/pages/images/COP%206th%20Edition%201%20October%202010.pdf

Medicines Australia (MA).

http://www.medicinesaustralia.com.au/pages/images/Code-of-Conduct-Edition-16.pdf

## Appendix E
## National Boards and professional colleges
## Codes and guidelines

Dental Board of Australia

http://www.dentalboard.gov.au/Codes-and-Guidelines.aspx

Medical Board of Australia

http://www.medicalboard.gov.au/Codes-and-Guidelines.aspx

Nursing and Midwifery Board of Australia

http://www.nursingmidwiferyboard.gov.au/Codes-and-Guidelines.aspx

Pharmacy Board of Australia

http://www.pharmacyboard.gov.au/Codes-and-Guidelines.aspx

The Royal Australasian College of Physicians

http://www.racp.edu.au/page/policy-and-advocacy/ethics

The Royal Australasian College of Surgeons

http://www.surgeons.org/racs/college-resources/publications-(1)/position-papers/code-of-conduct

Australian Orthopaedic Association

http://www.aoa.org.au/Libraries/eCM_Files/PositionStatement_web2010_pdf.sflb.ashx

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# Annexures

## Examples of industry association educational material

- MTAA postcard for use by sales force personnel in field
- Medicines Australia brochure "*A healthy relationship – the pharmaceutical industry and the healthcare professional*"
- Medicines Australia brochure for consumers "*A healthy relationship – your doctor and the pharmaceutical industry*"