Australian Government

Department of Health

SECRETARY

Secretary
Code of Conduct Committee
Medicines Australia
16 Napier CLOSE
DEAKIN ACT 2600

Dear Sir/Madam

Medicines Australia Code of Conduct Review Submission

Thank you for inviting the Department of Health to make a submission in relation to Medicines Australia's review of its Code of Conduct. I have attached the Department's submission.

The Department supports Medicines Australia's ongoing development of its Code of Conduct and progress towards greater transparency around the interactions between therapeutic goods companies and healthcare professionals associated with the promotion of therapeutic goods. In this context, the Department has identified opportunities in the Code to further support the quality use of medicines through the provision of information collected by therapeutic goods companies (for example through post-marketing surveillance studies) to the Therapeutic Goods Administration and/or the Pharmaceutical Benefits Advisory Committee. The submission also contains a number of suggestions for change in relation to specific matters within the Code of Conduct (Part 1).

In addition, the Department seeks the support of Medicines Australia in safeguarding the effectiveness of antimicrobial products by including provisions in the revised Code of Conduct that encourage member companies to promote appropriate prescribing and use of these products (Part 2).

The Department is aware that Medicines Australia is consulting separately on options for introducing greater transparency about payments and transfers of value between pharmaceutical companies and health professionals, and that publication of data by a third party has been identified as an option, with the Australian Health Practitioner Regulation Agency (AHPRA) provided as an example of a relevant body. It is important to note that AHPRA is an independent statutory authority established under state and territory legislation and is only authorised to collect, retain and publish data in accordance with that legislation.

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If you need to discuss any aspect of the Department's comments or require further information, please contact Ms Celia Street, Assistant Secretary, Best Practice Regulation and Deregulation Division on (02) 6289 5324 or email: *Celia.Street@health.gov.au* .

Yours sincerely

Jane Halton PSM
Secretary

24 December 2013

Medicines Australia Code of Conduct Review – Department of Health Submission (Part 1)

High Level Principles in the Code

The Department notes that the following areas of the Working Group on the Promotion of Therapeutic Goods' high level principles do not appear to be explicitly referenced in the Medicines Australia Code of Conduct 17th edition:

- Shareholdings and/or other financial interests by healthcare professionals in therapeutic product companies and/or products;
- Celebrity endorsements; and
- Funding of patient groups.

Medicines Australia may wish to incorporate these areas into the 18th edition of the Code of Conduct.

Specific Comments

The following comments relate to specific sections of Medicines Australia's 17th edition Code of Conduct and are provided for the Code of Conduct Committee's consideration in developing its revised Code of Conduct.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Introduction *Transparency and Accountability* (page 7)	The pharmaceutical industry in Australia recognises that the community expects companies to be transparent and accountable for their conduct. The Code also reflects the industry's commitment that all activities with, or materials provided to healthcare professionals, patients and members of the general public must never bring discredit upon, or reduce confidence in the industry.	The Department suggests that these provisions be expanded to reflect a commitment to increasing the information publicly available on new medicines considered by the Pharmaceutical Benefits Advisory Committee (PBAC). The expectation is that this would include making publicly available the evidence used by the PBAC in considering applications and the reasons for recommendations on use and access. This information would include submissions, evaluation reports and committee minutes. This would allow for greater understanding and appreciation of the evidence and balance of factors (benefits, costs and risks), used by the PBAC in its deliberations. In keeping with the spirit of current requirements in the Code for provision of substantiating data to healthcare professionals (Section 1.2), it should not be acceptable for a company to claim as 'confidential' relevant information.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 1 - *Nature and Availability of Information and Claims* (pages 7-12) & **Section 2** - *Promotional material directed at healthcare professionals* (pages 13-26)	**Sub-section 1.4** – Unapproved Products and Indications *(Page 10)* **General Principles** *(Page 13)*	The Department considers it important that in these sections, companies be reminded that it is an offence under section 22(5) of the *Therapeutic Goods Act* 1989 (the TG Act) to advertise a therapeutic good (by any means) for indications other than those entered in the Australian Register for Therapeutic Goods for that good and that practitioners are required to comply with codes of professional conduct as issued by their registration boards.
Section 2 - *Promotional material directed at healthcare professionals* (pages 13-26) & **Section 13** - *Relationship with the general public* (pages 46-50)	**General Principles** *(Page 13)* **Sub-section 2.4** Internet, social media and eNewsletters **including Table 3** – Summary of Requirements for Other Media *(Pages 22- 24)* **Sub-section 13.1** – General Principles *(Page 46)*	The Department considers it important that in these sections, companies be reminded that it is an offence under section 42DL(1)(f) of the TG Act to advertise to the public a therapeutic good that contains a substance included in Schedules 3 (except those in Appendix H), 4 and 8 of the Poisons Standard.
Section 2 - *Promotional material directed at healthcare professionals* (pages 13-26) & **Section 13** - *Relationship with the General Public* (pages 46-50)	Any limitations to the terms of PBS listing should be clearly disclosed and easily identifiable by a reader. No attempt should be made to minimise this disclosure as it should be a prominent feature of any promotional material and a genuine communication vehicle to advise prescribers of this important information. The disclosure of this information must accurately reflect the current PBS listing but may be a paraphrase or précis of that information. Other funding information can be added to the body of the promotional item	The Department notes reference in both Sections to the promotion of listings in media releases and promotional information that is provided to both healthcare professionals (Section 2) and the general public (Section 13.4). The Department suggests that references should not be limited to PBS and National Immunisation Program only and could also refer to information relating to changes in other government programs including the Life Saving Drugs Program.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
	for example, National Immunisation Program. The purpose of a product specific media release is to provide current, accurate and balanced information about products available in Australia (this includes a new product, indication, a change in funding on the National Immunisation Program (NIP), or new or changed PBS or NIP listing) and therefore must include information about the product's precautions, adverse reactions, warnings, contraindications and interactions.	Section 2 could also be cross-referenced to section 13.1 to reinforce that "promotion of products covered by the code would breach Commonwealth Therapeutic Goods Legislation and the Code, which stipulate that prescription products must not be promoted to the general public".
Section 4 - *Medical Education directed at healthcare professionals* (page 30)		The Department suggests that the difference between "Educational material" and "Promotional material" be clearly defined and delineated.
Section 5 - *Company Representatives roles and Ethical Conduct* (page 31)		The Department suggests that the Code be explicit about standards that prevent industry from lobbying members of advisory groups or bodies in an attempt to influence the outcome of deliberations.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 7 - *Product Starter Packs* (pages 33-34)		The Department suggests a clearer differentiation between starter packs and product samples, noting that the glossary states that 'starter packs' are referred to as 'samples' by healthcare professionals. There are starter pack issues (containing no more than 1/3 of the usual total pack) that may not necessarily be relevant to many sample packs. There could be confusion in terminology here that need to be clarified. Access to appropriate medicines as starter packs or samples is a major component of quality use of medicines. Therefore prescribers should be able to access a broad range of medicines that would include the individual components of multiple component packs as well as the full multiple component pack and a range of different strengths. This ensures appropriate access to medicines for specific patients groups such as paediatric and elderly and facilitates adequate titration of doses for patients taking multiple drugs.
Section 8 - *Product Familiarisation Programs (PFPs)* (page 35)		The Department suggests the inclusion of text and reporting against collected data that emphasises the need for companies to ensure responsibility for the safe use of a product that covers the lifespan of a product including the safe disposal of unused medicines (along the lines of the text included for Product Starter Packs under 7.12).

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 8 - *Product Familiarisation Programs (PFPs)* (page 35) ...cont.		The Department notes the expectation placed on companies to ensure patients are aware of the fact that the ongoing subsidised supply of a product provided under a PFP is not guaranteed. The Department would encourage Medicines Australia to strengthen the requirement for companies to adopt greater responsibility for advising the patient that there are no guarantees of future availability of a medicine at a concessional rate any time into the future. The Department suggests that this should occur and be reaffirmed with patients at all stages of the distribution/supply chain. In particular, in order to ensure patients are properly informed the Department supports the strengthening of Section 8.4 to require patients to sign a consent form that states they are fully aware and agree to the conditions under which they are participating in the PFP. In addition, the Department would see value in the standard information provided to patients and the consent form they are asked to sign being made available on the company's website. The Department suggests the Code highlight the need for sponsors to consider any proposed restrictions to subsidised access in the development of PFP's. The Code, as it stands, provides consumers with limited avenues for addressing any issues they may have with the ongoing supply of items issued under a PFP. MA may wish to consider including text on how consumers can progress ongoing supply issues under a PFP. The Department suggests that the Code requires greater transparency on the collection of data resulting from a PFP. It suggests that the findings and analysis of data arising from a PFP be made available on the company's website as well as being made available to the TGA/Drug Utilisation Sub-Committee/Pharmaceutical Benefits Advisory Committee.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 8 - *Product Familiarisation Programs (PFPs)* (page 35) ...cont.	**Sub-section 8.1** *(Page 35)* A company will make available the rationale for a PFP without delay but in any event in no longer than ten (10) working days.	The Department suggests that this section be clarified to indicate: • to whom the company will make the rationale available; • how the rationale should be made available; and • what triggers the commencement of the 10 working day period.
	Sub-section 8.10 *(Page 35)* & **10.10** - Post-Marketing Surveillance studies	The *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch* has been renamed to *Australian Requirements and Recommendations for Pharmacovigilance Responsibilities of Sponsors of Medicines* which is published on the TGA website at http://www.tga.gov.au/safety/australian-pharmacovigilance-sponsors-00.htm.
	Sub-section 8.10 *(Page 35)* Suspected adverse drug reactions spontaneously reported during the PFP must be reported to the TGA in accordance with the current TGA *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.*	As PFPs can provide early access to a new medicine and potentially involve large numbers of patients, companies should have in place an appropriate protocol for systematic collection and analysis of patient safety data and the subsequent submission of this information to the TGA in accordance with established protocols.
Section 10 - *Post-Marketing Surveillance (PMS) studies* (page 44)		The Department suggests that the section be expanded to connect post-market surveillance (PMS) activities undertaken by companies with the post-market programs conducted by both the TGA as regulators and PBAC. This information could usefully inform any reviews of medicine use in clinical practice.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 10 - *Post-Marketing Surveillance (PMS) studies* (page 44) … cont.	**Section 10.2** (page 44) Post-Marketing Surveillance studies must be research which is intended to generate data on safety parameters of a product that has been approved for registration when used in accordance with the Product Information (PI).	The Department suggests that Clause 10.2 would benefit from the inclusion of text that refers to the generating of data that is based on effectiveness as well as safety parameters.
Section 13 - *Relationship with the general public* (pages 46-50)		The Department suggests the Code includes provisions that demonstrate Medicines Australia's commitment to open and unambiguous data and analysis, particularly relating to PBS expenditure. In particular all statistics and analysis published by Medicines Australia and its member companies should accredit the source of all data used.
	Sub-section 13.1 - General Principles *(Page 46)* & **Sub-section 13.8** - Use of the Internet *(Pages 49-50)*	The Department considers it important that a sentence be included to make it clear to companies that where promotional material (including disease state information) is linked with a specific prescription product Consumer Medicine Information (CMI) and PI available to the general public it is likely to be considered prescription medicine advertising and in breach of section 42DL(1)(f) of the TG Act. Company websites also should not have disease state information in association with the company's prescription products. This is likely to be considered prescription medicine advertising and also in breach of section 42DL(1)(f) of the TG Act. Inclusion of such a sentence would make these sections consistent with section 13.7 which states disease education "activities must not include any reference to a specific prescription product".

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 13 - *Relationship with the general public* (pages 46-50) …cont.	**Sub-section 13.7** - Disease Education activities in any media *(Pages 48-49)* The name of the pharmaceutical company must be identified on any disease education activity but should not be given prominence.	Provision of disease information to the public is beneficial but only if it is done in a generic way. The inclusion of the company's name or link to their website in any disease education program may be considered a 'de-facto' promotional activity. Medicines Australia could consider developing a mechanism for including de-identified company references in such programs.
	Sub-section 13.8 - Use of the Internet *(Pages 49-50)* An advertisement is defined as any statement which is intended (directly or indirectly) to promote the use or supply of a product. Reference or linkages to other reputable information sources that provide valuable educational information that would enhance a member of the general public's understanding of a disease area. When making such a reference or linkage a clear screen displaying the following statements must appear before the information can be accessed: • that the information a reader is about to be referred to may not comply with the Australian regulatory environment and that readers should refer to the CMI for products to fully understand the terms of a product's registration in Australia; • that the intent of providing this material is informational and not as advice; and • any information provided by this source should be discussed with the reader's healthcare professional and does not replace their advice	This definition of 'advertisement' should be amended to reflect the TG Act definition of 'advertisement' which has been adopted in the Glossary of the Code. Companies should be reminded that the definition of advertisement is very broad and the objective test is whether an ordinary, reasonable person would think that the material was intended, whether directly or indirectly, to promote the use or supply of the therapeutic goods. A company should not provide a link from the company's website, disease state website or patient support program website to any site that promotes a specific prescription medicine.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 13 - *Relationship with the general public* (pages 46-50) …cont.	**Sub-section 13.9** - Social media Suspected adverse drug reactions noted during monitoring of Social Media sites must be reported to TGA in accordance with the current TGA document *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch*	Refer to the comment on page 5 of the submission in relation to **sub-section 8.10**.
Section 14 - *Relationship with Health Consumer Organisations* (page 51)		The Department welcomed the strengthening of the guidelines relating to the relationship with health consumer organisations (Section 14) in the 17th Edition of the Code. The Department notes that the first reporting period ends 30 April 2014 and will be interested in the breadth of information captured in the ensuing report, particularly the level of disclosure relating to travel and engagement in health related activities. The Department suggests that the reporting in this section should capture information in a manner consistent with Section 9 (Relationship with Healthcare Professionals), taking into account likely amendments resulting from the recommendations of the Transparency Working Group.
Section 17 - *Materials for use with patients (patient aids)* (page 52)	Items that are more likely to be used outside the home must not be product branded but may be branded with a company name and/or a logo.	Patient aids should not be product branded, as this could be considered to be an offence under section 42DL(1)(f) of the TG Act, under which it is an offence to advertise to the public a therapeutic good that contains a substance included in Schedules 3 (except those in Appendix H), 4 and 8 of the Poisons Standard.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 18 - Patient Support Programs *(Pages 52-53)*	The healthcare and wellbeing of patients must be the primary objective of a Patient Support Program.	Patient support programs (PSPs) have the potential to be diverted from their primary purpose and used as 'brand promotion'. This section should be strengthened by developing criteria to ensure that the PSPs are not used as promotional tools. Statements that could be misinterpreted and allow promotion as a secondary objective should be revised. The Department suggests it would be better to state "The healthcare and wellbeing of patients must be the only objective of a Patient Support Program."
	a) If a company provides or intends to provide any payment to a healthcare professional in return for any administrative or other work associated with enrolling a patient in a Patient Support Program, this payment, including the amount and scope of this payment, must be disclosed in writing to a patient prior to their enrolment in the program.	Full and transparent disclosure is supported.
	b) Any payment for the work undertaken by a healthcare professional in such programs must be commensurate with the work undertaken. Such payment should not be capable of influencing or intended to influence the prescribing or dispensing of a specific prescription product.	Any payments should be included in the company's reporting of financial support, grants etc. in the interests of being open and transparent about the conduct and management of a PSP.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 18 - Patient Support Programs *(Pages 52-53)* … cont.	c) No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs.	This paragraph is broad and requires further clarification including: • What is encompassed under 'material that will enhance positive health outcomes and compliance' • does 'material' include items such as glucometers, or is the reference to brochures and guidance documents? Does material relate to becoming involved only or also to being compliant once enrolled? • Should the material be tied to the particular treatment regime such as a blood glucose monitor for a diabetes PSP? • Should there be an upper limit on the value of the material?
	d) The information provided to the patient prior to their enrolment in a Patient Support Program must include balanced, accurate and correct information about the potential risks of the medicine.	The Department suggests the following changes to the dot point. "**All** information provided to the patient prior to their enrolment in a Patient Support Program must be balanced, accurate and correct**, including** information about the potential risks of the medicine".
	f) All information provided to patients must comply with Sections 13.6 and 17 of this Code.	The Department considers it important that this reference be amended to "All information provided to patients must comply with Sections 13 and 17 of this code", as any information contained on a PSP website should also comply with sections 13.1, 13.2, 13.3, 13.7, 13.8 and 13.9 of the Code.
	h) The Consumer Medicine Information document for the medicine must be given to the patient prior to their enrolment or must be one of the first documents provided to a patient following their enrolment in the program.	The CMI provided to the patient must be the same version as published on the TGA website, otherwise, it could be considered to be promotional. This should be stated in this section.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 18 - Patient Support Programs *(Pages 52-53)* … cont.	i) The data collected from these programs must not be used for any purpose other than to increase positive health outcomes and never for promotional activities. Individual patient data may be collected in a de-identified manner for the purpose of safety monitoring.	Any patient safety data collected should be analysed and the results submitted to the TGA in accordance with established protocols.
	However, companies may not collect data for the purpose of making a claim about a product.	The intent of this sentence is unclear. The Department suggests that the phrase be clarified to "However, companies may not collect data for the purpose of making a ***therapeutic*** claim about a product".
	However, if data is collected in a Patient Support Program using appropriate scientific and statistical rigour, under a research protocol, such data may be used to communicate to healthcare professionals.	There should be further clarification of the types of information that can be communicated to healthcare professionals. Use of such data for health professional communication purposes should still be subject to the other conditions set out in the Code. Companies should also be reminded that the provision of information to healthcare professionals needs to comply with section 22(5) of the TG Act. Further, any release of patient information must comply with Australia's Privacy Legislation.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
Section 21 – *Complaints* (pages 54-55) & **Section 30** - *Complaints and Monitoring* (pages 62-63)		The Department continues to support the need for a strong, robust and consistent complaints mechanism that enables action to be taken (if required) in circumstances where the community and individuals are provided with misleading information that may result in outcomes that do not support the National Medicines Policy objectives. The Department notes the role of the Monitoring Committee (Section 30) and its commitment to conduct reviews throughout the financial year(s). In addition, the process for conduct of a review and the referral process to the MA Code of Conduct committee are noted. Furthermore, the Department notes the important role that Medicines Australia has to investigate and impose consistent penalties on matters which come to its attention, for example in the media.
GLOSSARY (pages 77-81)	**Advertisement** in relation to therapeutic goods as defined in the *Therapeutic Goods Act 1989* includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.	A 'reasonable person' test is applied to the interpretation of "intended" in the definition of 'Advertisement' contained in the TG Act. That is, any statement, pictorial representation or design that a 'reasonable person/consumer' would be likely to perceive as intended, whether directly or indirectly, to promote the use or supply of the relevant therapeutic goods, would be considered an advertisement under the TG Act.
	Promote means, in the context of the definition of 'advertisement', all informational and persuasive activities, the purpose, actual or likely effect of which is to induce or discourage the purchase, sale, supply and/or use of therapeutic products.	In contrast, the definitions of "***Promote***" (and related terms) require interpretation of "*purpose*", which would be reliant on the subjective viewpoint of the company's "intent"., for example "***Promotional material***" refers to "*... the purpose of encouraging the usage of a product.*" As a result, the "promotion" definitions may result in inconsistencies with the definition of "***Advertisement***" that conflict with the prohibition on prescription medications from being promoted directly to the public.

Section	Medicines Australia – 17th Edition Code of Conduct	Comment
GLOSSARY (pages 77-81) … cont.	**Promotion, Promotional or Promotional claim means** any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information. **Promotional material** means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.	In particular, the definition of "***Promotion, Promotional or Promotional claim***" stipulates that "*statements concerning efficacy, rate of adverse reactions or other cautionary aspects' of a product are considered promotional.*" However, these statements could also be included in PIs and CMIs as materials that can be given to the public according to section 13 of the Code. Section 13 of the Code also states that product information approved by the TGA, for example, is not promotional. Depending on how they are presented, who they are provided to and whether they are product/company branded; PIs and CMIs could be considered advertising and possibly in breach of the TG Act which prohibits the advertising of prescription medications to the public. The Department is of the view that the interaction of these definitions and the provision of the PI and CMI to the public by sponsors of prescription medicines are likely to provide ongoing compliance concerns. (It should be noted that while the TGA provides similar information on its website in the form of the Australian Register of Therapeutic Goods database, PI and CMI documents, consumers cannot search the information based on indication and therefore does not support self-treatment but once they have been prescribed a medicine, they can easily locate the information).

Medicines Australia Code of Conduct Review – Department of Health Submission (Part 2)

Promoting appropriate use of antibiotics to combat antimicrobial resistance

The World Health Organization (WHO) has identified antimicrobial resistance (AMR) as one of the key global health issues facing our generation.

While the emergence of AMR is driven by a complex interaction of factors, there is overwhelming evidence that the use and overuse of antibiotics is a significant driver. This, compounded by a lack of development of new antibiotics, presents a serious risk to public health.

The Australian Government is taking steps to address AMR, including through the development of a National AMR Prevention and Containment Strategy. However the responsibility for addressing this issue has to be shared across government, industry, professions and the community.

Conserving the effectiveness of current antimicrobials is one of the main pillars of defence against AMR. This approach will not only reduce the threat of resistance, but will also prolong the useful lifespan of these drugs. This will be of benefit both for patient care and for the medicines industry.

The Medicines Australia Code of Conduct provides an important opportunity to raise the profile of AMR issues within the pharmaceutical industry and to support conservation efforts.

While the current Code of Conduct refers to a general commitment to Quality Use of Medicines (QUM) and rational prescribing, given the serious threat to patient safety presented by AMR, it is now timely to consider the inclusion of stand alone provisions within the Code to address this important group of drugs – antimicrobials, and in particular, antibiotics.

Specific provisions in the Code should ensure that companies provide accurate information to providers, dispensers, and the general public that stresses the importance of the judicious use of antimicrobials. Advertising and promotional material and product information relating to antimicrobial products should acknowledge that inappropriate prescribing and use may contribute to the emergence of antimicrobial resistance.

Advice should indicate that the use of antimicrobials in Australia be primarily guided by Australian national consensus guidelines, or accepted local adaptations of such guidelines, or where possible, by infectious diseases specialist advice where guidelines are unclear or new agents not yet covered by the guidelines are being considered.

The WHO notes that in combating antimicrobial resistance, a challenge is posed by 'pharmaceutical promotion focused on increasing sales irrespective of the effects on health often leads to irrational use of antimicrobials'. The inclusions suggested above will help safeguard against this and contribute to Australia being a leader on this important issue.