Australian Government

Department of Health

Dr Richard Chadwick
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Australian Competition & Consumer Commission
GPO Box 3131
Canberra ACT 2601

Dear Dr Chadwick

Medicines Australia Limited application for revocation and substitution A91436 - A91440 - interested party consultation

Thank you for seeking comment from the Department of Health in relation to the application by Medicines Australia for re-authorisation of the 18th edition of its Code of Conduct by the Australian Competition and Consumer Commission.

I have attached some comments on matters within the Code of Conduct that could be drawn to the attention of Medicines Australia. In addition, the Department is suggesting that Medicines Australia could assist in the broader movement to safeguard 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.

If you need to discuss any aspect of the Department's comments or require further information, please contact Ms Catherine Winter (Director, Regulatory Policy Branch) on (02) 6289 1676 or email: *Catherine.Winter@health.gov.au*

In the interim we would be interested in being informed about further developments with the Code, including whether it is re-authorised.

Yours sincerely

Andrew Stuart
Deputy Secretary
11 September 2014

DEPARTMENT OF HEALTH
INPUT TO THE AUSTRALIAN COMPETITION AND CONSUMER COMMISSION
MEDICINES AUSTRALI A LIMITED – REVOCATION AND SUBSTITUTION APPLICATION – A91436-A91440

GENERAL COMMENTS

It is noted that the Code of Conduct may intersect with regulatory standards and practice guidelines for health professionals, including doctors. The Australian Health Practitioner Regulation Agency is established under state and territory legislation to provide support to the fourteen independent national health practitioner registration boards, and may be able to assist the Commission in identifying any issues regarding the operation of the code alongside health practitioner regulatory material.

It is noted that amendments to the Code of Conduct have appropriately specified new standards of conduct in response to emerging issues, including four standards of specific interest to the Therapeutic Goods Administration (TGA). These are:

1. *Unapproved products and indications*: permitting companies to make information available about unapproved products and indications through a public website; noting that this permission does not extend to promotion to healthcare providers or inclusion of promotional information. (Section 1.4)

2. *Currency of information requiring companies to ensure, in response to a change in the TGA approved product information* that:
   - **i.** a review and update to ensure the currency of information and of promotional materials, and
   - **ii.** direct communication of all changes of clinical significance made to the TGA approved product information. (Section 3.2 and 3.3)

3. *Product labels*: requiring companies to supply labels for the healthcare professional to use when supplying a product starter pack. (Section 7.8)

4. *Transparency*: requiring companies to report on a transfer of value to individual healthcare professionals for services including advice, market research, education grants, pending the consent of the health professional. (Section 41 in full).

The inclusion of these standards is supported, and it is recognised that the four conduct standards referred to above represent a change for companies and expects that Medicines Australia's Monitoring Committee (Section 32 to 34) and Complaints Committee (Section 21-24) will take an active role in monitoring and responding to compliance issues and reporting unintended consequences to ensure that:

- Section 1.4 does *not* result in increased demand for unapproved products/indications;
- Sections 3.2 and 3.3 result in improved information currency;
- Section 7.8 does *not* inadvertently mislead healthcare professionals in their role in complying with their various regulatory requirements for supply of Australian Register of Therapeutic Goods (ARTG) products not produced in Australia; and
- Section 41 enables improved assessment of potential bias and conflict about information sources for a range of audiences.

SECTION	COMMENT
Introduction ***Guiding principles* (page 7)**	Guiding principle (g) states *"All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients."* There is no reference in this section, nor in any other part of the Introduction, of any expectation that clinical trials and scientific research should be conducted in accordance with the *National Statement on Ethical Conduct in Human Research, 2007* [updated March 2014](National Statement). The Code references other Codes and legislation in this section, so a reference to the National Statement would be consistent with this approach. It is suggested that MA consider adding a statement to encourage all researchers to ensure that an open access version of their publication is made available.
***Transparency and Accountability* (page 9)**	It is suggested that 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. The information that could be made public includes submissions to, evaluation reports and committee minutes of the PBAC. 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 1 - *Nature and Availability of Information and Claims* (pages 11-14) **&** **Section 2 - *Promotional material directed at healthcare professionals* –** General Principles **(page 15)**	It is considered 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	COMMENT
Section 2 - *Promotional material directed at healthcare professionals* (pages 15-29) **&** **Section 13 - *Relationship with the general public* (pages 50-55)**	It is considered 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 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 – *Educational material directed at healthcare professionals* (page 33)	The difference between "Educational material" and "Promotional material" needs to be clearly defined and delineated.
Section 7 - *Product Starter Packs* (pages 36-37)	It would be helpful for there to be 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.

SECTION	COMMENT
Section 8 - *Product Familiarisation Programs (PFPs)* **(page 38-39)**	It is suggested that MA consider strengthening the requirement for companies to advise patients that there are no guarantees of the future availability of a medicine at a concessional rate, and that this advice be reaffirmed with patients at all stages of the distribution/supply chain. It is suggested that the Code could require greater transparency on the collection of data resulting from a product familiarisation program (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. Sub-section 8.1 should 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. In relation to Sub-section 8.10, 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.
	The aim of a PFP is to allow the medical profession to evaluate and become familiar with a product. Section 8 describes the enrolment of patients (paragraphs 8.1, 8.6 and 8.10), obtaining the consent of patients (paragraph 8.4) and in some cases, the 'rigorous collection of individual data' (paragraph 8.9). A PFP may constitute an activity for which the requirements of the *National Statement on Ethical Conduct in Human Research* (National Statement) apply. However, this section makes no reference to the National Statement.

SECTION	COMMENT
Research (page 48)	The introduction in this section outlines that the provisions apply to post-market surveillance studies and market research conducted by or on behalf of a company. It advises that "clinical research such as Phase I, II and III clinical trials is governed by the Commonwealth therapeutic goods legislation; the ethical principles described in the NHMRC *National Statement on Ethical Conduct in Human Research*; and a number of Guidelines and Policies issued by State and Territory Health Departments". There is no statement outlining any expectation of compliance with the National Statement. In addition, this section contains no reference to requirements that apply to other types of research, such as the examples provided under the following headings: • Post Marketing Surveillance (PMS) studies (Section 10) • Ghost Writing (Section 11) • Market Research with Healthcare. (Section 12) Other activities that may require consideration by a Human Research Ethics Committee and may constitute research are not clearly indicated as such. This includes: • Product Familiarisation Programs (PFPs) (see below) • Market research with the general public (see below) • Patient Support program (see below).

SECTION	COMMENT
Last paragraph under **Research,** relating to Disclosure and publication **(page 48)**	It is suggested that this section direct the attention of Companies to the IFPMA/EFPIA/PhRMA/JPMA *Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases* (2009) and *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010) in relation to disclosure and publication. This section could also refer to the obligation on researchers to register clinical trials in a publicly accessible register prior to the beginning of the clinical phase of research (*National Statement on Ethical Conduct in Human Research* 3.3.12) (National Statement). This section should also refer to the obligation on researchers and institution to comply with the principles related to the dissemination and publication of research in the National Statement and the *Australian Code for the Responsible Conduct of Research* (2007). MA could consider amending the code to include a positive obligation on Members to: • encourage researchers to provide data obtained from clinical trials to a publicly accessible register; • limit the use of agreements which directly or indirectly (i.e. by providing the Member with an outright veto over publications) restrict the freedom of a researcher to publish their results, including negative results; and • be in accordance with the National Statement, ensure a researcher discloses any restrictions on publication to the reviewing HREC.
Section 10 - *Post-Marketing Surveillance (PMS) studies* **(page 48)**	It is suggested that MA could expand this section 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	COMMENT
Section 11 - *Ghost writing* (page 49)	Ghost writing describes inappropriate conduct where the contribution of a writer is not acknowledged in a publication. In contrast to ghost writers, professional medical writers disclose their involvement and funding source and follow ethical publication guidelines. Assistance from professional medical writers is acceptable; assistance from ghost writers is not. To ensure transparency of authorship or contribution to a publication, companies should follow the principles described in the IFPMA *Joint Position on the Publication of Clinical Trial Results in the Scientific Literature* (2010). This section should make reference to the obligations on researchers and institutions relating to authorship that are set out in the *Australian Code for the Responsible Conduct of Research* (2007) and to the recommendations of the International Committee of Medical Journal Editors in *Defining the Role of Authors and Contributors*.
Section 13 - *Relationship with the general public* (pages 50-55)	It is suggested that MA consider amending the Code to include provisions that demonstrate its commitment to open and unambiguous data and analysis, particularly relating to PBS expenditure. In particular all statistics and analysis published by MA and its member companies should credit the source of all data used.
Section 13.7 - *Materials for use with patients (patient aids)* (page 52)	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	COMMENT
Section 13.11 - *Market research with the general public* (page 55)	Market research may constitute an activity for which the requirements of the *National Statement on Ethical Conduct in Human Research* (National Statement) apply. However, this section makes no reference to the National Statement.
Section 17 - *Patient Support Programs* **(Pages 57-58)**	It is suggested that it would be better to state "The healthcare and wellbeing of patients must be the only objective of a Patient Support Program." The following is suggested: **Section 17, b):** 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 17, c):** This paragraph is broad and could benefit from 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 diabetes PSP? • Should there be an upper limit on the value of the material? **Section 17, f):** 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. **Section 17, h):** The Consumer Medicine Information 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. In relation to data that is collected in a Patient Support Program, the Department suggests there should be further clarification of the types of information that can be communicated to healthcare professionals.

SECTION	COMMENT
Section 17 - *Patient Support Programs* **(Pages 57-58)** …**cont.**	The last paragraph of this section outlines '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. Such data may be cited as 'data on file', following the requirements of Section 1.1, and must be consistent with the body of evidence'. This activity may constitute an activity for which the requirements of the *National Statement on Ethical Conduct in Human Research (*National Statement) apply. This section may benefit from referencing the National Statement.
Section 24 - *Conflict of Interest* (page 63)	This section does not distinguish between a person disclosing an interest, and the determination of whether or not such an interest constitutes a conflict of interest with another party. The Code may benefit from greater clarity in this area.
Section 34 - *Conflict of Interest* (page 70)	This section does not distinguish between a person disclosing an interest, and the determination of whether or not such an interest constitutes a conflict of interest with another party. The Code may benefit from greater clarity in this area.
GLOSSARY **(page 90)**	**Advertisement:** It is suggested that MA consider adding the 'reasonable purpose' test to its *'Advertisement'* definition to be fully consistent with the TG Act, from where its definition has been sourced. 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.

ADDITIONAL INPUT

Safeguarding the Effectiveness of Antimicrobial Products

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 AMR.

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 AMR, 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.