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22 September 2014

Dr Richard Chadwick
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Dr Chadwick

Medicines Australia: Application for Revocation and Substitution A91436-A91440

This letter responds to the additional third party submissions received by the ACCC in respect of Medicines Australia's application for authorisation of Edition 18 of the Code of Conduct (the ***Code***).[1]

1 Department of Health submission

Medicines Australia addresses below the Department of Health's (the ***DoH***) submission. The DoH raised several of these issues with Medicines Australia during the Code review process and amendments were made to Edition 18 to reflect the DoH's views:[2]

- **Reference to the National Statement on Ethical Conduct in Human Research**: the DoH suggests that the Code should refer to this Statement in various sections. Medicines Australia does not consider that it is possible for the Code to refer to every statement or guideline which governs the prescription medicines industry. In relation to the Code's Introduction specifically, Medicines Australia notes that the Introduction has been drafted so as to adopt the 'Guiding Principles' from the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA's) Code of Practice (2012). The IFPMA Code sets out principles for the ethical standards expected of the medicines industry globally, which Medicines Australia contributed to developing.
- **Scope of the Code**: the DoH suggests that:
  - the Code should refer to the obligations of researchers, such as by including a statement encouraging researchers to ensure that an open access version of their publications is made available. As the Code does not apply to researchers or

[1] Submissions of Dr Ken Harvey, Professor Philip Morris and the Department of Health, provided to Medicines Australia by the ACCC on 16 September 2014.

[2] The DoH submission to the Code Review Panel, which addresses several of these issues was provided to Medicines Australia on 21 December 2013 and is available at http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-review/20132014-submissions/

research institutions Medicines Australia considers that the Code is not the appropriate vehicle to encourage researchers to publish the results of their research;

- amendments be made to the Code in respect of clinical trials. The conduct of clinical trials is regulated by legislation and by regulatory guidance documents issued by the TGA, the NHMRC and other organisations such as public health organisations. As the Code does not regulate clinical trials Medicines Australia considers that the Code is not the appropriate vehicle to deal with the conduct of clinical trials; and
- the Code should be amended to increase the information publicly available on new medicines considered by the Pharmaceutical Benefits Advisory Committee (***PBAC***). Medicines Australia is participating in discussions with the DoH on how to improve the transparency of the PBAC processes. There are a number of factors that need to be considered concerning data that is submitted to the PBAC. Regardless, section 1.2 of the Code already requires companies that reference, as substantiating evidence for a claim, documents provided to the PBAC for its evaluation to provide a copy of that document to another party on request. Companies cannot claim that this information is confidential and decline to provide it to the requesting party.

- **References to the Therapeutic Goods Act**: the DoH suggests that cross references to the *Therapeutic Goods Act 1989* (Cth) (***TG Act***) be included in sections 1 and 2 of the Code. Medicines Australia will include these references in the Code Guidelines, which will be drafted for Edition 18 if the Code is authorised. Medicines Australia will also refer in the Code Guidelines to the codes of conduct published by healthcare professional bodies, although it notes that the Code itself does not regulate the conduct of healthcare professionals.
- **Cross references**: the DoH suggests that section 2 of the Code (which deals with promotion to healthcare professionals) include a cross reference to section 13 (which deals with interactions with the general public). Medicines Australia considers that as these sections deal with different conduct it may potentially be confusing to include the suggested cross-references.
- **Product Starter Packs**: the DoH suggests that clearer differentiation is required in section 7 between starter packs and product samples. Medicines Australia will consider this issue and intends to include further explanation in the Code Guidelines for Edition 18.
- **Product Familiarisation Programs (*PFPs*)**: in Edition 18 of the Code Medicines Australia has made amendments which address several of the DoH's comments on PFPs. The Code:
  - includes a new requirement in section 8.4 that a company must provide a patient information document explaining that the product supplied under the PFP will only be provided for a fixed period, after which time the product may only be available on a private prescription if it is not reimbursed by the PBS at that time. The patient must sign that document indicating their consent;
  - was amended in Edition 17 to clarify that the 10 working day period following a request for a copy of the rationale of a PFP starts from the date of the request; and
  - reinforces that suspected adverse drug reactions must be reported according to requirements under the TG Act.

  In relation to publishing information on PFP data, Medicines Australia is concerned that making these data available on a member company website could be regarded as 'promotion' of a prescription pharmaceutical as the data would be product specific.

- **Section 13 of the Code**: the DoH suggests that section 13 of the Code should be amended in respect of the provision of data and patient aids. In relation to data, in Edition 18 of the Code Medicines Australia has included a requirement in section 13.1 that all public statements must be referenced to their source. In relation to patient aids, the existing Code provides that any item (including patient aids) that is used outside the home (ie where a member of the public could see the item) may not be product branded: section 13.7.
- **Patient Support Programs**: Medicines Australia has adopted several of the DoH's suggested amendments to section 17 of the Code in Edition 18 including amending:
  - paragraph one of section 17, which provides that the 'health and wellbeing of patients must be **the** objective of a Patient Support Program' (emphasis added), not the 'primary objective' of such a program as previously drafted; and
  - section 17(f), to refer to compliance with section 13.

  Medicines Australia will also consider including further detail on section 17(c) in the Code Guidelines.

2 Consent to disclosure

In response to the further submissions of Dr Harvey and Professor Morris which propose that Medicines Australia member companies could refuse to deal with healthcare professionals who do not consent to having information regarding them published, Medicines Australia:

- considers that prohibiting member companies from facilitating directly medical education for healthcare professionals who do not consent to disclosure may prevent interactions that ultimately improve patient care. The public benefits of such interactions are not controversial and have been recognised by the Australian Competition Tribunal;[3]
- notes that member companies regularly support educational events run by third party providers such as professional colleges. In this regard, the new transparency regime in Edition 18 of the Code requires member companies to report on transfers of value associated with providing financial support to third parties: section 41.3.5;
- refers to the results of the Cegedim Strategic Data survey provided to the ACCC on 16 September 2014 which suggest that the majority of healthcare professionals are likely to consent to disclosure; and
- reiterates the comments in section 2.4 of its letter to the ACCC of 28 August 2014 as to why Medicines Australia considers it inappropriate to require member companies to boycott healthcare professionals who do not consent to disclosure.[4]

Medicines Australia also reiterates the comment in section 5.4(b) of its 2 July 2014 submission, that a regime which compels members to boycott healthcare professionals who choose not to consent to disclosure will serve to exacerbate the uneven playing field that exists between members of Medicines Australia and generic manufacturers. Medicines Australia disagrees with the suggestion that no such disadvantage will arise as member companies and generic manufacturers deal with different types of healthcare professionals (pharmacists vs doctors). Medicines Australia refers to:

- the definition of 'healthcare professional' in Edition 18 of the Code which states:[5] '**Healthcare professional** means a healthcare professional registered to practice in Australia who in the

[3] *Re Medicines Australia Inc* [2007] ACompT 4 at [187].

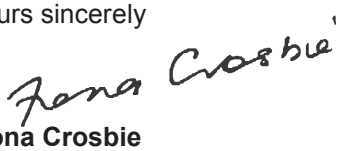
[4] See also section 5.4(b) of Medicines Australia's submission in support of authorisation dated 2 July 2014.

[5] Code of Conduct Edition 18, Glossary.

course of their professional activities may prescribe, dispense, recommend, supply or administer a prescription medicine in Australia'. This definition captures both pharmacists and doctors. Accordingly, the new transparency provisions in the Code will apply to interactions between member companies and both doctors and pharmacists; and

- the estimate in section 6 of Medicines Australia's letter to the ACCC of 16 September 2014, that at least 35% of medicines supplied under the PBS by volume are supplied by non-member companies, such as generic manufacturers. These figures make clear the competition faced by member companies from generic manufacturers for the supply of such medicines.

Yours sincerely



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