Australian Government

Department of Health and Ageing

Mr David Jones
Director
Adjudication Branch
Australian Competition & Consumer Commission
GPO Box 3131
Canberra ACT 2601

Dear Mr Jones

Medicines Australia Limited application for revocation and substitution A91316-A91320 - Interested party consultation

Thank you for seeking comment from the Department of Health and Ageing in relation to the application by Medicines Australia for re-authorisation of the 17th edition of its Code of Conduct by the Australian Competition and Consumer Commission.

For your information, I have attached some comments on specific matters within the Code of Conduct that could be drawn to the attention of Medicines Australia.

If you need to discuss any aspect of the Department's comments or require further information, please contact Dr Peta O'Connell (Acting Director, Regulatory Policy Section) on (02) 6289 3798 or email: *peta.o'connell@health.gov.au* .

Yours sincerely

Peter Woodley
Assistant Secretary
Blood Organ & Regulatory Policy Branch
9 August 2012

Department of Health and Ageing – Comments on specific matters

REFERENCE	DRAFT CODE CONTENT	COMMENT
8.1 - Product Familiarisation Programs *(Page 40)*	A company will make available the rationale for a PFP without delay but in any event in no longer than ten (10) working days.	It is unclear what event triggers the 10 working days. The TGA considers this requires further clarification.
8.10 *(Page 41)*	Suspected adverse drug reactions spontaneously reported during the PFP must be reported to the Advisory Committee on the Safety of Medicines (ACSOM) in accordance with the current TGA Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.	Adverse Drug Reactions should be reported **to the Therapeutic Goods Administration (TGA)** (not ACSOM). Details on how to report an adverse reaction to a medicine can be found on the TGA website at www.tga.gov.au/safety/problem.htm#defect
10.5 - Post-Marketing Surveillance studies *(Page 52)*	When a company is intending to carry out a Post-Marketing Surveillance Study it must advise the Advisory Committee on the Safety of Medicines (ASCOM) of its intention.	These studies should be reported **to the TGA** (not ACSOM)
10.10 - Post-Marketing Surveillance studies *(Page 53)*	Suspected adverse drug reactions noted during Post-Marketing Surveillance Studies must be reported to ACSOM in accordance with the current TGA *Australian Guidelines for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch.*	Adverse Drug Reactions should be reported **to the TGA** (not ACSOM),

REFERENCE	DRAFT CODE CONTENT	COMMENT
13 - Relationship with the general public *(Page 55)*	**13.1 – General Principles**	Section 13.1 of the draft Code provides that the Consumer Medicine Information (CMI) and Product Information (PI) documents are credible non-promotional sources of information on a company's products. It also provides that a company may make the PI and CMI available to the public providing they appear in their entire form, and are not amended, abridged, or displayed in a promotional manner. The provision of CMI and PI in certain circumstances may breach the prohibitions relating to the publication or broadcast of advertisement about prescription medicines (refer to paragraph 42DL(1)(f) of the *Therapeutic Goods Act 1989* (the TG Act)). For example, the inclusion of promotional material published alongside a company's CMI and PI for a prescription medicine on a website and when viewed in its entirety is likely to be considered advertising of prescription medicines to the public. Consideration should be given to including a provision to make it clear to companies that they cannot have promotional material associated with the CMI and PI when making these documents available to the general public.

REFERENCE	DRAFT CODE CONTENT	COMMENT
13 - Relationship with the general public *(Page 58)*	**13.7 – Disease Education activities in any media**	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. Currently, advertisements under the banner of disease education could be considered to be aimed at encouraging consumers to search for a particular company's medicine and to influence their medical practitioner to prescribe this medication. If Medicines Australia is seeking to ensure responsible disease education activities in the media, it should develop a mechanism for including de-identified company references in such programs.
18 - Patient Support Programs *(Pages 62-64)*		Patient support programs could be used as 'brand promotion' late in the patent cycle to support/develop ongoing patient preference for the innovator medicine in the face of generic competition. Medicines Australia should have suitable criteria for these programs in the Code which would identify whether they could be considered of a promotional nature. Some provisions in the Code could allow for the promotion of medicines via wording that is not as strong as in previous editions of the Code. For example, in relation to Patient Support Programs, statements such as "The healthcare and wellbeing of patients must be the primary objective of a Patient Support Program." (Page 62, last para., 3rd sentence) could allow promotion as a secondary objective of the company. If the statement were strengthened to read "The healthcare and wellbeing of patients must be the only objective of a Patient Support Program." there could be no misinterpretation.

REFERENCE	DRAFT CODE CONTENT	COMMENT
18 - Patient Support Programs *(Page 63, last para, point 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.	Consideration could be given as to whether verbal disclosure to the patient of the payment to the healthcare professional should also be required prior to enrolling, to ensure this information is fully disclosed.
18 - Patient Support Programs *(Page 63, last para, point 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.	Noting that payment of healthcare professionals commensurate with the activities required to be undertaken in the administrative or other work involved in the Patient Support Programs is disclosed to patients prior to enrolling in the program, consideration could also be given to including these payments in the reporting of financial support, grants etc. This approach would reinforce the obligation to be open and transparent about the conduct and management of a Patient Support Program, and is less likely to be interpreted as promotional.
18 - Patient Support Programs *(Page 63, last para, point 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 statement appears to inadvertently exclude services and products as being able to be provided (e.g. telephone support, pedometer, blood glucose monitor). Further clarification of what is encompassed under 'material that will enhance positive health outcomes and compliance' would be beneficial.
18 - Patient Support Programs *(Page 63, last para, point g))*	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.	While it is appropriate to highlight that the potential risks of the medicine do need to be included, <u>all</u> of the information should be balanced, accurate and correct. The sentence could be changed to say "The information provided to the patient prior to their enrolment in a Patient Support Program must include balanced, accurate and correct information***, including*** about the potential risks of the medicine".

REFERENCE	DRAFT CODE CONTENT	COMMENT
18 - Patient Support Programs *(Page 63, last para, point 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.
18 - Patient Support Programs *(Page 64, first para, sentence 2)*	However, companies may not collect data for the purpose of making a claim about a product	The intent of this sentence is unclear. We suggest that the phrase 'for the purpose of making a claim about a product' be clarified to demonstrate it refers to making a therapeutic claim about a product.
18 - Patient Support Programs *(Page 64, first para, sentence 4)*	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.
GLOSSARY *(Page 90)*	**Advertisement** in relation to therapeutic goods as defined in the *Therapeutic Goods Act 1989* includes any statement, pictorial representation of design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.	The glossary to the draft Code of Conduct (draft Code) notes that the definition of 'advertisement' is as set out in the *Therapeutic Goods Act 1989* (the Act). The TGA interprets the "intention" set out in the definition as an objective intention. That is, the intention would be assessed on how a reasonable consumer would perceive particular materials. If the reasonable consumer would think that the material was intended, whether directly or indirectly to promote the use or supply of the relevant therapeutic goods, then that would be considered an advertisement under the Act. It is noted that there is a typographical error in the definition of 'advertisement' ".....pictorial representation **of** design...." instead of ".... pictorial representation **or** design.....".

REFERENCE	DRAFT CODE CONTENT	COMMENT
Page 94) *(Page 94)* *(Page 94)*	**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. **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.	However, the definition of 'promote' (and related terms), and promotional material as set out in the glossary appears to take into account the actual or likely purpose of the advertiser. In addition, the effect of these definitions in conjunction with what are allowable information materials that can be given to the public under section 13 of the draft Code, such as PI and CMI, appears to be inconsistent with the definition of "advertisement" under the Act and the prohibition in relation to the advertisement of prescription medicines direct to the public. The definition of promotion or promotional, or promotional claim appears to indicate that statements concerning efficacy, rate of adverse reactions are promotional. However, it is possible that the product information may contain the above information, and section 13 of the draft Code states that product information approved by the TGA for example is not promotional. In addition, depending on how the product information or consumer information is presented may be considered promotional. Product information and consumer medicine information would always represent the attributes of a product as defined in the draft Code. The Department considers that the interaction of these definitions, and the provision of the product information and consumer medicine information to the public by sponsors of prescription medicines is 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).