Consumers Health Forum of Australia

30 July 2012

Dr Richard Chadwick
General Manager
Adjudication Branch
Australian Competition and Consumer Commission
GPO Box 3131
CANBERRA ACT 2601

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Dear Dr Chadwick

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

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Australian Competition and Consumer Commission (ACCC) on the application by Medicines Australia for authorisation of its Code of Conduct Edition 17.

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF and its members have a strong interest in the ethical promotion of therapeutic goods. CHF was closely involved in the development and implementation of the 16th Edition of the Medicines Australia Code, and provided a submission to the Review of the Medicines Australia Code of Conduct in November 2011. We were also involved in the Working Group on the Promotion of Therapeutic Products, chaired by Anne Trimmer, which provided recommendations to Government in March 2011.

CHF supports the efforts of Medicines Australia to ensure ethical promotion of therapeutic goods by its members, and welcome the incorporation of new provisions which strengthen the Code. We do, however, have some concerns about the adequacy of certain provisions of the Code, particularly relating to disclosure of payments to medical professionals. These are outlined in further detail below.

Welcome additions to the Code

CHF notes certain elements of the Code have been strengthened, and we welcome these amendments:

- Section 13.9 now includes additional requirements regarding social media, including that companies are responsible for all content on company-initiated or controlled social media sites and activities; all companies should have policies and procedures describing the roles and responsibilities of employees and contractors when interacting with social media to ensure compliance with the Code of Conduct; and a requirement that suspected adverse drug reactions noted during monitoring of social media sites must be reported to the TGA.

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- Section 14 (particularly section 14.4) provides for increased transparency of company sponsorship of health consumer organisations, including through publication of reports of support for health consumer organisations on the Medicines Australia website. We note that it remains the responsibility of the company to inform a health consumer organisation that any sponsorship received will be publicly disclosed (section 14.5).

- CHF particularly welcomes amendments to Section 18, regarding Patient Support Programs, following revelations last year about pharmacists receiving payments to enrol consumers in these programs without disclosure of these payments to the consumers. We are pleased that this section now emphasises the 'obligation to be open and transparent about the conduct and management of a Patient Support Program', and that any payment provided to a healthcare professional for enrolling a patient in a patient support program must be disclosed to the patient in writing prior to their enrolment. We also note the strengthened requirements regarding information that must be provided to consumers on enrolment, including the fact that they can opt out at any time, information regarding who will hold their personal details, and the Consumer Medicine Information document.

  CHF does have some concerns about provisions in Section 18 regarding the inclusion of information on Patient Support Programs in product packaging. These are outlined in more detail below.

- Section 19 now explicitly states that no company representative may access or obtain data from dispensary software systems.

Adequacy of reporting requirements

Edition 17 of the Code requires Medicines Australia member companies to provide reports of aggregate amounts of all payments made to, or sponsorship of, healthcare professionals for advisory boards and consultancy arrangements and attendance and speaking at medical conferences and educational events. Member companies are *not* required to provide the names of individuals who have received payments or sponsorship, or the amount of funding provided to each individual.

CHF argues that this does not provide a sufficient level of transparency, nor does it ensure that these payments and sponsorships are 'able to withstand public and professional scrutiny', as is required in the Code. If details of these payments are not made publicly available, then this 'public and professional scrutiny' is simply not possible.

CHF accepts that there may be legitimate reasons for health professionals to receive payments and sponsorships from pharmaceutical companies, but we argue that public disclosure at the individual level is necessary if consumers are to have confidence that these financial relationships are motivated by the education of the health professional to ensure improved consumer health outcomes, rather than health professionals' or industry's financial interests.

> **We urge the ACCC to require individual level, rather than aggregate level, reporting of payments and sponsorships to health professionals as a condition of authorisation of the Code.**

Adequacy of financial penalties

CHF is aware that the financial penalties associated with breaches of the Medicines Australia Code are higher than those outlined in other Australian therapeutic goods industry self-regulatory codes. They are, however, substantially lower than penalties in other countries, particularly the United States.

We note that some companies continue to breach the Medicines Australia Code of Conduct, and therefore we question whether the financial penalties for breaches have a sufficient deterrent effect.

> **We urge the ACCC to give consideration to whether the financial penalties associated with breaches of the Code are sufficient to protect Australian health consumers from unethical promotional activities, and urge an increase in penalties consistent with international requirements.**

Management of Product Familiarisation Programs
Section 8 of the revised Code outlines requirements around the conduct of Product Familiarisation Programs (PFPs), through which new medicines are made available to eligible consumers prior to their listing on the PBS. The Code states that no formal protocol is required for PFPs, and that individual patient data and personal details of patients are not to be collected through PFPs.

CHF argues that it should be a requirement that any information regarding adverse events that occur during PFPs is made available to the regulator and to clinicians. Currently, the Code states that suspected adverse drug reactions 'spontaneously reported during the PFP' must be reported to the Advisory Committee on the Safety of Medicines. Given the value of adverse event data collected during PFPs to both the regulator and to clinicians, CHF argues that the Code should require that sponsors proactively engage with clinicians and the regulator regarding any safety concerns or other issues, rather than waiting for spontaneous reports.

> **We urge the ACCC to require that sponsors be required to proactively engage with clinicians and the regulatorregarding safety concerns during Patient Familiarisation Programs, rather than relying on spontaneous reporting of adverse events.**

Provision of pack inserts promoting Patient Support Programs

As noted above, CHF has concerns about amendments to the section of the Code relating to Patient Support Programs (section 18), which permit companies to include information about the availability of a Patient Support Program and how to enrol in such a Program as an insert in the product package. There is no requirement for an enrolment form to be reviewed or approved by the Therapeutic Goods Administration.

CHF questions the appropriateness of including information on Patient Support Programs as pack inserts. The TGA is currently undertaking a review of medicines packaging and labelling, which specifically addresses pack inserts. According to the Consultation Paper released for the review:

A pack insert is a document that provides consumers with more detailed information about the medicine, such as more detailed directions for use than those provided on the medicine container or primary packaging.[1]

Where pack inserts are provided, they play a key role in providing consumers with information that supports them to use the medicines appropriately and safely. The inclusion of extraneous information, such as information on Patient Support Programs, could result in consumers disregarding other information contained in the package that is essential to the safe use of the medicine. While CHF recognises that Patient Support Programs may support quality use of medicines, we argue that including enrolment forms within product packaging will not support this goal.

CHF also notes that the TGA is proposing a regulatory change that will not permit advertising material to be included as a pack insert. While the Code states that enrolment package inserts included in medicines packaging 'must not be promotional', an argument could be made that these inserts are advertising material for the Patient Support Program, raising potential issues if this regulatory change goes ahead.

We urge the ACCC to require the removal or alteration of the section of the Code permitting enrolment forms for Patient Support programs to be included as pack inserts as a condition of authorisation of the Code, in recognition of the potential risks for quality use of medicines.

Handling of complaints against non-members

CHF notes that, according to section 23, complaints relating to the conduct of non-members will be forwarded to the non-member with an invitation to have the complaint adjudicated by the Code Committee. If the non-member declines the invitation, the Code states that 'Medicines Australia shall have the right, but not the obligation, to forward this complaint ... to the TGA or the ACCC'.

While we recognise that the Code relates to the conduct of Medicines Australia members and that Medicines Australia is not obliged to deal with complaints regarding the conduct of non-members, CHF considers that this is an issue that needs to be considered by the ACCC. The Working Group on the Promotion of Therapeutic Products which reported to Government in March 2011 recommended that compliance with an identified industry code of conduct should be a requirement for registration on the Australian Register of Therapeutic Goods. This recommendation was not accepted by Government, but provides an indication of one mechanism that could be used to protect consumers from inappropriate promotion of therapeutic products, regardless of whether their sponsors are members of industry associations with codes of conduct.

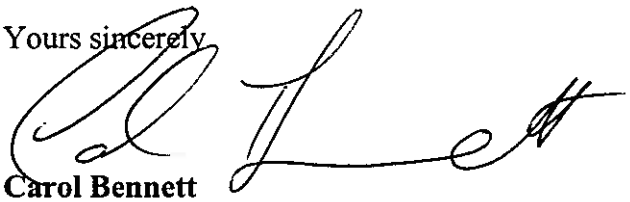
We urge the ACCC to consider how the handling of complaints against non-members of industry associations can be more effectively addressed.

[1] TGA 2012 *TGA Medicine Labelling and Packaging Review: Consultation Paper*, available online at http://www.tga.gov.au/pdf/consult/consult-labelling-packaging-review-120524.pdf.

CHF appreciates the opportunity to provide a submission to the ACCC's consultation, and awaits the draft determination with interest. We look forward to involvement in future stages of public consultation.

If you would like to discuss the issues raised in this submission in more detail, please contact CHF Deputy Chief Executive Officer, Anna Greenwood.

Yours sincerely



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