6 July 2010

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

Dear Dr Chadwick,

Re: Generic Medicines Industry Association Pty Ltd applications for authorisation [A91218 & A91219] – request for interim authorisation

Thank you for providing the opportunity for Medicines Australia to make a submission in respect of the Generic Medicines Industry Association's (GMiA) request for interim authorisation of its Code of Practice, second edition.

We note that the ACCC will only grant interim authorisation in special circumstances and is unlikely to grant interim authorisation if doing so would permanently alter the competitive dynamics of the market or inhibit the market from returning to its pre-interim state if final authorisation is later denied.

Medicines Australia does not support interim authorisation being granted for GMiA's Code of Practice. As was stated in Medicines Australia's submission concerning GMiA's application for authorisation, we consider that the Code as currently drafted is weak. The GMiA Code of Practice:

- Does not provide for sufficient transparency as to the promotional and educational activities of GMiA members;
- Provides for inadequate sanctions; the sanctions imposed under the GMiA Code should be equivalent to the sanctions available under the Medicines Australia Code of Conduct for similar behaviour; and
- The external complaints handling process will not adequately avoid conflicts of interest and is not sufficiently independent of the members of GMiA, despite the amendments proposed by GMiA in its further submissions to the ACCC.

GMiA has requested interim authorisation because it wants the Code Complaint Committee (CCC) to consider a complaint it received on 21 April 2010 ('the complaint') against a GMiA member. The ACCC should consider what would be the status of any decision made by the CCC under an interim authorisation if final authorisation of the Code is not granted, or is granted with Conditions that alter the process for considering complaints or the sanctions that may be imposed by the CCC. If, as Medicines Australia has argued, the level of monetary sanctions is increased by reason of a Condition imposed on the GMiA Code by the ACCC, the validity and adequacy of any sanction imposed under the Code if granted interim

authorisation would be called into question. Similarly, if the composition of the CCC is altered by a reason of a Condition imposed by the ACCC, the process for finding the subject company in breach or not in breach of the Code under an interim authorisation would be called into question. Further, if the subject company is found in breach of the Code under interim authorisation but subsequently the ACCC declines to authorise the Code, the subject company might consider that it has been dealt with unfairly. These matters strike at the heart of effective self-regulation under industry Codes of Conduct.

The GMiA seeks interim authorisation in order to resolve the complaint, which it received 21 April 2010. It was therefore over two months before GMiA sought interim authorisation. It cannot now argue that there is any urgency to resolve the complaint.

With regard to the question of whether the market would return to its pre-interim state if final authorisation is denied, Medicines Australia submits that the ACCC take into its consideration the current dynamics of the therapeutic goods market in Australia and particularly the prescription medicines market. On 30 June 2010 the Parliamentary Secretary for Health, the Hon. Mark Butler MP, released a Position Paper on the Promotion of Therapeutic Goods. This paper was issued in response to "*on-going public concern raised about promotion of therapeutic goods to healthcare professionals and the lack of a level playing field across the therapeutic goods sector regarding the requirements and enforcement of self-regulatory codes of conduct*". A copy of the Position Paper is attached to this letter.

The Government has stated in the Position Paper that its Policy Objective is to ensure that decisions on management options for consumers are based on sound clinical evidence and are not driven by incentives or other influences. Strong, effective and consistent industry self-regulatory codes of conduct are central to achieving this objective. Medicines Australia does not consider that granting interim authorisation of the GMiA Code of Practice will promote the achievement of a level playing field in the therapeutic goods sector in Australia. We recommend that interim authorisation should not be granted.

Thank you again for the opportunity to provide a submission on the application from GMiA for interim authorisation of its Code of Practice.

Yours sincerely,

Donna Edman
Acting Chief Executive

POSITION PAPER

ON THE

PROMOTION OF THERAPEUTIC GOODS

There has been on-going public concern raised about promotion of therapeutic goods to health care professionals and the lack of a level playing field across the therapeutic goods sector regarding the requirements and enforcement of self-regulatory codes of conduct.

Policy Objective

The Government aims to ensure that decisions on management (including treatment) options for health needs are based on sound clinical evidence, not driven by incentives or other influences, and that self-regulatory codes of conduct are effective in minimising the potential for any promotional activities to compromise the quality use of medicines and to increase cost pressures on the health system.

Background

The professional relationship between health care professionals and therapeutic goods companies is governed by industry and professional codes of conduct, not by government regulation. A number of the therapeutic goods industry associations have codes of conduct/practice which include guidelines on ethical business practices and socially responsible industry conduct. Breaches by some industry association members and the absence of any effective oversight for non-members have the capacity to undermine public confidence in the health sector, create damaging public perceptions of the therapeutic goods industry, and raise doubts about the prescribing decisions of health professionals.

Existing codes are inconsistent in terms of their requirements, application, enforcement and penalties. These inconsistencies between the standards expected of different groups within an industry, and between members and non-members of industry associations, have created an uneven playing field.

On 8 September 2009, the Parliamentary Secretary for Health, the Hon Mark Butler MP, released a media statement responding to concerns about inappropriate marketing to medical professionals. Since then, Mr Butler and officials have met with key stakeholders from industry, health profession organisations and consumer groups to discuss actual or perceived weaknesses with the current system of self-regulation. The key issues raised by different groups were: the need for high level principles underpinning sector specific codes; how to deal with non-members; and the structure of the complaints system. There was broad acceptance by industry of the need to reform the existing arrangements.

The Government's Position – Strengthening Self-Regulation

The Australian Government supports self-regulation of industry conduct, including for promotional activities undertaken by therapeutic goods companies. Accordingly, the Government is proposing, in the first instance, that industry strengthen and standardise self-regulation through developing an industry framework for universal adherence to consistent industry-wide codes based on a common set of high level principles.

While this is the preferred approach, if consistent arrangements are not realised, then legislative options consistent with the Government's policy objectives, including universal coverage and consistency across the sector, could be put in place in 2012. This could include enforcement arrangements to ensure compliance with these objectives.

The Australian Government expects the arrangements that underpin the relationship between the therapeutic goods industry and health care professionals are appropriately regulated to minimise the possibility of undue influence in the decisions of health care professionals to prescribe, dispense, supply or purchase products and to ensure that independent medical decision-making is maintained.

Common Principles

The set of high level principles to be developed by industry will provide clear expectations for the conduct of promotional activities by companies in the therapeutic goods industry. They might cover: common core standards; principles of conduct including specific elements required for each code; and governance arrangements such as compliance training, reporting and independent complaint mechanisms. Achieving consistency would require industry associations to review their codes and revise them, as necessary, to align with the high level principles.

Scope

The Australian Government expects all sponsors of high-risk therapeutic products - both members and non-members of industry associations - will comply with a relevant code of conduct.

The application process for the registration of these products on the Australian Register of Therapeutic Goods would provide an opportunity for sponsors to nominate the code with which they intended to comply. In this way, those companies within the therapeutic goods sectors (ie prescription medicines, higher risk over-the-counter medicines and higher risk medical devices) more likely to direct promotional activities to health care professionals will be the primary target group.

Promotion of lower risk *listed* therapeutic goods will continue under the current self-regulatory arrangements. This however, could be reviewed at a later stage.

Non-members of industry associations will not be obliged to become members to elect to be covered by a code. Complaints about potential breaches of a code by a non-member could be referred to the relevant code of conduct committee for investigation and determination.

Reciprocal Arrangements with Health Care Professionals

The therapeutic goods industry and health care professionals participate in a two-way relationship and, for that reason, there is a need to ensure the standards for conduct of health care professionals align with the standards expected of the therapeutic goods industry. Health care professional groups (including medical groups, pharmacists and nurses) are often subject to their own codes of conduct which include provisions for ensuring that there is no conflict of interest in participating in promotional activities offered by the therapeutic goods industry.

Australia's new National Registration and Accreditation Scheme begins on 1 July 2010. From this date, ten health professions will be regulated by nationally consistent legislation. Under this legislation, the Australian Health Practitioner Regulation Agency (AHPRA) is responsible for establishing general requirements for the development of health profession standards. In developing the high level

principles, industry would be advised to collaborate with AHPRA to ensure consistent ethical standards for the interaction of health care professionals with the therapeutic goods industry.

Government Endorsement

Government endorsement of the high level principles will rely on them being consistent with the objectives and principles of the National Medicines Policy (NMP). Further information on the NMP is available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1.

As part of industry's broad consultation process, and in line with the medicines industry's responsibilities as a partner to the NMP, the draft principles will need to be presented to the NMP Committee for comment. The common core standards will also need to comply with the World Health Organization's 1988 *Ethical Criteria for Medicinal Drug Promotion* and the Australian Competition and Consumer Commission's *Guidelines for Developing Effective Voluntary Industry Codes of Conduct.*

Conclusion

The therapeutic goods industry is a mature industry which has previously demonstrated its commitment and ability to make self-regulation work. More effective self-regulation through the development and implementation of high level principles embedded in all codes could improve confidence that decisions on management of health needs are based on sound clinical evidence and not driven by incentives from the therapeutic goods industry. This will reduce pressure for additional government intervention.

Comments / Inquiries

Any comments on the Government's Position Paper should be directed via e-mail to industrycodesofconduct@health.gov.au by Friday 30 July 2010. Alternatively, if you have any inquiries please telephone (02) 6289 8604.