Consumers Health Forum of Australia

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

Dear Dr Chadwick

Medicines Australia Limited application for revocation and substitution A91436 - A91440– 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) consultation on the application by Medicines Australia for authorisation of its Code of Conduct Edition 18 (the Code).

We appreciate the opportunity to contribute information, on behalf of Australian health consumers, to the Commissions' deliberations on this important matter.

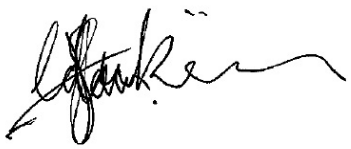
Overall in relation to the MA code, CHF recommends:

- Full transparency surrounding the relationship, and any transfers of value, between industry and healthcare professionals;
- Effective and consistently enforced sanctions for breaching the code;
- Consumer safety to be prioritised over industry interests, and
- A single Code for the therapeutic goods industry.

In light of the proposed Code's failure to meet these principles, CHF would recommend that the ACCC not authorise this code.

Should you require any further information, please do not hesitate to contact us.

Yours sincerely



Adam Stankevicius
Chief Executive Officer

31 July 2014

PO Box 3099, Manuka ACT 2603 ■ Unit 9, 11 National Circuit, Barton ACT 2600
Tel: (02) 6273 5444 Fax: (02) 6273 5888 Email: info@chf.org.au Web: www.chf.org.au
ABN 82 146 988 927

Submission to the Australian Competition and Consumer Commission on

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

August 2014

Introduction

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Australian Competition and Consumer Commission (ACCC) consultation on the application by Medicines Australia (MA) for authorisation of its Code of Conduct Edition 18 (the Code).

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. As such, CHF and its members have a strong interest in the ethical promotion of therapeutic goods.

CHF has welcomed and supported MA's work in this area, recognising that MA has taken leadership on this issue that extends beyond the usual remit of its work. As highlighted through our previous submissions to reviews of the Code, CHF has long advocated for individual level disclosure of payments made by companies to healthcare professionals and we have supported and commended the work of the Transparency Working Group (TWG) and MA in developing the Discussion Paper in September 2013.

Background

Codes of practice or conduct provide consumers with reassurance that there are standards that must be met, and penalties which apply, for practitioners in relation to certain matters. Codes exist in both legislative and non-legislative environments, and can sometimes be the reason for one regime over the other.

Codes of conduct are disparate across the health system, with some sectors having relatively strong and regularly-reviewed codes, while other sectors have lax or under-developed codes. In the absence of legislation, CHF has consistently supported and prompted health industry associations to develop codes of conduct for their members, with differing degrees of success.

In this context, we have paid close attention to the work which Medicines Australia has undertaken in relation to its Code of Conduct.

In our previous submission to ACCC on the 17th edition of MA's code of conduct, CHF suggested further changes to improve transparency that included:

- requiring individual level, rather than aggregate level, reporting of payments and sponsorships to health professionals
- giving consideration to whether the financial penalties associated with breaches of the Code are sufficient to protect Australian health consumers from unethical promotional activities, and urging an increase in penalties consistent with international legislative trends
- considering how the handling of complaints against non-members of industry associations can be more effectively addressed.

CHF thus welcomed the ACCC's decision to make individual level disclosure of payments and 'transfers of value' from companies to healthcare professionals a condition of its authorisation of Edition 17 of the Code, for inclusion in Edition 18 of the Code.

Unfortunately, we find the proposed Code fails to meet these conditions or consumer expectations.

Overall, while CHF supports the efforts of Medicines Australia to ensure ethical promotion of therapeutic goods by its members, we are disappointed with the inadequacy of certain provisions of the Code, particularly relating to disclosure of payments to medical professionals. We believe the proposed version of the code fails to meet the transparency mandate that ACCC, and consumers expected MA to deliver and also fails to meet the principles of transparency that MA's own TWG proposed in June 2013.[1]

Our submission addresses issues and specific clauses relating to the Code, before providing comment on the broader concerns we have around the self-regulatory model across the therapeutic goods industry in Australia. CHF's comments on the Code relate to: Patient Support Programs; Product Familiarisation Programs; financial penalties, abuse of the code by non-members and adequacies of reporting and transparency requirements.

Issues and Concerns with the 18 Edition of the Code

Welcome additions to the Code

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

- Additional requirements to ensure that adequate safety information is included in relation to efficacy or other promotional claims
- The strengthening of sections related to the promotion of unapproved products or indications
- Additional media requirements to cover electronic media such as smartphone applications, electronic tablets and other mobile devices and software;
- Informed consent protocols around Product Familiarisation Programs such as a signed section for patient to provide consent, and
- Strengthened requirements around material associated with patient aids.

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. CHF has ongoing concerns about the potential these programs have to cause significant harm to consumers, especially through rapid consumer intake without adequate support to healthcare professionals.

A rapid intake of a large number of consumers through PFPs is an issue when those consumers present to emergency departments that are unaware or ill equipped to provide treatment for patients experiencing adverse events. In a recent PFP managed by Boehringer Ingelheim there were reports noted in ACCC's Determination to Edition 17 of the Code, that most prescribing and dispensing software carried inaccurate information about the medicine. Hospital staff simply did not know or have access to information that would allow them to provide the level of care consumers needed.

[1] Medicines Australia, Transparency Working Group, Principles of Transparency

Regulatory frameworks contribute to ensuring the safety of consumers who use new medicines. These include pharmacovigilance requirements upon sponsors, information provision of Product Information (PI) and Consumer Medicine Information (CMI), healthcare professional knowledge of antidotes and adverse event management measures.

Companies should ensure that a PFP is underpinned by up to date and unbiased information, including PI and CMI, available from a variety of electronic and hardcopy sources. Member companies should also ensure that healthcare professionals are adequately trained to discuss the risks associated with its use with the consumer before prescribing. PFPs should not be rolled out until healthcare professionals have received training about the new medicine and only after adequate and up to date information is available for them to access online or through the company. The risks to consumers and the health system are very high if these processes are not managed appropriately. [2]

Consumers should be given information about the PFP that they can take home to review in their own time, and would benefit from being able to access dedicated information and telephone help-line for the life of the PFP.

CHF recommends that the Code should include clear requirements for companies conducting PFPs to train healthcare professionals and to provide adequate and accurate information about the medicine. An information and advice line should also be set up by the company to operate for the life of the PFP.

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. [3]

We note that some companies continue to breach the Medicines Australia Code of Conduct[4], and therefore we question whether the financial penalties for breaches have a sufficient deterrent effect.

We recommend 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.

We also recommend that such penalties should be put into a special account for the support of consumer research and representation, in a manner similar to how governments use proceeds of crime funds to support crime prevention activities. CHF understands that this is

[2] BMJ, 2014, Dabigatran and statins: faith, hype, and transparency
[3] Physician Payments Sunshine Act Final Rule: Quick Reference Guide
[4] Code of Conduct Annual Report 2013

something MA has done in the past, through the creation of a Special Purpose Fund, which has funded some laudable community projects.[5]

Provision of pack inserts promoting Patient Support Programs

As raised in our previous submission to the 17th edition of the Code, CHF has concerns about amendments to the section of the Code relating to Patient Support Programs (section 17), 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.

Pack inserts play a key role in providing consumers with information that supports them to use the medicine appropriately and safely. Pack inserts compensate for the limited space available on small containers and should only contain the most important information needed by consumers to support quality use of medicines. The safety of consumers may depend upon the information contained on pack inserts. Including non-essential information such as advertising and promotional material or information about PSPs, diminishes the importance of inserts and could result in consumers discarding essential information on inserts.

CHF recommends that a clause prohibiting package inserts to promote PSPs should be included in the Code. Package inserts promoting PSPs are arguably advertising material and not essential to the safe use of medicine.

Handling of complaints against non-members

CHF notes that the proposed version of the Code continues to inadequately address complaint processes against non-members. As noted in Section 25, 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 the Federal 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 (ARTG). [6]

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

[5] Medicines Australia, Annual Report 2011-12
[6] Working Group on Promotion of Therapeutic Products, Report to Parliamentary Secretary Catherine King

therapeutic products, regardless of whether their sponsors are members of industry associations with codes of conduct.

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

Adequacy of Transparency and Reporting Requirements

CHF's main concerns with the latest issue of the Code are dominated by the inadequacies of the proposed Transparency model.

CHF has provided comment on aspects of the Transparency Model with the aim of achieving better informing healthcare consumers and the Australian community. Consumers should have access to all the information necessary to allow them to decide for themselves what the drivers of their healthcare professional's prescribing behaviour might be.

- **Inadequate threshold of reporting**

CHF is disappointed with MA's proposed $120 threshold for monitoring and reporting. This is most disappointing considering MA's own TWG released a discussion paper that proposed stringent monetary limits of $25 or $10. [7]

CHF continues to support full disclosure of all payments over the $10 threshold for recording and reporting of payments made to individual practitioners. This would capture items of low monetary value, such as lunches at a healthcare professional's office, which, when one-off may not be a significant amount, but when aggregated over a period of a year could total a substantial figure. More important than the actual monetary threshold however, is the capturing of data that reflects how often health practitioners and industry interact.

A $120 threshold proposed under the current provisions will fail to record and report a majority of industry-health practitioner interactions, and thus exclude most of the events with the potential to be influence prescribers.

- **Obtaining Consent for Reporting**

CHF notes that the provision of individual level disclosure hinges on Industry obtaining consent from health practitioners. While we acknowledge MA's and pharmaceutical companies' obligations to comply with privacy legislation, we do not believe that this should be a significant inhibitor to effective transparency.

Payments should only follow transparent pathways, whereby consent for disclosure should be embedded in any contract where there is a transfer of value between health practitioners and industry. A robust and effective process is undermined where practitioners can obtain gifts or payments without any commitment to ensure transparency and disclosure of these arrangements.

[7] The Transparency Model Discussion Paper

We note that practitioners could choose to withdraw their consent at any point, even after having granted initial permission to disclose. CHF argues that in such a circumstance, it is only reasonable that the practitioner should be obliged (through the terms of the original agreement) to repay the value of the gift or payment to the company which provided it. This would allow privacy laws to be adhered to, while ensuring that no benefit accrues without disclosure.

CHF also notes that some of MA's current members already apply these principals of transparency in countries like the US. In an FAQ published by Novartis in the US they highlight the fact that *"Novartis is committed to complying with all transparency reporting laws. The only way to avoid appearing on the Novartis Vaccines and Diagnostics disclosure to CMS is to decline meals, education materials, grants and all other reportable payments and transfers of value."*[8]

Moreover, without a financial disincentive, the complex reporting, checking and follow through iteration proposed by MA, will only provide incentives for practitioners to opt for the non-disclosure option, rendering the entire individual level disclosure intent of the system meaningless.

- **Repository of Recorded Disclosure**

CHF is also disappointed to note that in the first phase of implementation, MA is proposing that the reports on disclosure be listed on each industry member's website. This would imply that a consumer will have to essentially look through reports hosted on all of MA's member websites before they can completely unravel the relationship between their health practitioner and industry. Clearly, this is an inappropriate way to assist transparency.

A central database, that can collate disclosure data linked to individual practitioners (through identifiers such as the AHPRA UID numbers) is a critical component of the transparency model, and we are disappointed that this has not been more explicitly proposed in the new Code. It is difficult to comprehend how commercial information providers are able to easily collect and compile payments information, for the purposes of packaging and re-sale as a product[9], yet the relevant industry association isn't able to undertake a similar exercise to ensure consumers have access to this information.

Broader issues around Regulatory Frameworks in Australia

CHF recognises and applauds the leadership MA has taken across the industry in relation to a code of conduct. However we note the challenges the Code faces in operating in a system where there are several different self-regulated codes, often with no authorisation, in different parts of the therapeutic goods industry.

At present, there are several different self-regulated codes in place for different parts of the therapeutic goods industry, covering members of Accord Australia, AusBiotech, the Australian Dental Association (ADA), the Australian Self Medication Industry Association

[8] Novartis, Payments to Healthcare Professionals FAQ's
[9] Pharma in Focus Research, 'KOL Speaker Fees 2014: how much should you pay?', 2014.

(ASMI), the Complementary Healthcare Council of Australia (CHC), the Generic Medicines Industry Association (GMIA), In Vitro Diagnostics (IVD) Australia, the Medical Technology Association of Australia (MTAA), and Medicines Australia. These codes vary widely in areas such as:

- Expected standards for members
- Monitoring provisions
- Application and enforcement
- Levels of penalties and sanctions
- Processes for making and managing complaints.

CHF has previously called for a single code of conduct or regulatory framework to address this variability, as well as other limitations in the existing self-regulation regime.

These include:

- The lack of clarity surrounding the most appropriate code and complaints-handling body
- The tendency of codes to fall behind the expectations of consumers and the community
- The tendency of codes to fall behind the expectations and practices of high-performing sectors of the industry, due to the need to accommodate a range of member companies within industry codes
- The lack of application of industry codes to non-members, resulting in equity and compliance issues.

CHF thus continues to advocate for the establishment of a single, rigorous code of conduct for all pharmaceutical and therapeutic goods industries, for all members and non-members of industry associations alike. As noted earlier, CHF supports the recommendation of the Working Group on the Promotion of Therapeutic Products[10], which addressed the need for adherence to industry codes by non-members as well as members. This can be achieved by ensuring that as a condition of registration/listing/inclusion of a product on the ARTG, all applicants must mandatorily nominate the relevant code of practice to which they will subscribe.

The Government's response to this Working Groups' recommendation was to maintain the emphasis on self-regulation, and to encourage industry to harmonise their codes of conduct and invite non-members to join industry associations. However, as the proposed MA code demonstrates this is a failing model, and CHF believes that legislative measures are required as voluntary participation is failing to deliver the outcomes desired.

A poll of CHF's voting members conducted in 2013 revealed that over 90 per cent of responding consumers support the objectives of introducing Government legislation to address these issues, with only 5 per cent opposing and 2 per cent undecided.[11] This

[10] Working Group on Promotion of Therapeutic Products, Report to Parliamentary Secretary Catherine King
[11] CHF Submission to the Senate Standing Committee on Finance and Public Administration Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

highlights the desire among consumers for a regulatory regime that promotes transparency, improves consistency and compliance across industry and ensures the highest standards of regulation.

In light of the current failing self-regulatory model, CHF considers it appropriate to have a broader discussion on the re-introduction of the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill of 2013*, which we have previously welcomed and supported.

Conclusion

Overall, while CHF recognises that some issues are beyond the direct control of MA and require the involvement of other stakeholders, we would discourage the ACCC from authorising a code that does not deliver on the transparency mandate that ACCC, and consumers, required of the new Code.

CHF considers that the ethical promotion of therapeutic goods is essential if consumers are to be confident that their health professionals' decisions are based only on the consumers' best interests, rather than on inappropriate incentives or marketing strategies.

As CHF has highlighted through our previous submissions and comments on the Code, the purpose of the Code should be to illuminate the nature of the relationship between healthcare professionals and pharmaceutical companies, not to construct a system which serves to conceal those relationships. In this context, CHF recommends that the ACCC not authorise this Code and refer it back to MA for further consideration.

CHF notes that a great deal of detail will need to be determined prior to the implementation of any rigorous and accountable regulatory framework, but we believe this is a significant step that Australia needs to take. The practicalities of rolling out such as scheme will require wide consultation with all the relevant stakeholders, including consumers.

CHF appreciates the opportunity to provide input to this significant consultation, and looks forward to the ACCC's draft determination.

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (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 does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.