Medicines Australia Code of Conduct Review

Report of Consumer Workshops on the Medicines Australia Code of Conduct

1 March 2009

RPR CONSULTING

1 Introduction

In August 2008, Medicines Australia embarked on the triennial review of Edition 15 of the Code of Conduct (the Code). The primary purpose of this review is to ensure that the provisions of the Code and its administration remain appropriate and relevant to the current Australian environment, including the interests of consumers, government, healthcare professionals and the community.

As part of the review, Medicines Australia undertook two face to face consultation workshops with consumer organisations and individual consumers, with a view to improving the utility and effectiveness of the Code from the consumer perspective. The workshops were held on the 4th February 2009 in Sydney and 5th February 2009 in Melbourne, attended by 19 people and 11 people respectively. Attendees included consumers from different parts of Australia, representing a range of health consumer organisations as well as representatives from Medicines Australia. A list of organisations affected is shown as Attachment 1.

There was a set agenda for both meetings, shown as Attachment 2. The meeting began with a presentation on the Code and review process, given by Deborah Monk, Director of Innovation and Industry Policy for Medicines Australia. The remainder of the meeting was devoted to hearing the views of consumers about the Code. The program anticipated some areas that consumer representatives might want to discuss, but allowed for those present to shape the discussion around the issues of concern to them.

This report documents the major themes arising from the two meetings. Each section of the report represents one of the issues raised by workshop participants, describing the issue, why it is important and what suggestions were made about how the issue could be addressed in the next revisions of the Code. The report is authored by Ann Porcino, Director of RPR Consulting, who also facilitated the workshops.

2 What works

Participants were asked early in the meeting to identify strengths and weaknesses of the current code. The strengths identified include the following:

- **that there IS a code that articulates ethical behaviour**: the Code is dynamic and robust. Australia is leading the world by having it
- **the commitment by many pharmaceutical companies to the Code**: companies have responded well to being scrutinised by their peers and have taken big steps to improve practices in order to adhere to the Code
- **the Code is brief and concise**: although not a unanimous view, people generally favoured the form and length of the Code
- **systems works well**: processes are in place and working well; complaints are resolved in a reasonable amount of time; there are a sound range of enforceable sanctions; and there is reasonable transparency in the review process
- **consumers are represented**: on the Code committees and in the review process

- **other agencies are involved**: such as the Therapeutic Goods Administration and the ACCC and this gives balance to the process.

3 Broad views about the Code and consumers

3.1 Recognition of the important role consumers and HCOs play in QUM

There was a strong view put at the Sydney workshop, which was echoed by discussions in Melbourne, that the Code is no longer in step with the current reality of how significantly health consumers and health consumer organisations (HCOs) are involved in and contribute to the quality use of medicines. Health consumers are no longer passive recipients of advice on their health care; many are now heavily engaged in decision making about the medicines that they will use, how they will use them and why. Many consumers are expected/encouraged to self manage, resulting in consumers needing accurate and relevant information about the medicines they use.

Participants were concerned that the Code does not recognise this. It gives most attention to relationships and dealings between pharmaceutical companies and health professionals, with far less emphasis on interactions with the general public. They suggested that a substantial re-think of the Code is required which tackles ethical practices in dealings between pharmaceutical companies and health consumers and HCOs.

Concrete suggestions for change included:

- re-wording the preface to describe the important role that health consumers and HCOs play in the quality use of medicines
- developing and expanding sections of the Code to include more detailed and nuanced understanding of how consumers self manage and participate in their own health care; for example greater emphasis on how pharmaceutical companies communicate good information without promoting their products
- referencing the "*Working Together – a guide to relationships between health consumer organisations and pharmaceutical companies"* at key places throughout the document, and thereby enshrining the principles espoused in this guide as part of the Code.

3.2 Consumer awareness of the Code

Both meetings indicated that the awareness of the existence of the Code and how it might be used by consumers is very low and that this needs to be addressed in the coming period. It was noted that until the Code is geared more toward consumers (see discussion above) it will be difficult to engage consumers and HCOs in thinking about it. None-the-less, participants supported MA undertaking a more assertive and extensive campaign to familiarise HCOs with the Code and promote it to them. An awareness campaign directed at consumer organisations rather then at individual consumers or the general public was felt to be of greatest value in the coming years as a first step towards raising the profile of the Code. Suggestions given about what MA could do included:

- MA writing a short article on the Code review which HCOs could use to publicise the existence of the Code in their own communiqués to members

- MA launching the new Code to HCOs through a planned and concentrated process designed to engage as many HCOs as possible.

3.3 Relationship with HCOs

Section 9.9 was generally felt to be inadequate and needing extensive revision to recognise the increasing and significant contribution that consumers and HCOs now make to the quality use of medicines. It was felt that the Code needs to acknowledge and deal with company sponsorship of consumer conferences and relationships with HCOs in a far more detailed manner in line with coverage in parts of section 6 and 10, perhaps drawing more extensively on the ideals and practices described in *Working Together*.

3.4 Consumer representation on Code Committees

There was a general view that having only one consumer representative on the Code, Appeals and Monitoring Committees was inadequate, particularly when the Code Committee is considering a matter which relates to advertising to consumers.

4 Product information and materials

4.1 Advertising in prescribing software (section 3.9)

There was a very clear view from both workshops that the Code should prohibit companies from advertising in any part of prescribing software packages. Participants felt strongly that pop up advertisements are likely to have a significant influence on doctor's prescribing decisions because they appear at the point when a doctor is making his/her decision about the best medication to prescribe. A number of people saw this advertising as a blatant manipulation of doctors.

Also of concern to participants at both meetings is the impact that prescribing software advertising can have on consumers, who may see the advertisements on the doctor's screen and be influenced to ask their doctor to prescribe a particular medicine as a result.

Whilst it was the strong opinion of the majority of participants that a change to the Code is necessary, as the current Code allows advertising in prescribing software, a small number of people were hesitant to be so categorical, fearing that removal of these ads could reduce the amount of information available to doctors, particularly about new medications on the market.

4.2 Other advertising in doctor's surgeries

The discussion about advertising in prescribing software led participants to a further discussion of other forms of advertising available in doctor's surgeries.

A few participants argued that brand name reminders were also prompts to a doctor to prescribe a particular medicine and that restrictions should be placed on all such forms of advertising.

Of greater concern were the materials provided by pharmaceutical companies for doctors, which are either intended to be left behind or are unintentionally left behind. It was pointed out that these materials are often promotional in nature and, though

meant for doctors, are sometimes given to patients, and therefore act as a form of advertising to patients.

The view of participants was that the Code should require that anything produced for doctors – either paper or web based – should:

- either not be promotional or should be specifically labelled as being promotional
- be clearly labelled as being for a doctor's use only
- be clearly branded with pharmaceutical company name so that it can't be confused as a CMI.

4.3 Product starter packs

Sydney workshop participants did not have any comments to make about section 5 of the Code which covers starter packs, but Melbourne participants had a robust discussion about this section of the Code. There were differences in view about the value of these packs and what the Code should say about them.

There was a view expressed by some participants that starter packs serve no useful purpose except for the marketing of pharmaceuticals and that they should be banned. Others felt that starter packs are vital for some consumers, particularly those on lower incomes and/or who use multiple medications, because they allow the consumer to test - free of charge - what medications suit them the best and at what dosage.

In the end the meeting agreed that there would be value in MA sourcing or undertaking some research on how starter packs are used, which might inform the next review of the Code.

4.5 Consumer Medical Information (CMI)

The inadequacy of the current Australian mechanism for the distribution of Consumer Medical Information (CMI) was raised by participants at both workshops. It was generally felt that the problems with CMI could not be addressed through the Code. It was never-the-less felt that if and when there is opportunity to make changes to the Code which strengthen the provision of CMI to health consumers, this should be pursued. Some suggestions for how this might occur were given, for example:

- CMI could be included as part of the context for quality use of medicines in the preface to the Code and/or
- the responsibility that pharmaceutical companies have to get CMI to patients could be emphasised in the provisions of the Code
- section 9.7 could include reference to CMI.

5 Relationships with health care professionals and involvement in educational events (sections 6 and 10)

The discussion about two sections of the Code – sections 6 and 10 – tended to blend together at both workshops due to the overlapping nature of these two sections of the Code. The main points of concern or issue are described below:

- **the assumption that events are only attended by health care professionals**: The workshops noted that an essential flaw in these sections is the failure to recognise that increasingly consumers attend meetings and conferences which were originally intended for health care providers only. This arises because of the increasing role of consumers in self management and QUM. When consumers attend health professional meetings, they also view trade displays and other pharmaceutical advertising and the Code needs to acknowledge this and place appropriate regulations in place to ensure that information being provided is accurate and balanced.
- **terminology is a problem**: There was general agreement that many of the words in section 6 and 9 are not well defined, leading to the potential for ambiguous interpretation of these sections. The phrases "extravagant" "consistent with professional standing of the delegates" and "professional development" were given as examples. Whilst wanting there to be greater clarity in the next Code about these phrases (e.g. when is a meal "extravagant") participants also recognised that it is really hard to define these concepts exactly and for every circumstance. In the end there was agreement that the major loopholes should be addressed in an attempt to leave less open to interpretation.
- **the provision of alcohol by pharmaceutical companies at events for health professionals should be explicitly banned by the Code**: Participants from both workshops expressed the view that the Code should explicitly ban pharmaceutical companies from paying for alcohol at educational events. Whilst this was by no means a unanimous view, those who favoured the prohibition sited the following reasons:
    - educational events should be provided in an active learning environment, and alcohol generally detracts from the capacity for people to take in information accurately and fully
    - people under the influence of alcohol may make decisions that they would not make otherwise, including being open to greater influence by the pharmaceutical company
    - an inordinate amount of energy at Code meetings is devoted to sorting out what is an appropriate expenditure on alcohol and this diverts attention and energy from more important matters
    - companies must keep extensive records about alcohol provided at events and this would be alleviated if it simply was not allowed.
- **the recipients of hospitality provided in association with education events**: Participants to the workshops felt that the Code must be explicit about who is entitled to benefit from the hospitability provided at education events, particularly where these are delivered in medical practices. The general view was that hospitality should only be provided to those attending the event because if others also partake in meals, without attending the educational activity, the hospitality becomes deliberate company advertising. There was also a view that pharmaceutical companies should keep a public register of people who participate in their activities, so that there is more transparent accounting about doctors who have been involved.

6 Relationships with the general public (section 9)

Some participants presented a strong view that pharmaceutical companies don't ever really do education, and that it is almost always advertising and should be seen as such. This view was not shared by all consumers at the workshops, though there was unanimity about the need for more work to be done to lessen the 'grey zone' between what is education and what is clearly promotional or advertising activity. A number of suggestions were given about how to do this:

- **changing the terminology**: Some participants felt that instead of referring to 'media', 'promotion' and 'patient education' as the section currently does, that it should be divided into the two categories of 'media' and 'communication'. Not everyone was convinced, however, that this would be an improvement.
- **using more categorical language**: Stronger language was called for throughout section 9, particularly sections 9.4 and 9.5; for example instead of using words like 'may' the language should be 'should' or 'must'.
- **active monitoring of adherence to this section:** Participants wanted MA to ensure that this section of the Code is actively monitored over time, and that the outcomes of monitoring are made known widely to industry.
- **require more ethical media releases**: There was a view that the Code should be changed to require media statements to include both the potential benefits and adverse reactions arising from a new medication and where the evidence comes from (particularly in section 9.2.1).
- **greater transparency**: Participants wanted companies to be explicitly required to declare doctor's interests and association with a pharmaceutical company when they speak on behalf of a drug to a patient or group of health consumers.

7 Expanding the Code coverage

Workshop participants identified a number of ways they thought the Code could be expanded as described below.

7.1 New communication technologies

The first of these is the way that the industry uses communication technology (such as blogs) to reach consumers and health care professions. Participants felt that these avenues of communication must be encompassed in the Code as there is significant potential for violations of the principles of the Code. At the same time there was concern that the pace of technology change is so fast, and changes are often so significant, that specific regulations, pertaining to one or other communication application were not advisable. Rather, the meetings favoured:

- the development and articulation of over-riding principles about what is permissible and what is not, e.g. companies are not permitted to disguise their identify when communicating with consumers/health care professionals through new technology avenues
- the development of case studies to exemplify the application of these principles, perhaps for inclusion in the Code Guidelines

- the Monitoring Committee of MA regularly and systematically monitoring how members are using new technology to communicate with consumers and health care professionals.

7.2 Clinical trials

The second area that now requires coverage in the Code is clinical trials. Participants to the Melbourne workshop argued for inclusion of clinical trials on two grounds:

- that clinical trials are increasingly being conducted in Australia, whereas previously they have been conducted overseas
- that clinical trials may sometimes be used for marketing or promotional purposes that would be unacceptable under the spirit of the Code – a small number of participants, for example, were concerned that doctors can potentially be influenced to heavily promote trials to their patients if they are being provided with incentives to recruit patients to a trial provided.

There was discussion about whether other processes, such as application of NHMRC guidelines, might not be robust enough to prevent the types of violations which were of concern to Melbourne participants. In the end, most participants were of the view that the next edition of the Code should include guidelines about clinical trials if only through cross referencing documents from key organisations involved in clinical trials.

7.3 Wider range of companies

Some participants wanted the Code to be applicable to companies which produce complementary medicines and generic drugs.

8 Application of the Code

8.1 Sanctions

Participants from both workshops were clear and vocal about the fact that they did not think current sanctions were adequate. They wanted to see the type and magnitude of the sanctions changed so that they provide:

- real disincentive for companies who breach the Code
- consequence for breaches which are commensurate with the harm caused.

There was widespread agreement as to the nature of reforms that are needed:

- Fines need to be raised – a maximum fine of $100 thousand was seen as falling well short of the financial penalty that would be required to discourage breaches
- The variance between fines for moderate and severe breaches should be clearer, so that there is a clear distinction between the two and both are high enough to act as a deterrent.
- The Code should include provisions for requiring companies to demonstrate changes to company policies and practices that minimise the likelihood of repeat breaches of the Code.
- There should be ‘name and shame’ provisions in the Code, which result in public accountability for breaches of the Code.

- When corrective action is required, there must be provisions in the Code that allow the Code Committee to determine the details of the required action(s), including wording of any corrective notices. This is to ensure that corrective notices are not simply used by the company to promote their products a second time. Corrective action must also be commensurate with the harm caused; so, for example, retraction notices should be run for the same period as the original advertisement.

8.2 Reorienting approach to Code administration

There was a strong view that the process of applying the Code should be open to dramatic overhaul in the years ahead. The consensus seemed to be that there should be planning now for change in how the Code is strategically used, with the goal of moving away from a complaints-driven approach to a quality improvement approach whereby the Code drives industry best practice. Features of this approach would include:

- regular audits of companies to determine the extent of compliance with the code
- mechanisms for publicly recognising good practice.

The role of the existing Monitoring Committee in monitoring activities across MA membership in a more formalised and systemic way was acknowledged as a pre-cursor to what the future might hold. Participants suggested that money raised from sanctions in excess of the cost of administering the current Code could be used to fund the evolution of the system.

8.3 Conflict of interest/independence of the Code

An issue which was discussed at both meetings was the perceived lack of independence of the Code from the pharmaceutical industry which it seeks to regulate. Participants pointed out that those involved in the pharmaceutical industry are the members of MA and that the industry therefore has effective control not only of the standards of ethical practice enunciated in the Code but of the processes that monitor adherence to these standards. In essence, they said, the people and companies restrained by the Code are the very ones who set up what the boundaries will be and the Code is only as restrictive as the pharmaceutical industry wants it to be.

Possible solutions to this identified by participants include:

- that there be a greater role for consumers in establishing the Code and in the operations of the Code Committee
- MA seeks mechanisms to ensure true independence of the Code and the complaints process from the pharmaceutical industry.

9 Next steps

This report of the Consumer workshops will be sent to workshop participants and to the Code of Conduct Review Panel to inform the Panel as they develop the 16th edition of the Code.

Attachment 1

PARTICIPANT LIST

SYDNEY – 4TH FEBRUARY 2009

Arthritis Australia
Arthritis NSW
Cancer Voices Australia
Choice
Consumer Health Forum of Australia
Consumer Health Forum of Australia
Consumer Health Forum of Australia
Consumer Health Forum of Australia
Diabetes Australia NSW
Diabetes WA
Epilepsy Association of SA & NT Inc
Health Consumers' Council of WA
Health Consumers' Council of WA
Health Consumers' Council of WA
Leukaemia Foundation
Mental Illness Fellowship of Australia
National Association of People Living With HIV/AIDS
The Australian Lung Foundation
The Australian Lung Foundation

MELBOURNE – 5TH FEBRUARY 2009

Alzheimer's Australia
Breast Cancer Network Australia
Breast Cancer Network Australia
Breast Cancer Network Australia
Cochrane Consumer Network
Consumer Health Forum of Australia
Consumer Health Forum of Australia
Haemophilia Foundation Australia
Health Consumers' Council of WA
Health Consumers' Council of WA
Kidney Health Australia

Attachment 2

Code of Conduct Review – Consumer Workshops

Program

9.30 – 10.00	**Morning tea and registration**
10.00 – 10.15	**Welcome and introductions**
10.15 – 10.35	**Overview of the Code of Conduct Review** Deborah Monk, Director Innovation and Industry Policy, Medicines Australia
10.35 – 11.00	**What works and what doesn't in the current Code: your issues identified**
11.00 – 12.00	**Review of specific sections of the Code** This part of the meeting will be to be shaped by issues identified by consumers, but is likely to include**:** ▪ Section 3.9: Advertising in prescribing software ▪ Section 5: Starter packs ▪ Section 9: Relationship with the general public ▪ Section 10: Relationship with health care professionals; *and* ▪ Section 6: Involvement in educational symposia, congresses and satellite meetings
12.00 – 12.45	**Lunch**
1.00 – 2.45	**Review of specific sections of the Code, continued**
2.45 – 3.15	**Review of the complaints and appeals process**
3.15 – 3.30	**Summary of feedback and close**
3.30 – 4.00	**Afternoon Tea**