Allens Arthur Robinson

23 July 2009

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Dear Richard

Medicines Australia Limited Section 91C application

Independent Audit Report on Review of Code of Conduct

We refer to the application made by Medicines Australia Limited under subsection 91C(1) of the *Trade Practices Act* 1974, seeking revocation of authorisations granted in respect of Edition 15 of the Medicines Australia Code of Conduct and substitute authorisations in respect of Edition 16 of the Medicines Australia Code of Conduct, as lodged with the Australian Competition & Consumer Commission on 30 June 2009.

As noted at Section 5(g) of the submission attached to that application, the review process which produced Edition 16 of the Medicines Australia Code of Conduct was subject to Independent Audit by Dr Simon Longstaff of the St James Ethics Centre. We also note that Dr Longstaff retained the law firm Gilbert + Tobin to assist him with his Independent Audit. We have now received Dr Longstaff's Audit Report, and attach it for your consideration.

As you will see, Dr Longstaff's Audit Opinion states:

> As a result of the investigations carried out as part of this Audit, I have formed the opinion that:
>
> - submissions have been sufficiently widely sought from stakeholders;
> - all relevant stakeholders have been consulted or have had the opportunity to provide their input as part of the Review;
> - the Review has actively and respectfully engaged with all stakeholders to determine how and why the Code might be improved;
> - the submissions to the Review have been duly considered and appropriate amendments to the Code made, or (where applicable) that there is an appropriate rationale for not amending the Code as submitted;
> - the procedures followed in relation to the Review of the Code have met community expectations; and
> - overall the Review process has been comprehensive and effective.
>
> I am of the view that the Review has been conducted in a manner which upholds the benefits of, and is consistent with the rationale for, developing a voluntary industry code of conduct, as set out in Section 2 of the ACCC Guidelines

If you have any questions, please let us know.

Yours sincerely

per

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Independent Audit of the Review of the Medicines Australia Code of Conduct Edition 15

Audit Report

Objectives

Medicines Australia has undertaken a triennial review (**the Review**) of the Medicines Australia Code of Conduct Edition 15 (**the Code**).

In December 2008 I was engaged to conduct an independent audit of the Review process (**the Audit**). Specifically, the objective of this Audit was to independently evaluate the Review process to ensure:

- that the Review has been comprehensive;
- that the Review has been effective;
- that the Review has been conducted with an appropriate level of independence; and
- that all relevant parties have had a proper opportunity to contribute to the Review.

Scope

I conducted the Audit:

- within the parameters set out in paragraphs 1 and 2 of the Terms of Reference for the Independent Audit of the Review (Appendix 1);
- having regard to the suggested review criteria set out in Appendix 4 of the ACCC *Guidelines for developing effective voluntary industry codes of conduct* (February 2005) (**the ACCC Guidelines**) http://www.accc.gov.au/content/index.phtml/itemId/658186 and
- having regard to the stated benefits of, and rationale for, developing a voluntary industry code of conduct as set out in Section 2 of the ACCC Guidelines (and as reproduced below).

Matters not considered

In conducting this Audit, I have limited my review to process-related issues only - for example, whether the Review procedures employed by Medicines Australia met the criteria set out in the Terms of Reference and the suggested review criteria set out in the ACCC Guidelines. I have not considered substantive issues concerning the content of the Code itself.

Audit Opinion

As a result of the investigations carried out as part of this Audit, I have formed the opinion that:

- submissions have been sufficiently widely sought from stakeholders;
- all relevant stakeholders have been consulted or have had the opportunity to provide their input as part of the Review;

- the Review has actively and respectfully engaged with all stakeholders to determine how and why the Code might be improved;

- the submissions to the Review have been duly considered and appropriate amendments to the Code made, or (where applicable) that there is an appropriate rationale for not amending the Code as submitted;

- the procedures followed in relation to the Review of the Code have met community expectations; and

- overall the Review process has been comprehensive and effective.

I am of the view that the Review has been conducted in a manner which upholds the benefits of, and is consistent with the rationale for, developing a voluntary industry code of conduct, as set out in Section 2 of the ACCC Guidelines and reproduced below:

Some of these benefits include, but are not limited to:

- greater transparency of the industry to which signatories to the code belong;

- greater stakeholder or investor confidence in the industry/business;

- ensuring compliance with the Trade Practices Act to significantly minimise breaches;

- a competitive marketing advantage.

Other reasons for developing a voluntary industry code include:

- it is more flexible than government legislation and can be amended more efficiently to keep abreast of changes in industries' needs;

- a code is less intrusive than government regulation;

- industry participants have a greater sense of ownership of the code leading to a stronger commitment to comply with the Trade Practices Act;

- the code acts as a quality control within an industry;

- complaint handling procedures under the code are generally more cost effective, time efficient and user-friendly in resolving complaints than government bodies.

Audit Procedures

The procedures followed in undertaking this Audit involved the following:

- reviewing documents and correspondence concerning the selection of the Code Review panel ("**CRP**");

- obtaining and reviewing copies of all notices, advertisements, publications and media releases advertising the Code of Conduct review and informing interested parties of the time and method by which submissions may be made,

- obtaining and reviewing correspondence sent to stakeholders inviting submissions to be made;

- obtaining and reviewing distribution lists for notices and correspondence inviting submissions;
- reviewing the 'Invitation to make a submission' template;
- reviewing correspondence sent to consumer organisations giving notice of the consumer workshops to be conducted;
- reviewing the list of persons and organisations invited to consumer workshops;
- reviewing notes from the consumer workshops and the report (draft and final) from the independent workshop facilitator;
- attending as an observer a number of CRP meetings and teleconferences;
- obtaining and reviewing meeting notes from CRP meetings not attended;
- obtaining and reviewing copies of all submissions made to the CRP;
- obtaining and reviewing notes and minutes of CRP panel member meetings with individual stakeholders;
- corresponding directly with a number of consumer representatives who attended the consumer workshops, including the Consumers' Health Forum and CHOICE;
- corresponding directly with health care professional representative groups including the Doctors Reform Society;
- participating as an observer in stakeholder (Medicines Australia members and non-members) briefings on proposed amendments to Code of Conduct including participation as an observer in a teleconference briefing with health consumer representatives.

I was assisted (and in certain cases represented) in many of these activities by Gilbert + Tobin, a law firm that I engaged to provide me with advice and assistance in relation to the Audit.

Audit Observations and Conclusions

1 Selection of CRP

1.1 Observations

Nominations for appointment to the CRP were sought by Medicines Australia from its member companies, and the CRP was ultimately made up solely of representatives of these member companies. The CRP did not include a consumer representative/representative from a health consumer organisation (**HCO**) or a health care professional (**HCP**) representative.

One consumer group called into question the independence of the review process given this constitution of the CRP.[1] It was suggested that the process could be enhanced by the appointment of an independent reviewer to conduct the Review.

[1] Choice submission No 1 dated 30 Sep 08 September

In response to this suggestion, the Chairman of the CRP appointed me to independently audit the review process.

In my opinion, the absence of an HCO and/or HCP representative on the CRP placed a greater burden on the CRP than might otherwise have existed to ensure that the Review process was conducted effectively and transparently, and to take specifically into account and consider the views expressed by consumer organisations and those organisation representing HCPs. Particularly in relation to issues which may be, or may be expected to be, of interest or concern to HCOs or HCPs, the absence of such representatives on the CRP made it incumbent on the CRP to seek, proactively, specific input from the appropriate representative bodies.

1.2 Conclusions

Based upon the outcomes discussed below, particularly in Section 5: "*Consultation with HCOs*" and the undertaking of direct consultation by CRP members with individuals and organisations making submissions, I am satisfied that the CRP discharged this greater burden and therefore overcame any procedural deficiency which may otherwise have resulted from the absence of a consumer representative or HCP representative on the CRP and that the review has been conducted with an appropriate level of independence.

2 Call for submissions

2.1 Observations

Direct invitations to make written submissions were sent by Medicines Australia to those organisations and individuals listed in Appendix 2. These organisations comprised member and non-member pharmaceutical companies, organisations representing HCPs, HCOs and relevant government departments.

A pro forma letter (Appendix 3) sent to these bodies was comprehensive and invited the recipient to comment 'on the current Code of Conduct (Edition 15), including any areas that require amendment or areas that are not adequately covered by the Code'.

Recipients were directed to a submission template which was available on the Medicines Australia website. The submissions template offered persons wishing to make a submission the opportunity to include any general comments on the Code in addition to specific comments on each section.

In addition to direct invitations for submissions, Medicines Australia published advertisements in publications directed at HCPs such as *Medical Observer* and *Australian Doctor* calling for submissions and running for 2 weeks.

The initial closing date for submissions (10 October 2008) was extended (to 28 February 2009). At the CRP meeting on 12 March 2009, the CRP resolved to continue to accept submissions until at least the end of April. These dates were initially extended because the advertisements mentioned above did not run the first time they were placed (due to an oversight by the publications) so were placed again. Accordingly, an extension of time was necessary. The basis for a second extension arose in the course of the CRP meeting on 12 March 2009, primarily as the CRP wanted to ensure that all parties attending the consumer workshops (see below) had an opportunity to make a written submission. Further, it was recognised by the CRP that stakeholders may wish to make further written submissions following face to face consultations with stakeholders on the proposed changes, which took place in April.

At the option of the organisation or individual, submissions could be marked "*confidential*". In addition, stakeholders could elect whether or not to permit Medicines Australia to publish

the submission on its website and whether or not to allow Medicines Australia to quote from the submission in any report prepared in relation to the review.

2.2 Conclusions

I am satisfied that submissions have been widely sought from stakeholders. I am also satisfied that all relevant stakeholders have been consulted or have had the opportunity to provide their input as part of the Review, and that sufficient time was allowed for submissions to be formulated and submitted.

3 CRP meetings (discuss review/consideration of submissions/individual meetings/consideration of consumer workshop

3.1 Observations

My representative attended CRP meetings on 12 March, 24 March, 28 April and (via teleconference) on 13 May 2009. In these meetings, it was demonstrated that the CRP members had a thorough working knowledge of the issues raised in the written submissions received from stakeholders.

Debate in relation to issues raised in submissions was vigorous and robust. Issues raised in submissions were identified and discussed in detail.

Each CRP member was assigned a particular section of the Code to review, and to draft suggested amendments for subsequent discussion with the group.

The meetings were held once a month from 9am till 4pm. The fine details of proposed amendments were discussed at length.

It was observed in the course of these meetings that the CRP considered as paramount the need and desire to ensure that the revised code enhance the requirements of transparency in the pharmaceutical companies' relationships with HCPs.

Direct consultation was undertaken (outside these meetings) with certain individuals and their input discussed at the meetings[2].

I note that the minutes recording the discussions and deliberations which took place at each of the CRP meetings are deficient in that they are high level and do not fully capture the detailed nature and intensity of the debate which took place on many of the proposed amendments to the Code. Whilst this deficiency in itself is not a cause for concern, the effect of it is that an independent observer not having been in attendance at the CRP meeting, is left unaware of the level of vigorous debate which did in fact occur.

3.2 Conclusions

Based upon observations made of the conduct of CRP meetings, I am satisfied that the submissions to the Review have been duly considered by the CRP, the procedures followed in relation to the Review of the Code have met community expectations, and overall the Review process has been comprehensive and effective.

[2] Aaron Guttmann directly consulted with Dr Ken Harvey from La Trobe on the issue of starter packs and then sought to re-open discussion on that issue at the 12 March CRP meeting in order to put forward Dr Harvey's views.

4 Stakeholder feedback meetings/briefings

4.1 Observations

During April and May 2009, each CRP member was 'assigned' one or more corporations or individuals with whom to meet, in order to discuss the proposed changes to the Code and to obtain any feedback. A schedule of meetings and issues for discussion as prepared by the CRP is at Appendix 4.

CRP members were required to report back to the CRP with any stakeholder feedback. Generally, CRP members reported that stakeholders were appreciative of the level of consultation undertaken and input sought and that most believed that their views had been fully and diligently considered and appropriate amendments made. Written reports were generated, or oral feedback was given and discussed at the CRP meetings on 22 April 2009 and 28 April 2009.

Further, once the CRP had effectively finalised its Review process, and just prior to submitting to the Medicines Australia Board its recommendations for revision of the Code, the CRP held 2 stakeholder briefings to notify and explain to stakeholders the changes that were being proposed. A briefing for Medicines Australia member companies was held on 19 May 2009. A briefing for non-member stakeholders was held on 22 May 2009, attended primarily by advertising agency representatives, public relations agencies and promotional equipment suppliers.

Both briefings were attended by a large number of people. Questions at both sessions were mainly directed towards when the proposed amendments, if adopted, would be in force and what the amendments might mean in practice for industry participants.

4.2 Conclusions

Based upon observations made of the ongoing consultation between the CRP and stakeholders, I am satisfied that submissions have been sufficiently widely sought from stakeholders, all relevant stakeholders have been consulted or have had the opportunity to provide their input as part of the Review, and the Review has actively and respectfully engaged with all stakeholders to determine how and why the Code might be improved.

5 Consultation with HCO representatives

5.1 Observations

Written submissions were sought and received from a number of consumer health organisations, including CHOICE and the Consumers' Health Forum of Australia.

The CRP convened, at the expense of Medicines Australia, consumer workshops which were conducted in Sydney and Melbourne on 4 and 5 February 2009 respectively. These workshops were conducted by Ann Porcino, a director of RPR Consulting, who acted as an independent facilitator. A list of attendees is at Appendix 5.

No formal evaluation was undertaken as to the conduct of the consumer workshop and delegate satisfaction. However, informal feedback was given to the CRP secretariat from some consumer delegates and, with the exception of one report (discussed below), all feedback was positive. Typical comments indicated that the delegates found the workshop 'useful', 'extremely well run and organised and achieved a great deal of output in a short time', 'a great workshop'.

A report was prepared by the independent facilitator, reporting on the format of the meeting and documenting the major themes arising at each of the workshops – the issues

raised, why an issue was important to consumers and what suggestions were made for revision. The report was prepared by the facilitator in draft form and submitted to the CRP for review and comment on whether it was agreed that the report accurately reflected the issues raised and the discussions which took place. A final report was prepared by the facilitator and submitted to the CRP in April 2009. A copy of the report showing the changes between the draft and final versions is at Appendix 6 (**the Consumer Workshop Report**). The changes made to the report were typographical and grammatical in nature. A copy of the Consumer Workshop Report was provided to workshop attendee. My representative made direct and personal contact with a number of delegates in attendance at the consumer workshop to seek their views on the usefulness and effectiveness of the consultation process. Each of those delegates expressed the view that the workshop was, a well-conducted, well-planned and constructive experience and they expressed appreciation for the opportunity to be heard.

Negative written feedback was provided by one delegate who advised that he represented an organisation called 'Health Consumers' of WA'.[3] This delegate expressed the view that he felt that 'on a number of occasions, issues raised by consumer reps were not in the debate as the topic was deemed to be outside the Code'.

In addition, this delegate expressed the view that, in holding the workshop, the CRP was merely seeking to 'tick the box' in relation to consultation with HCOs, and that there was no requirement to act further on changes suggested by HCOs or to provide further feedback. This delegate did also note that the workshop involved 'vigorous interaction on the part of all consumers'.

I caused further enquiries to be made of this delegate with a view to investigating these concerns. The delegate recalled that 'on at least 2 occasions somebody raised an issue' which was said by the CRP representatives in attendance to be outside the scope of the Code. However, when pressed, this delegate could not recall precise details of the issues raised. His primary concern was that the Code was set up by the pharmaceutical companies and it was those companies which set the 'paradigm' for what was to be regulated and what was not.

The other concern voiced by this delegate was that, to his mind, there was no further requirement on the CRP to act on the input received from the consumer workshop, to determine that any or all of the recommendations for changes to the Code should be adopted, within any particular timeframe or at all.

More positively, this delegate commented that he thought that the concept of the consumer workshop is 'excellent', that the facilitation mechanism 'worked well', that by including consumers as the CRP has sought to do would produce a 'better outcome', but that he would have to wait and see the finished product before assessing how effective and successful the process was.

Enquiries were also made of a colleague of this delegate who was also in attendance at the same workshop. This colleague considered that the workshop was well conducted and beneficial, and did not necessarily share the views expressed by his colleague.

Nevertheless, I had some concerns about the suggestion that restrictions or limitations had been placed on the scope of the Review, and that debate had not been permitted on topics that were deemed to be outside the parameters of the current Code. I raised those concerns in writing with the CRP Chairman on 30 March 2009 (see Appendix 7). The CRP's response to this issue is considered separately below in Section 6: Scope of Review. Based upon the matters set out in Section 6, I have concluded that the CRP panel has carefully and

[3] See Report prepared by Brian Stafford of Health Consumers' of WA dated 9 February 2009.

properly considered the appropriate scope of matters to be considered in the Review process.

A teleconference was convened on 26 May 2009 for the purpose of briefing the consumer delegates on the final changes to the code being proposed. My representative participated in this teleconference as an observer. The consumer delegates participating in this conference again expressed appreciation at being consulted and confirmed that they considered the process had been well conducted. A copy of the CRP's minutes of this teleconference is at Appendix 8.

As to the issues raised in the consumer workshops, I have observed that those issues were set out in a detailed note which was provided to CRP members at the CRP meeting on 12 February 2009. My representative was informed that these notes were transcribed by the CRP Secretariat directly from the whiteboard discussion notes from the consumer workshops. The issues set out in that note were discussed in detail by the CRP at its meeting on 12 February 2009.

The Consumer Workshop Report was provided (in final form) to CRP members on 28 April 2009.

A teleconference of the CRP was held on 13 May 2009. One of the stated purposes of that teleconference was to 'revisit and ensure all matters [raised in the consumer workshops] have been covered'. My representative participated in this teleconference as an observer. During this teleconference the CRP reviewed each section of the Consumer Workshop Report with a view to assessing whether it had properly considered all issues raised at the workshops. The discussion was detailed and involved consideration by the CRP of each of the issues raised with a view to ensuring specifically that the CRP had debated each of the issues raised. At the end of the teleconference the CRP concluded that each of the issues raised by consumers at the consumer workshops had been considered and dealt with in the course of the Review. I am satisfied that this conclusion was justified.

Specifically, I note that a number of the key issues and recommendations raised at the consumer workshops have been taken into account by the CRP and commensurate changes to the Code have been recommended to address those issues. A schedule, setting out some of the changes to the Code, which responds to issues raised in the consumer workshops, is at Appendix 9.

5.2 Conclusions

Based upon these enquiries, I am satisfied that the interested consumer representatives were consulted and were afforded a genuine opportunity to provide their input as to how and why the Code might be improved.

Based upon these enquiries, I am satisfied that the submissions and comments made by consumer health organisations were duly considered and appropriate amendments to the Code made, or (where applicable) that there was a considered rationale for not amending the Code as submitted.

6 Scope of Review

6.1 Observations

The terms of reference under which the CRP (Appendix 10) is operating contain a mandate to the CRP to consider 'any issue which may arise as a result of the consultation process' (in addition to particular issues specifically identified for consideration). Further, in its letter to stakeholders calling for submissions, Medicines Australia sought comment on Edition 15 of the Code 'including any areas ... that are not adequately covered by the Code'.

As I have observed above, a delegate at the consumer workshop expressed the view that he felt that 'on a number of occasions, issues raised by consumer reps were not in the debate as the topic was deemed to be outside the Code'.

In an interim report issued on 21 April 2009 (at Appendix 11) **(my Interim Report)**, I raised a concern with the CRP as to whether the scope of the Review had been properly considered and whether matters which ought to have been considered had been incorrectly excluded on the basis that they were not matters covered by the existing Code and therefore outside the scope of the Review.

In response to my raising this issue, the Chairman of the CRP gave diligent consideration to the proper scope of the Review and depicted his views in the graph which is at Appendix 12. This graph was tabled and discussed at length at the CRP meeting on 22 April 2009.

As a result of the Chairman's consideration of this issue and the CRP's concurrence with the Chairman's delineation of the scope of the Review, a further proposed amendment was agreed upon and endorsed by the CRP in relation to clinical trials to the extent that they involve the provision of hospitality by pharmaceutical companies and HCPs involved in clinical trials.

6.2 Conclusion

Based on the CRP's response to the issue of determination of the proper scope of the review and the making of further consequential recommendations for amendments to the Code, I am satisfied that the submissions to the Review have been duly considered and appropriate amendments to the Code made, that the procedures followed in relation to the Review of the Code have met community expectations, and that overall the Review process has been comprehensive and effective.

7 Consultation with HCP representatives

7.1 Observations

Written submissions were invited from various bodies representing HCPs. Submissions were made by a number of these bodies including the Australian Medical Association, Royal Australian College of General Practitioners, the Royal Australasian College of Physicians and the Australian General Practitioners' Network.

Of note, no written submission was received from the Doctors Reform Society **(DRS)**. I am aware that the chairman of this organisation has been outspoken in his criticism of the Code.[4]

I contacted the Chairman of the DRS to confirm that the DRS was aware of the Review and, if so, to ascertain why it did not make any submission. I was informed by Dr Tim Woodruff, the Chairman of the DRS, that it is the view of the DRS that the whole system of self-regulation by way of Code of Conduct within the pharmaceutical industry is flawed and that the system should be replaced by government regulation. In light of this view, he considered that making a submission in relation to amendments to the Code was a waste of time.

In my opinion, the concerns expressed by Dr Woodruff fall outside the scope of this Audit, as they do not relate to the conduct or effectiveness of the Review process.

[4] See quote in article in Medical Observer dated 19 September entitled "*Pressure on pharma industry to get tougher on code breaches*".

7.2 Conclusion

Based upon these observations and enquiries, I am satisfied that submissions have been sufficiently widely sought from HCP representatives; that HCPs have been consulted or have had the opportunity to provide their input as part of the Review; that the Review has actively and respectfully engaged with HCPs to determine how and why the Code might be improved and the submissions made have been duly considered and appropriate amendments to the Code made.

8 Influence of Medicines Australia Board on Review process

8.1 Observations

Following consideration of issues raised in written submissions and at the consumer workshops, and following the preparation by the CRP of draft revisions to the Code, the CRP recommendations for proposed revisions were submitted to the Board of Medicines Australia for consideration and approval.

In my Interim Report, I raised a concern about the level of independence being exercised by the CRP in relation to this process. The observation which gave rise to this concern was a circumstance where, because the Board of Medicines Australia had indicated it would not accept a particular CRP proposal for amendment of the Code (namely an amendment to require companies to report/disclose their costs incurred in hosting international meetings with HCPs in attendance) the CRP seemed prepared not to pursue any such proposal.

I expressed the view to the CRP that, regardless of what the Medicines Australia Board may ultimately resolve, to ensure the transparency and effectiveness of the Review, the CRP ought to make its recommendations to the Board independently and without having regard to any views expressed by the Board. I further expressed the view that I would expect that the final decisions of the Board, determining whether or not to accept or reject the CRP's recommendations for revisions to the current Code, would be fully documented and its reasons for accepting or rejecting particular proposals made publicly available.

At the CRP meetings on 22 April and 28 April 2009, the CRP discussed this issue and accepted all changes considered necessary by the CRP should be recommended to the Board of Medicines Australia regardless of any preliminary views expressed by the Board.

On that basis, the CRP revisited the issue of whether or not to extend reporting requirements as discussed above. Detailed discussion and debate ensued about whether to recommend to the Board that the change be made. There was no consensus amongst the CRP as to whether the amendment was required. No one member felt 'strongly' that the change was necessary and most preferred to leave the Code unchanged in this respect on the basis of a view that the current reporting requirements seem to be working. The CRP also noted that this issue had not been raised by any stakeholders/submission makers and so there was no need to push for extension. Nevertheless, one CRP member had a differing view and supported an expansion of the reporting requirements with a view to enhancing the position of transparency. The CRP also considered whether the broader community view would be that the reporting requirements should be expanded. As a result of this discussion, the recommendation for a change was ultimately made to the Board. The CRP reported to stakeholders at the briefing held on 19 and 22 May 2009 that the Board was seeking the views of the MA members as to whether or not it should accept this proposal for amendment. My representative was subsequently informed that the majority of Medicines Australia members were not in favour of this amendment and accordingly, the Medicines Australia Board resolved not to accept the CRP's proposal for amendment.

8.2 Conclusion

Apart from this one particular issue, in relation to which I consider the CRP responded appropriately, I am satisfied that the CRP have not allowed any prematurely expressed views of the MA board to influence the recommendations for proposed changes. Accordingly, I am satisfied that the procedures followed in relation to the Review of the Code have met community expectations and that overall the Review process has been sufficiently independent, comprehensive and effective.

Dr Simon Longstaff
Executive Director
St James Ethics Centre

7 July 2009

Appendix 1

Review of Code of Conduct Edition 15

Terms of Reference for the Independent Audit of the Review

1. Purpose of the Review Audit

The primary purpose of the Code Review is to ensure that the provisions of the Code and its administration remain appropriate and relevant to the current Australian and international environment, taking into consideration the interests of consumers, government, healthcare professionals and the industry.

The Auditor will evaluate whether the Code Review has been comprehensive and effective and whether the draft 16th edition of the Code demonstrates a high standard of industry self-regulation and meets consumers' and other stakeholders' expectations. It is not expected that the Auditor will duplicate the Review; rather the Auditor will evaluate the effectiveness of the Review and whether all relevant parties have had appropriate opportunity to contribute to the Review.

The ACCC Guideline: *Guidelines for developing effective voluntary industry codes of conduct* (February 2005) describes the primary performance criteria for a Code review in an example three-yearly review report summary (Appendix 4). The Auditor will determine the relevance of the suggested performance criteria to the review of the Medicines Australia Code of Conduct and, for those criteria considered relevant, evaluate the review of the Code against them.

2. Particular issues to be considered

In addition to the recommended criteria for a review of the Code, the Auditor will consider and report on whether:

submissions have been widely sought from stakeholders
all relevant stakeholders have been consulted or have had the opportunity to provide their input as part of the review

- the review has actively and respectfully engaged with all stakeholders to determine how and why the Code might be improved.
- the submissions to the review have been duly considered and appropriate amendments to the Code made, or that there is an appropriate rationale for not amending the Code as submitted.
- the Review of the Code is meeting community expectations and will maintain an effective self-regulatory Code.

3. Reporting requirement

The independent Auditor will provide ongoing advice and feedback to the Code Review Panel during the Review as necessary to ensure the best outcome from the Review. The Auditor may also communicate with the Board during the Review if required.

A final written report will be provided to the Medicines Australia Board on the Review of the Code by the end of May 2009.

Appendix 2

Letters to the following companies/organisations providing advice of the review of Edition 15 of the Code of Conduct

Company/Organisation	
Abbott Australasia	Member Company
Actelion Pharmaceuticals Australasia	Member Company
AIDS Council of NSW (ACON)	Health Consumer Organisation
Alcon Laboratories (Australia)	Member Company
Allergan Australia	Member Company
Alphapharm Pty Ltd	Non-member Company
Alzheimer's Australia	Health Consumer Organisation
AMGEN Australia	Member Company
AMRAD Pharmaceuticals Pty Ltd	Non-member Company
Arrow Pharmaceuticals Ltd	Non-member Company
Arthritis Australia	Health Consumer Organisation
Arthritis NSW	Health Consumer Organisation
ASCEPT	Representatives on the Code & Appeals Committees x 3
Aspen Pharmacare Australia Pty Ltd	Non-member Company
Asthma Australia VIC	Health Consumer Organisation
AstraZeneca	Member Company
Australasian Medical Writers Association	Organisation/business working with pharmaceutical industry
Australian Competition and Consumer Commission	Government or statutory body
Australian Federation of AIDS Organisations	Health Consumer Organisation
Australian General Practice Network	Peak healthcare professional body & AGPN representative on the Code Committee x 1
Australian Lung Foundation	Health Consumer Organisation
Australian Medical Association	Peak healthcare professional body & AMA representatives on Code & Appeals Committees x 2
Australian Nursing Federation	Peak healthcare professional body

Australian Pituitary Foundation	Health Consumer Organisation
Australian Prescriber	Publisher NPS
Australian Publishers Bureau	Organisation/business working with pharmaceutical industry
Australian Thalassaemia Association	Health Consumer Organisation
Baxter Healthcare Pty Ltd	Member Company
Bayer Australia	Member Company
Biochemie Australia Pty Ltd	Non-member Company
Biogen Idec Australia	Member Company
Boehringer Ingelheim	Member Company
Boots Healthcare Australia Pty Ltd	Non-member Company
Brain Foundation	Health Consumer Organisation
Bristol-Myers Squibb Australia	Member Company
Cancer Council Australia	Health Consumer Organisation
Cancer Council NSW	Health Consumer Organisation
Cancer Voices Australia	Health Consumer Organisation
Cancer Voices Victoria	Health Consumer Organisation
Carer's Australia	Health Consumer Organisation
Celgene	Member Company
CHOICE	Peak consumer body
CMP Medica Australia	Organisation/business working with pharmaceutical industry
Commercial Eyes	Member Company
Consumers' Health Forum of Australia	Peak Health Consumer Organisation & CHF representatives on Code, Appeals & Monitoring Committees x 6
Council On The Ageing NSW	Health Consumer Organisation
Covance	Member Company
CRI Australia Pty Limited	Non-member Company

CSL Limited	Member Company
Deacons	Chairman Code & Appeals Committees
Dentsply (Australia) Pty Ltd	Non-member Company
DermaTech Laboratories	Non-member Company
Diabetes Australia	Health Consumer Organisation
Doctors Reform Society	Peak healthcare professional body
Eli Lilly	Member Company
Epilepsy Action Australia	Health Consumer Organisation
Epilepsy Association of SA & NT Inc	Health Consumer Organisation
Epilepsy Australia NSW	Health Consumer Organisation
Epipharm	Non-member Company
Ferring Pharmaceuticals Pty Ltd	Non-member Company
Galderma Australia Pty Ltd	Non-member Company
Generic Medicines Industry Association	Peak generic medicines association
GenPharm Australia	Non-member Company
GenRx	Non-member Company
Genzyme Australasia Pty Ltd	Member Company
Gilead Sciences	Member Company
GlaxoSmithKline Australia	Member Company
Haemophilia Foundation	Health Consumer Organisation
Health Communication Network	Organisation/business working with pharmaceutical industry
Healthcare Council Advertising Federation of Australia	Organisation/business working with pharmaceutical industry
IDT Australia	Member Company
IMS Health Australia	Member Company
Innovex	Member Company

iNova Pharmaceuticals	Member Company
International Brain Tumour Alliance/Cancer Voices	Health Consumer Organisation
Ipsen	Member Company
Janssen-Cilag	Member Company
Jean Hailes Foundation	Research and consumer body
John G Kelly & Associates	Chairman Code & Appeals Committees
Juvenile Diabetes Research Foundation	Health Consumer Organisation
Kendle	Member Company
Kidney Health Australia	Health Consumer Organisation
KPMG	Member Company
Leukaemia Foundation	Health Consumer Organisation
Lundbeck Australia	Member Company
Macular Degeneration Foundation	Health Consumer Organisation
Mayne Pharma Pty Ltd	Non-member Company
Mental Health Council of Australia	Health Consumer Organisation
Mental Illness Fellowship of Australia	Health Consumer Organisation
Mental Illness Fellowship of Australia, SA	Health Consumer Organisation
Merck Serono Australia	Member Company
Merck Sharp & Dohme (Aust)	Member Company
Mundipharma	Member Company
National Association of People Living With HIV/AIDS	Health Consumer Organisation
National Asthma Council (NAC)	Health Consumer Organisation
National Breast Cancer Centre	Health Consumer Organisation
National Coordinating Committee on Therapeutic Goods	Government or statutory organisation
National Heart Foundation (NHF)	Health Consumer Organisation
National Heart Foundation, ACT(NHF)	Health Consumer Organisation

National Heart Foundation, Victoria (NHF)	Health Consumer Organisation
National Prescribing Service	Non-profit organisation providing medicines information and resources
National Seniors Association	Peak Consumer Organisation
National Stroke Foundation	Health Consumer Organisation
Norgine	Member Company
Novartis Pharmaceuticals Australia	Member Company
Novartis Vaccines	Member Company
Novo Nordisk Pharmaceuticals	Member Company
Nycomed	Member Company
Octapharma	Non-member Company
Osteoporosis Australia	Health Consumer Organisation
Palliative Care Australia	Health Consumer Organisation
Pfizer Australia	Member Company
Pharmaceutical Benefits Division, Department of Health and Ageing	Government or statutory organisation
Pharmaceutical Society of Australia	Peak healthcare professional body
Pharmacy Guild of Australia	Peak healthcare professional body
Pharmion Pty Ltd	Member Company
Pretium	Member Company
PricewaterhouseCoopers Legal	Chairman Code & Appeals Committees
Princeton Publishing	Member Company
Prostate Cancer Foundation of Australia	Health Consumer Organisation
Quintiles	Member Company
Regulatory Policy and Governance Division, Department of Health and Ageing	Government or statutory body
Restless Legs Syndrome Australia	Health Consumer Organisation
Roche Products	Member Company

Royal Australasian College of Surgeons	Peak healthcare professional body
Royal Australian & New Zealand College of Psychiatrists	Peak healthcare professional body
Royal Australian College of General Practitioners	Peak healthcare professional body
Royal Australian College of Physicians	Peak healthcare professional body
Royal College of Healthcare	Peak healthcare professional body
Royal College of Nursing	Peak healthcare professional body
Royal College of Pathologists of Australasia	Peak healthcare professional body
Rural Doctors Association	Peak healthcare professional body
Russell Kennedy	Chairman Code & Appeals Committees
SANE Australia	Health Consumer Organisation
Sanofi Pasteur	Member Company
sanofi-aventis	Member Company
Schering-Plough	Member Company
Servier Laboratories (Aust.) Pty Ltd	Member Company
Sigma Pharmaceuticals Pty Ltd	Non-member Company
Sleep Disorders Australia	Health Consumer Organisation
Smith & Nephew	Member Company
Society of Hospital Pharmacists	Peak healthcare professional body
Solvay Pharmaceuticals	Member Company
Strategic Resolution	Chairman Code & Appeals Committees
Therapeutic Goods Association	Government or statutory body
UCB Pharma	Member Company
Vision2020	Health Consumer Organisation
Wyeth Australia	Member Company

Appendix 3

3 September 2008

«Title» «First_Name» «Last_Name»
«Position»
«Company»
«Address_1»
«Address_2»
«City» «State» «Postcode»

Dear «Title» «Last_Name»

Medicines Australia is embarking on the triennial review of Edition 15 of the Medicines Australia Code of Conduct. We seek your comments on the current Code of Conduct (Edition 15), including any areas that require amendment or areas that are not adequately covered by the Code.

Objectives

The primary purpose of the 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 industry. In this way we intend that the Code will remain as the pre-eminent standard for the conduct of pharmaceutical companies. In ensuring this purpose is achieved, the Medicines Australia Board has determined that the Review should consider the following principles:

- Protection of patient safety;
- Quality use of medicines;
- Industry conduct will withstand with public and professional scrutiny;
- Appropriate dissemination of information about industry products to healthcare professionals and the general public;
- The role of industry in complementing the practice of medicine and pharmacy;
- Compliance with current legislative environment; and
- Identification of any new or emerging issues/trends from other countries or areas that may impact the operating environment.

To direct the review of the Code, Medicines Australia has established a Code Review Panel, chaired by Mr Will Delaat, Chairman, Medicines Australia.

The Code Review Panel is now seeking broad stakeholder input to, and comment on, the existing Code in order to develop a draft edition 16 of the Code for consideration by member companies in early 2009.

Submissions should be based upon issues that will add value to the Code and which will enhance Medicines Australia's Code of Conduct standing as a world leading Code and will continue to meet public and professional scrutiny.

The 'Submission Template' can be downloaded from the Medicines Australia website at http://www.medicinesaustralia.com.au/pages/page223.asp

Alternatively contact Medicines Australia on 02 6122 8500 to obtain a copy via email or mail.

Please send submissions to the Secretary of the Code of Conduct Committee

Email: secretarycodecommittee@medicinesaustralia.com.au

Mail: Secretary Code of Conduct Committee
Medicines Australia
16 Napier Close
DEAKIN ACT 2600

Fax: 02 6282 6299

Closing date for submissions: Friday 10 October 2008

Yours sincerely

Ian Chalmers

Code Review Panel Meetings with Stakeholders

Organisation	Code Review Panel	Meeting Date	Issues raised
HCN (Sydney) Lisa Leckey Manager, HNC Strategic Solutions 02 9467 6115 Lisa.leckey@hcn.co.au	Will and Deborah		• There is evidence to support that advertising in Prescribing Software does not unduly influence the prescribing behaviour of doctors; it has the benefit of improving and supporting clinical decisions at the point-of-care e.g. the Zocor example • There is a very valuable and positive educative opportunity arising from advertising in point of care software that should be evolved. • There is evidence to support that Prompts or the like can improve the quality use of medicine (QUM) and drive positive patient outcomes. • In order to continue to achieve the objectives of providing Practitioners with relevant, timely, educative content for the purpose of driving QUM outcomes and manage information overload, we need to ensure that relevant health technology is used in an educative and supportive manner – prompting doctors as to when new information on drugs and treatments as they become available.
CHOICE (Sydney) Michael Johnston Senior Policy Officer – Health 02 9577 3374 mjohnston@choice.com.au	Libby and Jude		First Submission • An independent body to administer the Code. • The ability for the Code of Conduct Committee to impose an immediate order for a company to cease promotional activities (where they are still ongoing) pending the next formal hearing. Corrective advertisements should be required to run for the same length of time as the original advertising campaign. • A maximum fine of $1.1 million for all breaches of the Code. • The Code of Conduct Committee to take into account the potential gain (whether or not realised) from the breach in considering the size of the penalty. • Detailed reasons for the level of the fine to be included in the minutes of the meetings. • Remove suspension or expulsion as a sanction. • All determinations of breaches of the Code should include a requirement for the subject company to review their internal

			management processes and compliance programs. • Better monitoring of marketing statements and activities of pharmaceutical sales representatives. Supplementary Submission (after Consumer Workshops) • **Five-member panels for hearing complaints with an** independent chair (lawyer with Trade Practices experience) and other members selected from pools of nominated representatives depending on the complaint. • The pool of Chairs to be appointed following consultation with key stakeholders and endorsement of the Minister for Health and Ageing. • Where pharmaceutical companies provide funding or in-kind assistance, the company should require disclosure by the health consumer organisation in its annual report as a condition of the assistance; and • Pharmaceutical companies should also disclose support provided to health consumer organisations. This could be done in the form of a summary report released by Medicines Australia.
Medical Update (Sydney) Gary Smith 02 9016 7116	Tony		• To ensure education events are measurable and more accountable companies should provide slides to MA for review, together with invitations • Larger meeting should be filmed with copy sent to MA for review • This would lead to companies briefing speaker sand less 'off label' discussion • Videos could be provided to rural HCPs
Creative Promotions (Sydney) Rowan and Barbara Isaacs 02 8874 1200	Heather has already had one teleconference with this company, will follow up		• Comments removed for confidentiality
AFA Health Council (Sydney) Genevieve Murphy 02 8297 3800	Heather has been asked to present at the AFA workshop – can talk to AFA Healthcare Council at this time	23/4 & 24/4	• Websites and social media • **Electronic distribution of** promotional material • Media releases • Definition HCP • Conference reporting

Elsevier (Sydney) Simon Lilly Medical Communications Director 02 9422 8556 s.lilly@elsevier.com	Ken		• Comments removed for confidentiality
Walters' Kluwer Health (Sydney) James Dunston Business Development Manager 02 9276 6621 James.dunston@wolterskluwer.com	Brett		• Restricting the monetary limit of educational materials would result in a decrease in educational literature available to doctors for themselves and their patients • We would argue that the brand reminder section should remain as it currently is in the Code of Conduct guidelines.
GMiA (Sydney)	Brett and Tony		• Whilst GMiA has no comments to make on Edition 15 look forward to being involved in the consultation process.
NPS (Sydney) Georgina Green 02 8217 8704 ggreen@nps.org.au	Leanne and Wes		• Concerns about the use of samples & CMI must be included in the starter pack, rather than 'should' • Lack of clarity around some trials using free trade packs, which either lack ethics approval and informed patient consent, or more closely resemble marketing campaigns than drug trials. • Code has evolved into a long complex document that is now accompanied by additional Guidelines. These companion documents are dense and not approachable by a lay reader. We suggest, however, that Medicines Australia develop a simpler document that would be more comprehensible to consumers. • Further information on levels of evidence and substantiating data • Advice to HCPs of 'Boxed warning' • Review use of secondary advertisements • BNRs and type of items – no beach towels, umbrellas, camping chairs etc • No branding of patient support programs • No advertising in prescribing software • Articles should not be ghost written and then submitted for publication

			in the name of an expert. • Training in QUM • **Need to specify** whether general practice nurses qualify as authorised healthcare professionals. • PFPs • **Educational** meetings can only be termed educational where the prime purpose is education and the educational objectives are clearly articulated in promotional materials and by the hosting company representatives • Section 8 only refers to market research. Some trials take place which only have a marketing objective, and these should also be covered by the Code. • It would be appropriate for ADRAC to be advised of and be able to review and comment on PMS study protocols, or even better an independent study guidance group to design protocol. • If there is payment to a health professional then there is a case that the PMS protocol should be subject to review by a Research Ethics Committee, as would apply to any other research. Medicines Australia could convene such a research ethics committee. • Companies should not collect personal information on health professionals for the purposes of marketing. For example, obtaining details of an individual doctor's prescribing from electronic prescribing packages. • Media releases and content • **Disclosure of membership** of Advisory Boards
RACP (Sydney) Professor Shane Carney 02 9269606 mary.osborn@racp.edu.au	Sophie and Shaun		• Section 9.9 Relationship with the Health Consumer Organisations (HCO's) are that they should insist that any financial support by Industry must be clearly disclosed in the HCO's annual report. • Section 10.6 Consultants and Advisory Boards. The Minutes of Advisory Board meetings must include Actions from the meeting as well as achievements relating to previous Advisory Board meetings. This is to ensure that such boards have an effective impact on medication use, research, etc rather than simple education /influence.

Centre for Health Initiatives (Wollongong) Danika Hall 02 4221 5811 dh14@uow.edu.au	Jim and Ken (Teleconference)		• Sections 9, 9.4, 9.5, 9.6.2 • Specifically disease awareness campaigns
NHF – Victoria (Melbourne) Dr Christine Latif 03 9321 1589 Christine.latif@heartfoundation.org.au	Jude (Teleconference)		• Starter packs for display – should state empty or not containing active ingredients • Code should more clearly state that promotion should not distort the true value/situation/effect • Generic name should be at least 2mm
Haystac (Melbourne) Jacqueline Lodewyke 03 8689 2230 j.lodewyke@haystac.com.au	Aaron		• eNewsletters and links to PIs • Definition of what constitutes a medical publication versus a general public publication • Need a section on new product Advertorials • Further clarification around product specific media statements to the general public required • Need a specific section on the issue of media releases • Need a specific section on healthcare professionals being paid an honorarium to write content for general media articles (non product specific). • Does the honorarium need to be disclosed? What format does it need to be disclosed in?
RACGP (Melbourne) A/Professor Ron Tomlins Chair, National Standing Committee for Quality Care 03 86990574 Dr Brendan Grabau – new Director Education	Ian and Heather (already plans to meet new CEO and Education Director)	24/4	• Disease specific groups – undue influence • DTC – media releases and use of experts and evidence • No superlatives to be permitted • Mailing of promotional material to HCPs prohibited • No advertisements in prescribing software • Access to patient practice information must be managed in accordance with the requirements of federal and state privacy legislation, supplemented by the RACGP's *Standards for General Practice.* • Patients require adequate information to ensure that any secondary use of private health information data is in accordance with ethics

			principles. The RACGP recommends that the Code refers prominently to all appropriate legislation. • The RACGP recommends that its members participate only in research that has ethical clearance. • The RACGP also notes that some pharmaceutical companies have been sponsoring small group activities and "research" in general practice, often under the guise of ongoing professional development. Medicines Australia needs to monitor this trend, to ensure that practice data is not provided to pharmaceutical companies or that pharmacological approaches to treatment are not over-emphasised. • The RACGP recommends a standard statement of pharmaceutical company sponsorship declared for each person of influence at the meeting. This could include the quantum for each pharmaceutical company involvement. • This valuable strategy allows pharmaceutical companies to contribute to the future research of the nation at arm's length. The RACGP believes that such approaches should be further explored. • All research undertaken in general practice must have approval of a properly constituted ethics committee. • The current fines for breaches of the code too low - $100K - $500K
Ken Harvey (Melbourne) 0419 181910 k.harvey@medreach.com.au	Aaron and Ed		• MA to support the call for uniform standards to regulate pharmaceutical promotion across all categories of medicinal drugs; one Code; one complaint (and appeal) process, one monitoring process and one set of effective sanctions, including corrective advertising orders and fines related to the sales income of the product and company involved. • Pharmaceutical advertisements should contain balanced information about the drug generic name and its key risks and benefits, in comparable area, font size and type face to that used for the brand name and illustrations. • The endorsed MA education program for medical representatives, now conducted in association with the University of Queensland, should be transparent with respect to how well its curriculum covers ethical conflicts, industry criticism and the challenges in keeping the PBS sustainable while ensuring equitable access to necessary medicines for all Australians. Industry critics should also have a small involvement in this course. • The remuneration of medical representatives should be linked on their achievement of quality use of the medicines, not merely increased

			sales. • Medical representative conduct should also be randomly monitored by the MA monitoring committee. • To prevent sales of these products to patients by health practitioners these packs should be clearly labelled "Starter packs – for non-commercial use only". • Section 6.8 should be repealed. Conference fees, travel, accommodation and daily expenses of health professionals should not be funded by industry unless the person involved is substantially contributing to the program as a speaker or Chair. • Consideration should be given to industry redirecting a moiety of their promotional / education budget to the NPS (via MA) for independent educational activities. • Full disclosure of what the industry sponsorship entails must be made publicly available. • Full disclosure of industry hospitality, speakers travel, consultants fees, and any other remuneration in cash or kind to health professionals or their employing organisations must be made public. • Effective sanctions must include corrective advertising orders (in the same media and using the same space) and fines imposed related to the sales income of the company and product involved. In addition, 50% of fine income should be passed on to the National Prescribing Service for independent educational activities.
Bernard O'Shea (Melbourne)	Code Update with all Code Committee Chairs and Members	20/4	• Comments removed for confidentiality
Henry Ko (Melbourne) 0427379886 talk2henry@gmail.com	Code Update with all Code Committee Chairs and Members	20/4	• Sponsorship of "journal clubs" - no guideline on the sponsorship of these events. • Opposed to sponsoring of "journal clubs" for only a single department from a hospital or practice. However, I do see greater value in sponsoring, if it needs to be done, of "journal clubs" where professionals come from different hospitals or practices or geographic regions. This is more analogous to a conference or meeting where a lot more people get a benefit from attending. • My reasoning is that if departmental staff want to hold a "journal club" why can't the hospital or the staff themselves pay for it? This is the norm in other professions. • Should there be more emphasis on compliance procedures to help

			companies report things correctly first time every time? • Lack of detail of submissions seemed to be a problem, as was incorrect data on costs and attendees.
Tom Simpson (Hobart) Manager Pharmacy Department 03 6222 8450 Tom.Simpson@dhhs.tas.gov.au	Jim (Teleconference)		• No requirement for a secure system is really a necessity – HCPs accessing information. • BRNs should be permitted for non-patient care items (eg furniture etc within a practice or hospital) • Not necessary to be this prescriptive about where the BNRs "might" be able to be used. • Competition prizes at conferences exempt from Code • Starter packs – use in discharge from hospital • PFPs – ongoing • Entertainment - *This requirement does not apply to conferences organised by professional societies but sponsored by companies."* - *Entertainment may be supported in part by sponsorship but not in whole, and must not be lavish or indulgent* - *Events that are organised by companies must not include entertainment.* • Code Committees should include: - One representative of the Society of Hospital Pharmacists of Australia (SHPA); and - One representative of the Pharmacy Society of Australia (PSA)
Mental Illness Fellowship (Adelaide) Margaret Springgay Executive Director 08 8221 5072 mifa@ozemail.com.au	Libby (teleconference)		• 1.4 Could be clearer – does this mean written approval with each occurrence of his/her name? Or approval can be done once for all subsequent? • 2.1.2 Such alteration is approved in writing? Can it be verbal approval? • 2.2.3 Clinically significant drug/drug interactions [not clear in text] • 2.4.1 Not clear what happens to boxed warning after 12 months? Should it go under contraindications? • 8.1.5 Advise ADRAC of its intentions in writing? Would verbal do? • 8.2.2 Also not based on number of prescriptions? Written by

			consultant • 9.2.1 Do they have to specify that a warning is boxed and is significance of the boxed warning understood by the public? How do the public know this? • 9.6.2 Again public may not be aware that warning is boxed & significant • 12.1.2 What happens after the imposed fine if they still don't take corrective action? I would refer to 12.1.4 about repeated breaches • 13.2 No carer representatives on Committees
AGPN (Canberra) Leanne Wells General Manager Policy & Development Skye Cappuccio Senior Policy Adviser 02 6228 0812 scappuccio@agpn.com.au	Deborah and Heather	15/4	• Code must support evidence clinical practice and rational prescribing through responsible marketing • Any revisions must ensure continual monitoring and regulation of practices that may in any way threaten QUM • Support provisions that promote informed decision making and QUM on behalf of patients • Educational and promotional activities must not inconvenience or compromise the integrity of HCPs and EER to be reported
DoHA (Canberra) David Learmonth	Deborah and Heather	15/4	• Only promote PBS indications • **Starter packs/PFPs should include** information that they are provided for a limited period and what will happen if not PBS listed • Section 8 to be amended to include all post market research. • Addition to Section 9 – interaction with government employees
AMA (Canberra) Dr John Gullotta 02 6270 5400 drjohngullotta@bigpond.com	Deborah and Heather	15/4	• Supports self regulation • Sections 1 and 8 – reference to NHMRC research and whether studies used comply with these guidelines and levels of evidence • Timely update of PIs • No advertising in prescribing software • Starter packs – equal prominence to brand name and generic name • Use of the internet – more guidance • EERs – add column with therapeutic class and statements on invitations from companies that they comply with the principles of the

			Code
CHF (Canberra) Carol Bennett 02 6273 5444	Deborah and Heather	15/4	• Consumers divided over independence of Code administration and Committees • Concern that the Code in its entirety only applies to member companies • Awareness of the Code by consumers is low – need more education activities for consumers to raise awareness • Font size – comparison brand name to AAN • Prescribing software – no advertising • Definition of extravagant • HCPs should disclose finding received when participating in clinical trials • Media releases to the public should include references • Strengthen reference to WTG – include principles in the Code • Level of fines should be increased • More emphasis on internal company compliance • Need for pro-active monitoring • Additional information on new technologies • More information on what is a vexatious or frivolous complaint • MA to provide an analysis of trends
PSA (Canberra) Grant Martin (Acting CEO) Kay Sorimachi Director Policy and Regulatory Affairs Pharmaceutical Society of Australia 02 6283 4777	Deborah and Heather	15/4	• The Pharmaceutical Society of Australia strongly believes the membership of the Code Committee should be expanded to include a representative of the Society.
TGA (Canberra)	Deborah has had telecom with Rohan Hammett	? March	

Palliative Care (Canberra) Bruce Shaw National Policy Director 02 6232 4433	Heather		• Except perhaps in the area of raising awareness among all prescribers of appropriate medicines for palliative care purposes, the Code does not seem to either hinder or, indeed, help, this cause. • Certainly the template submission form does not apply to us. Accordingly, we will not be making a formal submission in that sense to the review, though we are happy for you to include this among responses should you wish. • We appreciate your keeping us in the loop, not just on this issue, but on other issues, such as PBS listing and quality use of medicines.

Panel Member	Stakeholder
Will	HCN
Deborah	HCN, AMA, CHF, AGPN, PSA, DoHA, All Code Committees
Heather	AMA, CHF, AGPN, PSA, DoHA, RACGP, Creative Promotions, AFA, Palliative Care, All Code Committees
Sophie	RACP
Leanne	NPS
Libby	CHOICE, Mental Illness Fellowship (Teleconference)
Jude	CHOICE, NHF Victoria (Teleconference)
Shaun	RACP
Ed	Ken Harvey
Aaron	Haystac, Ken Harvey
Brett	Walters Kluwer Health, GMIA
Wes	NPS
Tony	Medical Update, GMIA
Ken	Elsevier, CHI (Teleconference)
Jim	CHI (Teleconference), Tom Simpson (Teleconference)

Appendix 5

Consumers Code Review Workshop
Invitation to the following Health Consumer Organisations and Individuals

Health Consumer Organisation	Attendees
Alzheimer's Australia	2
Arthritis Australia	1
Arthritis NSW	1
Asthma Australia	1
Breast Cancer Network Australia	1
Cancer Council WA	0
Cancer Voices Australia	1
Carer's Australia	0
Cochrane Consumer Network	1
Consumer Health Forum of Australia (Does not include CHF representatives on Code Committees)	1
Diabetes Australia	0
Diabetes Australia NSW	1
Diabetes WA	0
Epilepsy Association of SA & NT Inc	1
Haemophilia Foundation Australia (CEO HFA also alternate Code Committee member – included as a Committee representative)	0
Health Consumers' Council of WA	6
Heart Foundation WA	0
Kidney Health Australia	1
Leukaemia Foundation	1
Meningitis Centre	0
Mental Illness Fellowship of Australia	1
MS Australia	0
National Association of People Living With HIV/AIDS	1
National Asthma Council (NAC)	0
National Heart Foundation, Victoria (NHF)	1
Osteoporosis Australia	0
Prostate Cancer Foundation of Australia	0
SANE Australia	0
The Australian Lung Foundation	2
Other organisations and individuals	
CHOICE	1
CHF representatives on the Code, Appeals and Monitoring Committees (and alternates)	7

Appendix 6

Medicines Australia Code of Conduct Review

Report of Consumer Workshops on the Medicines Australia Code of Conduct

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1 March 2009

PPR 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

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- **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.

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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.

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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:

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- 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*.

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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.

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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.

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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.

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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.

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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.

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- **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.

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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.

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- **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.

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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:

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- **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.

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- **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.

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- **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.

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consumers can also be offered incentives to participate in trials or be 'bullied' into participating by their health care professional.

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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.

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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:

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- 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

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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.

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
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**

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Appendix 7

30 March 2009

Will Delaat
Chairman, Code Review Panel
Medicines Australia
Level 1, 16 Napier Close
Deakin ACT 2600

By fax: 02 6282 6299

Dear Will

Independent Audit of Review of Medicines Australia Code of Conduct (Edition 15)

I refer to the Code Review Panel (CRP) Meetings on 12 March 2009 and 24 March 2009, which Leanne Meyer of Gilbert + Tobin attended on my behalf.

I am advised by Ms Meyer that the CRP participants at those meetings demonstrated a good working knowledge of the various written submissions made by stakeholders. There was robust debate on the issues being discussed and a number of issues raised in submissions, which had not yet been considered, were identified and placed on an agenda for discussion at a further CRP meeting.

However, I do wish to raise one issue of concern with you at this point which I believe requires some clarification.

I understand that at one point during the CRP meeting on 12 March one of the CRP members raised the issue of the pharmaceutical companies' relationship with healthcare professionals (HCPs) in the context of clinical trials. The member observed that the limitations which the Code placed on the provision of hospitality by pharmaceutical companies to HCPs in the course of promotional activities did not apply when those same companies were engaging with HCPs in the conduct of clinical trials. A number of CRP members stated that their companies took the approach that clinical trials were covered by the Code of Conduct and abided by the Code limitations accordingly. Discussion then commenced about whether the Code should be expanded to include clinical trials. However, I am advised that further discussion on the topic was terminated on the basis that the Code governs promotional activities and is not intended to cover clinical trials. This issue was therefore deemed to be outside the scope of the review. I am advised that a comment was made to the effect that the Medicines Australia Board would not be expecting discussion on such matters in the course of the review process.

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This dialogue seems to indicate that certain boundaries have been set defining the issues which are open for consideration in the review process. It is unclear to me what these boundaries are and I seek clarification from you in this regard – especially as there is only an incomplete reference to the relevant discussion recorded in the 12 March 2009 meeting notes under section 4.4 Training – "does the Code apply to CRAs."

The Terms of Reference for the Code of Conduct Review (TOR) are broad. They expressly recognise that the Code of Conduct is regarded as "the pre-eminent standard for the conduct of pharmaceutical companies in all facets of their relationships and communication with healthcare professionals and members of the general public."

The TOR require the CRP to consider "any issue which may arise as a result of the consultation process".

Further, the direct invitation extended to stakeholders and interested parties to make written submissions called for comments on the "current Code of Conduct (Edition 15), including any areas that require amendment or areas that are not adequately covered by the Code".

Notably, the issue of clinical trials and whether the Code should be expanded to cover clinical trials was raised as an issue in the Consumer Workshop held in Melbourne on 5 February 2009. Quite apart from my concerns about the limitations which are possibly being placed on the scope of the review, given that there is no consumer representative on the CRP I am of the view that a greater burden is placed on the CRP to ensure that all issues raised by consumers are fully and properly considered and addressed in the review process.

As a matter of principle, I am of the opinion that the Code of Conduct review should not be limited in scope by what the existing Code covers.

I would appreciate the opportunity to discuss this issue with you with a view to making any necessary interim recommendations to ensure that this issue is properly addressed in the course of the review.

Notes from 26 May 2009 Teleconference with Consumer Workshop Participants

Participants
Ms Lorien Ruane – CHF
Ms Anne McKenzie – CHF Representative on the Code Committee
Ms Judith Maher – CHF Representative on the Appeals Committee
Ms Ainslie Cahill – Arthritis Australia
Ms Leanne Meyer – Gilbert + Tobin
Mr Tim Bensen – Health Consumers' Council of WA

Apologies
Mr Peter Canavan – National Association of People Living With HIV/AIDS
Mr John Stubbs – Cancer Voices
Mr Robert Cole – Epilepsy SANT

Medicines Australia
Ms Heather Jones
Ms Deborah Monk

Ms Monk welcomed participants to the teleconference. Participants introduced themselves and their organisations. Ms Monk introduced Leanne Meyer and explained her role in the independent audit process.

The purpose of this teleconference was to review the final report of the consumer workshops from Ann Porcino and discuss the issues raised and how they were dealt with by the Code Review Panel.

Ms Monk discussed each of the sections of the report and explained the amendments to the Code that had been made consistent with the comments from the workshops, or explained why no change had been made to the Code. The following numbering of sections follows the numbering in the Workshop Report.

<u>3.1 Recognising the role of consumers</u>

- New introduction – expanded and gives structure
- Principles of what we are trying to achieve articulated more clearly
- Recognises the *Working Together Guide* and includes principles in the Code

<u>3.2 Consumer Awareness</u>

- As part of the Code Awareness campaign Medicines Australia will be communicating with all stakeholders, including HCOs.
- CHF has verbally indicated that it is keen to partner with Medicines Australia in such a campaign, where appropriate.

3.3 Relationship with HCOs

- Anew section on relationship between industry and HCOs has been included in Edition 16
- Requirement for publication of any sponsorship of a HCO (financial and non-financial) – but not the monetary value of the sponsorship.
- Prohibit a company from seeking to be the sole sponsor of a HCO to the exclusion of mother sponsors.
- Responsibility on companies to inform the HCO that it will make the disclosure.

Mr Bensen commented that these were good amendments.

3.4 Consumer representation on Code Committees

- Edition 16 has been amended to include 2 consumer representatives on each of the three Committees where the complaint or monitoring review is in relation to activities with the general public or patients.
- Current members of Medicines Australia Code Committees commented that it would be worthwhile to have an induction process for representatives on all Committees. This should also include the alternate nominees. Medicines Australia agreed and will implement this with the introduction of Edition 16.

4.1 Advertising in prescribing software

Advertising in prescribing software will be prohibited in Edition 16

- Participants were pleased with this amendment

4.2 Other advertising in doctor's surgeries

- Ms Monk explained that Panel members considered that it is already clear that material supplied to them is promotional/advertising. Materials for patients are also identifiable as such. All materials produced by a company must include the company name.
- In relation to branded items, the new Code will further restrict brand name reminders to items for use in the medical practice or pharmacy. This was to avoid leakage of branded items like pens and notepads into places such as restaurants and taxis.

4.3 Product starter packs

Ms Monk noted that there had been mixed views expressed at the consumer workshops. Also, these provisions had been approved by the National Coordinating Committee for Therapeutic Goods (NCCTG) and that the Panel had decided not to make any amendments.

4.4 Consumer Medicine Information (CMI)

- Participants reiterated the views expressed at the workshops that Medicines Australia should support the need for consumers to have access to CMIs and noted that there were other reviews and discussions relating to the provision of CMIs.

- Ms Monk advised that MA and the Code Review Panel supported the need for consumers to receive CMI. The Panel had considered that CMI is adequately covered in the Code. Noting a comment from CHF, the Code will continue to encourage the provision of CMI via prescribing software.

5 Relationships with health care professionals and involvement in educational events

- Participants commented that the new provisions were much clearer and appreciated the inclusion of the new sections regarding attendance by non-HCPs at trade displays.
- One member expressed some reservation about the provisions concerning appropriate levels of hospitality. Ms Monk responded that it is difficult to be more specific about cost as a company must consider the balance between the educational component and the hospitality provided. After the first round of educational event reports summary information on complaints (breach and no breach) was provided to member companies. Companies are now well aware of what is acceptable/not acceptable. All educational events a company holds or sponsors are publicly available on the Medicines Australia website.
- In relation to the provision of alcohol at evening education events, the Panel had commented that the attendees at these educational events were in a position to make their own decisions on the consumption of alcohol. The Code states that alcohol must not be served at in-institution events (for example journal clubs and grand rounds).
- In relation to the terminology in the Code, the Panel had accepted that some wording was ambiguous – the language has been amended to include 'must' rather than 'should' and words such as 'extravagant' have been removed. It is expected that the new Code provisions and Guidelines will clarify issues such as appropriate hospitality.
- In relation to the issue of pharmaceutical companies keeping a public register of people who participate in their activities Ms Monk explained that industry already reports all educational events they hold or sponsor.

6 Relationships with the general public

- The provisions of the Code pertaining to relationship with the general public have been reorganised and expanded. The language is also more categorical.
- Ms Monk explained the changes relating to media releases to the general public so that companies are clearer about what a media release 'must' include; 'must not' include and 'may include'. The emphasis is on the prohibition of promoting prescription medicines to consumers.

7.1 New communication technologies

- The Code has been expanded to include social media and new communication technologies.
- The Guidelines will be expanded to provide more clarification and examples.
- The Monitoring Committee already has the power to review any material or activity covered by the Code.

7.2 Clinical trials

- Edition 16 includes reference to research and the organisations that regulate the conduct of clinical trials. It will also specifically refer to the appropriate provision of hospitality, travel and accommodation in association with conducting clinical trials. The prohibition on providing entertainment or paying for or subsidising family members to attend clinical trial-related meetings is also explicit.

7.3 Wider range of companies

- Medicines Australia's Code can only relate to prescription medicines. It has lobbied strongly for the Government to agree that the whole Code should apply to non-member companies, but has so far been unsuccessful in persuading the Government to make this change.

8.1 Sanctions

- Monetary fines have been increased in Edition 16 and there is further delineation between the levels of fines.
- The outcomes of all complaints are publicly available on the Medicines Australia website in the Code Annual Report and Quarterly Reports.
- Other sanctions were discussed by the Panel and the Guidelines that will accompany Edition 16 will include updated information on determining Code sanctions (already in a separate document on the Medicines Australia website).
- The Code Committee can require companies to change their internal policies and operating procedures and will require a company to give evidence of this to the Code Committee.

8.2 Reorienting approach to Code administration

The Code is reviewed every three years. The provisions have been greatly expanded and there is increased transparency.
Medicines Australia will be looking at whether the administration of the Code can be made more independent over the next 3 years, like the system that operates in the UK.

- As part of the Code awareness campaign, more emphasis will be placed on the role of the Monitoring Committee

8.3 Conflict of interest/independence of the Code

All permanent members of the Committee are nominated by independent bodies. These are in the majority on the Committee.
Medicines Australia will continue to look at how the Code operates and other options for greater independence.

Participant comments

- Judith Maher commented that it was an excellent job and Edition 16 was a huge improvement. Judith also made reference to the fact that there was no barrier to individual complainants; including that there were no provisions that would allow a finding of abuse of the code (frivolous or vexatious complaint) against a non-industry complainant.

- Anne McKenzie agreed with Judith and was pleased that the Panel was taking on board the feedback and concerns. She was pleased to be part of the process and was of the view that the Code was moving in the right direction.
- Ainslie Cahill stated that the proposed changes were very comprehensive.

Implementation Timeframe

Ms Monk provided the following timeframe for the implementation of Edition 16 of the Code:

- 15 June 2009 – General Meeting of Members to adopt Edition 16 of the Code
- 30 June 2009 – Application for authorisation made to the ACCC
- July 2009 – ACCC will call for public comment on our application for authorisation of Edition 16 of the Code
- End September (approximately) – ACCC will issue its draft determination and invite further public comment on this draft determination.
- December 2009 – ACCC will issue its final determination
- 1 January 2010 – subject to ACCC granting authorisation, Edition 16 of the Code will become effective

Appendix 9

Medicines Australia Code of Conduct Edition 15 - Review

Schedule of major issues raised at Consumer Workshops and resulting amendments to Edition 16 of the Code of Conduct

Issue Raised	Change Made
Advertising in prescribing software	section 2.5 – advertising in prescribing software now prohibited
Application of the Code - Sanctions	section 24 – monetary fines increased to a maximum of $250,000.
Expanding Code coverage - New communication technologies	Section 12 – Relationship with the general public has been expanded, particularly to cover explicitly all forms of media including social media. New section 12.9 making explicit that promotion to the general public via social media such as Facebook, YouTube, MySpace, Twitter, blogs and wikis are prohibited.
Expanding Code coverage – clinical trials	recognition that sections of the Code which apply to interactions between companies and HCPs providing consulting services also apply to interaction when conducting clinical research.
Consumer representation on Code Committees	Sections 19-35 Administration of the Code. Amended to provide that where a complaint or an appeal is in relation to an activity or material directed at the general public or patients, a second consumer representative will be appointed to the Code of Conduct Committee and the Appeals Committee respectively.
Relationships with general	Provisions of the Code pertaining to relationship with

public	the general public expanded. Language made more categorical.
Relationships with HCOs	Preface to Code of Conduct re-worded to describe the important role that health consumers and HCOs play in the quality use of medicines. New Section 13 on the relationship between companies and HCOs.
Terminology used in the Code ambiguous	The CRP accepted that some wording was ambiguous – the language has been amended to include 'must' rather than 'should' and words such as 'extravagant' have been removed.

Appendix 10

Attachment 1

Code of Conduct Review – Edition 15

Terms of Reference

1. Purpose of Review

The primary purpose of the review is to ensure that the provisions of the Code and its administration remain appropriate and relevant to the current Australian and international environment, taking into consideration the interests of consumers, government, healthcare professionals and the industry.

The objective of reviewing and revising the Code of Conduct is that the Medicines Australia Code is regarded as the pre-eminent standard for the conduct of pharmaceutical companies in all facets of their relationships and communication with healthcare professionals and members of the general public. Through demonstrably ethical conduct supported by a rigorous and effective Code the industry's reputation and trust with key stakeholders, including healthcare professionals, government and consumers, will be enhanced.

In ensuring this objective is achieved, the Review will ensure the following principles are reflected in the Code:

- The protection of patient safety through the provision of timely, current, accurate and balanced information
- That industry conduct will be able to withstand public and professional scrutiny
- The right and responsibility of the industry to disseminate information about its products in an appropriate manner to healthcare professionals and the general public
- Recognition of the role of industry in enhancing the practice of medicine and pharmacy and supporting the Quality Use of Medicines
- The right and responsibility of industry to provide and support ongoing education for health professionals
- Ensuring compliance with current State and Federal legislation

2. Particular issues to be considered

In addition to any issues which may arise as a result of the consultation process the following items will need to be considered:

- The Industry Taskforce recommendations, as endorsed by the Board
- Other industry and health professional Codes of Conduct or Codes of Practice. The Code Review Panel will consider the following:
  - International pharmaceutical organisations' Codes of Practice
  - Healthcare professional organisations' position statements and guidelines on the relationship between with healthcare professionals and the pharmaceutical industry.

- Advice from the MA HCOWG and Consumer groups on the relationship between Health Consumer Organisations and the pharmaceutical industry.

- ACCC Authorisation
  - the strategy for achieving authorisation will be guided by legal advice, which will determine the most effective and convincing arguments to propose to the ACCC and to ensure that, over the next 18 months, we have collated and developed evidence of MA's and the industry's conduct to support our propositions.
  - MA will continue to communicate with the ACCC in relation to compliance with the Condition requiring reporting of educational events. In this context the review of the Code is likely to be also discussed. Specific communication with the ACCC about particular amendments to the Code will be considered from a necessity and strategic perspective.

3. Stakeholder consultation

The following is a list of stakeholders with whom we will directly consult, in addition to the public announcement of the Review:

- ACCC
- AGPN
- Advertising Federation of Australia
- AMA
- APAC (or at least all stakeholders represented on APAC)
- ASCEPT
- Australian Medical Writers Association
- Australian Nursing Federation
- CHF
- Code of Conduct and Appeals Committee Members
- CHOICE
- Doctors Reform Society
- DoHA – eg Regulatory Policy and Governance Branch and Pharmaceutical Benefits Division
- Medical Publishers
- Ministers for Health and Consumer Affairs
- Monitoring Committee Members
- NPS, including *Australian Prescriber*
- PHARM
- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia
- RACGP
- RACP – and some key individual medical colleges and societies
- Rural Doctors Association
- Society of Hospital Pharmacists
- TGA

Appendix 11

21 April 2009

Will Delaat
Chairman, Code Review Panel
Medicines Australia
Level 1, 16 Napier Close
Deakin ACT 2600

By fax: 02 6282 6299

Dear Will

Independent Audit of Review of Medicines Australia Code of Conduct (Edition 15)

I refer to my appointment as Independent Auditor of the Medicines Australia Code of Conduct Review.

Please find enclosed a report setting out my Interim Findings and Recommendations (Interim Report).

I have prepared this Interim Report and submit it to you at this stage to allow the CRP time to consider and address the matters which are of concern to me, prior to the review process being finalised.

This report incorporates the issue raised with you in my letter dated 30 March 2009.

It would be beneficial for us to meet and discuss the matters set out in this Interim Report. I look forward to hearing from you to arrange a mutually convenient time for this purpose.

Yours sincerely

Dr Simon Longstaff Executive Director
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Independent Audit of the Review of the Medicines Australia Code of Conduct Edition 15

Interim Findings/Recommendations

Objectives

Medicines Australia is undertaking a triennial review (**the Review**) of the Medicines Australia Code of Conduct Edition 15 (**the Code**).

I have been engaged to conduct an independent audit of the Code review process (**the Audit**). Specifically, the objective of this Audit is to independently evaluate the Review process to ensure:

- that the Review is being carried out comprehensively;
- that the Review is being carried out effectively; and
- that all relevant parties are being afforded a proper opportunity to contribute to the Review.

Scope

I am conducting the Audit in accordance with:

- the Terms of Reference for the Independent Audit of the Review; and
- the ACCC *Guidelines for developing effective voluntary industry codes of conduct* (February 2005).

Interim Findings/Recommendations

As a result of investigations, observations and enquiries undertaken to date, I have identified a number of provisional deficiencies in the Review process, each of which are set out below in this Interim Report. I am of the view that each of the deficiencies identified are, at this stage, remediable and I have made recommendations accordingly.

Issue 1: Constitution of Code Review Panel (CRP)

Nominations for appointment to the CRP were sought by Medicines Australia only from its member companies, and the CRP was ultimately made up solely of representatives of these member companies. The CRP does not include a consumer representative, a health care professional (**HCP**) representative or a government/public policy representative.

One consumer group called into question the independence of the review process given this constitution of the CRP.[1] It was suggested that the process could be enhanced by the appointment of an independent reviewer to conduct the Review.

It was in response to this suggestion that the Chairman of the CRP appointed me to carry out the Audit.

[1] Choice submission No 1 dated 30 Sep 08

In my opinion, regardless of the fact that I have been appointed to conduct the Audit, the absence of a consumer and/or HCP representative on the CRP places a greater burden on the CRP than might otherwise have existed to ensure that the review process is conducted effectively and transparently and to specifically take into account and consider the views expressed by consumer organisations and those organisation representing HCPs. Particularly in relation to issues which may be, or may be expected to be, of interest or concern to consumers or HCPs, the absence of such representatives on the CRP makes it incumbent on the CRP to proactively seek specific input from the appropriate representative bodies. It also places a greater burden on the CRP to diligently consider and deal with each of the issues raised and debated at the consumer workshops conducted by the CRP (see discussion below).

Issue 1: Recommendation(s)

Conduct face-to-face consultations between the CRP, each consumer group and each HCP representative group having made submissions.

Ensure that each and every one of the comments raised in the consumer workshops are discussed and considered in a separate meeting for this purpose.

Issue 2: Restrictions on Scope of Review

During the CRP meeting on 12 March one of the CRP members raised the issue of the pharmaceutical companies' relationship with HCPs in the context of clinical trials. The member observed that the limitations which the Code placed on the provision of hospitality by pharmaceutical companies to HCPs in the course of promotional activities did not apply when those same companies were engaging with HCPs in the conduct of clinical trials. A number of CRP members stated that their companies took the approach that clinical trials were covered by the Code of Conduct and abided by the Code limitations accordingly. Discussion then commenced about whether the Code should be expanded to include clinical trials. However, further discussion on the topic was terminated on the basis that the Code governs promotional activities and is not intended to cover clinical trials. This issue was therefore deemed to be outside the scope of the review. A comment was made to the effect that the Medicines Australia (**MA**) Board would not be expecting discussion on such matters in the course of the review process.

This dialogue seems to indicate that certain boundaries have been set defining the issues which are open for consideration in the review process.

The Terms of Reference for the Code of Conduct Review (**TOR**) are broad. They expressly recognise that the Code of Conduct is regarded as "*the pre-eminent standard for the conduct of pharmaceutical companies in all facets of their relationships and communication with healthcare professionals and members of the general public.*"

The TOR requires the CRP to consider "*any issue which may arise as a result of the consultation process*".

The direct invitation extended to stakeholders and interested parties to make written submissions called for comments on the "*current Code of Conduct (Edition 15), including any areas that require amendment or areas that are not adequately covered by the Code*".

Further, this issue – clinical trials and whether the Code should be expanded to cover clinical trials – was raised as an issue in the Consumer Workshop held in Melbourne on 5 February 2009. More generally, in a written report dealing with the consumer workshop held in Melbourne, one delegate noted that "*on a number of occasions issues raised by the*

consumer reps present were not included in the debate as the topic was deemed to be outside of the Code."[2]

Quite apart from the issue of limitations being placed on the scope of the review, given that there is no consumer representative on the CRP I am of the view that a greater burden is placed on the CRP to ensure that all issues raised by consumers are fully and properly considered and addressed in the review process.

I am of the opinion that the Code of Conduct review should not be limited in scope by what the existing Code covers.

Issue 2: Recommendation(s)

Revisit the issue of whether clinical trials and CRAs should be covered by the Code.

Revisit and reconsider any other issues made in submissions or raised at the consumer workshops that were dismissed as a result of not being within the scope of the current Code.

Hold face-to-face meetings with stakeholders/parties who have raised issues deemed to be outside the scope of the current Code.

Issue 3: Independence of CRP recommendations to MA Board.

Following consideration of issues raised in written submissions and at the consumer workshops and the preparation and settling by the CRP of draft revisions to the Code, some of the proposed revisions were submitted to the Board of Medicines Australia for consideration and approval. The Board rejected the CRPs proposal to amend the Code of Conduct to require companies to disclose their costs involved in hosting international meetings with HCPs in attendance. The reported reasoning of the Board in rejecting this change was that it did not want to "provide fuel to the critics", that people might take the list of disclosed expenses and costs and pick through them, and that if the costs were disclosed it would be bad from a "public image" point of view.

A CRP member asked the chairman to explain the status of the Board's rejection of the proposed amendment ie. what did that mean for the proposal. The chairman explained that the Board's decision was final, the *status quo* was to be maintained and the change would not be made.

In my opinion, regardless of what the MA board may ultimately resolve to ensure the transparency and effectiveness of the Review, the CRP must make its recommendations for revisions to the MA board independently and without having regard to any views expressed by the MA Board.

The final decisions of the MA board, determining whether or not to accept or reject the CRPs recommendations for revisions to the current Code, should then be fully documented and its reasons for accepting or rejecting particular proposals should be made publicly available.

Issue 3: Recommendation(s)

Revisit the discussion/re-instate the CRPs recommendation to amend the Code to require companies to disclose their costs involved in hosting international meetings with HCPs in attendance.

Refrain from having the MA board comment on any proposed change until the CRP report proposing amendments is finalised and submitted to the MA Board for final consideration.

[2] Report by J Brian Stafford dated 9 February 2009.

Ensure that the CRP makes its recommendations for amendments without taking into account any previously expressed Board view.

Ensure that the MA fully and precisely records its consideration and decision-making process in relation to each proposed amendment.

Issue 4: Consumer Workshop – report of independent facilitator

Medicines Australia convened, at its expense, consumer workshops which were conducted in Sydney and Melbourne on 4 and 5 February 2009 respectively. Invitations to attend and participate were extended to Health Consumer Organisations (**HCOs**). These workshops were conducted by an independent facilitator. A number of issues were raised by HCOs in these forums.

The independent facilitator who conducted the consumer workshop has compiled a draft report on the issues raised. The report was provided in draft to allow input from those in attendance representing the CRP at the consumer workshops. The final report has not yet been prepared and is therefore not yet available for review.

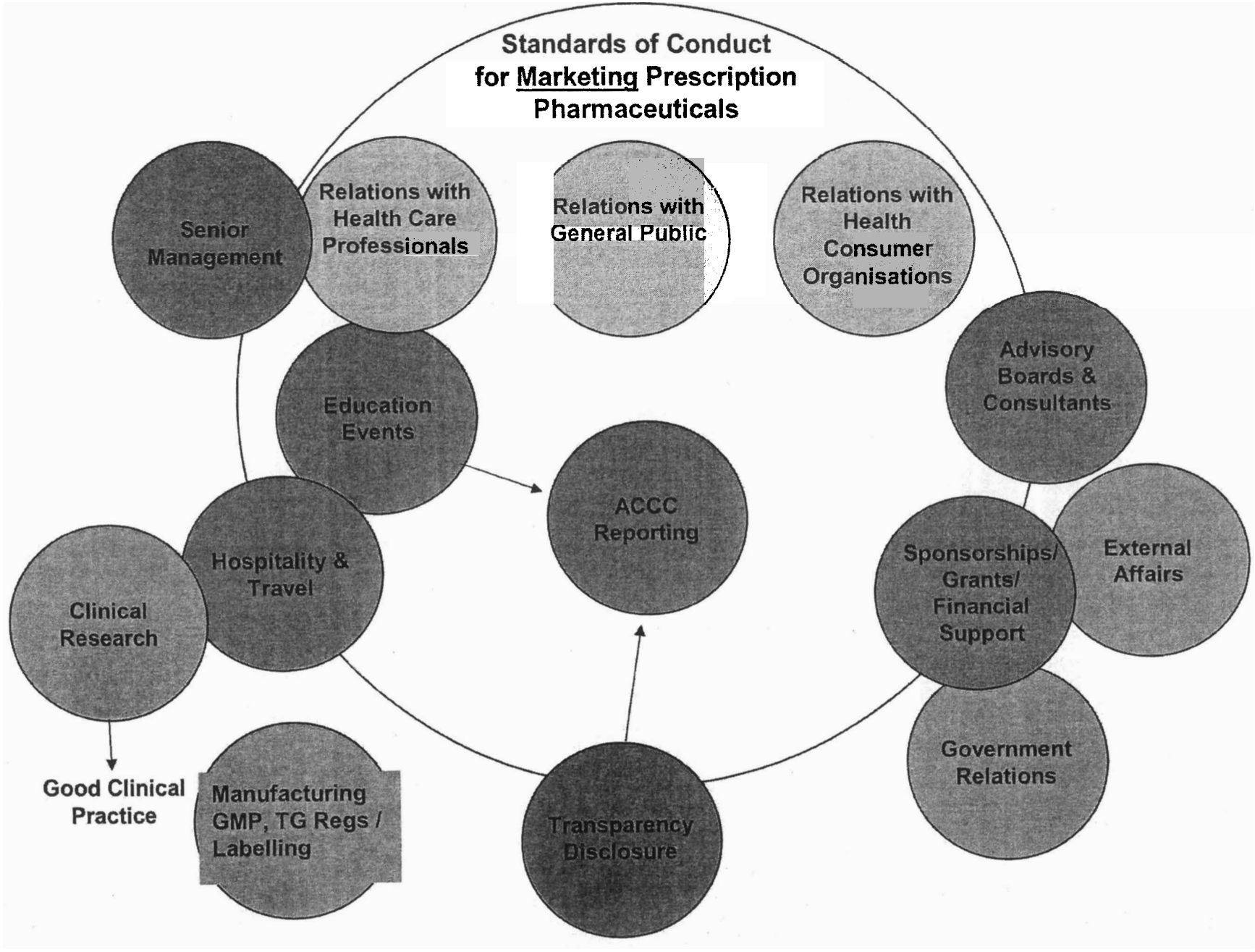
I am concerned to ensure that the final report of the facilitator accurately reflects the facilitator's independent view of the issues raised by HCOs in these forums. Accordingly, the input into the report by the CRP representatives should be limited to comments made to ensure that the facilitator's report accurately reflects the views and comments expressed at the workshops.

Issue 4: Recommendation(s)

No action required at this stage. To be reviewed when final report is prepared and reviewed.

Dated: 21-IV-2009 Dr Simon Longstaff

SCOPE OF THE CODE OF CONDUCT



Appendix