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24 August 2012

Richard Chadwick
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601

Dear Mr Chadwick

Application for Revocation and Substitution A91316, A91317, A91318, A91319 and A91320

We act for Medicines Australia in respect of its application for authorisation of Edition 17 of the Medicines Australia Code of Conduct (the ***Code***). Medicines Australia welcomes the opportunity to respond to the submissions received by the ACCC and provides specific comments below.

1. Increasing fines

Some submissions suggest that fines for contravening the Code should be increased in Edition 17. Drs Purssey, Atkins, Jureidini and Vitry propose that fines of up to $1 million should be imposed on member companies which contravene the Code (a 400% increase on the current maximum fine of $250,000 for a single contravention).[1]

Edition 17 of the Code provides for a range of sanctions that can be imposed on member companies, not only fines. Other sanctions include a requirement to modify or discontinue a practice and a requirement to publish a corrective statement.[2] Member companies take these sanctions seriously and the available sanctions do act as an effective deterrent. Indeed, the Australian Competition Tribunal (***Tribunal***) in *Re Medicines Australia* accepted that a requirement for corrective advertising or corrective letters would be a significant sanction that may have reputational consequences.[3]

In relation to fines, Edition 16 substantially increased the fines that can be imposed on member companies, with the penalties for moderate and severe breaches increasing by

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[1] Member companies which contravene the Code may also face a cumulative maximum fine of $300,000, depending on the conduct in question.

[2] Section 2.6. The Code Committee also has the power to forward a complaint/appeal to the Therapeutic Goods Administration (***TGA***) or the ACCC if a subject company does not pay a fine within 30 days, and to publicise the failure to comply.

[3] *Re Medicines Australia Inc* [2007] ACompT4 at [164].

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50% and 100% respectively. The fines in Edition 17 of the Code remain substantially higher than those in similar industry Codes.[4]

The effectiveness of the Code's sanctions in providing a deterrent effect is demonstrated by the increased level of compliance with the Code. As outlined in Medicines Australia's submission, the number of complaints received by Medicines Australia declined from 2007/2008 to 2010/2011, despite the fact that the Monitoring Committee continues to review a similar number of promotional materials each year.

The *Therapeutic Goods Act 1989* provides for additional penalties (including fines and imprisonment) that can be imposed on pharmaceutical companies and individuals who contravene the provisions of that Act.[5]

For these reasons, Medicines Australia is of the view that it is not necessary to increase the quantum of fines in Edition 17 of the Code.

2. Disclosure of payments to individual healthcare professionals

A number of submissions propose that Edition 17 of the Code be revised to require member companies to report publicly on the sponsorship of individual doctors to attend educational events, by name.

Medicines Australia has already taken considerable steps to increase transparency

In Edition 17 of the Code, Medicines Australia has incorporated a significant number of new measures that substantially increase transparency surrounding the relationship between member companies and healthcare professionals. These include requirements for member companies to provide detailed information regarding (a) sponsorship of healthcare professionals to attend educational events held by third parties, (b) sponsorship of healthcare professionals to speak at educational events, and (c) sponsorship of healthcare professionals to act on advisory boards or provide other consulting services.

The new reporting requirements represent a significant change from Edition 16 of the Code and serve to increase the existing public benefits associated with the Code - benefits that were recognised by the ACCC when authorising Edition 16.[6]

Medicines Australia is committed to increasing transparency further

Although Medicines Australia has made substantial changes in Edition 17 of the Code, Medicines Australia is committed to increasing transparency further. On 14 August 2012 Medicines Australia established a working group (the ***Transparency Working Group***) to develop additional transparency measures. The Transparency Working Group will be

[4] See for example the Generic Medicines Industry Association (***GMiA***) voluntary code of practice, authorised by the ACCC on 3 November 2010. That code provides for fines ranging from $20,000 (for a moderate breach) to $40,000 (for a severe breach) and $75,000 (for a serial breach): section 14.2.

[5] See for example penalties in s19B of the *Therapeutic Goods Act 1989* (Cth) for offences relating to importing, exporting, manufacturing or supplying certain goods.

[6] ACCC: Determination Medicines Australia Code of Conduct 16th edition, 3 December 2009 at [5.65]. See also the Tribunal's comments in *Re Medicines Australia Inc* at [314] where it noted that absent the Code there is no external regulatory system in place to constrain the conferring of benefits on healthcare professionals by pharmaceutical companies.

chaired by Medicines Australia Board member Dr Dominic Barnes, and a number of stakeholders have already been invited to join the group, including the Australian Medical Association (***AMA***), the Royal Australian College of Physicians, the Consumers Health Forum (***CHF***), CHOICE, the GMiA and the Pharmacy Guild of Australia. Medicines Australia has published Terms of Reference for the Transparency Working Group which include a requirement for the group to, among other tasks, evaluate different models for further transparency and develop principles to govern further transparency surrounding payments and other transfers of value between healthcare professionals and the pharmaceutical industry. A copy of the Terms of Reference is attached.

The Transparency Working Group will meet monthly from September 2012 and will release a final report by December 2013, in addition to two interim reports in December 2012 and June 2013.

A key focus of the Transparency Working Group will be how to implement the most effective transparency model in Australia, while avoiding problems experienced internationally in relation to certain transparency models. In this regard, a number of submissions suggest that Edition 17 of the Code should be amended to reflect similar disclosure requirements to those contained in the United States Physician Payments Sunshine Act (***PPSA***).[7] Medicines Australia is concerned that these suggestions do not take account of (a) the significant implementation problems and subsequent delays associated with the implementation of the PPSA in the United States and (b) the fact that alternative transparency models (such as healthcare professional based approaches) are available and should be assessed for relevance to Australia.

In relation to implementation issues surrounding the PPSA, one area that has caused particular concern in the United States is the formulation of rules surrounding disclosure requirements.[8] The Centres for Medicare and Medicaid Services (***CMMS***) were tasked with the role of drafting the rules which accompany the PPSA. The rules specify the process for complying with the requirements of the PPSA, such as the manner in which disclosure will be made and the form it will take. Instead of establishing a working group and consulting with relevant stakeholders from the outset, CMMS issued the rules in draft first and then called for stakeholder input. CMMS received over 300 submissions in response to the draft rules. The volume of the submissions that raised practical concerns led CMMS to form a working group to ensure that the final rules consider, address and include contributions from all stakeholders. The final rules are yet to be published.

For these reasons Medicines Australia does not consider that it is appropriate to amend Edition 17 of the Code to require member companies to report on the sponsorship of individual doctors by name. Rather, Medicines Australia submits that the most effective

[7] The PPSA forms part of the Patient Protection and Affordable Care Act: Sec. 6002 "Transparency reports and reporting of physician ownership or investment interests". The PPSA was passed in March 2010 but is yet to be implemented.

[8] It is expected that the PPSA will generate reporting costs in the order of US$183 million per year (annualised over the first three years). These costs include those associated with an estimated 3,788,000 hours of time that will be spent by physicians and teaching hospitals in reviewing the benefits attributed to them by pharmaceutical companies in their reports. See: https://www.federalregister.gov/articles/2011/12/19/2011-32244/medicare-medicaid-childrens-health-insurance-programs-transparency-reports-and-reporting-of#p-260

way to ensure that this issue is addressed **effectively** is to engage in a thorough, detailed process of stakeholder consultation **before** simply adopting one particular transparency model. The Transparency Working Group will facilitate this process. Its establishment demonstrates that Medicines Australia's members are committed to increasing transparency and implementing standards that are considered best-practice in the local industry and globally.

3. Representation on Code governing body

Several submissions propose that Medicines Australia amend Edition 17 of the Code to include consumer and healthcare professional representatives on the "Code governing body". As outlined in the submission, the Code provides for three Code Committees and a Secretariat. Medicines Australia does not operate any other ongoing committees in relation to the operation of the Code. Currently:

- consumer representatives participate on the Monitoring Committee, Code Committee and Appeals Committee; and
- each of these committees also includes permanent healthcare professional members, such as a representative from the Royal Australian College of General Practitioners on the Monitoring Committee, and representatives from the Royal Australian College of Physicians and the AMA on the Code and Appeals Committees.

In addition to the existing broad representation of stakeholders on these committees, Edition 17 of the Code has been amended to increase stakeholder representation. Under Edition 17:

- meetings of the Monitoring Committee will require a quorum of three full members. One of the members must be a Medicines Australia representative and another a consumer representative from CHF;
- observers may be invited to Monitoring Committee meetings; and
- the composition of the Code and Appeals Committees has been amended to include, as full members, a pharmacist representative from the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia or the Society of Hospital Pharmacists of Australia, in circumstances where the complaint under consideration relates to an activity or material directed to the practice of pharmacy.

4. Self regulation and application of the Code to non-members

Some submissions suggest that the Code should apply to non-member companies. By way of example, CHOICE notes that the Code does not apply to non-member companies such as Ranbaxy. Some submissions also suggest that a self-regulatory approach is generally not appropriate for the pharmaceutical industry.

With respect to suggestions that the current self-regulatory approach should be reassessed before re-authorising the Code:

- the Tribunal accepted the significant benefits of developing and complying with industry codes in *Re Medicines Australia*;[9]
- as recently as December 2011, the Australian Government expressed a preference for a self-regulatory approach in relation to therapeutic goods;[10] and
- the ACCC *Guidelines for developing effective voluntary industry codes of conduct* recognise the benefits in developing and complying with voluntary industry codes.[11]

Medicines Australia submits that an effective voluntary code that complements and extends beyond the reach of statutory regulation is of significant public benefit. In this regard, Edition 17 of the Code will continue to provide the benefits of a strong, voluntary industry code which is "best in class".

In relation to the application of the Code:

- All pharmaceutical companies selling products within Australia are entitled to become members of Medicines Australia, including generic pharmaceutical companies.
- Medicines Australia's members supply at least 86% of medicines supplied under the PBS and adherence to the Code is a requirement of membership of Medicines Australia.
- All prescription medicines must be registered on the Australian Register of Therapeutic Goods. As a condition of registration of prescription medicines the TGA requires that promotional materials relating to the registered goods must comply with the Medicines Australia Code.

Of course, Medicines Australia would like to see all participants in the prescription medicines industry comply with the standards reflected in the Code. However, Medicines Australia does not believe that this issue goes to the question of whether the Code should be authorised in its current form.

5. Patient Support Programs

Some submissions raise concerns that Patient Support Programs may blur the boundaries between the provision of information about disease and health management and the promotion of a medication. Dr Vitry suggests that such programs should be prohibited entirely by the Code and the Department of Health and Ageing (***DoHA***) suggests that the Code should contain suitable criteria for these programs which would identify whether such programs could be considered to be of a promotional nature.

Edition 17 of the Code significantly strengthens the Code's provisions governing Patient Support Programs. These amendments increase the level of transparency surrounding Patient Support Programs and ensure that such programs remain informative and are not

[9] At [308].

[10] TGA reforms: A blueprint for TGA's future, December 2011, p11.

[11] ACCC *Guidelines for developing effective voluntary industry codes of conduct* July 2011, p3.

promotional. Specifically, section 18 of the Code has been amended to, among other things:

- provide a definition of "Patient Support Program", which outlines the relevant principles in relation to such programs;
- require the development of a rationale for each Patient Support Program;
- require the disclosure to patients of any payments made to healthcare professionals in return for work undertaken in relation to such programs, prior to a patient's involvement in the program;
- require that data collected from these programs must not be used for any purpose other than to increase positive health outcomes and never for promotional activities; and
- note that Patient Support Programs may only be offered to patients who have already been prescribed a prescription only product.

Section 18 of the Code therefore provides stringent procedural and disclosure requirements in relation to such programs and contains suitable criteria in order to ensure that such programs are not promotional.

In relation to other suggestions made by the DoHA regarding section 18 of the Code:

- The Code regulates the activities of member companies, it does not regulate healthcare professionals. The Code cannot require healthcare professionals (such as pharmacists) to disclose to patients verbally any payments that the healthcare professional may receive in association with administering these programs.

  Section 18 of the Code does require member companies to disclose in writing any payments made to a healthcare professional **prior** to a patient's enrolment in the program. This amendment in Edition 17 of the Code ensures that the patient receives direct disclosure about any payments made to healthcare professionals and therefore increases transparency surrounding the relationship between member companies and healthcare professionals.
- As a result of consumer consultation during the Code Review process for Edition 17, Medicines Australia amended the Code to require that information provided to patients prior to their enrolment "must include balanced, accurate and correct information about the potential risks of the medicine": section 18(g). Medicines Australia will amend this section as suggested by the DoHA to read that the information "must include balanced, accurate and correct information, *including* about the potential risks of the medicine".
- Any material, including Consumer Medicine Information (***CMI***), that is provided to the general public may not be promotional (see further below). This is recognised in section 13 of the Code, which reflects the requirements of Commonwealth Therapeutic Goods legislation. Accordingly, there are no circumstances in which CMI provided to a patient could or should be 'promotional'.
- Interactions between member companies and healthcare professionals are already regulated by the Code (see sections 2, 4, 8, 9 and 12) and the Code provides

extensive guidance surrounding the types of information that can be communicated to healthcare professionals. The introduction to the Code also makes it clear that adherence to the Code in no way reduces a company's responsibilities to comply with Commonwealth and State Therapeutic Goods legislation, the *Competition and Consumer Act 2010* and the *Privacy Act 1988*.

For the reasons above Medicines Australia does not consider that section 18 of Edition 17 of the Code requires amendment, aside from the minor wording amendment suggested by the DoHA. Patient Support Programs play a key role in supporting the quality use of medicines and there are significant public benefits to these programs (including the improved health and well-being of consumers) which justify their continued development, operation and use.

The CHF has raised a concern in relation to the appropriateness of inserting enrolment leaflets for Patient Support Programs into product packaging. The TGA has agreed that a patient enrolment form for a Patient Support Program may be included within a medicine package so long as it complies with the prohibition on promotion to consumers and states that the Patient Support Program is not authorised or approved by the TGA. Section 18 of the Code imposes such conditions on member companies. The Medicines Australia Monitoring Committee also intends to review these enrolment forms during one of its regular reviews of the activities of member companies.

6. Other submissions

- **Product Familiarisation Programs (*PFPs)***: Section 8 of the Code appropriately regulates the use of PFPs by member companies. This section has been amended in Edition 17 to introduce additional specificity as to when a PFP can be used (outlined in detail in Medicines Australia's submission) and these amendments further strengthen the Code's effectiveness. Medicines Australia does not consider that this section requires additional amendment at this stage. Further to the DoHA's submission, Medicines Australia will confirm in the Code of Conduct Guidelines that the rationale for a PFP must be provided to a party within 10 working days from the date a copy of the rationale is requested.
- **No promotion to the general public**: DoHA submits that the Code should include a provision to make it clear that companies cannot publish promotional material alongside CMI or Product Information (***PI***), as this may result in the advertising of prescription medicines to the public. Promotion of prescription products to the general public would contravene both the Commonwealth Therapeutic Goods legislation and the Code.[12] There are **no** circumstances in which a company is allowed to publish CMI or PI (which is not promotional) 'alongside' promotional material accessible by the general public. This is already recognised in section 13 of the Code which outlines the relationship that member companies may have with the general public and which provides detailed guidance on the circumstances in

[12] In considering Edition 16 of the Code the ACCC recognised that the Code "encourages compliance with legislative prohibitions on advertising to the public and results in a public benefit": Edition 16 Determination at [5.24].

which member companies may interact with the public. Section 13.8 explicitly states that companies may not promote prescription medicines to the general public via the internet.

- **Disease Awareness Campaigns**: Dr Vitry submits that disease awareness campaigns should be prohibited by the Code. Medicines Australia considers that disease awareness activities serve a strong community purpose by educating consumers to recognise symptoms and encouraging consumers to seek medical advice in circumstances where they might not otherwise do so (e.g. because they are embarrassed). Approaching a doctor is particularly important for conditions where early intervention is critical. Important examples include depression and other mental illnesses.

  Australian legislation prohibits direct to consumer advertising of prescription medicines while jurisdictions such as the United States and New Zealand do not have similar prohibitions. Edition 17 of the Code provides detailed guidance on the use and control of disease awareness activities, so that they can continue to serve a community purpose while also ensuring that they do not constitute promotional activity.[13]

  In these circumstances Medicines Australia does not consider that section 13.7 of Edition 17 of the Code requires amendment.

- **Adverse drug reactions and Post-Marketing Surveillance Studies**: The DoHA submits that adverse drug reactions and Post-Marketing Surveillance Studies should be reported to the TGA and not to the Advisory Committee on the Safety of Medicines (***ACSOM***). The current *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by the Drug Safety and Evaluation Branch* published by the TGA provides that individual case reports of suspected adverse drug reactions should be provided to the Adverse Drug Reactions Advisory Committee (ADRAC), which has since been replaced by ACSOM.[14] However, Medicines Australia understands that a new draft Guideline proposed by the TGA (currently delayed) will require such events to be reported directly to the TGA. Accordingly, Medicines Australia is prepared to amend sections 8.10, 10.5 and 10.10 of the Code to provide that adverse drug reactions and Post-Marketing Surveillance Studies be reported to the TGA.

- **Complaint process**: The complaints process is identical for both industry and non-industry complainants (although non-industry complainants do not have to pay a bond if they wish to appeal a decision and their identity may be kept confidential). Medicines Australia publishes detailed Guidelines regarding lodging and responding to complaints.[15] These Guidelines note that (a) non-industry

[13] Section 13.7.

[14] A copy of the current Guidelines is available at http://www.tga.gov.au/safety/australian-pharmacovigilance-guideline.htm#currentreq

[15] These Guidelines are available on the Medicines Australia website at http://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/

complainants may choose to contact the pharmaceutical company to discuss their concerns before lodging a complaint and to seek an explanation, (b) following a complaint, a copy of the complaint and the company's response to the complaint will be provided directly to the Code Committee and (c) if an appeal is lodged, the complainant receives a copy of the company's response and each party has an opportunity to review all relevant documents. Medicines Australia considers that the complaints process is effective and appropriate.

- **Glossary**: Medicines Australia acknowledges the typographical error in the definition of 'Advertisement' in the Code and will amend the definition accordingly. In relation to the DoHA's comments on the definitions of 'Promote', 'Promotional, Promotional or Promotional claim' and 'Promotional material', Medicines Australia notes that these definitions have remained unchanged in at least the last five editions of the Code and are well understood by the industry. The interaction of these definitions has not to date given rise to any compliance concerns.

Yours sincerely

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Transparency Working Group
Terms of Reference

Medicines Australia is establishing a broad-based working group to develop measures and policies that will further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. The working group will be tasked to:

1. develop principles to govern the further transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry, with the interests of health consumers as the primary objective
2. evaluate different models for further transparency, with particular reference to initiatives associated with disclosure of payments to healthcare professionals under consideration in other countries, including the US, UK and other EU countries;
3. consult with all relevant stakeholders to ensure that their perspectives are considered
4. identify efficient and effective mechanisms to promote further transparency of payments and transfers of value between industry and healthcare professionals; and
5. provide a report with recommendations to each Working Group member organisations' governance board or committee. This report will also be publicly available.

The primary purpose of any further transparency measures will be to enable health consumers to be better informed about the nature of payments and transfers of value between healthcare professionals and the industry in general, as well as such interactions with industry by their own healthcare professionals.

The Working Group will provide input based on the perspectives of their constituencies with the interests of health consumers as their primary concern, and will consult with health consumers and healthcare professionals in developing their recommendations. The Working Group will determine the most effective consultation mechanism to engage with all relevant stakeholders.

Background to the establishment of the Working Group

Medicines Australia has recently completed a review of the Code of Conduct, which is undertaken regularly every three years. Several submissions to the review proposed the adoption of measures like the US Physician Payments Sunshine Act in Australia. This legislation requires reporting by pharmaceutical and medical device companies of payments or other 'transfers of value' to physicians where the aggregate amount of payments is greater than $100 in a calendar year. Reporting is required to be by physician name.

However, the US is currently the only country that has imposed a requirement for payments to physicians to be publicly reported by individual physicians by name. This requirement has been extensively delayed in implementation by the US Government in order to respond to operational and implementation issues raised in

consultation on the proposed implementation rule. Models under consideration in other countries include where each physician would make information available to their patients which describes the physician's relationships with pharmaceutical companies. In this way the relevant information would be made directly available to individual patients when they are visiting the physician.

The Code Review Panel, which developed the revised Code of Conduct, considered these issues, submissions and inputs during the review. It recommended that further transparency in relation to payments to healthcare professionals should be provided in Edition 17 of the Code through reporting of aggregate payments to healthcare professionals for participation on Advisory Boards, provision of consultancy services, and sponsorships for attending educational meetings. It recommended that further consideration and consultation was required before imposition of any requirement for reporting of payments at an individual healthcare professional level.

Membership of the Working Group

The Working Group will be chaired by Dr Dominic Barnes, General Manager, Shire Australia on behalf of the Medicines Australia Board.

Invitations to provide a representative to join the Working Group will be extended to the following organisations:

- Australian Medical Association
- Consumers Health Forum
- CHOICE
- Generic Medicines Industry Association
- Healthy Skepticism
- Office of the Australian Information Commissioner (formerly Privacy Commissioner)
- Pharmaceutical Society of Australia
- Pharmacy Guild of Australia
- Royal Australasian College of General Practitioners
- Royal Australian College of Physicians
- Royal Australian College of Surgeons

- Two Medicines Australia Member Company managing directors

The Working Group will be supported by a Secretariat from Medicines Australia – led by Ms Deborah Monk, Director, Innovation and Industry Policy.

The Working Group will specifically consult with organisations which are recognised as having a high degree of interest in the work of the Working Group, including but not limited to the following organisations:

- Australian Nursing Federation
- Doctors Reform Society
- Heart Foundation Australia
- Medical Technology Association of Australia (MTAA)

- NPS
- Regulatory Policy and Governance Branch, Department of Health and Ageing

Meetings

Working Group meetings will be held monthly in either Sydney or Canberra. Medicines Australia will meet the function room / facilities costs. If needed, teleconference and/or webinar facilities will also be made available for members to join meetings. The intended duration of meetings is half-day or less.

Each member of the Working Group will need to fund the cost for their attendance at Working Group meetings.

Timeframe

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