Australian Competition
&
Consumer Commission

PRE-DECISION CONFERENCE

Minutes

Applications for revocation and substitution A91316 - A91320 lodged by Medicines Australia Limited

12 November 2012

The information and submissions contained in this minute are not intended to be a verbatim record of the pre-determination conference but a summary of the matters raised. A copy of this document will be placed on the ACCC's public register.

Pre-Decision Conference:
Applications for revocation and substitution A91316 - A91320
lodged by Medicines Australia Limited

12 November 2012

Australian Competition and Consumer Commission Offices located in Sydney, Canberra and Melbourne by video conference facilities. Teleconference from Byron Bay

Attendees:

Australian Competition and Consumer Commission
Sarah Court, Commissioner (in Melbourne)
Rose Webb, Executive General Manager, Mergers and Adjudication Group (in Canberra)
Richard Chadwick, General Manager, Adjudication Branch (in Melbourne)
Darrell Channing, Director, Adjudication Branch (in Canberra)
Tess Macrae, Senior Project Officer, Adjudication Branch (in Melbourne)
Mark Basile, Project Officer, Adjudication Branch (in Melbourne)
Emma Gordon, Lawyer (in Melbourne)
Alistair Beasley, Economist (in Melbourne)

Medicines Australia Limited (in Melbourne)
Mr Brendan Shaw, Chief Executive Officer
Ms Deborah Monk, Director, Innovation and Industry Policy
Ms Sophie Hibburd, Manager, Code of Conduct
Ms Fiona Crosbie, Partner, Allens

Generic Medicines Industry Association (in Sydney)
Ms Kate Lynch, Chief Executive Officer

Dr Ken Harvey (Choice), Adjunct Associate Professor, School of Public Health, La Trobe University (in Melbourne)

Professor Ian Haines, Adjunct Clinical Associate Professor, Monash University at Cabrini Health (in Melbourne)

Australian Medical Association (in Melbourne)
Dr Elizabeth Feeney

Consumers Health Forum of Australia (in Melbourne)
Ms Carol Bennett, Chief Executive Officer
Ms Dewi-Inala Zulkefli, Project and Policy Officer

GlaxoSmithKline Australia (in Melbourne)
Ms Lisa Maguire, Associate Director Corporate Affairs (Spokesperson)
Mr Glynn Mayne, Compliance Manager

Mr Bruce Arnold – Lecturer, School of Law, Faculty of Business, Government & Law, University of Canberra (in Canberra)

The Pharmacy Guild of Australia
Stephen Armstrong, National Director, Health Economics (in Canberra)

Mr Ray Moynihan, Senior Research Fellow, Bond University; Columnist BMJ, MJA (by teleconference)

Apologies:

Professor Philip Morris

Conference commenced: 11am AEST

Submissions received from interested parties are available at www.accc.gov.au/authorisations.

Commissioner Court welcomed attendees, made some introductory remarks outlining the purpose of the conference, declared the pre-decision conference open and invited Dr Ken Harvey on behalf of the party that called the conference, Professor Philip Morris, to make an opening statement. Commissioner Court noted that the issues that resulted in the most interest from interested parties were whether the Code should require the reporting of sponsorship/fees paid to individual healthcare professionals ('individual disclosure'), followed by the level of the sanctions and the ban on brand name reminders.

Dr Harvey read the submission provided by Professor Morris (attached).

Individual disclosure

Mr Shaw submitted that the industry is serious about further increasing transparency, which is why Medicines Australia's membership overwhelmingly supported increased transparency and reporting of aggregate payments in edition 17 of the Code. Mr Shaw submitted that Medicines Australia wants to take the lead by establishing the transparency working group to work through the options. Mr Shaw noted that Medicines Australia wants to be sure that it chooses the best model, with reference to international developments and in consultation with stakeholders (including the AMA, health professional colleges, consumer groups, pharmacists, and academics). Mr Shaw noted that the Sunshine Act in the US has taken three years to develop and still has not reached final implementation.

Ms Monk said that the key is in ensuring a relationship of trust between the consumer and healthcare professionals and this was discussed in the first meeting of the working group. Ms Monk submitted that medicines Australia invited a number of bodies to attend the working group to represent different interests and a divergence of views. Ms Monk noted the numerous submissions were received in relation to the Sunshine Act and the delays in its implementation.

Commissioner Court sought a response to the view that three years is too long to wait to revise the Code and the working group will not report until December 2013.

Mr Shaw did not rule out the possibility but was reluctant to commit to a shorter period without finding out more and exploring the options, given the US experience.

Ms Monk did not want to pre-empt the outcomes of the working group. Ms Monk also noted that the review of the Code is quite lengthy once you account for consultation and the application for authorisation.

Professor Haines, an oncologist, commented on his experience of receiving payments from pharmaceutical companies to attend conferences and sit on advisory

groups and his view that doctors now have a sense of entitlement to receive these benefits. Professor Haines was sceptical about the effectiveness of self-regulation. Professor Haines submitted that in 2006 Australia was a world leader in transparency and his expectation was that Medicines Australia was working towards individual disclosure. Professor Haines acknowledged that the 17th edition of the Code is an improvement on the previous edition but feels that there is momentum which has been lost and that community expectations have changed.

Professor Haines submitted that research and published articles has gone from being independent studies to pharmaceutical company sponsored studies that have flooded the market, and he is concerned that research data is kept confidential. Professor Haines noted the problems with the Sunshine Act but nonetheless considered hidden payments should stop as it encourages waste and prescribing of drugs that in his view may not be properly tested and are very expensive. Professor Haines submitted that doctors are more likely to accept legitimate payments if there is individual disclosure. Professor Haines noted that Medicines Australia member companies are critical for the development of new drugs there just needs to be openness in the relationship between companies and doctors.

Ms Bennett submitted that the community does have expectations about health practitioners having the consumers' best interests in mind. Ms Bennet considered that individual disclosure is in everyone's best interests and therefore a 'no brainer'. Ms Bennett submitted that the ACCC's 2009 decision was that this would be addressed in the current edition of the Code; however there has been ongoing and unnecessary delay. Ms Bennett submitted that this issue needs to be addressed as soon as possible.

Dr Harvey tabled a recent petition about this issue. Dr Harvey submitted that Australia will fall behind other countries in this area. Dr Harvey submitted that full disclosure is crucial and if there are no changes to the Code, he and his signatories will take the matter to the Australian Competition Tribunal to have this issue addressed. Dr Harvey noted that it is important that the reason for the hospitality is disclosed because there are many good reasons to provide hospitality to doctors.

Mr Arnold submitted that most people think that there are conflicts of interest in providing doctors with these benefits and one way to deal with this is to disclose the financial support that doctors choose to accept. Mr Arnold submitted that Medicines Australia is avoiding meeting best practice despite the level of concern, and it should not be another six years until this is addressed. Mr Arnold dismissed the excuse of it being too difficult, submitting that there are no privacy issues.

Mr Moynihan agreed with the ACCC's analysis but felt that the ACCC should require, rather than encourage, Medicines Australia to address this issue. Mr Moynihan submitted that the in 2006 Australia was accelerated to the forefront of transparency and now we know much more about the companies' marketing strategies.

Dr Feeney submitted that while the AMA wants to encourage consumers to have trust in the system, she encouraged caution as disclosure does not show the nature of the relationship. Dr Feeney was concerned that any changes should be structured to address the perceived problem, and that the outcomes of the Sunshine Act and the working group are not yet known. Dr Feeney submitted that care should be taken not to demonise these types of relationships as there are good elements to them.

Mr Moynihan advocated for comprehensive disclosure (everything over $10 value) rather than choosing what is in and what is out which could encourage gaming. Mr Moynihan noted that there has been a lot of talk about the Sunshine Act taking a

long time, but for 2-3 years a number of companies in the US have been disclosing payments.

Ms Maguire submitted that for the last few years GSK has self-disclosed. While GSK supports moving on individual disclosure and has the data available, there needs to be input from all stakeholders such that three years is a good timeframe.

Mr Shaw submitted that most parties in the room want increased transparency but while Medicines Australia is happy to move forward, there are a number of practical issues (logistics, administration, companies outside Medicines Australia, privacy, validity of reports, disputed data, agreement of doctors, what payments can be disaggregated and what cannot, costs and benefits of the system ($184 million to run the Sunshine Act), threshold of when it kicks in (e.g. $10), and competition issues between member and non-member companies). Mr Shaw submitted that a competition issue arises if the cost of the system affects companies to a differing extent.

Commissioner Court asked whether the other parties accept that there are complexities in individual disclosure.

Ms Bennett submitted that we could spend years arguing about how to do this but unless we start doing it, it will never happen.

Dr Harvey noted the arguments about complexity but submitted that these could be sorted out in a year's time. Dr Harvey submitted that members could change their contracts with doctors to enable individual disclosure as of next year. Dr Harvey noted that the only way to include non-members is a uniform and mandatory code of conduct.

Other concerns

Ms Bennett submitted that while the penalties under the Code are a little higher than other industries they are much lower than other countries, and do not disincentivise repeat breaches. Ms Bennett considers that product familiarisation programs (PFPs) have lead to adverse events that could be dealt with in the Code by requiring that adverse events be reported and that members interact with the Department of Health and Ageing to enable early detection of problems. Ms Bennet also asked that the ACCC not allow pack inserts for PFPs because they act as adverts for the PFP and may be a distraction from more legitimate information in the pack. Ms Bennett also suggested requiring compliance with an identified industry code to ensure products are promoted ethically.

Ms Monk clarified that adverse event reporting is an obligation of registering a product with the TGA and that the Code requires that PFPs and pack inserts should not be promotional.

Ms Bennet submitted the act of inserting pack inserts is promotional in itself, and distracting.

Mr Arnold submitted that a substantial penalty in itself is not going to shape decision making, but it signals to the broader community that something has been done wrong. Mr Arnold considered that more meaningful penalties are required to send the right signal.

Dr Harvey submitted that it is hard work for a health practitioner to make a complaint to Medicines Australia, including appearing in person, and not many people would find it worth their while. Dr Harvey considered that the US has a significant number of fines

because of the whistleblower policy. Dr Harvey submitted that the average level of fine in Australia does not seem to send any sort of message.

Ms Maguire submitted that it is the Code of conduct, not the fines, that directs conduct.

Mr Shaw submitted that the data does shows that the number of breaches has fallen, and while fines are part of the process, corrective notices and retraction letters etc are just as important for alerting doctors. Mr Shaw submitted that there is quite an extensive process for Medicines Australia to help individuals to make complaints.

Ms Monk outlined the process for an individual to make a complaint, including extensive assistance provided by Medicines Australia staff such as the offer of an independent facilitator at Medicines Australia's expense regardless of the quality of the application.

Commissioner Court invited any comments on any other issue, including the point raised about Australia being a market leader in this area in the past.

Mr Shaw agreed to provide a list of the issues that need to be resolved prior to implementing individual disclosure and the reason that it will take time.

Mr Shaw submitted that we have the opportunity to be the leader in this area but that overseas countries have jumped into it before it has been fully thought through, while Medicines Australia has the opportunity to do it properly.

Ms Lynch asked that the ACCC reject the proposal to prohibit brand name reminders because of the commercial interactions of generic medicines in pharmacies and the reduction in competition and lack of public benefit as a result of this proposal.
Ms Lynch also clarified why GMiA members are covered by the provisions of the Code that deal with advertising.

Mr Shaw submitted that Medicines Australia thinks that community expectations have changed and its members consider that brand name reminders are not so critical any more. Mr Shaw submits that Medicines Australia would like a level playing field in that space.

Commissioner Court confirmed that no party wished to make any further comments. The Chair closed the conference by noting that parties could provide further submissions to the ACCC by Monday 19 November and that the ACCC would provide participants with a record of the conference, which would also be placed on the ACCC's public register.

Conference closed: 1.00pm AEST

Submission by Professor Philip Morris

ACCC Pre-determination Meeting Monday 12 November 2012

Submission by Prof Philip Morris

Dear Meeting Chair Commissioner Court,

I would like to thank the ACCC for the opportunity of having my submission read out to participants at the start of the meeting since I am not able to be at the meeting in person.

I requested this meeting because I believe the ACCC is making a mistake in authorizing the Medicines Australia Code of Conduct for three years.

In 2009 the ACCC in its final determination noted the following:

Sponsorship of healthcare professionals to attend educational events

5.43. At the conference, Professor Philip Morris submitted that sponsorship carries greater influence on the behaviour of healthcare professionals compared to the receipt of various brand name reminders, and considers that public disclosure of sponsorships provided by pharmaceutical companies to healthcare professionals should form part of the Code. Professor Morris submits that sponsorship is usually targeted at opinion leaders and is generally extensive, including overseas travel and accommodation.

5.44. Dr Harvey and Dr Vitry submit that the pharmaceutical industry is going through unprecedented change in terms of an acceptance of the need for transparency.

5.45. Professor Morris submits that public disclosure of the names of the recipients of sponsorship would increase transparency, and that the medical profession should be made aware of any monetary ties a speaker has with a pharmaceutical company and the value of these ties.

5.49. The ACCC accepts there is likely to be merit in providing greater transparency around the sponsorship provided to healthcare professionals by pharmaceutical companies to attend educational events. However more work is needed to be done to address the issues such as privacy and the effects of greater transparency on a range of stakeholders.

5.50. The ACCC encourages industry and Medicines Australia to consider these issues with respect to the disclosure and transparency of such sponsorship.

Despite this recommendation by the ACCC Medicines Australia has done little on responding to this request and proposed no changes to its Code on the matter of individual disclosure and transparency. Medicines Australia has offered to set up a transparency working group which will report by the end of 2013. There is no commitment to present a change to the Code at that time and there is no commitment that any proposal will be incorporated into the Code before the three-year period of ACCC authorization has expired.

This arrangement will mean that the implementation of adequate individual transparency concerning gifts (cash payments, honorariums, and sponsorship in-kind support) from pharmaceutical companies to health practitioners will be delayed for three years. This is completely unsatisfactory given the importance of transparency around gifts for the maintenance of public confidence in the health professions and the pharmaceutical industry.

I note in the ACCC draft determination the ACCC proposes to restrict the authorization period to three years despite Medicines Australia requesting a five-year period. The ACCC reduced the period to three years so that Medicines Australia could finish work on transparency issues and make any necessary changes to the Code.

If the ACCC is serious in its desire to expedite the inclusion of appropriate transparency arrangements in the Code and if Medicines Australia is committed to do the same, then the requisite work of the transparency working group and a recommendation about changing the Code could be completed and submitted to the ACCC for re-authorization by the end of 2013. This would mean that a revised Code of Conduct incorporating rules regarding individual disclosure and transparency could be in place by the start of 2014.

The importance of individual disclosure and transparency of payments and gifts from the pharmaceutical industry to health practitioners cannot be overemphasized. Cash payments and honoraria are paid to health practitioners for participation in pharmaceutical company advisory boards and meetings, and as speaker's fees. Sponsorship in-kind support is given to health practitioners to attend national and international professional meetings.

In my opinion these gifts are not given to any health practitioner – they are reserved for key opinion leaders (health practitioners who by their standing are likely to influence the practice of medicine and prescription of drugs) and to health practitioners who have experience prescribing large amounts of companies' medications.

These payments can amount to substantial amounts of money (especially in the case of overseas business class travel, five star accommodations, and registration fees to expensive international conferences with associated pre-meeting and post-meeting gatherings, to far away and expensive destinations – up to $20,000 per gift) on any one occasion and some health practitioners receive multiple gifts of this nature per year. Indeed some health practitioners can get to rely on one or two overseas trips per year being sponsored by pharmaceutical companies.

In this setting it is not surprising that conflicts of interest arise. This is especially the case when the amounts involved in the gifts are large and when the health practitioner might hope a similar gift might be offered in the future.

Conflict of interest temptations can be in the form of errors of commission or errors of omission. Errors of commission involve promoting pharmaceutical products of the company providing the payments or sponsorship in-kind support. Errors of omission involve minimizing or overlooking adverse qualities of pharmaceutical products of the company providing the payments or sponsorship in-kind. I have encountered conflict of interest challenges in both directions.

The problem with the current arrangements in the Code of Conduct is that these conflict of interest issues and the way individual health practitioners deal with them are hidden from the health professions and from the public.

There needs to be a transparent and accountable way that gifts from the pharmaceutical industry to individual health practitioners is monitored so that professional practice and advice to the professions and the public is seen to be independent of inappropriate influence. Ultimately this will involve an individual register of payments and sponsorship in-kind to health professionals being made available to professional organizations, government and to the public.

Health professionals who accept gifts from pharmaceutical companies do this on a free-will basis. There is no compulsion to accept these gifts and there is no professional requirement to accept company payments, honoraria or sponsorship in-kind. Therefore, health professionals who know that these payments will be made transparent and who are not comfortable with this will be free to decline the gifts. While legitimate privacy issues need to be addressed, the greater good is achieved by public disclosure of these payments that are at present hidden.

The health professions and the public are aware that pharmaceutical companies provide gifts to health professionals. At the moment these gifts to individual health professionals are hidden. This concealment raises the risk of bringing the health professions into disrepute. The transparent disclosure of gifts as requested by the ACCC will work to enhance the standing of the health professions and the pharmaceutical industry.

In summary, I would like to ask the ACCC to make the following changes to its draft determination.

1. Reduce the period of authorization of the Code of Conduct to one year (2013).

2. Request Medicines Australia to submit a revised Code to include arrangements covering transparency of relationships between the pharmaceutical industry and individual health professionals for authorization at the end of 2013.

3. Request Medicines Australia increases the number of informed critics of their current Code regarding transparency matters on the transparency working group. I would be pleased to assist Medicines Australia in this capacity.

Dr Ken Harvey will be able to expand on these points in my absence.

Thank you.

Prof Philip Morris.