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From Fiona Crosbie / Emma Marsh

To **Scott Gregson**, Australian Competition and Consumer Commission

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~~Confidential Email~~ HM

Dear Mr Gregson

Medicines Australia

Applications for revocation and substitution

Thank you for your letter of 7 June and for meeting with Emma Marsh and representatives of Medicines Australia (***MA***) on 14 June. As foreshadowed, we set out below MA's comments in relation to the Commission's proposal to amend the wording of proposed condition C1 to require MA member companies to provide the Monitoring Committee with a greater level of information on the educational events they have sponsored, and to require the Committee to publish this information in its annual report.

1. Executive summary

MA is willing to accept the imposition of condition C1 on the authorisation of Edition 15 of the Code requiring ongoing monitoring of company-sponsored educational meetings and appropriate reporting of the outcomes from this review, as set out in the Commission's draft determination issued on 26 April 2006.

The wording of condition C1 in the draft determination mirrors the final wording of condition C1 imposed in relation to Edition 14 of the Code, except that the length of the reporting period has been reduced from three months to one month.

However, MA members cannot accept the Commission's proposal to amend condition C1 to require more detailed reporting by members and the Monitoring Committee, as set out in your letter of 7 June 2006.

MA is concerned that the Commission's proposal gives rise to issues almost identical to those raised in relation to proposed condition C1 in the Commission's draft determination in respect of Edition 14. This condition was withdrawn and replaced after extensive discussion between MA and the Commission.

MA is concerned that the Commission's proposal to amend condition C1 is flawed. MA is further concerned as to the legal basis on which the Commission seeks to amend condition C1.

Specifically:

- there is no factual basis for the Commission's proposal to amend condition C1. The Monitoring Committee has been conducting annual reviews of company sponsored educational meetings and symposia since 2003. On no occasion has the Monitoring Committee found it necessary to refer an issue to the Code of Conduct Committee as a complaint;
- it impugns the reputation of the medical profession and the character of MA industry executives;
- it creates an anti-competitive effect by requiring the disclosure of commercially sensitive information;
- MA members will be placed at a disadvantage compared with non-members, which may deter some companies from being members of MA. This cuts across the Commission's stated views that self-regulation is to be encouraged, particularly through the use of industry codes;
- it will create an unnecessary and unduly onerous administrative burden on members and MA;
- the information proposed to be published will not deliver any discernible benefit to consumers or healthcare professionals;
- it has the potential to undermine public confidence in the industry and in its products;
- it may dissuade healthcare professionals from attending legitimate and valuable educational events; and
- it may adversely affect competition between venue providers.

2. Background

When MA applied to the Commission in 2003 for authorisation of Edition 14 of the Code of Conduct, the draft determination issued by the Commission included a proposed condition C1 relating to reporting by MA member companies about company sponsored educational meetings. The Commission substantially amended the wording of the condition following extensive correspondence between this firm (on behalf of MA) and the Commission, and discussions at meetings between representatives of this firm, MA and the Commission.

The final condition C1 reflected the expanded activities of the Monitoring Committee which were already being undertaken by MA before the Commission issued its draft

determination in respect of Edition 14 (see section 9 of AAR's letter to Paul Palisi dated 5 August 2003). The aim of this condition was to improve the ability of the Code to regulate properly the provision of benefits to healthcare professionals and to improve transparency by providing public access to the Monitoring Committee's report. The condition required companies to provide certain details for all educational meetings and symposia held or sponsored by that Company during a selected three month period that is not revealed to the companies in advance.

The wording of proposed condition C1 in the Commission's draft determination issued on 26 April 2006 in respect of Edition 15 mirrors the final wording of condition C1 imposed in relation to Edition 14, except that the length of the reporting period has been reduced from three months to one month.

In our letter of 4 May 2006, we included a table setting out MA's proposed method of reporting on the Monitoring Committee's review of company sponsored meetings to comply with the proposed condition. Your letter of 7 June 2006 indicates that the Commission considers that the proposed report content may not provide adequate detail to ensure an appropriate level of transparency and attached a table indicating the type of information which the Commission considers should be reported. We understand from our meeting with you on 14 June 2006 that the Commission intends to amend the wording of proposed condition C1 to require MA member companies to provide the Monitoring Committee with more detailed information on the educational events they have sponsored, and to require the Committee to publish this information in its annual report, along the lines of the information listed in the table attached to your letter of 7 June 2006.

As foreshadowed at our meeting with you, MA members cannot accept such a proposal for the reasons set out in sections 3 and 4 below (which to a large extent repeat the concerns raised with the Commission in 2003 in relation to proposed condition C1 in the Commission's draft determination in respect of Edition 14).

3. MA's submissions

MA submits that the Commission's proposal to amend condition C1 is flawed. MA is further concerned as to the legal basis on which the Commission seeks to amend condition C1.

In determining an application for authorisation, the Commission is required under s90 of the TPA to ensure that any proposed limitations on competition are justified because the potential detriment arising from any lessening of competition is outweighed by the public benefits flowing from the proposed restriction.

The Commission is concerned to ensure transparency surrounding the provision of benefits to healthcare professionals. MA submits that condition C1 contained in the draft determination and MA's proposed method of reporting as set out in our letter of 4 May 2006 already achieves this aim. MA further submits that the proposal to amend condition C1 may in fact have significant anti-competitive effects, resulting in a public detriment, and at the same time will not result in any increase in public benefit. This is discussed in further detail in section 4 below.

We are instructed that there is no overseas precedent of a competition regulator imposing such a condition. Further, we know of no other industry in Australia which is subjected to any comparable disclosure regime. MA seeks clarification of the legal basis on which the Commission seeks to justify its attempt to regulate the industry in this way.

We set out in section 4 below a number of specific problems identified by member companies of MA in relation to the proposal to amend condition C1 which further support MA's submissions above.

4. Implications of the proposal to amend condition C1

(a) No issues have required referral to Code of Conduct Committee as a result of Monitoring Committee's annual reviews

The Monitoring Committee has been conducting annual reviews of company sponsored educational meetings and symposia since 2003. On no occasion has the Monitoring Committee found it necessary to refer an issue to the Code of Conduct Committee as a complaint.

Two things follow from this:

- There is no factual basis for the Commission's proposal to amend condition C1;
- The statement in paragraph 6.89 of the Commission's draft determination is incorrect:

> However, the reports do not provide some of the details that the Commission requested be included, such as the number of meetings that raised concerns, nor what aspects of the meetings were of concern.

MA would be grateful if this statement could be corrected in the Commission's final determination.

As explained in the Monitoring Committee's reports, copies of which were attached to our letter of 15 March 2006, no invitations to meetings have ever raised concerns such that an issue was required to be referred to the Code of Conduct Committee as a complaint. Whilst the Monitoring Committee has brought certain issues to the attention of members, through minutes of meetings, Code newsletters, in the Code Guidelines and in the Code of Conduct Annual Report, these have been to provide members with best practice recommendations to further improve the content of invitations to company sponsored events, such as to ensure full details of the educational content and duration are provided in advance to participants.

(b) Impugning the reputation of the medical profession and the character of MA industry executives

The proposal to amend condition C1 would also seem to be based on an unwarranted and unjustified presumption by the Commission that the prescribing habits of doctors are influenced inappropriately by pharmaceutical companies, and that normal and legitimate business activities within the pharmaceutical industry should be regulated. Not only does this impugn the reputation of the medical profession as a whole, but it ignores the doctors' primary obligations towards their patients (as reiterated in the Australian Medical

Association's own Code). It is also, by implication, an apparently baseless denigration of the character of MA industry executives.

Further, the Commission seems to have assumed that the provision of benefits to health care professionals is otherwise unregulated by legislation or common law. We disagree with this assumption, given the extent to which the provision of benefits is already regulated by various State legislation specifically prohibiting inappropriate payments to the medical profession as well as other legislation dealing with bribery and secret commissions (this conduct is also specifically prohibited by the Code). There is also the risk of product liability claims either by way of cross-claim by a doctor or a direct claim by a consumer if a consumer can establish that a pharmaceutical company induced a doctor to prescribe a medicine inappropriately. While such a claim may be unlikely, in the current climate doctors are extremely cautious about exposing themselves to any increased liability risk.

(c) Anti-competitive effect

Ironically, the Commission's proposal to amend condition C1 would result in competitors being required to disclose commercially confidential information. This would include providing detailed information in relation to their marketing strategies (what meetings are being held, when and where, and their cost), albeit after an event has concluded. It would also include providing information regarding the nature and scale of investment by MA member companies (as opposed to non-member companies) in medical community education programs (particularly as investment in these programs has implications for investment in other areas of industry-medical community interaction).

This would stymie legitimate competition by enabling competitors to imitate the initiatives of others in the industry, as well as providing an inappropriate commercial advantage to new entrants and particularly companies that are not members of MA that are only bound by the Code to the extent of the requirements set out in the marketing approval granted to them by the TGA. It is worthwhile noting that the Commission has not proposed that condition C1 would apply to non-members, presumably in recognition that it is not practical for this to be encompassed by the TGA's marketing approval requirements.

Further, MA members will be placed at a disadvantage because the activities of companies that are not MA members will not be reported at all. Non-members' conduct will go unnoticed, or it will be assumed incorrectly that these companies are not providing educational events for health professionals.

The publication of such detailed information about company activities may even deter some companies from being members of MA, which would significantly undermine the purpose and benefits afforded by the Code. Clearly, this is not in the interests of the pharmaceutical industry as a whole, particularly in circumstances where industry support for the Code, as well as the support of relevant stakeholders such as the TGA, the Department of Health and Ageing, the Australian Medical Association, the Australian Pharmaceutical Advisory Council, the Pharmaceutical Health and Rational Use of Medicines Committee and the Consumers' Health Forum, is very high.

Ultimately, the disclosure of the details proposed by the Commission could all lead to the standardisation of benefits. This reduction in legitimate competitive activity could result in

an overall decrease in the educational benefits provided to medical professionals and a corresponding decrease in the public benefit flowing from the better education of health professionals, which we assume is not something the Commission would wish to encourage.

Further, the public reporting of this level of information could lead to a different standard of benefits and hospitality being offered to the same cohort of health care professionals by different sectors of the pharmaceutical industry: the over-the-counter medicines, complementary medicines and medical devices sectors would be free of the constraints affecting the prescription medicines sector.

(d) Administrative Burden

In 2005, the Monitoring Committee reviewed almost 2100 invitations to educational meetings and symposia held during a three month period. One company supplied information in relation to 431 different events held during that period. MA appreciates that the Commission proposes to reduce the period of the review to one month, but this still means the Monitoring Committee is likely to review some 700 educational events and symposia.

MA submits that it would be unduly onerous for each member company to report to MA on each individual event sponsored by that company in a one month period each year in the increased level of detail now proposed by the Commission. The proposed level of reporting detail is, MA submits, unnecessary given that much of this information is obvious from the hard copy invitations supplied to the Monitoring Committee by each company.

Your comments at our meeting on 14 June indicated that the Commission has no reason to believe that the Monitoring Committee is not adequately performing its role. However, requiring the Monitoring Committee to include more detail in its annual report is contrary to your comments.

MA reiterates that membership of the monitoring Committee is largely independent of MA, as follows:

Permanent members	• Chairman – consultant with industry experience in marketing and knowledge of the Code (selected from a panel of three)
	• One representative from each of the RACGP and the AMA
	• A consumer representative nominated by the Consumers' Health Forum
Rotating members	• One representative from the college and/or society from the therapeutic class being reviewed
	• One MA member company Medical Director and one MA member company Marketing Director, neither of which have a conflict of interest in the therapeutic class under review
Advisors	• MA Code Secretary

- MA officer responsible for scientific and technical affairs

The proposed requirement for companies to supply the total cost of hospitality for every meeting covered by the Condition will not necessarily provide a true indication of the intended budget and/or outcome of the meeting.

For example, it is not unusual for companies to offer accommodation to participants in a two or more day meeting for those who wish to take advantage of it, whilst others may prefer to attend on a daily basis when the event is held in their home town or city. This makes a per head calculation difficult to interpret.

In relation to meetings generally (whether or not accommodation is offered), it is possible that many fewer than those who accept an invitation actually attend. This could skew the report, depending on whether the total cost is calculated based on the actual number of attendees or the anticipated number of attendees.

The proposed requirement to supply the total cost of the function will be distorted in a similar way to the cost of hospitality by the need to take into account those accepting an invitation compared to those who actually attend.

(e) No discernible benefit to consumers or healthcare professionals

While we understand that the Commission is seeking to ensure greater transparency in relation to provision of benefits to healthcare professionals, the Commission's role is not to regulate the level of transparency regarding educational functions sponsored by pharmaceutical companies *per se*. Clearly any information that is required to be provided must do so in a meaningful way so that it meets the test of delivering a discernable public benefit in the context of counter-balancing any possible public detriment arising from anti-competitive activities.

Unfortunately, the imposition of an amended condition C1 will result in the publication of what is largely irrelevant information to consumers. Because of the prohibition on advertising prescription medicines to the general public, few people are aware of the supplier of their medicines and so are unlikely to make the connection in order to assess whether provision of an educational event and associated hospitality by a particular company will have potentially had an influence on their medical treatment. Also, given that doctors are not to be individually named (and MA is not suggesting that they should be), it is impossible to measure any potential conflict of interest in any event. Further, if the detailed information proposed by the Commission were published, it would likely run into more than a hundred pages of text as, based on the previous reviews, some 700 events would be reported upon individually.

Healthcare professionals and their governing bodies such as the AMA and the RACGP must and, MA submits, do, take responsibility for deciding which benefits offered by pharmaceutical companies should be accepted by prescribers without giving rise to potential conflicts of interest which have the capacity to compromise the treatment decisions made by the health care professional. In particular we refer to the AMA's Code of Ethics and the AMA Position Statement Regarding Doctors' Relationships with the Pharmaceutical Industry. Ultimately, the final judgement as to whether the benefit is

appropriate must be made by the recipients of the benefits themselves, who have a duty of care to consider best patient outcomes.

MA also questions the value of certain elements proposed to be included in the summary of events sponsored by member companies. For example, under "Type of function" the Commission has proposed descriptors such as "meeting", "presentation", "conference/symposium" and "CPE session". However, several of these descriptors may be used to describe a single event – a conference usually involves a number of presentations and may have been awarded professional CPE points by a medical college. Notwithstanding the difficulty in using an appropriate descriptor for a particular event, we question what value this information would have to a member of the general public and how it would assist in determining the public benefit of the activity. MA submits that while there is educational value provided in these events, such descriptors are inadequate to convey this. Similarly, the descriptors "guest speaker", "panel discussion" and "new product presentation" under the heading "Nature of function" can be severally applied to a single event, and do not provide meaningful information to consumers.

(f) Potential to undermine public confidence

The potential for misinterpretation or misuse of the information proposed to be supplied pursuant to amended condition C1 by elements of the media or consumer groups is very real and could cause patients to question the value of their medicines, ultimately discouraging them from filling a prescription or from taking their medicines altogether.

It is very difficult to convey the content, scope or value of education and information provided at an event, yet it is easy to apply a value judgment to the use of a particular venue or the amount spent by companies individually or collectively in providing education to healthcare professionals.

The proposed identification of individual companies and level of detail proposed to be provided about the educational meetings they sponsor is likely to be misinterpreted by members of the public, the media and others. MA submits that members of the public and the media would compare the activities of different companies without taking into account the overall size of a company, the number of products it markets, the number of representatives employed etc. This may result in unjustified adverse publicity and damage to company reputation. Without providing a significant amount of relevant background information on the educational value of each event, which would be difficult and impractical, the proposed publication of certain details concerning hospitality will encourage a biased perception of company activities and will not assist in achieving the transparency desired by the Commission.

The level of detail that the Commission proposes companies should provide will expose both healthcare professionals and pharmaceutical companies to public criticism by those who lack understanding as to the genuine educational benefits of the meetings. This is not in the public interest.

MA wishes to draw the Commission's attention to the significant negative media coverage that arose following release of the draft determination through misunderstanding and misinterpretation of the authorisation process and the role and mandate of the Commission. Annexure A provides a number of examples of media articles published in

May 2006. These articles reveal the tendency of the media to misinterpret a simple statement of fact by the Chairman resulting in an untrue picture of both the industry and the medical profession.

(g) Potential to dissuade healthcare professionals from attending educational meetings

The disclosure of the specifics of educational meetings as proposed by the Commission may also have the counter-productive effect of deterring doctors from attending legitimate and valuable educational events.

We have commented above that the media has a tendency to paint untrue pictures of the industry. Because the month in which the Monitoring Committee will review educational events will not be known in advance, it will be incumbent on companies to disclose to attendees in advance of every meeting that the company may be required to disclose the specific details of the proposed meeting to the Monitoring Committee and ultimately in the public domain. This could have the effect of deterring doctors from attending relevant meetings or conferences and so deprive them of an important source of education and information, as well as depriving the medical profession of genuine opportunities for networking and gaining vital professional accreditation points. Ultimately, this could lead to a less informed healthcare profession.

In some medical fields where there is a small number of practising specialists it would be relatively easy to deduce that a particular doctor attended a meeting (for example, through location of the venue and knowing that a doctor in that medical specialty practised in the location). For the reasons described above, this too might deter doctors from attending valuable educational events.

(h) Potential impact on venue providers

MA has often been criticised by venue providers since the introduction of Edition 14 of the Code for "banning" or "black balling" certain venues for educational meetings and symposia. Whilst this is incorrect (MA puts the onus on each company to justify its selection of a venue as complying with the Code) the publication of a list of venues that have been used without raising a complaint, as proposed by the Commission, may be interpreted as a "positive" list.

Further, the publication of the cost of holding an event at a particular location might have perverse effects in the market, such as the exertion of pressure to select one venue over another solely on the basis of cost rather than its suitability as a location to provide education. Increased transparency in relation to costs charged by venue providers could also adversely affect competition between them.

5. Conclusion

MA confirms that is willing to accept the imposition of condition C1 on the authorisation of the Code requiring ongoing monitoring of company-sponsored educational meetings and appropriate reporting of the outcomes from this review as set out in the draft determination. We trust that, in the light of the submissions made above, the Commission will now recognise that its proposal to amend condition C1 is flawed.

We look forward to meeting with you again to discuss this issue.

Yours sincerely

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Annexure A

Extracts of media articles following the release of the draft Determination

Drug firms accused over doctor 'perks'

EXCLUSIVE · Crackdown proposed on gifts, inducements

DRUG companies are facing tougher scrutiny of their relations with doctors, after accusations that they are offering improper inducements and using doctors to promote expensive, but unproven cancer treatments.

Australia's competition regulator Graeme Samuel has proposed tougher regulations to clamp down on drug companies that offer perks and gifts to doctors as an inducement to prescribe their medicines.

But in a damning finding, Mr Samuel said he was virtually powerless to change a system that was failing to stop the pharmaceutical giants improperly promoting their products.

The Age, Page 1, Tue 2 May 2006

`Schmoozing' drug firms go too far

PHARMACEUTICAL firms face a renewed crackdown on the wining and dining of doctors who prescribe their drugs, amid evidence they are flouting industry guidelines on schmoozing.

Breaches of a voluntary code of conduct by drug manufacturers, designed to rid the industry of perceptions that doctors can be bribed to prescribe certain drugs, have included paying for meals at top restaurants and chartering ``luxury'' cruise boats for doctors.

The industry's code says any hospitality provided to doctors should be ``simple and modest''.

But the Australian Competition and Consumer Commission has called for tighter monitoring of the rules amid concerns that they are being ignored.

The Australian, Page 5, Tue 2 May 2006

Consumers' Association Calls For Regulation of Drug Advertising

The Federal Government must act now to protect consumers following the ACCC's admission that it is virtually powerless to change relationships between drug companies and doctors, says the Australian Consumers' Association.

ACA Media Release, 2 May 2006

Relationships with drug companies must be surgically clean

Watchdog must have the power to ensure ethical relations between doctors and **drug companies**.

. . .

However, a damning report by Australia's **competition** regulator, Graeme Samuel, has found that **pharmaceutical** giants are finding ways of undermining this code, and in this case the watchdog is virtually powerless to change a system that promotes corporate interests. Mr Samuel has proposed tougher regulations to clamp down on perks and gifts to doctors as an inducement to **prescribe medications**. He has suggested that the regulations be amended to subject **drug companies** to spot checks and to ensure that all benefits offered doctors are listed.

The Age, Page 14, Wed 3 May 2006

Flawed Code stays put

The national consumer watchdog has admitted regulations meant to stop drug companies offering inducements to doctors are largely failing.

Medical Observer, 10 May 2006