Our Reference: 2.1.7.8.1.1

15 August 2014
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Australian Competition & Consumer Commission
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Dear Ms Macrae,

Re: A91436-A91440 – Medicines Australia Limited - submission

Introduction

The Australian Society of Anaesthetists (ASA) appreciates the opportunity to provide a submission in regard to the Medicines Australia's *Code of Conduct Edition 18* (the Code), which is a voluntary industry code of conduct for the prescription medicines industry in Australia. The ASA is the peak body representing the professional interests of Australian anaesthetists. The ASA's vision is to support, represent and educate our members to enable the provision of the safest anaesthesia to the community.

This approach the Code has adopted is more in line with Holland's 2012 Code of Conduct for the Disclosure of Financial Relationships and the European Federation of Pharmaceutical Industries and Association Code of 2013 where participation in transparency is voluntary. However the Code is by no means comparable to the US Open Payments (the Physician Payments Sunshine Act) or similar regimes in France, Portugal and Turkey which support government regulation and mandated full public disclosure.

Medicines Australia's application for the reauthorization of its Code is supported in principle. The ASA acknowledges the improvements made for transparency around payments to individual health care professionals from 2012 when Edition 17 limited its authorization to two years to the current duration of five years. However the ASA would like to draw the ACCC's attention to a couple of points of interest. Namely issues revolving around ***transparency*** and ***privacy***.

Transparency - Section 41

The ASA supports the enhanced transparency powers provided under Section 41 of the Code entitled 'Transparency Reporting.' This new regime for the reportage of transferals between a pharmaceutical

company and an Australian medical specialist may lend itself towards improving public confidence in our healthcare system.

However the quantum of its impact cannot be measure prematurely and prior to the new regime's commencement date of 1 October 2015 and with its additional 5 year authorization period. The ASA agrees with the statement that "transparency is a cornerstone in fostering trust between government, industry, healthcare professionals and patients."[1] But transparency should not come at a cost of the fundamental tenements expressed in our new privacy laws.

Privacy & Informed Consent

Section 41.3.2 stipulates that any company which intends to show a commercial relationship between a pharmaceutical company and an Australian medical specialist should also seek informed consent from the medical specialist in question. Compliance to the Australian Privacy legislation under the *Privacy Act 1988 (Cth)* should be as accountable to patients as they are to practitioners.

With the recent Federal Privacy Laws being amended and the provisions of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* commencing on 12 March 2014, the 13 APPs concerning health care should be read holistically. The definition of personal information covers an identified individual or from which the identity of an individual may reasonably be ascertained.

Paid Consultants & Commercial Influence

Healthcare professional consultants are included under Section 41.3.1 in the reportable transfers as they relate to preparing for promotions or training. However there is an absence when concerned with paid consultants in the area of research and development with work inclusive of clinical trials. Such professionals exist on advisory boards and may contribute in leading and influencing discussion with the outcome of certain research.

Transparency in this realm would assist greatly to determine whether or not such decisions made and opinions provided are not solely influenced by any contract for any specific commercial gain. However in order to remain consistent with the new privacy laws, information on payment to healthcare professionals will hit an impasses when disclosure on payments cannot be given without explicit and expressed consent from the healthcare professional.

Regulation & Additional Red Tape

The other clear alternative is a regulatory regime that may involve the Regulatory Policy and Governance Division of the Department of Health and the Therapeutic Goods Administration for the ACCC to defer to. However this would also involve potentially more red tape and more cost to the tax paying public at large. This is clearly inconsistent with the current policy view of our existing Coalition government.

Clash: Privacy Laws vs *Competition and Consumer Act 2010*

Medicines Australia can be classified as an industry association with its opt-in authorization regime. This leads to the suggestion that such a regime has been created to minimize any risk of legal action under the *Trade Practices Act 1974* now the *Competition and Consumer Act 2010* that could be deemed as anti-competitive conduct in the eyes of the ACCC.

[1] p.72 of the Code

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However there is a potential clash in the law between the new principles espoused under the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* and the *Competition and Consumer Act 2010*. The sections in the later act may conflict with transparency and privacy issues, in particular s45 (Contracts, arrangements or understandings that restrict dealings or affect competition), s46 (Misuse of market power) and s47 (Exclusive dealing).

While the ASA accepts in principle the need for transparency it also recognizes the base impact of codes which may inadvertently be deemed as anti-competitive because it alludes to an agreement between different parties to behave in a certain way. This potential legal rubric and policy paradox causes us some concern.

Conclusion

The ASA recognises some common criticism of this Code. Namely that there is a lack of assurance for full public disclosure due to the option provided from health professionals to essentially opt-out. And that there is no easily searchable and centralised database website for the consolidating of information outside of pursuing each Medicines Australia member company's website individually.

Perhaps the lack of disclosure works in favour with the continual existence of Medicines Australia to maintain their membership since there are therapeutic goods and generic companies who do not fall under any self-regulatory regime. But there is a problem with consistency under the pervading shadow of competition.

Therapeutic goods industry associations like the Generic Medicines Industry Association do not have any transparency provisions in their codes. Other non-members like the Indian generic company Ranbaxy are not bound to this self-regulatory Code. Opting out of the Code authorisation may end up diminishing the ACCC's persuasive powers.

However there has been some improvements. Broadly speaking the Code encourages healthcare professionals to consent to disclosure. It trust professions to self-regulate while allowing doctors to opt out. This option appears to be an attempt to ameliorate the underlining legal tensions which exist between issues of transparency and privacy. And for this reason the ASA supports the Code in principle

Yours sincerely,

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