A91436-A91440 – Medicines Australia Limited – Submission after draft determination by Dr Ken Harvey.

This submission deals with two issues: the draft determination produced by the ACCC on October 17, 2014 and the request by Medicines Australia for interim authorisation dated November 13, 2014.

The draft determination by the ACCC

First of all, I commend the ACCC for providing a detailed analysis of the background to the 18th Edition of Medicines Australia Code, the changes proposed and an excellent summary of submissions received.

The proposed condition of authorisation

The ACCC proposes to impose a condition to ensure that all relevant transfers of value by pharmaceutical member companies to individual healthcare professionals are reported.

I support the imposition of this condition.

As many submissions have pointed out, allowing an opt-out provision for transfers of value (as proposed by Medicines Australia) would mean that those health professionals receiving the most amount of money from industry (whom we want to know about most) will be the least likely to consent to disclosure.

I do not agree with the submission from the AMA recommending that this condition be deferred for twelve months from the date the new Code of Conduct comes into effect. The new transparency reporting requirements outlined in Edition 18 of the Code do not commence until 1 October 2015 allowing plenty of time for "health practitioners to think about and plan for their ongoing relationships with pharmaceutical companies". The additional delay proposed by the AMA is unacceptable.

Imposing a condition relating to hospitality reporting

The 18th Edition of Medicines Australia Code sets a maximum of $120.00 for one meal (including beverages) and eliminates hospitality reporting. Medicines Australia claim that this will ensure that any hospitality is appropriate while reducing the reporting burden for member companies.

I agree with others that $120.00 is too high a threshold for the cost of a meal and beverages and is not in accord with average consumer expectations. However, I also have sympathy with the need to reduce burdensome reporting requirements on Medicines Australia members.

My own view is that hospitality (above a threshold amount) should be added to the transfers of value reported under the new individual reporting regime. A threshold amount of around $50.00 would eliminate the need for reporting GP lunches provided by drug reps (which Australian companies say they have not got the systems in place to track) but should pick up the more substantial hospitality provided at company functions.

Whether to require the drug name to be reported

Cancer Voices Australia have reiterated that relevant drug names should be included in the reporting. They believed that without a link of some kind to a drug name, it will be difficult for a consumer/patient to understand the information or to recognise its potential relevance.

However, key opinion leaders are often hired by companies for their expertise in a general area, for example oncology or rheumatology, and their participation on an industry advisory board or in company sponsored education may involve a broad area of clinical management as distinct from the use of a specific drug.

Having said that, I agree that if a health professional has been involved in advising or educating about a specific drug then that information should be made public.

I***ssues around a centralised database for reporting***

A key principle of Medicines Australia Transparency Working Group was:

"5. Report the monetary transactions and transfers of value by individual, identified healthcare professional and company in a form that is readily accessible and meaningful to the public"

- http://medicinesaustralia.com.au/files/2012/08/20130527-TWG-Principles-for-Transparency.pdf

The ACCC noted that the utility of individual reporting would be greater if consumers (and health professionals) could easily search for transfers of value provided to a particular healthcare professional in the one database (web site) as distinct from the numerous individual company web sites proposed by Medicines Australia.

I agree!

At the very least (failing agreement on a unique common identifier) member companies should send a spreadsheet containing transfers of value to individual health professionals to Medicines Australia for consolidation and publishing on the MA web site.

If this material was sorted by type of health care professional, practitioner surname, given names, principal practice address and company it should be possible to put together the information for most practitioners.

Whether breaches of the Code should be better publicised

Reports by Medicines Australia Code of Conduct Committee are available on their web site:

- http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-reports/

These are invariably picked up by the medical press, see:

- http://www.australianprescriber.com/magazine/36/6/artid/1469
- http://www.australiandoctor.com.au/news/latest-news/drug-company-fined-over-campaign-to-get-patients-t
- http://www.medicalobserver.com.au/news/false-claims-pharma-companies-fined

Consumer groups and the lay press also publicise relevant issues albeit less frequently:

- http://www.choice.com.au/media-and-news/consumer-news/news/medicines-australia-new-code-of-conduct-290714.aspx
- https://www.chf.org.au/pdfs/chf/20140703-MED--Doctors-and-pharma-fail-transparency-test.pdf
- http://www.theage.com.au/national/drug-companies-fined-record-18m-20080725-3l3c.html

My own view is that breaches of the Code could be better publicised in the lay media and I support the ACCC's suggestion that a media release should be issued by Medicines Australia to highlight new reports.

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Whether R&D should be reported, individually or in aggregate

In several submissions Dr Geoff Smith noted, "irrefutable evidence that shows a clear association between pharmaceutical funding for clinical trials and pro-industry results". He believed that industry funding of researchers influencing the direction of their research. In addition, he pointed out that these researchers influenced many others as they were often called upon (and paid) by companies to present their research at medical and scientific meetings. Dr Smith believed that the ACCC should impose a further condition of Medicines Australia Code that would require the reporting of payments and other transfers of value made by the pharmaceutical industry to health professionals for conducting research.

The alternative view is that most research funding is allocated to institutions or departments, not individuals. In addition, researchers who acted as industry key opinion leaders, for example by sitting on for company advisory boards and delivering company sponsored education, would have these transfers of value disclosed under the proposed Code provisions (and the ACCC condition). There is also an increasing thrust for researchers involved in industry sponsored research to declare such conflicts of interest on clinical trial registers and in subsequent publications. There are also strong moves to ensure that all trial results (including negative outcomes) are made publically available on trial registers, see: http://www.who.int/ictrp/results/en/

In light of the above, and given the pragmatic aim of minimising the reporting burden of industry, my own view is that it is appropriate to exclude reporting of research funding from Medicines Australia Code.

The request by Medicines Australia for interim authorisation

Medicines Australia seeks interim authorisation of Edition 18 for a period starting from the date authorisation of Edition 17 expires to 21 days following the ACCC's final Determination on Edition 18.1. This is because the ACCC proposes that it will not make a final Determination in this matter before the authorisation of Edition 17 of the Code expires on 11 January 2015.

Medicines Australia also notes that the new transparency reporting requirements outlined in Edition 18 of the Code do not commence until 1 October 2015 and, as a result, if interim authorisation of Edition 18 of the Code as drafted is granted there will be little difference, if any, to the current position under Edition 17 of the Code in respect of transparency reporting until that time.

I support Medicines Australia request for interim authorisation.

Dr Ken Harvey
Adjunct Associate Professor
School of Public Health and Preventive Medicine
Monash University
www.medreach.com.au
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