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

Summary

On July 2, 2014 Medicines Australia submitted edition 18 of their Code of Conduct to the ACCC for authorisation. Subsequently, the ACCC has called for submissions (by August 1, 2014) on the likely public benefits and effect on competition, or any other public detriment, from the proposed arrangements.

I acknowledge the effort that Medicines Australia has made to consult widely about edition 18 of their Code and the good-will that they, member companies and other parties brought to the consultations.

Regardless, I submit that edition 18 of Medicines Australia Code has failed to deliver the key outcome raised by many interested parties in deliberations about edition 17 of the Code: transparency on individual payments made to healthcare professionals (consistent with developments in the U.S.) which would have maintained community confidence in these transactions.

It has also failed to deliver on key principles agreed to by Medicines Australia Transparency Working Group whose participants included member companies and a diverse range of health professional and consumer groups. These principles include:

- Enabling consumers to make well informed decisions about their healthcare options, taking into account their healthcare providers' involvement with companies;
- Covering all monetary transactions and other transfers of value between a company and an individual healthcare professional;
- Reporting 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;
- Providing access to the information in a single, public repository, that is readily searchable.

While the latest Code encourages healthcare professionals to consent to disclosure it also allows them to opt-out while retaining the financial and related benefits of their interaction with member companies. This is Claytons transparency. It will not allow consumers and others to make informed decisions taking into account healthcare providers' involvement with companies.

The main reason for this failure is Medicines Australia concern about the lack of a level ethical playing field across Therapeutic Goods Industry Associations and also with non-members. This issue was the subject of the government's 2010 "Working Group on Promotion of Therapeutic Products" but whose recommendations have yet to be implemented. As Medicines Australia application to the ACCC notes (5.4(b)):

> "Furthermore, a regime which compelled the members of Medicines Australia to boycott healthcare professionals who choose not to consent to disclosure would serve to exacerbate the uneven playing field that exists between members of Medicines Australia and the generic manufacturer members of the GMiA.
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> This consequence would follow because member companies of Medicines Australia could not deal with such individuals, who may include opinion leaders, while companies which are not members of Medicines Australia, such as the generic manufacturer members of the GMiA would not be required to comply with such requirements.
>
> Although Medicines Australia encourages those companies to join Medicines Australia and therefore be subject to the transparency regime in the Code, it cannot force them to do so.

> Medicines Australia member companies should not be further affected adversely because they choose to lead the way in setting new standards of transparency by introducing a reporting regime that is best in class in Australia."
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> "In Medicines Australia's view, it is important that if a transformation of this magnitude is to be achieved, the model adopted needs to be effective and have the support of stakeholders."

In my view, the "transformation" required will never be achieved by self-regulation alone. There are too many vested interests who support the status quo. As mentioned above, other therapeutic goods industry associations have not adopted transparency provisions in their own Codes and many have also opted out of ACCC Code authorisation (and thus being subjected to ACCC persuasive powers). In addition, there are increasing numbers of non-members of therapeutic goods industry associations (for example, the Indian generic company Ranbaxy Australia) who are not bound by any self-regulatory Code. Furthermore, health professional organisations have also failed to address &/or incorporate transparency provisions in their own Codes.

Medicines Australia argue that disclosing transfers of value from those health professionals who consent (and lumping together the total value of benefits received and the numbers of those who do not) is an incremental improvement (and public benefit) on the previous Code and thus their latest Code should be authorised.

I disagree. I submit it would be to the public detriment to authorise a Code that fails to deliver on the key principles agreed to by Medicines Australia Transparency Working Group, including the key outcome raised by many interested parties in deliberations about edition 17 of the Code: transparency on individual payments made to healthcare professionals (consistent with developments in the U.S.).

Accordingly, it is my view that the ACCC should not provide a fig-leaf of respectability to edition 18 of Medicines Australia Code by authorising the flawed outcome achieved. Rather they should defer authorisation and refer this mess back to where the responsibility lies: the Regulatory Policy & Governance Division of the Department of Health, the TGA and the government, all of whom have failed to address the limitations of self-regulation.

The background to Medicines Australia latest Code of Conduct.

In 2009, the U.S. Institute of Medicine produced a report titled, "Conflict of Interest in Medical Research, Education, and Practice". The report noted that,

> "While collaborations between industry and health professionals are desirable, widespread financial ties bring significant risks of undue influence on professional judgements, potentially jeopardizing the integrity of medical research, education, clinical practice and public trust in medicine.

The report recommended,

> "The U.S. Congress should create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians and other prescribers, biomedical researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities".

The resulting U.S. Open Payments (the Physicians Payment Sunshine Act) set a new benchmark in transparency, mandating full public disclosure of these relationships in the United States with data collection commencing August 2013 and public reporting by September 2014.

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In Australia, the Australian Competition and Consumer Commission (ACCC) raised the issue of disclosing payments to individual healthcare professionals in its consideration of edition 16 of Medicines Australia Code in 2009. This issue was raised again in many submissions to Medicines Australia and the ACCC concerning edition 17 of the Code.

In August 2012, Medicines Australia established a Transparency Working Group to identify measures and policies to further enhance transparency surrounding transfers of value between healthcare professionals and the pharmaceutical industry. Working Group participants were drawn from a broad cross-section of the Australian health sector, including member companies and a diverse range of health professional and consumer groups. The U.S. Physicians Payment Sunshine Act was used as a starting point although it was hoped that a less complex and more pragmatic model could be developed for Australia.

In December 2012, the ACCC limited the authorisation of edition 17 of Medicines Australia Code to two years rather than the five years sought in order to encourage Medicines Australia to improve transparency around payments to individual doctors.

In February 2013 Senator Richard Di Natale introduced the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill into the Senate. The Bill proposed to amend the Therapeutic Goods Act 1989 to create offences related to the provision of payments, services or certain other inducements to medical practitioners by pharmaceutical companies; to provide penalties for making such inducements and reporting requirements. Both the government and the Senate committee that reviewed the Bill supported a self-regulatory approach and noted the ongoing initiatives of Medicines Australia in this regard. The Bill lapsed.

By May 2013 the Working Group had finalised a set of Transparency Principles which it felt were applicable to all therapeutic goods companies. These included:

- Openness to public scrutiny, which will reduce the perception and risk that payments and other transfers of value from a company to a healthcare professional compromise the independence of their decision-making;
- Enabling consumers to make well informed decisions about their healthcare options, taking into account their healthcare providers' involvement with companies;
- Covering all monetary transactions and other transfers of value between a company and an individual healthcare professional;
- Reporting 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;
- Providing access to the information in a single, public repository, that is readily searchable;
- Enabling the information to be reviewed and agreed by healthcare professionals and companies prior to publication.

In June 2013 a Transparency Model Consultation and Discussion Paper was produced which included various implementation options on which the group had failed to reach a consensus. One important example was the levels of payment that needed to recorded and reported. Numerous submissions were received about the options presented to inform the Code of Conduct Review.

A few days after the Consultation and Discussion Paper was released the European Federation of Pharmaceutical Industries and Associations (EFPIA) published a transparency model that all its member associations had agreed to adopt. Unlike the U.S. Open Payments (Sunshine) Act, the EFPIA model excluded small transfers of value (such as food and beverages that cost under $US10.00 and totalled less than $US 100.00 per year). Rather the EFPIA model focused on large transactions of value such as payments for consultancies, conference registration and travel, and advisory board

membership. In addition, members of Medicines Australia stated that their IT systems could not currently track smaller payments such as lunches provided to GPs but they were able to track larger contractual payments included in the EFPIA model.

Concerns also emerged about the impact of Australian Privacy Principles on implementing the recommended transparency principles. Principle 2 states that individuals must have the option of being anonymous or pseudo-anonymous while Principle 9 notes that an organisation may not adopt a government-related identifier as its own identifier**.**

This information was presented to meetings of stakeholders and consumer workshops. At the latter, concern was expressed that the transparency debate was only occurring with Medicines Australia members; not members of other Therapeutic Goods Industry Associations and especially not non-members. This led to a discussion of the merits of regulation compared to self-regulation. It also produced additional submissions to the Code of Conduct Review.

In August 2013 Medicines Australia established a Code Review Panel which, for the first time, included representatives from the consumer and healthcare professional sector. While debate continued over the next 10 months the final version of the revised Code was that agreed solely by members of Medicines Australia.

On July 2, 2014 Medicines Australia submitted the revised Code to the ACCC for authorisation. Medicines Australia CEO Brendan Shaw said, "This new Code sets new standards in the transparency in these interactions which is unprecedented in the Australian health sector". However, consumer advocates and Senator Richard Di Natale were unimpressed.

When compared to the Transparency Principles agreed by all parties, the revised Code has two major problems. First, it provides no assurance that many transfers of value will be made transparent on an individual basis for health professionals. This is because it includes an opt-out clause that allows transfers of value to be hidden from public view. Why would a health professional disclose this information if he/she does not have to? This view appears to be supported by AMA president Associate Professor Brian Owler who was reported as saying, "The code struck the right balance. Its purpose is not to target individual doctors but to keep pharmaceutical companies accountable". However, Senator Richard Di Natale noted, "The voluntary nature of disclosure makes the code next to meaningless. It's like making a breathalyser voluntary for drink drivers".

For example, it would appear that even if doctors signed an industry contract accepting both payment and public disclosure (which Medicines Australia has not suggested that member companies should make mandatory), having used the benefits, doctors could still opt of out disclosure prior to publication when presented with a record of their benefits for checking.

The second major problem relates to the failure by Medicines Australia to implement a single web site for consolidating information about transfers of value from health professionals provided by different companies. Without this, consumers and interested health professionals will have to trawl all the web sites of all Medicines Australia member companies to collate their own list of transfers of value from a single doctor in whom they are interested. Consumer groups were insistent that a single web site that consolidated this information was crucial to ensure transparency. The Australian Health Practitioner Regulation Agency (AHPRA) identifier had been suggested as one way of linking practitioner records of member companies but this was thought to be ruled out by privacy Principle 9.
There are additional reasons why the revised MA Code is so weak:

- Other therapeutic goods industry associations (e.g. GMiA) have not adopted any transparency provisions in their own Code and have also opted out of ACCC Code authorisation (and thus being subjected to ACCC persuasive powers);
- There are increasing numbers of non-members of therapeutic goods industry associations (for example the Indian generic company Ranbaxy Australia) who are not bound by any self-regulatory Code;
- Health professional organisations have also failed to address &/or incorporate transparency provisions in their own Codes.

Given the above, it's not surprising that many members of Medicines Australia were worried that attempting to force full disclosure on health practitioners would them at a competitive disadvantage with other therapeutic goods companies, especially generic companies. As Medicines Australia application to the ACCC notes (5.4(b)):

> "Furthermore, a regime which compelled the members of Medicines Australia to boycott healthcare professionals who choose not to consent to disclosure would serve to exacerbate the uneven playing field that exists between members of Medicines Australia and the generic manufacturer members of the GMiA.
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Regardless, it is clear that the revised MA Code Edition 18 has failed to deliver the key outcome raised by many interested parties in deliberations about edition 17 of the Code: transparency on individual payments made to healthcare professionals (consistent with developments in the U.S.). It has also failed to deliver on a number of key principles agreed to by Medicines Australia Transparency Working Group whose participants included member companies and a diverse range of health professional and consumer groups.

All of which highlights the problems of self-regulation raised in 2010 by the government's "Working Group on Promotion of Therapeutic Products". This working group provided principles for harmonising the disparate therapeutic good industry Codes and also addressed the need for adherence to industry codes by non-members by recommending that an applicant nominate the relevant code of practice to which it will subscribe, as a condition of marketing approval by the Therapeutic Goods Administration (TGA).

The Government's response (in 2013) was merely to set up "A Codes of Conduct Advisory Group" to assist industry to implement the recommendations of "The Working Group on Promotion of Therapeutic Goods". There is only one report of the first meeting of this group currently in the public domain and it is unclear what, if any, progress has been made to address the issues raised above.

Meanwhile, in addition to the USA, countries such as France, Portugal and Turkey have now embraced government regulation of transparency. My own view is that Senator Richard Di Natale's Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill requires revisiting. For example, a revised bill could make transparency (and other ethical considerations) a condition of market authorisation by the TGA.

In conclusion, Medicines Australia argue that disclosing transfers of value from those health professionals who consent (and lumping together the total value of benefits received and the numbers of those who do not) is an incremental improvement (and public benefit) on the previous Code and thus their latest Code should be authorised.

I disagree. I submit that it would be to the public detriment to authorise a Code that fails to deliver on the key principles agreed to by Medicines Australia Transparency Working Group, including the key outcome raised by many interested parties in deliberations about edition 17 of the Code: transparency on individual payments made to healthcare professionals (consistent with developments in the U.S.).

Accordingly, the ACCC should not provide a fig-leaf of respectability by authorising edition 18 of Medicines Australia Code. Rather they should defer authorisation and refer this mess back to where the responsibility lies: the Regulatory Policy & Governance Division of the Department of Health, the TGA and the government, all of whom have failed to address the limitations of self-regulation.

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Dr Harvey has a long-standing interest in the relationship of the Therapeutic Goods industry with health professions. He was a member of the WHO group of experts that wrote, "Ethical Criteria for Medicinal Drug Promotion". He has been a member of the Royal Australasian College of Physicians Ethical Guidelines Working Party. He has represented the Consumers Health Forum on the Department of Health & Ageing's Working Group on Promotion of Therapeutic Products and Medicines Australia's Transparency Working Group and Code Review Panel.