Blanch, Belinda

From: Alastair MacLennan <alastair.maclennan@adelaide.edu.au>
Sent: Monday, 28 July 2014 11:48 AM
To: Adjudication
Subject: Need for Federal control and mandatory centalised disclosure of financial links between health professionals and the therapeutic goods industry

Categories: Submission

Dear ACCC,

Self-regulation by the pharmaceutical and alternative health industries and opt-out clauses allow continuing biased lobbying, and unethical practices.

In 2012, when edition 17 of Medicines Australia Code was released, you limited its authorisation to 2 years, rather than the 5 years sought, to encourage Medicines Australia to improve transparency around payments to individual health care professionals.

This was in accord with international developments such as the US Open Payments (the Physicians Payment Sunshine Act), which mandated full public disclosure of these relationships.

Edition 18 of Medicines Australia Code has now been submitted for authorisation. It "encourages" healthcare professionals to consent to disclosure. However, it also allows them to opt-out of disclosure while retaining the financial and related benefits of their interaction with member companies. This will not allow consumers and others to make informed decisions taking into account healthcare providers' involvement with companies. As 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". See: http://tinyurl.com/mlczolk.

Medicines Australia Code is weak because other therapeutic goods industry associations have not adopted transparency provisions in their own self-regulatory 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, Australian health professional organisations have also failed to address &/or incorporate transparency provisions in their own Code. It's therefore not surprising that many members of Medicines Australia were worried that attempting to force full disclosure would put them at a competitive disadvantage with other therapeutic goods companies, especially generic companies.

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.

The alternative view is 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, I agree with the 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 Australian Department of Health, the Therapeutic Goods Administration (TGA) and the government, all of whom have failed to address the limitations of self-regulation.

A number of counties such as France, Portugal and Turkey have now embraced government regulation of transparency in addition to the USA. I also believe that Australian legislation should also make transparency (and other ethical considerations) a condition of market authorisation by the TGA.

Yours sincerely,

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