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MEDICINES AUSTRALIA CODE 17th EDITION

I am writing in response to invitation by the ACCC for public comment on the application by Medicines Australia Limited for reauthorisation (application for revocation and substitution) of its *Code of Conduct*, Edition 17 (A91316- A91320).

Application of the *Code* has strong public policy implications, including potential adverse impacts on individual patients through inappropriate prescribing by medical practitioners and unwanted consequences for the Australian taxpayer through payments under the national health system.

A rigorous analysis by the Commission of the Code will inhibit continuation of undesirable practice involving general and specialist practitioners, corporate health service groups and providers of pharmaceuticals, medical devices and services (including pathology and radiology services, where there is substantial industry concentration). That analysis consistent with substantive concerns raised by the Commission's overseas peers and by health sector figures such as La Trobe University academic Dr Ken Harvey. It is clear that leading corporations that are expected to participate in the *Code* have engaged in egregious bad practice (signalled for example by the recent multi-billion dollar settlement in the US involving GlaxoSmithKline). It is also clear that individual medical practitioners and health groups, along with some academics, have fostered that bad practice.

The *Code* does not provide a substantive and adequate response to what are fundamental issues involving a range of actors in the health sector. The application for revocation and substitution provides an opportunity for the Commission, in the national interest, to address a significant market failure. In essence, if industry and individuals are to enjoy self-regulation that regulation must be meaningful, with effective enforcement of a *Code* that represents best practice rather than embodying a Potemkin Village approach to industry responsibility.

The history of health sector regulation in Australia and overseas demonstrates that we cannot expect meaningful change – in essence an abandonment of what I recently described as pharmaceutical payola – unless the Code reflects the commercial imperatives of service delivery in Australia and the weakness of professional ethics regimes, evident through the willingness of practitioners to accept (and in some instances demand) benefits that have a tangible financial value and raise legitimate concerns about probity frameworks.

The Commission should thus hold Medicines Australia to account; rather than signing off on a document that pays lip service to real concerns it should require Medicines Australia (and through that organisation, the health sector) to try harder.

Basis

This submission is made on a personal basis and does not necessarily represent the views of the Canberra Law School (University of Canberra) or the University's Health Faculty.

It reflects a background in industry regulation over twenty years and research into health sector regulation, in particular law regarding complementary therapies/diagnostics and law regarding innovation in the health sector.

The following paragraphs do not involve what might reasonably construed as a conflict of interest. The author is not under retainer to or has equity in a pharmaceutical or health services organisation.

Full Disclosure

The proposed 17th edition of the *Code* from Medicines Australia does not require full disclosure of payments to individual practitioners and health service groups. (The latter are significant, given ongoing changes in practice structure, with for example the progrsssive demise of the 'sole practitioner' general practitioner model).

The *Code* does require member companies to identify aggregate benefits provided to practitioners regarding 'events' (speaking and attendance engagements), consultancies and 'professional board' participation. Best practice requires a higher degree of transparency, a disclosure that is potential interest to consumers, regulators within the private sector and entities such as the Australian Taxation Officer that have legitimate public policy concerns about the nature, prevalence and scale of disclosed/undisclosed rewards. There is no compelling reason for Medicines Australia – with the support of the professional Colleges and other stakeholders – not to establish a more granular disclosure. Full disclosure is consistent with overseas developments such as reporting under the 'Physicians Sunshine Act'.

The value of meaningful disclosure, with information not being significantly blurred through reliance on aggregate data, was acknowledged by the Commission in its 2009 determination, with the comment that

> At the pre-decision conference, the issue regarding the lack of transparency around the sponsorship of pharmaceutical companies to healthcare professionals to attend educational events, including international events, was raised. The ACCC encourages Medicines Australia to continue to work with industry to increase transparency around the relationships between pharmaceutical companies and healthcare professionals.

Medines Australia is unlikely to move to best practice unless required to do so. Leading actors such as GlaxoSmithKline, who might be expected to embody a global gold standard in terms of the articulation of policy and day by day implementation of that policy, have clearly failed. There is no reason to belief that Glaxo's misbehaviour is unrepresentative. From a national regulatory perspective if we cannot expect the stars of 'Big Pharma' to behave, how can trust organisations that are much smaller and that in the nutraceuticals market face a more competitive environment. The Commission's stance on the Code sends a message to the overall health sector, rather than just to a handful of pharmaceutical giants.

Suggestions by Medicines Australia that it will address the problem through internal inquiries, notably establishment of a working group, and that data collection costs will be prohibitive should be regarded by the Commission as unpersuasive. They are reminiscent of St Augustine's no doubt very well-meant prayer: give me chastity, o Lord, but not quite yet. If there is no misbehaviour there is no basis for embarrassment. Ffears about a 'witch hunt' appear to be misplaced. Lack of transparency, rather than disclosure, fosters suspicion. The basis for claims that data collection will impose major or disproportionate costs is unclear.

Coverage

The value of the Code is eroded by the Medicines Australia membership structure, which does not encompass all major actors in the sector.

There is agreement among observers that it would be desirable to include substantial entities such as Ranbaxy Australia that are offering substantial inducements but as noted by other observers fall outside the Medicines Australia and Generic Medicines Industry Association codes. It should be of profound concern to the Commission and to other regulators or health sector policymakers that entities have substantial scope for engaging in regulatory arbitrage. The Therapeutic Goods regime has not successfully addressed that arbitrage, a regulatory incapacity that poses concerns for entities in the pharmaceutical and complementary products sector.

Engagement

Given concerns regarding the current co-regulatory regime it is worth revisiting the Commission's 2011 Guidelines for developing effective voluntary industry codes of conduct.

A greater degree of engagement by industry with other stakeholders – in particular consumer associations and other civil society bodies – would enhance the legitimacy of the Code development process and enable industry to better address potential misconceptions. It is disappointing that Medicines Australia appears to be reluctant to fully engage with health sector stakeholders.

Suasion

Regulatory analysts have recurrently expressed concern about the triviality of sanctions that can be – or merely are – imposed by regulators such as the Australian Communications & Media Authority or bodies such as Medicines Australia that operate under co-regulatory regimes. A token financial penalty is not a meaningful deterrent, particularly for entities that do not have a major stake in the industry and indeed may not plan to be active in a few years time. Some entities are clearly unfussed by notions of corporate reputational damage, particularly when small-scale financial penalties signal to the mass media that the offence was insignificant.

In considering the Code I suggest that the Commission explore the scope for meaningful penalties. A US$3 billion settlement grabs attention and shapes behaviour. Token penalties under the current regime do not.

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