Comments regarding the conditions the ACCC proposes to impose on any authorisation of Edition 18 of Medicines Australia Limited's Code of Conduct

I fully support the ACCC's proposal to require Medicines Australia to amend the Code to require (1) the reporting of all transfers of value (2) reporting in an identical, accessible format (3) the implementation of a centralised database (4) enable Medicines Australia to request non-material amendments to the conditions and (5) remove the condition requiring reporting of food and beverages.

I note, however, that the ACCC does not intend that the Code be amended with regard the reporting of payments or other transfers of value to health care professionals for pharmaceutical research. I am not sure whether this was its intention, or whether this was an oversight. In attachment A, 'Reporting of all relevant transfers of value', the proposed amendment reads, "Companies must not make a transfer of value of a kind referred to in section 41.3.1 unless …..". This section of the Code of Conduct Ver. 18, specifically excludes "payments for consultants in relation to research and development work, including the conduct of clinical trials".

In my two previous submissions to the ACCC, I have tried to highlight the critical importance of transparency in relation to payments and other transfers of value to health care professionals for clinical trials. These payments substantially outweigh all other payments and fund activity that forms the basis of evidence-based medicine. There is now indisputable evidence that pharmaceutical funding for research biases the outcomes and that this, in turn, distorts the evidence base.

As an example, a narrative review of melatonin-based therapies for depression by Prof Ian Hickie and A/Prof Naomi Rodgers (The Lancet, Vol. 378 August 13, 2011) was criticised for overstating the efficacy of Agomelatine, a melatonin analogue produced by the pharmaceutical company Servier. Professor Hickie disclosed that he had 'led projects for health professionals and the community supported by drug industry partners [including] Servier' and that he had participated in a 'multicentre clinical trial of Agomelatine' and 'family-practice-based audit of sleep disturbance and major depression, supported by Servier'. A/Prof Rogers disclosed that she had received 'grant support' and 'honoraria for lectures' from Servier.

In their article, they reference 105 articles, about one third of which were studies of Agomelatine. Of those references on Agomelatine, I was able to access 50% of them from the Department of Health's online journals. **All** of the articles accessed had received payments or other transfers of value from Servier.

This raises the whole issue of how we construct the evidence base that underpins evidence-based medicine. Clearly, a meta-analysis of these studies would not eradicate the potential problem of biased results. I would strongly argue that payments and other transfers of value for research should be included in the reporting requirements. This would provide an opportunity for other health care professionals to better understand and judge the evidence base that underpins their practice.

I would also argue that consideration should be given to the retention of records of payments and other transfers of value on a central database for 5 years (rather than the proposed 3). It would have little impact on the cost of maintaining the database but would greatly assist in increasing transparency, particularly in relation to pharmaceutical trials. For example, in the case of Hickie and Rodgers cited above, it would have been far more convenient and informative to have been able to search on a central database for information about payments or transfers of value to the authors of the referenced articles rather than having to go to online journals.

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