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To: Adjudication
Subject: ACCC - Medicines Australia Limited - Revocation and Substitution - A91436 - A91440 - interested party consultation

Categories: Submission

To the ACCC:

In 2012, I signed a petition to the ACCC on the authorisation of edition 17 of Medicines Australia Code of Conduct supporting comprehensive disclosure of payments to health professionals by the pharmaceutical industry, similar to the U.S. Physicians Payment Sunshine Act. I was one of 450 people to sign this petition.

As a result, you limited the authorisation of edition 17 of Medicines Australia Code to 2 years rather than the 5 years sought in order to encourage Medicines Australia to improve transparency around payments to individual health care professionals.

Since this time, another country, France, has also instituted a Sunshine Act requiring companies to disclose all payments by pharmaceutical companies to health professionals, the 'Loi Bertrand'. Like the US Physicians Payment Sunshine Act, the *Loi Bertrand* sets strict rules for disclosure of all transferred sums over a specific minimal monetary value ($10 in the US; 10 euros in France). It ensures posting of all payments within 6 months of receipt and establishes a single searchable database in which the public can easily access information concerning all manufacturers' payments to physicians.

Edition 18 of Medicines Australia Code has now been submitted for authorisation. The provisions introduced for transparency of physician payments fall far short of these two initiatives in three main ways:

1) Physicians have the possibility to opt out of disclosure, as disclosure only occurs following each individual physicians' consent. This requirement makes a mockery of the newly introduced transparency requirements, making them by definition provisional and partial. The public's right to make informed healthcare decisions, with full knowledge of financial links between healthcare professionals and industry, is in essence denied through this provision.

2) Required payments are 'activity based' rather ensuring overall disclosure covering all financial transactions. This allows for an enormous amount of 'wiggle room', as companies can define new relationships and activities that do not necessarily fall within the boundaries of listed categories. A blanket provision, with a minimum sum above which all transactions must be covered, is much easier to implement and avoids the potential problems of judgments concerning activities that may or may not fall under the rubric of consulting versus some other arrangement, for example. It is appropriate to include reporting of the purpose of the financial transaction (e.g. research, consultancies, advisory boards, speaking bureaus, etc.) but the requirement for reporting should not be linked to the activity falling within a specified category of activities.

3. 3) There are no provisions in place for a single searchable database in which all transactions are listed. A patient seeking a new healthcare provider or a consumer group seeking a consultant's advice is unlikely to have the resources to search through each company's website and within each company, each activity based listing. For transparency of financial links to work properly, public information access must be assured. Without the creation of a single searchable database, complexity hinders information access.

In relation to point 3: the Code does include provisions for payments to Health Consumer Organizations by all companies to be made public, and for these payments to be listed on Medicines Australia's website. This is a positive step, especially as it appears to involve a single searchable website. A similar approach is needed for payments to individual health professionals.

The Medicines Australia Code states that it is based on provisions agreed upon by EFPIA (the European Federation of Pharmaceutical Industry Associations). It does not include an explanation of why this weaker model was chosen versus the approach embodied in the national Sunshine Acts listed above.

The argument that disclosure of transfers of value from consenting health professionals, and of the total value of benefits received for those who do not consent, 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. and France).

The ACCC should not authorise the flawed and incomplete outcome achieved in edition 18 of Medicines Australia Code. Rather they should defer authorisation and refer this situation to 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. Australia needs legislation that makes transparency, and other key ethical considerations, a condition of market authorisation by the TGA.

The rationale for a legislative approach, rather than reliance on a code that provides a partial and imperfect solution to the current problem of lack of transparency, is the public health imperative to ensure that health professionals' fiduciary responsibility to their patients takes precedence over any financial links to pharmaceutical manufacturers.

Full transparency of all financing of health professionals by industry is an initial necessary step to make this possible, along with easily accessible public information on financial arrangements. In my opinion, this step is necessary but insufficient, as it does not address the extent of overall financing or the financial links that can distort professional education, disease diagnoses and thresholds for care, guideline development and prescribing practices. Inappropriate industry influence on standards for medical care has negative effects on the quality of care and on patient health, leading to unnecessary medication use, choice of products with poor safety or effectiveness profiles and a harmful degree of polypharmacy in the elderly.

Edition 18 of the Medicines Australia Code highlights the deficiencies of the current self-regulatory model in many ways, not only in relation to transparency. These include for example:

- the lack of a firewall prohibiting sponsoring companies from having any involvement in development of the content and choice of speakers for sponsored 'independent' educational events;
- the lack of explicit provisions forbidding all day-to-day gifts of food to health professionals and office staff;
- the lack of prohibition of provision of 'starter packs' (free samples), as these have been shown to distort prescribing practices;
- the lack of prohibition of company involvement in treatment guideline development, either through direct sponsorship, sponsorship of a third party, or financial links to members of expert panels developing guidelines. All of the latter have been shown to distort guideline development in a way that broadens disease definitions and lowers treatment thresholds;
- the lack of prohibition of one-to-one visits between health professionals and sales representatives either in hospital or in the community (as is the norm for example in Swedish hospitals) ;
- the lack of explicit information standards for the oral as well as the written portion of sales representatives' visits and provisions for active monitoring of visits, to address the problem of lack of information provision on serious harmful effects of promoted medicines (as has been shown in my research and that of colleagues);
- a weak standard to prevent ghostwriting and publication management by companies (IFPMA Code, 2010), which only addresses clinical trial publications and fails to address editorials, review articles, conference presentations, articles for publication in the lay media, information materials produced by professional, consumer and patient groups, and many other types of publications, as well as failing to ensure that the company and/or author who wrote the outline or first draft of an article is prominently listed as an author, rather than being only acknowledged for medical writing assistance;
- vague standards for advisory boards, which do not necessarily ensure that these boards are required for activities related to product development or distribution, but instead allow for advisory boards to be used as a means of

marketing products to physicians, and entering into consulting relationships with a large number of practicing professionals;
- no prohibition of professional involvement in manufacturer ‘speakers’ bureaus’ that contribute to brand-specific marketing activities.

This list is not comprehensive but highlights a few of the deficiencies in Edition 18 of the Code in comparison with information that has become publicly available internationally, both through research on marketing activities and through legal cases. These activities concern the involvement of professionals in pharmaceutical marketing and the involvement of the pharmaceutical industry in the training of professionals and in developing standards for medical care. Both the industry and professionals have a legitimate, important role to play in society, but these roles should not be confused. Professionals have a fiduciary responsibility to their patients; companies to their shareholders. Confusing these roles is detrimental to public health and patient care, however, as it leads to important shifts in health care.

Please feel free to get back in touch with me if you require additional information.

Thank you in advance for your attention to this matter.

With best regards,

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