Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013:
Submission by Dr Mary Osborn

My recommendations are based on my recent PhD thesis (1) and from my contribution to the "Working Group on Promotion of Therapeutic Products" (2).

While the amendments will strengthen the existing Medicines Australia's Code of Conduct (3) they will not encourage the pharmaceutical industry to decrease inducements offered to Australian doctors. Secondly there are no conditions in the amendment that resource evaluation and monitoring of inducements to the Australian medical profession. Without any effort to benchmark these proposed amendments and publish the results the current situation will continue.

Each amendment will be addressed separately as follows:

1. Item 1: This item amends the title of Chapter 5 of the Act to make reference to inducements.

   Item 2: This item inserts several new sections into the Act which define new offences related to the provision of money, services, or other possible inducements to medical practitioners by pharmaceutical companies.

   Proposed subsection 42DR(1) has regard to seminars or conferences that take place overseas and makes it an offence for a pharmaceutical company to arrange or sponsor a conference or educational seminar for Australian doctors that takes place overseas. It does not prohibit companies from hosting events within Australia, or for hosting events overseas that are not aimed primarily at Australian prescribers (doctors), nor does it prohibit Australian doctors from attending events outside Australia. This is intended to curtail the possibility of hosting an educational event in a tropical or otherwise exotic location which may act as an inducement.

   Proposed subsection 42DR(2) is intended to otherwise place limits on overly lavish hospitality. Specifically, subparagraph 42DR(2)(b)(i) specifies that the company may only spend $100 per head on catering and entertainment, but subparagraph (2)(b)(ii) allows for a higher value to be prescribed in regulations, to allow for inflation or adjustments that otherwise fix the value in line with the educational purpose of these events.

Response

In almost every country, mutually dependent relationships exist between health care professionals and the pharmaceutical and medical device industries. Potential sources of influence include the giving of gifts, including medical equipment, provision of drug samples, funding of research, education, staff positions, travel, support for scientific meetings and contact with pharmaceutical representatives. Receipt of industry support can result in actions that are directly supportive of industry and notably, alter prescribing choices.

A survey of physicians and physicians-in-training practising and living in Australia or New Zealand(4) to determine the impact of factors which might influence awareness of the Royal Australasian College of Physicians (RACP) ethical guidelines found that awareness of the ethical guidelines for

ethical interactions with the pharmaceutical industry(5)was high but compliance was low. Most respondents believed that it was unrealistic and inappropriate to prohibit contact between physicians and the pharmaceutical industry. On the other hand most respondents believed that sponsorship of research or education from the pharmaceutical industry should be provided through an independent arm's length committee. Almost two thirds of the respondents did not believe that the marketing of new drugs by the industry assisted them in making prescribing decisions.

The low level of awareness of the ethical guidelines among trainees in this survey is of concern, given data that gifts from industry can affect health care costs and can have a negative impact on physicians' knowledge, attitudes, and behaviours. Brody and Light suggest that the medical profession, through its widespread interaction with the pharmaceutical industry has compromised the integrity of medical science and the ability of patients to trust the advice offered to them (6). This has resulted in an approach to prescribing medicines which does not support Quality Use of Medicines (QUM) principles. Marketing and promotion of medicines can be effective and necessary, but can also adversely affect QUM (7).

Unmanaged potential conflicts of interest that may result from a high level of engagement with the pharmaceutical industry pose risks to the integrity of the medical profession and may erode the trust between patients and the physician (8). It must be acknowledged that physicians and trainees are practising in a highly commercialised environment (9, 10).

Having an understanding of how interactions with the pharmaceutical industry may result in potential conflicts of interest is important, given the evidence that this relationship can distort research, clinical practice and policy. Using sources of independent information to deal with conflicts of interest is a helpful way of understanding the consequences of reciprocity. Disclosure itself will not solve the problem, as the problem is in the first instance due to the acceptance of money or gifts from the pharmaceutical industry, which leads to a conscious or unconscious obligation to reciprocate. This reciprocation may assist the pharmaceutical industry in that the receiver may be more favourable to the industry or at least remain silent or less critical than they otherwise would be about the failings of a company or its products.

2. Proposed section 42DR specifies that certain inducements are prohibited and provides a penalty for making such inducements.

   Proposed section 42DS creates new offences related to unreported inducements provided by pharmaceutical companies to medical professionals.

Response

Relationships with the pharmaceutical industry are a controversial topic on which members of the medical profession have expressed strong views. In view of this, it has been suggested that conflict of interest policies based on self-regulation are unlikely to succeed, as clinician groups are not prone to regulating themselves(11).

An evaluation of USA legislation requiring the pharmaceutical industry to report gifts to providers cited information obtained concluding that disclosure laws were constructive in improving transparency about the physician-industry relationship(11). However, transparency on its own does not necessarily reduce the level of influence or the amount of gifts received by physicians from the

industry. The Institute of Medicine has published a comprehensive set of recommendations on how to deal with conflict of interests mentioned in the amendments (12).

Evidence presented by Stamatakis et al highlight the case for tighter regulation on how the pharmaceutical industry and healthcare professionals interact (13). Some indicative steps towards redefining how promotion of drugs can be achieved through a more objective, patient- population and society- benefit direction free from conflict of interests are being conducted. These include action taken in both United States and Europe, such as the Sunshine Act in the United States that requires drug companies to declare all payments and hospitality or gifts they give to doctors. In Denmark, companies have been required to declare their payments to doctors since 2008, in Scotland, doctors have to declare such transactions themselves, and France is currently preparing such legislation.

Greater transparency in the form of post-marketing pharmacovigilance, with respect to the use of independent sources of evidence-based information for prescribing decisions is required in Australia. Consumer groups in other countries have advocated for change. In Europe the transfer of the European Medicines Agency (EMA) to the Health and Consumer Policy Directorate rather than the Enterprise and Industry Directorate, is seen as an opportunity for more openness. The EMA requirement that all new drug applications provide evidence of benefit in studies that use clinical end points over an adequate length of time and greater transparency about evidence used to make decisions should reduce the risk of conflicts of interest(14). It has also been suggested that the European Commission raise the budget for investigator-driven clinical trials to remove dependence on industry funding. Further suggestions are that it fund independent studies in addition to data produced by drug companies, and explore the clinical potential of drugs with no commercial appeal but of potential public health value (15).

3. Proposed subsection 42DS(1) specifies that a pharmaceutical company cannot pay for a medical practitioner to attend a conference or seminar, including travel or accommodation costs, unless that medical practitioner is a representative of the company sponsoring the event. In the event that a company does provide travel, accommodation or other recompense to a medical practitioner to attend the event on their behalf, that compensation is a reportable payment and must be reported under the requirements of section 42DT.

   Proposed subsections 42DS(2) clarifies what it means for a sponsoring company to make a payment to a registered medical practitioner, including paying for a practitioner to attend an event, paying a fee, paying for research, making a donation or giving a gift.

   Proposed section 42DT outlines the new requirements regarding the reporting of payments to medical practitioners.

   Proposed subsection 42DT(1) specifies that regulated corporations, i.e. pharmaceutical companies as defined in section 42DQ, must prepare an annual report and make it public.

   Proposed subsection 42DT(2) specifies that for each reportable payment, as defined in section 42DQ, the report must detail the amount, recipient, date, and the reasons the payment was made. These reasons might include a description of services rendered in

exchange for the payment. The medical practitioners receiving the payments are to be named individually, as specified in paragraph 42DT(2)(a)(ii).

Proposed subsection 42DT(3) specifies that the report is to be made public on the website of the corporation, no later than 1 month after the end of the financial report and for 5 years thereafter.

Proposed subsection 42DT(4) outlines in detail which payments constitute reportable payments. This includes any fee or honorarium paid to a medical practitioner or his or her employer; providing a service; paying travel or accommodation; providing funds to be used for research; making a donation to charity or giving any gift with a value over $25.

Proposed subsection 42DT(5) provides exceptions to the above for medical practitioners who are employees of the company or otherwise engaged by the company for the majority of their time. The corporation does not have to report the remuneration of employees who are registered medical practitioners, but must do so if those doctors are engaged on an ad hoc or part-time basis.

The reporting requirements in section 42DT to do not apply to payments made to any individual who is not a registered medical practitioner. These provisions are intended, in the public interest, to discourage payments and other incentives that may unduly influence prescribing behaviour, but not to otherwise place restrictions on commerce between drug companies and individuals in the normal course of affairs.

Response

Section 42DS to Section 42DT raise serious questions about whether there is sufficient impetus from government regulatory agencies to enforce existing regulations governing drug promotion or to introduce new solutions. None of these new amendments treat regulation of drug promotion as a public health concern. Unless this changes, the public can expect a continuation of the status quo.

4. Section 42DU specifies the penalty for failure to provide the report as required at 3,000 penalty units.

Response

The Health Action International (HAI)(16) produced a report on funding models for the regulation of promotion of pharmaceutical products. The report suggests that relying solely on fines as a way of funding a regulatory agency is fraught with problems. Weak regulations only encourage industries to engage in deceptive practices without violating the code and incurring any penalties, however, if regulations include inbuilt strategies whereby initial code violations incur financial penalties and then penalties increase if violations continue (17).

5. Item 3

Clause (1) specifies that sections 42DR and 42DS relating to prohibited inducements and unreported inducements apply to acts or omissions beginning on 1 January 2014.

Clause (2) specifies that where an act contravening these sections is alleged to have occurred between two dates, one of which is before 1 January 2014, it shall be considered to have occurred before that date.

Response

Outcomes from Clause 1 and 2 need to monitored and evaluated for effectiveness. Change will not occur until more evaluations are conducted on interventions that demonstrate achievable outcomes such as improving transparency and deterring the pharmaceutical industry from offering gifts of inducement to Australian doctors and for Australian doctors to stop accepting inducements.

Without monitoring and evaluation of their application, these amendment have limited effect and may provide illusory reassurance. If the professional associations are dependent on financial assistance from the pharmaceutical industry they are unable to effectively oversee the independence of their membership. Translating the amendments into actual practice requires awareness, openness, collegiate and formal discussions, education and training. This level of discourse needs to be part of a permanent training program and throughout doctors career as well and in the workplace.

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