

# Australian Greens Dissenting Comments

## Introductory

1.1 The Australian Greens wish to provide dissenting comments to the report by the Senate Standing Committee on Finance and Public Administration into Senator Di Natale's *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013*.

1.2 The integrity of the professional relationships between pharmaceutical companies and medical practitioners is of paramount importance in maintaining the quality of health care in Australia. This Bill intended to safeguard the integrity of those professional relationships through regulation and transparency. This inquiry provided a good opportunity for the community to discuss this important issue. The inquiry attracted a good range of submissions and quality evidence which helped to inform this discussion.

1.3 The question at hand was whether there is a problem of undue influence by pharmaceutical companies over the prescribing habits of medical practitioners. While some of the submissions raised substantive issues with the scope of the Bill, there was a general agreement amongst submitters and witnesses that the problem of undue influence either exists, or that there is a perception in the broader community that such undue influence exists. Industry is aware of this perception and appears to be moving in the direction of transparency to address it. The Australian Greens believe that the clearest and most effective way to address these concerns is through legislation.

1.4 The Greens have considered the substantive issues that were raised throughout the inquiry and accept the need to amend the Bill.

## Applicability to other industries

1.5 While this Bill was premised on the need to preserve the integrity of the professional relationships between pharmaceutical companies and medical practitioners, the inquiry has made clear the fact that the need for transparency within the field of therapeutic goods is broader than just this one industry. Comment submitted by the Department of Health and Ageing points out that the Bill in its current form will exclude other relationships between therapeutic goods companies and health professionals.<sup>1</sup> The Greens accept that the broader community will benefit by the transparency envisaged by this Bill being extended to other therapeutic goods companies such as those that sell medical devices.

1.6 Therapeutic goods are currently covered by eight codes of conduct. Simplifying this situation would be consistent with a decades-long trend towards more efficient and harmonised regulation of industry. The Greens note concerns regarding the potential for overly complex regulation to create an uneven playing field, but feel that this Bill presents an opportunity to overcome the existing patchwork of regulations, and deliver a consistent regulatory environment for therapeutic goods and services in this country.

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1 Department of Health and Ageing, *Submission 24*, p. 7.

## Recommendation 1

**1.7 That the bill be amended to include interactions between health professionals and vendors of other therapeutic goods besides pharmaceuticals.**

### Voluntary Codes

1.8 Both the Australian Government and therapeutic goods industry noted a preference for self-regulation. The inquiry heard that while this decreases the cost to the Australian taxpayer, there are many well-documented problems with self-regulation, including that:<sup>2</sup>

- Multiple codes of conduct, the content of which vary significantly across industry sectors, creating an uneven playing field;
- It is difficult to improve standards due to industry oversight and veto;
- Codes can represent lowest common denominator standards by requiring majority sign off;
- Numerous codes can increase complexity for consumers trying to navigate the regulations when filing a complaint; and
- Voluntary codes don't apply to non-members, greatly reducing their reach and effectiveness.

1.9 The voluntary nature of codes of conduct is a key concern. There is no legal obligation for industry actors to join a trade association and become bound under a code of conduct. Industry actors who have no intention of conducting themselves in a responsible manner simply choose not to submit themselves to an association's code of conduct. The inquiry heard that the Generic Medicines Industry Association of Australia (GMiA) provides an option for non-members to voluntarily sign up to the GMiA code of conduct without joining the association, and that to date, no company had chosen to do so. The inquiry further heard that in 2012, Ranbaxy Australia offered pharmacists \$14,648 worth of free Trovas stock (a generic atorvastatin) and a 90% discount for subsequent orders. This offer appeared to breach the Codes of Conduct of both GMiA and Medicines Australia. A complaint was submitted to GMiA but Ranbaxy declined to participate in an investigation of this complaint as it was not a member of any self-regulated industry association.<sup>3</sup> Such is the nature of voluntary self-regulation that a company facing action under an industry association Code of Conduct could simply leave the association to avoid the sanction.

1.10 Several submissions called for a move to a co-regulation model to strengthen existing industry codes.<sup>4</sup> This co-regulation model would require that each company should agree to abide by an applicable industry self-regulatory code in its entirety as

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2 Dr Ken Harvey, *Submission 4*, p. 3.

3 Dr Ken Harvey, *Submission 4*, p. 4.

4 See for example, Medicines Australia, *Submission 16*, p.3; MTAA and IVDA, *Submission 6*, p. 1; Dr Ken Harvey, *Submission 4*, p. 6.

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part of registering a product on the Australian Register of Therapeutic Goods (ARTG). The Australian Greens note that such a model was also a recommendation of the Government's own Working Group on the Promotion of Therapeutic Products. The Australian Greens further note that the Government chose not to support that recommendation in their response to the 2011 report, but adopted a "wait and see" attitude.<sup>5</sup>

1.11 The Australian Greens note that various submissions to the inquiry were informed by other work currently underway in this field, including the work of the Codes of Conduct Advisory Group established in early 2013. That there are positive developments occurring by other means does not preclude the relevance of this Bill. This Bill will create a broad, consistent and enforceable context in which Codes of Conduct can operate more effectively. Legislation will not supplant industry Codes of Conduct, but will deliver a minimum level of compulsory regulation in this field. The Australian Greens consider a co-regulatory model requiring mandatory industry participation in a Code of Conduct system would be preferable to the current regime, but that legislation targeted to address existing deficiencies in regulation would deliver a better result.

### **Transparency Working Group**

1.12 The Australian Greens note that Medicines Australia have established the Transparency Working Group (TWG), that intends to report in June 2013. We find it encouraging that the TWG contains members (such as Dr Ken Harvey of the School of Public Health at La Trobe University) who made submissions to this inquiry in support of greater transparency in the therapeutic goods industry. While the TWG's recommendations will still be voluntary, they will no doubt contribute to the ongoing discussion around adequate regulation of this sector and will hopefully progress improvements in Codes of Conduct in line with the intentions of this Bill.

### **Training for doctors**

1.13 Evidence presented to this inquiry raised concerns regarding the proposed regulations preventing Doctors from obtaining further professional education. The Australian Greens appreciate the need for legitimate and appropriate educational interaction between healthcare professionals and those who supply the products they prescribe. These interactions ensure Australian healthcare professionals are engaged and informed about medical developments. The Australian Greens also appreciate that many doctors are subsidised to attend sponsored events and that they attend in good faith to engage and information share with peers, ultimately improving health outcomes.

1.14 The inquiry heard evidence that non-transparent inducements such as funded travel and sponsored attendance at conferences can encourage conscious or unconscious reciprocity by the recipients of largesse. This reciprocity can manifest itself in uncritical uptake of newer, expensive and less well-evaluated products; and underutilisation of more cost effective drugs and devices. These relationships have

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5 *TGA Reforms: A blueprint for TGA's future*, 2011, p. 25.

also been shown to distort published medical evidence by influencing how studies are designed and conducted, as well as which studies are published and which are not.

1.15 Evidence suggests that such patronage by commercial entities of medical practitioners has the capacity to skew doctors' ongoing education towards areas where industry chooses to invest and that sponsored education may unduly focus on the newest and most expensive therapies. Given this tension between the need for the ongoing education of doctors and the commercial imperative of sponsored education, the Greens note that it would be better if ongoing education was provided through a neutral agency like the National Prescribing Services (NPS). A non-aligned clearing house of information would allow Australia's medical practitioners to remain up-to-date with developments in their field without the lens of commercial interest distorting their view. This might include the use of cutting-edge medicines but also, for instance, new uses for existing therapies.

1.16 Evidence submitted to the inquiry by GlaxoSmithKline suggests that medical practitioners can struggle to find the time and money to undertake further education and profession development.<sup>6</sup> Given this circumstance and the potential for industry sponsorship to result in skewed medical application, it would make sense to provide practitioners with assistance from a neutral party like the NPS rather than leaving such facilitation to industry.

### **Online publication in central place**

1.17 Evidence was presented regarding the publication of transparency reports which raised concerns regarding the Bill's provisions for reporting on the websites of industry entities. It was pointed out that transparency reporting on numerous commercial websites would be difficult for consumers to access effectively and that the information would be more easily accessed via a single, public repository. The Australian Greens note that Medicines Australia's Transparency Working Group also supports such a centralised portal, enabling the information to be audited and validated by healthcare professionals and companies, and supported by an educational process to assist all parties to interpret the information in context.<sup>7</sup> The Australian Greens agree that such a central repository of information would be superior to the reporting provisions originally proposed, and that the Bill should be amended to reflect that improvement.

### **Recommendation 2**

**1.18 That the bill be amended so that reporting requirements are satisfied with publication to a searchable central repository, rather than on the web sites of individual companies.**

### **Other issues with the Bill**

1.19 Submissions received by the inquiry raised other concerns with the Bill which should be taken into consideration. The University of Sydney suggested that

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6 GlaxoSmithKline, *Submission 17*, p. 4.

7 Dr Ken Harvey, *Submission 4*, p. 1.

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definitions of the parties to which the Bill applies may be problematic and unintentionally exclude or include certain groups based on their ability to prescribe.<sup>8</sup> The Australian Greens accept this criticism and would see the definition of 'registered medical practitioner' improved in an amended Bill.

1.20 The University of Sydney also raised concern with the definition of 'regulated corporation' in the Bill suggesting that it may capture universities that import regulated pharmaceuticals for medical research or to conduct clinical trials on behalf of international pharmaceutical companies, exposing them to the penalties and regulatory requirements intended for that industry.<sup>9</sup> The Bill is not intended to apply to universities in this way, and the Australian Greens would see such parties specifically excluded in an amended Bill or the Explanatory Memorandum amended to make it clear that such cases were excluded.

1.21 Pfizer also noted that the Bill failed to provide a mechanism for doctors to check the validity of the details of reports which are required to be provided on company websites under section 42DT of the Bill.<sup>10</sup> The Australian Greens accept this criticism and note that the proposal by the Medicines Australia Transparency Working Group for "a single, public repository, enabling the information to be audited and validated by healthcare professionals and companies" provides an effective remedy to the Bill's original lack of facility.

## **Conclusion**

1.22 The inquiry made it clear that there are serious concerns regarding the transparency and integrity of the therapeutic goods sector in Australia. This Bill would address those concerns by bringing Australia up to world's best practice in terms of transparent disclosure and reduction of conflicts of interest arising in the medical profession as a result of their interactions with industry.

## **Recommendation 3**

**1.23 That the bill be passed.**

**Senator Richard Di Natale**  
**Senator for Victoria**

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8 The University of Sydney, *Submission 23*, p. 3.

9 The University of Sydney, *Submission 23*, p. 3.

10 Pfizer Australia, *Submission 8*, p. 3.

