



**CHF Submission to the Senate Standing Committees on
Finance and Public Administration Inquiry into the *Therapeutic
Goods Amendment (Pharmaceutical Transparency) Bill 2013***

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The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomes the introduction of the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* (the Bill) and the opportunity to comment on the Senate Standing Committees on Finance and Public Administration Inquiry into the Bill (the Inquiry).

The promotion of therapeutic goods to health professionals by industry has long been an area of concern for CHF. CHF considers that the ethical promotion of therapeutic goods is essential if consumers are to be confident that their health professionals' decisions are based only on the consumers' best interests, rather than on inappropriate incentives or marketing strategies.

Our submission draws on consultation with our membership, which includes organisations advocating for older consumers, disease specific groups and networks, state and territory peak consumer organisations and individual consumers. CHF's submission also draws on consultations undertaken on the promotion of therapeutic goods and pharmaceutical transparency, including dedicated consultation on this Bill.

General Comments

CHF welcomes the introduction of the Bill, which recognises the concerns of a range of stakeholders regarding the need for improved transparency in the promotion of therapeutic goods, and addresses limitations in existing self-regulation mechanisms. CHF also supports the stated objectives of the Bill:

The proposed Act will replace the industry code with legislation that sets more stringent restrictions on the interactions between pharmaceutical companies and physicians that minimises the opportunity to provide inducements and thereby unduly influence prescribing behaviours. The bill forbids payment for doctors to travel or attend education seminars and scientific conferences domestically and overseas, bans the sponsorship of educational meetings intended for Australian doctors outside Australia, limits gifts and overly lavish hospitality, and requires full reporting of any fees paid to prescribers outside the company.

At present, there are several different self-regulated codes in place for different parts of the therapeutic goods industry, covering members of Accord Australia, AusBiotech, the Australian Dental Association (ADA), the Australian Self Medication Industry Association (ASMI), the Complementary Healthcare Council of Australia (CHC), the Generic Medicines Industry Association (GMIA), In Vitro Diagnostics (IVD) Australia, the Medical Technology Association of Australia (MTAA), and Medicines Australia. These codes vary widely in areas such as:

- Expected standards for members
- Monitoring provisions
- Application and enforcement
- Levels of penalties and sanctions
- Processes for making and managing complaints.

CHF has previously called for a single code of conduct to address this variability, as well as other limitations in the existing self-regulation regime. These include:

- The lack of clarity surrounding the most appropriate code and complaints-handling body
- The tendency of codes to fall behind the expectations of consumers
- The tendency of codes to fall behind the expectations and practices of high-performing sectors of the industry, due to the need to accommodate a range of member companies within industry codes
- The lack of application of industry codes to non-members, and resulting compliance issues. CHF notes that this issue in particular was highlighted in the outline to the Bill's Explanatory Memorandum.

While there is concern among some stakeholders that the Bill represents a significant departure from existing self-regulatory codes and measures, CHF welcomes the opportunity for consumers, health professionals and industry to debate the merits of various regulatory models.

A poll of CHF's voting members has revealed that over 90 per cent of responding consumers support the objectives of the Bill, with only 5 per cent opposing and 2 per cent undecided. This highlights the desire among consumers for a regulatory regime that promotes transparency, improves consistency and compliance across industry and ensures the highest standards of regulation.

Comments on Specific Clauses

Proposed Section 42DR

CHF supports proposed subsection 42DR(1), which would end the practice of pharmaceutical companies hosting overseas events for Australian doctors. Many consumers who have contacted CHF in response to this Bill have expressed concerns in relation to this practice, and are disappointed by reports of industry-hosted events aimed at Australian doctors being held at luxury overseas resorts. Most consumers consider this practice to be an inducement. CHF also supports proposed subsection 42DR(2), which places monetary limits on extravagant hospitality.

While much of the feedback that CHF has received supports the measures outlined in this proposed section, we note that consumer organisations working on issues relating to rare cancers have voiced concerns regarding the impact this Bill may have on the ability of doctors to attend seminars and conferences on that subject. However, CHF believes that existing provisions in the Bill address these issues. The Bill does not prohibit Australian doctors from attending events outside Australia, nor would it prevent companies from hosting events within Australia or overseas (provided the latter are not aimed exclusively at Australian prescribers).

CHF supports proposed subsection 42DR, and welcomes measures to end the practice of pharmaceutical companies hosting overseas events for Australian doctors.

Proposed Section 42DS

CHF supports the intent of proposed section 42DS. However, CHF does not believe that there is a need to restrict sponsored travel within Australia to organisational representatives as proposed under 42DS(1a)(ii), provided this sponsorship is reported and the travel is for legitimate educational activities. CHF also recommends the removal of 42DS(2c), which would prevent companies from making charitable donations on behalf of doctors. CHF instead suggests that these activities be reported as outlined in proposed section 42DT.

CHF recommends the amendment of 42DS to enable charitable donations from companies on behalf of medical practitioners, as well as sponsored travel and accommodation for legitimate educational activities within Australia. These activities should be subject to disclosure and reporting under proposed section 42DT.

Proposed section 42DT

CHF strongly supports the new reporting requirements for payments to medical practitioners outlined under this section. Consumers consulted by CHF on this Bill accept that there may be legitimate reasons for health professionals to receive payments and sponsorships from pharmaceutical companies, but called for public disclosure at the individual level to ensure that these financial relationships are motivated by the education of the health professional to ensure improved consumer health outcomes.

On this basis, CHF believes that the Bill's proposed reporting requirements would provide greater transparency than existing measures under the recently adopted Medicines Australia Code of Conduct, which requires member companies to provide reports of aggregate amounts of all payments, sponsorship, advisory fees and speaking fees. Measures under the existing self-regulatory regime do not require companies to provide the names of individuals who have received payments or sponsorship, or the amount of funding provided to each individual.

CHF presented these arguments throughout recent consultations on the revised Medicines Australia Code of Conduct. We have also emphasised the fact that aggregated data does not provide a sufficient level of transparency, nor does it ensure that these payments and sponsorships are 'able to withstand public and professional scrutiny', as is required under the Code. If details of these payments are not made publicly available, then this 'public and professional scrutiny' is simply not possible.

CHF notes that the Australian Competition and Consumer Commission (ACCC) has given the industry two years to strengthen disclosure mechanisms under the Medicines Australia Code of Conduct. However, CHF remains concerned that the Code only applies to companies that voluntarily join Medicines Australia.

CHF supports proposed section 42DT, and welcomes the inclusion of reporting requirements at an individual level, rather than aggregate level.

Proposed section 42DU

CHF has long supported the application of meaningful sanctions for unreported inducements provided by pharmaceutical companies to medical professionals, and welcomes the measures outlined in proposed section 42DU.

CHF supports the sanctions outlined in proposed section 42DU.

Other Comments

Currently, there is wide variation across several self-regulated codes for different parts of the therapeutic goods industry. CHF has long argued for consistency of standards and sanctions across the industry, and calls for the Bill's application beyond pharmaceutical companies (for example, medical device companies and sponsors).

CHF recommends that the Bill's definitions be amended to apply across the therapeutic goods industry.

Conclusion

CHF welcomes the introduction of the Bill, and welcomes measures to build a regulatory regime that promotes transparency, improves consistency and compliance across industry and ensures the highest standards of regulation.

CHF supports proposed sections 42DR, 42DT and 42DU. CHF supports the intent of proposed section 42DS, but recommends it be amended to enable charitable donations from companies on behalf of medical practitioners, as well as sponsored travel and accommodation for legitimate educational activities within Australia. These activities should be subject to disclosure and reporting under proposed section 42DT. CHF also recommends that the Bill's definitions be amended to apply across the therapeutic goods industry.

We would welcome the opportunity to expand on this submission at a hearing of the Inquiry.



The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach thousands of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.