The Hon. Mark Butler, MP
Parliamentary Secretary for Health
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Amsterdam, 15 September, 2009

Re: Media release, 8 September 2008, "Ethical Promotion of Therapeutic Goods"

Dear Mr Butler,

Originator pharmaceutical companies spend 23% of turnover on marketing, while only 17% is allocated to research and development, according to a recent European Commission report.[i] This dependence on marketing clearly demonstrates why companies cannot be allowed to police their own promotional activities. As companies, decisions about promotion will always be based on the marketability and expected returns of a medicine, not on its public health benefits.

Your stated goal of achieving "the highest ethical benchmarks to address the issue of improper influence in marketing" is unlikely to be met through continued reliance on self-regulation by the very companies who market the medicines. There is a strong evidence to suggest that self-regulation does not provide sufficient protection against the misleading promotion of medicines.

Inevitably, commercial pressure will perpetuate misleading promotional 'information' because the central goal of promotion is to increase sales, not improve public health. In order to address the health dangers that arise from misleading promotion, the full range of stakeholders affected by medicines' policy must be involved in the debate about regulation. Health Action International (HAI) Europe is alarmed that the Australian Therapeutics Goods Administration (TGA) is planning to conduct these discussions without all stakeholders actively taking part.

The credibility of a bilateral discussion between industry and government without other stakeholders, such as health professionals and consumer groups, is tenuous at best. Creating "a level playing field on marketing obligations" for medicines requires input from all stakeholders affected by the policy's content, not only those with a commercial interest in the outcome of the discussions.

Since its inception, HAI Europe has been a staunch advocate for the rational use of medicines in the interest of the highest standards of public health and safety. Weak regulation of pharmaceutical promotion compromises that goal. Self regulation often displays all the signs of being weak in that:

- There are no independent technical assessments of the science behind the claims
- There is no independent monitoring of the process
- It is not responsive or slow to respond to complaints from public
- There are inadequate measures for corrective statements to balance misinformation
- There are no meaningful sanctions to deter re-offending

Though it has been 21 years since the World Health Organization (WHO) first published its *Ethical Criteria for Medicinal Drug Promotion*, many governments still devote too few resources to the regulation of pharmaceutical promotion. A strong and independent regulatory system overseen by the government is ultimately the more responsible long-term choice because it yields fewer prescribing mistakes, fewer adverse affects, and so, reduces the threat to public health as well as the healthcare costs associated with treating such mistakes.

To focus on the 'inconsistencies between codes of conduct" misses the much bigger problem of accepting self regulation for an industry that markets products that are fundamentally linked to public health outcomes. We believe that a more appropriate system of regulation should operate one code to all therapeutic claims and promotional practices; one complaint (and appeal) process, one monitoring process; and one set of effective sanctions, including corrective advertising orders and fines related to the sales income of the product and company involved.

In addition, we support recommendations from Australian public health stakeholders for a process that is overseen by government, funded by industry (through product registration fees), and carried out by an independent committee representative of all stakeholders. Such a system would be more consistent with the 2007 World Health Assembly Resolution WHA 60.16.5 on the Rational Use of Medicines, urging member states (including Australia) to:

> *"Enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor promotion of medicines, and to develop and implement programmes that will provide independent, non-promotional information about medicines".*

HAI Europe urges you to reconsider the bilateral discussions on the regulation of pharmaceutical promotion and instead, open the debate to allow perspectives from all the stakeholders who will be affected by this policy. Rational use of medicines is not only the responsible choice for public health, but also the responsible choice for public health budgets; and by pursuing tighter control of promotional activities that compromise rational use, the government can protect both.

Yours sincerely,

Teresa Leonardo Alves,
Coordinator, HAI Europe

[i] European Commission. DG Competition. Executive Summary of the Pharmaceutical Sector Inquiry Report. 8 July 2009.
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

Executive Agency for Health and Consumers

This arises from the Developing Rational Use of Medicines in Europe project, which has received funding from the European Union, in the framework of the Health programme