# HAI EUROPE submission to the Australian Government's Position Paper on the Promotion of Therapeutic Goods

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This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years institutional experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.
Our authority rests on our integrity and independence from commercial and political party interests, proven research excellence and evidence-based advocacy.

- HAI Europe promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

## Summary

HAI Europe welcomes the opportunity to comment on the Australian's government position paper on the Promotion of Therapeutic Goods. We support the Australian Government's aim to ensure that therapeutic management decisions, including diagnosis and treatment, are guided by sound clinical evidence, and not driven by commercial incentives.

## Key issues

### *Evidence supports government oversight*

There is ample evidence that self-regulation of pharmaceutical promotion is not sufficient to ensure public health priorities are upheld. A solid regulatory framework which includes some form of government oversight is needed to ensure that at all times public interests are upheld, rational use of medicines is encouraged and drug-induced harm is reduced.

In a highly competitive market, pharmaceutical companies have a legitimate responsibility to their shareholders to increase profitability by increasing sales. This is achieved through the promotion of pharmaceutical products to healthcare professionals and directly to the public. However, responsibility to shareholders has often been shown to be at odds with the protection of public health.

### *Enshrining in the duties of the pharmaceutical companies into national legislation*

For pharmaceutical promotion to be appropriately enforced and to be effective there needs to be a legislative framework through which the government can lay out principles and norms for compliance in respect of; commitments to transparency, independent monitoring, complaints procedure and any subsequent sanctions. Moreover, adherence to these principles and regulations should be considered as a pre-requisite for any application for marketing authorization to the Australian Therapeutic Goods Administration (TGA).

### *Stakeholder involvement in the development and monitoring of the Code*

Those directly affected by pharmaceutical policies should be able to contribute to the regulatory process. Most notably, codes should be developed in partnership with all stakeholders, including patients, consumers and civil society. Monitoring of the Code implementation and enforcement should be steered by one single independent body or committee, under the auspices of the TGPA, and gather representatives from all interested parties.

### *WHO Ethical Criteria: key principles to be upheld*

The guiding principles to be applied in pharmaceutical promotion should remain the WHO Ethical Criteria for Medicinal Drug Promotion, adopted in 1981. In that publication, promotion was described as: "...all the information and persuasive activities by manufacturers and distributors in order to induce the prescription, supply, purchase and/or use of medicinal drugs." Most importantly, the document also established the criteria to be met: "…all promotion making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks... Comparison of products should be factual, fair and capable of substantiation"; and highlighted the fact that "Promotional material should not be designed so as to disguise its real nature."

In respect of advertisements to the general public, the paper elaborates that these "should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners". Even though these criteria were approved more than two decades ago, they are still valid for all WHO Member States and they should be supported through an enforcement framework at national level.

### *Conclusion*

In this short response we focus on key principles that should be considered, but we wish to express our support for the detailed submission *Background Notes for the Working Group: Reflections on the Position Paper on the Promotion of Therapeutic Goods* (Appendix 1).

Teresa Alves
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