

# HAI GLOBAL PROJECT FACT SHEET

Regulation of Pharmaceutical Promotion: Assessment, Analysis & Advocacy Part Two

## Practical Implementation of the WHO Ethical Criteria for Medicinal Drug Promotion



### Rationale

It has been 21 years since the World Health Organization (WHO) first published its *Ethical Criteria for Medicinal Drug Promotion*. Most governments still devote few resources to the regulation of pharmaceutical promotion; many rely primarily on industry self-regulation, through voluntary codes of conduct. The WHO *World Medicines Situation Report* concludes that just around half of the surveyed countries<sup>1</sup> reported that they regulated pharmaceutical promotion in some way.<sup>2</sup> Yet, fundamental tensions remain between commercial interests in selling medicines and public health priorities.

The nature, extent and role of pharmaceutical promotion has changed radically since the publication of the WHO's Ethical Criteria in 1988. At the 60<sup>th</sup> session of the World Health Assembly in 2007, a resolution on Rational Use of Medicines (WHA60.16) was adopted. The resolution urged Member States...

**“to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor drug promotion, and to develop and implement programmes that will provide independent, non-promotional information on medicines.”**

In response, HAI Asia-Pacific initiated a project to take an in-depth look at how the Ethical Criteria were being applied by governments. In 2008, in a scale-up project, HAI Global and HAI Asia-Pacific established the **Regulation of Pharmaceutical Promotion Initiative**. Project One, which focuses on the development of indicators to assess national regulation of pharmaceutical promotion, is discussed in the factsheet *Measuring the Impact of Pharmaceutical Promotion*. Project Two is described in detail below.

### PROJECT TWO: Practical Implementation of the WHO Ethical Criteria

#### Goal

To offer practical proposals to countries on how to incorporate the principles of the WHO Ethical Criteria into national legislation and regulation.

#### Design

This element will provide governments with tailored guidelines for modifying their existing national legislation and regulations based on the country assessment conducted in Project One. This part of the initiative will also produce a 'template' for regulation of promotion and capacity building at a country level.

Overtoom 60, III  
1054 HK Amsterdam  
The Netherlands  
lilia@haiweb.org  
www.haiweb.org

## Objectives

- to provide a concrete tool for governments to improve national regulatory approaches and standards
- to develop a detailed standard against which existing laws and practices can be compared
- to deliver an advocacy tool for NGOs, health professionals, and consumer groups to improve national efforts to control promotion.

## Output

A detailed set of guidelines that will become the basis for model national legislation to enable governments to improve national regulatory standards for pharmaceutical promotion and to ensure that promotional activities do not threaten public health needs.

As a long-term output, there are also plans to produce a Manual to facilitate assessment, analysis, and policy development on national regulation of pharmaceutical promotion.

## Work Plan

- briefly describe the WHO Ethical Criteria for Medicinal Drug Promotion and outline reasons why such 'criteria' are necessary but not sufficient in providing practical advice on how the promotion of medicines can be controlled at a national level;
- propose a form of wording for each of the criterion that will enable it to be incorporated into model national legislation;
- address the key forms of direct and indirect pharmaceutical promotion occurring in the 21<sup>st</sup> century (and expected to occur in the future) in different parts of the world and point out new promotional practices that would not be sufficiently controlled by the Ethical Criteria;
- suggest legal wording to supplement the WHO Ethical Criteria;
- include a brief 'problem definition' that regulation aims to solve in each section following the Ethical Criteria, with examples and a reference to the research evidence;
- provide in legal language, enforcement mechanisms that could be used or adapted by national governments.

For more information on this project, please contact Dr. Lilia Ziganshina, Project Officer,  
HAI Global: [lilia@haiweb.org](mailto:lilia@haiweb.org)

## END NOTES

<sup>1</sup> Ratanwijitrasin S, Wondemagegnehu E (2002). Effective drug regulation: a multicountry study. *World Health Organization, Geneva*. pp. 149.

<sup>2</sup> World Health Organization (2004). World medicines situation. *World Health Organization, Geneva*. Available at: [http://www.searo.who.int/LinkFiles/Reports\\_World\\_Medicines\\_Situation.pdf](http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf) (Accessed on 20<sup>th</sup> November 2008)