

## Medicines promotion: Assessing the nature, extent and impact of regulation

### Rationale

Medicines can play an important part in health care. However, irrational prescribing and use often result in inappropriate or harmful treatment, a waste of resources and increased drug resistance. As a result, many countries have introduced a legislative framework to regulate the promotional activities of the pharmaceutical industry, but they vary widely regarding content, implementation and enforcement. In developing countries especially, overstretched health systems may have difficulties allocating sufficient resources to regulate promotion.

While the industry plays a central role in developing and producing medicines, there is a clear tension between industry's need to expand product sales and public health priorities. In fact, the World Health Organization (WHO) sets out:

*“an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way.”<sup>1</sup>*

In many developing countries, industry promotion is often the main or only source of information about medicines for health professionals and consumers. In developed countries, the sheer volume of promotion as well as industry involvement in continuing medical education, clinical research, patient groups and other areas, make its promotional messages unavoidable and persuasive.

### Background

In 1988, the WHO produced the *Ethical Criteria for Medicinal Drug Promotion* in an effort to help countries safeguard public health. This document remains the gold standard against which not only promotional activities are judged, but also national and regional efforts to regulate promotion, ranging from legislation to self-regulatory codes. Unfortunately, the WHO Ethical Criteria do not provide for any kind of sanctions and they lack advice on how the recommendations should be implemented.

At the 60<sup>th</sup> World Health Assembly in 2007, a resolution on the 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.”<sup>2</sup>*

### The Project

**HAI, with support from MeTA and DGIS, is developing a tool which will provide a comprehensive assessment of promotional practices and regulation in countries.**

## Objectives

The project aims to determine:

- **The scope of regulation on pharmaceutical promotion in countries**
- **The impact and effectiveness of the regulatory framework on promotional practices**

For this purpose, HAI will help countries identify:

- National legal provisions on promotion as well as existing mechanisms to implement and enforce them
- Existing forms of unethical promotion occurring in the country
- Any gaps in the regulatory framework that need to be addressed

## Methodology

HAI's research tool, developed with support from MeTA and DGIS, and input from the WHO and a team of promotion experts, will combine desk research, key informant interviews, and sample data collection to provide a more complete picture of the national situation, and will include:

- An analysis of relevant laws, guidelines or codes related to the promotion of medicines
- An assessment of existing mechanisms for implementation and enforcement
- Key informant interviews for in-depth analysis of the actual situation
- Measurement of specific promotion outcomes (such as direct-to-consumer advertisements, the work done by sales representatives and the use of generics)

## Output

The research tool should provide a detailed overview of a country's current profile concerning promotion. This will include:

- The strengths and weaknesses of the regulatory framework
- Any outstanding enforcement issues
- An understanding of the political context and stakeholders' positions regarding regulation

The findings will shed light on the efficacy of pharmaceutical promotion regulation, highlight the areas in which regulation needs strengthening and provide the basis for recommendations to improve national policies on promotion. National surveys carried out using this tool should provide an evidence base upon which countries can make policy choices to improve the rational use of medicines.

*For more information about this project, please contact Carole Piriou, HAI Global Project Officer, Rational Use of Medicines projects, [carole@haiweb.org](mailto:carole@haiweb.org)*

<sup>1</sup> World Health Organization. Clinical Pharmacological Evaluation of Drug Control. WHO, 1993.

<sup>2</sup> Resolution 60.16 on Rational Use of Medicines. 60<sup>th</sup> World Health Assembly, 2007