



Medicines Promotion: Assessing the Nature, Extent and Impact of Regulation

Report and Preliminary Methodology for Pilot-testing

Contents

Introduction	3
Acknowledgements.....	3
Project report	4
Rational Use of Medicines, Medicines Promotion and regulation	4
Project.....	6
Looking ahead	9
Final preliminary methodology for pilot testing	11
Document check list.....	12
Data compilation.....	15
Interview Schedule: Key Informant from Drug Regulatory Authorities.....	23
Interview Schedule: Healthcare Professional Informant	27
Interview Schedule: Key Informant from Civil Society Organisation or Patient Group or WHO country office	31
Interview Schedule for the Pharmaceutical Industry, the Insurers, and the Media.....	35

Introduction

This report, which precedes the assessment tool itself, outlines the premise and context which has led to the development of a methodology to investigate the regulatory framework of medicines promotion in the context of national settings. The project has developed a methodology to gather information on any given countries' regulatory practice that is aimed at controlling the extent and influence of pharmaceutical promotion. As a tool to gather data on regulation, it complements the World Health Organization's (WHO) Ethical Criteria for Medicinal Drug Promotion¹. The project has been conducted by Health Action International (HAI) Global and co-funded by the Medicines Transparency Alliance (MeTA) and the HAI global Programme, under the guidance of an advisory group of international experts.

Acknowledgements

Project editors and report authors
Carole Piriou and Elizabeth Hayes, HAI Global

Project supervisor at MeTA
Wilbert Bannenberg, Technical Director

The list below includes members of the Advisory Group (denoted with a *) as well as individuals who provided input during the development of the methodology.

Elodie Brandamir, MeTA
Guitelle Baghdadi-Sabeti, WHO-Geneva*
Wilbert Bannenberg, MeTA*
Christa Cepuch, HAI Africa*
Marieke Devillé, MeTA
Andy Gray, University of KwaZulu-Natal, South Africa*
Jinani Jayasekera, HAI Asia-Pacific*
Denis Kibira, HEPS Uganda/HAI Africa
Richard Laing, WHO-Geneva*
Joel Lexchin, York University, Canada*
Roberto López-Linares, HAI-Latin America and the Caribbean (AIS-LAC)*
Benoît Marchand, HAI-Nicaragua (AIS-LAC)*
Barbara Mintzes, University of British Columbia, Canada*
Mohammed Ramzy, WHO-EMRO*
Tim Reed, HAI Global
Fatima Serhan, WHO-Geneva
Lilia Ziganshina, Kazan State Medical Academy, Russian Federation

We would also like to acknowledge the contribution of the respondents in Peru, Uganda and Kyrgyzstan who commented on a first version of the methodology.

¹ Ethical criteria for Medicinal Drug Promotion WHO 1988

Rational Use of Medicines and Medicines Promotion

When medicines are used rationally, patients receive appropriate treatment, in doses that meet their individual requirements, for an adequate period of time. We can add to this that rational use of appropriate medicines reflects the lowest cost both to the patient and/or their community². However, it is estimated that globally “half of all medicines are prescribed, dispensed or sold inappropriately, and half of all patients fail to take them correctly. Overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards.”³ Since medicines can account for between one quarter to two thirds of national health spending in developing countries, the potential for poor health outcomes and resource wastage is acute.⁴ For example, in developing countries, out-of-pocket spending on medicines can be an enormous burden on households, the majority of which may already be struggling to meet basic needs⁵. Add to this the problem of anti-microbial resistance, whereby antibiotics are no longer effective for treating the infections for which they were originally developed. Irrational overprescribing has made a significant contribution to this devastating global problem⁶.

A crucial component to promote the appropriate use of medicine is accurate information on medicines to healthcare professionals and consumers. While the pharmaceutical industry plays a central role in developing and producing medicines, there can be a tension between industry’s need to expand product sales through the promotion of its products and the public health priority of rational use. In fact, the World Health Organization (WHO) has called it “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.”⁷

To document this, findings based on the systematic review of research on the impact of medicines promotion on health professionals’ behaviour, knowledge and attitudes consistently shows that prescribers who rely on promotion as their main source of information tend to prescribe less appropriately, prescribe more often and adopt new medicines faster.⁸ Another review concluded that the link between greater exposure to and reliance on promotion on one hand, and less appropriate prescribing on the other, met epidemiological criteria for causation.⁹

In many developing countries, lack of resources results in promotional activities by the industry being the main or sole source of information about medicines for health professionals and consumers. Moreover throughout the world, the sheer volume and variety of persuasive medicines promotion, such as the commercial interest in the sponsorship of continuing medical education, article ghost writing, clinical research, patient group funding and influence, and so on, make promotional messages almost unavoidable.

² Promoting rational use of medicines: core components 2002. WHO Policy Perspectives on Medicines No.5, Geneva, World Health Organization, 2002.

³ The rational use of drugs. Report of the Conference of Experts. Geneva, World Health Organization, 1985.

⁴ WHO | 10 facts on essential medicines 2009

http://www.who.int/features/factfiles/essential_medicines/essential_medicines_facts/en/index1.html

⁵ Prescription for healthy development: increasing access to medicines. Millennium Project Task Force 2005

⁶ WHO Global Strategy for Containment of Antimicrobial Resistance 2001 WHO/CDS/CSR/DRS/2001/2/EN

⁷ World Health Organization. Clinical Pharmacological Evaluation of Drug Control. WHO, 1993

⁸ Drug promotion, what we know, what we have yet to learn WHO and HAI 2005

⁹ Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000; 283: 373-380

The question then is what can be done to control the unethical nature of pharmaceutical promotion that so distorts the use of medicines that individual health outcomes are poorer, there is a worldwide growth in anti-microbial resistance, and a misuse of scarce health resources.

Regulation of Medicines Promotion

In 1988, the WHO took a landmark step and published the *Ethical Criteria for Medicinal Drug Promotion*¹⁰ in an effort to help countries safeguard public health by offering guidelines on what might constitute an ethical way of promoting medicines. This document is not only the gold standard against which promotional activities might be judged, but remains a blueprint for international, national and regional efforts to regulate promotion, ranging in type from government legislation to pharmaceutical industry self-regulatory codes of practice.

In an attempt to prompt action from member states, a resolution on the rational use of medicines (WHA60.16) was adopted at the 60th World Health Assembly in 2007. 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.’¹¹

The WHO does not make regulations, and does not insist member states adopt legislation, so the WHO Ethical Criteria do not include any kind of advice on sanctions for breaches of ethical promotion, and they lack any advice on how the recommendations should be implemented, rather it is left to the member state.

To date, fewer than half (49%) of the world’s countries have introduced a legislative framework to regulate the promotional activities of the pharmaceutical industry¹². Results from a WHO study¹³ show that regulatory frameworks vary widely regarding content, implementation and enforcement. In developing countries especially, overstretched health systems may have difficulties allocating sufficient resources to support robust regulation. Indeed, many regulatory bodies fail to provide the tools, such as guidelines and standards, needed to support effective regulation. Regulatory gaps also occur where laws have been enacted but the regulatory agency fails, for various reasons, to implement its mandate.

When legal framework does not exist, the control of promotional activities is often left to the pharmaceutical industry itself, through self-regulation with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) code of practice¹⁴ or national industry codes.

Although voluntary codes of practice have been criticized for shortcomings in their coverage, for being poorly enforced and lacking deterrent sanctions, they are nevertheless often the only mechanism for restraint.¹⁵

¹⁰ <http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf>

¹¹ Resolution 60.16 on Rational Use of Medicines. 60th World Health Assembly, 2007

¹² World Medicines Situation WHO 2004

¹³ Ratanwijitrasin S, Wondemagegnehu E. *Effective drug regulation: a multicountry study*. Geneva, World Health Organization 2002

¹⁴ IFPMA Code of Pharmaceutical Marketing Practices 2007

Few attempts have been made to map and comprehensively explore the regulatory situation in countries regarding medicines promotion control. This is a crucial first step to determine the current barriers and best approaches to the control of promotion, in order that an effective promotion framework, which enshrines the rational use of medicines and protects public health, might be constructed.

As mentioned above, there has been little research on the impact of regulatory structures concerning medicines promotion, but the WHO has published two methodologies which informed this project.

The WHO's *Good Governance for Medicines*¹⁶ indicators are explicitly designed to assess countries' vulnerability to corruption. The program has so far revealed that in most countries where it has been applied, the area of medicines promotion is often poorly appreciated by regulatory officials, in spite of misleading promotion being of 'worrying proportions'¹⁷.

"Effective Drug Regulation: A Multi-country Study"¹⁸ is also of key relevance to this project and involves a similar literature review and key informant interviews methodology, but as its authors acknowledge, it falls short of providing an investigation of outcomes. It focuses on the organisational structure of regulatory authorities and the regulatory tools available for implementation and enforcement.

These two methodologies and the WHO Ethical Criteria provided crucial background information for HAI's methodology development.

Project

For all these reasons, HAI Global in collaboration with MeTA, has developed a methodology (accompanying this report) to help countries gain an overview of the national regulatory framework and assess key stakeholders' perceptions of the regulatory situation regarding medicines promotion.

Although unethical promotional practices and irrational use of medicines are global issues, regulatory practices are usually local (national or regional), and depend on many factors, including the social, political and economic context of regions, countries, and populations. Because of this context-specific nature of regulation, policy recommendations cannot be provided without an extensive understanding of the country's specific situation. It is hence necessary to investigate what the regulatory texts stipulate, but also to map the structure of the drug regulatory authority and related bodies, and to gather testimonies and opinions of the different stakeholders involved in or affected by medicines promotion.

Objectives

The methodology aims to determine:

- The scope of regulation on pharmaceutical promotion in country settings

¹⁵ Putzeist M. Self-regulation of drug promotion. A cross-sectional analysis of the practical codes and WHO ethical criteria on the promotion of medicines. Unpublished report. 2009

¹⁶ <http://www.who.int/medicines/ggm/en/>

¹⁷ ReMed conference, oral communications on GGM progression in Benin and Cameroon, Nov 2009, Paris

¹⁸ Ratanwijitrasin S, Wondemagegnehu E. *Effective drug regulation: a multicountry study*. Geneva, World Health Organization 2002

- The impact and effectiveness of the regulatory framework on promotional practice

For this purpose, HAI developed a methodology to help countries identify:

- National legal provisions on promotion as well as existing mechanisms to implement and enforce them. This includes assessing the extent of self-regulation by the pharmaceutical companies where relevant.
- Examples of existing forms of unethical promotion occurring in the country and how they breach legislation or codes of practice
- Any gaps in the regulatory framework that need to be addressed

Methods

A draft methodology was developed by HAI Global and reviewed by an international advisory group comprising public health, pharmaco-epidemiological, pharmaceutical policy and methodological experts (see acknowledgements). The draft tool aimed to assess the impact of promotion regulation using a semi-structured questionnaire and an interview guide, targeting key informants from a wide range of stakeholders. The tool was first submitted to the project's advisory group for comments and was subsequently reviewed by key informants in three countries where MeTA is active: Kyrgyzstan, Peru and Uganda. Both parts of the draft tool were updated in terms of length and content following the review.

The methodology comprises a literature review section and semi-structured interview questionnaires for key informants to scope the extent and effectiveness of national regulatory policies on promotion and related perceptions. It provides information on the national situation by looking at the literature available, the structures in place for implementation and enforcement, and the perceptions of stakeholders (gathered through key informants). Regulatory policies are defined here to include: direct government regulation, self-regulation by pharmaceutical and advertising industries, and any relevant policies affecting industry, the media, professional and patient organisations.

HAI's research tool combines desk research and in-country key informant interviews and includes:

- 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

The literature review comprises a "document checklist" and a "data compilation" tool. This part of the scoping exercise is to be carried out by a local researcher, preferably someone with background knowledge of his/her country's regulatory framework. Training sessions targeted to the local researchers should be held to familiarise them with the project, and a practical guide should be developed to assist third parties to carry out the scoping exercise by themselves (see below, "looking ahead").

The literature review is a backbone of the scoping project as it assesses the type, depth and breadth of any given regulatory structure and the legislative landscape and context in which it is enshrined.

However, whilst the existence of regulation of promotion can be an almost quantitative exercise, a more qualitative empirical question resides in their interpretation and systematic enforcement. Hence, semi-structured interviews of the stakeholders involved in or affected by promotion are needed to obtain further information. These key informants include regulators, pharmaceutical industry representatives, payers and/or insurers, health professionals and consumer associations, health service administrators, patient groups, and regional WHO pharmaceutical advisors depending on country context.

It is important to keep in mind that the key informant interview schedules provided with this report are templates that are made to be updated upon completion of the literature review, so as to contextualise them to the country social, political, economic and regulatory environment.

Ethically, it is the suggestion here that it is necessary that the consent of the Ministry of Health is obtained before research takes place, and it is highly recommended that its cooperation is sought, as political will is a key factor driving policy changes.

Literature review: “Document Checklist” and “Data Compilation” tool

The “Document Checklist” is intended to guide the researchers through the collection of relevant documents, which are then used to fill the “Data Compilation” tool. This checklist is not exhaustive as to which type of regulatory documents might exist, but rather enables the researcher to prospect in different directions in order to find relevant documents where they exist. It allows the compilation of texts in relevant area and provides hints as to what kind of documents could be found. For example, the field test of the methodology underscored that legislation relevant to the promotion of medicines can be found in trade or consumer’s protection related legislation or adherence to self-regulatory codes may be available from the pharmaceutical industry association.

The available documents are to be collected and catalogued and the process detailed, as accessibility of regulatory documents is an important factor affecting transparency.

The regulatory documents available then answer questions in the data compilation tool on the regulatory structure and the provisions concerning medicines promotion, using original excerpts where possible to minimise bias.

Those questions include the scope of regulation (e.g. which forms of promotion are covered), the mechanisms in place for monitoring and enforcement and the existence and nature of provisions concerning violations. The description of the bodies responsible for issuing regulation, monitoring its effects and enforcing it is then sought.

Key Informants interviews: 4 interview schedules templates

The key informant interviews are crucial to discuss the actual regulatory situation, issues of political commitment, human and financial resources, whether the codes or laws are enforced etc. with all the stakeholders. The interviews schedules provided here are templates, and need to be adapted in each country after the literature review has been carried out, so that they are refined to investigate a country’s specific context.

Key informant’s interviews (approximately 10 per country) explore current practice, models of regulation under consideration, barriers to effective regulation, and ‘best practice’. They inform a variety of issues, ranging from political commitment to rational use and regulating promotion, to the actual practices at the primary care level. For further recommendations, the context in which the

policies were developed, how transparent the regulatory process is, and who is involved in the decision-making process are investigated.

Depending on their background, and the context analysis, informants are asked their opinions, advice, and information about barriers to enforcing legislation and how to overcome them.

This need to adapt the question to the key informants' background is the rationale for having four different interview schedules depending whether the informant comes from:

- Regulatory authorities
- Healthcare professions
- Civil society, patient organisations and WHO country offices
- The pharmaceutical industry, payers/insurers, and the media

This allows using the most of the areas of expertise in each category, while keeping the interviews concise enough to be carried out during a single session.

Research Outcomes

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

- The strengths and weaknesses of any regulatory framework
- Issues related to the implementation and enforcement of the existing regulation
- An understanding of the political context and stakeholders' positions regarding regulation

By highlighting the strengths and weaknesses of any national system, be it constitutional, legislative or self-regulatory, the methodology enables researchers to locate gaps in the regulatory framework and highlight best practices in various areas. Advocacy options will emerge from cross country comparisons.

Looking ahead

The country profiles obtained through this assessment should, in turn, help inform country-specific policy recommendations to control promotion more efficiently and promote rational use. 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. Successful examples from other countries can be used to provide recommendations and strengthen the interpretation of the law.

The discussion on the methodology led to the development of a new component that would assess the "on the ground" situation by looking at promotion issues at the health facility and patient levels. This

need for field data is also stressed in the WHO “Effective Drug Regulation” report¹⁹. Members of the Advisory Group mentioned the importance of analysing promotional material found in health facilities or conducting surveys of sales representatives’ behaviour. This would inform the actual levels of enforcement of the law, regulation, guideline or code.

The Advisory Group agreed that a second research component should be developed to enable HAI to gather data at the facility and patient levels. It was thought that this addition to the present methodology would make it more robust and better ensure that it gathered information that would inform countries about important aspects of their regulatory system’s effectiveness in controlling particular medicine promotion practices and encouraging rational use. It will also enable the monitoring of the impact of any policy change in a given country.

It is anticipated that the methodology will be run as a pilot in countries representing global and regional diversity, GDP and regulatory context. The advisory committee determined that an important output would be a practical guide to assess regulation practices and examples of best practices that would result from the scoping exercise. Moreover, it is recommended that guidelines be developed to train the researchers carrying out the literature review and the key informant interviews in an effort to enhance comparability of the data. HAI will continue to discuss this with the Advisory Group and will work to have a draft ready for use during the pilot testing phase. The revised manual and the full methodology will then be shared as an open access resource.

Conclusion

Controlling the promotion of medicines is a crucial step in encouraging the rational use of medicines. Very little is known about existing regulatory frameworks governing medicines promotion, apart from the fact that few countries possess efficient ones, and that regulatory provisions and structure vary considerably across the world. The methodology accompanying this report addresses the need for information on various frameworks for medicines promotion by providing a means by which extensive data on regulatory structures can be gathered. It allows an analysis at different levels, by assessing the situation from a theoretical/technical point of view (laws, decrees, codes etc.) and the qualitative opinion of key stakeholders.

The research outcomes will help increase transparency in regulatory activities and provide a picture of the strengths and weaknesses of national systems. This will in turn lead to policy recommendations that promote good practice, public health and consumer’s protection.

¹⁹ Ratanwijitrasin S, Wondemagegnehu E. *Effective drug regulation: a multicountry study*. Geneva, World Health Organization 2002



Final preliminary methodology for pilot testing

Part I p. 12-22

Literature review: Document check-list and data compilation tool

Part II p. 23-38

Key informant interview schedules



Document check list

This checklist is indicative and aims at helping the researcher in his work by giving him indications as to which documents might be relevant to medicines promotion control. Many countries might have only few of these documents available. The material found shall be used as support to answer the questions in the data compilation part.

Document	Exist/does not exist	Name of the document and date	Source (if available on the Internet, please include URL)	Reason ,if not provided
	Legislative documents			
Medicines regulation law/ act				
National Medicines Policy				
If relevant, provisions pertaining to medicines promotion in:				
Supranational/regional agreements				
Sub national policies/laws				
Advertisement law				
Commerce law				
Consumer protection law				

Other (guidelines, codes)				
	Self regulation			
Pharmaceutical industry code(s)				
Related procedures for enforcement				
	Other relevant documents			
Procedures for:				
-obtaining pre-approval of advertisements for medicines				
-complaining about medicines promotion				
-sanctions and enforcement				
Annual reports/descriptive material on the work of regulatory authorities on promotion				
List of institutions or departments involved in promotion regulation and the areas they cover (organigram)				
Number of staff involved in promotion regulation and their positions (organigram)				

Description of activities the bodies involved in promotion regulation				
Conflicts of interests policies of the bodies involved in promotion regulation				
Published research on promotion in the country (GGM/MeTA/other)				
Other relevant policies/regulation from:				
Professional associations				
Medical schools				
Hospitals				
Scientific offices				



Data compilation

The following form is to be filled as much possible with excerpts from documents collected with the help of the 'document checklist'.

The part 'scope of the regulation' part is to be filled for each relevant law, code or guideline collected. The following parts request details on the body (or bodies) in charge of issuing, monitoring and enforcing those documents. In certain countries all those functions are undertaken by the medicines regulatory authorities. In others, the task of monitoring and enforcing the law is delegated to the private sector.

<i>Scope of the regulation</i>	
1. What is defined as 'advertisement'?	
2. What is defined as 'promotion'?	
3. What are the provisions concerning medicines promotion/ advertisement?	
4. Does it cover traditional medicines, complementary medicines? How?	

5. Do advertisements have to comply with approved product information/label?	
6. Are certain categories of medicines banned from advertising? Which ones (unregistered medicines, narcotics...)?	
7. Is advertising to the general public authorised? For which substances? Through which media?	
8. For which medicines is advertising to health professionals authorised? Through which media? (E.g. medical journals only?)	
9. What information has to be included in an advertisement? Specify by media type.	
10. Are requirements for advertising identical for exported and/or imported medicines and/or locally produced medicines?	
11. Are there minimal qualifications listed as necessary to be a pharmaceutical sales representative? What are they?	
Forms of promotion covered: what is written about...	
12. Gifts/payments to doctors or other health professionals	
13. Pharmaceutical sales representatives' interactions with healthcare professionals	
14. Discounts and rebates on medicines	
15. Distribution of free medicine samples	
16. Sponsorship of Continuing Medical or Pharmacy Education	

17. Sponsorship of scientific meetings	
18. Information to patients (package inserts contents)	
19. Packaging and labelling	
20. Internet and related social networking media	
21. Post-marketing studies	
22. Clinical trials and promotion	
23. Promotion of off-label indications	
24. Other	

<i>Issuing regulation/codes/guidelines</i>	
1. Which body (ies) issue(s) regulations on medicines promotion?	
2. What is its stated mission?	
3. How is the body governed?	
4. Number of full-time equivalent staff for medicines promotion regulation?	
5. Budget for medicines promotion regulation in USD and as percentage of total budget for pharmaceuticals	
6. What are its other activities?	
7. Funding mechanisms (fees, fines and/or public funds?)	
8. How is information about regulation disseminated/made public? Through official publications, newsletters, websites?	
9. Can staff of the regulatory body also work in/be funded by the pharmaceutical industry? Sit on boards?	
10. To whom is the body responsible for issuing regulations accountable?	

<i>Monitoring medicines promotion</i>	
1. Is there a governmental system in place for monitoring of medicines promotion? Any other monitoring system, such as an industry self regulatory system or other body?	
2. If so, is it active monitoring (collection of samples, watching television advertisements, pre-approval) or passive monitoring (complaint mechanisms by competing companies and/or consumers)? Describe	
3. Which body is responsible for monitoring?	
4. What is its stated mission?	
5. How is the body governed?	
6. Number of full-time equivalent staff for monitoring medicines promotion?	
7. Budget for monitoring medicines promotion in USD and as percentage of total budget for pharmaceuticals	
8. What are the body's other activities?	
9. Funding mechanisms (fees, fines and/or government?)	
10. If pre-approval: Which material, on which media, for which audience, for which substances?	
11. What are the criteria/requirements for pre-approval? Are they publicly available? If so where?	
12. Who develops those criteria?	

13. Is there a fee for submitting promotional material for pre-approval? How much is it in USD?	
14. If there is a complaint mechanism, who can complain?	
15. Are complaints published? Are the outcomes published?	
16. What is the timeline for the complaint mechanism to be completed from the time the complaint is filed?	
17. How is information about monitoring activities disseminated/ made public?	
18. Can staff of the monitoring body also work in/be funded by the pharmaceutical industry? Sit on industry boards?	
19. To whom is the body responsible for monitoring accountable?	

<i>Enforcing medicines promotion regulation</i>	
1. Which body enforces the law?	
2. What is its stated mission?	
3. How is the body governed?	
4. Number of full-time equivalent staff for enforcement of medicine promotion regulation?	
5. Budget for enforcing medicines promotion regulation in USD and as percentage of total budget for pharmaceuticals	

6. What are its other activities?	
7. Funding mechanisms (fees, fines and/or public funds?)	
8. What are the sanctions: warning letters, issue of corrective advertisement, prohibition of the advertisement, fines, revocation of registration, jail, expulsion from association (for industry self-regulation)?	
9. What is the range of sanctions (for fines: in USD). List offences and sanctions range.	
10. Are the sanctions made public? How?	
11. Is there an appeal mechanism?	
12. Who can appeal? To whom?	
13. What is the timeline for the appeal process from when the appeal is launched until its completion?	
14. Can staff of the enforcement body also work in/be funded by the pharmaceutical industry? Sit on industry boards?	
15. To whom is the body responsible for enforcement accountable?	
16. Are civil society and/or other stakeholders asked for comments on pending decisions?	
17. Are the reasons for the decisions published?	

Others	
1. What are the relationships between the different bodies/departments involved in medicines promotion regulation (issuing regulations, monitoring and enforcement)	
2. Do companies producing and/or selling medicines have to disclose their budget for promotion and advertising? How and where is this disclosure made? How much is that budget at a national level for a given year?	
11. How is generic substitution regulated? (E.g. substitution by pharmacists)	
12. How is prescribing regulated?	
13. Is there a legal provision requiring the government to provide independent information on medicines to health professionals and/or consumers?	



Interview Schedule: Key Informant from Drug Regulatory Authorities

COUNTRY:

DATE AND LOCATION:

RECORDING: YES NO

INTERVIEWEE

FULL NAME:

TITLE AND AFFILIATION:

E-MAIL:

ADRESS:

PHONE NUMBER:

INTERVIEWER

FULL NAME:

E-MAIL:

REMARKS:



General introduction:

The purpose of this interview is to gather information on the regulatory system in your country concerning medicines promotion. In many countries this is a grey area, there is little awareness about the legislation, what is authorised and what is not. We want to learn more about the regulatory framework, but we also want to know what are the promotional practices used in <COUNTRY> to advertise medicines. The goal is to identify problems and best practices by gathering this information in multiple countries. We review the legislation and interview key stakeholders, such as Drug Regulatory Authorities, healthcare professionals, civil society, the pharmaceutical industry, etc. With this, we hope to provide recommendations to strengthen regulatory systems to improve medicines use and public health in general. After the assessment in your country will be carried out, we will get back to you with the findings.

Did you see the fact sheet on the project? Do you have questions about it?

First of all, I would like you to introduce yourself and to talk to me briefly about the main areas you focus on in your work.

Do you think you are the right person I should talk to in order to learn more about promotional practices?

If not, could you let me know of other people you think might be able to provide valuable contribution?



1. Does the government provide or support independent information on medicines to health care professionals and/or consumers?
2. What do you think of the content of advertisements for medicines in general? Do you think that information in advertisements is consistent with the actual product characteristics?
3. Are prescription-only medicines advertised to the public? In which ways? Are there disease awareness campaigns in your country? Do they display brand names?
4. Are consumers exposed to advertisements from other countries? Which countries? Through which media? Are they different from advertisements from your country? How?
5. Do doctors or pharmacists receive discounts, rebates or bonuses as an incentive to prescribe and dispense more?
6. Are medicines prescribed by brand or generic name? Does it vary between sectors (public and private)? How?
7. Is generic substitution allowed? Who is allowed to substitute? Is it done in actual practice? What do patients think about it?
8. Who is involved in the processes by which medicines are selected to be supplied and/or reimbursed? What is the influence of pharmaceutical companies?
9. Do patient organisations advocate for specific medicines to be registered or reimbursed in your country? Who funds these organizations?
10. Are medicines sold informally on the (black) market, in kiosks? Are those activities monitored? By whom?

Does the pharmaceutical industry have an official role in the regulation of drug promotion? Which sort of role? If the industry self regulates its promotional activities, does the government have an oversight on the mechanism? How? If not, do you think it has an informal role? How?
11. What proportion of the promotional material is approved when going through the pre approval process (if applicable)?



12. Are there concerns about promotional activities? Who is taking action? Consumers? Industry competitors? Do you know of formal complaints being filed? What was the outcome? What do you think of the complaint mechanism?
13. Are there penalties against offenders? How many penalties were applied in the last five years? Can you give examples? Are they published? Do the sanctions deter future violations? If not, why?
14. What do you think of the budget and staffing allocated to the regulation of drug promotion is sufficient?
15. In your opinion what are the main strengths in the control of drug promotion in your country?
16. In your opinion what are its main weaknesses?
17. Have important developments affecting drug promotion regulation taken place during the past few years? Are there important upcoming events which will likely influence medicine promotion regulation in your country or region? Please describe them
18. What is the first thing you would do if you were in a position to change the regulatory situation on medicine promotion?



Interview Schedule: Healthcare Professional Informant

COUNTRY:

DATE AND LOCATION:

RECORDING: YES NO

INTERVIEWEE

FULL NAME:

TITLE AND AFFILIATION:

E-MAIL:

ADRESS:

PHONE NUMBER:

INTERVIEWER

FULL NAME:

E-MAIL:

REMARKS:

**General introduction:**

The purpose of this interview is to gather information on the regulatory system in your country concerning medicines promotion. In many countries this is a grey area, there is little awareness about the legislation, what is authorised and what is not. We want to learn more about the regulatory framework, but we also want to know what are the promotional practices used in <COUNTRY> to advertise medicines. The goal is to identify problems and best practices by gathering this information in multiple countries. We review the legislation and interview key stakeholders, such as civil society, Drug Regulatory Authorities, healthcare professionals, the pharmaceutical industry, etc. With this, we hope to provide recommendations to strengthen regulatory systems to improve medicines use and public health in general. After the assessment in your country will be carried out, we will get back to you with the findings.

Did you see the fact sheet on the project? Do you have questions about it?

First of all, I would like you to introduce yourself and to talk to me briefly how you are interested in promotion of medicines

Do you think you are the right person I should talk to in order to learn more about promotional practices?

If not, could you let me know of other people you think might be able to provide valuable contribution?



1. Where do healthcare professionals usually go for information on medicines? Are there sources of independent information? Which sources do you use? How do you know about them?
2. What do you think of the content of advertisements for medicines in general? Do you think that information in advertisements is consistent with the actual product characteristics?
3. Do healthcare professionals use treatment guidelines? Who is involved in their development? On which basis?
4. Are medicines promoted for uses outside of approved indications? Which ones? Do you have examples?
5. Do companies sponsor professional development such as scientific events or Continuing Medical Education? Do sponsors have a role in choosing the speakers or setting the agenda?
6. What is the usual process to have a medicine added to a hospital formulary? Do you think medicines promotion influences this process? In what way?
7. What information is given to patients when medicines are dispensed? (Package inserts and labelling available?)
8. Are prescription-only medicines advertised to the public? In which ways? Are there disease awareness campaigns in your country? Do they display brand names?
9. Do patient organisations advocate for specific medicines to be registered or reimbursed in your country? Who funds these organizations?
10. Do patients request for specific brands of medicines? How much influence does it have on prescribing practices?
11. Are prescription medicines available over the counter? Is this a widespread phenomenon? (What proportion of sales?)
12. Are medicines sold informally on the (black) market, in kiosks? Are those activities monitored? By whom?
13. Are you exposed to advertisements from other countries? Which countries? Through which media? Are they different from advertisements from your country? How?



14. Are medicines prescribed by brand or generic name? Does it vary between sectors (public and private)? How?
15. Is generic substitution allowed? Who is allowed to substitute? Is it done in actual practice? What do patients think about it?
16. What is the relationship between health care professionals (doctors, pharmacists, others) and pharmaceutical companies?
17. Do doctors or other health professionals receive gifts from medicines providers or producers? What kinds of gifts are most common? What do you think of this practice?
18. Do doctors receive free samples of medicines? How many free samples of medicines do doctors receive on average in a month? What do you think about this practice?
19. Do doctors or pharmacists receive discounts, rebates or bonuses as an incentive to prescribe and dispense more?
20. Are there concerns about promotional activities? Who is taking action? Healthcare professionals? Consumers? Industry competitors? Do you know of formal complaints being filed? What was the outcome? What do you think of the complaint mechanism?
21. Are there penalties against offenders? Are they published? Do the sanctions deter future violations? If not, why? Is corrective information given to healthcare professionals? Give examples.
22. In your opinion what are the main strengths in the way medicines promotion is regulated in your country?
23. In your opinion what are its main weaknesses?
24. Have important developments affecting drug promotion regulation taken place during the past few years? Are there important upcoming events which will likely influence medicine promotion regulation in your country or region? Please describe them.
25. What is the first thing you would do if you were in a position to change the regulatory situation on medicine promotion?



Interview Schedule: Key Informant from Civil Society Organisation or Patient Group or WHO country office

COUNTRY:

DATE AND LOCATION:

RECORDING: YES NO

INTERVIEWEE

FULL NAME:

TITLE AND AFFILIATION:

E-MAIL:

ADRESS:

PHONE NUMBER:

INTERVIEWER

FULL NAME:

E-MAIL:

REMARKS:



General introduction:

The purpose of this interview is to gather information on the regulatory system in your country concerning medicines promotion. In many countries this is a grey area, there is little awareness about the legislation, what is authorised and what is not. We want to learn more about the regulatory framework, but we also want to know what are the promotional practices used in <COUNTRY> to advertise medicines. The goal is to identify problems and best practices by gathering this information in multiple countries. We review the legislation and interview key stakeholders, such as healthcare professionals, Drug Regulatory Authorities, civil society, the pharmaceutical industry, etc. With this, we hope to provide recommendations to strengthen regulatory systems to improve medicines use and public health in general. After the assessment in your country will be carried out, we will get back to you with the findings.

Did you see the fact sheet on the project? Do you have questions about it?

First of all, I would like you to introduce yourself and to talk to me briefly about the main areas you focus on in your work.

Do you think you are the right person I should talk to in order to learn more about promotional practices?

If not, could you let me know of other people you think might be able to provide valuable contribution?



1. Where do consumers usually go for information on medicines? Are there sources of independent information? Which sources do you use? How do you know about them?
2. What do you think of the content of advertisements for medicines in general? Do you think that information in advertisements is consistent with the actual product characteristics?
3. Are consumers exposed to advertisements from other countries? Which countries? Through which media? Are they different from advertisements from your country? How?
4. What is the relationship between health care professionals (doctors, pharmacists, others) and pharmaceutical companies?
5. Do doctors or other health professionals receive gifts from medicines providers or producers? What kinds of gifts are most common? What do you think of this practice?
6. Do doctors receive free samples of medicines? What do you think of this practice?
7. Do doctors or pharmacists receive discounts, rebates or bonuses as an incentive to prescribe and dispense more?
8. Who is involved in the processes by which medicines are selected to be supplied and/or reimbursed? What is the influence of pharmaceutical companies?
9. Do patient organisations advocate for specific medicines to be registered or reimbursed in your country? Who funds these organizations?
10. Do companies sponsor professional development such as scientific events or Continuing Medical Education? Do sponsors have a role in choosing the speakers or setting the agenda?
11. Are medicines sold informally on the (black) market, in kiosks? Are those activities monitored? By whom?
12. Are prescription medicines available over the counter? Is this a widespread phenomenon? (What proportion of sales?)
13. Are medicines promoted for uses outside of approved indications? Which ones? Do you have examples?



14. Are prescription-only medicines advertised to the public? In which ways? Are there disease awareness campaigns in your country? Do they display brand names?
15. Are medicines prescribed by brand or generic name? Does it vary between sectors (public and private)? How?
16. Is generic substitution allowed? Who is allowed to substitute? Is it done in actual practice? What do patients think about it?
17. Are there concerns about promotional activities? Who is taking action? Consumers? Industry competitors? Do you know of formal complaints being filed? What was the outcome? What do you think of the complaint mechanism?
18. Are there penalties against offenders? Are they published? Do the sanctions deter future violations? If not, why?
19. Are consumers/ civil society organisations involved in regulating promotion? Does the pharmaceutical industry have an official role in the regulation of drug promotion? Which sort of role?
20. If the industry self regulates its promotional activities, does the government have an oversight on the mechanism? How? If not, do you think it has an informal role? How?
21. In your opinion what are the main strengths in the way medicines promotion is regulated in your country?
22. In your opinion what are its main weaknesses?
23. Have important developments affecting drug promotion regulation taken place during the past few years? Are there important upcoming events which will likely influence medicine promotion regulation in your country or region? Please describe them.
24. What is the first thing you would do if you were in a position to change the regulatory situation on medicine promotion?



Interview Schedule for the Pharmaceutical Industry, the Insurers, and the Media

COUNTRY:

DATE AND LOCATION:

RECORDING: YES NO

INTERVIEWEE

FULL NAME:

TITLE AND AFFILIATION:

E-MAIL:

ADRESS:

PHONE NUMBER:

INTERVIEWER

FULL NAME:

E-MAIL:

REMARKS:



General introduction:

The purpose of this interview is to gather information on the regulatory system in your country concerning medicines promotion. In many countries this is a grey area, there is little awareness about the legislation, what is authorised and what is not. We want to learn more about the regulatory framework, but we also want to know what are the promotional practices used in <COUNTRY> to advertise medicines. The goal is to identify problems and best practices by gathering this information in multiple countries. We review the legislation and interview key stakeholders, such as civil society, Drug Regulatory Authorities, healthcare professionals, the pharmaceutical industry, etc. With this, we hope to provide recommendations to strengthen regulatory systems to improve medicines use and public health in general. After the assessment in your country will be carried out, we will get back to you with the findings.

Did you see the fact sheet on the project? Do you have questions about it?

First of all, I would like you to introduce yourself and to talk to me briefly how you are interested in promotion of medicines

Do you think you are the right person I should talk to in order to learn more about promotional practices?

If not, could you let me know of other people you think might be able to provide valuable contribution?



1. What do you think of the content of advertisements for medicines in general? Do you think that information in advertisements is consistent with the actual product characteristics?
2. Do patients request for specific brands of medicines? How much influence does it have on prescribing practices?
3. Do doctors or pharmacists receive discounts, rebates or bonuses as an incentive to prescribe and dispense more?
4. Are prescription-only medicines advertised to the public? In which ways? Are there disease awareness campaigns in your country? Do they display brand names?
5. Are prescription medicines available over the counter? Is this a widespread phenomenon? (What proportion of sales?)
6. Are medicines sold informally on the (black) market, in kiosks? Are those activities monitored? By whom?
7. Does the pharmaceutical industry have an official role in the regulation of drug promotion? Which sort of role? If the industry self regulates its promotional activities, does the government have an oversight on the mechanism? How? If not, do you think it has an informal role? How?
8. Do patient organizations advocate for specific medicines to be registered or reimbursed in your country? Who funds these organisations?
9. Who is involved in the processes by which medicines are selected to be supplied and/or reimbursed? What is the influence of pharmaceutical companies?
10. Are medicines prescribed by brand or generic name? Does it vary between sectors (public and private)? How?
11. Is generic substitution allowed? Who is allowed to substitute? Is it done in actual practice? What do patients think about it?



12. Do companies sponsor professional development such as scientific events or Continuing Medical Education? Do sponsors have a role in choosing the speakers or setting the agenda?
13. Are medicines promoted for uses outside of approved indications? Which ones? Do you have examples?
14. Are there concerns about promotional activities? Who is taking action? Healthcare professionals? Consumers? Industry competitors? Do you know of formal complaints being filed? What was the outcome? What do you think of the complaint mechanism?
15. In your opinion what are the main strengths in the way medicines promotion is regulated in your country?
16. In your opinion what are its main weaknesses?
17. Have important developments affecting drug promotion regulation taken place during the past few years? Are there important upcoming events which will likely influence medicine promotion regulation? Please describe them.
18. What is the first thing you would do if you were in a position to change the regulatory situation on medicine promotion?