This presentation 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.
Promoting Rational Use

Focus on unethical pharmaceutical promotion

• Education
• Assessment
• Analysis
• Advocacy
• Promotion strongly influences prescribing and medicine use
• Health professionals underestimate this influence
• The pharmaceutical industry is a frequent information source on new drugs
• Funding of key opinion leaders, continuing education, and research predicts content favourable to the sponsor’s drug

Review of research evidence
Norris et al 2005
http://www.drugpromo.info/
WHO/HAI Initiative
Education on Pharmaceutical Promotion

• Drug promotion database
  http://www.drugpromo.info/

• Survey of medical & pharmacy faculties
  http://apps.who.int/medicinedocs/en/d/Js8110e/

• Curriculum development
  ➢ Pilot testing
  ➢ Training and implementation
Education on drug promotion
Survey of identified educators, 2005
137 medical, 91 pharmacy = 228 (46% response rate)
<table>
<thead>
<tr>
<th>Key educational aims</th>
<th>Percent n=228</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical appraisal of drug promotion</td>
<td>77%</td>
</tr>
<tr>
<td>Greater use of independent information sources</td>
<td>76%</td>
</tr>
<tr>
<td>Improved prescribing or dispensing after graduation</td>
<td>64%</td>
</tr>
<tr>
<td>Expose students to different perspectives</td>
<td>52%</td>
</tr>
</tbody>
</table>
Those who allocated less time (one half day or less) were less likely to judge the education to be successful.

<table>
<thead>
<tr>
<th>How much time spent?</th>
<th>Pharmacy</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Half day or less</td>
<td>20%</td>
<td>37%</td>
</tr>
<tr>
<td>4 to 9 hours</td>
<td>25%</td>
<td>31%</td>
</tr>
<tr>
<td>10 hours or more</td>
<td>55%</td>
<td>28%</td>
</tr>
</tbody>
</table>
“It is time for medical schools to end a number of long-accepted relationships and practices that create conflicts of interest, threaten the integrity of their missions and their reputations, and put public trust in jeopardy.”

- Institute of Medicine. Conflict of Interest in Medical Research, Education, and Practice, April 2009
Pilot educational manual

Understanding and Responding to Pharmaceutical Promotion

A Practical Guide

First edition
Working Draft for Pilot Field Testing

World Health Organization/Health Action International Collaborative Project
What topics are covered?

1. Promotion of medicines and patient health
2. Techniques that influence the use of medicine
3. Analysing drug advertisements
4. Promotion to consumers
5. Ethical conflicts of interest
6. Regulation of drug promotion
7. Using unbiased prescribing information
8. Promotion, professional practice and patient trust
US PROMOTIONAL SPENDING, 2004

US$ 57.5 billion in promotional spending in the U.S. in 2004

Unmonitored promotion

Samples

e-promotion, mailings, trials

Sales representatives

Journal ads

Meetings

DTCA

Gagno MA, Lexchin J. PLoS Medicine, 2008
Prescriptions for gabapentin by diagnostic category
What information should an advertisement contain?

*Indian Journal of Dermatology, Venereology, Leprology, 2005*
# Common influence techniques

<table>
<thead>
<tr>
<th>Unconscious influences</th>
<th>How they are used in pharmaceutical sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trust in experts</td>
<td>“Professor Z recommends medicine B”</td>
</tr>
<tr>
<td>Trust in peers</td>
<td>“Medicine X is the most frequently prescribed medicine for indication Y”</td>
</tr>
<tr>
<td>Trust in people we like</td>
<td>Use of attractive, friendly representatives.</td>
</tr>
<tr>
<td>Helping those who help us</td>
<td>Use of gifts, including free samples of expensive medicines.</td>
</tr>
</tbody>
</table>
EFFECTS OF “CME” ON VOLUME OF PRESCRIBING

Before a Free Trip — And After

Researchers tracked the change in prescriptions written for a new intravenous antibiotic at one hospital after a pharmaceutical company invited physicians on an all-expenses-paid trip to a luxurious West Coast resort where the drug was promoted.

Drug is added to hospital formulary.
Invitations arrive for the trip.
Doctors meet at the resort.
Prescriptions spike after promotion.

Prescribing at major medical institutions

Orlowski et al. Chest 1992
Sample exercise – Debate

Divide students into debating teams of 4 to 6 people.

Team 1: There is no ethical conflict in physicians and pharmacists accepting money from pharmaceutical companies.

Team 2: It is ethically unacceptable for physicians and pharmacists to accept money from pharmaceutical companies.
Next steps

• Evaluating manual in a pilot study to look at its effectiveness and at areas for improvement
• Revising of material
• Producing a final manual

• WHY DO THIS STUDY?
Pilot protocol

• Randomised controlled trial

• 20 volunteer sites:
  10 intervention sites
  10 control sites
  pharmacy and medical schools

• Quantitative and qualitative methods
to assess change in students’ knowledge, attitudes and skills
Pilot participation

Requirements:
● Medical or pharmacy students

● Site prepared to teach all manual chapters

● Site able to teach within one academic year (12 months)

● Ethics approval gained where required
Volunteers!

- Participating in pilot study
- Testing the manual in your setting
- Contact HAI Global
  Email: lisa@haiweb.org
Pharmaceutical Promotion: A major barrier to rational use

- 1988: WHO Ethical Criteria
- 2007: WHA Resolution on RUM
- Country requests for assistance
- Calls from civil society, governments, donors and the WHO for action
Regulation of Pharmaceutical Promotion: The way forward?

• The WHA Resolution (WHA60.16) urges 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.”
Scoping work

- HAI developing methodology to “scope” current legislation/regulations aimed at controlling promotion
Methodology tools

The methodology relies on:
- document checklist
- literature review
- questionnaire for key informants
- measuring outcomes “on the ground”
Implementing the Criteria

• Using scoping data
• Improving legislation/regulations
• Offering draft language based on EC
Looking ahead

Methodology to scope national legislative/regulatory frameworks (Scoping) + Drafting/implementing model legislation to regulate pharmaceutical promotion = Improved means to curb unethical promotion and advance public health

Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.
Thank you
www.haiweb.org