Patient Information & DTCA in Europe

Teresa Leonardo Alves
Coordinator
Health Action International Europe
teresa@haiweb.org

HAI Briefing
21st May 2008
In 1900...
<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bravo</td>
<td>0.30%</td>
</tr>
<tr>
<td>Real advance</td>
<td>2.34%</td>
</tr>
<tr>
<td>Offers some benefit</td>
<td>6.81%</td>
</tr>
<tr>
<td>Can help</td>
<td>14.60%</td>
</tr>
<tr>
<td>Nothing new</td>
<td>69.02%</td>
</tr>
<tr>
<td>Unacceptable</td>
<td>3.18%</td>
</tr>
<tr>
<td>No decision</td>
<td>3.83%</td>
</tr>
</tbody>
</table>

La Revue Prescrire, 2006
6.5% of all hospital admissions are due to ADRs

Pirmohamed, 2004
Drug Promotion – a conflict?

Public Interest

Rational use of medicines

Pharmaceutical Industry Interest

Maximize sales and returns to shareholders
2002 - Proposal for EU legislative change

- EU Commission proposed a pilot project to allow direct-to-consumer advertising in Europe for asthma, diabetes and AIDS drugs
- Rejected by the European Parliament 494 to 42
- Rejected again by the EU Council in 2003.
- CSO mobilisation: HAI Europe’s role
Fast forward to 2008
European Political Landscape

- Pharmaceuticals still governed by DG Enterprise
- EU Pharmaceutical Forum - large industry representation «» PPP as solutions
- New, vocal and industry-supported patient groups came into play
- Initiative presented under the guise of improving information to patients
Déjà vu all over again?

Information = Advertising!
EU Commission opens door... to DTCA?

• In the legal framework proposed in February 2008, companies would be able to:
  – Communicate directly to the public about their products in all media including TV, radio and internet.
  – Provide information about scientific studies
Why this proposal falls short...

- It is based in a flawed report
- It reflects conclusions of Pharmaceutical Forum
- Manufacturers have an inherent conflict of interest
- Specifically rejects comparative information
- It goes against WHO Ethical Criteria for Drug Promotion
- No health rationale presented to change legislation: Precautionary principle
- Framework opens door to abuse
- Deregulation will lead to weakened legislation: the EU ban on DTCA «» smokescreen
What is prohibited under current EU regulations?

- EU Directive:
  - Article 88 (a) prohibits *advertising* of prescription drugs to the public
  - Article 86 (2) allows information on diseases, as long as there is no direct or indirect reference to a specific product
Allergy may lead to asthma. Snotty nose, stuffy nose or red, irritated eyes may be more serious than you think. Allergy is a disease that, in itself, may lead to asthma.
Unbranded pharmaceutical advertising

- “Disease-mongering” – expanded disease definitions in order to increase sales
- Inaccuracies about disease prevalence, risks, potential treatment benefits
- Failure to comply with standards in WHO Ethical Criteria
- Regulatory response is generally inadequate
NOVARTIS ‘disease-awareness’ TV ads, the Netherlands

Ethical Criteria definition of promotion: stimulates sales

- 't Jong GW et al. British Medical Journal 2004;328:931
Why be concerned?

Can prescription drug advertising lead to harm to health or sustainability of public healthcare?
## Estimated percent of Vioxx sales from DTCA

Based on year 2000 spending and sales data

<table>
<thead>
<tr>
<th>DTCA spending in 2000 (^1)</th>
<th>$160 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Vioxx sales in 2000 (^1)</td>
<td>$1,518 million</td>
</tr>
<tr>
<td>Mean returns (ROI) per $ invested(^2)</td>
<td>$3.66</td>
</tr>
<tr>
<td>Estimated sales from DTCA ((DTCA spending \times ROI))</td>
<td>$588.5 million</td>
</tr>
<tr>
<td>Estimated percent of total sales</td>
<td>39%</td>
</tr>
<tr>
<td>Estimated no. of extra DTCA deaths(^3)</td>
<td>~17,800</td>
</tr>
</tbody>
</table>

---

2. Gascoigne D. *DTC at the crossroads: a direct hit… or miss?* IMS Health 2004
What is happening...

• Opposition from public-health related groups, consumers, payers, healthcare professionals, independent patient organisations

• Contributions to consultation & its evaluation to be made public in May 2008

• EU Commission Directive scheduled to be discussed in October 2008

• Essential to mobilize CSO voice
In conclusion:
Put public health and welfare first

- The public needs unbiased, accurate, comparative information on the pros and cons of all treatment choices, including the option not to treat – not disguised or undisguised advertising.

- Legislation banning unethical drug promotion should be enacted and enforced.

- Industry has a clear role to play:
  - Improve quality of product information, packaging and patient information leaflets;
  - Full public disclosure of all pre- and post-market drug effectiveness and safety studies