Response to European Commission  
Public Consultation, Legal Proposal on Information to Patients

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Barbara Mintzes,  
Assistant Professor,  
Department of Anesthesiology, Pharmacology & Therapeutics,  
University of British Columbia, Vancouver, Canada B.C. V6T 1Z3  
bmintzes@chspr.ubc.ca

Background

I am replying to the Commission’s consultation on information to patients as an academic expert who has researched the effects of direct-to-consumer advertising of prescription medicines on the prescribing and use of medicines. I also work with a research team at the University of British Columbia, the Therapeutics Initiative, which carries out systematic reviews of the effectiveness and safety of new medicines, and which produces a drug information bulletin for physicians and pharmacists in the province of British Columbia, the Therapeutics Letter (available at www.ti.ubc.ca).

I am also a member of Health Action International (HAI-Europe), am on the advisory board of La Revue Prescrire in France, and have been involved in review of EMEA patient information leaflets with HAI-Europe. My response to this consultation thus reflects both expertise on the research evidence concerning the effects of direct-to-consumer advertising, and on independent information on medicines for the public and health professionals.

Recommendations:

1. Article 88, Directive 2001/83/EC should be maintained intact as it provides a legislative safeguard against introduction of direct-to-consumer advertising. There is no public health rationale for weakening or amending this prohibition.

2. Any proposal for legislative change to allow pharmaceutical companies to provide additional ‘patient information’ on prescription medicines to the public in the European Union raises concerns about introduction of direct or disguised prescription drug advertising. The only form of information currently prohibited in law is advertising; presumably changes to advertising are under discussion. This needs to be discussed openly and honestly. The term ‘patient information’ should not be used as a proxy for pharmaceutical advertising. EU Member States have endorsed the WHO Ethical Criteria for Medicinal Drug Promotion. These criteria specify that promotion, “should not be designed so as to disguise its real nature.”

3. If the aim is provision of good-quality, objective, reliable and non-promotional information on medicinal products, there is no place for disguised or direct pharmaceutical advertising as an information source. Prescription medicines are serious medical treatments, and those who are ill and seeking medical care are a vulnerable population. They are not ‘consumers’ in an open marketplace; they are EU citizens and residents with healthcare needs. Experience with advertising in the U.S. and New Zealand has shown just how poor the quality of the information
is. Medicines are presented as though they are 100% effective. Messages are emotive and often promote fear that mild symptoms may represent a more serious underlying disease. Risks of medicine use are frequently minimized. The choice of which product to advertise is also highly problematic. In the US, more money was spent advertising Nexium (esomeprazole) than any other prescription medicine. This is an isomer of omeprazole (Losec or Prilosec); at equipotent doses it would be biologically implausible to expect a difference in action on the body. AstraZeneca has spent US $1.2 billion over 6 years on US DTC advertising for this product, which only exists as a means of extending patent protection. Schering-Plough and Merck spent US $200 million in 2007 advertising Vytorin (ezetimibe + simvastatin) to the US public. Simvastatin is off-patent and available generically at a much lower price. There is no evidence that ezetimibe reduces the risk of heart attack or stroke; the only clinical trial evidence available until April 2006 was limited to lowering of cholesterol, by blocking absorption. In April 2006, the first clinical trial was completed on effects on arterial plaque. Ezetimibe did not affect the build-up of arterial plaque. Publication of this trial did not occur until April 2008. The manufacturers would have been aware of trial results when they spent US $200 million spent on advertising in the US in 2007. The US public had no access to this information. Similarly, Merck spent US $550 million advertising Vioxx (rofecoxib) to the US public, mainly after the results of the VIGOR trial had shown an increase in cardiovascular events and total serious adverse events. The list could go on. Had all of these advertising campaigns been called ‘patient information’ instead and perhaps used a ‘shopping channel’ approach on television, they would have been as problematic from a public health perspective in terms of product choice.

4. The public needs access to independent, comparative information on the pros and cons of all available treatment options, including non-drug options and the option not to treat. Pharmaceutical manufacturers are not an appropriate source of comparative health information, as they cannot be expected to provide information about their own products that would interfere with sales, or about their competitors’ products that would lead to higher sales at their own expense. Nor can they be expected to inform the public that it is best to avoid drug treatment if this would interfere with product sales. Pharmaceutical manufacturers are first and foremost responsible to shareholders to maintain sales and profitability. This creates an irreconcilable conflict of interest in terms of health and medicines information provision.

5. It is naïve at best and disingenuous at worst to expect that a clear line can be drawn between advertising and ‘non-promotional information’ provided on television, radio, newspaper, magazines billboards or other media (including as paid communication) by pharmaceutical manufacturers about their prescription medicines. The ‘patient information’ under discussion in this consultation document appears to be advertising by any other name. There is extensive experience in many parts of the world, including the European Union, with disguised prescription drug advertising. The current initiative, rather than addressing this problem with a regulatory solution to prevent misleading information provision in disguised advertising, appears to aim to create a higher volume of misleading disguised advertising. There is also experience in many jurisdictions, including in Canada, with pre-screening by ‘co-regulatory’ bodies, that bodes ill for the likelihood of effective prevention of messages with a negative public health impact.
6. If the aim of this initiative is to ensure that access to patient information leaflets, EPARS, and other approved product information is similar across all countries of the European Union, no change to Article 88 is required. The EMEA could develop a more extensive web portal linked to national websites.

Additional background information: public health impacts in Canada
The situation in Canada is of relevance to the current EU consultation, in that Canada prohibits direct-to-consumer advertising of prescription medicines, but has introduced limits to enforcement of the law in response to strong pressure from the pharmaceutical and advertising industries. One of the key initiatives to limit enforcement was an administrative policy that attempted to define non-promotional ‘information’ from pharmaceutical manufacturers. This has led to a plethora both of direct and disguised advertising. Although the volume of drug promotion is not nearly as high as in the US, with full direct-to-consumer advertising of prescription drugs, many promotional messages reach the public with negative public health impacts. This is despite pre-screening by ‘co-regulatory bodies’ (Advertising Standards Canada and the Pharmaceutical Advertising Advisory Board). Examples include unbranded off-label promotion for Xenical (orlistat) by Hoffman-LaRoche for women wanting to lose a few pounds, unbranded advertising messages using fear of death to sell a cholesterol-lowering drug (Pfizer, Lipitor) and television advertisements for several drugs that have been subject to Health Canada safety advisories, including Diane-35 (ciproterone/estradiol) and more recently Celebrex (celecoxib). The messages in these advertisements often directly contradict the safety advisories recommending limited and judicious use.

I was asked to examine the public health implications of direct-to-consumer advertising in Canada for the Health Council of Canada, an independent agency with joint provincial, territorial and federal government membership, set up in 2002 to oversee the accountability and transparency of Health Care Services in Canada. I am enclosing a copy of the January 2006 report, given the relevance to the current consultation. Available at: