Consumers International
Response to the European Commission
Consultation on a Legal Proposal on Information to Patients.

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About Consumers International

Consumers International (CI) is the only independent global campaigning voice for consumers. With over 220 member organisations in 115 countries, we are building a powerful international consumer movement to help protect and empower consumers everywhere. For more information, visit www.consumersinternational.org

CI is a not-for-profit company limited by guarantee, company number 4337856, and registered charity number 1122155.

CI has been working on defending consumer protection in relation to health for over twenty years. Our current work focuses on supporting credible solutions to prevent irresponsible drug marketing through our Marketing Overdose campaign (www.marketingoverdose.org)

Key messages

1. CI fully endorses and supports the submissions of The European Consumers' Organisation (BEUC). In particular, we urge the EC take note of the policy options outlined by BEUC on what credible steps can be taken to improve patient access to drug and health information within the existing legal framework (page 7).

2. In light of this policy framework, we also firmly assert that DG SANCO must be allocated as the lead agency on medicines policy in relation to patients, and be appropriate resourced and mandated as such. Our recommendations in this respect are based on observation of the overwhelming industry bias in the consultation and decision making process taken by the EC thus far, and in the skewed weight given to industry concerns on competitiveness as a result.

3. In addition to the gaps and recommendations made by BEUC, CI would like to stress the following points in relation to the EC proposal from an international consumer perspective:

A. Eroding consumer protection through a weak monitoring structure

As stated in the BEUC response, a key issue from a consumer protection perspective that has not been resolved via the current legal proposal is the lack of a coherent distinction between advertising and non–promotional information.

However the EC proposal seeks to manage this fundamental problem through the establishment of a monitoring structure. The proposed national code of conduct and monitoring mechanism bears a stark resemblance to the prevailing self-regulatory approach taken in monitoring advertising of prescription drugs by the pharmaceutical industry and risks replicating the same problems evident in the regulation of drug promotion, in the arena of consumer information.

In principle, the national co-regulatory body should require independence from the pharmaceutical industry in order to avoid potential conflicts of interest. However the role of independent providers of drug and health information has been grossly overlooked in this structure. Rather the current proposal would see drug companies sitting in judgement of themselves (a perversion of the concept of natural justice), and we do not believe that patient

groups who receive a significant portion of their funding from drug companies would be in an appropriate position to criticise their donors in this context.

On the basis of research carried out in relation to the regulation of DTDA in Europe CI is concerned that such systems are too weak, industry focused and ineffective to give consumers adequate protection.

Large numbers of serious, recent and repeated breaches of marketing codes were found, especially regarding prescription drug advertising. Between 2002 and 2005 there were 972 breaches of the ABPI code. Alarmingly the largest proportion of the breaches – more than 35% - had to do with misleading drug information.[1] This shows that the current regulatory framework is clearly insufficient to prevent systemic violations of marketing regulations, and to ensure the highest possible level of consumer protection.

Furthermore, the overall lack of documented approval procedures for drug promotion is conspicuous. Nineteen of the twenty companies are obligated under the European Federation of Pharmaceutical Industries (EFPIA) Code of Practice on the Promotion of Medicines to clear all promotional materials before they are released. Despite these obligations however, only four companies (AstraZeneca, Bristol-Myers Squibb, Novartis, and Roche) describe clear corporate procedures for the approval of all promotional materials.[2] Such examples show that industry self-regulation of drug promotion is weak and is generally inadequate to protect consumers from potentially misleading claims.

CI would like to reiterate support for BEUC's position that the proposal fails to differentiate between information and advertising. This fundamentally highlights the need to prevent the pharmaceutical industry from acting as a primary source of consumer health information.[3] Instead, the EC should ensure a European public health information system that is supplemented by effective regulation of drug marketing and emphasises independent provision of *appropriate* health and medicines information to consumers.

B. US experience of DTCA

As previously stated, CI does not accept that the proposal makes a sufficient distinction between information provision and advertising. Despite the claims made in the proposal CI believes that information provision dominated by an industry bias and delivered in the methods suggested will amount to advertising in all but name. It is reasonable to suggest that if the pharmaceutical industry is successful in this challenge they will, over time, take further steps to weaken the ban on advertising. Therefore it is relevant to look at the experience of countries where DTCA is legal, in particular the United States.

Research published in the New England Journal of Medicine[4] in 2007 points to the challenges to effectively regulating consumer focussed promotion from industry sources. They also demonstrate the staggering level of resources that are levied by the drug industry in such promotion activities and calls into question whether this is the most effective and efficient method of informing consumers of health and medicines issues. For example: total spending on

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[1] Consumers International. 2006. *Branding the Cure: A Consumer Perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe*. pg. 16

[2] Ibid. pg 22.

[3] In addition to poor performance on self-regulation of marketing, the drug industry also faces the immense challenge of positive bias. For example, in one study 84% of industry-sponsored studies showed positive results compared to 62% of those with no backing from drug manufacturers (Source: Ibid. p. 26).

[4] Donohue, Julie M; Cevasco, Marisa and Rosenthal, Meredith B. 2007. Decade of Direct-to-Consumer Advertising of Prescription Drugs. In *The New England Journal of Medicine*. August 16, 2007, Volume 357:673-681. Number 7.

pharmaceutical promotion grew from $11.4 billion in 1996 to $29.9 billion in 2005. Although during that time spending on direct-to-consumer advertising increased by 330%, the number of letters sent by the FDA to pharmaceutical manufacturers regarding violations of drug-advertising regulations fell from 142 in 1997 to only 21 in 2006.[5]

In addition, research has shown that when consumers receive drug and health information from industry-dominated sources, the impacts include the medicalisation of consumer lifestyles at the expense of messages about prevention or non – medical solutions and increased cost of health care with little evidence of improved health outcomes. This matters because there is evidence that advertising plays a very important role in affecting which medicines a patient receives: More than 30 percent of Americans asked their doctors for prescriptions based on drug advertisements, according to a new joint study by the Kaiser Family Foundation, Harvard School of Public Health and USA Today. Within that group, more than 80 percent had the prescription filled by a doctor.[6]

Our research has shown that existing regulatory mechanisms in the EU need to be strengthened and harmonised across EU member countries. However, by opening the door for greater industry influence in drug and health promotion, the EC proposal reinforces fragmented national approaches to this issue and amounts to a further erosion of consumer protection from a health policy perspective.

C: The international implications of the EC proposal

CI believes that in light of the considerable effort by the pharmaceutical industry to expand operations in emerging markets, the EU legal proposal could set a dangerous precedent for countries who are simply not equipped to cope with the monitoring and enforcement of information to patients as envisaged by this proposal. In particular our research from developing and emerging markets illustrates[7]:

- Less than one sixth of countries have a well-developed system of drug regulation
- Even a relatively well-developed emerging economy country like India lacks the capacity to warn consumers and take effective regulatory action when a drug is recalled abroad. Vioxx was still available on the domestic market a whole year after it was officially banned.

This weak enforcement capacity has led to major social responsibility breaches by European multinational companies in the area of drug marketing. Our research highlighted many such practices, including examples of flawed information provided by Novartis in Pakistan, unqualified claims of safety by Glaxo Smith Kline and potentially misleading claims by Roche in Thailand.[8]

Whilst the proposal only refers to changes in European regulations it would be naive to suggest that any change would not influence decision-making in other parts of the world. Therefore it is important for the EC to consider the impact that such changes could have outside Europe – particularly in countries without the regulatory capacity that exists within the EU.

[5] Ibid.
[6] Source: http://www.politico.com/news/stories/0308/8938.html
[7] Consumers International. 2007. *Drugs, Doctors and Dinners: How Drug Companies Influence Health in the Developing World.* Pg. 7
[8] Ibid. pages 27-29.