HAI EUROPE RESPONSE

THE EC LEGISLATIVE PROPOSAL ON "INFORMATION TO PATIENTS"

Amsterdam, 15 October 2008

Dear Sir/Madam,

We are aware that the Commission is about to release a legislative proposal on "information to patients" (amending Directive 2001/83/EC on the Community code relating to medicinal products for human use).

We understand that this proposal includes modifications to Article 88, which would allow pharmaceutical companies to carry out some forms of advertising of prescription drugs to the public that are currently prohibited in Europe.

Any weakening of Article 88 is unacceptable from both a public safety and a cost perspective. Advertising of prescription drugs to the public – whether disguised as "patient information" or not – has been shown to lead to higher expenditures for medicines without any additional benefits to health or health care quality. Supporting legislation that will ultimately lead to higher government health expenditure at a time of economic uncertainty is unconstructive and fiscally irresponsible.

We would like to highlight the following points about the proposed changes to Directive 2001/83/EC for your consideration:

- Prescription drug advertising raises serious public health concerns because it stimulates widespread use of new drugs before their potential for harm is fully known.
- The right to publish "information" in printed media is very obviously direct-to-consumer-advertising (DTCA). Moreover, "advertorials" are known to be even more influential than outright advertising.
- The experience of rofecoxib (Vioxx®) in the USA demonstrates how much harm can be caused by directly and heavily promoting prescription medicines to patients and consumers.
- Article. 86 of Directive 2001/83/EC already allows the industry to provide information to patients, including "factual information", responses to queries, and disease related information in the media. Tackling the asymmetrical enforcement of this article across member states does not require any legislative changes.
- Deficiencies in DTCA monitoring by the Food and Drug Administration (FDA) in the USA reflects a lack of resources for this monitoring role. These same resource difficulties would apply in most EU member states.
- "Factual informative announcements" on prescription medicines by the industry are of little value for patients' treatment regimes but are of enormous value in reminder adverts for the pharmaceutical companies. Their main purpose is to stimulate additional sales through emotive branding images and messages.
- "Information which presents the medicinal product in the context of the condition to be prevented or treated" is structurally biased when comparative information is not allowed, as is the case in the Commission's proposal.
- "Medicinal product-related information about non-interventional scientific studies" is based on partial (or even flawed) epidemiological studies or commercially oriented phase 4 research ("seeding" trials) generated by the very same companies producing the prescription medicines.
- There is no overarching public health benefit to allowing pharmaceutical companies to rewrite summaries of product characteristics and package leaflets that have already been cleared by health regulatory authorities.

Health Action International (HAI) supports consumer and patient rights to independent, relevant, unbiased and comparative information about health, medicines and treatment. However, the proposed amendments do not contribute to this right and, instead, jeopardize patients' and consumers' ability to make informed decisions about their health.

We respectfully request that the Commission reconsider its support for the proposed changes in light of their potentially damaging effects on public health, healthcare and fiscal responsibility in the European Union.

Yours faithfully,

Teresa Alves, ***HAI Europe***

Overtoom 60, II
1054 HK Amsterdam
The Netherlands
terri@haiweb.org
www.haiweb.org