

EC Pharma Package Article 100b: Opening the door to advertising

11 December 2008

As DG Enterprise's pharmaceuticals package came up for discussion at the college of Commissioners yesterday, all eyes were on the contentious proposal on 'information to patients' that is undoubtedly a relaxation on regulations for direct-to-consumer-advertising (DTCA) of prescription-only medicines in Europe.

Advertising or promotion of prescription medicines stimulates widespread use of new medicines before their potential for harm is fully understood. Yet, the proposals open the door to such promotion by allowing pharmaceutical companies to publish 'information' in health-related printed media, including health supplements, despite the fact that advertorials are known to be more influential than outright advertising.

Article 100b gives pharmaceutical companies a free reign to present "the summary of product characteristics, labelling and the patient information leaflet of the medicinal product...in a different way" than is currently permitted under EU regulations. This is a redundant public health measure given that this information is already available on the European Medicines Agency (EMA) website for centrally approved products and on some national regulatory agencies websites for other products. The only real rationale for a change in the law is the commercial benefit of expanding the marketing reach for pharmaceutical companies operating in Europe.

The same article foresees the provision of "Factual informative announcements" on prescription medicines by the industry, which are of little value for patients' treatment regimes but of enormous value as reminder adverts for their products. They are hugely effective at inflating sales through emotive branding images and messages.

The proposed system of self-regulation or co-regulation to review information prior to dissemination is of little comfort, given that those with a clear conflict of interest would be handed authority over the information provided to patients and consumers.

HAI Europe is urging Parliamentarians to consider carefully whether the Member States of the European Union really want to join the minority club of two (The United States and New Zealand) that allow prescription-only medicines to become just another branded commodity.

For more information on DTCA in Europe, please go to:

<http://www.haiweb.org/10122008/Issue%20Quick%20Sheet%20DTCA.pdf>

<http://www.haiweb.org/10122008/DTCA%20Chronology%20Document.pdf>

The proposal is available at:

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_en.htm

The logo for Health Action International (HAI) Europe, featuring the letters 'hai' in a large, white, lowercase font over a dark blue background with a faint map of Europe. Below 'hai', the word 'EUROPE' is written in a smaller, white, uppercase font.

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PRESS RELEASE

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