

Information to patients

Health organisations urge MEPs to reject Commission proposals

By Sophie Petitjean | Wednesday 17 November 2010

Ahead of the European Parliament's vote on the directive on information to patients, which will take place on 23 November, four health organisations have called on MEPs to oppose the European Commission's proposals with regard to the public provision of information relating to drugs subjected to medical regulation, specifically for a directive to modify Directive 2001/83/CE and a regulation to modify (EC)726/2004. In a 16 November letter, the Association Internationale de la Mutualité (AIM), Health Action International (HAI) Europe, the International Society of Drug Bulletins (ISDB) and the Medicines in Europe Forum (MIEF) have objected to pharmaceutical companies being the sole judge of how and when to provide information on their products to patients.

In adopting reports by Christopher Fjellner (EPP, Sweden), on 28 September, environment and public health officials focused proposals on patients' interests and limited direct information. Thus, a minimum of information, such as the approved contents and the most recent summaries of the product's characteristics and labelling was suggested by the evaluation report, which added that these should be made available via restricted media, namely a website for this specific purpose to be set up by member states or specialised booklets. Other information, such as the environmental impact of a product, prices, changes to packaging and instructions would be available only with prior approval.

But for the four associations, the modifications are still not sufficient, as they argue that the establishment of certain national control systems would lead to self-regulation, behind which the pharmaceutical companies could hide while the comitology procedure would liberate the Commission from further responsibility. The proposals, they argue, even if further modified, would generate more bureaucracy, expose patients to greater risks and bring additional costs for member states, which would have to deal with the consequences. "In spite of the modifications proposed by the ENVI committee, the goal of the Commission's proposals remains the same: to further prohibit access to information for consumers of drugs that are subject to medical regulation. [...] However, in terms of public health, and even acknowledging the risks and additional costs that it would generate, greater prohibition applied to pharmaceutical companies, even concerning information, must be maintained," declared the four health organisations.

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