



Pharmaceutical companies “informing” the public: one step closer to legalising reminder advertising for prescription drugs?

The proposals improved by ENVI Members of European Parliament still do not benefit patients and some provisions are even detrimental

On 28 September 2010, the European Parliament’s Environment, Public Health and Food Safety Committee (ENVI) gave its verdict on the European Commission’s proposals aimed at legalising direct-to-consumer advertising (DTCA) of prescription drugs. This vote was pivotal (a). The Members of the European Parliament (MEPs) improved the European Commission’s proposals substantially (1-3). However certain loopholes still remain.

Prior approval of “information” by Member States. The MEPs have clearly expressed their reservations about allowing direct communication from pharmaceutical companies to the general public. In particular, they voted in favour of the prior approval of any “information” from pharmaceutical companies by health authorities before it is made publicly available (D- AM 13) (b). They also refused to allow the distribution by health professionals of brochures and “patient-information” from pharmaceutical companies without any health authority control (D- AM 31).

Yet, at the same time, the MEPs agreed that certain Member States can continue to use control systems established before 31 December 2008, once they have been approved by the Commission (D- AM 55). This could lead to *de facto* approval of a system based on self-regulation (monitoring by associations composed entirely of pharmaceutical companies), or on co-regulation (if the organisation also involves players other than pharmaceutical companies).

In the current uncertain economic climate, if Member States are obliged to monitor and approve “information” from pharmaceutical companies before it is made publicly available, they will inevitably have to face the following questions: is it better to devote public resources:

- to providing the public with independent, comparative information and to increasing the transparency of the drug regulatory agencies?
- or, contrary to that approach, to attempt to enforce laws, and to monitor the pharmaceutical industry? With the latter approach, is it feasible for the health authorities to check every document, website and its updates thoroughly? And, while record fines of up to several billion dollars have failed to dissuade pharmaceutical companies from infringing the current regulations on advertising (4), is it plausible that the health authorities will manage to impose sufficiently dissuasive penalties? (c).

Several forms of disguised advertising rejected. MEPs clearly rejected several forms of disguised advertising that were proposed by the Commission to enable pharmaceutical companies to communicate directly with the public about their prescription drugs, including:

- refusing to allow for pharmaceutical companies to execute commercial campaigns claimed to be in the interest of public health (D- AM 26);
- refusing to allow for the dissemination of information in which elements taken from the officially approved information could be presented “*in a different way*” (D- AM 33);
- refusing to allow for pharmaceutical companies to disseminate medicinal product-related information to the general public about non-interventional scientific studies, or about preventive or treatment measures; and refusing to allow for the dissemination of “information” that presents the drug in the context of the condition to be treated or prevented (d) (D- AM 33);
- refusing to allow for “information” from pharmaceutical companies to be published in newspapers, magazines and similar publications aimed at the general public” (D- AM 34).

However, if the European Commission is left to define the criteria for distinguishing between “information” and advertising (D- AM 15) as well as numerous other guidelines, particularly the code of conduct on what types of information can be made available to the public (comitology procedure), it will put an end to democratic debate - a debate that is surely necessary with such controversial proposals.

There are still too many opportunities for pharmaceutical companies to reach the public, giving companies an unacceptable advantage over other players. In addition to the officially approved information on their product (e), which will have to be presented in a way that “*faithfully represents the officially approved information*” (D- AM 33(1)), and oral or written answers to patients’ questions (D- AM 34), the MEPs agreed that pharmaceutical companies can make various other types of “information” about their products available to the public, including: environmental impact, price, pack changes, adverse-reaction warnings, instructions for use including through videos (“*moving images*”), reimbursement, preclinical tests and clinical trials contained in the public assessment report, and answers to frequently asked questions (D- AM 33(2)).

The media that can be used to disseminate this information are:

- printed documents (showing the company’s contact details in case patients have further questions (D- AM 41));
- and any websites that the marketing authorisation holder wishes to use, on condition that the websites are registered with the health authorities of a Member State, that the websites’ content is identical to the content of the website that was first registered, and that the pharmaceutical company is clearly identified (D- AM 58 and AM 59).

The company is free to choose which Member State it registers its websites in, and the Member State’s health authorities are then responsible for monitoring the websites (D- AM 63). The MEPs requested that modifications to the content of these websites should also be monitored (D- AM 60).

These websites, which can include videos, will allow identification of members of the public who use them, after requesting their explicit consent, and must not be used to proactively distribute unsolicited content (D- AM 61).

The websites must include a link to the Community database (Eudrapharm), which contains information about health products (D- AMs 50, 62 and 66). However, there is a risk that the independence of Eudrapharm will be undermined, particularly with regard to its content, by measures that unacceptably favour “information” from pharmaceutical companies over information for patients produced by other actors in the healthcare sector (patients’ organisations, consumer groups, organisations representing health professionals, health insurance bodies, etc.) (f).

Where is the benefit for patients in these legislative changes? What cost to Member States? One may wonder what real benefit patients will derive from the “information” that the MEPs agreed to allow pharmaceutical companies to disseminate:

- what is the public health benefit of allowing pharmaceutical companies to inform the public about the price and reimbursement of prescription-only medicines? Is it not simply a pretext to use reminder advertising as a marketing strategy? (g) (5); patients need independent comparative information if they are to be enabled to make informed choices (h).
- does it make sense to entrust the task of warning patients about the adverse effects of medicines to the pharmaceutical companies that sell them, when experience continues to show that companies tend to try to conceal information that damages the image of their products (examples in the last decade include the pharmacovigilance scandals involving *rofecoxib* (Vioxx^o) in 2004, and *rosiglitazone* (Avandia^o) in 2010)? (6,7);
- would it not be better if frequently asked questions were identified during the phase in which the package leaflet is tested on a sufficient number of representative patients, and the answers were incorporated into the final package leaflet (implementation of article 59(3) of Directive 2001/83 consolidated)?
- in the name of environmental protection, is it a top priority to allow pharmaceutical companies to tell consumers about the environmental impact of the products they market? Would it not be better, for example, to organise campaigns to raise public awareness about how medicines cause water pollution and to encourage citizens to return unused medicines to the pharmacy, so that they can be destroyed correctly?

The current European legislative framework is clear and already allows pharmaceutical companies to make the officially approved information available, for example, by referring the public to drug regulatory agency websites, where this information must be accessible.

The changes proposed will not bring significant added value for patients. On the contrary, they will generate additional bureaucracy, causing a significant increase in expenditure. They will also expose patients to more risks, and incur higher costs for Member States (i.e. to manage any adverse effects caused by medicines that patients either did not need, or should have avoided due to drug interactions with their existing treatments, etc.) (9,10).

Some progress in transparency. One notable advance is the adoption of the requirement for health professionals who deliver information on a medicine in public or in print to declare their interests (D- AM 29), as is already the case in France (8).

The MEPs also assigned a greater role to Member States, and in particular to their drug regulatory agencies, as proactive providers of health information, by stating that the public should at least have access to (D- AM 79):

- the officially approved information on the medicine;
- independent information about the diseases and health conditions that are to be treated with the medicine;
- measures for preventing these diseases.

Paradoxically, the MEPs did not adopt important amendments to the Regulation that would have truly increased the transparency of the drug regulatory agencies. Neither public access to the database on adverse effects (Eudravigilance) nor public access to the clinical trials database (EudraCT) were adopted.

In summary. The MEPs have improved the European Commission's initial proposals by refusing to support several forms of disguised advertising, and by proposing that monitoring by the Member States' health authorities be the main safeguard. However, despite these palliative improvements, neither the proposed Directive nor the proposed Regulation represent an advance for European citizens or Member States. On the contrary, these proposals would mean additional bureaucracy, higher expenses, and greater risks for patients (9,10,11).

Any product information that is provided by those who sell them must be presumed to be promotional. In public health terms, **given the health risks and the additional cost, the ban on the advertising of prescription medicines by pharmaceutical companies, even when disguised as "information", must be maintained.**

Medicines are not other, normal consumer products. **In order to protect public health, we urge MEPs to reject these proposals outright at the plenary session to be held on 23 November 2010. And we urge the Ministers for Health of the Member States to continue to refuse to consider these unnecessary proposals, which would damage public health.**

Notes:

a- Indeed, in the face of opposition from civil society and Member States, Commissioner Dalli (Directorate General for Health and Consumers, known as "Sanco") recognised the need to "re-assess" the European Commission's initial proposals, but he indicated that he would wait for the vote on the first reading to learn the European Parliament's position (ref. 12).

b- We show in brackets the numbers of important amendments presented in the reports adopted in ENVI Committee. Amendments (AM) presented in the report on the proposed Directive (ref. 2) are preceded by "D- AM"; and amendments presented in the report on the proposed Regulation (ref. 3) are preceded by "R- AM".

c- The fact that the penalties for failure to comply with the requirements regarding the dissemination of information by pharmaceutical companies are to be determined at the Community level (D- AM 68) and that the authorities are permitted to publish the names of pharmaceutical companies that infringe regulations (the "name and shame" principle) (D- AM 67) are interesting approaches, but do not go far enough.

d- However, amendment 22 to the Directive opens the way for reminder advertising of therapeutic classes: information about health and diseases can be used to refer to classes of drugs, even if individual products cannot be mentioned.

e- The officially approved information on a drug is represented by the labelling (which must always include the international nonproprietary name (D- AM 19)), mock-ups of packaging items including the package leaflet, the Summary of Product Characteristics, and Public Assessment Reports prepared by the health authorities, and any updates thereof. One amendment to the Directive lays down that European Public Assessment Reports prepared by the health authorities must "list the other available therapeutic options and whether the new medicinal product brings about a therapeutic value" (D- AM 45), whereas the Regulation does not specify this point.

f- Two amendments to the Regulation would undermine the independence of how Eudrapharm is run. Whereas the Regulation stated that Eudrapharm would be managed "independently of pharmaceutical companies", an amendment challenges this independence by specifying that it should be managed "*independently of the commercial interests of pharmaceutical companies*" (R- AM 10), which opens the door to pharmaceutical companies taking part in the running of Eudrapharm.

Another amendment obliges the European Medicines Agency to include in the Community Eudrapharm database "information" submitted by pharmaceutical companies to national authorities and approved by those authorities (R- AM 12). While the "information" that pharmaceutical companies want to disseminate to the general public will be promoted on the Community's Eudrapharm database, other actors in the healthcare sector (patients' organisations, consumer groups, organisations representing health professionals, health insurance bodies, etc.) will be unable to make the independent information they produce available there.

g- Reminder advertising is a standard marketing practice that aims to remind the general public of the name of a particular brand by using every possible opportunity to write or talk about the product, using in particular branding and emotive messages.

h- Useful patient information should enable users to analyse their concerns, give them a realistic idea of the evolution of their health status, help them to understand when further investigations are necessary, to know what treatments exist and what they can expect from them, and to make informed choices (or participate in the choice) among the different available options.

Selected references from the Medicines in Europe Forum's literature search:

- 1- Our joint analysis of the Commission's initial proposals in December 2008:
AIM, ESIP, ISDB, MIEF "Legal proposals on "information" to patients by pharmaceutical companies: a threat to public health" (6 March 2009)
www.prescrire.org/docus/LegalProposalsInfoPatient_JointPaper_March2009.pdf.
- 2- The version of the Directive as amended by the ENVI Committee (report by MEP Fjellner) (123 pages)
www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0290+0+DOC+WORD+V0//EN&language=EN
- 3- The version of the Regulation as amended by the ENVI Committee (report by MEP Fjellner) (37 pages).
www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0289+0+DOC+WORD+V0//EN&language=EN
- 4- Barrett D "Pfizer to pay record \$2.3B penalty for drug promos" *Associated Press* 2 September 2009.
- 5- Mintzes B, Morgan S, Wright JM. "Twelve years' experience with direct-to-consumer advertising of prescription drugs in Canada: a cautionary tale" *PLoS One*. 2009 May 27;4(5):e5699. (freely available)
- 6- Prescrire Editorial Staff "How to avoid future Vioxx^o-type scandals" *Prescrire Int* 2005; **14** (77): 115-117.
- 7- Wang AT et al. "Association between industry affiliation and position on cardiovascular risk with rosiglitazone: cross sectional systematic review" *BMJ* 2010 Mar 18;340:c1344. doi: 10.1136/bmj.c1344.
- 8- Article L4113-13 du Code de la Santé publique français créé par Loi n°2002-303 du 4 mars 2002 - art. 26 JORF 5 mars 2002.
- 9- Kravitz et al. "Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial" *JAMA* 2005; 293: 1995-2002.
- 10- Mintzes B et al. "How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA" *CMAJ* 2003; 169 (5): 405-412.
- 11- US Government Accountability Office (GAO) "Prescription drugs. Improvements needed in FDA's oversight of direct-to-consumer advertising" November 2006. www.gao.gov: 52 pages.
- 12- "Publicité grand public pour les médicaments de prescription ? Un automne 2010 crucial" *Rev Prescrire* 2010; 30 (323): 700 – 701.



AIM. The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org. Contact: rita.kessler@aim-mutual.org.



HAI Europe. Health Action International (HAI) is an independent global network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org. Contact: katrina@haieurope.org.



ISDB. International Society of Drug Bulletins (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, it has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact: president@isdbweb.org; secretary@isdbweb.org.



MiEF. Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.