



Brussels, 13 July 2010

Towards direct-to-consumer advertising of prescription drugs in Europe? *Upholding patients' rights to reliable information*

Summary:

- MEPs will soon be voting on the highly controversial patient “information” proposals (a Directive and a Regulation) (vote in the Environment, Public Health and Food Safety Committee (ENVI) scheduled for September 2010).
- This could be an opportunity to transform these proposals from a threat to public health into progress for patients. To do this, MEPs must vote for the amendments aimed at enhancing access to non-promotional, independent and comparative information. Of particular importance are those amendments boosting the transparency of European and national Drug Regulatory Agencies.
- The *Medicines in Europe Forum*, *Health Action International (HAI) Europe* and the *International Society of Drug Bulletins (ISDB)* also urge MEPs to uphold the strict ban on direct-to-consumer advertising. For example, pharmaceutical companies must not be allowed to publicly disseminate “information” derived from official information, while selectively highlighting the benefits of the drugs and glossing over potential adverse drug reactions. Experience has shown how skilfully advertisers can exploit this sort of loophole.

Evidence gathered in the USA shows that direct-to-consumer advertising (DTCA) for prescription drugs is highly profitable for companies, and disastrous for public health and health budgets (1-3).

Since the start of this decade, pharmaceutical companies have been lobbying for the ban on DTCA of prescription drugs to be lifted (4). In the face of stifling innovation, the pharmaceutical companies' marketing efforts are now targeted at patients in order to protect the volume of drug sales and to foster future growth (a).

In 2002, in order to protect public health, MEPs massively rejected (by 494 votes to 42) a proposal to lift the ban on DTCA of prescription drugs, even though it would have been introduced under the guise of a “pilot project” (4).

Despite this, pharmaceutical companies, some press groups and the European Commission continued to push for this ban to be lifted. And in December 2008, the European Commission's DG Enterprise and Industry proposed highly controversial Directive and Regulation (b).

These proposals are currently under discussion at the European Parliament (5,6). The vote in the Environment, Public Health and Food Safety Committee (ENVI) is scheduled for September 2010.

Advertising under another name: the terms may change but the aims are the same. Under the proposal, it is no longer called direct-to-consumer “advertising”, but direct-to-consumer “information”; it is no longer a question of the companies' right to advertise but of the patients' right to access information... (7). In reality, the European Commission's proposals on patient-“information” on medicines focus on a single aspect: enabling companies to communicate directly to consumers about their prescription drugs (8).

Crucial amendments. Guaranteeing patients' access to relevant, reliable information needs to be governed by strict control of direct-to-consumer communication by pharmaceutical companies, which should be confined to official information, while the health authorities should play a greater part in information sharing.

Some 300 amendments to the Directive proposal have been filed, and 30 to the Regulation proposal (9-12). The amendments to the Directive proposal show that many MEPs are aware of the dangers inherent in allowing companies to communicate directly to the public on prescription medicines (c).

If there is no majority to reject the whole text (amendment 28 to the Directive), the debate should, above all, focus on the **content of the “information” that companies would be allowed to provide and on the type of media they would be permitted to use**. For example, several MEPs propose to:

- restrict the dissemination of this “information” to clearly recognisable company websites (amendments 181 and 267);
- ban the use of videos (amendment 260);
- emphasise the need for monitoring by competent authorities in each Member State (amendments 54, 58, 75, 231, 239 and 248) **(d)** (9,10).

Meanwhile, amendments to the Regulation proposal would help improve **the transparency of European and national Drug Regulatory Agencies**, thus giving them a more active role as information providers, through:

- summaries of European Public Assessment Reports (EPAR) listing the various therapeutic options (amendments 6 and 13), also available from the Eudrapharm database (amendment 22);
- public access to European databases on adverse drug reactions (Eudravigilance) (amendment 19) and to databases on clinical trials (amendment 23);
- access to the agendas and minutes from the European Medicines Agency (EMA) (amendment 29);
- permitting the public to attend some EMEA committee meetings (amendment 30) (11,12).

Beware of opening the floodgates. Although MEPs have clearly spotted the dangers of DTCA for prescription drugs, they may not have anticipated all the potential hazards lurking in the current proposal. To suggest that companies may circulate “information” where the “*content does not go beyond the information contained in the leaflets, summaries of product characteristics and evaluation reports*” (amendments 64 and 146 to the Directive) would, in effect, open the floodgate for “creative” advertisers to put out their promotional messages. Evidence shows that, in reality, these messages do not resemble the official information because they are selectively edited, focusing on the products’ favourable characteristics and understating the risks of adverse drug reactions **(e)**.

Key amendments need to be supported, such as those authorising the companies to present the official information in its entirety on their websites (amendments 63, 113, 130, 133 and 167 to the Directive), and those amendments banning modification of the official information (amendments 137, 214 and 235).

Essentially, the current situation, with a clear ban on DTCA for prescription drugs, with few very specific exceptions, should be reaffirmed: article 86 and amendments 83 and 120 to the Directive, allow for the coherency of the text to be preserved.

There is a lot at stake. Patients’ rights to reliable, independent and comparative information need to be guaranteed to empower them to make their own informed choices.

The Medicines in Europe Forum, Health Action International (HAI) Europe and the International Society of Drug Bulletins (ISDB) therefore urge MEPs to transform the Commission’s proposals into real progress for the public by voting for the amendments that would close the door to advertisers, and by supporting those amendments that would give patients access to reliable, independent and comparative information. Efforts should first be focused on the information held by the European and national authorities whose lack of transparency is increasingly being challenged (13-15).

Medicines in Europe Forum

HAI Europe

ISDB

HAI Europe. Health Action International (HAI) Europe is an independent European network of health, consumer and development organisations working to increase access to essential medicines and improve rational use. More info: www.haiweb.org. Contact: teresa@haiweb.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, ISDB has 79 members in 40 countries around the world. More info: www.isdbweb.org. Contact: press@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.

Notes:

a- For example, in recent years, pharmaceutical companies have intensified their “awareness raising” and “information” campaigns on illnesses and drugs and so-called “disease management” or “compliance” programmes, have set up and provided considerable sponsoring for patient associations serving their interests, and have invested in social networks (Facebook, Twitter, Wikipedia, blogs) as vehicles for their promotional messages (a practice known as “buzz marketing”).

b- During the many consultations organised by the European Commission, civil society unanimously expressed its opposition to these proposals which jeopardise public health (ref. 16). Many Member States also clearly expressed their opposition to these proposals (refs. 17,18,19). The new Commissioner at the Directorate General for Health and Consumers (known as SANCO), who became in charge of this initiative, has acknowledged the need to reconsider these proposals, but will wait for the vote on the first reading (ref. 20).

c- Many amendments have been filed to uphold the ban on direct-to-consumers communication on prescription drugs by pharmaceutical companies via print media (amendments 6, 72 and 165), via “*campaigns run by the industry in the interest of public health*” (amendment 108), via “*items supplied by holders of marketing authorisations to health professionals for distribution to patients*” (amendment 120 or 121), and via “*information on non-interventional studies*” on prescription drugs (amendment 162).

d- The experience of DTCA in the United States and “direct-to-doctor advertising” in Europe has shown that the “oversight authorities” tend to discover breaches too late, when the damage has already been done and it is difficult for them to impose sanctions. This inevitably gives a political slant to the question: should the public authorities use their limited resources to a) ensure the law is enforced and to control the pharmaceutical industry, or b) to intervene upstream and invest in validated procedures so as to provide the general public with independent, comparative information?

e- See some revealing examples of this type of misleading message in the presentation by Barbara Mintzes at a public expert meeting in the European Parliament chaired by MEPs Dr Thomas Ulmer (PPE, Germany) and Carl Schlyter (Greens, Sweden) on 3 December 2009 (ref. 21).

References:

- 1- 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.
- 2- Kravitz et al. "Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial" JAMA 2005; 293: 1995-2002.
- 3- 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.
- 4- Medicines in Europe Forum "BigPharma's health information: a growing danger in Europe" (March 2007). www.prescrire.org/docus/InfoPatientsEN.pdf : 4 pages.
- 5- "Proposal of a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use" eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0663:FIN:EN:PDE: 30 pages.
- 6- "Proposal of a Regulation of the European Parliament and of the Council amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency". eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0662:FIN:EN:PDE: 22 pages.
- 7- "Medicines. Rapporteur insists on patients' rights to information" Europolitique 31 May 2010; (3988): 5.
- 8- 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 : 5 pages.
- 9- Fjellner C. "Draft report in ENVI Committee on the proposal for a Directive" www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-439.410+02+DOC+WORD+V0//FR&language=EN: 29 pages.
- 10- "Amendments 28-300 to the draft report in ENVI Committee on the proposal for a Directive". www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-441.215+02+DOC+WORD+V0//EN&language=EN: 197 pages.
- 11- Fjellner C. "Draft report in ENVI Committee on the proposal for a Regulation" www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-439.412+01+DOC+WORD+V0//EN&language=EN: 10 pages.
- 12- "Amendments 3-31 to the draft report in ENVI Committee on the proposal for a Regulation" www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-441.030+01+DOC+WORD+V0//EN&language=EN: 25 pages.
- 13- European Ombudsman. "European Medicines Agency should review refusal to release reports on adverse drug reactions" Press release, 10 May 2010. www.ombudsman.europa.eu/press/release.faces/en/4819/html.bookmark
- 14- European Ombudsman. "European Medicines Agency should disclose clinical reports on anti-obesity drugs" Press release, 7 June 2010. www.ombudsman.europa.eu/press/release.faces/en/4940/html.bookmark
- 15- HAI Europe, ISDB, Medicines in Europe Forum. "EMA transparency draft policy is just window dressing" Press release, 24 September 2009. www.isdbweb.org/documents/uploads/sept2009/EMEA_transparency.pdf
- 16- Joint open letter by 18 organisations "Patient 'information' by pharmaceutical companies comes up against almost unanimous opposition from civil society" 5 June 2008. www.prescrire.org/docus/En_LetterInfoMinistersConsilium_20080605.pdf : 6 pages.
- 17- Assemblée nationale "Résolution sur le paquet « médicament »" 26 décembre 2009. <http://www.assemblee-nationale.fr/13/europe/resolutions/ppe1998.asp>: 3 pages.
- 18- Deutscher Bundestag "Beschlussempfehlung und Bericht des Ausschusses für Gesundheit" 2 juin 2009. <http://dip21.bundestag.de/dip21/btd/16/132/1613266.pdf>: 5 pages.
- 19- "EU countries set to block pharma 'ads plan'" 25 May 2009. www.euractiv.com: 2 pages.
- 20- Letter from Mr John Dalli, Sanco European Commissioner to MEP Leinen dated 15 April 2010: 1 page.
- 21- Mintzes B "Direct to Consumer "Information" by the pharmaceutical industry - a déjà vu?" Speech at the European Parliament. 3 December 2009. www.aim-mutual.org/uploads/fmanager/news/d_mintzes_eu_meeting.pdf: 20 slides.