



Brussels, 14 September 2010  
Briefing paper

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

### **Summary:**

- On 28 September 2010, MEPs will 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)). This could be an opportunity to transform the proposals from a threat to public health into real progress for patients.
- In order to do so, MEPs must uphold the strict ban on direct-to-consumer advertising (DTCA). For example, pharmaceutical companies must not be allowed to:
  - publicly disseminate “information” derived from official information, while selectively highlighting the benefits of drugs and glossing over potential adverse drug reactions;
  - publicly disseminate “information” on prices, pack changes, adverse-reaction warnings, which refer to a specific product. Such announcements would *de facto* allow ‘reminder advertising’. Evidence has shown how skilful advertisers can exploit such a loophole.
- MEPs must also vote for the amendments aiming to enhance access to non-promotional, independent and comparative information held by the European and national Drug Regulatory Agencies.

Evidence gathered 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). 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 (4).

Since the start of this decade, pharmaceutical companies have been lobbying for the ban on DTCA of prescription drugs to be lifted (a) (4). In December 2008, the European Commission’s DG Enterprise and Industry proposed a highly controversial Directive and Regulation (5,6). These focus on a single aspect: enabling pharmaceutical companies to communicate directly to consumers about their prescription-only medicines (b) (7).

**Beware of opening the floodgates.** Although many MEPs have clearly spotted the dangers of DTCA for prescription drugs (read on page 2), all the potential hazards lurking in the current proposal need to be taken into account:

- To suggest that companies may disseminate “information” where the “*content does not go beyond the information contained in the leaflets, summaries of product characteristics and evaluation reports*” 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 (c).

- To allow companies to publicly disseminate “information” on prices, pack changes, adverse-reaction warnings, etc. would *de facto* allow ‘reminder advertising’ (d). Reminder advertising is a well-known marketing practice that aims to remind the general public of the name of a particular brand by using any opportunity to communicate about that product (8).

**Crucial amendments to support.** Patients’ access to reliable information needs to be governed by strict control of direct-to-consumer communication by pharmaceutical companies, which should be confined to official information (for instance posting patient leaflets and the summary of product characteristics (SPCs) on their website), while health authorities should do more to share information.

The 300 amendments to the proposed *Directive* indicate that many MEPs are aware of the dangers of the European Commission proposals (9,10). If there is no majority for rejecting the whole text (**D-amendment 28 to the Directive**), key amendments that need to be supported are:

- amendments filed to uphold the ban on direct-to-consumer communication on prescription drugs by pharmaceutical companies via print media (**D- amendments 6, 72 and 165**), via “*campaigns run by the industry in the interest of public health*” (**D- amendment 108**), via “*items supplied by holders of marketing authorisations to health professionals for distribution to patients*” (**D- amendment 120 or 121**), and via “*information on non-interventional studies*” on prescription drugs (**D- amendment 162**). In addition, the current legal framework, which sets **a clear ban on DTCA for prescription drugs, with few specific exceptions, should be reaffirmed**: article 86 of the Directive and **D-amendments 83 and 120**, allow the coherence of the text to be preserved;
- amendments authorising the companies to present the official information in its entirety on their websites (**D- amendments 63, 113, 130, 133 and 167**), limiting modifications of the official information (**D- amendments 137, 214 and 235**) and limiting the use of videos (**D- amendment 260**);
- amendments restricting the dissemination of this “information” to clearly recognisable company websites (**D- amendments 181 and 267**);
- amendments emphasising the need for monitoring by competent authorities in each Member State (**D- amendments 54, 58, 75, 231, 239 and 248**) (e).

Meanwhile, amendments to the proposed *Regulation* would help improve **the transparency of European and national Drug Regulatory Agencies**, granting the authorities a more active role in information provision, by:

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

Efforts should first be focused on the information held by the European and national authorities whose lack of transparency is increasingly being challenged (13,14).

**Improving official information.** We do not support the proposal to include a “drug fact box” in the patient leaflet (**D- amendment 129**). The principle of a “summary of essential information” was already massively rejected during the discussions on the pharmacovigilance proposals (in fact, “essential information” for one patient is not necessarily “essential information” for another patient). Rather than implementing a “drug fact box”, the officially approved leaflet should be made more useful and accessible to patients by ensuring that pharmaceutical companies consistently fulfil their obligations to consult with target user groups (enforcement of article 59 of Directive 2001/83/EC consolidated) (**f**).

**The MiEF, HAI Europe and the ISDB urge MEPs to transform the Commission’s proposals into real progress for patients** by choosing the amendments that close the door to advertisers, and supporting those that grant citizens’ access to reliable, independent and comparative information.

**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](http://www.haiweb.org). Contact: [teresa@haiweb.org](mailto: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](http://www.isdbweb.org). Contact: [press@isdbweb.org](mailto: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](mailto:pierrechirac@aol.com).

## Notes:

a- In the face of stifling innovation, the **pharmaceutical companies' marketing efforts now target patients** in order to protect the volume of drug sales. 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 sponsorship 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. 15). Many **Member States also clearly expressed their opposition** to these proposals (refs. 16,17,18). The new Commissioner at the Directorate General for Health and Consumers (known as SANCO), who is now in charge of this initiative, has acknowledged the need to reconsider these proposals, but will wait for the vote on the first reading (ref. 19).

c- See some **eye-opening examples** of misleading messages in the Barbara Mintzes' presentation 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. 20). See also a fictional example about the medicinal product Vioxx<sup>o</sup> that was withdrawn from the market in 2004 for safety reasons (ref. 21).

d- Article 86 point 2 of Directive 2001/83/EC consolidated allows for: "*— factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims*" [our underline], not to be covered by the Title VIII (advertising).

e- The experience of DTCA in the United States and "direct-to-doctor advertising" in Europe has shown that the authorities **discover breaches later in the process, when damage has already been done** and it is difficult 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?**

f- In addition, it would be wise to await the assessment report that is going to be prepared "*regarding the readability of the summaries of product characteristics and the packaging leaflets and their value to the healthcare professionals and the general public*" (ref. 22). The pharmacovigilance proposals state that "*following an analysis of the above data, the Commission shall, if appropriate, put forward proposals to improve the layout and the content of the summaries of product characteristics and of the packaging leaflet to ensure they are a valuable source of information for healthcare professionals and the general public as appropriate*" (ref. 22).

## 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](http://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](http://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:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0663:FIN:EN:PDF): 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:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0662:FIN:EN:PDF): 22 pages.
- 7- 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](http://www.prescrire.org/docus/LegalProposalsInfoPatient_JointPaper_March2009.pdf) : 5 pages.
- 8- 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)
- 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](http://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](http://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](http://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](http://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 "Ombudsman welcomes release of adverse reaction reports by the European Medicines Agency" Press release, 11 August 2010. [www.ombudsman.europa.eu/press/release.faces/en/5251/html.bookmark](http://www.ombudsman.europa.eu/press/release.faces/en/5251/html.bookmark)
- 14- "Prescrire files a complaint against the European Medicines Agency (EMA)" Press release 1 September 2010. <http://english.prescrire.org/en/81/168/46507/0/NewsDetails.aspx>
- 15- 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](http://www.prescrire.org/docus/En_LetterInfoMinistersConsilium_20080605.pdf) : 6 pages.
- 16- Assemblée nationale "Résolution sur le paquet « médicament »" 26 décembre 2009. <http://www.assemblee-nationale.fr/13/europe/resolutions/ppe1998.asp>: 3 pages.
- 17- Deutscher Bundestag "Beschlussempfehlung und Bericht des Ausschusses für Gesundheit" 2 juin 2009. <http://dip21.bundestag.de/dip21/btd/16/132/1613266.pdf>: 5 pages.
- 18- "EU countries set to block pharma 'ads plan'" 25 May 2009. [www.euractiv.com](http://www.euractiv.com): 2 pages.
- 19- Letter from Mr John Dalli, Sanco European Commissioner to MEP Leinen dated 15 April 2010: 1 page.
- 20- 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](http://www.aim-mutual.org/uploads/fmanager/news/d_mintzes_eu_meeting.pdf): 20 slides.
- 21- Prescrire Editorial Staff "Le mot de Gaspard : Morceaux choisis" Rev Prescrire 2010; 30 (323): 645. [www.prescrire.org/Fr/B075BE72132E6562B92FE7D7D9B6F810/Download.aspx](http://www.prescrire.org/Fr/B075BE72132E6562B92FE7D7D9B6F810/Download.aspx)
- 22- Council of the European Union DG C I "Outcome of the informal Trialogue on 16 June 2010: Proposal for a Regulation and a Directive on pharmacovigilance" Updated Working document ; Brussels, 18 June 2010.