



Brussels, 21 October 2011  
Joint Analysis

## Revised proposals on “information” to patients: Still an open door to advertising of prescription-only medicines by pharmaceutical companies

***Direct-to-consumer “information” on prescription medicines by manufacturers exposes citizens to misleading messages, puts public health at risk and threatens Member States’s social protection systems.***

On 11 October 2011, the European Commission published its revised legislative proposals on “information” to patients on prescription-only medicines (a)<sup>1</sup>.

The most detrimental provisions (i.e. direct-to-consumer communication via printed media) were removed, and other positive pharmacovigilance provisions were inserted as a consequence of the *benfluorex* (Mediator<sup>®</sup>) scandal in France (b).

Despite the efforts made by the European Commission to improve the original proposals, the revised versions **still do not meet the need of citizens for reliable and comparative information (c)**. In addition, they **fail to protect citizens from advertising disguised as “information” about prescription-only medicines**, and could even lead to the **implementation of “reminder advertisements” in Europe**.

Contrary to the European Commission’s Better Regulation principle, the means put forward to achieve the aim of “better informed citizens on prescription medicines” are inappropriate, since they rely on pharmaceutical companies to communicate about the products they sell despite their unavoidable conflict of interest; and the proposals would – as a consequence of that ill-founded choice – lead to increased administrative burdens.

**Regrettable confusion of role between pharmaceutical companies, health authorities and health professionals.** The revised proposals put forward the “obligation” for pharmaceutical companies to place official information on their websites as a progress worth to be monitored by Competent Authorities (*D- article 100b (1) & article 100e*) (d). However, Competent Authorities already provide public access to this official information about medicines, notably using the European database on medicines Eudrapharm (*articles 57(1)(l) and 57(2) of Regulation (EC) No*

---

a- This revision had to occur because the original 2008 proposals, aiming at the legalisation of direct-to-consumer advertising (DTCA), faced the strong opposition of the Civil Society, of Member States in the frame of the Council, and of the European Parliament.

b- The medicinal product *benfluorex* (Mediator<sup>®</sup>) was indicated as an adjuvant diabetes treatment for over 30 years, although the evidence for its efficacy was limited. In reality, this amphetamine had long been used, and extensively so, as a weight-loss drug. It took the determination of a French pulmonologist, who conducted a case-control study, for the decision to be taken to withdraw *benfluorex* (Mediator<sup>®</sup>) from the French market in 2009 and from the European Union in June 2010, and yet its extremely serious adverse effects (which were responsible for 500 to 2000 deaths in France, particularly due to heart valve deformities) had been concealed for a very long time!

c- 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 know what treatments exist (including non-drug therapies) and what they can expect from them, and to make informed choices (or participate in the choice) among the different available options. Comparative and independent information is therefore indispensable if patients are to be enabled to make informed choices.

d- We show in brackets the numbers of the articles we refer to preceded by “D- article x” when presented in the proposed Directive.

726/2004) and Drug Regulatory Agencies' safety portals (*article 106 of Directive 2010/84/EC*). Why should European citizens, as a society, need to invest resources in monitoring such a redundant "obligation" and blur the roles of pharmaceutical companies with those of competent authorities?

Resources would be better allocated to:

- strengthen the content and the user-friendliness of the National and European Competent Authorities databases on medicines, and to promote their use among the public;
- monitor whether pharmaceutical companies abide to their obligations when designing and producing packages and patient information leaflets (i.e. consultations with target patient groups) in order to ensure that these are more useful and user-friendly (*enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE*).

At a time where "sunshine acts" are being implemented in several Member States to foster and further advance the independence of health professionals from pharmaceutical companies (e)<sup>2</sup>, these proposals would allow health professionals to act as mere "brochure distributors" on behalf of pharmaceutical companies: "*printed materials about a medicinal product prepared by the marketing authorisation holder [would be allowed to be] made available to the general public (...) through health professionals*" (D- *article 100c (a)*) (f).

Rather than pursuing all possible avenues to communicate directly to the public about prescription-only medicines, the pharmaceutical industry should refocus its efforts on its core public health role: that of developing new medicines for real unmet health needs.

**No added value of the "information" to be made available by pharmaceutical companies, but enough loopholes for 'disguised advertising'.** In addition to the officially approved information on their products, the revised proposals would allow pharmaceutical companies to communicate on the environmental impact of their medicinal products, as well as on prices and pack changes (D- *article 100b point 2 (a), (b), (c)*). What is the public health rationale in allowing to inform the public about the price of prescription-only medicines? For environmental protection, it would be more efficient to organise public awareness campaigns about medicines impact on water pollution and to encourage citizens to return unused medicines to their pharmacies, to be appropriately destroyed. **Are these specific provisions anything else but a pretext to establish reminder advertising as a marketing strategy (g)?**

Other disquieting proposals warrant particular caution. These would allow pharmaceutical companies to:

- place **videos** (so-called "moving images") on their websites (D- *article 100b point 2 (d)*), a communication channel that can easily convey promotional messages;
- make available "**information" on pre-clinical and clinical trials** (D- *article 100b point 2 (e)*). Evidence indicates that "information" released by companies on their pre-clinical and clinical trials is often used to prime the marketing launch of a new product, even if its safety profile is uncertain and requires further research. What is urgently needed is open access to all data from all clinical trials so that independent researchers can put an end to the selective reporting of pharmaceutical companies<sup>3</sup>, and so that patients and consumers can be fully aware of the harm-benefit balance of a new medicine;
- make available "**frequently asked questions" and their answers** (D- *article 100b point 2 (f)*). It would be preferable to identify such questions during the package leaflet testing on a sufficient number of representative users, and to incorporate those answers in the patient information

---

e- The Physician Payment Sunshine Act requires pharmaceutical companies to make publicly available the amounts of money and other gifts given to physicians, in order to help identify conflict of interest.

f- The inclusion of "*a postal address or e-mail allowing member of the general public to send comments to, or requests (...) from, the marketing authorisation holder*" (D- *article 100d 2(d)*) shows how such "information" is likely to be used for promotion, enabling pharmaceutical companies to contact patients directly, bypassing healthcare professionals.

g- Reminder advertising is a well known 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.

leaflet (*implementation of article 59(3) of Directive 2001/83 consolidated*). This would prevent marketing departments from cherry picking particular “questions” used to diffuse certain promotional messages;

- make available any **“other types of information approved by competent authorities that are relevant to the proper use of the medicinal product”** (*D- article 100b point 2 (g)*). Such a vague definition of “information” would lead to massive submission of materials to Competent Authorities for review. Given the large disparities in the monitoring approach accepted in different Member States (see below), this proposal is far from reassuring in terms of “information” quality.

**Any pharmaceutical companies’ “information relating to human health or diseases”** would be allowed **“provided that there is no reference, even indirect, to individual medicinal products”** (*D- article 100a point 2 (b)*). At present, pharmaceutical companies already make the most of the opportunities provided by the current legislation to communicate to the public on diseases and conditions, often going beyond the established limits, by conducting disease “awareness” campaigns and spreading disease mongering. The inclusion of the adjective “individual” means that companies would be allowed to promote a therapeutic class and to address several medicines as part of a “therapeutic strategy”.

In summary, all this “information” is of little value for patients’ treatment regimes. However, it is of enormous value for pharmaceutical companies as **reminder advertisement**. Evidence from Canada, where reminder advertisings are allowed, shows how these are effective at inflating sales through emotive branding images and messages<sup>4</sup>.

**Is pre-clearance sufficiently robust to protect the public against infringements?** Given the inherent promotional nature of the information provided by pharmaceutical companies, to apply the general principle of having information pre-approved by competent authorities is - as underlined by the European Parliament - the only mechanism to help distinguish companies’ “information” from advertising (*D- article 100 g*). Yet, the possible derogations from this general principle (as described in *D- article 100 g point 2*) would lead to asymmetries and inequalities in the quality of the information being made available in different Member States (**h**).

Moreover, the information approved by one Competent Authority in one Member State could be reproduced on other websites in other Member States without further right for the latter to monitor the “information” except in few specific cases (*D- article 100 h (1)*). The most permissive competent authorities – probably those lacking the resources to effectively implement a robust monitoring process – would therefore risk to be overloaded by pharmaceutical companies’ submissions.

In the current uncertain economic climate, Member States will inevitably have to decide whether it is better to allocate public resources:

- to make Competent Authorities provide independent, comparative information to the public, and to increase the transparency of the drug regulatory agencies?
- or, contrary to that approach, to accept to lift the ban on direct-to-consumer advertising, and consequently to have to monitor pharmaceutical companies in order to attempt to enforce the laws? With the latter approach, would it be feasible for health authorities to check every document, website and its updates thoroughly (**i**)? And, while record fines of up to several billion dollars have failed to dissuade pharmaceutical companies from infringing the current regulations

---

**h-** These derogations 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).

**i-** Experience revealed the US Food and Drug Administration difficulties in monitoring pharmaceutical promotion due to lack of resources [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].

on advertising<sup>5</sup>, is it reasonable to expect that health authorities will manage to impose sufficiently dissuasive penalties?

**Direct-to-consumer advertising (DTCA) puts public health at risk and threatens Member States's social protection systems.** According to the European Commission, “5 % of all hospital admissions are due to an adverse drug reaction, 5% of all hospital patients suffer an adverse drug reaction and adverse reactions are the fifth most common cause of hospital death”<sup>6</sup>.

The lessons learned from health expenditures in the United States (where direct-to-consumer advertising (DTCA) is allowed) and from direct-to-physician advertising in Europe indicate that **excessive promotion of new medicinal products leads to an increased demand for medicinal products that consumers do not necessarily need**<sup>7</sup>.

The revised proposals provide avenues for pharmaceutical companies to choose on which of the medicines and on which of the conditions they will communicate directly to patients. There will inevitably be a bias in favour of the most profitable medicines they commercialise themselves, even when other medicines with a better benefit-harm balance exist for the same condition, or when non-pharmaceutical therapies would be an option. Inevitably, citizens will be unduly exposed to drug-induced harm.

This will result in increased costs for Member States's social protection systems, notably to manage the consequences of adverse effects caused by a medicine that patients either did not need, or should have avoided due to drug interactions with their existing treatments.

**To conclude.** The current European legislative framework is clear and already allows pharmaceutical companies to make the officially approved information available, for example, by redirecting the public to the websites of drug regulatory agencies. As other types of “information” provided by pharmaceutical companies cannot be reliable nor comparative, this Directive and this Regulation are of little value for European citizens.

More worryingly, these proposals could lead to the **acceptance of direct-to-consumer reminder advertisements in Europe, resulting in greater risks for patients and consumers. This is a useless exercise for both Europeans and Member States, adding to additional bureaucracy and increased costs.**

Medicines are not mere consumer goods. **In order to protect public health, we urge the Ministers of Health of all EU Member States to continue to refuse to consider these unnecessary proposals on “information” to patients.** The new pharmacovigilance measures contained in the revised proposals should be adopted separately.

If European citizens' access to relevant health information is to be really improved, a more ambitious strategy is needed. Our concrete proposals include:

- make the officially approved leaflet more useful and accessible to patients (*enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE*);
- improve the communications skills of health professionals (undergraduate education); put in place a “Sunshine Act” in Europe in order to foster health professionals' independence from pharmaceutical companies' influence; encourage the development of independent continuing education programmes for health professionals (training in critical appraisal skills; basics of evidence-based medicine);
- encourage national agencies to become proactive and more transparent providers of information so as to guarantee public access to full clinical data both before and after a product is marketed.

*International Society of Drug Bulletins (ISDB)*  
*Medicines in Europe Forum (MiEF)*



**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).

---

#### Selected references from our literature search:

- 1- [http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments\\_en.htm](http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm)
- 2- Godlee F "A sunshine act for Europe" *BMJ* 2011 ; 343.
- 3- The Cochrane Collaboration "The Cochrane Collaboration urges free access to all data from all clinical trials: end to selective reporting can reduce the risk of harm to patients" Press Release 5 October 2011 ; Oxford, UK.
- 4- 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 ; 4(5): e5699. doi:10.1371/journal.pone.0005699.
- 5- Barrett D "Pfizer to pay record \$2.3B penalty for drug promos" *Associated Press* 2 September 2009.
- 6- European Commission "Explanatory memorandum" in "Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use" Brussels, 10.12.2008 (COM(2008) 665 final ; 2008/0260 (COD) (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0665:FIN:en:PDF>)
- 7- Kravitz et al. "Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial" *JAMA* 2005; **293**: 1995-2002; 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.