



Joint briefing paper
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Legal proposals on “information” to patients by pharmaceutical companies: a threat to public health

Summary:

An old tale: The implementation of “Direct-to-consumer advertising” (DTCA) in Europe has been a priority for pharmaceutical companies since the last EU pharmaceutical legislation review in 2001. Over the past 8 years, the European Commission has strived to see it through by multiplying public consultations and by reinventing it under the guise of “Direct-to-consumer information” (DTCI). If its aim truly is to improve European citizens’ access to relevant medicines’ information, then a more ambitious strategy is needed (read our proposals on page 4).

The only real rationale for the Commission’s proposals to change the current EU legislation seems to be to benefit the commercial interests of pharmaceutical companies by expanding their markets. This is a useless exercise for both Europeans and Member States, representing additional bureaucracy and increased cost and putting patients at risk. These proposals, therefore, need to be withdrawn.

Directive 2001/83/EC on the Community code relating to medicinal products for human use prohibits the direct advertising of prescription-only medicines to the general public (article 88).

Despite the European Parliament’s overwhelming rejection of attempts to legalize direct-to-consumer advertising (DTCA) of prescription drugs in 2003 [the term used by the Commission was “advertising”]¹, the pharmaceutical industry, supported by the European Commission (particularly DG Enterprise and Industry), has continuously sought direct access to patients. Indeed, the public is seen as the strategic key to broadening the market for pharmaceutical products².

Since 2003, and particularly during 2007 and 2008, DG Enterprise and Industry spent a lot of money holding numerous “pseudo-consultations” on ‘information to patients’³. On every occasion, the wider public health community has unanimously stated that the pharmaceutical industry cannot be considered as a reliable source of unbiased information, due to obvious and unavoidable conflicts of interest^{4,5}.

In June 2008, during the Health Council, several Member States questioned the need for a new legislation on patient information, while others doubted whether it would improve the situation; many of them underlined the crucial role of health professionals in the provision of tailored information to patients.

¹- Already, in 2002, an explanatory memorandum concerning the 2002 proposal to modify Directive 2001/83/EC clearly laid out the aim of this proposal in the following terms: “It is proposed that there should be public advertising of three classes of medicinal products. This type of information would be subject to the principles of good practice to be adopted by the Commission and to the drafting of a code of conduct by the industry.”

²- Benzing L “In search of the Holy Grail; the quest for brand loyalty in prescription marketing” Patient marketing group. Site internet <http://www.dtcperspectives.com> accessed 4 June 2007: 5 pages.

³- The European Commission’s report submitted to the European Parliament and the Council on 20 December 2007 deviated from the Parliament and Council’s request by confining itself to information on prescription drugs, and was highly criticized (poor quality, lack of clear methodology, surprising conclusions biased in favour of direct-to-consumer information by pharmaceutical companies and ‘based’ on a very incomplete and biased inventory of available sources of information).

⁴- Joint open letter from 18 organisations “Patient “information” by pharmaceutical companies comes up against almost unanimous opposition from civil society” www.prescrire.org/docus/En_LetterInfoMinistersConsilium_20080605.pdf.

⁵- The Commission itself recognised: “The great majority of the respondents [to the consultation held in February 2008] had a view that the ban on direct-to-consumer advertising of prescription-only medicines should be maintained, making sure that there is a clear distinction between advertising and non-promotional information. However, it was agreed that such a distinction is not easy to establish”.

Despite this opposition, the current legal proposals on patient “information” will open the door to direct promotion by pharmaceutical companies, which is a nonsense in terms of meeting patients’ real needs (read below).

- **Need for independent comparative information, tailored to each patient.** 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.

► *Were the aim to really improve information to patients in order to enable them to make informed choices, then reliable comparative information would have been considered as the prime principle⁶. Paradoxically, this criterion has been excluded from the list (proposed article 100 d 2. 3)!*

- **Inevitable conflicts of interest, already duly acknowledged.** During the consultation process, drug companies themselves acknowledged that the frontier between advertising and "patient information" is not clear-cut, and the EU Commission itself recognises the existence of “*certain modalities of information where the distinction between advertising and non-promotional information is more difficult to establish*”⁷. The same dilemma had already been addressed during the previous pharmaceutical review in 2001. Moreover, the Pharmaceutical Forum failed to reach a consensus about the “quality criteria”⁸. This clearly undermines the credibility of the Commission’s claim to uphold the ban on advertising for prescription medicines.

In a highly competitive environment, drug companies must promote their products above the use of other preventive or curative options, thus any "information" they provide will be, by definition, of a promotional nature⁹. This inevitable conflict of interest means that a drug company could never be expected to provide reliable information.

► *The “lack of a coherent distinction between advertising and information” is a seemingly insurmountable obstacle.*

► *The proposals to permit pharmaceutical companies to broaden the scope of the campaigns they are allowed to produce “in the interests of public health” (proposed article modifying article 88(4)), and to communicate on non-interventional studies (proposed article. 100 b (d)) are two more examples demonstrating that the aims of these proposals are to allow direct-to-consumer promotion of prescription medicines and to build loyalty to brand products: even the Commission has recognised that non-interventional studies are “often of poor quality and frequently promotional”¹⁰.*

► *In addition, the already existing provision of “Factual informative announcements” on prescription medicines by the industry (article 86 transferred in the proposed article 100 b (c)) is of little value for patients’ treatment regimes. However, they are of enormous value as reminder adverts for their product, and are hugely effective at inflating sales through emotive branding images and messages¹¹.*

- **Make-believe regulations do not protect against infringements.** The Commission proposes that “*monitoring should take place after dissemination of information, with certain exemptions*”. Measures intended to control direct-to-consumer advertising in the United States and direct-to-prescriber advertising in Europe have clearly failed. The relevant ‘regulatory bodies’ tend to detect infringements too late, often when the damage has already been done, and have difficulties imposing penalties¹². There are no dissuasive sanctions. And, who would possibly trust that ex-ante control by Member States, through not-legally binding measures such as "self-regulation" based on a "code of good conduct" or "co-regulation" (*proposed article 100 g 2*), would properly safeguard direct-to-consumer communication?

⁶- Remember the diabetes data sheet, sent out for consultation in May 2007, which was supposed to serve as a "model" as part of a public-private partnership after more than two years’ work by the Pharmaceutical Forum. It has been unanimously found of mediocre quality and useless.

⁷- Explanatory memorandum COM(2008) 663 page 6.

⁸- ESIP and AIM “Joint Position Statement on Information to Patients on Diseases and Treatment Options”. ec.europa.eu/enterprise/phabiocom/docs/pf_20070626_esip_aim_joint_statement.pdf: 1 page.

⁹- The Directorate for Competition’s “Pharmaceutical sector enquiry - preliminary report” shows how far pharmaceutical companies are going to delay competition. The proposals on “information to patients” are yet another tactic to delay generic competition by building "brand loyalty" to their own medicines.

¹⁰- “EU pharmacovigilance: public consultation on legislative proposals” (point 3.2.5). Dec 2007. ec.europa.eu/enterprise.

¹¹- Mintzes B “La publicité directe au public pour les médicaments : une pilule pour chaque maladie ou une maladie pour chaque pilule ?” Rev Prescrire 2006: <http://www.prescrire.org/editoriaux/EDI26685.pdf>.

¹²- General Accounting Office (GAO) “Prescription drugs: improvements needed in FDA’s oversight of direct-to-consumer advertising”. November 2006. www.gao.gov/new.items/d0754.pdf: 52 pages.

► ***This inevitably leads to a political debate: should public authorities use their limited resources to act as law enforcers and control the pharmaceutical industry, or rather be proactive and invest in validated processes towards the provision of independent and comparative information to the general public?***

• **Instrumentalisation of health professionals becoming advertising distributors.** The Commission proposes that “material provided by the marketing authorisation holder to healthcare professionals for distribution to patients” is not covered by the title VIIIa (Information and advertising) (*proposed article 100a point 2 (b)*). This means that “materials” prepared by the pharmaceutical companies would not be subject to any control (no “quality criteria”, nor monitoring to comply with). This is tantamount to advertising. The EU Commission will be reducing health professionals to mere “brochure distributors” on prescription medicines on the behalf of pharmaceutical companies¹³.

The inclusion, in any “information” provided by pharmaceutical companies, of “a mail address or e-mail address allowing the general public to send comments to the marketing authorisation holder” (*proposed article. 100 d point 2 (d)*) shows how such “information” is likely to be used for promotion, enabling pharmaceutical companies to contact patients directly, bypassing the health professionals.

► ***“Direct-to-consumer advertising” (DTCA), under the guise of “direct-to-consumer information” aims to increase sales by contacting directly the public directly and bypassing health professionals***¹⁴.

• **Biased impact assessment.** The results of the “impact assessment” are absurd: according to the assessment, if adopted, direct-to-consumer information on prescription medicines, when controlled by national health authorities, would cost up to 88 billions euros and save up to 329 billions euros over the forthcoming 10 years (including 200 billions from better compliance [valued by additional “quality-adjusted life years” - QALYs]...).

Looking at the lessons learned from health expenditures in the United States (where DTCA is allowed) and from direct-to-physician advertising in Europe shows that excessive promotion of new medicinal products leads to an increased demand for medicinal products that consumers do **not necessarily need**¹⁵. The burden of additional harm and unwarranted health spending (notably the cost of managing adverse drug reactions) created is greatly underestimated. It is only estimated as 5 billions, while at the same time the legal proposal on pharmacovigilance underlines that “*It is estimated that 5 % of all hospitalisation 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*”!

The impact study’s flawed methodology¹⁶ may explain these illogical estimates. Most notably, the effects of “awareness”, “prevention”, “interaction [with health professionals]” and “compliance” can all be achieved through the promotion of independent public health campaigns on specific conditions, driven by the authorities and thus avoiding “disease mongering”¹⁷.

► ***The results of the biased impact assessment overlook the proposal’s impact on the financial sustainability of Member States’ public health systems.***

• **The legislative changes proposed are useless and even counterproductive.** The European regulatory framework is clear (articles 86(2) and 88 of Directive 2001/83/EC modified by Directive 2004/27/EC):

- Pharmaceutical companies are already permitted to provide information to the public on diseases¹⁸ and to answer specific and individual questions (*article 86 transferred in the proposed article 100 b (a)*).

- Disseminating the officially approved documents (art. 100b a) on prescription-only pharmaceuticals, namely the SPC and package leaflet on pharmaceutical companies’ websites is already possible under current EU legislation (i.e. France, the Netherlands, etc.). Hence, there is no real need for changes to allow their publication on marketing authorisation holders’ websites. Marketing authorisation holders can

¹³- These brochures are for example being included in some community pharmacies computer programmes that are used to manage sales.

¹⁴- Mintzes B “La publicité directe au public pour les médicaments : une pilule pour chaque maladie ou une maladie pour chaque pilule ?” Rev Prescrire 2006 : <http://www.prescrire.org/editoriaux/EDI26685.pdf>.

¹⁵- 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.

¹⁶- The “methodology” was blatantly flawed: using questionnaires solely in English, some of the respondents to previous consultations received the questionnaire, others not, with no justification being given as to the selection criteria; questions were irrelevant or even precluded a reliable answer; there were incoherence between the principal option of regulation proposed in the questionnaire and the hypothesis chosen by the Commission in the consultations.

¹⁷- Disease mongering is a well documented marketing practice consisting to create of a ‘disease’ using symptoms.

¹⁸- They make the most of the opportunities provided by this framework, often going beyond with disease “awareness” campaigns and even disease mongering.

simply place a link from their own websites to those of the regulatory agencies, where the information would be available.

To allow the pharmaceutical industry to draw up documents using only some of the elements of the SPC (Summary of Product Characteristics), disconnected from the others elements needed to understand them properly, and to produce a “free-style” leaflet makes no sense (*proposed article 100 b (b)*): it is inefficient and potentially confusing to have two types of leaflets circulating, one officially approved and a rewritten version produced by the manufacturer. The risk is that it will lead to the public dissemination of promotional information on prescription only medicines.

► *If the aim is to harmonise practices in Members States, actions at Member States’ level would be the best way to ensure equal interpretation/enforcement of articles 59¹⁹ and 86.*

Concrete proposals for improvement

A more ambitious strategy is needed to really improve European citizens’ access to relevant health information. Our concrete proposals include²⁰:

- make the officially approved leaflet more useful and accessible for patients (improve the readability and structure of the information conveyed, as well as the provision of adverse effects’ information and recent pharmacovigilance decisions) by ensuring that pharmaceutical companies consistently abide by their **obligations relative to drug packaging and patient leaflets** (i.e. consultations with target patient groups) (enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE);
- optimise **communication between patients and health professionals**: informing patients and fulfilling their needs implies a relationship of trust and interpersonal dialogue, which are the core responsibilities of the healthcare professions;
- encourage **national agencies to become proactive and more transparent providers of information** so as to guarantee full public access to data on the efficacy and safety of medicines and other healthcare products both before and after a product is marketed;
- **develop and reinforce existing sources of comparative, unbiased information on treatment choices**;
- put a **rapid and permanent end to the confusion of roles between the pharmaceutical companies and other actors** in the healthcare sector: full implementation and enforcement of the European regulation on pharmaceutical promotion, including measures to ensure that article 88 of Directive 2001/83/EC, is not weakened or undermined.

To conclude. As the “information” by pharmaceutical companies can not be reliable nor comparative, the whole directive proposal has no added value for European citizens. The only real rationale for the Commission’s proposal to change the current EU legislation seems to be to benefit the commercial interests of pharmaceutical companies by expanding their marketing reach. This is a useless exercise for both Europeans and Member States, representing additional bureaucracy and increased costs.

One of the Commission’s central responsibilities is the protection of the health of European citizens (article 152 of the European Treaty). Support for industrial competitiveness must not be allowed to supersede public health interests. These proposals should therefore be withdrawn. The pharmaceutical industry should refocus its efforts on its core public health role, which is to develop new medicines to meet patients’ needs.

*Association Internationale de la Mutualité (AIM)
European Social Insurance Platform (ESIP)
Health Action International (HAI) Europe*

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

¹⁹- Article 59 of Directive 2001/83/EC modified by Directive 2004/27/EC lays down the specific role for the pharmaceutical companies in improving the quality and clarity of labelling and the package leaflet.

²⁰- Our concrete proposals for improvements are available at:
http://www.isdbweb.org/pag/documents/relevant_health_information_000.pdf (Joint declaration of HAI europe, ISDB, AIM, BEUC “Medicines in Europe Forum Relevant health information for empowered citizens”).



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.



ESIP. The *European Social Insurance Platform* (ESIP) represents a strategic alliance of over 40 statutory social security organisations in 16 EU Member States and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality. More info: www.esip.org. Contact: esip@esip.org.

Note: ESIP members support this position in so far as the subject matter lies within their field of competence.



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: 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, their members include 79 members in 40 countries around the world. More info: www.isdbweb.org. Contacts: jschaaber@bukopharma.de; fvandeveld@prescrire.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: europedumedicament@free.fr.