AIM

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Updated Joint Analysis

Amended proposals on "information" to the public: Opening the door to advertising of prescription-only medicines by pharmaceutical companies

Allowing manufacturers to provide direct-to-consumer "information" on prescription medicines to the public exposes citizens to misleading messages puts public health at risk and threatens Member States' social protection systems.

On February 10th 2012, the European Commission adopted amendments to the proposals on ""information" to the public on prescription-only medicines"[1]. These amendments have split the revised proposals - from 11 October 2011) - into two distinct proposals, relating to "Information to Patients" and "Pharmacovigilance" respectively (**a**). Most notably, there have been no changes to the content of the revised proposals on "Information to Patients" - adopted in October 2011; hence the concerns expressed in our previous analysis remain valid.

The most detrimental provisions (i.e. direct-to-consumer communication via printed media) were removed in 2011, at the same time that other positive pharmacovigilance provisions were inserted as a consequence of the *benfluorex* (Mediator°) scandal in France (**b**).

Despite the efforts made by the European Commission to improve the 2008 original proposals, the amended versions **still do not meet the need of citizens for reliable and comparative information** (**c**). In addition, they **fail to protect the wider public from being targeted with prescription-only medicines advertising disguised as "information".** The amended proposals 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 "better informed citizens on prescription medicines" are inappropriate; since the onus would be on pharmaceutical companies to communicate about the products they sell despite their unavoidable conflict of interest. As a consequence, the proposals would lead to increased administrative burdens.

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a - The adoption of these proposals follows Commissioner Dalli' s announcement on 2 December 2011 at the Council on Employment, Social Policy, Health and Consumer Affairs (EPSCO). In fact, Member States have reiterated their reluctance to discuss these proposals. By separating the two issues, the Commission hopes to facilitate discussions and speed the decision-making process.

b- The medicinal product *benfluorex* (Mediator°) was authorised as an adjuvant diabetes treatment for more than 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. Only after determined French pulmonologist conducted a case-control study the drug was withdrawn from the French market (in 2009) and from the European Union (in June 2010). The producers had deliberately concealed benfluorex's very serious adverse effects (heart valve deformities have been estimated be responsible for 500 to 2000 deaths in France alone)**.**

c- Useful patient information should enable users to analyze 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.

A regrettable confusion of roles among pharmaceutical companies, health authorities and health professionals. The amended 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 are already providing public access to this official information, notably through the European database on medicines Eudrapharm (*articles 57(1)(l) and 57(2) of Regulation (EC) No 726/2004*) and Drug Regulatory Agencies' safety portals (*article 106 of Directive 2010/84/EC*). Why should European citizens, collectively, invest resources in monitoring such a redundant "obligation" and contribute to blurring the roles of pharmaceutical companies with those of competent authorities?

Resources would be better allocated to:

- Strengthen the content and user-friendliness of 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 the United States and in several Member States (Denmark, France, in some regions of the United Kingdom) to foster and further advance the independence of health professionals from pharmaceutical companies[2] (**e**), 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 from 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 companies communicate about the environmental impact of their medicines, as well as on prices and pack changes (*D- article 100b point 2 (a), (b), (c)*)**.** In order to uphold environmental protection, it would be more efficient to organise public awareness campaigns about the impact of medicines 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:

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d- In brackets the numbers of the articles referred to, preceded by "D- article x" for specific notation in the proposed Directive on Information to Patients.

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(e)) 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, through emotive branding of images and messages.

- Place **videos** (so-called "moving images") on their websites (*D- article 100b point 2 (d)*), a communication outlet 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 when the drug's safety profile is uncertain and requires further research. **Open access to all clinical trials and pharmacovigilance data is urgently needed so that independent researchers can put an end to selective reporting[3], and so that patients and consumers can be made 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 phase by surveying an adequate number of representative users, and to incorporate those answers in the patient information leaflet (*implementation of article 59(3) of Directive 2001/83 consolidated*). This would prevent marketing departments from selecting particular "questions" used to diffuse specific 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 the massive submission of materials to Competent Authorities for review. Given the large disparities in the monitoring approach across different Member States (see below), this proposal is far from reassuring in terms of "information" quality.

Any information from pharmaceutical companies *"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 limits established, they disseminate disease "awareness" campaigns and spread disease mongering. The inclusion of the adjective "individual" into the legislative text means that companies would be allowed to promote a therapeutic class, or to refer to several medicines as part of a "therapeutic strategy".

In fact, all this "information" is of little value for patients' treatment regimes. However, it is of enormous value for pharmaceutical companies when disseminating **reminder advertisements**. Evidence from Canada, where reminder advertisings are allowed, showcases how this type of marketing approach is effective at inflating sales, through emotive branding of images and messages[4].

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 websites in other Member States without granting further right to the latter to monitor the "information", except in specific cases (*D- article 100 h (1)*). The most permissive

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 (when the monitoring body also includes stakeholders other than pharmaceutical companies).

competent authorities –those lacking the resources to effectively implement robust monitoring– would risk to be overloaded by pharmaceutical companies' submissions.

In the current uncertain economic climate, Member States and Members of the European Parliament (as lawful representatives of all Europeans) will inevitably have to decide whether it is it better to allocate public resources:

- To enable Competent Authorities to provide independent, comparative information to the public, and to increase the transparency of drug regulatory agencies?
- Or, contrary to that approach, to accept to lift the ban on direct-to-consumer advertising, and thereafter to monitor pharmaceutical companies in an attempt to enforce the new laws? With the latter approach, would it be feasible for health authorities to thoroughly assess every single document and website as well as their updates (**i**)? And, while record fines of several billion dollars have failed to dissuade pharmaceutical companies from infringing the current regulations on advertising[5], 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 State'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*"[6].

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

The amended proposals provide avenues for pharmaceutical companies to select which medicines and conditions to communicate about to patients. There will inevitably be a bias in favour of the most profitable medicines, even when other products with a better benefit-harm balance are available for the same condition, or when non-pharmaceutical therapy would be an option. Inevitably, citizens will be unduly exposed to drug-induced harm.

This will result in increased costs for Member State'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.

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 drug regulatory agencies' websites. As other types of "information" provided by pharmaceutical companies cannot be reliable or 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 discuss these unnecessary proposals on "information" to patients.**

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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: 52 pages].

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

- Formulate **officially approved leaflets that are more useful and accessible to patients** (*enforcement of article 59 of Directive 2001/83/EC modified by Directive 2004/27/CE*);
- **Put in place a "Sunshine Act" in Europe** to foster health professionals' independence from pharmaceutical companies' influence; improve the communications skills of health professionals (undergraduate education); 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.

Association International de la Mutualité **(AIM)**
International Society of Drug Bulletins **(ISDB)**
Health Action International Europe **(HAI Europe)**
Medicines in Europe Forum **(MiEF)**

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.aimmutual.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 their rational use. More info: www.haieurope.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, 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.

Selected references from our literature review:

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8- Wackel Philippe "German Parliament rejects EU plans on pharma information to patients" APM, Berlin, 13 February 2012: 1 page.
9- Rosso-Debord V (Député UMP de Meurthe-et-Moselle) "Communication sur les propositions révisées du « paquet médicaments » (E 6711 et E 6712)" 12 Février 2012.