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Joint press release

Revised proposal for a Directive on "information" to patients: some improvements, but risks of DTCA (direct-to-consumer advertising) remain

On October 11 the European Commission published its revised Directive proposal on "information" to patients about prescription-only medicines. The revised proposal is a response to the opposition to previous drafts by the end of 2010, considered by the European Parliament and the Council of Ministers of Health to be inadequate, as they did not uphold patients' safety and public health.

An open door to disguised advertising of prescription medicines

Despite improvements, **the revised proposal leaves an open door to advertising**, since the industry would still be allowed to communicate to the general public on numerous potentially promotional information about their products (for example information about preclinical and clinical testing, pricing, packaging changes, answers to "frequently asked questions", etc.). Online videos on websites run by companies would be allowed, and disease awareness campaigns could be used to promote therapeutic classes ("*provided that there is no reference (...) to individual medicinal products*").

In addition, **the role given to health professionals is unacceptable**, with doctors and pharmacists being considered as mere facilitators, redistributing materials prepared by manufacturers to their patients. **Health professionals should not be used to endorse and heighten the credibility of promotional and marketing activities targeted to patients.**

No added value but a real danger to public health and health financing systems

The *Medicines in Europe Forum*, the *International Society of Drug Bulletins* (ISDB) and *Health Action International (HAI) Europe* **oppose any weakening of the current regulations on advertising of prescription-only medicines in Europe**.

They consider that the revised Directive proposal:

- **still does not respond to patients' needs** for **reliable, independent and comparative information**, to help them to make informed choices. The priority should be to improve the transparency of Drug Regulatory Agencies;

- **maintains a confusion of roles**, while the pharmaceutical industry should rather refocus on its public health role, that of seeking new treatments for unmet medical needs. The Directive proposal would further exacerbate the disproportionate allocation of the industry's resources: research and development activities (representing 17% of sales) versus promotional activities (23% of sales), as highlighted by the European Commission itself in January 2009 in its report on the Pharmaceutical Sector Enquiry;

- **can worsen public health** (increased medicines consumption and irrational use resulting in more adverse reactions and drug interactions) **and lead to an unjustified increase in pharmaceutical**

expenditure impacting negatively on health care systems. The disproportionate costs inherent in the pre-approval process of pharmaceutical companies' communications – deemed necessary due to their promotional nature – will be borne by Regulatory Agencies, to the detriment of their other real public health responsibilities.

The revised proposal for a Directive on "information" to patients threatens the sustainability of health financing systems, and does not serve the interests of citizens. **The *Medicines in Europe Forum, the ISDB* and *HAI Europe* therefore call on all European Union's Health Ministers to continue to refuse to study this legislative proposal**. The pharmacovigilance measures contained in the redrafted proposal should be discussed and adopted separately.

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

More information:

More detailed joint analysis of the revised proposals freely available: http://english.prescrire.org/Docu/DOCSEUROPE/RevisedInfoProposals_Analysis_2011oct_FINAL.pdf (5 pages)

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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.

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. Contacts: teresa@haiweb.org & rose@haieurope.org.