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HAI Europe's response to the EU Commission public consultation on Key ideas of a legal proposal on Information to Patients

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Summary

In the consultation published on 5 February 2008, the European Commission proposed a legal framework through which, among many other features, pharmaceutical companies would be allowed to communicate directly to the European public about their prescription medicines. It becomes clear that despite the vehement opposition of many interested groups expressed in the responses to previous consultations on the same theme[i] the Commission is keen to deregulate direct-to-consumer advertising on prescription medicines in Europe under the guise of improving information to patients.

HAI Europe deplores the misleading use of the term "Patient Information" in reference to changes to the current restrictions on manufacturers' rights to promote their products to the public. In a highly competitive environment, pharmaceutical companies have a responsibility to their shareholders to increase profitability by increasing sales. This is achieved through pharmaceutical promotion and is inconsistent with the needs of patients and the public for independent, unbiased information. This need for information can only be met by providers without conflicts of interest.

HAI Europe stresses the importance of article 88 of Directive 2001/83/EC, which is the only legislative safeguard against full introduction of direct-to-consumer advertising of prescription drugs. Article 88 and 86 should be maintained intact. There is no public health rationale for weakening or amending this prohibition. However, the Commission's proposal for a legal framework foresees an increased role for the pharmaceutical industry in providing information to patients. This will introduce an opportunity for companies to supply information of promotional nature directly to consumers, and to all intents and purposes will contribute to a relaxation of the current restriction, which precludes any direct or indirect advertising of prescription medicines to the public in Europe (Article 86.2 and Article 88).

The long-lasting intention of DG Enterprise & Industry to liberalize the promotional and advertising of the pharmaceutical sector is of grave concern. Particularly when viewed against a background of the previous initiative to introduce Direct-to-consumer-advertising, which was forcefully rejected by the European Parliament in 2003.

It is with much apprehension that HAI Europe and its partners sees the emergence of a proposal for a legal framework altering existing legislation when the report of its impact assessment study is still pending. This is contrary to any plausible reasoning – Why conduct a public exercise of this type before disseminating the study's findings? Is the Commission afraid of what the results might show?

In spite of the Commission's proposal to ostensibly *put the interests of patients first*[ii], the process has been singly geared towards setting *rules on the provision of information by marketing authorisation holders*, i.e. focused on industrial interests over and above the interests of patients and consumers.

HAI Europe invites the Commission to read attentively our responses to public consultations submitted by our civil society organisations on two previous occasions[iii]. These are our 10 key messages:

1. **No proposal which may inform legislative change should be based on a flawed report produced without clearly defined methodology and in such an opaque manner**. The report put forward by the European Commission in December 2007 omits important information. No mention is made to independent sources of information about medicinal products. It therefore provides an **incomplete account** of the available initiatives which aim to provide information to patients on medicinal products throughout the European Union, thereby denying readers the opportunity to make an informed decision.

2. **The proposal reflects the conclusions of the Pharmaceutical Forum, a high-level group whose legitimacy and constituency has been questioned**. This group has, since its inception, failed to operate in an open, transparent and democratic manner. Independent organisations and individuals with experience in providing health and medicines information to the public have been excluded from the Pharmaceutical Forum.

3. **The Pharmaceutical industry should not be given a role in providing the public with comparative information on pharmaceutical drugs and other medical treatments, because of the inherent conflict of interest**. Pharmaceutical companies have a responsibility to their shareholders to increase profitability by increasing sales. This is achieved through pharmaceutical promotion and is inconsistent with the needs of patients and the public for independent, unbiased information. This need for information can only be met by providers without conflicts of interest.

4. **The first priority should be to ensure all information on drug safety and effectiveness submitted to regulatory authorities is publicly available**, including all pre-market laboratory and clinical data and post-marketing studies. In addition, the Commission needs to strongly encourage regulatory agencies in all EU Member States to implement their transparency obligations. HAI Europe recommends that the Commission take an active role in ensuring that all Member States meet their statutory obligations. Additionally, the Commission could provide a centralized web portal with access to all Patient Information Leaflets and European Public Assessment Reports. Much of the purported gap in patients' and consumers' information would be reduced if statutory obligations were met.

Pharmaceutical companies have a very specific part to play in promoting rational use of medicines, one which is strictly limited to improving the quality and clarity of the package labelling and patient information leaflets in compliance with the law (article 59). Evidence suggests that the pharmaceutical industry already have difficulty in implementing this minimum requirement. Enforcement of these obligations by EU member states must be strongly encouraged by the Commission.

5. **Patient information should help users to analyse their concerns,** to realistically assess their medical status, to understand when further investigations are necessary, to know what treatments exist, along with their respective benefits and drawbacks, and to choose (or participate in the choice) among the different available options. In order to make genuinely informed choices, above all, **patients need reliable comparative data**. But this crucial criterion has been arbitrarily excluded from the "quality criteria" proposed by the European Commission: «Comparisons between medicinal products should not be allowed»[iv].

6. **The legal framework proposed by the Commission goes against the WHO Ethical Criteria for Medicinal Drug Promotion.** In 1981 the World Health Organization adopted the Ethical Criteria for drug promotion[v]. In that publication, promotion was described as: "...all the information and persuasive activities by manufacturers and distributors in order to induce the prescription, supply, purchase and/or use of medicinal drugs."

Most importantly, the document also established the criteria to be met: "…all promotion making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks... Comparison of products should be factual, fair and capable of substantiation"; and highlighted the fact that **"Promotional material should not be designed so as to disguise its real nature."**

In respect of advertisements to the general public, the paper elaborates that these "should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners". Even though these criteria were approved more than two decades ago, they are still valid for all WHO Member States. If the EU Commission is interested in diverting from the core concepts established, as outlined in the legal framework being proposed, then the WHO and its Director-General should be properly consulted.

7. **Precautionary principle**. Paradoxically, at a moment when the international health community is keen to recognise the conflict of interest inherent in the provision of information on medicines by the pharmaceutical industry[vi] and drug promotion as a key driver in the irrational use of medicines[vii], the European Commission is proposing public-private-partnerships as a solution to the "information desert" that it assumes Europe has become. Private-public-partnerships in information provision, involving either the pharmaceutical or medical device industry, represent clear conflicts of interest and inevitably will lead to irrational use of medicines and increased costs[viii]. **In countries where direct-to-consumer advertising of prescription drugs is allowed, several studies have shown that it creates patient demand, leading to over-prescription by physicians. It increases non-medically-justifiable health expenditure on drugs which expose patients to adverse effects.**

8. **The plan to allow companies to "*give information about scientific studies*" authorizes a dangerous marketing practice**. It stimulates demand, thus favouring the commercial launch of drugs being trialled for new indications on the basis of partial results, with insufficient time to evaluate the drug's efficacy and safety for such new indications. In a fiercely competitive climate, pharmaceutical companies are under pressure to champion the drugs they market to detriment of other preventive or curative means, making the "information" they provide promotional by nature. Their conflicts of interest are an insurmountable obstacle to objectivity.

9. **Opening the door to abuse.** The control of direct-to-consumer advertising in the USA or of direct-to-doctor advertising in Europe is a failure. Watchdog authorities end up with a restricted role: acknowledging abuse at later stage, often after the damage has been done, and struggling to apply sanctions. Bearing in mind that the US Food and Drug Agency has expanded its budget to improve the monitoring of direct-to-consumer-advertising by pharmaceutical companies, **the Commission's proposals to regulate "information to patients" seem to fall short. No previous (ex ante) controls are planned and sanctions are to be imposed retrospectively**, once the "information" has been disseminated and the public harm has taken place.

10. **HAI Europe stresses the importance of article 88 and 86 of Directive 2001/83/EC, which is the only legislative safeguard against introduction of direct-to-consumer advertising of prescription drugs. Article 88 and article 86 should be maintained intact.** There is no public health rationale for weakening or amending this regulation. However, the Commission's proposal for a legal framework foresees an increased role for the pharmaceutical industry in providing information to patients. This will introduce an opportunity for companies to supply information of promotional nature directly to consumers, and to all intents and purposes it will contribute to a relaxation of the current law, which precludes any direct or indirect advertising of prescription medicines to the public in Europe (Article 86.2 and Article 88).

Prior to any legislative proposal, Health Action International (HAI) Europe calls on the European Commission to fulfil its mission of protecting public health (article 152 of the Treaty establishing the European Community).

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[i] European Commission – Enterprise and industry directorate-general "Outcome of the public consultation on a Draft report on current practices with regard to the provision of information to patients on medicinal products" 19 October 2007: 9 pages. http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_10/d-34327-summary-of-consultation-responses.pdf

[ii] European Commission Public consultation, Legal proposal on Information to Patients, page 3

[iii] Health Action International's Response to the High Level Pharmaceutical Forum Public consultation on Health-related information to patients available at:
http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/docs/R-059_en.pdf

Health Action International Europe's Response o the Draft Report on , available at
http://www.haiweb.org/20072007/20070628HAIEuroperesponsetothedraftreportonprovis.pdf

[iv] European Commission Public consultation, Legal proposal on Information to Patients, page 7

[v] WHO Ethical Criteria for Medicinal Drug Promotion, available at
http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip08e/whozip08e.pdf accessed 7 April 2008

[vi] Progress in the Rational Use of Medicines, WHA60.16. *WHO Website*:
http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R16-en.pdf accessed 7 April 2008

[vii] Prosser, Almond and Walley *Family Practice* 2003; 20:61-68

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.

Kravitz et al. "Influence of patients requests for direct-to-consumer advertised antidepressants: a randomized controlled trial" *JAMA* 2005; 293: 1995-2002.

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[viii] Lazarou et al. *JAMA*, 1998;279:1200-1205

Lasser et al. *JAMA*, 2002;287:2215-2220