



HAI Europe  
Jacob van Lennepkade 334T  
1053 NJ Amsterdam  
The Netherlands  
Tel: +31 20 683 3684  
Fax: +31 20685 5002  
Email: [teresa@haiweb.org](mailto:teresa@haiweb.org)  
Web site: <http://www.haiweb.org>

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## **Health Action International Europe's Response to the Consultation on the Draft report on current practices with regard to the provision of information to patients on medicinal products**

### **Summary**

The report's review of sources of patient information on drugs and other treatments is so incomplete that it casts doubts on the Commission's willingness to address the issues raised by the article 88a, namely the provision of information and its risk and benefits for patients. Consequently, the report's conclusions are exclusively biased in favour of allowing drug companies to communicate directly with the public, further undermining the Commission's credibility to consider public health needs above commercial interests.

### **Key points**

These are the key points raised by HAI-Europe in its response to the consultation on the Draft report on current practices with regard to the provision of information to patients on medicinal products:

1. No proposal which may inform legislative change should be based on a report produced without clearly defined methodology and in such opaque manner.
2. The draft report which is being put forward by the European Commission omits important information, for example, by not mentioning 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.
3. The draft report 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. Organizations and individuals with experience in providing health and medicines information to the public have not been consulted in the Pharmaceutical Forum.

4. The Pharmaceutical industry should not have a role in providing the public with comparative information on drug and other medical treatments, because of the inherent conflict of interest reflected in such a role. Pharmaceutical companies have a responsibility to their shareholders to promote sales and profitability. This is inconsistent with the needs of patients and the public for independent, unbiased information. This need can only be met by providers without conflicts of interest.
  
5. The first priority in meeting unmet public information needs should be to ensure all information on drug safety and effectiveness that is submitted to regulatory authorities should be 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 these transparency obligations.
  
6. The Commission's report correctly states that statutory information is only partially available to patients and consumers in different Member States, and that access varies widely from country to country. HAI 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 gap in patients' and consumers' information would be reduced if statutory obligations were met.
  
7. 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 should be maintained intact. There is no public health rationale for weakening or amending this prohibition.
  
8. The Commission's report recommends an increased role for the pharmaceutical industry in providing information to patients. Currently, the pharmaceutical industry faces a single restriction in law in Europe: no direct or indirect advertising of prescription medicines to the public is allowed (Article 86.2 and Article 88). HAI Europe deplores the Commission's attempt to undermine this prohibition, and especially deplores the misleading use of the term "Patient Information" in reference to restrictions on manufacturers' rights to promote their products to the public.

## Industry-provided information creates demand for medicines

Following a period of dynamic research and development output, the pharmaceutical industry has been facing hard times, with patents on blockbuster drugs expiring and fewer promising new products in the pipeline. Confronted with these difficulties, pharmaceutical companies have devised a range of commercial strategies, one of which is to advertise their products – including prescription drugs – directly to the public<sup>i</sup>.

In the push to allow direct communication with patients in the European Union, pharmaceutical companies are marketing advertising as ‘information’. Information from pharmaceutical companies does not assist patients to make informed choices. It simply creates demand for particular medicines by manipulating consumers<sup>ii iii iv v</sup>.

Demand for particular medicines is created in two ways: by generating demand for one medicine over other treatments – usually a newer more expensive medicine that is still on patent; or by making consumers think they need a medicine when they do not, by promoting medicines as solutions to less severe symptoms or by disease creation – making people think they are sick when they are well.

## The draft report: the unmet mandate

Even though the attempt to introduce direct-to-consumer advertising for diabetes, asthma and HIV/AIDS in Europe in 2002 failed, pressure from industry to reintroduce the debate has continued unabated<sup>vi</sup>. This is despite an overwhelming vote by the European Parliament (494 votes to 42) and Council against such an introduction.

When the following amendment was introduced to Directive 2004/27/EC in April 2004, the European Parliament asked the Commission to examine ways to improve provision of patient information in Europe:

*“the Commission shall, following consultations with patients’ and consumers’ organizations, doctors’ and pharmacists’ organizations, Member States and other interested parties, present to the European Parliament and the Council a report on current practice with regard to information provision and its risks and benefits for patients.”*

Regrettably, the report under consideration falls short from its remit and clearly fails to supply an accurate overview of the current practices in information provision about medicinal products in Europe.

Were the Commission to meet the mandate entrusted it by the Parliament, independent research would have been conducted to identify and quantify the real needs and desires of European citizens for information about medicines. Due attention would have been paid to providing substantive evidence about the benefit to patients of the many existing sources of information to which they have access. Likewise, an overall assessment of the risks involved

in information provision would prove essential to understanding the nature of the problem at hand, if any. This has not happened. The basic research on information needs, benefits and risks requested by the Parliament has not been carried out.

**Even though the parliament did not ask the Commission to examine ways to assist the industry to promote its products to the European public, the present report portrays the pharmaceutical industry as the only provider of information able to fill the “information desert” that it assumes Europe has become.**

Despite arguments to the contrary, there is a wealth of information available about medicines in Europe<sup>vii</sup>. What patients and general public often lack are the skills, training and experience to evaluate it and distinguish between promotional material (direct advertising), promotional material that masquerades as information (disguised advertising) and unbiased information.

HAI Europe believes that **contrary to the conclusion of the report, the pharmaceutical industry has no role in providing the public with comparative information on drug treatments, because of its inherent conflict of interest<sup>viii</sup>. Companies must maximize sales and profitability on behalf of shareholders; this is inconsistent with an impartial presentation of the pros and cons of all treatment options, including competitors and their own.** The public’s and patients’ information needs can only be met by providers without conflicts of interest.

## **An incomplete and methodologically flawed report**

The Commission’s report contains fundamental flaws.

As to process, the **methodology** used to prepare the Commission report on patient information in Europe is **described in vague terms** and in just a few lines. The main body of the report is badly organised and unclear and the annexes are incomplete. No list is included of the individuals and organizations who were consulted when the report was produced and the table listing sources of information fails to indicate who supplied information within each Member State, apart from regulatory agencies. Additionally, the table entitled *Information available on the Internet* only lists approved product information and accompanying administrative documents and omits all other types of information. The text accompanying this table mentions a few other sources of information, provided by various sources in a few Member States only, without providing details on how these initiatives were financed, methods used to produce the information, or what types of information are covered.

**The report presents a limited and incomplete account of the current practices** relating to the provision of information on medicinal products in Europe. No mention is given to information providers independent of the pharmaceutical industry and regulatory bodies. Independent drug bulletins (33 in the European Union), health professionals’ organisations, patients and consumer groups, agencies that carry out pharmaco-economic evaluations, health technology assessment groups, healthcare service providers, drug reimbursement

agencies, and patients' health education organisations established by Member States, are all examples of independent information providers ignored by the report.

The paper only takes on board the quality criteria developed by the Pharmaceutical Forum, a high-level group which has since its inception, failed to operate in an open, transparent and democratic manner. The Pharmaceutical Forum failed to disclose criteria for membership or exclusion from the committees, minutes and proceedings in a timely manner, if at all. Consequently, the legitimacy of such a group, and its outcomes, is open to question.

Much of the analysis of information provision practices contained in the **report focuses on the internet**. This inevitably raises issues as to the representativeness of the information accrued, as internet users are but a specific sub-group of the European population<sup>ix x</sup> with demographic, geographic and health characteristics which differ considerably from those who are the main consumers of medicines: the elderly<sup>xi xii xiii xiv</sup>.

**The report provides the incomplete and flawed inventory of sources of information in Europe and fails to fully disclose the methods used to produce this inventory. Preference is given to initiatives that include the pharmaceutical industry and independent initiatives are ignored. It is no surprise then that the authors conclude the pharmaceutical industry's role as information provider must be expanded. A consistent bias in the report's methodology has led to a similar bias in conclusions. This is inconsistent with sound social science research or public policy.**

**It is therefore our opinion that no proposal for legislative change should be based on this report which has been produced without clearly defined methodology, with a consistent bias and with such lack of transparency.**

### **The need for comparative information**

The report states that patients have a "fundamental right" to information on medicines. In order to make an informed choice among available options and services, treatment and non-treatment, patients need access to **independent, unbiased and comparative information**<sup>i</sup>. This cannot be provided by the pharmaceutical industry.

Newly diagnosed patients can be extremely vulnerable. They do not require information that has been designed in order to meet the pharmaceutical industry's need for a competitive advantage. **Patients and the public need information that is independent of any need to promote product sales. The health industries cannot meet this need as no company can be expected to paint its own product in an unfavourable light, to promote competitors' products over its own, or to explain how to best avoid the use of its products.** There is a fundamental conflict of interest in such an approach.

The report bypasses the important role to be played by healthcare professionals in the provision of information about medicines to patients, identifying them as mere intermediaries for information provided by pharmaceutical companies.

National regulatory authorities and the EMEA are gatekeepers to information. Regulatory agencies are also responsible for ensuring the availability and quality of patient information leaflets, assessment reports, and also information on drug safety, as required by EU transparency obligations. However, European Public Assessment Reports (EPAR) are only available for centrally authorised products, which represent a low percentage of the overall medicines available in the EU. In addition, the information provided in the EPAR summary on product efficacy or safety is not sufficient to allow a thorough appraisal of treatment options by patients.

Moreover, pharmaceutical companies can be guilty of withholding "key information", such as evidence of health risks associated with their products or evidence of inadequate efficacy. Recent examples such as the Vioxx disaster, SSRI antidepressants in children and adolescents, or the current Zyprexa and Avandia scandals are sobering; adverse effects are often minimized and evidence of lack of benefit or of harm is sometimes even concealed by pharmaceutical companies.

Health professionals, patients and the public have a fundamental right to the complete body of scientific evidence on the health effects of medicines. Without access to this information, all medicine use is by definition uninformed. When this information access is partial and biased – for example the common practice for companies to publish the results of one more positive trial and fail to publish a second more negative trial – medicine use is consciously misinformed.

**Therefore, HAI Europe calls for all information on drug safety and effectiveness included that submitted to regulatory authorities, and all pre-market laboratory and clinical data and post-marketing studies, to be made publicly available. In addition, the Commission needs to strongly encourage regulatory agencies in all EU Member States to implement these transparency obligations.**

The current legislation does not prevent the industry from providing health-related information, provided it does not, directly or indirectly, refer to its products (Directive 2001/83/EC article 86). However, there are many examples in Europe of health information provided by companies with an intent to promote product sales, such as Pfizer promotion of Lipitor through its cardiovascular information campaign in France, Novartis' promotion of Lamisil through its toenail fungus campaign in the Netherlands, etc. These campaigns are often characterized by an exaggeration of disease risks and a misrepresentation of the need for treatment as compared to epidemiological and clinical trial evidence. Given this experience to date, any more to rely on the industry for public health messages – with its vested interest in convincing more people that they need treatment – is likely to lead to more problematic and unreliable messages and to a focus on conditions for which the company has a product to sell, rather than necessarily those of greatest public health concern. The Commission's report not only entirely omits reference to strategies to avoid "disease mongering" in future: it is suggesting initiatives likely to intensify the problem.

## Drug promotion and irrational use of medicines

In May 2007, the World Health Assembly adopted a resolution on ‘Progress on the Rational Use of Medicines’<sup>xv</sup>. Most notably, the resolution calls upon WHO Member States:

*“to enact new, or enforce existing, legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor promotion of medicines, and to develop and implement programmes that will provide independent, nonpromotional information about medicines.”*

Paradoxically, at a moment where the international health community is keen to recognise the conflict of interest inherent in the provision of information on medicines by the pharmaceutical industry and drug promotion as a key driver in the irrational use of medicines<sup>xvi xvii xviii xix</sup>, **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<sup>xx xxi</sup>.**

**HAI Europe stresses the importance of article 88 of Directive 2001/83/EC, which is the only legislative safeguard against a full introduction of direct-to-consumer advertising of prescription drugs. HAI deplores this consultation as the Commission’s attempt to undermine this prohibition. Article 88 must be maintained intact and fully implemented and enforced in all Member States.**

## Concrete proposals

The **European Public Health Executive Agency** could provide both pan-European information on disease epidemiology and comparative information between countries:

- Prevalence rates by disease, age and sex, with a breakdown by country and region, including discussion of reasons for inter-country differences;
- Complication rates, with information on average timing and range of timing of expected complications from disease diagnosis (provided with a similar breakdown of data: per country, elaborating on explanatory factors for potential differences between countries);
- Links and/or references to accurate, independent, unbiased information from non-commercial information providers on the epidemiology and natural history of the disease/condition.

**DG Sanco and EMEA** could jointly provide comparative information on availability and prices of different treatments and could provide easy links to approved product information in a centralized location, including patient information leaflets, EPARS, reports such as pre-

market drug reviews that form the basis for regulatory decisions, post-market regulatory documents including Periodic Safety Update Reports (PSURs), safety advisories etc.

The **European Medicines Evaluation Agency** (EMA) could provide information on available drug treatments:

- What products have been approved in the European Union;
- Links to approved product information and European Public Assessment Reports (EPARs);
- Links to pre-market drug evaluations complete clinical trial information concerning all drugs approved through the centralized or decentralized procedures, and any reviews of drugs carried out by the Committee of Medicinal Products for Human Use (CHMP), since the EMA came into existence in 1995;
- Comparative pricing information between products and countries;
- National and European safety advisories on medicinal products;
- Links to sources of independent, unbiased comparative information.

The following **changes are needed** if the aim is to bring about real improvement in medicinal products' information to European citizens:

- Rapid and permanent end to the confusion of roles played by pharmaceutical companies in the provision of information on medicines;
- Recognition of the many existing independent sources of information in European Union Member States;
- Development and reinforcement, in each Member State, of the existing sources of reliable comparative information on available treatment (and non-treatment) options;
- Action to ensure that pharmaceutical companies consistently respect their obligations to provide high quality drug packaging and patient leaflets;
- Full enforcement of European regulations on pharmaceutical advertising, including measures to ensure that article 88 of Directive 2001/83/EC is not weakened or undermined;
- A guarantee of the full transparency of drug regulatory agencies, to ensure that the public has access to data on the efficacy and safety of medicines and other healthcare products, both before and after a product is marketed;
- Provisions for the direct consumer reporting of adverse drug reactions, which will contribute to improvements in the use of medicines.

## **Conclusion - Public Health: an overriding priority**

Health Action International is an independent global network of over 200 organisations and individual members with 25 years experience in representing the voice of civil society, the poor and the marginalised in medicines policy debates. Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

**HAI believes that it is the duty and mandate of the European Union to safeguard the interests of public health over and above the interests of its industrial constituency. To this end, it must reassess the legitimacy of this report and its consultation.**

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