DIRECT TO CONSUMER INFORMATION

BEUC response to the European Commission consultation on a legal proposal on information to patients

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Summary

BEUC and its member organizations strongly support the consumer right to access high quality information about health, medicines and treatments. However we believe that the European Commission proposal, as outlined in the consultation paper, is far from meeting patients' and consumers' needs and expectations, for the following reasons:

- It doesn't set out an information strategy but just provides the pharmaceutical industries greater flexibility to provide information directly to the public on prescription medicines;
- It focuses exclusively on the industry whose commercial interests are in conflict with the consumer right to unbiased, comparative and non promotional information, and doesn't explore any appropriate alternatives;
- It is based on an unworkable distinction between information and adverting;
- It will allow the industry to choose on which particular disease or specific medicine and to what extent the "information" will be provided and how much money to spend on it;
- It will give rise to detrimental consequences, including a push towards high margin medicines, an increase on health care costs, a bias against non-drug therapies and a pressure on the doctor/patient relationship;
- It is not based on a comprehensive assessment of consumers information needs and on a thorough analysis of the benefits and risks of a change in the legislation;
- It disregards the opinions expressed by the health community in previous consultations;
- The proposed validation mechanisms, the monitoring system and the co-regulatory approach are extremely weak, costly and inefficient.

Therefore, we ask the European Commission to reconsider its preliminary proposal and to proceed, in cooperation with the Member States, to the development of a comprehensive health information strategy that:

- puts health interests first;
- relies on and promotes good and independent sources of information;
- enable consumers to choose and compare different medicines and treatments options;
- truly addresses inequalities in the access of health information.

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BEUC and its member organizations are deeply concerned about the developments within the Commission services on information to patients and in particular about the ideas for a legislative proposal outlined in the consultation paper launched on 5 February 2008[i].

1. Information vs. Advertising

The main element of the Commission proposal is "to present a clear distinction between advertising of and information provided on prescription medicines" and "information that is allowed and not allowed" but it doesn't provide any definition of information.

On the basis of the provisions of the EU legislation on advertising[ii], we strongly believe that it is not possible and realistic to make a distinction between information and advertising, especially when the information comes from a commercially interested party.

However, even if a workable distinction could be made, we would still be against the lifting of current restrictions on the information that pharmaceutical companies can give directly to the public about prescription medicines for the following reasons:

a) The over-riding reason is the conflicts of interest that will ensue if the current restrictions are lifted. Pharmaceutical companies may have billons of euro at stake for one medicine and this fact will inevitably affect their information policy, and the amount to be spent on information on that medicine.

b) If the restrictions are lifted, individual companies will be free to choose:

- The particular diseases on which information will be given;
- The specific medicines on which information will be provided;
- The information to be given about each medicine (provided it is not directly misleading) and most important of all;
- The amount of resources to allocate to information on which medicines.

The resulting mix of information will not correspond to overall patient needs or public health priorities but will be weighted towards the priorities of the individual pharmaceutical companies. We can also assume that the weight of company-sourced information would be particularly overwhelming in those Member States with least to spend on health services generally.

c) More specifically, if the restrictions were lifted we could expect:

- A bias towards high margin medicines;
- A bias towards the medicalisation of various conditions;
- A bias against non-drug therapies and improving lifestyles;
- Pressure on the doctor/patient relationship;
- Pressure on the health care budget;
- Increased costs;
- A move toward direct reporting to the companies of adverse effects[iii].

In overall terms, we strongly believe that allowing pharmaceutical companies to provide information directly to the public will not solve the problems consumers face in accessing high quality health information. Moreover, it will not help them to make an informed choice, will have a cumulative "dis-educational" effect and will not lead to better health outcomes.

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2. Push, pull and validation

The Commission states that "a distinction should be made between cases where the patient is passively receiving the information (push) or actively searching for the information (pull) in terms of the monitoring mechanism".
BEUC believes that it is unrealistic to think that such a distinction can be made and that it can be effectively monitored.

Moreover the proposal doesn't include any validation of the information: no authorisation or prior approval is foreseen. The pharmaceutical industries will be able to disseminate information on prescription-only medicines through TV and radio programmes, through printed material actively distributed, through information in printed media or thought audiovisual and written material provided to patients by health care professionals. The monitoring system proposed is based on the principle "Do and tell" and information providers will be required only to "inform national co-regulatory bodies about their activities before action is taken".

Although in the consultation paper as well as in the report on current practices with regard to information to patients on medicinal products[iv] the Commission acknowledges that "the quality of information is currently very variable, in particular in view of the Internet where the providers have no or limited accountability towards EU citizens", it doesn't foresee any validation ex ante or ex post for information provided on websites.

3. Comparative information

To be effectively engaged and actively participate in their health care consumers need more and better information about health and diseases and must be enabled to compare and choose between different treatments and different medicines.
The Commission preliminary proposal fails to meet these needs not only because it explicitly excludes comparison between medicinal products but also because it focus exclusively on the industry.
"Comparative" is an essential criteria to define high quality information; the industry cannot be considered as an impartial source of high quality information precisely because it is not in the position to provide comparative information between medicines and between other treatment options.

4. Monitoring and co-regulation: not efficient and not effective

The proposed monitoring system and the co-regulatory approach are extremely weak and don't ensure consumers rights to unbiased and high quality information.

It is not clear what the content of the national code of conduct will be, which will be its terms of reference and which will be its legal status in the context of the co-regulatory framework.

There is also a lack of clarity on how the national co-regulatory body should work, how the members will be appointed, who will define the rules, how its activities will be funded, what will be its tasks, what is the commitment expected from each member.

The EU advisory committee will not have any binding power and it will be difficult to ensure consistency between the different national codes of conducts and therefore a harmonisation of the practices of information provision, which is described as one of the main objectives of the proposal.

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BEUC recognises the EMEA as a central and impartial source of information and we are extremely surprised that the proposal denies the agency any role and also states that "no scientific assessment of information will be necessary".

Worse, pharmaceuticals industries will be members of the co-regulatory bodies and will be asked to judge and punish themselves. Sanctions will be imposed retrospectively and only in cases of "repeated and severe cases of non-compliance". We consider these provisions unacceptable and against consumers' and public health interests.

We also believe that in this context, co-regulation, exactly as self-regulation, is not sufficient to ensure a high level of consumer protection: evidence[v] shows that self-regulation, together with guidelines for sales representatives or for advertisements and government controls of post-marketing surveillance are ineffective.

It is interesting to note that in a report[vi] for the US Congress, the United States Government Accountability Office (GAO) points out that the monitoring of pharmaceutical companies communication activities in the US is not working properly and that for the FDA is nearly impossible to enforce compliance and prevent consumers' exposure to false or misleading advertising. "Studies GAO reviewed suggest that DTC advertising has contributed to increases in drug spending and utilization, for example, by prompting consumers to request the advertised drugs from their physicians, who are generally responsive to these requests".

The Commission stresses that the current restrictions would not be lifted in any way that would lead to a US-style regime of medicine advertising. Nevertheless, the changes it envisages may still have in Europe effects similar to those in the US, (even if not as intensive or as immediate). We believe therefore that the experience of the US has important implications for Europe and is indeed an effective argument against the lifting of the current restrictions at this stage.

5. The objectives of the proposal

According to art.88 of the Pharmaceuticals Directive 2001/83/EC "the Commission shall, if appropriate, put forward proposals setting out an information strategy to ensure good-quality, objective, reliable and non promotional information on medicinal products and other treatments and shall address the question of the information source's liability".

BEUC considers that the ideas outlined in the consultation papers do not meet the European Parliament and European Council demands as:

- The proposal does not set out an information strategy but just "creates a framework for the industry to provide certain information on their medicines to the public" [vii];
- It focuses only on medicinal products and not on other treatments;
- It doesn't address the issue of the liability of the information source.

The consultation paper also states that the main objectives of the legal proposal are:

1. Establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.

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2. Maintaining the ban on direct-to-consumer advertising of prescription medicines, making sure that there is a clear distinction between advertising and non promotional information.
3. Providing rules that harmonize practices on information to patients in Member States.
4. Avoiding unnecessary bureaucracy, in line with the principles of Better Regulation.

BEUC considers that the Commission proposal is far from achieving these objectives as:

1) It rely exclusively on the industry while, in order to enable EU consumers to get unbiased information, it is essential to consider a larger number of sources and find ways to reinforce the good ones[viii] and those that the citizens trust the most[ix]: patients/consumers should receive health related information from independent bodies and health specialists and not from the pharmaceutical industry. Because of the inherent conflict of interest the pharmaceutical companies faces in communicating about their own products they cannot be considered as an impartial source of information.

2) The Commission proposal doesn't provide any definition or concrete example showing that a clear distinction between information and advertising can be made. Even when information provided by the industry is scientifically correct, it can be biased by omission, thus not objective and in last analysis promotional. We also consider that most of the provisions outlined in the paper, especially those referred as "Pushed information", call the ban on advertisement into question.

3) Inequalities of access to health information depend on a number of factors such as level of literacy, individual engagement, economic and social conditions. Setting "rules on the provision of information by the marketing authorisation holders" is not the answer to the problem. The European Commission and the Member states should not delegate to commercial partners the harmonisation of the information provision. They should first ensure that statutory information is equally provided in all the Member States and that the legislation is fully implemented. They should also look at other policies (e.g. education) that have a significant impact on health information.

4) The national co-regulatory body, the code of conducts and the whole monitoring structure will create a big administrative burden for all the stakeholders and especially for the competent authorities. It will also be very costly: money spent for the monitoring could be better used to support independent sources of information.

6. Information rights and obligations: the industry and the patients

According to the European Commission "the industry possesses key information on their medicines but this information can not currently be made available to patients and to health care professionals throughout the EU"[5]. We don't share this view: pharmaceutical companies have a legal duty to provide detailed information for each of the drug they produce in the patient information leaflet. They can respond to patients' specific inquiries, provide information on vaccines, advertise non-prescription medicines, make disease awareness campaigns and provide information about health (art.86, Directive 2001/83/EC).

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On the other hand, several experiences have shown that pharmaceutical companies fail to disclose important information regarding their products and that improvements are needed to ensure transparency on pharmacovigilance data and clinical trials[xxi]: instead of speaking about the "right of the industry" to provide information[xii] we should speak about the industry "obligations" to provide complete and timely information and foster the existing legislation.

7. An haphazard decision making process

Any change in the current legislation regarding the provision of information on prescription medicines might have a huge impact on all consumers' everyday life as well as on the health care systems. It therefore needs a thorough analysis and an extensive consultation with the wider health community.

The draft proposal and more generally the Commission work on information to patients is not based on a comprehensive assessment of consumers information needs and on a thorough analysis on the benefits and risks of relaxing the current provisions on what and how the companies can communicate directly to the public about prescription medicines.

In addition, in developing the proposal, the Commission does not appear to have carried out any analysis of the economic impact of a change in the legislation, in particular with regard to:

- the consumption of medicines; will more people take more medicines as a result of more information from pharmaceutical companies? Are there circumstances in which pharmaceutical companies would wish to provide Direct To Consumers' Information that is intended to reduce or have no impact on the demands for products?
- the price of medicines; will the cost to companies of providing more information be recouped by higher prices or by greater sales/consumption?
- competition in the pharmaceutical sector – between branded and generics, and between large companies and SMEs.
- advertising revenue of print publications, radio and TV.
- health care budgets – whether as a result of higher prices, increased consumption or other factors.

The European Commission did not even wait for its own impact assessment before presenting the proposal:DG ENTERPRISE commissioned a study to an external consultancy to assess different policy options (status quo, legislation, self-regulation and co-regulation) while in the consultation proposals the Commission seems to have already opted for one of them, co-regulation.

This is the fourth consultation on information to patients the Commission launched in the last ten months but it is clear that the outcomes of the previous consultations and the opinion of the health community have not been taken into account[xiii].

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8. How to effectively improve patients' information

BEUC and its member organizations strongly support the right of access to quality, independent and balanced health information for all those who need it, including information about medicines, as an important contribution to the autonomy, dignity, health and well-being of patients and citizens.

We are a long way from achieving this aim that can only be achieved by developing a broad health information strategy rooted in a wider and coherent health policy. At EU level, this can best be done in cooperation with Health Ministers through the Open Method of Coordination. The first priority should be to develop a consensus on a health information strategy and then to take more specific decisions, including on information about medicines, in the context of a broad health information policy.

Information needs are very complex and highly individual and it is essential both for policy makers and for health professionals to identify these specific needs and respond accordingly[xiv].

BEUC has already suggested in several occasions the policy options listed below to improve information to patients within the existing legal framework:

How to improve the provision of information on medicines

- Fostering the role of the EMEA as a central and impartial source of information about medicines;
- Making statutory information, i.e. the package leaflet, equally available and accessible in all member states;
- Ensuring transparency of the medicines regulatory agencies to guarantee access to drug evaluation and pharmacovigilance data;
- Making pharmaceutical companies fulfil their obligations concerning the disclosure of safety information;
- Ensuring the existing European regulation on drug promotion is enforced and that the doctor/patient relationship and prescription behaviours are not influenced by any marketing technique;
- Improving package information leaflet content and relevance as a information tool. BEUC contributes to and strongly supports the EMEA initiative on the readability of the package information leaflets and EPAR summaries;
- Speeding up the process of the inclusion in the Eudrapharm database of information on all the medicines authorised via the different authorization procedures;

and more generally on health:

- Improving the visibility of some trusted websites such as the EMEA and the EU health portal web sites (which, at the moment, are very difficult to find through a normal web search) and exploit synergies between them;
- Fostering national platforms for health information;
- Implementing health education programmes in schools and for the wider public;
- Developing networks of libraries for health;
- Investigating the possibility of having an EU logo that identifies reliable sources of information that comply with core principles for high quality information;
- Developing and reinforcing good sources of health information;
- Giving financial support to initiatives that consider social and cultural aspects;
- Supporting information initiatives at EU, national, regional and local level (ex. EU wide campaigns for prevention and promotion, EU health Portal, Public health programme funded projects).

BEUC called the European Commission to conduct a comprehensive study to identify and quantify patients and consumers needs for information on medicines and health related information[xv].
Together with a large number of health NGOs we also urged the European Commission to follow the European Union Health policy Forum recommendations to carry on a mapping exercise to identify all initiatives and policies addressing the different aspects of health information[xvi].

9. Conclusion

We ask the European Commission to reconsider its preliminary proposal and not to allow the pharmaceutical industry to provide the so-called "non-promotional information" to the public.
We also urge the Commission, as well as the other EU institutions and the Member States, to frame information on medicines within a wider policy of promoting better health information for all.
Last but not least, the competence on medicines should be shifted from the Directorate General responsible for the competitiveness of the industry to the Directorate General responsible for public health and consumer protection. This would ensure that medicines are considered as a genuine public health issue and not from an industrial perspective. It would also help to find a better balance between public health and economic interests and to ensure that patients and consumers needs are put first[xvii].

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[i] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802.pdf

[ii] - Directive 2001/83/EC on **Community code relating to medicinal products** for human use
Article 86, *'advertising of medicinal products' shall include any form of doorto- door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:*

a. *the advertising of medicinal products to the general public,*
b. *advertising of medicinal products to persons qualified to prescribe or supply them,*
c. *visits by medical sales representatives to persons qualified to prescribe medicinal products,*
d. *the supply of samples,*
e. *the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,*
f. *Sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,- sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.*

- Directive 2007/65/EC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television **broadcasting activities**
Article 1 (i) "*television advertising" means any form of announcement broadcast whether in return for payment or for similar consideration or broadcast for self-promotional purposes by a public or private undertaking or natural person in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations, in return for payment.*

- Directive 2006/114/EC concerning **misleading and comparative advertising**
Art. 2 : advertising' means the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services,including immovable property, rights and obligations.

- Directive 2003/33/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the **advertising and sponsorship of tobacco products**
Art. 2 (b) "advertising" means any form of commercial communications with the aim or direct or indirect effect of promoting a tobacco product;

[iii] A strong, transparent and efficient pharmacovigilance system, BEUC, February 2008.

[iv] Report on current practices with regard to the provision of information to patients on medicinal product, European Commission, December 2007.

[v] - Drug promotion what we know, what we have yet to learn, WHO/HAI, 2005.
- The influence of the Pharmaceutical Industry report of the House of Commons Health Committee, 2005.

[vi] United States Government Accountability Office, Prescription drugs, Improvements needed in FDA's oversight of DTCA, November 2006.

[vii] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_02/info_to_patients_consult_200802.pdf, page 6

[viii] Relevant Health Information for Empowered Citizens. September, 2006. Joint Declaration of Health Action International-Europe, International Society of Drug Bulletins, Association Internationale de la Mutualite, BEUC and the Medicines in Europe Forum.

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[xi] Kirsch I, Deacon BJ, Huedo-Medina TB, Scoboria A, Moore TJ, et al. (2008) Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration. PLoS Med 5(2)

[xii] Vice-president Verheugen speech at the Pharmaceutical Forum, September 2005.

[xiii] Summary of the public consultation responses - Draft Report On Current Practice With Regard To Provision Of Information To Patients On Medicinal Products http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_10/d-34327-summary-of-consultation-responses.pdf

[xiv] A coherent and patient centred information system, BEUC, June 2007.

[xvi] Joint Statement – Information to patients: the way forward, September 2007.

[xvii] Put Health First, BEUC, October 2007.

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