



# INFORMATION TO THE PUBLIC ON PRESCRIPTION MEDICINES

BEUC position

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**Ref.:** X/068/2010 - 21/09/10

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## Summary

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

1. It is based on an unworkable distinction between information and advertising;
2. It doesn't define an information strategy but just provides pharmaceutical companies greater flexibility to provide information on their products directly to the public;
3. It will allow the industry to set the information agenda and choose on which medicines and on which diseases the information will be provided;
4. It opens the door to disease mongering (art.88), allowing companies to make campaigns on any issue that they consider to be in the interest of public health;
5. It increases inequalities in the provision of information between Member States;
6. It will give rise to detrimental consequences, including a push towards high margin medicines, an unnecessary increase in health care costs, a bias against non-drug therapies and a pressure on the doctor/patient relationship;
7. 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;
8. The proposed monitoring system is extremely weak, costly and inefficient;
9. The proposed enforcement measures are contradictory and increase legal uncertainty especially with regard to liability issues.

We call for the Commission and the Member States to develop a comprehensive health information strategy that:

- puts health interests first;
- relies on and promotes good and independent sources of information;
- enables consumers to make informed choices;
- truly addresses inequalities in the access to health information.

## **BEUC position<sup>1</sup> on the Commission legislative proposals<sup>2</sup> regarding information to the general public about prescription-only medicines**

### **1. General comments**

#### **1.1 Information vs. Advertising**

The right to information is one of the basic consumers' rights that BEUC and its member organisations promote and defend in all areas of consumers' interest. Information is a right and a value in itself, and especially in health care, it plays an important contribution to the autonomy, dignity, health and well-being of people. With regards to prescription medicines, being informed is vital to fully benefit from the therapy.

Medicines save lives but can also have serious side effects – according to the European Commission “it is estimated that 5% of all hospital admissions are due to an adverse drug reaction, 5% of all hospital patients suffer an adverse reaction and adverse reactions are the fifth most common cause of hospital death”<sup>3</sup> – therefore they should be used rationally and their consumption should not be promoted unless when strictly necessary from a medical point of view. For these reasons it is essential to keep a ban on direct to consumers advertising of prescription medicines and to maintain a clear distinction between promotional and non promotional information. While these are also defined as the main aims of the Commission proposal, we believe it fails to achieve them as it creates many grey zones in the definition of what is “information” and what constitutes “advertising”.

On the basis of the provisions of the EU legislation on advertising<sup>4</sup>, 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 still think that the proposed changes to the legislation are not in the best interest of consumers as they give the industry the prerogative to effectively set the information agenda.

Pharmaceutical companies may have billions of euros at stake for one medicine and this fact will inevitably affect their information policy. In other words, companies will be free to choose:

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1 This paper is a consolidated version of the BEUC positions expressed in previous public consultations on information to patients.

2 - Proposal for a Directive of the European Parliament and of the Council amending, as regards information to the general public on medicinal products subject to medical prescription, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

- proposal for a regulation amending, as regards information to the general public on medicinal products for human use subject to medical prescription, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

3 Proposal for a Directive of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

4 - Directive 2001/83/EC on Community code relating to medicinal products for human use.

- 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.

- Directive 2006/114/EC concerning misleading and comparative advertising.

- 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.

- 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).

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.

More specifically, the proposed changes to the legislation can lead to:

- A bias against non-drug therapies and improving lifestyles;
- A bias towards high margin medicines (in the US more than 54% of the expenditure on promotional information go to the 20 most expensive medicines<sup>5</sup>);
- A bias towards the medicalisation of various conditions;
- Pressure on the doctor/patient relationship;
- Pressure on the health care budget ( individual and public);
- Increased costs;
- A move towards direct reporting to the companies of adverse effects<sup>6</sup>.

Overall, we strongly believe that allowing pharmaceutical companies to provide information directly to the public in the terms proposed in the Commission proposal 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.

## 1.2 Consumers’ information needs

We think that the proposal fails to meet the real information needs of the patients and their cares for the following reasons:

1. *It does not set out a comprehensive and patient centered information strategy (as requested also by the European Parliament and the Council in 2004<sup>7</sup>) but just creates a framework for the industry to provide certain information on their medicines to the public:*

Patients need information all along the patient journey, including information to understand if something is wrong, information that gives them a realistic idea of the evolution of their health status, help them to understand when further investigations are preferable, to know what treatments exist and what they can expect from them, and help them share or make informed choices. While health information includes also measures to stay healthy and prevent illnesses, the Commission proposal focuses on the very last part of the patient journey, before or after a patient is prescribed a prescription medicine, and does not take into account the complexity of the issue and its public health implications.

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5 Donohue JM et al. "A decade of DTCA of prescription drugs" N Engl J Med, 2007; 357: 673-81.

6 - BEUC position on pharmacovigilance, BEUC, November 2009.

- A strong, transparent and efficient pharmacovigilance system, BEUC, February 2008.

7 Art.88 Directive 2001/83/EC.

2. *It doesn't ensure good-quality information on medicinal products and other treatments;*

Consumers need information that allows them to understand the relative value of a treatment compared to others and to put a therapy into a wider context. The proposal explicitly excludes comparison between medicinal products and focuses exclusively on prescription medicines. The industry cannot be considered as an impartial source of good quality information precisely because it is not in its interest to provide comparative information between medicines and between other treatment options. In order to enable consumers to get unbiased information, it is essential to consider a larger number of sources and find ways to reinforce the good ones<sup>8</sup> and those that people trust the most<sup>9</sup>, such as health care professionals.

3. *It doesn't ensure that the information is non promotional;*

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.

In addition it doesn't include any reference to images which, according to marketing theories and behavioural economics, are as powerful as text. Nor it addresses the role of new media and social networks.

4. *It increases inequalities in the access to information between Member States;*

According to the European Commission<sup>10</sup> there are a significant number of initiatives in all EU countries intended to provide information on medicines to the public. But there are still unacceptable variations between Member States in the amount and in the quality of the information available. However, with regard to the proposal, the establishment of regulatory bodies in each member state to oversee the framework, the national interpretation of what constitutes a "health related publication" and the lack of a workable distinction between advertising and information will make impossible to move towards more harmonisation.

It is also true that 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.

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8 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.

9 - Eurobarometer, 2003.  
- Which, 2008.  
- IPSOS, 2010.

10 Report on current practices with regard to the provision of information to patients on medicinal products, European Commission, 2007.

5. *It doesn't address the issue of information source's liability*

Sources of information about health issues are increasing in number, especially with advances in technology, but determining the trustworthiness of this information remains a prime concern. Those providing the information might be driven by potential financial gain or personal bias which may conflict with the interest of the patient. Furthermore, there is little "consumer protection" against inaccurate and misleading information. For example the national competent authorities have little power to enforce closure of unscrupulous websites.

The proposal even worsens these problems, for instance by allowing the multiplication of unnecessary information formats (e.g. two leaflets for the same product, one free style leaflet and one officially approved) and by increasing legal uncertainty in relation to liability and enforcement (e.g. information provided by third parties, registration of web sites, penalties).

6. *It doesn't oblige companies to provide the information consumers need the most*

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"<sup>10</sup>. We don't share this view: pharmaceutical companies have a legal duty to provide patients and health professional detailed information for each of the drug they produce in the patient information leaflet and in the summary of product characteristics. 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). They also have the duty to submit all the information at their disposal to the competent authorities.

On the other hand, several experiences<sup>11,12</sup> 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. The proposal refers to the industry's right to disseminate information about its products<sup>13</sup> while we should speak about the industry's "obligations" to provide complete and timely information and foster the existing legislation.

The proposal should be defined for and around the patient and it should ensure that the information provided is the one people really need. So far it has been defined for and around the industry commercial needs.

A lot of information will be put in the public domain but only little of it will be the information people are actively seeking.

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11 MHRA press release, March 2008,

[www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153](http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153)

12 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).

13 Vice-president Verheugen speech at the Pharmaceutical Forum, September 2005.

In addition the whole monitoring system will create a big administrative burden for all the stakeholders and especially for the competent authorities and will be very costly: money spent for the monitoring could be better used to support independent sources of information.

### 1.3 Assessing the impact

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 public health and health care systems. Therefore it should be subject to a thorough ex ante evaluation. This has not been the case for this proposal.

The Commission text is neither based on a comprehensive assessment of consumers' information needs, nor on a thorough analysis on the benefits and risks of relaxing the current provisions, or on what and how the companies can communicate directly to the public about prescription medicines.

Apart from the "instructions for use" or "contract terms", so far any direct communication from a company to consumers on a given product is considered advertising. The proposal introduces a new concept in the EU legislation: the provision of non promotional information by commercially interested parties. While the impact of direct to consumers advertising on the consumption of medicines has been assessed, the impact of "non promotional information" has not been predicted. In relation to this, it would be useful to understand also the differences in consumers' perception and appraisal skills when confronted with "advertising" and with "non promotional information".

It would also be necessary to assess the effects on public health of the combination of symptom advertising on TV and radio (without product claim as allowed by the existing legislation) and specific product information directly to consumers through the permitted channels.

Studies<sup>14</sup> conducted in the US show that Direct to Consumers Advertising (DTCA) has contributed to increases in drug spending and use, 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 to be taken into account when assessing the potential impacts of the proposal.

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- 14 - Rosenthal MB et al "Promotion of prescription drugs to consumers" N Engl J Med, 2002; 346(7):498-505.
- Mintzes B. et al "Twelve years' experience with DTCA of prescription drugs in Canada: a cautionary tale" PloS One vol.4 n.5.
  - Mintzes B. et al "How dose DTCA affect prescribing? A survey in primary care environments with and without legal DTCA" CMAJ 2003; 169(5):405-12.
  - Toop L. "The impac of advertising prescription medicines directly to consumers in New Zealand: lesson for Australia" Aust Prescr 2006; 29: 30-32).
  - Velo G., Moretti, U. (2008). Direct-to-consumer information in Europe: the blurred margin between promotion and information. British Journal of Clinical Pharmacology 66(5): 626-628.

Finally, 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:

- o 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?
- o the price of medicines: will the cost to companies of providing more information be recouped by higher prices or by greater sales/consumption?
- o spending on R&D: according to the European Commission sector inquiry<sup>15</sup> pharmaceutical companies spend only 1.5 % of their turnover on basic research intended to identify potential new medicines (17% on R&D as a whole) and 23% of their turnover on marketing activities directed to health professionals;
- o competition in the pharmaceutical sector – between branded and generics, and between large companies and SMEs;
- o revenues of publishers and media companies for the production and publication of the information;
- o health care budgets – whether as a result of higher prices, increased consumption or other factors.

## 2. Comments on specific elements of the proposal

### 2.1 Selling sickness

The new wording of art.88/4 allows the industry to make disease awareness campaigns on any topic "in the interest of public health" whereas the existing legislation limits this possibility to vaccination campaigns. We oppose this change as we think it will lead to disease mongering. In addition, art.86 of the existing legislation already grants companies the possibility of making campaigns on health issues - without product claims – and in relation to this we already see problems in the use of "disease awareness or "ask your doctor" campaigns: minor problems become medical problems (e.g. baldness), mild symptoms become a serious disease ( e.g. irritable bowel syndrome), personal or social problems become a disorder (e.g. shyness), risks become diseases (e.g. osteoporosis) and prevalence figures are maximized (e.g. sexual problems)<sup>16</sup>.

More generally we are concerned that - no matter the monitoring system - this directive will lead to the medicalisation of conditions and alter the consumers' perception of health and diseases.

Consumers have the right to know more about health and diseases but they also have the right to know the underlying objectives of these campaigns and the motivations of their sponsors.

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<sup>15</sup> Report of the pharmaceutical sector inquiry, European Commission, July 2009.

<sup>16</sup> - OCU ,and Test-Achats,2010.

- Moynihan R., Heath I., Henry D. (2002) Selling sickness: the pharmaceutical industry and disease mongering. *British Medical Journal* 324:886-91.



## 2.2 Content of the information

Art. 100b of the proposed directive defines the types of information that may be used in direct communications between pharmaceutical companies and the general public. They include:

- a) *"The summary of product characteristics, labelling and package leaflet of the medicinal product, as approved by the competent authorities"* whose dissemination is already allowed by the existing legislation;
- b) *"Information which does not go beyond the elements of the summary of product characteristics, labelling and the patient information leaflet of the medicinal product, but presents them in a different way"*. This will allow the companies to rephrase the content of the officially approved information. This also means that there will be two kinds of information on the same product: one officially approved and a free style one as designed by the industry with the result that consumers will be confused. We also consider redrafting the leaflets a waste of resources that could be better used to improve the "official" information, especially taking into account that the industry and the competent authorities (European Medicines Agency Working group for the Quality Review of Documents) invest a lot in user testing to improve the quality and readability of the leaflets and that there are already many ongoing initiatives to improve the officially approved information (e.g. the new legislation on pharmacovigilance). Finally, despite the quality criteria defined in art.100 d, by presenting the information in a different way companies could emphasize the benefits of their products and downplay the risks.
- c) *"Information on the environmental impact of the medicinal product, prices and factual, informative announcements and reference material relating, for example, to pack changes or adverse-reaction warnings"*.

Regarding the "environmental impact" it is necessary to clarify what it actually means and make sure that all the information on the safe disposal of the medicine are in the leaflet and not only on a web site or in a health magazine.

Information on "price" could expose the public to promotional statements such as:

"As of today, prescription medicine XH is 20% less expensive than before". Or "The new LK box now includes 30 tablets more than before" and be misused for marketing purposes as it has been done in Canada.

With regard to "factual announcements" we see an inconsistency with art.86 of the existing legislation which allows the dissemination of the same information but *"provided they include no product claims"*. The proposed change has not added value compared to the existing legislation in terms of the information provided.

Adverse reaction warnings should be available only in the wording approved by the authorities to avoid softening.

- d) *"Medicinal product-related information about non-interventional scientific studies, or accompanying measures to prevention and medical treatment, or information which presents the medicinal product in the context of the condition to be prevented or treated"*.

We think it will be impossible for the officials in the competent authorities who are asked to grant the authorisation for the dissemination of this kind of information to decide if this is information or if it is advertising. The Commission itself, in the public consultation on pharmacovigilance<sup>17</sup>, referring to non-interventional scientific studies<sup>18</sup> acknowledged that they are "*often of poor quality and frequently promotional*". Therefore they should not be used as a basis to inform the public.

### **2.3 Quality criteria**

We fully support the quality criteria identified in the proposal (art. 100d) but it is difficult to imagine how they will be monitored in practice by applying the provision of art. 100g. A missing important criterion that could be objectively verified and that is important for consumers is the provision of "comparative information" (see also point 2.1.2).

### **2.4. Communication channels**

We welcomed that the Commission reconsidered the initial option<sup>19</sup> to allow the use of TV and radio for communications about prescription medicines and excluded them from the final proposal but we consider that also "health related publications" (art. 100 c) should not be allowed for information dissemination. The information about a specific medication available for example in a "women health magazine" would be unsolicited and does not necessarily meet the information needs of the reader.

Not only health related publications can potentially include all printed media such as the health section of daily newspapers, but the fact that it will be up to the Member States to define the list of publications will lead to additional inequalities in the interpretation of the directive and therefore in the access to information (see also point 2.1.4). In addition, the inclusion or exclusion of a publication in the list of a given country can be easily challenged by publishers on the basis of the internal market legislation.

According to the existing legislation (art. 86) companies can have with a member of the general public "*correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product*". The new proposed text refers to general "request for information" and leaves room to abuses. For example, would this provision cover the information provided to a member of the public who registers to a newsletter responding to an announcement like "Do you want to know more about osteoporosis?" Will the information the consumer receive – including on specific prescription medicines - all solicited? Which parts of the legislation will apply to this kind of information? Who will monitor it? Who will be liable? What about privacy and data protection?"

### **2.5 Monitoring system and enforcement**

The proposal clarifies that information regarding medicinal products subject to prescription should be controlled before its publication but also contains an exception if "the content of the information has already been approved by the competent authorities or an equivalent level of adequate and effective monitoring is ensured through a different mechanism." The application of the exception as well as the use of

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17 Public consultation on pharmacovigilance, European Commission, 2007. Point 3.2.5.

18 Non-interventional scientific studies are studies conducted by pharmaceutical companies after the medicine has been put on the market.

19 Consultation on key ideas on information to patients, European Commission 2007.

alternative mechanisms is not clear and as it is, it seems insufficient to ensure that incomplete and promotional information doesn't reach the general public.

In addition, the text indicates that these methods may include the "*voluntary control of information on medicinal products by self-regulatory or co-regulatory bodies*" while the evidence<sup>20</sup> clearly indicates that self-regulation especially in the pharmaceutical sector, doesn't work. Experience with self-regulation shows that it is truly a passive form of scrutiny and not sufficient to ensure a high level of consumer protection<sup>21</sup>. Thus, it should not be used as a possible scrutiny mechanism.

The experience in the US shows that government monitoring also has its problems. In 2004, the FDA had to evaluate 15,458 campaigns. It goes without saying that this number makes any thorough analysis impossible. In practice the FDA examined only a small proportion of the material submitted<sup>22</sup>.

We also have reservations on the guidelines and code of practice that will be drawn up by the Commission as the experience shows that they do not work.

For example, the European Commission<sup>15</sup> collected 629 alleged violations – between 2005 and 2007 – to the Joint Declaration between European Federation of pharmaceutical associations (EFPIA) and the Standing Committee of European Doctors (CPME) that was aimed at avoiding/limiting potential abuses in promotional activities<sup>23</sup>. These breaches took the form of including inaccurate or incomplete information in promotional material or in providing inappropriate leisure activities to doctors.

One of the most unclear aspects of the monitoring system is the oversight of the web sites also taking into account the pace of change of on line content. As they are, the provisions also make it difficult for the competent authorities and for independent third parties (e.g. consumers' organisations) to ensure the enforcement of the legislation. Finally we are concerned that companies will choose to register their web sites in the Member States with least strict rules and least enforcement capacities.

In the European Commission's proposal, the European Medicines Agency is allowed 60 days to respond to information proposals submitted by manufacturers (art. 20 b of the regulation 726/2004). According to the Commission, such an application can be evaluated in 2½ days. If the 60-day time limit is exceeded, the proposal submitted by the industry can be considered as having been accepted. The industry can simply shut down such a system by submitting an excessive number of applications or by starting legal proceedings, as a result of which the original task (i.e. the prior testing of information) gets snowed under. The lack of sufficient resource capacity to carry out the tasks will produce a situation in which no control is exercised over the information in advance.

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20 Shapiro, M.F. (1997). Regulating pharmaceutical advertising: What will work? Canadian Medical Association Journal 156(3): 359-361.

21 - 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.

- Branding the cure, Consumers International, 2006.

22 - Abel G.A., Neufeld E.J., Sorel M., Weeks, J.C. (2008). Direct-to-consumer advertising for bleeding disorders: a content analysis and expert evaluation of advertising claims. Journal of Thrombosis and Haemostasis, 6: 1680-1684.

- Cooper R.J., Schriger, D.L., Wallace, R.C., Mikulich, V.J., Wilkes, M.S. (2003). The quantity and quality of scientific graphs in pharmaceutical advertisements. Journal of Gen Intern Med 2003, 18: 294-297.

23 Joint Declaration of CPME and EFPIA on the Cooperation between the Medical Profession and the Pharmaceutical Industry – June 2005.

It is interesting to note that in a report<sup>24</sup> 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 it is nearly impossible for the FDA to enforce compliance and prevent consumers' exposure to false or misleading advertising.

Experience shows that sanctions (art.100i) are not sufficient to prevent unethical practices. Not even escalating penalties for billions of dollars inflicted in the US<sup>25</sup> prevented breaches of the legislation as they are regarded as the 'cost of doing business'<sup>20</sup>. A "name and shame" system could help reducing abuses.

## 2.6 Liability and redress

Art. 100 a) allows the industry to disseminate information directly and indirectly through a third party: this raises important issues in terms of liability and questions the consumer's right to know who is responsible for the information provided and for which reasons it has been produced and disseminated.

Another major shortcoming of the proposal is the lack of any form of complaint and redress system. Misleading information about medicines can have serious health consequences and undermine consumers trust. A consumer friendly system should be put in place to give the consumers the right to complain in case he/she perceives the information provided is inaccurate or misleading and to seek redress and compensation in case of damages (see the case of Vioxx<sup>26</sup> in the US).

## 3. The way forward

Consumers have the right to high quality, unbiased and non promotional information about health and medicines.

Access to good information is of vital importance to all patients and carers but recognising the value of health information necessitates also a recognition of the importance of health literacy which may be broadly defined as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"<sup>27</sup>. The concept holds that people need more than basic literacy (reading, writing and numeric skills) if they are to participate in modern society; they must develop a number of literacies (e.g. quantitative literacy, media literacy, computer literacy). Efforts must, in this context, also be made to develop people's 'health literacy' so that they develop the competences to find, select and use the right information, and to navigate through the situation most of us face, of 'information overload'<sup>28</sup>.

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.

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

25 David Evans (2009), "Big Pharma's crime spree – Special Report", Bloomberg Markets, December 2009.

26 Merck Agreement to Resolve U.S. VIOXX® Product Liability Lawsuits: Agreement Provides for \$4.85 Billion Payment ([http://www.merck.com/newsroom/news-release-archive/corporate/2007\\_1109.html](http://www.merck.com/newsroom/news-release-archive/corporate/2007_1109.html))

27 Nutbeam, D (1998) Evaluating health promotion – progress, problem and solutions. Health promotion International, 13,27-43.

28 Recommendations on health information, EU Health Policy Forum, 2005.

Over the last four years we urged the EU to develop, in cooperation with the Member States, a comprehensive health information strategy that:

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

In several occasions BEUC has already suggested 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 EMA as a central and impartial source of information about medicines;
- Making statutory information, such as the package leaflets, equally available and accessible in all Member States, on-line and off-line;
- Improving package information leaflet content and relevance as a information tool. BEUC contributes to and strongly supports the EMA initiative on the readability of the package information leaflets and EPAR summaries;
- 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 that 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;
- 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 EMA 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;
- 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 (e.g. EU wide campaigns for health prevention and promotion).

BEUC, together with many health NGOs, also called the European Commission to conduct a comprehensive study to identify and quantify patients' and consumers' information needs and to carry out a mapping exercise to identify all initiatives and policies addressing the different aspects of health information<sup>29</sup>.

#### **4. Conclusions**

We are confident that the fact that the pharmaceutical policies are now a competence of the Directorate General responsible for health and consumers will at last help to ensure that any EU development on this issue will be addressed from a genuine health perspective. This also gives the Commission the opportunity to frame the discussion on information on medicines within a wider policy of promoting better health information for all. For these reasons we urge the European Institutions to reconsider the Commission's preliminary proposal and to focus on the consumer/patient right to information rather than on the industry right to communicate about its products.

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<sup>29</sup> Joint Statement – Information to patients: the way forward, September 2007.