INFORMATION TO PATIENTS (II)

BEUC position on the amended proposals

Contact: Ilaria Passarani – health@beuc.eu
Ref.: X/2011/127 - 20/12/11

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Summary

BEUC welcomes the Commission decision to reconsider its original, ill-conceived proposals on industry information to the general public on prescription medicines. Despite the efforts made so far, we believe the revised texts hold no added value for consumers. In particular the proposals:

- fail to meet consumers' information needs and expectations;
- do not bring any tangible benefit to consumers and to public health;
- leave room for various forms of promotional communication;
- allow industry to set the information agenda and choose on which medicines and which diseases the information will be provided;
- give rise to detrimental consequences, including a push towards high margin medicines, an unnecessary increase in healthcare costs, a bias against non-drug therapies and pressure on the doctor/patient relationship;
- undermine the consumer right to high-quality and unbiased information about health and medicines;
- create a big administrative burden for the competent authorities;
- increase inequalities in the provision of information between Member States.

We ask the EU institutions to give priority to the pharmacovigilance parts of the proposals and to other measures which:

- strengthen patient safety;
- bring tangible benefits to consumers;
- foster and promote independent sources of information on health and medicines;
- enable consumers to make informed choices;
- truly address inequalities in access to health information;
- provide the competent authorities with adequate powers and resources to enforce existing legislation and conduct public health campaigns;
- increase transparency in the pharmaceutical sector.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

BEUC position[1] on the Commission's revised legislative proposals[2] regarding information to the general public about prescription-only medicines

1. No added-value

BEUC welcomes the Commission's decision to reconsider the original, ill-conceived proposals adopted in 2009 and attempt to present a more 'patient-friendly' text.

We consider this a first tangible consequence of the shift of competence for pharmaceutical policy from DG ENTERPRISE to DG SANCO and the result of dialogue with stakeholders and with the other EU institutions who constructively criticised the original proposals for being industry oriented and opening the door to advertising of prescription medicines in Europe.

Following the failed "stress test" of the newly adopted pharmacovigilance legislation involving the case of Mediator[3], the Commission had to introduce additional provisions on pharmacovigilance. We support these measures but encourage the institutions to deal with them separately and approve them as soon as possible via a different legislative procedure.

The provisions considered most detrimental for consumers in the initial proposals (e.g. industry communication on printed media) have been removed, but despite this we still consider the proposals to offer no added value for consumers.

Indeed, the amended proposals:

- undermine the consumer right to high quality and unbiased information about health and medicines;
- leave room to various forms of promotional communication;
- fail to meet the consumers' information needs and their expectations;
- do not bring any tangible benefit to consumers and public health;
- create a significant administrative burden for the competent authorities;
- increase inequalities in the quality of information provided to consumers across the EU.

1 This paper is an updated version of the BEUC position on information to the general public on prescription medicines (X/068/2010) following the adoption by the Commission of modified proposals on 11 October 2011.

2 Amended 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.
Amended 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 Mediator, a diabetes medicine containing Benfuorex and commonly used as a weight loss product, has been linked to between 500 and 2,000 deaths in France due to heart failure. The product remained on the market for many years despite clear warnings as to safety problems and showed a lack of coordination among the national competent authorities as well as significant problems in the relationship between the industry and the competent authorities.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

2. Information vs. Advertising

The right to information is one of the basic consumer rights which BEUC and its member organisations promote and defend in all areas of consumer interest. Information is both a right and a value in itself, and especially in healthcare it makes an important contribution to the autonomy, dignity, health and well-being of people. Well informed patients can be more actively involved in the decisions regarding their treatments and have a meaningful dialogue with their health care professional. With regards to medicines, being informed is vital also 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"[4] – therefore they should be used rationally and their consumption should not be promoted unless strictly necessary from a medical point of view. For these reasons, it is essential to keep a ban on direct advertising of prescription medicines to consumers and to maintain a clear distinction between promotional and non-promotional information.

On the basis of the EU legislation provisions on advertising[5], we believe it is not realistic to make a clear distinction between information and advertising when the information comes directly from a commercially interested party.

The introduction in the revised text of the general principle of pre-vetting is considered a tool to try to make such a distinction, but many derogations foreseen make it meaningless. In any case, even if a workable distinction could be made, we still contend that the proposed changes to the legislation are not in the best interests of consumers as they effectively give the industry the prerogative to set the information agenda. The resulting mix of information will not correspond to overall patient needs or public health priorities, but rather will be weighted towards the priorities of 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 expenditure on promotional information goes to the 20 most expensive medicines[6]);
- a bias towards the medicalisation of various conditions;
- pressure on the doctor/patient relationship;
- pressure on healthcare budgets (individual and public);
- an increase in costs.

---

4 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.

5 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.

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

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

Overall, we strongly believe that allowing pharmaceutical companies to provide information to the public according to the terms of the Commission proposals 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 "diseducational" effect and will not lead to better health outcomes.

3. Too many risks of promotional communication

Many provisions of the revised proposals expose consumers to the risk of being confronted with promotional communication disguised as information:

- Art. 100b 1) and Art.100 e) of the Directive introduce an obligation for companies to make available the so-called **statutory information**, meaning the labelling, package leaflets, the assessment reports and summary of the product characteristics as approved by the competent authorities. This could be perceived as a positive development. Yet the proposal does not specify how these documents should be made available by companies and in which format (e.g. alphabetic list). Can a link to a leaflet be placed in a web page containing information on the disease treated by the product? In any case these provisions have limited added-value taking into account that this information is already made available by the competent authorities. Also, even if not explicitly mentioned, the obligations regarding statutory information seem to apply to all medicinal products, but all the other types of information are allowed under the directive on a voluntary basis and this means it is up to the industry to decide which information, on which medicine and on which disease information should be provided.

  Money spent in duplicating the information already made available by the competent authorities could be better used to improve the reader-friendliness of package leaflets and other official documents disseminated among the public. The resources spent in monitoring compliance with these provisions could be used to improve the content and increase awareness of the medicines portals of the EU and national competent authorities.

- The original proposals allowed companies to conduct campaigns on any issue in the interest of public health. Everybody, including the European Parliament, acknowledged the risks associated with it. The Commission abandoned the idea but introduced a new element in the same article which also poses risks of disease mongering. The new wording allows companies to refer to the therapeutic class of medicines in their **health campaigns** (art. 100 a point 2). This means that companies can run campaigns on depression and make a general reference to anti-depressants even if they cannot mention the name of a product. Evidence from the US shows that with direct to consumer advertising, when a product is advertised, sales increase among the entire therapeutic class. In other words it is more profitable to advertise the therapeutic class than a single product.

  This adds to the already existing problem 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

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

diseases (e.g. osteoporosis) and prevalence figures are maximised (e.g. sexual problems)[7].

More generally we are concerned that - no matter the monitoring system – the proposals will lead to the medicalisation of conditions and alter 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.

- The Commission reintroduced the provision on **printed material** produced by pharmaceutical companies as a channel of communication, despite various stakeholders and the European Parliament asked for it to be omitted.
  Companies can distribute pamphlets and brochures directly to a consumer upon request. The modalities for the request and the handling of personal information of the requesting person are not defined, and this leaves room for 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 receives – including on specific prescription medicines - all be solicited?

- Pamphlets and brochures designed by companies can also be distributed in doctors' surgeries and in pharmacies. **Healthcare professionals** become mere distributors of information produced by the company selling the medicine. We expect in practice that this information will not be provided on all medicines, but on the most profitable medicines and to the detriment of non-drug therapies and generics. For example, it could be easy to find a pamphlet on a weight-loss medicine, but not a brochure on how to eat healthily or on physical activity.

  This provision is highly detrimental - not only because it unduly influences the doctor/patient relationship, but also because it undermines consumer trust in advice from healthcare professionals, trust that is questioned more and more these days due to the increased perception among the general public that many health professionals are under pressure from aggressive marketing activities by pharmaceutical companies.

- 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 has happened 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 "provided they include no product claims". The proposed change has not added value to the existing legislation in terms of the information provided. Adverse reaction warnings should be available only in the wording approved by authorities to avoid softening. In addition, it is unclear what **"environmental information**" actually means. Information on the environment that consumers can actually use and benefit from is information on how to correctly dispose of the medicine

7 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.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

after its use. This information should be clearly indicated in the packaging and in the leaflet of the products.

- Allowing **moving images** (Art. 100b, point d) to be displayed on a company's website can lead to promotional messages even if the information provided is factual and objective. Images can be much more powerful than words in conveying messages.

- Companies should be obliged to disclose information on all **preclinical and clinical trials** (Art.100 b, point e), including the failed tests and should not be allowed to select what information and on which product to disclose it. Objective information on clinical trials can be biased by omission and used for promotional purposes. Several experiences[8,9] 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 possibility for companies to publish a summary of **frequently requested information** (Art.100 b, point f) can lead to a situation whereby companies decide themselves on which aspects to communicate. What if the most frequently asked questions are only about the benefits of the medicine? How can this information be provided in a balanced and complete way? Also, it is unclear what "frequently" means.

- It is unclear what are the "**other types of information**" that will be allowed under Art. 100b, point 2 (g). The specific indication that the information will be approved by the competent authorities does not make a difference, not only because this is a general principle which applies throughout the text, but also because the derogations to the general principle also apply to this article. The vague wording leaves room for abuses and different interpretations among Member States.

4. Weak and costly approval and monitoring system

Aside from the "instructions for use" or "contract terms", currently any direct communication from a company to a consumer on a given product is considered advertising. These proposals introduce a new concept in EU legislation: the provision of non-promotional information by commercially interested parties. To respond to this challenge the Commission introduced the general principle of prior vetting by the competent authorities. While we support the prior approval as the only means of helping to make the distinction between information and promotional communication, we maintain reservations on its feasibility, efficacy and cost-effectiveness taking into account the many possible derogations and the major administrative burden it will create.

All Member States in the EU pre-approve the labelling, package leaflets, assessment report and the summary of product characteristics for all products on the market. This is not considered contrary to freedom of speech enshrined in national constitutions as

8 MHRA press release, March 2008, www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON014153

9 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).

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

these documents accompany the product. National competent authorities also pre-approve the content of vaccination campaigns and they can do that because it is considered a derogation from the rules on advertising. Provided the proposals label the content as "information to the general public" some countries have raised constitutional problems with the pre-vetting of information as it is considered on the verge of censorship. We believe that in such circumstances public health considerations supersede the principle of freedom of speech, also because we consider all the elements of the proposal an exception to advertising rules - exactly like the vaccines campaigns.

In any case, the derogations introduce significant **inequalities** in the quality of the information provided to consumers in different Member States as the information will be subject to different level of assessment. Also, all Member States will have to accept pre-vetted information by the European Medicines Agency for all centrally approved products. This means that in the same country the information on some products will be validated and it will not be validated for products approved under the decentralised procedure. This also translates into different levels of consumer protection between and within Member States.

Considering a practical example, if France decides to apply the derogation and Belgium decides to pre-approve the information, Belgian consumers will have validated information from their national competent authorities and more free in style, un-vetted information from French websites on the very same products in their language.

Even if not explicitly mentioned, in those countries applying the derogations, the information can be monitored via self-regulatory mechanisms. In this respect, evidence[10] clearly indicates that self-regulation in the pharmaceutical sector does not work. Experience with self-regulation shows that it is truly a passive form of scrutiny and insufficient to ensure a high level of consumer protection[11].

The pre-vetting and the monitoring system will create a huge administrative burden and will require a lot of resources. This means additional pressure on the national competent authorities and the European Medicines Agency who are already confronted with important financial constraints.

We fear that precisely those national authorities who have least resources and enforcement capacity will receive the highest number of submissions and will be overloaded.

In the Regulation, the European Medicines Agency is allowed 60 days to respond to information proposals submitted by manufacturers. According to the Commission, such an application can be evaluated in one day. 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 safeguards by submitting an excessive number of applications or 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 resources to carry out the tasks will produce a situation in which no prior control is exercised over information.

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

11 '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.

It is interesting to note that in a report[12] 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 Food and Drink Administration (FDA) to enforce compliance and prevent consumer exposure to false or misleading advertising. 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. Consequently, the FDA examined only a small proportion of the material submitted[13].

5. Enforcement and redress

Another unclear aspect of the monitoring system is the oversight of websites also taking into account the pace of change in online content. As they stand, the provisions also make it difficult for the competent authorities and independent third parties (e.g. consumer organisations) to ensure the enforcement of the legislation.

Experience shows that sanctions (Art. 100i) are insufficient to prevent unethical practices. Not even escalating penalties for billions of dollars inflicted in the US[14] prevented breaches of the legislation as they are regarded as the 'cost of doing business'[20]. The 'name and shame' principle introduced in the revised proposal is welcomed, but insufficient to prevent abuses.

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 consumer trust. A consumer-friendly, effective and unbiased system should be put in place to give consumers the right to complain in case they perceive the information provided to be inaccurate or misleading, and to seek redress and compensation in case of damages (see the case of Vioxx[15] in the US).

6. No benefits

The proposals do not bring any tangible benefits to consumers. They do not set out a comprehensive and patient-centric information strategy (as also requested by the European Parliament and the Council in 2004[16]), rather they merely create a framework for the industry to provide certain information on their medicines to the public.

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

13 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.

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

15 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)

16 Art.88 Directive 2001/83/EC.

Patients need information all along the patient journey, including information to understand if something is wrong, information which gives them a realistic idea of the evolution of their health status, helps 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. Despite the fact that health information includes measures on staying healthy and preventing illness, the Commission proposal focuses on the 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.

Consumers need information that allows them to understand the relative value of a treatment compared to others and to put a therapy in a wider context. The proposals explicitly exclude comparison between medicinal products and focus exclusively on prescription medicines. 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 existing ones[17] and those that people trust the most[18], such as healthcare professionals.

Inequalities of access to health information depend on a number of factors such as literacy levels, 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 Institutions should not delegate the harmonisation of information provision to commercial partners.

7. Other priorities

We consider that other issues should be the priorities for the pharmaceutical sector where we observe increasing problems in:

- availability of medicines in certain countries (e.g. Greece, Latvia etc.) due to commercial interests;
- accessibility of medicines to consumers who due to the financial crisis have more difficulties in co-payments;
- a lack of trust among consumers in the quality and the safety of medicines due to recent events - like the Mediator scandal - which questioned the independence of the scientific opinion of the competent authorities;
- enforcement of the ban on direct to consumer advertising on social media;
- undue influence of pharmaceutical companies on medical practice;
- overload of information on health and medicine from unreliable sources;
- enforcement capacities of national authorities with 'no teeth', both in terms of power and resources.

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

18 Eurobaromenter, 2003.
Which, 2008.
IPSOS, 2010.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

In the light of this we encourage the institutions at EU and national level to:

- ***Guarantee patient safety by strengthening and making more efficient the pharmacovigilance system.***

  We regret that a scandal such as that of Mediator was necessary to demonstrate that the recently adopted pharmacovigilance legislation (Directive 2010/84/EU and Regulation 1235/2010) didn't sufficiently address the loopholes in the EU pharmacovigilance system and that, even before its full implementation, corrective measures were needed. BEUC supports all the additional safeguards proposed in the current proposals as they strengthen the consumer right to know about the safety profile of the medicines available on the market, they ensure that safety problems are not disguised as commercial activities and that there is a more efficient coordination and information flow among the competent authorities when safety concerns on a given product arise. We question the need and the appropriateness of including these few additional measures in the controversial and long debated proposal on information to patients and we encourage the institutions to adopt them swiftly via a separate legislative procedure.

- ***Ensure access to and availability of medicines to all consumers in all Member States.***

  In some Member States consumers are confronted with problems in accessing medicines because of public budget constraints or because of commercial consideration of the industry. This is especially the case in small markets. It is urgent to address these problems and adopt measures to reduce inequalities in access to medicines between and within Member States: all consumers across the EU have the right to safe, innovative and affordable medicines.

  It is also important to put in place mechanisms to reward innovative medicines with a proven added therapeutic value, including using sensibly health technology assessments. In this respect we welcome the efforts of the Commission and the Member States in reinforcing cooperation on health technology assessment under the framework of the EUnetHTA Joint Action and of the Directive on the application of patients' rights in cross border health care.

- ***Provide wide access to information on health, prevention and promotion***

  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"[19]. This 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). In this context efforts must also be made to develop people's 'health literacy' so that they develop the competences to find, select and use the right information thereby navigating

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

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu

the situation most of us face of 'information overload'[20]. We are a long way from achieving this aim, one which can only be achieved by developing a broad health information strategy rooted in a wider and coherent health policy.

This includes:

- 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 independent sources of health information;
- giving financial support to initiatives that tackle social and cultural barriers to health literacy;
- supporting information initiatives at EU, national, regional and local level (e.g. EU wide campaigns for health prevention and promotion).

- ***Guarantee consumers have access to non-promotional and user-friendly information on medicines***

  The EU and national medicines portals created under the pharmacovigilance legislation and already in place at the EMA and most countries should be widely promoted to the general public as a central and impartial source of information about medicines. The pharmacovigilance legislation also reinforced the obligations of authorities to make all information on medicinal products publicly available. Efforts should now concentrate on continuing to make the content and layout of this information more user-friendly. BEUC contributes to and strongly supports the EMA initiative on the readability of the package leaflets and EPAR summaries.

- ***Effectively enforce the current ban on direct to consumer advertising***

  There are still too many breaches to the legislation on advertising and the problem is more acute on the internet and especially in social media.

- ***Increase transparency and independency of regulators***

  It is essential to put in place all measures to ensure medicine agencies independence from pharmaceutical companies, taking into account that at EU and national level more than 80% of their budget is funded by industry. The EMA policy on conflict of interests[21] should be extended to the EMA management board and be consistently adopted by national medicines agencies. The competent authorities should be provided with more 'teeth' to perform their tasks, both in terms of human capacity and in terms of financial resources from public budgets.

- ***Introduce stricter standards for the relationship between the industry and health professionals***

  The various codes of conduct on marketing activities directed to healthcare professionals proved highly inadequate to prevent undue influence by companies on prescribing behaviours. Just to give an example, in the context of the Pharmaceutical Sector Inquiry, a total of the 629 alleged violations (for the period June 2005 – end of 2007) were reported to the European Commission in

20 'Recommendations on health information', EU Health Policy Forum, 2005.
21 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

relation to the Joint Declaration between the European Federation of Pharmaceutical Associations (EFPIA) and the Standing Committee of European Doctors (CPME) aimed at avoiding and limiting potential abuses in promotional activities. These breaches took the form, for instance, of including inaccurate or incomplete information in promotional material or in providing inappropriate leisure activities to doctors[22].

The evidence calls for urgent measures to tackle the problem and to reinforce patient trust in the doctors' and pharmacists' professional advice.

The starting point should be disclosure of conflict of interests and financial transparency concerning events and hospitality, gifts and samples, donations, grants, research funding and educational seminars.

8. Conclusions

Consumers have the right to high quality, unbiased and non-promotional information about health and medicines. We call on the EU institutions to defend and promote this right when considering the revised proposals on industry information to the general public. We ask them to give priority to patient safety and to other measures which bring concrete and tangible benefits to consumers. We ask them to devote resources to improving access to medicines, to monitor the safety of medicine and to provide information from independent sources rather than to monitoring the provision of information from those selling the medicines.

END

22 European Commission Pharmaceutical Sector Inquiry, Final Report, July 2009.

BEUC, the European Consumers' Organisation
80 rue d'Arlon, 1040 Bruxelles - +32 2 743 15 90 - www.beuc.eu