



## **European Heart Network's response to the European Commission's Public Consultation on the legal proposal on information to patients**

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### **I Introduction**

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and likeminded non-governmental organisations throughout Europe with member organisations in 26 countries.

EHN plays a leading role in the prevention and reduction of cardiovascular disease through advocacy, networking and education so that it is no longer a major cause of premature death and disability throughout Europe.

Cardiovascular disease is the number one cause of death among women and men in Europe. It accounts for almost half of all deaths in Europe causing over 4,3 million deaths each year in the member states of the World Health Organization (WHO) European Region and more than 2 million deaths each year in the European Union. Cardiovascular disease is also a major cause of disability and a reduced quality of life. Cardiovascular disease is estimated to cost the EU economy over €192 billion/year. CVD cost the health care systems of the EU just under €110billion/year. Production losses due to cardiovascular disease mortality and morbidity cost the EU almost €41 billion and cost of informal care is just under € 2 billion/year.

EHN takes note that the public consultation document is preceded by a statement declaring that it does not represent an official position of the European Commission. Rather, it is a tool to explore the views of interested parties and the suggestions contained in the document do not prejudice the form and content of any future proposal by the European Commission.

The consultation follows a Commission Communication to the European Parliament and Council on current practices with regard to the provision of information to patients on medicinal products. This Communication, published in December 2007, concluded that evidence shows that the rules and practices on what information is available varies significantly among Member States resulting in unequal access of patients – and the public at large – to information on medicinal products.

The Commission document states that a forthcoming proposal to amend Directive 2001/83/EC would set rules on the provision of information by marketing authorisation holders and would be without prejudice to the provision of information by other actors. It is the Commission's declared intention that health care professionals should remain as they are today the primary source of health information.

## **II Key ideas of the forthcoming proposal**

The document states that a fundamental objective of the legal proposal should be to provide rules that harmonise practices on information provisions to patients on medicinal products. The document suggests the following key ideas for a framework for industry to provide certain information on their medicines to the public:

### **Advertisement**

The document suggests that the current ban on advertisement of prescription medicines to the general public should remain in place.

EHN welcomes this suggestion.

### **Scope, content and general principles of the new legal provisions**

The document suggests that the revision of Art. 88a of Directive 2001/83/EC should clarify the rules on information provided by pharmaceutical companies on prescription-only medicines. It states that, basically, communication not covered by the definition of advertisement should be regarded as 'information'. Such information should be compatible with approved summaries of product characteristics and patient information leaflets and should not contradict or go beyond key elements specified in them.

EHN believes that the suggested distinction between advertisement and information is fraught with difficulties. Information provided by a company producing and selling the product and which undoubtedly will be accompanied by name, logo, colours of the company (branding) is tantamount to advertisement.

A standard format for presentation of the information could be stipulated and could conceivably help in rendering the information non-promotional. However, there is no mentioning of criteria for presentation in the document for consultation.

## **Type of actions, content and monitoring of information**

The document suggests that a distinction should be made between the cases where the patient is passively receiving the information (“push”) or actively searching for the information (“pull”) in terms of the monitoring mechanism.

### ***Information “pushed” to the citizens***

A push of information includes dissemination of information on prescription-only medicines through TV and radio programmes, though printed material actively distributed, through information in printed media or through audiovisual and written material provided to patients by healthcare professionals.

EHN believes that branded information actively pushed to citizens is indistinguishable from advertisement.

EHN questions whether a general push of information on prescription medicinal products is warranted at all. The forthcoming proposal aims to reduce differences in access to information across the EU not to provide more and untargeted information to the general public.

### ***Information “pulled” by the citizens***

Patients use multiple sources for information on medicines. Pulling information from the internet and from company websites is part of the search for information.

The document gives a list of ‘quality criteria of provided information’ in its table (section 6) on key ideas of the forthcoming proposal information to patients. This table does not provide any criteria for the format for presenting the information. EHN believes that a standard format could make the information more easily understandable; this may help address accessibility to the information, limit inequalities and make the information more understandable.

## **III Quality criteria**

EHN agrees that information provided should be objective and unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information.

EHN also thinks that information provided should be complete, validated and presented in a standard format.

## **IV Monitoring and sanctions**

In terms of monitoring, EHN is concerned that the document merely suggests that information providers inform a national co-regulatory body about their activities before action is taken. Such an approach does not provide a mechanism for managing the process and ensuring that information is not in breach of criteria that have been set on quality of the information, presentation etc. EHN favours ex-ante validation of content and presentation. This could be done by national bodies or platforms that should be independent of pharmaceutical industry.

The document is vague about which sanctions would apply in case of repeated and severe cases of non-compliance by information providers. EHN suggests that sanctions must be sufficiently harsh so as to dissuade effectively companies from non-compliant activities.

## **V Conclusion**

The aims of the forthcoming Commission proposal amending Directive 2001/83/EC are to reduce the differences in access to information and to ensure the availability of good-quality, objective reliable and non-promotional information on medicinal products across the EU.

EHN finds the Commission document skewed towards broadening the scope for the pharmaceutical industry to communicate about its products, particularly through the opening up for active dissemination of information on prescription-only medicines for example through TV. EHN believes that active dissemination of information on prescription medicines go beyond the needs for reducing inequalities in access to information.

Much more care should have been given to the real needs of patients for information and how these needs can be met best. In particular, EHN believes that it is essential to have ex-ante validation by national bodies or platforms independent of pharmaceutical industry and with ample patient representation.

EHN is pleased that this document does not prejudge the form and content of any future proposal by the European Commission.

Finally, EHN believes that the responsibility for regulation on information to patients should be transferred to DG SANCO.