European Heart Network's response to the European Commission's amended proposal for the revision of the Information to Patients' Directive (2001/83/EC)

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About the European Heart Network and cardiovascular diseases

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and likeminded non-governmental organisations throughout Europe with members in 26 countries. The EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, education and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

Revision of the European Commission Information to Patients Directive

On 11 October 2011, the European Commission published a revised proposal amending its original proposal of 2008 on information to patients taking into account the vast majority of the European Parliament's amendments in first reading. The objective of the 'Information to Patients' Directive is to set out the framework whereby companies with marketing authorisation for a medicinal product may – and to some extent must – provide good quality and objective information on their prescription-only medicines to the general public.

EHN welcomes the amended proposal of the European Commission and acknowledges the substantial redrafting of the text. Most of the amendments, put forward by the European Parliament and supported by many European public health and patients' organisations, have been taken into consideration.

Advertising and scope of the Directive

One of the most controversial points in the initial proposal was the difficulty in differentiating between advertisement and information on prescription only medicines to the general public. By accepting the majority of amendments, put forward by the European Parliament in first reading, the European Commission now categorises many of the marketing authorisation holders' communications as advertisement. The expansion of the definition of advertisement is an improvement; however, some provisions in the new proposal still give rise to concern:

- The possibility for marketing authorisation holders to made publically available a summary of frequently submitted requests, and the answers to such requests (Art 100b, 2, f),
- The distribution of printed materials about a medicinal product in healthcare professionals' surgeries (Art 100c, a).

EHN is worried that these provisions may enable marketing authorisation holders to disseminate information that can be considered of a promotional nature and recommends that the marketing authorisation holders are not allowed to publish a summary of frequently submitted requests the answers to them. EHN also recommends that printed material about a medicinal product is not made available in healthcare professionals' surgeries. If the marketing authorisation holders produce such material, it can be given to healthcare professionals who may choose to give it to their patients when

they have prescribed the medicinal product, in addition to the physicians' explanations about the usage and effects of the drug.

EHN would like to underline that any revision of the Information to Patients Directive must prioritise information on medicinal products which are of high-quality, unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent with approved information.

Monitoring and Control of the Information

The amended proposal states that '*Member States shall ensure that information on authorised medicines is published, after it has been approved by the competent authorities*' (Art 100g, 1). EHN welcomes this modification which seems to answer our call for ex-ante validation of content.

However, such prior approval is subject to derogation. The amended proposal allows Member States to rely on other mechanisms of validation should a system of prior authorisation not be compatible with the constitutional rules of the Member State concerned or implemented by 31 December 2008 (Art 100g, 2a, 2b). We are concerned that this might create disparities between Member States and inequalities between European patients. EHN recommends that EU guidelines on approval and monitoring mechanisms are drawn up setting standards for monitoring and control of information.

Internet Websites

The European Commission, in its amended proposal, recommends that the Member State, in which the Internet website has been registered, shall be responsible for the content and the control of information made available. Again, EHN recommends that EU guidelines are drawn up providing a standard format for content and presentation of information given on registered websites.

Conclusions and recommendations

Whilst EHN welcomes the amended proposal by the European Commission, we are worried that some of the provisions could leave room for marketing authorisation holders to circumvent the prohibition on advertisement of prescription medicines only to patients.

We, therefore, call for uniform standards applicable across the EU Member States both for content and presentation to guarantee patients' equal rights to high-quality, unbiased and patient-oriented information on medicinal products.