

Joint statement from European Patient groups on

The European Commission's proposal to amend
the Directive on Community Code relating to Products for Human use
(Directive 92/28/EEC) - Articles 86 to 100

Patients demand access to information for ALL disease areas in Europe

Introduction

European patient groups believe that ALL patients, no matter their condition, background or nationality, have a fundamental and legitimate human right of access to all kinds of information about their health, medical conditions and the availability of treatments including knowledge of the best available management for their disease. It is a question of solidarity, equity and patients' rights.

We would draw attention to, and agree with the assertion in the Commission's legal text that patients have a "legitimate need" for information.

From our perspective EU patients/citizens need factually accurate, reliable, easily understandable information to be able to make informed decisions. They need to understand their condition and do want to receive information on treatments available.

As patients, we welcome information from different sources including the pharmaceutical industry, provided they meet the above-mentioned criteria, the ownership of the source is clearly identified and agreed safeguards are in place.

Such information would enable patients/citizens all over Europe to:

- enhance the ability to make informed decisions about best disease management in full partnership with health care professionals;
- optimize health outcomes through improved treatment compliance based on our belief that the more informed patients are, the better they understand their treatment and how medicines must be taken;
- make more effective and rational use of the therapies that are available and prescribed;
- increase awareness of risks / and benefits of prescription medicines and the importance of reporting and managing possible side effects;
- improve our quality of life by adopting preventive measures, seeking earlier diagnosis, recovering faster from illness, avoiding hospitalisation and invasive surgery, and enabling us to carry on with our normal daily routines.

As patients, we recognise that governments fear increased pressure on health care budgets since informed patient might demand better and more effective drugs for his/her diseases.

However, we consider this a positive consequence of better and more information to the public.

We argue that informed patients are more efficient and prudent users of health care resources. Often underprescribing, non-compliance or irrational prescribing are a heavier overall financial burden for health care and social security budgets. Better disease management increases the quality of life and well-being of patients.

Information should be seen as an enabling tool to improve health care for all EU citizens - not as a cost/control instrument for EU Member States.

Those suspicious of patient information base their arguments on the US experience of advertising. However, advertising is not equivalent to the provision of information. While we do not want US style advertising, European patient groups are happy to contribute to a more thoughtful and constructive debate, to find a solution for Europe appropriate to the Information Age.

10 April 2002

Co-signed by:

GAMIAN Europe

EUFAMI - European Federation of Associations of Families of Mentally Ill People

European Cystic Fibrosis Policy Network

Euro ATAXIA

European Coalition of Positive People

European Patients' Voice

EIWH - European Institute of Women's Health

EATG - European AIDS Treatment Group

DEBRA Europe

Retina Europe

The International Osteoporosis Foundation

AMD Alliance International - European Affairs Office

European patient groups cannot agree with the discriminatory approach taken by the present Commission proposal and we have the following detailed comments to offer:

ARTICLE 88 – INFORMATION RESTRICTED TO 3 DISEASE AREAS IN THE PILOT

Restricting the information pilot study to only three disease areas, Diabetes, HIV and Asthma, is inequitable because patients suffering from other diseases have exactly the same need for information as patients suffering from the 3 disease areas in the proposal.

"*Moving with the times*" is how the Commission referred to its proposals when they were released in July 2001. We feel that the proposed pilot is unacceptable in an open and democratic society, and any such new policy direction must apply to all diseases, unless there are justifiable public health reasons that would endanger anyone's health.

In fact, the pilot is a traditional way of approaching a challenge, and does not respond to patients' needs and demand for information in our Internet age.

If adopted it will be to the detriment of patients who will be without access to information in their own language and will create a divided society of informed and non-informed patients.

The proposed pilot study would not only create discrimination between patient groups in different disease areas; patients excluded from the pilot will have to wait at least 10 years before they too may be entitled to information (5 years for adoption and implementation of the proposal, and 5 more years for an evaluation report of the pilot).

In the interest of patients' rights, equity and solidarity we must ensure that the health divide is not further aggravated by such an information divide.

ARTICLE 86 - DEFINITION OF ADVERTISING

The definition of Advertising of a medicinal product is amended to include "*any activity ... designed to promote... awareness of the availability of medicinal products.*" This new definition is flawed and undermines efforts to distinguish between advertisements and other forms of information.

We believe in our right to information and this includes the right to know about available medicines. Inclusion of awareness of the availability of medicines under the definition of advertising might decrease the present information already available to patients.

The amendment will undermine information and education programmes produced by patient organisations and other external independent sources.

In the interest of a high level of health protection, which is a European Treaty goal, we feel that Patient education activities and disease awareness campaigns should be encouraged and not restricted, as long as such material respects the quality criteria set out above and has appropriate safeguards in place.

ARTICLE 88.2. - PRINCIPLES OF GOOD CONDUCT

The proposal heavily relies on the promulgation of guidelines which will apparently contain most of the detailed rules for communicating with patients. European patient groups wish to be consulted in a formal role to ensure that the communication, rules and criteria set are meaningful from the patient's perspective.