



EDF response to the European Commission public consultation: “Legal proposal on Information to patients”

April 2008

“In the development and implementation of legislation and policies to implement the present Convention, and in other decision-making processes concerning issues relating to persons with disabilities, States Parties shall closely consult with and actively involve persons with disabilities, including children with disabilities, through their representative organizations.”

Article 4, paragraph 3 of the Convention of the Rights of Persons with Disabilities

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Foreword

The European Disability Forum (EDF) welcomes the Public consultation on a legal proposal on information to patients. People with disabilities face discrimination in many areas of life, ranging from employment to education. In the area of healthcare services and access to medication, people with disabilities are often discriminated when being patients for a limited period of time or when facing the effects of a chronic illness.

This is the reason why EDF considers this public consultation as a very important step in order to harmonise standards of information to patients that nowadays are completely different from country to country affecting in the lives of people with disabilities and their health.

EDF has undertaken a consultation to its members to ensure that the reality of people with disabilities is taken into account in a legal proposal in information to patient.

1. The right to an independent information

It is important to start by saying that the objective of this regulation should be the harmonisation of the information to patients in order to ensure good, quality and independent information regarding treatments and medical assessment.

EDF does not share with the European Commission the definition that communication not covered by the definition of advertisement should be considered information. EDF experience proves that it should be the other way around, that communication not covered by the definition of information should be considered advertisement. In practice this means that we need a clear definition of what is information, and what is advertisement, what information can be provided by industry, and what can be provided by independent bodies.

For instance, if information is communication in a more understandable way of what is contained in information leaflet, this is a welcome development. However the inclusion of reference to studies on effect of medicines is more problematic, due to the danger of strong bias.

One of the main problems of people with disabilities is accessing independent information. People with disability including people with a chronic illness are particularly vulnerable to biased information and advertisement from the pharmaceutical industry. Organisations agreed in making the professionals the main source of information. It is nevertheless very important to ensure that

adequate mechanisms of control limit the capacity of the pharmaceutical industry to induce to unwarranted demand for their products.

2. Access to information

There is a need to create standards of access to information by people with disabilities. It is important to ensure that people with disabilities needing different sort of access facilities have equal access to information. Different formats of information are required for people with intellectual disabilities, learning disabilities, blind people, people with degenerative diseases, etc.

Printed information should be available in large print, with well contrasted colours, and on request in Braille. If information is provided through tv broadcasting there should be subtitles, sign language, and audiodescription...

The principle of accessing information from pharmaceutical industry and their products should be extended to healthcare services as the main place where information is provided and professional advice is delivered. It is important to ensure that patients can have enough information on their treatment so they can become participants to their own treatment. This is just possible when all alternatives are contemplated and completed and adequate information is provided. This will ensure that the patient also becomes an important source of information, instead of just being a target. Information should be a two way relationship when speaking about treatment.

The issue of access to information, participation and empowerment on the treatment is ensured by the development of communication mechanisms as well as supporting services for patients. This means individuals as well as the patients' organisations.

A priority area for action at European level is quality of information as a key element for people with disabilities. It is important that issues related to biased information, patient oriented information, accessible information and transparency are included in the legal proposal.

Support to patients and their families all along the treatment, including those that have life-term conditions such as chronic illnesses. It is a matter of fact that healthcare services in Europe are focused on treatment but they rarely ensure long term support for people with chronic illnesses or rare diseases.

Organisations of patients' should participate in the information strategies as the best source of information based on personal experiences.

3. Monitoring with participation of patients' organisations

The participation of the patients organizations in the implementation of the regulation is a key element to ensure that the accuracy and transparency of the system. It is important to ensure a full participation of patients' organizations at the national co-regulatory bodies, but also at the Advisory committee at EU level. The principle of participation should be applied at national and at European level.

Complaint mechanisms should be put in place in order to avoid drifts, such that we face on food packaging or food advertising.

The monitoring of the information to patients should include in the latest stage, and after confirmation of non compliance of legislation, sanctions. Sanctions must be dissuasive.

The impact assessment undertaken by the Commission contemplates regulation and self-regulation as equally important options. EDF does not believe in self-regulation strategies that have proven to be non-effective in order to ensure commitment from industry and therefore a clear legal framework should be the base of future voluntary approaches. The experience shows, in areas such as Corporate Social Responsibility, how the industry can have little commitment on issues where consumers do not have strong possibilities of imposing given standards.

This is even more the case in an area where the role of consumers has always been undermined. They have often been referred as 'patients' meaning they have to accept and bear, and they are not entitled to informed decisions.

Regulatory bodies dealing at national and European level on authorization for medicines, and control, should also have a monitoring role and should be the ones that set the code of conduct. Consumer organizations, as well as organizations of people with chronic illnesses and of patients should be part, together with industry, and doctors of a subcommittee for the definition of a code of conduct.

We believe in addition that it is important that the code of conduct that will allow the implementation of EU legislation should be agreed at European level, as to avoid the situation where certain practices are allowed in some member States and not in others, creating also confusion among consumers.

4. Conclusion

EDF congratulates the Commission for undertaking this initiative but it would like to see more commitment from the European Commission to ensure a more comprehensive legal proposal not just focus on advertisements but also tackling needs information for vulnerable groups that can easily be victims on the hands of strong market interests.

It is important to highlight that independent choice and access to information for many people with disabilities is still not possible. The European Commission following the Internal Market for a 21st century communication has committed to the principle that access for vulnerable groups such as people with disabilities should be ensure through the development of standards of accessibility. This legal proposal will show that the European Commission has undertaken that compromise with full commitment.

APPENDIX – About EDF

1 About EDF

The European Disability Forum (EDF) is the European umbrella organisation representing the interests of 50 million disabled citizens in Europe. EDF membership includes national umbrella organisations of disabled people from all EU/EEA countries, accession countries and other European countries, as well as European NGOs representing the different types of disabilities. The mission of the European Disability Forum is to ensure disabled people full access to fundamental and human rights through their active involvement in policy development and implementation in Europe.

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