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**TEDDY**  
**TASK-FORCE IN EUROPE FOR DRUG DEVELOPMENT**  
**FOR THE YOUNG**

**INSTRUMENT:** NETWORK OF EXCELLENCE  
**THEMATIC PRIORITY:** LIFE SCIENCES, GENOMICS AND BIOTECHNOLOGY FOR HEALTH

**TEDDY Comments on the European Commission document:**

**Legal proposal on information to patients**

**START DATE OF PROJECT:** 01 JUNE 2005  
**DURATION:** 5 YEARS  
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## Aim of the document

The aim of the present document is to provide the European Commission with TEDDY NoE comments on the document entitled "Legal proposal on information to patients".

## Background

The starting point of the proposal is represented by the Report, published on the 20<sup>th</sup> December 2007, concluding that:

- o rules and practices on what information can be available still vary significantly among Member States,
- o access to the information of patients and of the public in general is unequal while patients have become more empowered and proactive regarding the treatment of their illnesses.
- o quality and accountability of information, especially that available on the Internet, are very variable. It is preferable to give access to controlled and scientifically adequate information.

The proposal is aimed at modifying the current system by establishing a framework which provides citizens of EU Member States with understandable, objective, high-quality and non-promotional information about the benefits and the risks of their medicines, and which maintains the confidence of citizens, regulators and healthcare professionals.

It is based on a 'clear' distinction between advertising and information.

## Comments

By principle, the objectives of the proposal are acceptable and we agree patients are entitled to receive more high quality information by Industries, but a good controlled system of rules needs to be set up at European and National level.

Notwithstanding, possible negative impacts could arise from the proposal and some clarifications are needed. Those are listed below.

### Point 3.2

We agree that only information included in the SPC should be provided in a language easily understandable to the patients.

Other limited medicine-related information could also be given (information about scientific studies, prevention of diseases such as vaccines, accompanying

measures to medical treatments, prices) only if requested by patients and after approval of National/European Authorities.

In addition, it is necessary to rule on cases in which direct information should be avoided, such as: use of medicines devoted to children, use of drug for which an high risk of medical error or off-label use exist, use of drug with a reduced risk/benefit ratio.

**Point 3.3.1**

It is unclear how it would be possible to separate advertising from 'information' if such information is provided through radio, TV and printed media! We only agree with active information or information made in a scientific medical context, while passive information should be not considered because it is too similar to advertising.