



Reconnue d'utilité publique par décret du 14 août 1996 JO 22/8/1996
Agrément de représentation des malades devant les instances de santé JO 22/3/2007

**French national association of
Inflammatory Bowel Disease (IBD)
patients for research, support and
Information since 1982**

Brussels, December the 3rd 2009

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Patients' information expectations :

The case of French IBD patients



WHAT ARE IBD's ?

- Inflammatory Bowel Diseases (CD, UC)
- Over 1.5 millions persons suffering IBD in Europe, among them 15% are children
- Average diagnosis : 25-30 years old
- Chronic illnesses. Diseases you can't cure!
- Need for treatments to "heal", even surgery.
- For most patients, need to take treatments throughout their whole life

PATIENTS EXPECTATIONS FOR DRUGS' INFORMATION

- Patients want to know more about a drug before using it.
- Patients want to be informed about adverse drug reactions (ADR) and want to be listened to when they report ADR.
- Patients want to access understandable and reliable information.
- Patients want to exchange experiences of drugs through forums and associations

PATIENTS EXPECTATIONS FOR DRUGS' INFORMATION

Patients and their representatives want to participate at each step of information-making

- Among **Research Ethic Committees** on information contents given to patients for a clinical trial
- With **health authorities** to reread and complete information provided to GPs and specialists about drugs and life with IBDs
- With **doctors** to develop an easily understandable corpus of information to be given to newly diagnosed patients
- With **pharmaceutical companies** to develop therapeutic education programs to connect drugs to the real life of patients
- With **other patients** in order to build up information about their everyday lives

What would be the added-value of the directive ?

Does the directive answer these needs ?

NO. Real progress would be to **improve patient leaflets**

Patient leaflets prepared by pharmaceutical companies **MUST BE** reread, analyzed, completed and validated by other health actors including patients and their representatives to improve them (better application of article 59 of Directive 2001/83/CE consolidated)

On pharmacovigilance information?

NO. Real progress would be to **improve the transparency of health authorities** at both European and National level

Access to information, including on **adverse drug reactions**, should be improved: Patients are sentinel of the drug's safety

EUROPEAN STANDARDS, YES, BUT HIGH STANDARDS FOR PATIENTS, GIVING THEM A REAL OPPORTUNITY TO BE ACTORS IN THEIR OWN HEALTH.

In brief, from our perspective

Patients needs:

Evolve towards highest standards (reliable, independent information: the source matters!)
with improved access to information gathered by health authorities (particularly on adverse drug reactions).

Strengthen their participation at each step of information-making including direct notification of ADR to Health authorities.