

**WORKSHOP ON PATIENTS SAFETY**  
*Best Practices on Communicating Risks and the Value of  
Safety to Patients with Chronic Diseases*

**4 December 2007**

**Jean Monnet Building Luxembourg**

with the kind support of the

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DG Health & Consumer Protection**



## INTRODUCTION

Patients have the right to adequate, timely and comprehensive information on all aspects of safety and risk associated with their medical treatment. The quality of the information provided will be optimised if patients, clinicians, industry and regulators join their efforts and cooperate to reach that goal.

All stakeholders now recognise the vital role played by patient organisations in communication on safety and risk. The production of timely and audience-specific communication for national organisations by their umbrella organisations on key issues relating to the safety and risks of therapies is vital. The perception and evaluation of the risks incurred by using a treatment is differently perceived by the patients according to their diseases and the prognosis given.

The risks which patients are willing to undertake as part of medical treatment will differ from the voluntary risks they are willing to take from other life activities. The perception of acceptable risk will vary depending on the communication and information available to the patient, the severity, consequences for quality of life and probable outcome of their medical condition, the economy of their country and the choices available to them. It will vary also depending on their past experience and the level of communication from and between all stakeholders.

Patients know their disease; they know their daily quality of life.

Communication to patients is vital in assisting patients in their decision taking process on treatment and the responsibility they take by accepting the communicated risks of their chosen treatment.

Through plenary lectures, case study presentations and discussion in break out sessions, key issues on communication of safety will be explored. These will include:

- How should we define risk in relation to benefit for specific therapies and how should such risk be assessed for one off as opposed to life long treatment.
- Discussion of the factors which affect perception of risk such as education, medical history ,previous experience and perception
- Methods of communication including the relative merit of written, verbal, electronic or via the media.
- When to impart information and striking a balance between avoidance of un-necessary panic and undue withholding of information

The workshop will bring together clinicians, patients industry and EU commission officials to discuss on all these issues and lead to a broader understanding of this complex and interlinked topic among all attendees. The workshop aims to agree broad consensus recommendations on best practice on communication of the relevant risks and benefits of therapy in chronic conditions which may form the basis of further actions.

## PROGRAMME

### Workshop co-chaired by:

**Brian O'Mahony**  
*Irish Haemophilia Society*  
*representing Patients*

**Ingrid Klingmann**  
*European Forum for Good Clinical Practice*  
*representing Science*

**Jean-Marie Vlassembrouck**  
*Baxter World Trade*  
*representing Industry*

## PLENARY SESSION

- 09.00 **Welcome Remarks**  
Michael Griffith, *Retina Europe, former EPPOSI Chair*
- 09.10 **Legislation**  
Antoni Montserrat, *European Commission – DG SANCO*
- 09.30 **Critical elements in informed consent for therapy**  
Martin Härter, *University Freiburg*
- 09.50 **Optimising communication on risk, safety and benefit of therapy**  
Paul Giangrande, *Oxford Haemophilia Centre*
- 10.10 **Case Study 1: Foreseen Risk**  
Craig Ritchie, *Imperial College London*
- 10.25 **Case Study 2: Unforeseen Risk: Lipodystrophy in HIV**  
David Haerry, *European AIDS Treatment Group (EATG)*
- 10.40 **Case Study 3: Theoretical risk which becomes real: vCJD from Blood**  
Mark Brooker, *World Federation of Haemophilia (WFH)*
- 11.00 **Coffee break**

## 11.30 BREAK-OUT SESSIONS

### 1. Industry / Clinician

**Chair** Detlef Niese, *Novartis*  
**Rapporteur** Ingrid Klingmann, *European Forum for Good Clinical Practice (EFGCP)*

### 2. Industry / Patient

**Chair** David Watters, *International Patient Organisation for Primary Immunodeficiencies (IPOPI)*  
**Rapporteur** Jean-Marie Vlassembrouck, *Baxter*

### 3. Clinician / Patient

**Chair** Vincenzo Costigliola, *European Medical Association (EMA)*  
**Rapporteur** Brian O'Mahony, *Irish Haemophilia Society (IHS)*

- 13.00 **Lunch**
- 14.00 **Outcome of break-out sessions**
- 14.45 **Open Forum and Discussion**  
Moderator: Christine Lavery, *Society for Mucopolysaccharide and Related Diseases (MPS), EURORDIS*
- 16.00 **Preparation of final Key-Recommendations**  
Chairs: Ingrid Klingmann, *European Forum for Good Clinical Practice (EFGCP)*  
Jean-Marie Vlassembrouck, *Baxter*  
Brian O'Mahony, *Irish Haemophilia Society (IHS)*
- 16.30 **End of the Workshop**

## Questionnaire for Break-out Sessions

Break-out sessions will consider the following 4 topics and questions

1. **Define acceptable risk: view of Patients/ Doctors/ Industry**
2. **How to best communicate potential risks - When, Who and How ?**
3. **How can stakeholders (clinicians , industry...) ascertain if patients understand the risks?**
4. **The role of communication in building or destroying trust**

### **Definition of Risk and Risk Communication**

Risk is a danger or hazard, the probability of suffering harm.

Risk communication is the open exchange of information and opinion about risk, leading in the context of healthcare to better understanding and more informed decisions about clinical management and patient choice.

The balance between benefit and risk is continually assessed during the lifecycle of a product or therapy. Any changes to the benefit risk profile should be communicated on a timely, effective and open basis to health authorities, clinicians and patients

Due to the limited time available and the potentially enormous scope for discussion in the area of risk and risk communication, the following areas will NOT be covered during the conference:

- Medical error
- Informed consent in clinical trials
- Direct to patient advertising
- Individual patient and clinical views on acceptable risk. Views sought will be those of patient organisations, clinicians as a group and industry.

For additional information about our activities:  
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