

Information on benefits and risks of medicines:

Patients', consumers' and healthcare professionals' expectations

Background

- **Society's need for transparent information on medicines**
- **Interaction between patients and healthcare professionals**
- **Increasing availability of information on medicine through various media**
- **EMA Road Map 2010, patients' and consumers' organisations and healthcare professionals highlight:**
 - important challenge to provide adequate information on medicines that balances benefits and risks of medicines appropriately
- **Link to ongoing EMA initiatives**
 - CHMP reflection paper on the benefit-risk assessment methods
 - Innovative Medicines Initiative (IMI) call "Strengthening the monitoring of Benefit-Risk"

Project design

- **Project led by topic leaders from:**
 - Patients' and consumers' organisations
 - Healthcare professionals' organisations
 - Regulators
- **Survey consisting of simple questionnaire on benefit-risk**
(March to April 2008)
- **Compilation of answers from each party**
- **Discussion at the joint meeting at the EMEA on 5 June 2008 of:**
 - Patients' and Consumers' Working Party (PCWP)
 - Healthcare Professionals' Working Group (HCP WG)
 - CHMP chair
- **Preparation of the report**

Questionnaire

- 1. What is the benefit-risk of a medicine for you?**
- 2. Which information do you expect in terms of benefit, risk, and, benefit-risk balance of a medicine?**
- 3. Do you communicate benefit-risk information? If yes, how?**
- 4. What information on benefit-risk do you think is missing?**
- 5. What would you propose to improve information on benefit-risk of medicine?**
- 6. What is the minimum time necessary to address benefit-risk during a patient-healthcare professional consultation?**

General outcome

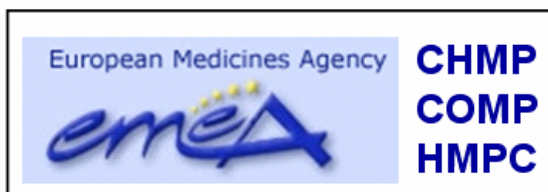
- Very good participation (~75%)
- Very rich contributions
- Opportunity for the three parties to exchange their experiences
- Discussion on key principles
- Joint report agreed



International Diabetes Federation



European Society for Medical Oncology



Results of the survey (1/2)

- **Patients' and healthcare professionals' expectations are very similar**
- **Important to distinguish benefit–risk:**
 - At individual level
 - At population level
- **To reconcile individual needs with data at population level, it is necessary to communicate high quality information on medicines**

Results of the survey (2/2)

- **Information on medicines**
 - Always communicate benefits and risks together
 - Clear information to help choose most appropriate treatment
 - Clear description of benefits and risks, both qualitative and quantitative
 - Factors which may influence a benefit or a risk in an individual should be clearly described
- **We do not have the “full picture” for all individual situations**
 - New technologies, such as pharmacogenomics, may help to give an improved prediction on benefit-risk for individuals
- **Facilitate access to information**
 - Need for summarised information as well as detailed documentation, cross-referenced

Proposals for action

- **Further explore how to optimise content and access to information on benefits and risks in summary of product characteristics, package leaflet and public assessment report**
- **Foster dissemination of information from regulators**
- **Prepare recommendations on the quantitative descriptions of benefits and risks**
- **Prepare recommendations on risk communication in areas of uncertainty**
- **Further explore how best to communicate on safety issues**
- **Continue interaction between the three parties**

Next step

Proposed actions to be developed with
PCWP and HCP WG as part of their
work programmes for the coming years