



European Commission

INFORMATION TO PATIENTS

European Commission Point of View

European Life Science Circle
“How to Ensure High Quality
Information to Patients”
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**THE COMMISSION REPORT ON CURRENT
PRACTICE WITH REGARD TO PROVISION
OF INFORMATION TO PATIENTS ON
MEDICINAL PRODUCTS**

*In accordance with Article 88a of Directive
2001/83/EC, as amended by Directive
2004/27/EC, on the Community code relating to
medicinal products for human use*



Objectives

- **Review of activities carried out in Member States**
 - **To respond to patient needs**
 - **Particular role of internet**
- **No strategy on Information**



Methodology

- **Information provided by Member States**
 - **Members of the Working Group on Information to Patients – Pharmaceutical Forum**
 - **National Competent Authorities**
- **Contributions from patients' groups**
- **Contributions from other stakeholders**
- **Literature**



Areas addressed by the Report

- **Basis for the Commission to consider a strategy on Information to Patients**
 - **Recognising important developments in society concerning patients' role and responsibilities**
 - **Recognising that access to reliable and good quality information is essential**



The societal developments

- **Health and health systems require informed patients and their active participation in decisions**
- **Primacy of dialogue between healthcare professionals and patients to consider new role of patients**
- **New paradigm requires access to adequate information on medicines**
- **Increased demand and access to information**



The current legal framework

- **Some of the tools in the current legislation**
 - **Patient leaflets**
 - **(E)PARs**
 - **EudraPharm Database**
 - **Transparency measures**

Current Practices at EU level and in the Member States

- **Community Register of Medicinal Products**
- **EU Health Portal**
- **Specific activities carried out by the EMEA**
 - **Recommendations on key areas**
 - **transparency and dissemination of information**
 - **product information**
 - **pharmacovigilance**
 - **interaction between the EMEA/CHMP and Patients' Organisations**



Current Practices at EU level and in the Member States

- **Public authorities/Product related information**
- **Additional Information**
- **Specific public-private partnerships or similar initiatives**
- **73% of Member States provide access via internet to PIL and SPC**
- **PARs: evolving process with 15% providing internet access**
- **Variety of databases**
- **Specific areas on Regulatory Agencies providing information to patients**



The Use of the Internet

- **Specific form of communication – superseding boundaries**
- **Widely used by patients and consumers to search for information**
- **Increase use, varying with age, education, socio-economic conditions**
- **Main tool used by Member States Competent Authorities**



The Use of the Internet

- **Number of issues to be addressed**
 - **Quality of information – need to validate information against agreed standards**
 - **Availability of access to certain parts of the population (e.g., costs, capabilities)**
 - **Response to patients with special needs**



Patients' needs

- **Increased role of patients in Healthcare provision**
- **Right of patients to information**
- **Choice of medicines, costs, adverse reactions**
- **Diversity of patients' needs (e.g. preventive, chronic or rare diseases)**
- **Specific tools**



Role of stakeholders

- **Primacy of availability and relevance of information vs source**
- **Patients preference for “pull” mechanisms**
- **Health professionals as the primary source of information**
- **Importance of partnership between healthcare professionals and patients**
- **Central role of Public Authorities**
- **Pharmaceutical industry as potential source**



Conclusions

- **Current practices**
 - **Specific mechanisms provided by legislation**
 - **Different practices in Member States**
- **From a Community perspective different approaches may lead to**
 - **Inequalities in access**
 - **Lack of EU quality standards for information**
 - **Uninformed choices**



Conclusions

- **Increase in the quality and appropriateness of information available to patients to contribute to better health conditions and more efficient use of resources**
- **Risks that better informed patients will demand more healthcare could raise concerns**
- **Balance between benefits and risks of providing information indicates need for clear rules applying to information, ensuring its objectivity and avoiding any promotional character**



Next steps

- **Consultation on the report**
 - **Until the 30 June 2007**
- **Opportunity to receive comments and positions from stakeholders**