TRANSPARENCY

EMEA/CPMP Working Group with Patients' Organisations

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The European Agency for the Evaluation of Medicinal Products

Transparency

- Institutional and legal basis
- Available tools
- Transparency initiatives

Transparency – Institutional and legal basis

- **EU Treaty (Declaration 17 of the Annex)**
  - "…Transparency of the decision-making process strengthens the democratic nature of the institutions and the public's confidence in the administration."
- **Council Regulation (EEC) No. 2309/93**
  - Public assessment reports, information on experts/declaration of interests
- **Council and Parliament Regulation (EC) No. 1049/2001**

Transparency – Limitations

- **Confidentiality constraints**
  - **protection of commercial and industrial secrecy,**
  - **protection of the individual and of privacy**

Transparency – Identified stakeholders

- Patients / Patients' groups / Public
- Health care professionals
- Academia/learned societies
- Pharmaceutical companies
- Regulatory authorities / governmental agencies
- Scientific / lay media

Transparency – Available tools

- EMEA Press Release and CPMP Monthly Report
- Summaries of CPMP Opinion (for initial applications, COMP)
- EPAR (European Public Assessment Report) – Product information
- EMEA / CPMP Public Statement
- Annual Reports, Work programme, SOPs, CPMP Guidance documents, etc.
- Dialogue with stakeholders

Transparency – Initiatives to improve existing tools

- Improvements to the EMEA Internet homepage
- Improvements to EPARs
- CPMP Summaries of Opinions for post-authorisation applications
- Availability of public information in relation to referral procedures
- Improvements to CPMP Press Releases / CPMP Monthly Reports
- Interactions with the EMEA's stakeholders in relation to human medicines

Transparency – Initiatives to improve existing tools

- Development of Questions & Answers (Q&A) document
- Amendments to product information
- Issuing safety bulletins for human medicines
- Improvements to CPMP Guidance documents

Conclusions

- **Other areas for improvement ?**