TRANSPARENCY WORKSHOP

Overview current EMEA transparency measures

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Introduction

- EMEA transparency started at the very beginning of the Agency with the creation of the EMEA website
- Steps
  - 1997 Workshop on transparency
  - 1998 points to consider on an EMEA communication policy and transparency on withdrawals of applications and post-authorisation communication

- 2000 public consultation on new EMEA transparency initiatives (23 measures)
- 2003 Workshop on transparency at the EMEA
  - Public consultation
  - New EMEA transparency measures

- Revision of the pharmaceutical legislation based on previous EMEA experience

General issues

- **Proactive** versus **reactive** disclosure of information/documents
- Disclosure of documents/information **(proactive)** and access to documents upon request **(reactive)**
- Same principles to be applied
- Deletion of commercially confidential information

Legal basis

- Article 73 Regulation (EC) No 726/2004
  - Regulation (EC) No 1049/2001 on access to documents applies to documents held by the Agency
  - Implementing rules adopted by Management Board
  - **"REACTIVE"** disclosure (upon request)
  - Public consultation on EMEA policy with list of documents until 2 March 2009

- Article 80 Regulation (EC) No 726/2004
  - **"PROACTIVE"** disclosure
  - Addressed to EMEA
  - General terms
  - Implementing rules to be adopted by the Management Board

Product related issues

- Legal obligations
  - Information on withdrawal and refusals
  - Summary understandable to the public
  - EudraVigilance appropriate levels of access (public consultation on EudraVigilance access policy until 2 March 2009)
  - Appropriate pharmacovigilance information to the public

- Publication opinions compassionate use and on specific obligations for conditional MA
- EudraCT, EudraPharm, EudraGMP

- Other initiatives
  - Summaries of opinions
  - Questions and answers
  - Designated orphan drugs submitted for Marketing Authorisation
  - Refusal and withdrawn applications for new indications

- Opinions/decisions on Paediatric Investigation Plans applications
- Information to patients and health care professionals

Largely beyond legislation requirements

- **In all cases after deletion of commercially confidential information**

Non product related issues

- Regulatory/scientific guidelines
  - Public consultation
  - Overview comments
- Committees activities: Press-release, monthly report, work programme
- Agency activities: Management Board (soon minutes with documents), annual report, work programme

What else?

- At EMEA level
  - Preparation of a Transparency Policy
  - Based on work already done or on-going
    - Public-Facing Online Information
    - EMEA Access to Documents Policy
    - EudraVigilance Access Policy
  - After consultation partners and stakeholders
  - Medical information sector and European Medical Information Network

EMEA and the network

- Common approach on the implementation of Article 126b of Directive 2001/83/EC on agendas/minutes
- Wording different from wording Article 126b Directive 2001/83/EC addressed to Member States
- Common approach on publication of PSURs, PSURs assessment reports/conclusions
- Recommendations from HMA
- Medical information network
- Communication network

CONCLUSION

- Increased expectations from entire society
- Necessary to increase credibility in the evaluation process/surveillance and to build confidence in the system
- EMEA is working in order to increase transparency
- EMEA is working on improving the website