Workshop
EMEA Transparency Policy
Draft Key Principles
22 January 2009

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Content

Outline of (draft) EMEA Transparency Policy

- What is Transparency and Rationale of EMEA Transparency Policy
- Objectives and pre-requisites
- Working Methodology
- Next Steps

Definition of Transparency and Rationale of EMEA Transparency Policy

- **Definition of transparency**
  - **Openness**
  - **Communication**
  - **Accountability**
- **Rationale for the EMEA Transparency Policy**
  - **addressing in a better way an increased demand from civil society for more openness**
  - **applying a more robust and consistent approach towards transparency in the various EMEA activities, combining all current transparency measures, addressing outstanding measures and tackling new challenges**
- **Relationship with Community legislation on transparency measures**
  - **The EMEA Transparency Policy has a wider scope going beyond current Community legislation. In addition, it will address all EMEA activities.**

Objectives
EMEA Transparency Policy

1. **To apply a more proactive approach towards transparency in the daily operation of the EMEA**

2. **To increase the understanding of:**
   - **Activities undertaken by the Agency and**
   - **Agency's opinion (including its rationale)**

3. **To further strengthen interaction with the EMEA Stakeholders**

4. **To enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System Network on transparency related aspects (whilst recognising the limitations provided by national legislation on freedom of information)**

5. **To promote good administrative and regulatory practices**

Objectives and pre-requisites of EMEA Transparency Policy

Objective #1

To apply a more proactive approach towards transparency in the daily operation of the EMEA

Pre-requisite

Redefine the balance between transparency and protection of commercial confidentiality by reviewing the principles of commercial confidential information through a dialogue with the EMEA stakeholders

➔ reduction of access to docs requests

Examples:

- **Current**: EMEA Press Releases, CXMP Monthly Reports, Public Statements, Q&A documents, SMOPs
- **Envisaged**: publication of agendas and minutes (implementation of joint EMEA/HMA recommendation), establishment of the public register of documents
- **Proposed**: public hearings (new PhV legislation), publication of PhV newsletters/safety bulletins

Objectives and pre-requisites (cont)

Objective #2

To increase the understanding of:

- Activities undertaken by the Agency and
- Agency's opinion (including its rationale)

Pre-requisites

- Raise the awareness of the EMEA and clarify the scope of the EMEA remit
- Further improve the clarification of the rationale for the Agency's opinion-making and provide communication material better adapted to the needs of the various stakeholders

→ Strengthening trust

Examples:

- **Current**: Organization of Workshops (e.g. 1st EMEA Media Workshop June 2008)
- **Envisaged**: Future Workshops (e.g. 2nd EMEA Media Workshop in 2009), further work to be undertaken in relation to EPARs

Objectives and pre-requisites (cont)

Objective #3

To further strengthen interaction with the EMEA Stakeholders

Pre-requisites

Define the level of interaction with EMEA stakeholders through discussion with all involved parties

Examples:

Current: Existing framework of interaction with Patients' and Consumers' Organisation

Envisaged: Review of existing framework of interaction with Patients' and Consumers' Organisations, preparation of framework of interaction with Healthcare Professionals' Organisation, establishment of EMIN (European Medical Information Network), MI Newsletters

Proposed: Review of interaction between the EMEA Scientific Committees and all stakeholders (including pharmaceutical industry, academia and learned societies), as well as the organisation of public hearings (new PhV legislation; should the concept be broadened?), or webstreaming of meetings.

Objectives and pre-requisites (cont)

Objective #4

To enhance and promote closer interaction with the NCAs within the frame of the EU Regulatory System

Network on transparency related aspects (whilst recognising the limitations provided by national legislation on freedom of information)

Pre-requisites

Ensure that the EMEA initiatives in the field of transparency are in compliance with and complementary to the recommendations outlined in the HMA Strategy Paper, and strive, as far as possible, for a common approach on key elements on transparency across the EU

Examples:

Current: Joint EMEA- HMA discussion on the principles of commercial confidential information

Envisaged: Implementation of the joint EMEA/HMA recommendations on the publication of agendas and minutes, HMA discussion on release of PSUR and PSUR Assessment Reports, discussions on PhVWP transparency measures, public consultation on the EudraVigilance Access Policy, establishment of EMIN

Objectives and pre-requisites (cont)

Objective #5

To promote good administrative and regulatory practices

Pre-requisites

Apply a consistent approach in the application of transparency throughout the Agency.

Put in place the necessary (technical) tools to allow for an efficient implementation of the EMEA Transparency Policy

Examples:

Envisaged: Revision of EMEA website and further development of the PFOI project, establishment of the public register

Proposed: Review of external and internal guidance, updating of SOPs and WINs, provision of training, drafting of specific Performance Indicators, drafting of an Impact Assessment and subsequent inclusion in the EMEA planning process (in terms of necessary human and financial resources

Working Methodology
EMEA Transparency Policy

Working Methodology

1. Inventory of the various transparency measures adopted by the Management Board over the past years and legal obligations put on the EMEA in the field of transparency

2. Gap analysis
   (ensuring consistency of the transparency measures implementation, where appropriate)

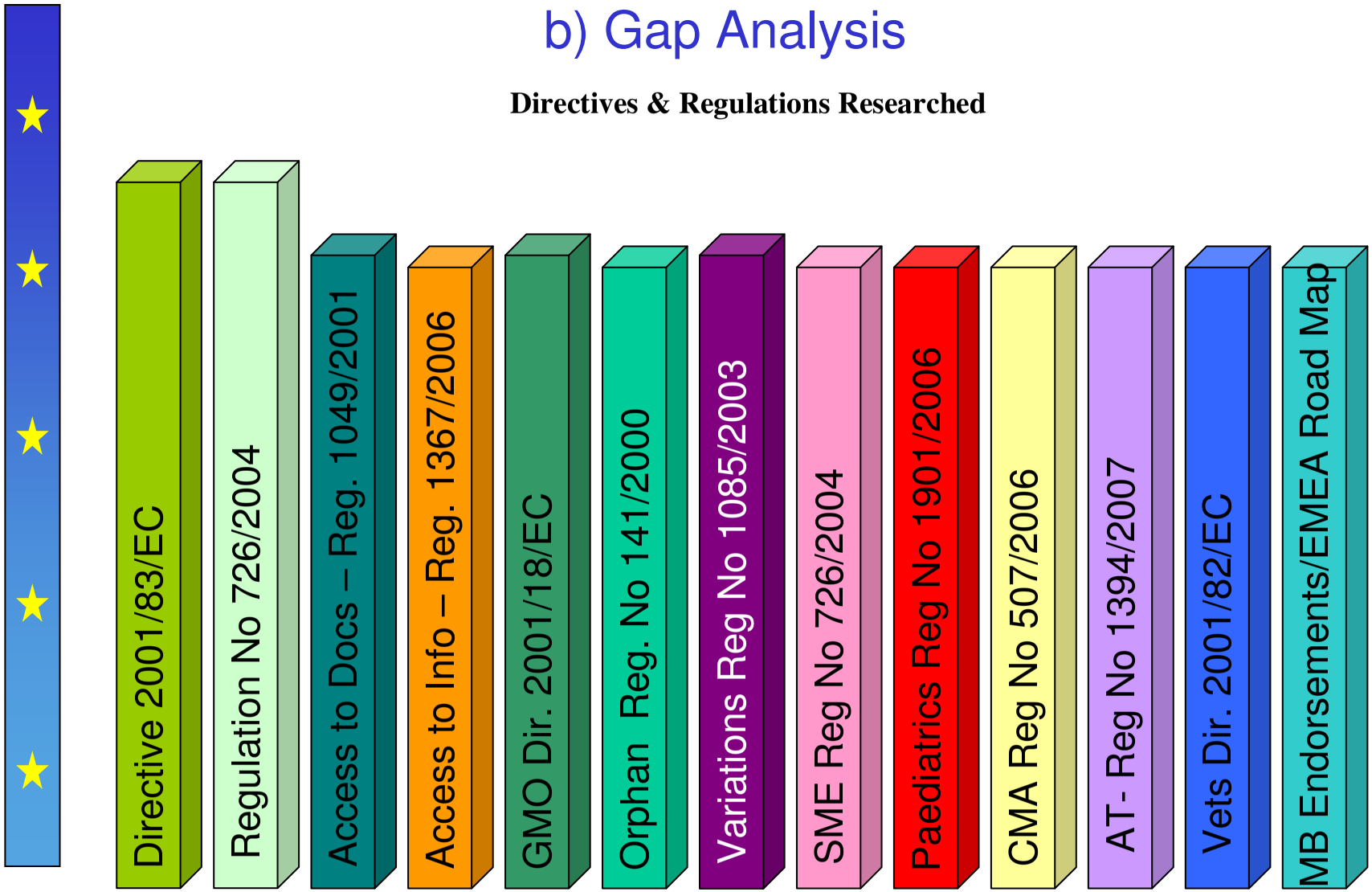
3. EMEA Road Map towards greater transparency: addressing the gaps and tackling new challenges through dialogue with the EMEA Stakeholders

Working Methodology (cont)

a) Inventory

b) Gap Analysis

Directives & Regulations Researched



Implementation of EMEA Transparency Policy

Implementation

1. Preparation of a high-level Impact Assessment of the agreed EMEA Transparency Policy

2. Subsequent consideration of the necessary (human) resources in the Agency's multi-annual planning

Transparency Project
Next steps

We are Here

22 January 2009

Workshop on the Development of EMEA Transparency Policy

Mid June 2009

Release of Paper on EMEA Transparency Policy

First week Sep 2009

2.5 months External consultation

Sep/ Oct 2009

If needed, 2nd Workshop on EMEA Transparency Policy

Mid December 2009

Finalised Paper on EMEA Transparency Policy

EMEA Transparency Policy
What we discussed today…

Outline of (draft) EMEA Transparency Policy

- Why➔ Rationale of EMEA Transparency Policy
- What we want to achieve➔ Objectives
- Tools/conditions to achieve objectives➔ pre-requisites
- How➔ Working Methodology
- Next Steps

Transparency Project

Thank you!

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Transparency Project Abbreviations

AT – ***Advance Therapies***

CC – ***Commercial confidentiality***

CCI – ***Commercial Confidential Information***

CMA – ***Conditional Marketing Authorisation***

CXMP – ***Committee for Medicinal Products***

EMIN – **European Medical Information Network**

EU – ***European Union***

GMO – ***Genetically Modified Organisms***

HMA – ***Heads of Medicines Agencies***

MB – ***Management Board***

MI – ***Medical Information***

NCA – ***National Competent Authority***

PFOI – ***Public-facing online information (EMEA project)***

PhV – ***Pharmacovigilance***

PhVWP – ***Pharmacovigilance Working Party***

PSUR – ***Periodic Safety Update Report***

Q&A – **Questions & Answers**

Reg – **Regulation**

SME – ***Small and medium-sized Enterprises***

SMoPs – ***Public Summary of Positive Opinions***

SOP – ***Standard Operating Procedure***

WIN – ***Work Instructions***