EMEA Transparency Workshop
Pharmaceutical Industry Views

22nd January 2009

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- The views expressed in this presentation are preliminary and represent views recently expressed by pharmaceutical companies /members of pharmaceutical industry associations on questions raised by the EMEA in preparation for the workshop of 22nd January 2009.
- These views cannot be considered to be binding for any pharmaceutical industry association

Current EMEA's Transparency Measures
(*Item 1)*

- Experience with the current EMEA measures
  - Overall the current level of transparency applied in the daily operations of the EMEA is appropriate however:
    - structure of the public website is not user friendly; difficulty for any user to find the information he/she is looking for.
    - publication of guidelines for public consultation:a few issues (e.g. announcements, deadlines)
    - variable levels of transparency of activities ongoing within the Agency

Expectations on Product Related Issues

(*Item 2)*

- Making public information on medicinal products

  Considerations that drive positions/policies

  – Provision of information that is useful (or potentially useful) to the public (in particular the Patients /their Families, Health Care Professionals)

  – Provision of information to foster trust

  – Protection of decision making process, purpose of audits, investigations, inspections etc

  – Protection of sensitive information and data (commercial interest, personal) ; sensitivity of some information may evolve over time

  (various presentations on commercial confidentiality aspects – afternoon session)

Expectations on Product Related Issues (cont'd)

- Medicinal Product before and after authorisation
  - Doc. Ref. EMEA/659316/2008/Final 'ouput of EMEA policy' currently reviewed by companies, associations: overall first impression is that policy is appropriate (appears to take into due consideration the principles /criteria listed on previous slide)

Expectations on Product Related Issues (cont'd)

- Specific transparency measures for emerging issues irrespective of the status of the authorisation of the medicinal product?
  - Blanket disclosure policy measures for emerging issues irrespective of the status of the autorisation would not serve public health; the principles listed on slide 3 will guide decision making on a case-by -case basis on the need for and nature of appropriate specific transparency measures; collaboration of applicants or marketing authorisation holders always necessary

Expectations on Non-Product Related Issues and EMEA Interaction with Stakeholders

(Items 3 and 4)

- Development and publication of guidelines and related documents

  Diverse experience (depending on area, topic, etc) concerning:

  – transparency in relation to the criteria for selecting a topic; transparency in relation to the involvement of experts; timing for consulting interested parties; opportunity to comment vs opportunity to contribute; organisation of workshops

  – transparency in relation to the treatment of comments

Expectations on Non-Product Related Issues and EMEA Interaction with Stakeholders (cont'd)

- Drafting of Committees, Monthly Reports etc
  - For most working parties:

    Transparency to be improved (example of possible welcome improvement would be to provide information on implementation of workplans)
  - Monthly reports: more information on time target deadlines for making public announced policy statements, draft or final guidelines etc,
- Some information on pilot projects (e.g. high level objectives, timelines, responsible unit or working party etc) would also be useful