EMEA Transparency Policy

- Current transparency level
  - Overall acceptable
  - Increase information on working parties/scientific committees
  - Further improve management of EMEA website
- Product related issues
  - Current recommendation acceptable
    - Pre-licence level of information
    - Post-licence (EPAR)
    - Withdrawal/negative opinion
  - Emerging issues
    - Specific measures not warranted

AESGP

EMEA Transparency Policy

- Non-product related issues
  - Increase information on working parties/scientific committees
  - Increase visibility of changes within documents
  - Timely publication of reports/guidelines
- EMEA/Stakeholder interaction
  - Working well
  - Increased access to EMEA contact details?

EMEA Transparency Policy

- In principle, EMEA Transparency Policy seems fine…..

- However:
  - Non-prescription medicines (OTC) are different to prescription medicines (Rx)
    - Some aspects need consideration

Principles of OTC

- Patents: OTC different to Rx
  - Typically not patented
- Timelines: OTC different to Rx
  - Pre-licence
    - Typically shorter development cycles for OTCs
  - Post-licence
    - Time to build brands/pharmacy training - different to Rx?
      - Innovator invests before launch
      - Competitors less investment ('faster' launch)
- Commercial positioning
  - Could be easy to determine from an OTC application

Consequences of Transparency

- Regulatory consequence
  - Regulatory timings may be shorter for followers
    - e.g. issues already addressed
- Commercial Consequence
  - Plans could be transparent
    - Easy to copy and/or counter
  - Significant commercial risk
    - Companies go to great lengths to keep plans confidential
      - e.g. invented name discussion (disclosure of discussion could give away future potential brand option information)

Consequences of Transparency

- Competitors
  - Shorter development time
  - Can enter market more quickly
  - Faster launch

Keep in mind potential negative impact on investment/innovation/applications

Transparency documents

- HMA-EMEA recommendations on transparency
- EMEA principles on deletion of confidential information for the disclosure of EMEA documents

  – In principle applicable as such to non-prescription medicines with exception of scientific advice (as preliminary position)
  – Further experience needed
  – Principles could *a priori* apply to other types of documents, not just assessment reports
  – Further reflection needed in the framework of the documents under consultation