Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

Transparency and commercially confidential information

EGA's perspective

Beata Stepniewska
Director of Regulatory Affairs
EGA

Access to Information versus Confidentiality

- **Complex environment:**
  - Permanent increase of demand from patients and health care professionals for early information on medicinal products
  - Need for transparency on the decision making process at the competent authorities' level
  - Increase of competition in the pharmaceutical sector
    - Access to information as part of a strategy

Access to Information versus Confidentiality

- **The principles supported by the EGA:**
  - Patients and health care professionals should have access to information which is important to them
  - Legal obligations of the authorities and the industry have to be fulfilled
  - The same principles and common rules regarding transparency should apply to the EMEA and the MSs

EMEA's Transparency Policy

- **EMEA initiatives to improve transparency on product and non-product related issues welcomed by the EGA**
  - List of products submitted before 20 Nov 2005 ☺
  - Various Eudra databases, publications on safety, revision of the website etc.
  - Open dialogue with stakeholders

Access to Information versus Confidentiality

- **Access to information should not become a tool for anticompetitive actions**
  - More court cases will not improve patients' access to information
  - Intellectual property rights have to be respected
  - Commercially sensitive information should remain confidential
- **Not contradictory to transparency policy**
- **Information which may not be commercially sensitive for an originator company could be highly sensitive for a generic medicines' producer**

Making Medicines Affordable

What is Seen as Commercially Sensitive Information from the Generic Industry's Perspective?

Highly Competitive Environment

- **Strong competition between generic medicines' companies**
  - No monopolistic position on the market due to lack of data exclusivity and patent/SPC protection
  - Time of granting the (first) MA is crucial
  - Know-how and regulatory strategy as a part of competition

Highly Competitive Environment

- **Publication of on-going procedures**
  - EMEA/HMA recommendation on transparency related to agendas/ minutes (Nov 2008)
    - Publication of on-going procedures: INN, type of application, therapeutic class
  - Court cases initiated after receiving information about on-going MA procedures
    - Access to the generics files in some MSs (data misused)
    - Confirmation in the EC Sector Inquiry Report
  - EGA preferred approach: DK/UK policy on publication of agenda
    - *Product for treating illness X; full/abridged application*

EMEA Policy

- **Concept of "commercially confidential" info**
  - *"Principles to be applied for the Deletion of Commercially Confidential Information for the Disclosure of EMEA Documents" (15.04.2007)*
  - Commercial interest of a natural or legal person, including intellectual property should be protected, unless there is an overriding public interest in disclosure
  - EGA supports confidential treatment of intellectual property, "know-how" and commercial secrets
  - Quality part of the dossier seen as confidential ☺☺☺
    - Including the API manufacturer and suppliers ☺
    - Polymorph form and particle size ☺

Making Medicines Affordable

EMEA Communication on Generic and Biosimilar Medicines

EPAR vs confidentiality

- **Publication of EPAR as a part of the communication on generic/ biosimilar medicines to the public and health professionals**
  - Still relatively limited experience
  - Current practice at EMEA is seen as positive with regard to the opportunity to comment on EPAR and the final content of EPAR
    - There is consistency in the format and content
    - First draft of EPAR could respect the guideline on commercially sensitive information more
  - Link to the QA on generic/ biosimilar medicines very useful
  - Diversity of PARs at the national level causes more problems

PSUR vs Confidentiality (1)

- **Commercially sensitive data in PSUR**
  - Commercial data
    - Sales data in the different countries including a total number of patients treated and breakdown by sub-population,
    - World-wide market authorisation status
- **All data related to individuals involved in a case**
- **All personal data**
  - the staff of a pharmaceutical company (eg, employees preparing and reporting PSUR or being the PhVQP) and business partners

PSUR vs Confidentiality (2)

- **Access to other parts of PSUR**
  - Data on completed and planned studies or safety examinations, method employed for statistics and other processing of data, signal generation etc.
    - Confidentiality policy coherent with the outcome of discussions at the Eudravigilance Steering Committee
    - More comments on draft of Eudravigilance Access Policy as a part of consultation by 2 March

Access to EMEA Documents (1)

- **Practical issue regarding access to documents and contact with the holder of information**
  - Very tight time limit for disclosure of documents (15 days)
    - Consultation with the holder of information within 5 days
    - Feedback to the holder whether information has been disclosed and if so what was disclosed
  - More comments on classification of documents and the procedure as a part of consultation by 2 March

Access to EMEA Documents (2)

- **EMEA statistics (June 2008):**
  - 92 requests/37 refused
  - 30% increase on 2006
- **EGA would welcome more information on this data**
  - Type of document requested?
  - Main reasons for refusals?

Conclusion

- Several initiatives to improve transparency on product and non-product related issues were welcomed by the EGA
  - Important communication process and trust building between Authorities and the industry
- Increase of cooperation between the EMEA and the MSs would be welcomed
  - Harmonised access to information independently of MS and of the procedure used for MA
- The EGA is willing to contribute to the debate on how to improve transparency and communication with all stakeholders
  - Discussion on the EMEA policy on access to EMEA documents

Making Medicines Affordable

Thank You !