

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



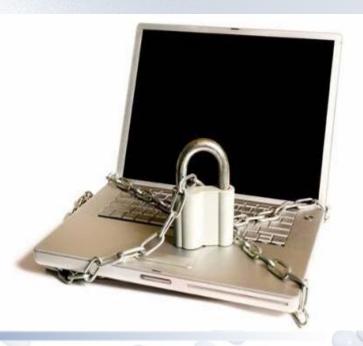


Access to Information versus Confidentiality

- 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



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 ②
 - Polymorph form and particle size ©



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



Thank You!

