Preparation of workshop with stakeholders at the EMEA on 22nd January 2008 - Key messages in relation to the importance of commercially confidential information

Public Access and Sensitive/Commercially Confidential Information

EFPIA supports making available to the public and in particular to the Patients and Health Care Professionals

- information to inform them of the existence of clinical trials and facilitate their participation in these trials
- information (protocol and/or results) to reduce duplication of trials on authorised medicinal products
- information to support the appropriate use of authorised medicinal products

In January 2005 the innovative pharmaceutical industry made a voluntary commitment to disclose appropriate clinical trials information via clinical trials registries and databases to meet the first two objectives.

The innovative (R&D based) pharmaceutical industry recognises that openness and transparency with respect to the work of the European Union Institutions "guarantees that the administration enjoys greater legitimacy and is more effective and more acceptable to the EU citizen". As a result the R&D based pharmaceutical industry supports openness and transparency with respect to the work of the EMEA to promote public health in compliance with the principles laid down in Regulation (EC) No 1049/ 2001.

As recognised in Article 4 of Regulation (EC) No 1049/ 2001 and Article 39(3) of the TRIPS agreement, disclosure of information, data and documents provided in confidence must not undermine the protection of legitimate commercial interest (including intellectual property) and personal information. Protection of the purpose of inspections, investigations and audits must also be taken into due consideration.

Looking after the legitimate commercial interests of innovative companies: a strategic business and public health objective

Innovative pharmaceutical companies contribute to public health by discovering and developing new medicinal products. However, these activities are sustainable only within an environment which recognises and appropriately protects intellectual property and know-how.

The knowledge of the existence of work on a new medicinal product might offer a commercial advantage to a competitor and adversely affect the originating company's return on investment which in time might have an impact on its capacity to invest into more research and development.

Information on the design of a development program (including a clinical development program) is important for public health reasons but it is also of great commercial value.

Knowledge of this information could benefit competitors and adversely impact the potential for return on investments

Intellectual Property Protection and Regulatory Data Protection are not uniformly applied across countries or regions. In an increasingly global world, public availability of information, data or documents submitted in confidence to regulatory bodies may be detrimental to the innovators in those markets in which protection is not available. Furthermore, where as a consequence the innovator company's overall return on investment is decreased, there will be a negative impact on the company's R&D investment capability, even in countries where IP, know-how and trade secrets are protected (i.e. including those where most new medicines are currently discovered and developed).

Guiding principles on confidentiality before a marketing authorisation has been granted or refused

In general, information about and any data submitted for ongoing procedures should in principle always remain confidential until a final and formal decision has been taken by the regulatory authority concerned.

Guiding principles on confidentiality after a product has been authorised

Product-specific discussions with authorities (e.g. during scientific advice procedures, briefing meetings, etc) should always remain confidential.

The detailed documents submitted by applicants and marketing authorisation holders to support protocol assistance- scientific advice procedures, briefing meetings, requests for agreement of paediatric investigational plans, applications for marketing authorisations, variations to the terms of marketing authorisations or activities in relation to the granting or maintenance of authorisations should in general considered to be commercially confidential. Therefore EFPIA believes that overall the classification proposed page 19 to 23 of the document entitled "Output of the draft EMEA Policy on the Practical Operation of Access to EMEA documents in the Context of the Authorisation and Supervision of Medicinal Products for human and Veterinary use" is appropriate.

Guiding principles on confidentiality of personal information

The confidentiality of personal information provided to the regulatory authorities (for example, data allowing the identification of individual patients/subjects, or allowing the identification of company personnel), should be respected.