Key stakeholders should share the responsibility of balancing the benefits and risks from new medicines, as the EBE workshop debated during the European Health Forum Gastein

Bad Hofgastein, 1 October 2009: The European Biopharmaceutical Enterprises (EBE) hosted a lunch workshop co-sponsored by EBE, Novartis and Roche during the European Health Forum Gastein on "Biopharmaceuticals: Balancing Benefits and Risks - Sharing Responsibility". The event highlighted the need to share responsibility amongst key stakeholders during the development process of a medicinal product, from its research and conception until its release on the market. Sharing responsibility would help ensure a balanced approach that reflects the interests of all parties concerned.

Speaking at the event, Christoph Thalheim, Secretary General of the European Multiple Sclerosis Platform, emphasised the importance for patients to play an active role in the healthcare debate. "*Patients are ready to accept a much higher risk than medical experts think IF the benefit is clearly described and likely to happen and if the risk information provides an educated guess on worst-case scenario and likeliness for this to happen*", stated Thalheim. He also underlined that patients are involved in several Working Parties at the European Medicines Agency and positive lessons can be drawn from such active participation.

The industry panellist, Dr. Trevor Mundel, Global Head of Development at Novartis Pharma, explained that there is a new paradigm shift from Efficacy-Safety to Risk-Benefit. This is introducing a profound change for the pharmaceutical industry and it has specific implications such as extensive phase III clinical data requirements, increased time and development costs for new products and significant post-marketing authorisation commitments for innovative medicines. From the biopharmaceutical industry's standpoint, an earlier collaboration with regulators and payors would be essential for a balanced benefit-risk development, on top of the important dialogue with patients.

"*Our EBE workshop in Gastein has contributed to establishing a new multi-stakeholder platform on benefit-risk balance. Such a forum helps foster better understanding of the roles and responsibilities of each stakeholder in the identification, assessment and management of risks during the development process of a medicinal product. It is important to highlight the need for a balanced and shared responsibility and to have benefits equally taken into consideration*" concluded Emmanuel Chantelot, EBE Executive Director and panel moderator.

Background Document – EBE Publication:
EBE initiated discussions on benefit-risk balance in 2008 around the "shared responsibility" concept, engaging with different stakeholders involved in the management of a disease and

the introduction as well as use of new medicines (industry, researchers, healthcare professionals, ethics committees, patients and regulators). In December 2008, EBE published a brochure on "Balancing Benefits and Risks: Sharing Responsibility" that can be accessed at the following link:

http://www.ebe-biopharma.org/documents/publications/Benefit_Risk_Balance_EBEbrochure_final_Dec08.pdf

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About EBE:
European Biopharmaceutical Enterprises (EBE) is the Brussels-based European trade association that represents biopharmaceutical companies of all sizes operating in Europe. It has 65 member companies, which are engaged in the research, development, manufacturing and marketing of new medicinal products using biotechnology. EBE also operates as the biotechnology arm of EFPIA, the European pharmaceutical industry federation.
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