EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2010
EMA/815144/2009
Human Medicines Development and Evaluation

Conference announcement

10 years of the Orphan Regulation in Europe

3-4 May 2010

The European Medicines Agency will hold a conference to celebrate the results of the Orphan Regulation implementation in Europe on **3-4 May 2010.** The meeting will take place at the Agency's offices in London.

The aim of this conference is to bring together patients, researchers, industry and regulators to discuss and share experiences with the development of orphan medicinal products.

The conference will open with a plenary session to introduce the theme and to cover topics centered to the implementation of the Orphan Regulation in Europe and the various incentives and initiatives related to orphan medicinal products in Europe.

At the heart of the conference there will be three parallel workshops scheduled for the second day of the conference. Each workshop consists of approximately two-hour sessions, each with a dedicated Chair to guide the discussions. To increase the coherence within a defined workshop, a member of the organizing committee will work with the session Chairs to coordinate the content and questions addressed to speakers. The three parallel workshops to choose from are:

Workshop 1:	**Development of products for rare diseases: incentives, reality and future direction**
Objectives:	Identify major areas where drug development is insufficient for orphan drugs
	Discuss reasons for lack of orphan designated drug development
	Propose mechanisms to further stimulate orphan drug development
	Discuss current incentives and future actions to improve development
Workshop 2:	**Research for rare diseases: translation into new drugs for rare diseases. The role of academic researchers**
Objectives:	Identify research needs for rare diseases

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	Discuss current instruments for research support and propose how to improve them
	Discuss different models of research promotion and their characteristics
	Recommend future actions to stimulate research for rare diseases
Workshop 3:	**Patients' view on the Regulation's implementation. What is still needed?**
Objectives:	Reflect on how the Orphan Regulation has addressed the patient needs in the EU
	Discuss how patient representatives have contributed to the regulatory activities as Committee members
	Discuss the most immediate challenges for the Regulation from the patient's point of view
	Recommend initiatives to ensure future success of the Regulation from a patient's perspective

The second day afternoon session will feature reports for all three workshops. An interactive panel of patients, industry and regulatory leaders will conclude on the issues of the day and perspectives on the future.

The agenda has been structured in a way to allow time for questions, answers and discussion.

Based on these discussions, a list of recommendations will be developed at the meeting and published in a meeting summary.

To express your interest in attending the conference and the workshop(s), please use the attached registration form and send it to: orphandrugs@ema.europa.eu before 19 April 2010.

Please note that approximately 120 places are available for the conference. A limited number of invitations covering travel and hotel expenses are available for patient representatives and health professionals. Spaces will be allocated on a first-come-first-serve basis with a maximum of two attendees per organisation.

The European Medicines Agency looks forward to welcoming you at the conference.

Contact

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