8th Workshop
Eurordis Round Table of Companies

“Impact of the EU Paediatric Regulation on Orphan Drug Development”

June 20th, 2008
Barcelona, Spain

Fundació Doctor Robert - Universitat Autònoma de Barcelona- Casa Convalescència

Programme

8:30 Welcome & coffee

MORNING 9:00 - 12:50
Chairpersons:
Dr Daniel Brasseur (Chair of the PDCO, EMEA) – Prof. Josep Torrent-Farnell (COMP, EMEA)

9:00 - 9:15 Welcome address

9:15 - 9:35 “Understanding the EU Paediatric Regulation”
(Dr Christoph Male, member of the PDCO, EMEA)

We intend to present the aims and the content of the EU Regulation.

9:35 - 10:00 “The Paediatric Committee of the EMEA: Experiences of the First Year”
(Dr Paolo Tomasi, EMEA)

A report from the experience of the PDCO both on orphan and non-orphan drugs, and perspectives for the future.

10:00 - 10:40 Discussion (40’)

10:40 - 11:00 – COFFEE BREAK

11:00 – 11:30 “The Double Challenge of Orphan and Paediatric: the US Experience”
(Dr Linda C. Ulrich, FDA/Office of Orphan Products Development)

11:30 – 12:10 “Industry Experience and Evaluation of the Legislative Framework”
(Dr Thomas Severin, Novartis and Mrs Marie-Christine Fortun, Orphan Europe)

12:10 – 13:00 Discussion (40’)

13:00 - 14:15 – LUNCH
14:15 -14:35  “The Role of Patients in the EU Paediatric Legislative and Non-legislative Framework” (Dr Tsveta Schyns, patient representative, candidate to the PDCO)

14:35 -14:55 “Ethical Issues for the Involvement of Children in Clinical Trials “ (Dr Paola Baiardi, TEDDY network)
The public perception of paediatric trials and the policies for access to data on paediatric drug development will also be discussed

14:55 -16:30 Discussion with panel including all stakeholders:
“How to Facilitate the Development of Drugs in Paediatric and Orphan Indications?”

Panel members: Speakers

16:30 End of Workshop