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

AFTERNOON 14:15 -16:30

Chairpersons:

Dr Kerstin Westermark (Chair of the COMP, EMEA) – Mr Yann Le Cam (CEO of EURORDIS)

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**