9th Workshop
Eurordis Round Table of Companies

“Significant Benefit of Orphan Drugs:
Impact on Clinical Development and Assessment”

December 12th, 2008
Les Salons de l’Aéro-Club de France
Paris, France

Programme

8:30 Welcome & coffee

MORNING: 9:00 - 13:00
Chairpersons:
Eric Abadie (Chair of the CHMP, EMEA) – Josep Torrent-Farnell (COMP member, EMEA)

9:00 – 9:20: Welcome address and presentation “From EU Policy Framework to Public Awareness: Rare Disease Day” (Yann Le Cam, Eurordis)

9:30 – 9:50: “Presentation of the Revised Guideline on elements required to support the medical plausibility and assumption of Significant Benefit for orphan designation” (Kerstin Westermark, COMP, EMEA)

10’ questions

10:00 – 10:20: “The Significant Benefit Criterion: the Experience gained at the Time of Designation and of Marketing Authorisation” (Jordi Llinares-Garcia, EMEA)

10’ questions

10:30 – 11:00: COFFEE BREAK

11:00 – 11:20: “Is there an Optimum Clinical Trial Design for Significant Benefit Demonstration? The Experience of the Scientific Advice Working Party (SAWP)” (Mira Pavlovic, SAWP)

10’ questions

11:30 -12:45: Panel discussion: Real-life Experiences of Significant Benefit (90’)
Panel includes all morning speakers, chairpersons and three contributors from the pharmaceutical industry: Alex H. West, GSK – Catarina Edjfaëll, Celgene – Franck Rauschen, Shire.

12:45 – 14:15: LUNCH
AFTERNOON: 14:15 -16:30
Chairpersons:
Kerstin Westermark (Chair of the COMP, EMEA) – Peter Saltonstall (CEO, NORD)

14:15 – 14:35: “What is the Potential Impact of Significant Benefit in the Field of Medical Oncology?” (Kateřina Kubáčková, COMP, EMEA)

10’ questions

14:45 – 15:05: “Why and How to Communicate on Significant Benefit?” (Yann Le Cam, Eurordis)

10’ questions


10’ questions

15:45 – 16:30: Discussion with panel and all stakeholders
Panel includes all afternoon speakers, chairpersons and two contributors from the pharmaceutical industry: Wills Hughes-Wilson, Genzyme – Karin Blumer, Novartis.

16:30 End of Workshop