EURORDIS - ERNST & YOUNG
Joint 14th Workshop of the Eurordis Round Table of Companies (ERTC)

"Mechanisms for the Implementation of the Clinical Added-Value (Relative Effectiveness) of Orphan Drugs, CAVOD"

Friday 27 May 2011
Barcelona, Spain

Sant Antoni Maria Claret, 171
Fundació Doctor Robert - Universitat Autònoma de Barcelona- Casa Convalescència

Agenda

Morning session

Chairpersons:

Kerstin Westermark (Committee for Orphan Medicinal Products (COMP), EMA)
Yann Le Cam (EURORDIS)

9:00 – 9:10: *Welcome address* ***(Yann Le Cam, EURORDIS)***

9:10 – 9:40: "What mechanism could be created for a European evaluation of the relative efficacy / relative effectiveness of orphan drugs (CAVOD)?" **- Pascale Augé (Ernst &Young) – presented by Stéphanie Daireaux (Ernst &Young) and Georgios Margetedis (EC/ EAHC)**

9:40 – 10:10: "The European CAVOD mechanism as an opportunity for HTA agencies to enhance their collaboration" **- François Meyer (EUnetHTA)**

10:10 – 10:40: "Industry viewpoint on the implementation of the CAVOD process" - **Wills Hughes-Wilson (Chair, Joint European Industry Task Force on Orphan Medicinal Products & Rare Diseases)**

10:40 – 11:10 - COFFEE BREAK

11:10 – 11:40: "How would the CAVOD mechanism impact EMA's work and what would the relationship be with the present EMA committees and parties?" **- Hans-Georg Eichler (EMA)**

11:40 – 12:10: "How can patients contribute to the CAVOD mechanism?" **Fabrizia Bignami (EURORDIS)**

12:10 – 13:00: Panel discussion: Speakers and panel members : **Ad Schuurman (MEDEV), Antoni Montserrat (European Commission/DG Health & Consumers)**

13:00 – 14:00 - LUNCH

Afternoon session

Chairpersons:

Pascale Augé (Ernst & Young)
Georgios Margetidis (European Commission/EAHC)

14:00 – 14:15: **Introduction to the parallel breakout sessions and presentation of the 4 discussion topics**: Pascale Augé, Ernst & Young

14:15 - 15:30: Parallel Breakout Sessions

1) Activities of the CAVOD process and practicalities for the preparation and endorsement of documents prior to, and at the time of, the positive opinion of the CHMP and at Marketing Authorisation
   Rapporteur: Meindert Boysen, NICE
   Facilitator: Stéphanie Daireaux, Ernst & Young
2) Organisation and infrastructures needed to implement the CAVOD mechanism
   Rapporteur: Yann Le Cam, EURORDIS
   Facilitator: Georgios Margetidis, EC/EAHC
3) Discussion around the European Research Plan (ERP): timelines, content, implementation and follow-up
   Rapporteur: Hans-Georg Eichler, EMA
   Facilitator: Pascale Augé, Ernst & Young
4) Activities in the CAVOD process and practicalities for the preparation and endorsement of the "Clinical Evidence Report"
   Rapporteur: Wills Hughes-Wilson, Joint European Industry Task Force
   Facilitator: Hicham Naim, Ernst & Young

15:30 – 16:15: Feedback from the parallel groups presented by the 4 rapporteurs

16:15 – 17:00: Discussion

17:00 End of the workshop