11th Workshop
Eurordis Round Table of Companies

"Improving Access to Orphan Drugs for all Patients Affected by Rare Diseases in Europe: EU Assessment of Clinical Added-Value of Orphan Drugs (CAVOD)"

December 11th, 2009
Paris, France
Les Salons de l'Aéro-Club de France

Agenda

8:30 Welcome & coffee

MORNING: 9:00 - 13:00
Chairpersons:
Dr. Eric Abadie (Chairman of the CHMP, EMEA)
Mrs Aurélie Vandeputte (DG Enterprise, European Commission)

9:00 – 9:05: *Welcome address*

9:05 – 9:35: "Assessing Drug Effectiveness - Common Opportunities and Challenges for Europe" – Dr. Nils Feltelius, Medicinal Product Agency, Sweden (due to unforeseen circumstances, Dr Kerstin Westermark presented on behalf of Dr Feltelius)
10' question time

9:45 – 10:15: "**EURORDIS' Proposal for the Practical Implementation of Policy Principles to Improve Access to Orphan Drugs in the EU"** – Mr.Yann Le Cam, CEO of EURORDIS.
10' question time

10:25 – 11:05: The Industry's point of view:
- **"Which Principles from the Proposal for CAVOD does Industry Support?"-** Mrs Wills Hughes-Wilson (Genzyme, EBE/ EuropaBio Orphan Drug Task Force)
- **"What Concerns does the Proposal for CAVOD raise for Industry?" -** Dr. Kevin Loth (Celgene, EFPIA)

10' question time

11:15 – 11:45 COFFEE BREAK

11:45 – 12:15: "What Role for EMEA in the Evaluation of the Relative Effectiveness of Orphan Drugs?"- Prof. Hans-Georg Eichler, Senior Medical Officer, EMEA
10' question time

12:25 – 13:00: Panel discussion: speakers and other panel members. Case study by patient representative (Christos Sotirelis, UK Thalassemia Society)

13:00 – 14:00: LUNCH

AFTERNOON: 14:00 -17:30
Chairpersons:
Dr. Kerstin Westermark (Chairperson of the COMP, EMEA)
Mr Jerôme Boehm (DG SANCO, European Commission)

14:00 – 17:30: Large panel discussion:
Speakers from the morning session, as well as Dr. Ad Schuurman (MEDEV) and Dr. François Meyer (EuNet HTA project).

Issues to be addressed:

- What should the report for CAVOD contain?
- What kind of recommendations should the report give?
- How to involve the national institutions that are supposed to take advantage of this report?
- What should the content of the annexes to the report be?
- What data should be collected for the revision of the report and in which timeframe?
- What will be the indicators that should be used to evaluate the efficacy of the CAVOD EU collaborative approach? How to measure quicker and better access to Orphan Drugs in EU?

Concluding remarks:

- **"The US Perspective on OMP and Relative Effectiveness"** Mary Dunkle (NORD,USA)
- **"Improving Access to OMP in EU"** Jerôme Boehm (DG SANCO, European Commission)

17:30 **End of Workshop**