



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Tourism, CSR, Consumer Goods and International Regulatory Agreements
Unit F5 Food and Healthcare Industries, Biotechnology

Access to Medicines in Europe

Meeting on Prioritisation

Thursday, 7 April 2011 in Brussels

Minutes

1. PARTICIPANTS

Member States:

[REDACTED] (BELGIUM), [REDACTED] (HUNGARY), [REDACTED]
(ITALY), [REDACTED] (THE NETHERLANDS), [REDACTED] (NORWAY),
Miguel VIGEANT GOMES (PORTUGAL), [REDACTED] (SWITZERLAND)

Organisations:

[REDACTED] (EFPIA), [REDACTED] (EPF), [REDACTED]
(ESIP), [REDACTED] (EuropaBio), [REDACTED]
(WHO), [REDACTED] (WHO)

Commission:

[REDACTED] (DG ENTR), [REDACTED] (DG ENTR), [REDACTED] (DG
ENTR)

2. INTRODUCTION / BACKGROUND

- [REDACTED] (EC) greets the participants and explains in her introductory note the background to this meeting:

In its Conclusions on Innovation and Solidarity in Pharmaceuticals, on December 2010 the 2nd, the Council invited the European Commission and the Member States to "take the initiative of updating the 2004 priority medicines report, in cooperation with WHO experts" (point 16) and to "continue to encourage the strengthening of coordination and prioritisation in the allocation of resources for pharmaceutical research to increase the probability of valuable innovations that meet unmet health needs, where appropriate through the development of partnerships" (point 17) and "Foster dialogue with stakeholders on : (...) access to medicines in Europe" (point 22)

- Tour de table

3. EXCHANGE OF VIEWS AND EXPERIENCES ON PRIORITISATION

- [REDACTED], WHO, presents the 2004 WHO Report on Priority Medicines for Europe and the World

http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf

- [REDACTED] presents the recently published Dutch report "New and needed. Medical products that make life better"

On the afternoon, participants described which criteria they use to prioritise on research for the industry, and on market access as well as price and reimbursement for Member States.

A number of themes were recurrent:

- How to find common language / ground among stakeholders? (ex of demographic and climate change debate)
- How to integrate priorities in pricing & reimbursement procedures?
- How to measure innovation in fields as prevention, adherence, quality of life?
- How to conciliate priorities of different stakeholders in order to achieve societal goals? (ex of safety)
- How to conciliate the different time perspectives of stakeholders? (long research timelines, annual budgets)

4. OPERATIONAL CONCLUSIONS

The group agreed that the 2004 report continues to be relevant in its structure and methodology. It should be updated by its authors (WHO) following a dual approach:

1. Check whether the therapeutic areas identified in the 2004 report continue to be appropriate: WHO should be asked to update the 2004 data in chapter 1 to 6 covering therapeutic areas. The issues of diagnostics will be added in those chapters whenever relevant.

2. Chapters 7 on cross-cutting themes and chapter 8 on new approaches to promoting innovation should be updated with a different methodology:

a) Cross-cutting themes: Important areas for development that might affect all therapeutic areas mentioned in 1)

- explore what could be added and integrated as possible items on the priority list such as patient adherence, prevention, organisational issues (health systems), delivery systems, patient group specific issues (children, women, elderly people) product stability, diagnostics and biomarkers, orphan drugs, safety, quality of life.

b) Approaches to promoting innovation:

- assess achievements to date to identify what has been working and what has not;
- identify ways of integrating priorities in the chain of product-development, from research to patient with special focus on the role of patients and payers.
- Identify possible common ground between private and public. What can be done to reduce time to market for important innovation

5. NEXT STEPS

The results of the meeting will be presented by Norway at the next Steering Group on access to medicines in Europe (Budapest 4 May).

The Steering Group will be asked to agree on:

- The proposed methodology for updating the 2004 report;
- If agreed, on creating a working group on the update of chapters 7 & 8 of the report; (WHO + voluntary participation, co-chair from a Member / EFTA State);
- If agreed, COM will explore ways to finance such an update.

Ideally, the updated report should be issued by its 10th anniversary, in 2014.