

## **Pharmaceutical Forum**

### **5th Meeting of the Steering Committee**

**22 May 2007, Brussels**

**Chairpersons:** Georgette Lalis, Director, Directorate-General for Enterprise and Industry and Andrzej Rys, Director, Directorate-General for Health.

**Participants:** See the list of participants in the Annex

#### **1. Introduction**

1. The Commission welcomed the members to the fifth meeting of the Steering Committee. The agenda and minutes were adopted without amendment.

#### **2. German Presidency**

2. Germany provided an update on relevant Presidency activities. It was highlighted the forthcoming conference in Bonn on 11 and 12 June 2007, concerning pharmaceutical innovation in the field of personalised medicines. It was also highlighted the Bremen Declaration of 13 March 2007 on Partnership and Responsibility in tackling HIV/AIDS with its focus on prevention, national responsibilities and the provision of affordable medicines. The German Health Minister will update the Pharmaceutical Forum on both initiatives.

#### **3. Format of the Pharmaceutical Forum**

3. There followed a discussion on the format of the Forum. The following key points were agreed:

- Ø Both the morning and afternoon sessions will be held in plenary;
- Ø Lead speakers, representing each of the forthcoming Presidencies, would introduce the discussions on the three working groups;
- Ø Following the introductions from the lead speakers there will be no fixed speaking order or limits on the number of interventions but Forum members would be encouraged to keep their contributions short;
- Ø Space in the meeting room will be limited but the Commission would investigate the possibility of having a 'salle d'ecoute' available for additional supporting officials;

- Ø The meeting would begin with a short session on innovation with contributions from the German Presidency on the Bonn conference and from DG Enterprise and Industry on the work of the Pricing & Reimbursement Group on innovation.

4. The Commission had proposed focusing discussion in the Forum on a few key questions concerning issues arising out of each of the working groups. A set of draft questions was tabled. The aim was to highlight core issues that had emerged in the three work areas. This approach was welcomed and some amendments suggested.

**Action point:** Comments and proposed amendments on the key questions to be sent to the secretariat by **Monday 28 May 2007**. A revised set of key questions would then be circulated.

## 4. Progress Report

### Information to Patients

5. The Commission provided an update of developments in the Information to Patients Working Group. The subsequent discussion focused on the quality principles and the remaining core outstanding issue of the use of the term 'objective' or 'unbiased'. The Committee explored the possibility of finding a definition that combined both terms using the following PGEU/CPME/EPF proposal as a starting point:

“When presented so as not to favour one product or approach over another, where alternative products or approaches may be valid or useful.”

As well as the Austrian proposal:

*"Information is:*

*Objective when it is based on facts and not influenced by prejudices or personal perceptions;  
Unbiased when it is impartial and presented without inappropriately favouring one product or approach over another, where alternative products or approaches may be valid or useful."*

6. This approach was agreed as a useful way forward but needed refining. There was also further discussion on other issues. Both AIM and ESIP expressed a general reserve on the information to patients section of the Progress Report as it did not, in their view; fully reflect their concerns with the approach taken by the working group.

7. France also raised concerns about the use of the term 'Partnership' to describe the approach to developing the diabetes model and stated that conclusions 8, 9 & 11 were matters of subsidiarity and should not be included. In addition, France also queried the extent to which the Working Group was able to contribute to the preparation of the Commission report on current practices with regard to information provision to patients on medicines.

**Action points:** Secretariat will reflect reserves expressed by AIM, ESIP and France. In addition, AIM & ESIP will submit additional comments setting out their position.

Secretariat will circulate a copy of the paper, adopted by the Working Group at its meeting on 23 June 2006 as a contribution to the Commission report on current practices on information provision.

#### Relative Effectiveness and Pricing & Reimbursement

8. The Commission provided an update on the progress in the Relative Effectiveness Working Group. It was stated that the main area of work has been developing the draft "Report on Data and Methodology in relation to Relative Effectiveness". The aim of the report is to provide an overview of the critical issues concerning data and methodologies used to perform relative effectiveness assessments. The subsequent discussions proposed a few amendments that were agreed. Where agreement was not possible, reserves would be set out in footnotes.

9. The Commission provided an update on progress in the Pricing & Reimbursement Group. There were no amendments proposed to the draft text.

### **5. General information**

10. Portugal informed the committee of Infarmed's plans under the forthcoming Portuguese Presidency, which included a pharmaceutical conference to be held on 19-20 November 2007 in Lisbon. Further details can be found at this link:

[http://www.infarmed.pt/portal/page/portal/INFARMED/EVENTOS/PRESIDENCIA\\_2007/PHARMINNO](http://www.infarmed.pt/portal/page/portal/INFARMED/EVENTOS/PRESIDENCIA_2007/PHARMINNO)  
[V](#)

### **6. Next Steps**

11. The date of the next meeting of the Steering Committee will be notified following the Pharmaceutical Forum.