

## **Pharmaceutical Forum**

### **2<sup>nd</sup> Meeting of the Steering Committee**

**30 March 2006, Brussels**

#### ***Draft note of the Meeting***

**Chairpersons:** Georgette Lalis, Director, Directorate-General for Enterprise and Industry and Bernard Merkel, Head of Unit, Directorate-General for Health and Consumer Affairs.

### **1. Introduction**

1. The chairperson welcomed the members to the second meeting of the Steering Committee. She explained that the new SANCO Director, Mr Rys, will become the new co-chair as soon as he takes up his post in June.

2. The minutes of the first meeting of 6 December 2005 were adopted, subject to an amendment noting that the draft mandate of the Pharmaceutical Forum was included in the original invitation letter to participants of 19 October 2005. The revised minutes will be added to the CIRCA site.

### **2. Updates of the Working Groups**

3. All three Working Groups have been kicked off and they have met since the first Steering Committee. The chairmen of the Working Groups were asked to present the progress made in the groups.

### **3. Relative Effectiveness Working Group**

4. The Italian representative gave a presentation on the progress made in the working group. The main aim is to increase mutual understanding on the key issues related to relative effectiveness assessments.

5. In order to develop a basis for discussion, and to take stock on the current state of play of relative effectiveness in the Member States, the working group had developed a questionnaire on the key issues. It covers a wide range of issues such as definition and

methodologies of relative effectiveness assessments and organizational aspects of carrying out assessments. In addition, it aims to collect data on different information sources.

6. Following the Italian representative's presentation, a discussion took place. The issue of what is meant by relative effectiveness was raised as a key to ensuring understanding of the problems. It was also clarified that the focus of the relative effectiveness working group is on post-market evaluation. He also stressed that it is important the working group concentrates on setting out the overall picture on the main issues in order to be able to identify good practices and possible ways to develop this area.

**Conclusions:** All Member States have been asked to respond to the questionnaire. The analysis of the replies will set out the general picture on how relative effectiveness assessments are carried out. It will also form the basis for further work.

The Steering Committee agreed on the approach taken by the working group. It will provide a further update of progress and proposals for deliverables for the Forum to the next Steering Committee.

#### **4. Information to Patients Working Group**

7. The chair of the Working Group gave an update on progress. The group met on 27 January 2006 and on 21 March to discuss the work programme. The broad objectives of the group are to consider how to improve medicine, disease-related and other treatment options information to patients and to propose ways to improve accessibility to information. In order to take work forward, the working group had agreed on establishing smaller drafting groups.

8. In practice the work is divided into three pillars. The chairman described the activities to be undertaken under pillar I on non-statutory information. The pillar, led by the UK with support from Italy, would focus on developing a model disease information package using *diabetes and coronary heart disease* as examples. The time schedule for this work is 6 months and thus, should deliver a proposal for the Forum.

9. The chairman set out the activities of pillars II and III. Pillar II, led by the EMEA, is on statutory information and will focus on developing existing proposals from the EMEA/CHMP Working Group with Patient Organisations on harmonised action at the EU-level to improve information on medicines. .

10. Pillar III, led jointly by Austria and the PGEU, will focus on access to information in specific health care settings such as pharmacies and hospitals. The time schedule for this work is 12 months and thus, the deliverable for the Forum is likely to be principles for action.

11. Following the updates members of the Committee made a number of comments with regard to the patients' needs on information, sources of information and the roles of health professionals in providing information.

12. The next meeting of the full working group is planned for 23 June 2006.

**Conclusions:** The chairmen of the subgroups will define how to best take work forward under the action pillars in order to develop proposals for the Forum.

The report of the Pillar II sub-group could provide the basis for the Working Group's contribution to the preparations of the report to the Council and the Parliament on information provision.

## 5. Pricing

13. The chairperson of the working group on pricing, explained progress made in the working group. Two meetings took place (10/2 and 24/3). The first meeting of the working group had focused on the overall objective, i.e. finding common ground between (1) control of budget for Member States, (2) reward of innovation for industry and (3) access to medicines for patients.

14. After the first meeting a list of potential key issues and topics to be addressed by the Working Group had been identified by the members of the group. For the second meeting, the Secretariat had prepared a map of key issues. These key issues are now grouped under four main work streams to focus progress:

- 1) Budget Control
- 2) Access to Medicines
- 3) Market and Trade
- 4) Transparency of Data

15. Independent academic experts will be preparing overviews on the first 3 workstreams, as basis for discussion in further meetings. The 4<sup>th</sup> workstream will be addressed in a separate setting (to be defined).

16. The Steering Committee agreed on the need for reliable and verifiable data. As this requires an extensive and technical process, this workstream should indeed be addressed in a separate setting, while the Working Group progresses on the other workstreams in parallel. The next meeting is planned on 19-20/6.

17. The Steering emphasized the need for a good coordination between the work of this Working Group and of the Working Group on Relative Effectiveness. It was encouraged that chairmen of both Working Groups meet regularly and that progress of both Working Groups will be discussed in parallel in this meetings of the Steering Committee.

18. Several participants of the Steering Committee emphasized the need to ensure that the Working Group will concentrate on ways to foster European R&D and to implement the outstanding recommendations of the G-10 report (Recommendation 3 and 6). A number of concrete helpful ideas were given and it was agreed to keep these elements on the agenda. It was also mentioned that although deliverables are expected to be mainly limited to raising awareness on the key issues, it would not be feasible to have those for the first Forum in September 2006.

**Conclusions:** The Steering Committee agreed on the approach taken by the Working Group.

A further update of progress and proposals for deliverables for the Forum will be communicated in the next meeting of the Steering Committee.

## **6. Pharmaceutical Forum**

19. The Forum will be on the morning on 29 September 2006 in Brussels chaired jointly by Vice President Verheugen and Commissioner Kyprianou. The programme of the Forum will be built on the discussions based on the progress reports and recommendations from the working groups.

20. During the first meeting of the Steering Committee consideration was given to including a special political topic in the Forum's agenda. This issue was discussed again and a number of subjects were considered. There was broad agreement that any special topic should have a broad theme encompassing competitiveness, research and patients. The scope for including a special topic will need to be considered further given the tight time constraints and the need to discuss progress in the working groups.

## **7. Next steps**

a.) The next meeting of the Steering Committee will be in summer [3 July] to agree the progress report and the deliverables to the Forum.

b) Finland and Germany would be asked to provide an update to the next meeting on priorities for their Presidencies.

c.) The Secretariat will circulate the draft note of the meeting and inform on the date of the next meeting.

SANCO C5 & ENTR F5

## **Annex**

### **1. List of participants**

#### Member States

Austria

United Kingdom

Portugal

France

Finland

Slovenia

Germany

Representatives European Parliament

and

EFPIA

ESIP

GIRP

PGEU

AESGP

CPME

EPF

EGA

EuropaBio

AIM

Georgette LALIS, DG Enterprise & Industry

Christian SIEBERT, DG Enterprise & Industry

Bernard MERKEL, DG SANCO

And other Commission officials