

Pharmaceutical Forum

6th Meeting of the Working Group on Information to Patients on Pharmaceuticals

15 October 2007, Brussels

Note of the meeting

Co-chairs: Mr Siebert, Head of Unit, Directorate-General for Enterprise and Industry; Mr Merkel, Head of Unit, Directorate-General for Health and Consumer Protection

Participants: See the list of participants in the annex

I. Welcome and introduction

1. The Chairmen welcomed the members to the 6th meeting of the information to patients working group.

2. The Commission set out the objectives of the meeting highlighting that this will be the last year of the Forum and therefore an important opportunity to develop projects. The Commission also thanked the members for their contribution to the success of the second Pharmaceutical Forum. The Forum adopted the Progress Report which will provide a mandate for the final working year. Moreover, the Conclusions of the Forum which have been adopted by the Steering Committee on 20 September provide a basis for future activities.

3. The Commission informed about a change in the timing of the agenda and an additional point to be added for a presentation by the Portuguese Presidency on their Conference on Pharmaceuticals Innovation. The revised agenda and the minutes of the last meeting were adopted.

Update on the Summary report of the public consultation on the pilot diabetes fact sheet and the quality principles

4. The Secretariat gave an update on the outcome of the public consultation on the quality principles and the diabetes model information package. The consultation had ended on 4 May 2007 and more than 70 contributions were received. Members had received in advance a copy of the draft summary report of the consultation which will be published on the Pharmaceutical Forum website in the near future. The key messages of contributions to the consultation can be found in the in the summary report.

Update on “Report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83/EC, as amended by Directive 2004/27/EC on the Community code relating to medicinal products for human use”

5. The Commission gave an update on the latest developments in relation to the public consultation on the Commission's report on current practice with regard to provision of information to patients on medicinal products in accordance with Article 88a of Directive 2001/83/EC. The public consultation had been successful; more than 70 responses were received until 30 June 2007.

6. Based on the outcome of the public consultation, the Commission is now preparing the final version of the report which will be sent to the European Parliament and the Council for consideration. Finally, The Commission told that an impact assessment is being carried out concerning future proposals stemming from Article 88a of Directive 2001/83/EC.

II. Work Plan 2007-2008

7. The secretariat presented the draft work plan 2007-2008 which contains sections for the three working groups (pricing & reimbursement, relative effectiveness and information to patients) in terms of work objectives and proposed deliverables. The work plan is based on the second Progress Report which has been adopted by the Pharmaceutical Forum as well as the Conclusions of the Forum which were adopted by the Steering Committee on 20 September. *(The presentation is attached to the draft note of the meeting.)*

8. The section on information to patients contains draft proposals for the following four work areas; 1.) Access and dissemination 2.) Quality; 3.) Practical implementation of the partnership for information package at the national level and; 4.) Looking at the future.

9. The Commission reminded that an implementation within the existing legal framework will need to be agreed and that all the members of the working group had an important role to play to provide a comprehensive package of concrete work as well recommendations for the final Pharmaceutical Forum in 2008.

10. Finally, it was agreed that some feed back between the working group on relative effectiveness and on information to patients will need to be ensured to benefit from each others efforts.

Access to and Dissemination of Information

11. The Commission presented the objectives for 2007-2008 being to develop a toolbox of health information existing in healthcare settings (hospitals, pharmacies and general practitioners). In parallel, a strategic paper would be prepared to address the issue of overcoming barriers to information in healthcare settings. In addition, the stakeholders would be invited to make a proposal to the working group for the creation of a platform if appropriate.

12. The working group agreed that the work will cover;

- Looking at the kind of support for information existing in pharmacies, hospitals and general practitioners.
- Identifying best practices
- Identifying existing barriers and proposing practical ways to improve access to and dissemination of information

13. A number of members expressed their interest in taking forward this work:
- Ø Leaders:
 - PGEU as a leader for access and dissemination in pharmacies
 - CPME as a leader for access and dissemination in general practitioners
 - HOPE as a leader for access and dissemination in hospitals
 - Ø Other members agreed to be involved:
 - Portugal, Greece, Finland
 - EPF, EATG, EFPIA

Quality

14. The Commission explained that the objective of this work area is to promote good quality information through two work streams; 1.) By developing a methodology to use the quality principles and; 2.) By initiating a proposal for a study to explore the possibility for setting up, testing and evaluating a European level mechanism to validate information to patients on diseases and treatment options.

15. In the work plan, the Commission proposes to link this latter to the impact assessment being conducted within the framework of the Article 88a of Directive 2001/83/EC. It was agreed that the working group will be informed on the development of the impact assessment procedure and further discussions could be organised once the results of the study will be available.

16. The working group recognised the importance of making the core quality principles operational at the national level. Austria has been particularly active in this area. Representative of Austria informed that they have already launched an exercise to test the quality principles in view of developing a methodology. Therefore, it was agreed that a methodology of use will be prepared based of the work carried out by Austria.

17. The members who expressed their interest in taking forward the methodology of use for the quality principles were:

- Ø Leader:
 - Austria, who will develop a methodology of use based on their national exercise
- Ø Other members agreed to be involved:
 - UK, Ireland, EPF, EFPIA, PGEU

Practical implementation of the partnership for information package at the national level

18. The Commission presented the third work area which aims to take forward at the national level the concept of building up partnerships for the development of information. The Commission reminded that this objective was a result of the conclusions by the Pharmaceutical Forum and the previous G10 process. Moreover, The Commission explained that the idea was to propose to Member States the creation, in temporary basis, of pilots/experimentations of partnerships for the development of fact sheet on the disease(s) of their choice with national partners. The collection of fact sheets which could constitute a

potential 'library on diseases and treatment options' with links to national databases. For Member States which already have 'partnership' structures generating information to patients it was suggested that they would be invited to develop proposals to develop further existing systems.

Presentations of national organisations developing information where other partners including industry are involved

19. Member States had been invited to present existing national experiences of partnerships. Austria, Sweden and the UK had agreed to give a presentation.

- **UK Project: Medicine Information Project**

UK representative presented the Medicine Information Project as a public private partnership which aims at delivering electronic information to patients on diseases and treatment options. The project is well recognised in the UK and highly trusted. Representatives of health professionals and industry are involved in the project. Fact sheets are indeed developed by health writers. *(The presentation is attached to the draft note of the meeting)*

- **Austria Project: Medicine and Reason**

Austrian representative presented a project called "Medicine and Reason" which is a public private partnership providing information to general practitioners on diseases and treatment options. Leaflets for patients are developed as well. *(The presentation is attached to the draft note of the meeting)*

- **Swedish Project: FASS.se**

Unfortunately the Swedish representative could not attend the meeting but it was agreed that his presentation could be planned for the next meeting

20. The working group welcomed the presentations of existing partnerships and agreed that the members should look at existing national partnerships to identify, at the European level, what lessons could be learnt and what information could be shared. France has expressed the same reserves as previously on the partnership with industry option. In order to illustrate other ways than partnership with industry, France has proposed to present her fact sheets on diseases and on treatment options and the methodology used to produce these information

21. Following this, the practical testing or implementation of partnerships at the national level would be looked at. Some members reminded the importance of developing a methodology for public private partnerships on information and identifying what are the key elements for information. Options for making available information at the European level towards a library could be investigated in a later stage but in general the idea of a "pool of information" was welcomed.

22. The working group agreed to start working on:

- The practicalities for sharing the existing information in a pool of information
- Gathering information on the existing partnerships (structures, functions, memberships) which would pave the way towards the creation of a methodology for public private partnerships on information

- Identifying what should be the key elements for information

23. The members who expressed interest in taking work forward:
UK (to confirm), Austria, Finland
EPF

Conclusions

Looking at the future

24. The Commission presented this final work area which should bring together all work done by the working group in order to identify key elements for a strategy on information to patients and to consider a need for a virtual network.
25. AIM representative presented briefly their concept of Quality label/Trustmark and the working group agreed that such approach could be considered in the future work.
26. Furthermore, the EPF with some other members the Forum (CPME, PGEU) as well as other stakeholders including consumers groups had developed a joint statement on information to patients which had already been shared to the members of the working group. Representative of EPF presented the “Joint Statement on Information to Patients: The Way Forward to an EU Health Information Strategy “. The working group welcomed this constructive input and agreed it will be a useful basis for considering how to develop this work area in the next meeting.
27. The Commission welcomed the involvement of a number of members of the working group to contribute to the implementation of the work plan. The Commission reminded the importance of taking forward at the national level the developments of the working group. All members were invited to share their interest to take part in one or more work areas in the following days. The Commission explained that leaders and the members involved in the work would be invited to develop working documents which would be presented at the next meeting.

III. Any other business and next meeting

28. Portuguese Presidency Conference on Innovation
The Portuguese representative invited members to the Portuguese Presidency Conference on Pharmaceutical Innovation planned for 19-20 November in Viesnu, Portugal.

Next meeting

The date and place of the next meeting will be decided after the work has been kicked off.

