PHARMACEUTICAL FORUM

7TH MEETING OF THE WORKING GROUP ON INFORMATION TO PATIENTS ON PHARMACEUTICALS

1 FEBRUARY 2008, BRUSSELS

Note of the meeting

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

Participants: See the list of participants in the annex

I. Welcome and introduction

1. Mr Siebert welcomed the members to the 7th meeting of the information to patients working group and informed that Mr Merkel, Head of Unit Health Strategy in the Directorate-General for Health and Consumer Affairs would not be able to attend the meeting as previously announced in the invitation, and will be replaced by Mrs Takki. Mr Siebert welcomed Antonie Egeland as a new member of the secretariat of the Pharmaceutical Forum. A new representative of PGEU was introduced.

Adoption of the minutes of previous meeting

2. The minutes of the previous meeting were adopted with modifications received from CPME and France. *(The adopted version were sent to the members on 4th February and posted on the CIRCA website)*

Adoption of the agenda

3. The Commission informed of a change to the agenda with an additional point added for an update on the Communication from the Commission to the European Parliament and the Council concerning the Report on current practices with regard to the provision of information to patients on medicinal products, in accordance with Article 88a of Directive 2001/83/EC. The new version was tabled at the meeting and adopted by the Working Group.

Update and follow-up on the Communication from the Commission to the European Parliament and the Council concerning the Report on current practices with regard to the provision of information to patients on medicinal products, in accordance with Article 88a of Directive 2001/83/EC

4. DG ENTR, informed the members that as indicated in the Communication concerning the Report on current practices with regard to the provision of information to patients on medicinal products recently published, the Commission is working on a legal proposal on information to patients. The aim of the proposal is to ensure good-quality, objective, reliable and non promotional information on prescription-only medicinal products to citizens and to harmonize the existing situation in Member States in this area. Members were informed that DG ENTR is preparing an assessment of the possible impacts of the forthcoming legal proposal, and in this context are sending questionnaires to relevant

stakeholders, including those represented in the Forum, to consider the different policy options. In addition, DG ENTR informed that a public consultation is to be launched soon on the key elements of the forthcoming draft proposal (*the public consultation has been launched in the meantime, on 5 February 2008, and the consultation documents are available at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm*). The results from the Impact assessment and the public consultation will contribute to the drafting of the legal proposal. Finally, the legal proposal on information to patients will be presented as a part of the Pharmaceutical package in October 2008. This Pharmaceutical package will include the Communication on the future of the single market in pharmaceuticals for human use, and legal proposals on information to patients, on pharmacovigilance and on counterfeit medicines. With regard to the legal proposal on information to patients the commission informed that the quality principles endorsed by the Forum are being considered and that details on the content of the principles will be included in the consultation document. Considering the Pharmaceutical package, the Commission clarified that separate consultations are and have been conducted for each legal proposal.

Information about the mandates for three of the work areas of the work plan

5. The Commission reminded the members that following the last meeting on 15 October 2007 mandates were prepared by the secretariat and the leaders of the work areas 1, 2 and 3 and submitted to the members for comments in December 2007. The mandates for the work areas 1 - *access to and dissemination of information in healthcare settings*, 2 - *Quality*, and 3- *Practical implementation of partnership for an information package at the national level* were adopted.

II. Work Plan 2007-2008

6. The Commission welcomed the active involvement of the leaders and other members of the working group in the development of the projects. It was recognised that the draft papers produced should lead to concrete outcomes as requested by the Forum in June 2007. The group was reminded that three meetings are planned for 2008, during which members should agree and endorse when possible the concrete projects developed, but also build up strategic recommendations to be submitted to the Forum as a "conclusion package" of the 3 years process.

Work Area 1: Access and Dissemination

7. The Commission introduced the first work area jointly led by CPME, HOPE and PGEU. She welcomed the two documents developed since the last working group meeting, the draft *overview of good and innovative practices in healthcare settings* and the draft *outline of a strategic paper mapping existing barriers and setting out preliminary proposals for practical ways to move forward* by members involved in this work area.

8. Representatives, from PGEU, presented on behalf of the three leaders of this work area the projects that have been carried out. The draft overview of good and innovative practices in healthcare settings is to be considered a "working document" for which additional inputs would be useful. Based on the examples collected, some recommendations could be developed to be included in the strategic paper. The draft outline of a strategic paper on barriers was presented. It contains mentioning of barriers and some recommendations for each healthcare setting. Next steps including development of general recommendations and general principles were proposed to the members.

9. Members agreed to provide other examples of good and innovative practices in the three healthcare settings, and in addition also information regarding national health information strategies. Considering the strategic paper, members welcomed the suggested approach and called for the document to be more consistent, focussing on what are the common barriers in the three healthcare settings and what overall solutions could be

proposed. Germany asked how to secure that information provided in the different settings would be the same; the idea of a general database was raised and proposed to be included in the strategic paper. Discussion on the inclusion in the strategic paper of considerations about non prescription medicines, the role of nurses in providing information, and access to information in non-healthcare settings where medicines are also available (a food store for instance) took place. The Commission advised to include some wording on future challenges in the document when they can not be included within the current scope of this work area. Finally, it was agreed that strategic recommendations should be resulting from this exercise. Members involved in this work area were invited to consolidate both documents for the next working group meeting. Member States contributions would be welcomed in the next 10 working days.

Work Area 2: Quality

10. The Commission introduced this work area by welcoming Austrian efforts in developing an in-depth study, *Qualitätskriterien für Gesundheitsportale*, Quality Criteria for Health Portal, which provides information on how to use of the Quality Principles endorsed by the Pharmaceutical Forum. The Commission informed that the Austrian pilot had been developed in German and considering the time necessary for its translation, no document in English have been communicated to the members of the Working Group.

11. The Austrian representative who is the leader of this work area, made a presentation of the study. The study provides a general overview of existing quality principles for health portals. A method for the use of the quality principles is proposed. The quality principles are not exactly the same as the ones endorsed by the Pharmaceutical Forum, but certain compatibility has been taken into account. Austrian representative suggested a timetable for the next steps to develop a draft methodology for the use of the quality principles based on the study. *(The presentation is posted on the CIRCA website)*

12. Finally, it was agreed that the essential part of the study will be translated into English. The leader of the work area will start developing a first draft of the methodology of the quality principles study.

Work Area 4: Looking at the Future

13. DG SANCO, presented the different initiatives in the directorate for Public Health on health information. These included the Health Portal, accessible in all EU languages, health promotion campaigns and a European health information and knowledge system. New projects in the field of health literacy and a "*my health space"* initiative were also mentioned. *(The presentation is posted on the CIRCA website)*

14. EFPIA welcomed the attention given by the Commission to health literacy and recommended to ensure the reference to the correct definition of health literacy. Ireland suggested having a single space where all the information on the work of the Forum but also other initiatives related to information to patients would be gathered. The Commission explained that this idea was part of the concept of a *Virtual Library* proposed by the secretariat, making sure that citizens are easily aware of existing initiatives and their outcomes.

15. The Commission reminded that in the 2007-2008 Pharmaceutical Forum work plan, the Commission have proposed:

1) To identify the key elements for an overall strategy on information to patient on diseases and treatment options
2) To reflect on the possibility of a virtual network on Information to Patient to exchange on the views/practices on the implementations of the outputs of the

Forum, including the quality principles, experience of national partnerships, sharing further information to feed the European library.

Considering the possibility of the creation of a network on Information to Patient to continue the work of the information to patient WG in the future, The Commission made it clear that any future activity should be complementary and not duplicate work already ongoing or planed in this field).

16. The Commission invited members for a brainstorming exercise on the two projects proposed in the 4th work area. In addition, he invited members to express their interest in co-leading the development of the key elements for an overall strategy on information to patient together with the Commission.

17. The EMEA representative informed that an EU regulatory network on medicines is planned to be created in 2008 as part of the EMEA work program for 2008, the Heads of Medicine Agency Strategy and EMEA Road Map EMEA therefore expressed an interest in being involved in the coordination between the different networks. Furthermore, it was agreed that EPF would co-lead with the Commission the work area 4; EMEA, Sweden, PGEU, CPME confirmed after the meeting the will would be involved in the activities in this work area whilst Finland and Ireland would provide Member State input when needed.

18. It was agreed that the key elements for an overall strategy on information to patient should cover the key aspects of information on diseases and treatment options. The Commission suggested that the document should focus on the work carried out under the activities of the working group and would in addition have a broader approach on what is feasible.

18. For the next working group meeting, a "bullet point" paper listing on what could be the key elements for an overall strategy on information to patients will be presented. Members involved in the 3 other work areas were invited to provide some strategic elements related to their mandate as a contribution for the development of this document. The outcomes of this exercise together with the projects carried out in the other work three areas might be used as a basis for the drafting of the final recommendations of the High Level Pharmaceutical Forum.

Work Area 3: Practical implementation of partnership for an information package at the national level

20. The Commission informed that the objective for this work area is to work on the question of partnership/collaborative approaches and what elements constitute core information. The Commission welcomed the active work of the leader of this work area, Sweden, with the involvement of other members who participated in the development of drafts as proposed in the work plan. The Commission reminded that all the drafts presented had also been subjected to a consultation among the members involved in the work area 3.

1. Examples of partnerships delivering quality information where other partners including industry are involved

21. The Commission informed that Member States had been invited to present their experiences with existing partnerships or collaborative approaches in the field of information to patient. Austria, with the Medicine and Reason Project, and the UK, with the Medicines Information Project, presented their initiatives during the working group meeting on 15 October 2007. The Commission announced that Germany, France and Sweden volunteered to present their own experiences either of partnerships or on methodologies to generate information to patients.

a. Germany: informed health online/ gesundheits- information

22. The Head of Health Information Department IQWIG, and Editor in Chief of the initiative informed health online/ gesundheits- information, presented the new German

initiative *gesundheits- information* from IQWIG, the German institute for quality and efficiency in healthcare. IQWIG is an independent body established by law, and which runs on state funding. This website will be a comprehensive "up-to-date" online encyclopedia of evidence-based health information in German and English. A systematic method had been put in place to develop the information ensuring quality assurance. While the information is developed within IQWIG, stakeholders - IQWIG bodies, Ministry and Board of Trustees - are invited to contribute in the consultation phase. The IQWIG board of trustees includes representatives of healthcare professionals, patient organizations, community stakeholders and pharmaceutical industry. The project participates in international collaborations, such as adaptation and translation with the French Haute Autorité de Santé and links on NHS Direct as a Knowledge partner. *(The presentation is posted on the CIRCA website)*

b. Sweden: FASS and other partnerships

23. The Swedish representative presented different examples of partnerships generating medical information to patients in Sweden. The online version of Swedish Health Care Direct is a public private partnership between county councils and the national cooperation of pharmacies providing advice on health issues such as symptoms, diseases, drugs etc. A phone call service exists (3.5 millions calls received per year). Other partnerships between the national authority and other partners include initiatives such as the Drug Guide and the Swedish Council on Technology Assessment in Healthcare. *(The presentation is posted on the CIRCA website)*

24. The representative from the Swedish cooperation of pharmaceutical companies in Sweden to present FASS.se. This website is a result of a public private partnership between the Swedish association of the pharmaceutical industry, the Swedish association of local authorities and regions, the Medicinal Products Agency, the pharmaceutical benefits board and the national corporation of pharmacies, the department of pharmaceutical biosciences from Uppsala University, the national poisons information centre, the Swedish environmental research institute and the Stockholm county. FASS.se was presented as the primary source of medicine information for patients, providing for instance product information generated from the companies itself, but also information on research and development, virtual health centre, and a new project called "my fass" which is a personalised webpage for patients under the general FASS website. *(The presentation is attached to the draft note of the meeting)*

c. France

25. The French representative presented different providers of information to patient in France and their respective methodologies of developing information. Specific information on the activities of the Haute Autorité de Santé, AFSSAPS, Ministry of Health, CNAMTS (National health insurance for working people) and INPES (National institute for prevention and health education) was provided. Availability of information on medicinal products, diseases and healthcare and therapeutic strategy are available from the website www.sante.fr. *(The presentation is posted on the CIRCA website)*

d. Overview of existing partnerships/collaborative approaches

26. Further to the presentations of different national experiences of partnerships/collaborations, the members of the Working Group recognised that a multitude of approaches to develop and deliver information exist. The possibilities for deepening the analysis of the various options for partnerships/collaborations by having an overview of what exists and further investigate with case-studies was welcomed by the members. EFPIA reminded that the concept of public private partnership should be considered in line with the recommendations of the G10 process.

27. As an initial step, The Commission introduced the draft table of an overview on the key elements of the structures of partnerships/collaborations. The table has been developed by the secretariat and was tabled at the meeting. It was explained that the objective of this document was not to compare which of the option were the best but rather to show different solutions. Members welcomed the draft table which contained information about seven

partnerships/collaborations. Finland advised to make this overview available to the public, and suggested to use the Commission Health Portal for this purpose. EPF recommended further investigations on the similarities and differences of the initiatives listed in the table. Germany suggested including the legal basis of the initiatives in the table. Members were invited to contribute to the table by informing the secretariat within 10 working days about similar initiatives of a national dimension and giving comments to the categories in the table.

2. <u>Methodology for Public Private Partnerships</u>

28. The Swedish representative presented the draft document "Ethical guidance for public private partnership" as a key element for any methodology for Public Private Partnerships. The document was developed taking into consideration what ethical principles partnerships/collaborations should respect. Members welcomed the document. IDF representative suggested including reference to penalties when partners do not respect written agreements. Members agreed that the document should be fine-tuned and would cover the questions of penalties or how to insure that ethical requirements area applied. Members were invited to come back with comments within 10 working days. *(The presentation is posted on the CIRCA website)*

3. <u>Draft of the key elements of information to patients on diseases and treatment options</u>

29. EPF representative introduced the draft of "Key elements of an information package". This proposed list was to be considered as a "wish list" where all the key elements for comprehensive information package for patients were listed. These shall provide a basis to assessing or benchmark existing material when developing new information to patient or improving and completing existing materials. *(The presentation is posted on the CIRCA website)*

30. EPF informed that the introduction of the document will be redrafted to target both the public and specialised groups such as information providers to help them better understand how to make the best use of this tool. EuropaBio suggested developing further the point on risk vs. benefit and the question of compliance. EuropaBio also questioned how pharmaceuticals should be named. After the discussions on whether it should be advised to refer in the document to the treatments with brand names of pharmaceuticals or INN / generic names, taking into account the differences in the national substitutions policies, EPF and the members involved in this work area were asked to come back to the next working group meeting with a proposal. Members were invited to submit comments within 10 working days.

III. A.O.B. and date of the next meeting

31. The Commission called for members involved in the work areas to further develop the documents and initiatives either to be presented or adopted during the next working group meeting. The chairman announced that the next working group meeting will take place on 14 March 2008. He advised that during the nest six weeks members are invited to make rapid progress in order to meet the objections set out in the work plan. Under the work areas 1, 2 and 3 documents will be proposed for adoption, while documents under work area 4 will be presented in the meeting.

32. EPF made an announcement to the members about their 2008 Annual Conference, 8-9 April, on Health Literacy. An invitation will be sent to the members of the Working Group by the secretariat on behalf of EPF.