Pharmaceutical Forum

4th Meeting of the Working Group on Information to Patients on Pharmaceuticals

7 December 2006, Brussels

Draft note of the meeting

Co-chairs: Mr Siebert, Head of Unit, Directorate-General for Enterprise and Industry; Mr Fahy, Deputy Head of Unit, Directorate-General for Health and Consumer Affairs and

Participants: See the list of participants in the Annex

1. Welcome and introduction

1. Mr Siebert introduced Mr Fahy, who had replaced Mr Merkel, as the new co-chair for the working group

2. The agenda and the minutes of the last meeting were also adopted.

2. Report on the Pharmaceutical Forum

3. The Commission provided an update on the High Level Pharmaceutical Forum which had its first meeting on 29 September 2006 which adopted the Progress Report, including the section on information to patients, unamended.

3. Questionnaire – Information to Patients in Member States

Commission Questionnaire

4. The Commission provided an update on the responses to the questionnaire on health-related information that had been circulated earlier in the year. The aim of the questionnaire was to provide background information for the group's work and for the preparation of the separate Commission report on the Provision of Information on Medicines as foreseen in art 88a of Directive 2001/83/EC. The Secretariat had received responses from 12 Member States and, in addition, from GIRP and EFPIA.

The Commission asked remaining members to submit their responses as soon as possible to allow the final report to be prepared for the next meeting of the group.

EPF Questionnaire

5. EPF representative gave a presentation (available on CIRCA) on a survey they had undertaken on information to patients. The final outcomes of the survey will be circulated to members ahead of the next meeting.

4. Progress Reports

6. Mr Siebert introduced the progress reports by highlighting the need to focus on the content of the consultation.

Pillar I – Diabetes factsheet

7. UK, Chair of the Pillar I drafting group, updated the working group on the diabetes fact sheet (circulated in advance) and sought the comments of the group. In the subsequent discussion a number of points were made including the importance of:

- Ø taking account of the diverse needs and experience of patients;
- Ø ensuring the information is evidence-based;
- Ø ensuring that the information is presented in a patient-friendly way;
- Ø focusing on key treatments rather than trying to reflect all the different national approaches to tackling diabetes; and
- Ø placing greater emphasis on life style issues.

Action Point: comments were requested by 13 December with a particular focus on:

- Ø additional references;
- Ø proposals for questions that could be included in the consultation; and
- Ø links for diabetes websites which meet the Quality Criteria for Health-related websites set out in the Commission Communication circulated on 8 December.

Pillar I – Quality Principles

8. UK representative also introduced the debate on the Quality Principles. The drafting group had been unable to agree on a set of quality principles. The main area of difference had been on the use of the terms "objective" and "unbiased" where the group had been unable to reach agreement on a definition of these terms. In the light of this, UK representative had prepared a compromise version (re-circulated on 1 December). The ensuing debate primarily focused on this issue.

9. The meeting was unable to agree on a version for consultation. It was then agreed that the quality principles would be circulated with all areas of disagreement identified.

Action Point: the Commission to circulate a version of the quality principles which highlights the areas of disagreement. Any comments and suggestions on terminology should be submitted to the Secretariat by 13 December.

Pillar II – EudraPharm Database

10. EMEA representative provided an update on the launch of the EudraPharm Database (launched on 6 December - www.eudrapharm.eu). Currently the database contains information, in English, on centrally authorised medicines. This is the first phase for the database which will be progressively upgraded. Later phases will add the other official languages together with improved search functions. Eventually it is hoped to add information on all authorised medicines in the EU.

Pillar II – Commission Report under Article 88a of Directive 2001/83/EC

11. The Commission provided an update on the Commission Report prepared under Article 88a of Directive 2001/83/EC. It was explained that he could not go into detail as the draft report was being finalised, however, he said that he expected the consultation to be launched in the first half of 2007. The Working Group will be informed when it is known when the consultation will begin.

12. UK representative expressed concern that the Working Group had not had more of an opportunity to contribute to the development of the report. The Commission pointed out that the Working Group had adopted the paper on Statutory Information on Medicines prepared by the EMEA/CHMP Working Group with Patients and Consumers' Organisations at its last meeting in June. This paper was taken into account in the preparation of the report and there will be an opportunity to discuss it at the next meeting. It would also be possible for all members to contribute directly through the forthcoming consultation exercise.

Pillar III – Access to Information

13. Austria set out the background to the work of the Pillar III sub-group. It was also referred to the work he had undertaken on dissemination of information by government bodies, via questionnaire, and he would report back to the next meeting. The Pillar III had three broad objectives:

- access to information in healthcare settings (focusing on hospitals and pharmacies);
- access to information without the support of healthcare professionals (primarily through the Internet); and
- dissemination of health information by government bodies.

14. The work on access to information through healthcare settings was taken forward through two workshops. The pharmacist representative (PGEU) introduced the workshop on access to information in pharmacies (report of the workshop held on 7 Nov was circulated before the meeting). The objective had been to bring community pharmacists and patients together to see how best to improve access to information in pharmacies. Underpinning the discussion was a collection of best practices on access to information in pharmacies (circulated). The outcome of the workshop is set out in the report but it was highlighted the following results:

- Patients wanted information on a broad range of health issues from their pharmacist;
- Patients wanted a consistent message from health professionals; and
- Pharmacists welcome information from a wide range of sources, including industry.

15. HOPE representative then summarised the outcome of the hospital workshop which had been held on 6 Nov 2006. The main objectives were to access citizen/patient information needs in hospitals, look at the barriers to meeting those needs and highlight examples of best practice. There was no attempt to define 'hospital' as the focus was on information needs. The report of the workshop (circulated) provides the outcome of the workshop in detail. It was highlighted the following key issues from the debate:

- Need to support health professionals to provide coherent information and advice to patients; and

- Health professionals should be more proactive in providing information but the focus must be on quality/ensuring patient safety than on the quantity of information provided.

16. The Commission, on behalf of Finland, then introduced the paper on review of research on the needs of particular patient groups and on existing information tools (circulated). He explained that this paper was designed to provide a brief summary of the existing research on key population groups and a 'toolbox' of existing resources of tools for patients/citizens to evaluate health information.

17. In the subsequent discussion it was agreed that the group could do more to make the output of the Pillar III work more inter linked with the work of Pillar I. One way to achieve this would be to bring the two together in the contribution for the Pharmaceutical Forum. It was agreed that a consultation could include questions on the issues raised by the workshops and the research paper.

Action point: Comments on the Pillar III documents and suggestions for related questions to be posed in the consultation should be sent to the secretariat by 13 December.

5. Open Consultation on Information to Patients

18. The consultation, which is expected to take at least 8 weeks, would be launched early in 2007 and would be put on-line through the Commission's Europa website. The consultation is planned to make clear that the documents are 'work in progress' and that the principle aim is to inform all interested parties of progress and to seek comments.

6. Planning for 2007

19. The next meeting of the Working Group is planned for 6 March 2007.