Pharmaceutical Forum

5th Meeting of the Working Group on Information to Patients on Pharmaceuticals

10-11 May 2007, Brussels

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

Participants: See the list of participants in the annex

1. Welcome and introduction

1. The Commission welcomed the members to the 5th meeting of the working group. It was explained that the main objective of the meeting was to identify key issues for discussion in the Forum and so the focus of discussion should be on the draft progress report.

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

2. Response to the consultation

3. The Commission tabled a paper providing an initial summary of the outcome of the consultation exercise on the core quality principles and the diabetes model package of information. There had been around 70 responses to the consultation covering a wide range of stakeholders as listed in the annex to the paper (a single copy of all the responses in full was also available by the secretariat).

4. Overall there had been a positive response to the consultation with strong support expressed for establishing a set of agreed European-level quality criteria and more equivocal support for the diabetes information package. Given that both documents were 'work in progress' it was not surprising that there were a number of critical comments on both the detail and the approach taken. This was especially the case for the diabetes package where respondents highlighted, among other issues, essential information that was missing, the need to make it more patient-centred and the importance of establishing a clearer dividing line between what is appropriate and useful to be delivered at a national- and European-level.

5. The subsequent discussion reflected a number of the issues highlighted in the consultation. The main points made in the substantial discussion were:

Diabetes Information Model

- Ø The response to the consultation had demonstrated the significant interest in information to patients;
- Ø The need to concentrate on what information exists already for health professionals and then amend it to make it suitable for patients;
- Ø Focus on establishing European links between information provision authorities across Europe rather than develop new material;
- Ø Develop better ways of involving patients and health professionals into the information development process;
- Ø Must avoid the risk of promoting 'best treatments'. This is only a judgement that can be made at the national level;
- Ø National authorities and/or the EMEA have the key role in authorising information; and
- Ø Introduce a varied approach to authorising information e.g. information already authorised for another purpose needs no further validation.

Core Quality Principles

- Ø Need clearer objectives for the quality principles with more information on methodology and ways to access information;
- Ø 'Patient-centred' should be a core principle;
- Ø It should be made clearer that the principles are designed for information producers not for patients;
- Ø No stakeholder should be excluded from information provision; and
- Ø Consider including comparative information.

6. The Commission concluded that there was agreement on the need for the quality principles. They clearly had to be improved and the outstanding issue of the use of the term 'objective' or 'unbiased' had to be resolved. However, the critical issue would be to decide how the principles should be taken forward.

7. On the diabetes model, the next steps were less clear. There was obviously a need for more substantial work to be done which must recognise what is appropriate for European-level information. It must also take account of existing information and be capable of translation into all the official languages.

Action points: a 'patient-centred principle' would be included in the core quality principles.

The secretariat would prepare a fuller evaluation of the consultation responses which would be circulated to the group for information and published on the Forum's website.

All consultation responses would be added to the Forum website as soon as possible.

3. Report on Current Practice with Regard to Provision of Information to Patients on Medicinal Products (Art 88a)

8. The Commission gave an update to the group on the latest developments with the Commission's report. He explained that a draft report on current information practice in the EU had been released for consultation which was due to end on 30 June 2007. The report deliberately contained no proposals for future action but was simply designed to provide a comprehensive overview of the current situation in Europe. The Commission will consider making proposals for future action in the light of the responses received.

9. A Member of the European Parliament followed up the Commission's update by making a presentation. In it he argued that European pharmaceutical legislation should contain an explicit statement of the right for patients to have access to objective information. He stated that there should be no relaxation of the ban on advertising of prescription medicines a platform but there should be a clear definition of information included as a quality principle. Information, put together within a self-regulatory framework, should be provided though a single electronic platform supervised by the EMEA. There would be a code of conduct enforced by an 'Information Examiner' supported by a 'Controlling Committee' who would be able to fine offenders.

10. In the subsequent discussion, some members expressed disappointment that the draft report had not included proposals. The Commission stated that the consultation would need to be concluded before proposals could be made.

Action point: the secretariat to circulate the presentation to the working group.

4. Progress Report

11. The Commission introduced this discussion highlighting the need for the Progress Report to focus on mechanisms and the way forward.

12. In the subsequent debate, the future of the Pillar III work was raised. It was agreed that this work had produced some useful output which should not be neglected. A number of suggestions were made on how to take this forward including, in particular, focusing on barriers to access to information. In addition, there was discussion on ways to link Pillar I and Pillar III work in particular by linking the quality principles that have emerged from the former to the criteria for judging quality that have emerged from the latter.

13. It was also suggested that all the various themes and work strands should be brought together in one overall strategy which could be complementary to the Commission's report on

current practice with regard to the provision of information. This could include consideration where the quality principles could apply within the context of Article 88a, bring in elements from the consultation exercise and circumstances where self-regulation might be appropriate.

14. It was further suggested that more work could be done to identify categories of information that could be subject to a sliding scale of control from information that had already been authorised through to information that could, subject to national approval, be governed by self-regulation.

15. At the end of the discussion the working group agreed that the Progress Report should include the following elements:

- Ø The diabetes model could be taken forward by a small separate expert group, although reflecting the membership of the working group, with a focus on developing the methodology for the model rather than the content;

- Ø A proposal for a platform for taking the work forward of the Pillar III group on access to information in health care settings;

- Ø Setting out the main elements of the quality principles (including patient-centred);

- Ø A possibility for a feasibility study into a validation mechanism taking account of financial implications and subsidiarity; and

- Ø Bringing together all the elements agreed for the Progress Report into an overall information strategy without prejudice to Article 88a of Directive 2001/83/EC.

5. Next steps

16. The secretariat will circulate a revised Progress Report as soon as possible for comments by 16 May. The revised report would then go to the Steering Committee for agreement before circulation to all Pharmaceutical Forum members. If adopted at the Forum's meeting on 26 June, the Progress Report would be published on the Forum website.