Pharmaceutical Forum

1st Meeting of the Working Group on Information to Patients on Pharmaceuticals

27 January 2006, Brussels

Draft note of the Meeting

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

1. Introduction

1. The chairman welcomed the members to the first meeting of the Working Group. He stressed that the objective of the Working Group was to tackle the "information gap" that had developed with the rapid growth of patient expectations and the use of modern technologies such as the Internet. In particular, the group should consider how best to take forward the recommendations of G10 Medicines Group to develop a Public Private Partnership to improve the quality of information available to the public.

2. The chairman concluded by summarizing the proposal for setting up an information tool and the mechanism to generate and validate that information, the proposed public private partnership. The details of the proposal were set out in the secretariat's working paper circulated before the meeting. The aim of the proposal was to find a realistic way forward at a European level that added value to national and regional initiatives and did not duplicate them.

3. The chairman then set out the basis for the six key questions which were circulated prior to the meeting. The questions had been developed to cover the main discussion topics in a structured format.

2. Presentations

4. To set the context for the debate the Commission called on some of the participants to set out their positions in brief presentations.

Finland

5. The Finnish representative presented the unpublished results of a study, undertaken by the Finnish National Agency for Medicines, on medicinal information provided to the general public by national regulatory authorities in the EU. Most Member States took part in the study. The study focused on the use made of Summaries of Product Characteristics (SmPCs),

leaflets and any websites devoted to consumers. The study showed that most national competent authorities had their own websites on which authorized SmPCs and leaflets were published. A few had their own special medicinal information section on the website.

Action point: The Finnish representative to circulate the study via the secretariat once published.

Austria

6. The Austrian representative, from the Department of International Affairs of the Austrian Health Ministry, presented a paper that he had circulated before the meeting. The objective of the paper was to put forward some common questions and principles. In particular, he stated that the focus must be on getting good quality information to patients and the starting point for the exercise should be on making the best use of existing sources of information i.e. national competent authorities, leaflets and pharmacies. He also highlighted the need to consider the information needs of particular patient populations such as in-hospital patients, children and the elderly.

EMEA

7. The EMEA representative provided an update of the development of the European Database on Authorised Medicines and the Agency's work with patient organisations. The Agency's working group with patient and consumers' organisations produced a number of recommendations in March 2005 which could be useful for this group (these were circulated at the meeting and are available on the CIRCA site).

8. The European Database will eventually contain information on all authorised medicines on the market in the EU. The database will be based on regulatory information i.e. the SmPCs, leaflets and labels for each product. It will also include information on treatment on children and on clinical trials. The objective is that it should become a prescribing tool for European doctors and a reference website on medicines for the public. The first stage of the database will become publicly available by the end of 2006.

EFPIA

9. The EFPIA representative emphasised the importance of well informed patients to ensuring high levels of health protection. He stated that industry could be one source of this information which would support, not replace, the health professional/patient dialogue which must remain the core source of information. EFPIA had developed a policy memorandum on the provision of health information (circulated at the meeting) which highlighted the need for multiple sources of information and the development of a comprehensive information strategy.

European Patients' Forum

10. The European Patients Forum representative, emphasised that the core issue for patients was to have unrestricted access to information. Although the Internet was not a perfect tool it was the only independent mechanism that patients had to access information. He expressed concerns at the proposal for a database which he feared may be too large a project to become established and there would also be concerns over its ownership.

3. Discussion

11. The presentations and the six key questions sent in advance of the meeting provoked considerable discussion. Outlined below is a summary of the key issues raised:

Public Private Partnership

12. The Commission deliberately did not define Public Private Partnership in their working paper to allow the working group to develop their own concept for the partnership. However, it was agreed that the use of the term Public Private Partnership could be confusing given the wide variety of such schemes that already exist. The key word was partnership and another title would be found.

Principles

13. The discussion highlighted the fact that "information", other than statutory information such as SmPCs and leaflets is not covered by European legislation. Therefore, the treatment of information varies widely across the EU. A useful exercise could be to develop principles of good communication which could be underpinned by a code of conduct.

Statutory Information

14. There was agreement that the leaflets accompanying the products provided a sound basis for patient information. However, as a number of representatives pointed out, they have limitations. In particular, the information provided is restricted to a specific medicine and not the disease for which it is being used.

Health professionals

15. There was consensus that the health professionals played the central role in providing information to patients. However, the focus of this working group was to consider complementary ways of supporting this relationship.

Scope

16. A critical issue to be resolved will be the scope of the exercise. It is important not to lose the focus of the work on the two core elements around which the work will revolve; information about medicines and patients' needs. ; Whatever was finally agreed must have these elements at its centre. The aim is to develop realistic and practical proposals that will deliver better information to patients.

Existing information resources

17. A lack of a comprehensive list of information sources in Europe was identified. The recently completed Finnish study on information provided by European national competent authorities is an excellent start but more information on other national initiatives would be helpful. The DataPharm website in the UK was highlighted as one example where information was collected from a variety of sources, including industry, and made publicly available after its quality was independently assessed. Once such a list was adopted it could provide a basis for the exchange of best practice.

Educational information

18. Another information gap identified was the availability of good quality educational information for patients to help them understand commonly used clinical and pharmaceutical terms such as risk/benefit ratio, side and adverse effects etc.

Patient representation

19. The European Patients Forum representative argued that there should be greater patient representation on the working group. This was supported by the working group.

4. Conclusions

20. The discussion covered a wide range of issues which were listed at the end of the meeting. The conclusions are based on these topics and grouped in order to form clear areas for consideration and action;

1. Information on treatment options including pharmaceuticals in the context of diseases and conditions

   The scope of the work should focus on information to patients on pharmaceuticals in the context of diseases/conditions.

   The working group agreed that there is a need to find new ways and approaches to develop a set of information on a disease/condition and the possible treatment options to provide patients with a comprehensive decision aid, not just information on separate pharmaceutical products.

2. Best practices on information to patients

   The working group agreed on the value of a quick survey/questionnaire on national best practices (both from competent authorities and NGOs) on information to patients and public private partnerships. This would supplement the results of the review of research already undertaken by the National Agency for Medicines in Finland. The working group could consider whether a further detailed study would also be necessary in this area.

   A needs assessment for improved information (format, ways to assess information, needs of special population groups etc.) was raised as an important element of ensuring that the activities of the working group will provide an additional and useful element for patients.

3. Information on pharmaceuticals provided in pharmacies and hospitals

   The working group raised the issue of how patient information on pharmaceuticals provided in pharmacies as well as in hospitals could be improved. Currently information is generally only provided after medicines have been bought. Moreover, in-patients usually have no access to information at all.

4. Information tools

   The working group agreed that although the main element in information to patients is the relationship between health professionals and patients, there is also a need to look into possibilities provided by new technologies and other information tools. In particular, the

role of the Internet in providing information was raised although, it was agreed that traditional means of information dissemination (e.g. leaflets) still had an important role.

5. Use of existing validated statutory information

The working group stressed the importance of taking into account existing practices, resources and initiatives and using existing and validated information (especially patient information leaflets and summary product characteristics) by making them more useful and accessible for patients. In connection to this, the working group could have a role in setting up principles and/or guidelines on information including standardisation of information where appropriate.

The importance of transparency was stressed, as well as the desirability of having broader consultation on the group's conclusions when they were developed.

22. In order to prepare for the next meeting of the working group, the Secretariat will draft a new working paper which will address how these key issues will be taken forward with an indicative time table.

5. Next steps

22. Following the meeting the Commission requested that all papers submitted by members for consideration by the group should be forwarded through the secretariat.

23. The next meeting will be on 21st March 2006 (not 17th March as planned)