Pharmaceutical Forum

2nd Meeting of the Working Group on Relative Effectiveness

17 May 2006, Brussels

Draft note of the Meeting

Chairpersons: Mr Merkel, Head of Unit, Directorate-General for Health and Consumer Affairs and Professor Silano, Italian Health Ministry.

Participants: See the list of participants in the Annex.

1. WELCOME AND MINUTES OF THE LAST MEETING

Mr Merkel welcomed the members to the second meeting of the Working Group. The proposed agenda was adopted. The first meeting of the Pharmaceutical Forum, on 29 September, is expected to focus on the work of the working group on information to patients. In addition, the work of the other working groups will be addressed in the Forum. The second meeting of the Forum is scheduled for the first half of 2007, to be held during the German Presidency..

A number of amendments to the minutes of the first meeting of the Working Group were accepted: by the members:
The text on the presentations by EMEA and the WHO were changed (the updated minutes of the first meeting will be circulated for information). Under point 3. Workplan, Spain asked for rephrasing of action 3; "…,the working group will in the longer run consider to write a document on how to organize an assessment, what kind of methodology to use and how to increase sharing of information and cooperation between Member States." AIM asked for more emphasis in the minutes on the fact that the work of this group should in the end benefit the patient. Furthermore, in the first meeting the representative of EuropaBio stressed that not only new products and technologies should be assessed on their relative effectiveness, but that effectiveness and efficiency of health care systems as a whole should be improved. This was not yet mentioned in the minutes but was agreed to be added.

The PowerPoint-presentations of all three presentations during this meeting of the working group are available on the CIRCA-site,

2. EXPERIENCES IN THE UK; RELATIVE EFFECTIVENESS ASSESSMENTS AND NICE

The UK representative described the work and functioning of NICE, mentioning the background, the activities of the network, stakeholder involvement and the independence of NICE. He stressed that NICE differs from other organizations in Europe dealing with relative effectiveness assessments. In particular, the assessments made by NICE are not used for any pricing or reimbursement decision as is the case for most organizations in other member

states. The assessments take on average 12 to 14 months (sometimes even longer; e.g. 2 years).

3. VIEWS OF ESIP ON RELATIVE EFFECTIVENESS ASSESSMENTS

The ESIP representative, made a short presentation on relative effectiveness assessment from the payers' perspective. She stressed the need for a common definition for Relative Effectiveness and related concepts. She stressed also that innovation *per se* must not be confused with effectiveness. The lack of data is one of the problems when assessing relative effectiveness and studies paid for by the sponsor do not always answer the questions raised by the Third Party Payers (TPP).
The EFPIA representative emphasized that data often become available only in clinical practice (after it has entered the market and it is reimbursed). The representative of EGA suggested that drugs should be temporarily reimbursed until a good assessment can be made on the basis of data from clinical practice.

The ESIP representative also mentioned the problem of indirect comparison and the selection of comparators. A common methodology should be developed and cooperation between TPP-institutions should be increased. Finally, she proposed the establishment of a European Institute of health to carry out clinical research, provide guidance for reimbursement and stimulate innovation etc.

4. EFPIA'S EXPERIENCE WITH RELATIVE EFFECTIVENESS ASSESSMENTS

The two EFPIA-representatives presented their ideas on how to compare relative effectiveness assessments in the EU. They set out some examples on which areas these comparisons could focus and suggested which countries would be interesting to be compared.

It was agreed that during the next meeting of the working group EFPIA will come with more concrete suggestions on which specific assessments to compare. EFPIA stressed that these assessment should not have a link with the marketing authorization process and that there should not be one assessment per product for the whole EU. EFPIA suggested to consider in the working group how relative effectiveness assessments can stimulate innovation and reflect on developing a new tool to handle uncertainty at the time of the launch of a product.

Remarks were made that for a balanced view also the submitted dossiers should be compared, as these vary between countries.

5. THE SUMMARY REPORT ON REPLIES TO THE QUESTIONNAIRE

On the basis of the discussion in the working group, the summary report has been updated. Extra input from Greece, the Czech Republic and Greece was added to the report.

6. NEXT STEPS OF THE WORKING GROUP ON THE BASIS OF THE SUMMARY REPORT

Paragraph 8 of the report concerning proposals for specific activities for the working group will be updated on the basis of discussions in the meeting and on the basis of consultation by email of the working group afterwards.

As a first concrete step, the secretariat will ask the members of the working group to fill in a template to get a better mutual understanding about what type of data is used and needed to do

an assessment (distinguishing relative efficacy, relative effectiveness and relative efficiency) and its sources. The contributions from the working group members will be brought together in a summary document.

7. PREPARATIONS FOR THE PHARMACEUTICAL FORUM ON 29 SEPTEMBER 2006

The Commission will draft conclusions for the Pharmaceutical Forum on the basis of the work of each of the working groups and will send it to the members of each group for approval. The Steering Committee will adopt these conclusions before they are sent to the Pharmaceutical Forum prior to the first meeting on September 29.

8. CONCLUSIONS

The third meeting of the working group is scheduled for11 October 2006 in Brussels.

Relative Effectiveness Working Group – Presence List

Brussels, 17.05.2006, 10.00-16.00 hrs - Room 12A, 12th floor, Breydel Building

Commission
Commission
Commission
Commission
EMEA
Italy
Austria
Belgium
Denmark
Estonia
Finland
France
Germany
Hungary
Ireland
Italy
Latvia
Lithuania
Netherlands
Poland
Portugal
Slovenia
Spain
Sweden
UK
AESGP
AIM
CPME
EFPIA
EGA
ESIP
EuropaBio
PGEU