

# 5th Meeting of the Working Group on Relative Effectiveness

**Brussels, 2 October 2007, 10.30 – 16.30 hrs**  
**Room 1 D, 1st floor, Centre de Conference Albert Borschette**

## *Note of the Meeting*

**Chairs:** *Morning session:* Mr B. Merkel, Head of Unit, Directorate-General for Health and Consumer Affairs and Professor V. Silano, Italian Health Ministry.

*Afternoon session:* Professor V. Silano, Italian Health Ministry and Ms M. Takki, Directorate-General for Health and Consumer Affairs

**Participants:** See the list of participants in the Annex.

## **1. Welcome and minutes of the last meeting**

Mr Merkel welcomed the members to the fifth meeting of the relative effectiveness working group. He explained the background of the Forum and the previous activities of the working group. He also gave a short review of the second high level Pharmaceutical Forum, held in June 2007, and introduced the conclusions of the Forum. Mr Merkel emphasised that the working group will need to focus its work on a set of concrete deliverables as set out in the Progress Report as well as in the Conclusions of the Forum.

Following the above mentioned introductory remarks, a tour de table took place to allow all participants to introduce themselves.

The draft agenda and the draft minutes of the fourth meeting of the working group held on 14 February 2007 were adopted.

## **2. Draft work plan 2007-2008**

The secretariat of the Pharmaceutical Forum presented the draft work plan 2007-2008. The work plan contains sections for each of the three working groups (pricing & reimbursement, relative effectiveness and information to patients) in terms of work objectives and the proposed deliverables. The work plan is based on the second Progress Report and the conclusions of the Forum, which both were adopted by the Steering Committee on 20 September. (*The presentation is attached to the draft note of the meeting.*)

The work plan provides clear directions for the Working Group to make final proposals and recommendations for the preparation of the Pharmaceutical Forum in 2008. In particular, it provides main objectives and sets out concrete deliverables requested by the Pharmaceutical Forum.

The relative effectiveness section contains draft proposals for three work packages based on the Progress Report 2007, and in particular, the conclusions 3, 4, 5 and 6 on relative effectiveness assessment:

#### *Work package 1*

For work package 1, the key objective is to work towards a European consensus on general principles, criteria and methodologies when performing national relative effectiveness assessments.

As a practical approach, the working group will consider developing a toolbox to provide support on how best to use data in relative effectiveness assessments.

#### *Work package 2*

For work package 2, the key objective is to consider which data are used and how relative effectiveness assessments are carried out in the Member States as well as related issues that arise. This will be made by looking at specific products or groups of products that have been on the market for a period of time. This would also allow the working group to work towards clarification on data requirements for carrying out a relative effectiveness assessment.

#### *Work package 3*

The key aim is to identify effective ways to foster dialogue and collaboration between the national authorities and other stakeholders (such as the industry, patient organisations, social insurers, consumer groups etc.) to improve relative effectiveness assessment in the EU.

### **3. Discussion**

Following the general presentation, the working group was invited to discuss and consider how the three above mentioned work areas set out in the work plan could be taken forward in practical terms.

The Belgian representative informed the working group on the activities of the pricing working group. The pricing group which had met on 1 October 2007 had suggested that the relative effectiveness working group would take the document prepared by the pricing working group into consideration in its work. The document, titled *Characterisation of the value of innovative medicines*, was provided to the members of the working group.

The discussion continued in the afternoon to agree on how to take the work forward in practice and to prepare a concrete implementation plan with a detailed time table for each of the three work packages. Members were invited to make proposals on the implementation.

Several members commented on the work plan; as a whole, there was a consensus in favour of taking concrete actions based on the structure suggested in the work plan. The need was

stressed, particularly for the work package 2, to develop a clear framework of the issues involved and, particularly for work package 1, to consider whether the previous draft report on data and methodology could be used in the future work.

For all the three above-mentioned work areas, the mandates will be drafted by the secretariat and then circulated among the members for comments. The adopted mandates will be provided to the members of the sub-group responsible for taking work forward (making use of electronic means of communication, whenever possible).

For the work packages, the following was agreed in terms of the implementation plans:

### **Work package 1: General principles, criteria and methodologies**

The UK, with support from AIM (tbc, AIM will inform after consultation with their members) agreed to take the lead. Others who want to participate can inform the secretariat within 3 weeks of the meeting.

The UK had already submitted a set of principles which are part of the draft report and could form the basis for the discussion on principles. The main task for this work package is to highlight general criteria, principles and methodologies to carry out relative effectiveness assessments.

The mandate will be drafted by the Secretariat.

### **Work package 2: Improving availability of data by testing of real-life examples**

In relation to the implementation of work package 2, the following issues were raised during the discussion:

- Importance to have practical examples of pharmaceutical products or groups of products
- Horizon scanning of new products in the pipeline was also mentioned
- What kind of data in clinical trials is essential for relative effectiveness assessments on new medicines? Would there be a possibility for cooperation between the Member States and companies to make needed data available?
- How EPARS (European Public Assessment Report) and NPARS (National Public Assessment Report) could be improved and used in the framework of relative effectiveness assessment should also be considered.

In addition, the possibility of using the expertise of some European networks with experience on relative effectiveness assessments and HTA, namely the European HTA network and MEDEV network, was also discussed.

Following the discussion it was agreed that the draft terms of reference will be revised to narrow the scope of the work and to define clearly the mandate (the new title will be "mandate"). In particular, clear objectives should be added to the mandate. The secretariat will revise the mandate with Austria after which all members will have a chance to comment it. The participants were asked to send their comments on the existing terms of reference in the coming weeks to the secretariat.

Furthermore, it was suggested that the mandate could contain further elements such as:

1. Data on how relative effectiveness assessments are carried out (a: before marketing; b: after marketing).
2. Horizontal issues (communication, dialogue)
3. Collaboration between national authorities as well as stakeholders
4. Updating of relative effectiveness assessments
5. The ways the outcome of the relative effectiveness assessments are used in clinical settings

The chairman proposed the following work strategy:

- Choose three medicinal products that are on the market since at least a year
- Check how their relative effectiveness was assessed at national level;
- Check whether, when and how they were reimbursed at national level;
- Check which data were used at the time of the first reimbursement and whether any reconsideration of the conclusion took place later on;
- Compare developments and conclusions of the above process in at least three Member States.

Austria proposed to take the lead for this work package. The other Member States showing interest were France, Belgium and the stakeholder representatives from EMEA and ESIP, the last one representing MEDEV as well. A mandate would be prepared for this work package in collaboration with the secretariat and circulated among the working group for agreement. If necessary, separate drafting meetings could be arranged by the secretariat to kick off the work in this area.

### **Work package 3: Development of networking and collaboration**

The members agreed on the need to consider European level cooperation among all the members participating in the Pharmaceutical Forum in the field of relative effectiveness assessment. It was agreed that as a first step, a document summarising the key elements of existing networks and cooperation arrangements would be prepared and provided for the working group to discuss.

The focus of the work will be to look at existing networks (such as the PPRI, EUnetHTA, MEDEV, country collaborations) and to set out their functions, structures, problems, etc. This will be discussed in the next meeting of the Working Group.

Sweden agreed to take the lead in this work package. ESIP and Italy will support Sweden in this work package.

The work strategy for work package 3 would be as follows:

1. Map what exists on networks and sharing information.
2. Analyse the existing networks.
3. Consider what an ideal network would look like based on the experiences of the Pharmaceutical Forum.

The work package on networking seemed to interest many. A mandate will be prepared by the secretariat and Sweden and then circulated for comments to the members.

#### **4. Any Other Business**

The document produced by the Working Group on Pricing and Reimbursement on innovation was briefly presented by the Chairman. He suggested that the relative effectiveness working group could consider especially the table 1 on page 2 of the document on potential benefits from innovative medicines and consider how to use it in the different work packages.

This document could also be a good starting point for the working groups to have a closer look at how to assess the value of a new medicine.

#### **5. Conclusions and Next Meeting**

The work plan was in general considered a good basis for work. However, it seemed that the three work packages were perceived as quite ambitious in terms of the time table and therefore their scope was discussed thoroughly.

The group agreed that as there is only one year left to prepare concrete deliverables needed to make recommendations for the Forum 2008, the activities have to be efficient in all three work packages.

##### **Next steps**

Mandates will be prepared for each work package with the leading countries by the end of October – beginning of November 2007.

The secretariat will circulate the draft mandates and have them agreed through emails by end October or beginning November.

The start of work on the work packages is foreseen by the end of November.

The members should contact the secretariat to inform of their interest in the three work packages.

The next meeting is scheduled for February 2008; the date will be agreed later on.

***END***