5th Meeting of the Working Group on Pricing of Pharmaceuticals

Brussels, 30 January 2007, Room 12A, 12th floor, Breydel Building

Draft note of the Meeting

Chairs Mr C. Siebert, Head of Unit, Unit F5, DG ENTR

Participants: See the list of participants in Annex.

1. WELCOME

Ms Lalis, Director Consumer Products, DG Enterprise and Industry, was apologized for this meeting.

Mr Siebert opened the meeting, with a special welcome to the representative of Romania as a new Member State. The Bulgarian representative was apologized. Several other new participants, being present for the first time in a session of the Working Group on Pricing, were introduced.

2. ADOPTION OF THE MINUTES MEETING 7-8/11/2006

Participants were invited for comments on the minutes of the 4th meeting of this Working Group on 7and 8 November 2006. Some comments were raised. Participants were offered the opportunity to still send comments before Friday 2 February 2007. Consequently, the Commission will distribute a finalised version of the minutes ASAP.

3. GENERAL POINTS/ANNOUNCEMENTS/OTHER WORK STREAMS

A. Status of other workstream Value of innovation

A session of the taskforce on innovation took place on 29 January 2007, prior to this session of the Working Group Pricing. Many participants had also assisted this taskforce meeting. The Commission brought a short overview of the main outcomes of that meeting.

- Objective, requested by the High-Level Forum of 29/9/2006, is to clarify the value of innovation. It is important to repeat that the objective is not to create a definition (top-down) of innovation, but rather collect the commonalities and differences in views of the Member States (bottom-up)

- The taskforce therefore has prepared a questionnaire to Member States to start discussion on three key questions:
  1. What value of innovation is recognised by Member States?
  2. How are these values identified and measured?
  3. How are the valuable innovations rewarded and incentivized.

- Nine countries replied the questionnaire already. Replies of several other countries are in preparation. Several other Member States expressed their intention still to send in replies. It was agreed that this will be possible till 21 February.
- The first replies nevertheless allowed some first findings:
  - Almost all Member States consider value of innovation in (1) therapeutic advance as well as in improvements of (2) quality of life as well as improvements of (3) socio-economic value. However the main and first interest always lays on therapeutic/clinical improvements.
  - Ideally these improvements are measured in one umbrella-algorithm, e.g. QALY (Quality Adjusted Life Years). Though in practice this is often not possible due to the lack of good data and information, in particular in the field of therapeutic/clinical improvement and QoL. In addition, measurements of QoL benefits are often subjective and not always relying on validated instruments.
  - Improvements of therapeutic/clinical value usually are best recognised, measured and rewarded in particular related to mortality, morbidity and life expectancy. Improvements of "socio-"value are well rewarded (mainly if related to public health e.g., pandemics or resistance to antibiotics), while "-economic" value is often rewarded in function of the evidence on economic benefits... QoL improvements are usually not rewarded as they are hard to prove.
- As next steps, the taskforce will collect further replies and draft a report to go to a written procedure within the taskforce by March. This report with findings, most related to question 1, will be brought back to the WG's on Relative Effectiveness and on Pricing. (The WG Relative Effectiveness will elaborate further on measurement of the value of innovation and related difficulties.)
- It was therefore proposed to organise a discussion during one of the next sessions in this Working Group Pricing on question 3: "how to reward innovation". This discussion can be based on the draft report of the taskforce, but also on the findings of the study of the Andalusian School of Public Health, of the evidence and arguments collected in the toolbox, in particular related to risks and benefits of practices towards rewarding innovation, and potentially of further assessment by Member States of their practices to reward innovation. Key findings of this discussion will then be added to the report of the taskforce.

A good and extensive discussion followed with as main elements of debate:

- There is a need to keep 2 separate, though related discussions. On the one hand, a discussion focused on (1) how to assess the value of innovation, where a lot can be

learned out of collaborating and sharing data and methodologies between Member States. On the other hand, a discussion focused on (2) how to reward valuable medicines. Although again there can be many learnings in sharing ideas, these final decisions, often including pricing and reimbursement, are individual decisions made by individual Member States, in function of local needs, priorities and resources.

- It was proposed to structure a potential debate on rewarding innovation around 4 levers a Member State has to do this: pricing decisions, reimbursement decisions, utilisation decisions (e.g., volume restrictions, clinical guidelines, …) and speed of access to market (e.g., conditional approval). A further debate followed on conditional approval, which to work well would require (1) from Member States a willingness to accept temporary uncertainty (because of limited availability of data) and (2) from companies the commitment to post-marketing studies, price flexibility and a guarantee of supply.

- The patient's representative (EPF) expressed not to understand why there is no better link between regulatory procedures leading to a marketing authorisation, and regulatory procedures leading to a pricing and reimbursement authorisation. Some potential practical suggestions to consider were brought up, like a broader use of information and databases managed by EMEA, a different design of clinical trials including proof of the value of a new medicine, and potential consultation of regulators in earlier phases of the pipeline allowing a targeted steering of drug-development towards medicines needed by society. Most of these elements are considered in the Working Group Relative Effectiveness.

- Further points mentioned to take into account and impacting a MS's possibility to reward innovation are the fact that a narrow price-range over the EU leads to differences in affordability given different economic resources (GDP/capita) in different EU Member States as well as the need for competition between products to ensure price reductions when reimbursement is reduced.

B. Transparency of Prices (progress in Transparency Committee)

The Transparency Committee met on 20/11/2006 and addressed the topic of transparency of prices. The Commission brought a briefing on the main outcomes of that meeting.

- The TC has agreed on taking up a pilot-case, to test how transparency of pricing data can be obtained and compared between Member States. In practice, price-levels of a selection of 15 medicines, well used and/or newly on the market will be collected from different Member States.
- To ensure comparability of the price-data, a template including the format in which to present the national data was presented, discussed and agreed upon. Gesundheit Österreich, (formerly known as ÖBIG), supports this technical side of the exercise.
- Although it is a voluntary exercise, most Member States have expressed willingness in participation. Several have already sent in the data, and participants of this Working Group were reminded that they can still do so till 5 February 2007.

- ÖBIG will collect, consolidate and analyse the data for the next Transparency Committee meeting , which probably will take place on 14 March, adjacent to the next meeting of this Pricing Group.
- In addition there was a proposal by France and Denmark to exchange the website-addresses of the publicly available databases on national prices. About half of the Member States have reported to this, and the secretariat has compiled and sent out a list including these addresses as well as basic information on how to use the databases and a national contact person for assistance.

A final question came whether Member States, by participating in this exercise comply with the reporting requirement of the Transparency Directive (art 2&3, Directive EC/89/105). This point was withheld for further consideration, depending on progress of and feedback to this exercise, at the next session of the Transparency Committee.

4. RESULTS STUDY

The contracted experts have completed the collection of data on the 6 selected pricing and reimbursement practices. 23 Member States have participated. Member State Participants of the Working Group were thanked for the support.

The experts brought a presentation with a short update of overview-tables, indicating application of practices per Member State, updated and completed with final Member State inputs. The report includes much information distilled from the individual Member States replies to the questionnaire. Each Member State participant is invited to double-check interpretation and reporting of these country-specific data in the report and send comments for change/updating/adding by 21 February at the latest.

In addition, the experts brought discussion-points on set-up and impact of 6 selected practices. Participants had the occasion to react briefly after discussion of each of the practices. These discussion points will be basis for further elaboration of the report and participants are invited to send their comments on them by 21 February at the latest.

5. BUILDING A TOOLBOX

Following up on a preliminary discussion during the 7 and 8 November session, a first draft discussion document was distributed to all participants. The document proposed an approach in three elements:

1. Building summaries of different cost-containment practices
2. Building an overview of good practices within pricing and reimbursement policies
3. As an option, updating the toolbox/further exchange and collection of Member State experiences

This document was briefly presented to the group, on which an extensive discussion followed with as main elements of debate:

- Depth: the toolbox needs to be evidence-based, not in a strict scientific way, but for each argument there is need to link to as much evidence as possible (studies,

literature, case reports, Member State experiences …). Where hypothetical arguments or claims, without evidence to-date are added, there is need for a clear indication. Other factors that might be added are an indication of the relative importance/weight of different arguments as well as the mentioning of contact people.

- Scope: There is a need to cover more than the six practices covered in the study of the Andalusian School of Public Health, and to cover also less known practices. Nevertheless, starting with these six mechanisms, on which evidence is available, will allow first progress by the June Forum and will give us an experience on how to expand the scope to other practices of interest. There is a particular interest in covering practices with specific effects of ensuring access or rewarding innovation. In addition it became clear that for some practices, several variations exist and are to be covered in the exercise.
- Template/terminology: several comments came on terminology, in particular related to the terms of "risks and benefits" (alternatively "potential" "advantages and disadvantages"?), "rewarding innovation" (replace by "promote innovation"?) and to the perspectives behind each of the impact areas (cost containment, access, reward). A suggestion could be to stick to used terminology in the templates, but to add an introductory paper to ensure a clear understanding of the template.
- Some comments emphasized the need to keep a balanced view on the three objectives (cost containment, reward for innovation, and access to medicines). This needs to happen as well per practice, within the summary template, as on a more global policy level.
- This toolbox exercise in the mid-term should aim for self-sustainability; thoughts on how to keep it update are to be elaborated.

To conclude, it was agreed that the Secretariat will prepare a new paper taking into account the different comments made.

6. CLOSING

- Next meetings are planned on 14-15 March 2007 and 26-27 April 2007
- An e-mail with practical next steps was sent out on 1 February 2007.