

11th Meeting of the Working Group on Pricing of Pharmaceuticals

**Brussels, 17-18 April 2008,
Room 12A, 12th floor, Breydel Building**

MINUTES

1. WELCOME AND PRACTICAL POINTS

Ms Georgette Lalis, Director of Directorate -General Enterprise and Industry, opened the meeting. Christian Siebert, Head of Unit of DG Enterprise and Industry, co-chaired the meeting. 25 Member States and 10 stakeholders were present (a list of participants is attached in annex).

EAEPC was invited to assist the session on Trade (3.). Eurordis was invited to assist the session on Orphan medicines (4.)

The proposed agenda of the meeting was adopted.

2. ADOPTION OF THE MINUTES MEETING 17-18/4/2008

The minutes of the last meeting had been distributed. One comment was made by the Netherlands. The minutes were adopted. A finalised version will be send.

3. TRADE AND DISTRIBUTION (PGEU-GIRP-AIM-ESIP)

This session has been developed with the help of 4 stakeholders (PGE U, GIRP, AIM and ESIP), and with the help of ÖBIG.

A well-functioning distribution system of pharmaceuticals is essential for every healthcare system. It is the shared belief of these 4 stakeholders that each distribution system therefore needs to ensure safety, security of supply and full access for all citizens as well as cost-efficiency. This is largely in line with the Working Group on Pricing's objective to balance access, cost-efficiency and reward for innovation. Nevertheless, distribution is often a less-known aspect of the pharmaceutical landscape.

The aim of this session was therefore to build common knowledge on the key elements in place in different Member States in order to organise the distribution of pharmaceuticals. Consequently, awareness was raised on several trends and changes that (can) affect the distribution landscape. The presentations were followed by a discussion in the Working Group, of which the main points are written down below.

All presentations have been made available on CIRCA.

- Introductory presentation (ÖBIG)

A first presentation brought an overview of the different elements of a distribution policy (e.g. channels of distribution and sales, ownership rules, margins and remuneration, establishment criteria, service levels, ...). For each element, main different options were presented as they are applied within different Member States (without meaning to be exhaustive).

The margins for wholesalers and pharmacists and the efficiency of distribution vary significantly between Member States, often depending on the types of margins and set-up of the distribution system. E.g., SE was reported to have the lowest margins within its state controlled supply system.

A main focus of discussion was then on price reductions of OTC, once prices are deregulated. PT and IT mentioned an initial price decrease of 20%, while PT also mentioned that prices had returned to original levels after 2 years.

- Integration of the supply chain (PGEU)

This presentation brought an overview of horizontal and vertical integration of the supply chain, focusing on elements like consolidation of ownership driven by pharmacies, wholesalers and manufacturers, as well as on the related legal elements.

- Mail-order and internet supply (AIM)

This presentation brought an overview on the use of mail-order and internet for the supply of pharmaceuticals, focusing on the difference between pharmacies with local or (cross-)national scope of activities.

EFPIA added that the Swiss system is very particular as it is driven by the high number of self-dispensing doctors.

PT mentioned that mail-order is possible in the country, as long as medicines are delivered to the patient by a pharmacist in person.

- Direct-to-Pharmacy supply (GIRP)

This presentation brought some changes in the distributor landscape like short-line wholesaling, direct-to-pharmacy supply and direct sales. All of them put the full-line wholesaling model at risk, as the most profitable products are taken out and no longer able to cross-subsidize for the broader portfolio of products.

A discussion followed on the use of the Public Service Obligation as stated in the EU Directive 2001/83/EC.

Direct-to-Pharmacy systems on medicines distribution are in place in UK and considered in PL. For the UK, EAEPC referred to a report by the Office of Fair Trading (OFT), mentioning a higher cost for the National Health Services and a decreased service to pharmacists. PL mentioned an (expected) 4% increase of costs to the end-consumer.

It was mentioned that, within a given country, the supply-margins remain the same for each system of supply, regardless of the type of supply and regardless the level of service given.

- Preparation of a Legal Proposal to combat counterfeit (European Commission)

An overview was brought of the Commission's current work in the field of counterfeit. This includes a study that was performed and a legal proposal that is under preparation.

EFPIA underlined the magnitude of the problem and the need for action.

Some smaller Member States mentioned that proposals should be carefully developed so that they do not cause more problems of availability in small markets. If this would happen, patients would anyhow look for alternative routes of supply, thus increasing the risk for counterfeiting.

EGA underlined the need for proportionate measures, targeted at the medicines at risk. Generic medicines do not show any increased risk for counterfeiting. Applying expensive technological solutions on cheaper generic medicines might create a need for price increases.

DAY 2 – 18 APRIL

4. ORPHAN MEDICINES

- Presentation draft proposal

A taskforce consisting of SL, IE, FR, EuropaBIO and Eurordis (on behalf of EPF) had developed a discussion paper on orphan medicines. Another representative of EuropaBIO and a representative of Eurordis have therefore assisted to this agenda point.

The underlying objective is to promote the sustainable development of valuable orphan medicines and, in particular, to ensure that all affected citizens in the EU can get sustainable access to these medicines.

The members of the taskforce were thanked for their work.

Several points came up after the presentation of the paper:

- Some concern was expressed regarding the success of some orphan medicines. This was attributed mainly to the fact that medicines, originally for an indication with an orphan status, expand into different indications, though at similar pricing levels as for the original indication, and while the total number of patients for all indications of the same orphan medicine still remain within the prevalence limit given by the orphan medicinal products Regulation. Though it was agreed that, although we should be aware of such medicines, most orphan medicines have a more limited turnover and this discussion on access to orphan medicines should focus on such medicines.
- Another factor is the 2 different designation criteria used to assign orphans status to a medicine: prevalence or the lack of expected profitability. In practice the first criterion is almost always used, although the second one would also be appropriate.
- Several Member States called for more transparency on the costs developing orphan medicines and justifying the high prices. This claim for high prices, combined with a early market access based on a limited number of data, while addressing a high medical need in life-threatening and/or serious and debilitating diseases, creates insecurity for funding Member States. Conditional reimbursement is indeed seen as a potential way forward, though this practice brings some concerns in itself. Similar concerns for more common diseases were addressed in the Guiding Principles paper and in the paper on Conditional Pricing and Risk Sharing, both adopted earlier by the Working Group.
- It was mentioned that cost-effectiveness is difficult to apply with orphan medicines, in particular as data are limited and standard accepted levels of cost-effectiveness usually do not fit to orphan medicines.

Member States were invited to send their further comments on the text. The paper will be updated along the comments given and discussed for adoption at the last session of the Working Group.

5. OTHER WORKSTREAMS

- Availability of medicines in small markets

An introduction was given on the status of the work. A taskforce consisting of SL, MT, EE, IC, EFPIA and GIRP have developed a discussion paper. We wish to thank the members of this taskforce for their work.

The overall objective of this document is to promote the sustainable availability and delivery of medicines to all European markets. This is in particular important for the smaller Member States, where some important medicines have never been made available.

The paper takes an economic approach, and it is therefore important to distinguish it from the regulatory effort that is ongoing in parallel. This effort was started by a report of the Heads of Medicines Agencies and is now followed-up by the Commission's pharmacoregulatory unit (ENTR/F2). Of course both efforts need to be coordinated.

The paper is not yet finalised but will be presented at the July session for discussion.

- Generics price and volume evolution

This workstream is prepared by EGA, leading a taskforce with EPFIA, IT, BE and MT. EGA mentioned the scope and objective to identify some differences between Member States in potential savings and access to medicines as well as regulatory differences. EGA, and the taskforce, is preparing some analyses that will be presented to next session of the Working Group.

6. TENDERING

- Presentation of outcome questionnaire (ÖBIG)

ESIP and ÖBIG have completed a survey with the Member States to understand who uses tendering in which field. About 20 Member States have participated. The secretariat wishes to thank the participating Member States for their interest and support.

ÖBIG has brought an overview of the main findings. It seems that tendering is used in many countries, but usually in specific settings. Most countries use it in their hospital setting or for specific public functions (vaccines/prevention, army, prisons, ...). Within some smaller countries, it is also used for out-patient medicines to ensure availability of medicines. The use of tendering in the out-patient segment within larger Member States is rather uncommon. The few existing cases are relatively recent and seem to have met a lot of complications, in particular of legal nature.

BE, as a rare country with a tendering experience in the out-patient segment (for Simvastatin and Amlodopin), summarized its general experiences as (1) a price-

reduction around 40%, (2) concerns over transparency of the process, given the need for equal treatment of all bidders, (3) the need for a strong legal basis, (4) concerns on the sustainability of supply of the entire market, (5) the risk of leakage of low -price products out of the market and (6) the need for a long-term view and need for flexibility given the frequent changes in the market (e.g. new alternative products, new potential companies supplying the medicine, ...). A last point mentioned, though on which BE has not yet been able to study impact, is the shift of utilisation towards more expensive products that fall outside the tendering procedure .

- Industry perspective

EuropaBIO has brought an additional presentation on tendering, based on a paper "Issues related to biopharmaceutical procurement". Some elements highlighted general issues for companies like integrity, transparency and frequency of tendering processes, though many issues were very specific for biotech medicines.

Other industry associations responded that this presentation focused rather on the topic of therapeutic equivalence than on the topic of tendering.

Some participants confirmed that tendering can work in small markets, but is still uncommon in larger markets where it meets many legal complications. It was concluded that the topic could be re-addressed at a later occasion; once more experience can be shared.

7. ANY OTHER BUSINESS

SL reminded the participants of the upcoming Brdo conference.

A representative of DG SANCO gave a short update of the status in the Working Group Relative Effectiveness.

8. NEXT STEPS

It was announced that the main findings of our 3 year work will be reflected in a Final Report to the High Level Forum (to take place on 2 October) . A draft Final Report will be presented for discussion and adoption at the next session.

Several parties expressed interest to keep the momentum and to ensure continuation of this process on Pricing and Reimbursement. This idea was already expressed by the Steering Committee. We will try to find some time during the last session to discuss this topic.

9. CLOSING

This next session will be organised on 2-3 July in order to finalise all workstreams and adopt a Final Report.

Christian Siebert announced that this had been his last session of the Working Group, as he will take charge of another department as from May. The participants thanked him for his support and chairmanship over the last 3 years and wish him all the best.