EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Tourism, CSR, Consumer Goods and International Regulatory Agreements
Unit F5 Food and Healthcare Industries, Biotechnology

Access to Medicines in Europe

Meeting of the Project group on facilitating supply in small markets

Thursday, 22 September, 2011 - Brussels

Minutes

1. PARTICIPANTS

[redacted] (Cyprus), [redacted] (Estonia), [redacted] (Iceland), [redacted] (Lithuania), [redacted] (Latvia), [redacted] (Malta), [redacted] (Slovenia), [redacted] (AESGP), [redacted] (EFPIA), [redacted] (EFPIA), [redacted] (EGA), [redacted] (EGA), [redacted] (ESIP), [redacted] (EUROPABIO), [redacted] (EUROPABIO), [redacted] (GIRP), [redacted] (GIRP), [redacted] (HOPE), [redacted] (PGEU), [redacted] (EMINET).

Excused: EPF, Norway, Also excused guest speaker [redacted] (Pharmaceutical Services Negotiating Committee, UK) due to unforeseen personal reasons.

2. INTRODUCTION

The co- Chairs (DG Enterprise & Industry and Slovenia) welcomed the participants to the first face to face meeting of the project group on facilitating supply in small markets launched in the framework of the Platform on access to medicines in Europe of the process of corporate responsibility in the field of pharmaceuticals.

Co-Chairs explained that participation in the projects is on voluntary basis and so is the co-chairing – in line with the approach that is being followed in all five projects that run in parallel in the Platform on access to medicines in Europe. A big part of the coordination of the project will be organised via e-mails, if necessary conference calls and face to face meetings with an optimum perspective to conclude in a time framework of eighteen months and if possible not exceeding two years. The objectives of the group are to enhance collaboration and exchange of best practices between interested stakeholders and reach practical outcomes linked with the Terms of Reference. To conclude the process and based on the experience, members will be invited to propose a list of best practices / recommendations for adoption by the Steering group.

COM requested for possible volunteer participation of a competent authority of a small market in the project group "Promoting good-governance for non-prescription medicines" as it is the only group under the platform that has not a small market perspective among the participants.

3. PRESENTATION OF THE TERMS OF REFERENCE

The first draft text of Terms of Reference was presented to the group taking into account the comments from the teleconference of July, 2011. There was a detailed examination of the text and there were many proposals for amendments. There was an agreement that the text would be in part redrafted based on the discussions preceded and then it would be circulated to the members for approval or possible additional remarks.

Some of the comments / proposals of the discussion were:

- The group will refer in particular to the small markets of Cyprus, Estonia, Iceland, Latvia, Lithuania, Malta and Slovenia which apart from being small markets have demonstrated problems of unavailability and / or continuity of supply of medicinal products and therefore this could lead to certain risks of public health.

- To make a clear reference that spill - over effects on other markets and the possible remedies should be confided to the countries referred to this project. Also ensure full commitment of all participants to avoid ramification through other markets in particular through international reference pricing and free movement of goods.

-EFPIA mentioned the need for clarification of the meaning of the term "commercial confidentiality" as used in the Terms of Reference. In the initial draft of the document, the interpretation of the term was given in the footnote. Slovenia proposed that the term be interpreted within the frame of EU rules that govern public procurement. The group agreed that the footnote text would be revised or omitted.

- Luxembourg will not be mentioned in the above list of small markets and will be contacted in case they would like to share their experiences with the group, in view of the fact that although is a small market they do not face problems of unavailability or shortage of supply.

-The group will focus on possible areas of co-operation on non regulatory issues but if any regulatory hurdles or enablers are detected during the process, they will be mentioned in the final recommendations. DG SANCO will be asked to participate in one of the future meetings of the group.

- The Commission will provide information on progress in the other projects of the Access to Medicines in Europe Program, as well as developments in the relevant legislative field in review of the Directive 89/105/EEC.

- It was decided to delete the reference of cross-border trade and insert consistent wording as much as possible throughout the text.

4. EXCHANGE OF EXPERIENCES OF COMPETENT AUTHORITIES

In the framework of exchange of ideas / experiences / best practices co-Chairs invited all members of the group, competent authorities and the other stakeholders to present their own perspective of the problem. At the first meeting two relative presentations were made, by Cyprus and Slovenia – presentations are attached. In relation to the presentation by Cyprus and due to the fact that EFPIA challenged the issue of tendering procedures in this market, EFPIA were committed to identify a "model – country" were these procedures operate better according to their opinion. The COM will approach the competent authority of this country that will be proposed by EFPIA and ask them to make a presentation to the group. With respect to Slovenian presentation, the group discussed the modalities and experiences with the list of urgently needed medicines as implemented in §15 of the Slovenian Medicinal Products Act, with medicines listed in data model consisting of ATC5, INN and pharmaceutical form.

5. NEXT STEPS

WG decided to share the documents via the CIRCA library system. Additionally:

- Amended text of Terms of Reference will be adopted through written procedure

- Next face to face meeting of the group will be held in Poland on the 14/12 before the Steering Group

- Between now and next meeting Eminet will prepare a draft template which will be sent to the members of the group before the next meeting for their comments. The aim is to have a template ready to use by the next meeting which will be used in order to map information of unavailability or shortages of supply.

- Eminet will present at the next meeting a first draft of a study on international experience on co-ordinated purchasing.

- Eminet will prepare two draft questionnaires in order to update information on the current situation: one for the competent authorities and one for the economic operators.