EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Tourism, CSR, Consumer Goods and International Regulatory Agreements
Director

1st conference call – Project *Mechanism of coordinated access to orphan medicinal products*

Minutes

30 November 2010, 10h00 – 12h00

Chair: [redacted]

Participants

[redacted], Austria
[redacted], Belgium
[redacted], Estonia
[redacted], France
[redacted], EURORDIS
[redacted], ESIP
[redacted], EFPIA
[redacted], EuropaBio
[redacted] EMINET
[redacted], European Commission

Introduction

The Chair welcomed the participants to the first conference call of the project *Mechanism of coordinated access to orphan medicinal products* launched in the framework of the platform *Access to medicines in Europe* of the process on corporate responsibility in the field of pharmaceuticals. It was explained that most of the coordination of the project will be organised via conference calls and exchange of emails. Members of the projects should be invited to meet in Brussels once per semester.

The Chair explained that participation in the projects was on a voluntary basis and should not commit organisations in future actions/initiatives outside the project. To conclude the project and based on the experience, members will be invited to propose recommendations for adoption by the Steering Group.

The chair welcomed the volunteering co-leadership of Belgium for this project. The current volunteering members to this project were presented: AIM, EPF, ESIP, EFPIA, EGA, EuropaBio, GIRP, Austria, Belgium, Estonia, Finland, France, Italy and Spain.

Presentation of the terms of reference – Belgium

Belgium, as the co-leader, presented the proposal of terms of references for the project they had developed.

The document had been circulated in preparation of the conference call. Based on the comments of the other members of the project, a revised version will be presented at the next steering group meeting organised on 17 December 2010. The Commission should then decide on the adoption of the document.

Discussion on the terms of reference

Participants in the conference call had a number of comments and suggestions to clarify the scope of the project as described in the terms of reference.

In particular, it was proposed:

- To clarify the work of the project on the definition of *common unmet needs* among the members

- To highlight further that one of the objectives of the project would be identify the hurdles for the development of a joint mechanism and to define possible structures and feasibility.

- To explore other ways apart from a *joint mechanism of coordinated access* to improve access to orphan drugs for EU Member States/citizens

- To strengthen in the document that the concept of solidarity is applying to private and public entities members of the project

- To consider in the development of the project the experiences, lessons learnt and potential ways forward with orphan medicinal products already on the market and to develop in a second step pilots for product(s) under development. None of the discussions should commit members of the project.

Next steps

- Members were asked to communicate their comments on the draft terms of reference for the project. While the initial deadline was fixed on 10 December, the Commission and Belgium kindly invite members to provide their **feedback by 6 December at the latest** in order to leave sufficient time for the preparation of the Steering Group.

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