Process on Corporate Responsibility in the field of Pharmaceuticals

Working methods for the platform on access to medicines in Europe

1. INTRODUCTION

This document proposes Working Methods for the Platform on access to medicines in Europe.

The outcomes of the platform will be based on the setting up and realisation of projects and the resulting recommendations.

The work will concentrate on several issues, with the help of dedicated projects :

- Mechanism of coordinated access to orphan medicinal products
- Capacity building on managed entry agreements for innovative medicines
- Facilitating the supply in small markets
- Promoting a good governance for non- prescription drugs
- Market access for biosimilars

The Commission may create additional projects to respond to future needs.

A broader reflection will also be conducted on how to identify areas with the highest medical needs for a prioritarisation of medicines development in the context of pricing and reimbursement decisions1 and how to characterise innovation2.

2. ORGANISATION AND WORKING ARRANGEMENTS

The platform will be developed on a two-tier structure, namely the Steering Group and the projects.

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1 This action should be carried out based on the report Priority Medicines for Europe and the World, commissioned by the Dutch Government during their Presidency in 2004, http://whqlibdoc.who.int/hq/2004/WHO_EDM_PAR_2004.7.pdf

2 This action should be carried out based on the Belgian Presidency report *"A call to make valuable innovative medicines accessible in the European Union – Recommendations for a coordinated action to stimulate, measure and valorise pharmaceutical innovation, Background report for the Ministerial Conference 23-24 September 2010",* http://www.inami.be/information/all/studies/study-20100923-24/pdf/background_report_en.pdf

2.1. The Steering Group

Each member of the platform on access to medicines in Europe was invited to designate its representative.

The meetings of the Steering Group will be chaired by the Commission Directorate General Enterprise and Industry (DG ENTR) in close collaboration with on going Presidencies of the EU. The meetings of the Steering Group should be organised whenever possible in conjunction to the biannual meetings of the network of pricing and reimbursement authorities. One additional annual meeting could be foreseen in Brussels if necessary.

The language of the Steering Group will be English and therefore, all working documents, notes and publications will be prepared in English.

The Commission may invite external experts to the meetings of the Steering Group or to projects. Experts involved in their personal capacity (academics or others) will be requested to disclose possible conflicts of interest prior to meetings.

A CIRCA website will be used to facilitate restricted communication between participants in the Steering Group.

2.2. The Projects

Each project will be lead by the Commission Directorate General Enterprise and Industry (DG ENTR) with the support of one Member State. The projects are organised by the Commission, who defines, in close cooperation with the co-leading Member Sate, their mandates and composition after consulting the Steering Group.

The organisations involved in the platform will have the possibility to volunteer experts, though participate in each project shall be on a voluntary basis. Each project should gather a good mix of entrepreneurial, societal and governmental views. Experts involved in a project should ensure its development by sharing experiences, by putting forward case studies and by potentially setting up ad'hoc pilot project. Focussed discussions, leadership, active and continued interest, constructive inputs and a flexible approach will be required if useful outcomes are to be achieved.

The projects will work according to their respective mandate and report to the Steering Group. The language of the projects will be English and therefore, all working documents, notes and publications will be prepared in English.

Most of the work of the projects should be carried out electronically. Conference calls should be organised according to the need expressed by the members of the project. The Commission might organise when necessary a meeting in Brussels with the maximum of one meeting per project every semester.

3. TRANSPARENCY

The Commission will publish by appropriate means, in the original language of the document concerned, any approved summary, conclusion, part of a conclusion or working documents of the platform, together with proceedings and reports.

All the documents of the Process will be subjected to the right of access to documents[3].

4. WORK PLAN

The following table proposes a work plan for the platform.

Meeting	Date	Objectives
Steering Group ***Brussels - Belgium***	24 Sept. 2010	Presentation of the Process and of the platform Opinion on the **terms of references**
Steering Group ***Bruges - Belgium***	17 Dec. 2010	Adoption of the **terms of references** and of the **working methods** **State of play of the projects** Exchange on how to identify areas with the highest medical needs for a **prioritarisation of medicines development**
Project 1: Mechanism of coordinated access to orphan medicinal products ***Brussels - Belgium***	Jan/Feb/March 2011	Adoption of the draft **mandate** by its members
Project 2: Capacity building on managed entry agreements for innovative medicines ***Brussels - Belgium***	Jan/Feb/March 2011	Adoption of the draft **mandate** by its members
Project 3: Facilitating the supply in small markets ***Brussels - Belgium***	Jan/Feb/March 2011	Adoption of the draft **mandate** by its members

[3] Article 255 of the treaty establishing the European Community, implemented through Regulation 1049/2001 of 30 May 2001, grants a right of access to European Parliament, Council and Commission documents to any Union citizen and to any natural or legal person residing, or having its registered office, in a Member State.

Meeting	Date	Objectives
Project 4: Promoting a good governance for non-prescription drugs ***Brussels - Belgium***	Jan/Feb/March 2011	Adoption of the draft **mandate** by its members
Project 5: Market access for biosimilars ***Brussels - Belgium***	Jan/Feb/March 2011	Adoption of the draft **mandate** by its members
Steering Group ***Hungary***	April/May 2011	Presentation of the **mandates of the projects** **State of play of the projects** Exchange on how to identify areas with the highest medical needs for a **prioritarisation of medicines development**
Project 1: Mechanism of coordinated access to orphan medicinal products ***Brussels - Belgium***	Sept/Oct/Nov 2011	**Development** of the project
Project 2: Capacity building on managed entry agreements for innovative medicines ***Brussels - Belgium***	Sept/Oct/Nov 2011	**Development** of the project
Project 3: Facilitating the supply in small markets ***Brussels - Belgium***	Sept/Oct/Nov 2011	**Development** of the project
Project 4: Promoting a good governance for non-prescription drugs ***Brussels - Belgium***	Sept/Oct/Nov 2011	**Development** of the project
Project 5: Market access for biosimilars ***Brussels - Belgium***	Sept/Oct/Nov 2011	**Development** of the project
Steering Group ***Poland***	Nov/ Dec 2011	**State of play of the projects** Exchange on how to identify areas with the highest medical needs for a **prioritarisation of medicines development**

Meeting	Date	Objectives
Project 1: Mechanism of coordinated access to orphan medicinal products ***Brussels - Belgium***	Jan/Feb/March 2012	**Development** of the project
Project 2: Capacity building on managed entry agreements for innovative medicines ***Brussels - Belgium***	Jan/Feb/March 2012	**Development** of the project
Project 3: Facilitating the supply in small markets ***Brussels - Belgium***	Jan/Feb/March 2012	**Development** of the project
Project 4: Promoting a good governance for non-prescription drugs ***Brussels - Belgium***	Jan/Feb/March 2012	**Development** of the project
Project 5: Market access for biosimilars ***Brussels - Belgium***	Jan/Feb/March 2012	**Development** of the project
Steering Group ***Denmark***	April/May 2012	**State of play of the projects** Exchange on how to identify areas with the highest medical needs for a **prioritarisation of medicines development**
Project 1: Mechanism of coordinated access to orphan medicinal products ***Brussels - Belgium***	Sept/Oct/Nov 2012	**Finalisation** of the project
Project 2: Capacity building on managed entry agreements for innovative medicines ***Brussels - Belgium***	Sept/Oct/Nov 2012	**Finalisation** of the project
Project 3: Facilitating the supply in small markets ***Brussels - Belgium***	Sept/Oct/Nov 2012	**Finalisation** of the project
Project 4: Promoting a good governance for non-prescription drugs ***Brussels - Belgium***	Sept/Oct/Nov 2012	**Finalisation** of the project

Meeting	Date	Objectives
Project 5: Market access for biosimilars ***Brussels - Belgium***	Sept/Oct/Nov 2012	**Finalisation** of the project
Steering Group ***Cyprus***	Nov/ Dec 2012	**Adoption of recommendations** based on the lessons learnt from the projects and from the discussions on how to identify areas with the highest medical needs for a prioritarisation of medicines development.

ANNEX – Membership of the projects

Project 1: Mechanism of coordinated access to orphan medicinal products

Lead: DG ENTR and Belgium

Members: AIM, EPF, ESIP, EFPIA, EGA, EuropaBio, GIRP, Estonia, Finland, France, Italy, Spain, Sweden.

Project 2: Capacity building on managed entry agreements for innovative medicines

Lead: DG ENTR and ?

Members: AIM, EPF, ESIP,CPME, HOPE, AESGP, EFPIA, EGA, EuropaBio, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Hungary, Italy, Latvia, Lithuania, Spain,Sweden, UK.

Project 3: Facilitating the supply in small markets

Lead: DG ENTR and ?

Members: EPF, ESIP, HOPE, PGEU, AESGP, EFPIA, EGA, EuropaBio, GIRP, Cyprus, Estonia, Latvia, Lithuania, Slovenia, Spain.

Project 4: Promoting a good governance for non- prescription drugs

Lead: DG ENTR and UK

Members: AIM, BEUC, CPME, EPF, PGEU, AESGP, Denmark, Spain.

Project 5: Market access for biosimilars

Lead: DG ENTR and Denmark

Members: AIM, EPF, ESIP, EFPIA, EGA, EuropaBio, Belgium, Czech Republic, Hungary, Ireland, Italy, Lithuania, Spain, Sweden.