EUROPEAN COMMISSION

PRESS MEMO

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Better access to medicines for patients in Europe

A significant progress was made in the work of the Process on Corporate Responsibility in the field of Pharmaceuticals with the endorsement of the outcomes of the Platform on Access to Medicines in Europe, at the meeting of the Steering Group in Ireland yesterday.

This Process was launched by Vice-President Tajani of the Commission responsible for industry and entrepreneurship, in September 2010, with the aim to promote a dynamic exchange between the national authorities, the industry and other public sector and civil society stakeholders.

The overall Process has been organised in three independent platforms:

- Ethics and Transparency

- Access to Medicines in Europe

- Access to Medicines in Africa

The Platform on Ethics and Transparency and most of the Platform on Access to Medicines in Europe have finalised their work. The work of the Platform on Access to Medicines in Africa, and of the Prioritisation Working Group under the platform on Access to Medicines in Europe will be concluded later this year.

1) With regards to the Platform on Ethics and Transparency, the aim was to reinforce ethical behaviour and transparency for all stakeholders in this sector and the outcomes are represented by a "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector". These outcomes were already endorsed at the previous meeting of the Steering group in Cyprus (November 2012) and will be made available at the following link :

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform-ethics/index_en.htm

2) The Platform on Access to Medicines in Europe was the most comprehensive Platform fostering debates on a variety of topics.

The deliverables for a better access to medicines in Europe under the Process on Corporate Responsibility in the Field of Pharmaceuticals have been finalised and are now available to the public.

Under the Platform on Access to Medicines in Europe, experts representing Pricing and Reimbursement authorities, industry (research based innovators generics and non-prescription medicines producers and academia) were invited to work towards consensus

based results, in five different project groups. Each of these project groups were chaired by one volunteer Member State and the Commission (represented by DG ENTR):

- Mechanism of coordinated access to orphan medicinal products was co-chaired by Belgium. The objective was to find collaborative ways to identify and assess the value added of orphan medicinal products. Agreement was reached on a final report. This includes "Key conclusions and recommendations", and an indicative set of criteria, such as available alternatives or response rate against which value could be assessed, so as to ultimately facilitate access for patients.

- Capacity building on Managed Entry Agreements (MEAs) for innovative medicines was co-chaired by Italy. This group had a threefold objective: first, to collect quantitative information on existing MEAs, then to categorise these different MEAs schemes and thirdly to assess their usefulness in light to their financial implications. The final outcome is a Report elucidating the above mentioned aspects.

- Facilitating the supply of medicinal products in small markets was co-chaired by Slovenia. The small markets examined during the work of this group were: Cyprus, Estonia, Iceland, Latvia, Lithuania, Malta and Slovenia. The group discussed possible solutions to increase availability of certain products in the previously mentioned small markets in Europe. Among others, it dealt with issues related to pricing and reimbursement practices, distribution procedures and other requirements to be complied with, when placing a medicinal product on a smaller market. A "Position Paper and Recommendations" identifying possible solutions was developed, for example sharing information amongst all parties concerned on supply problems.

- Promoting good governance for non-prescription drugs was co-chaired by the UK. The group examined the role of various actors in identifying the necessary elements to ensure availability, uptake and informed use of non-prescription medicines. It was also acknowledged that there is a diversity of factors affecting access to non-prescription medicines. In the final report the group advocates the significant role that these medicines can play in self-care in the existing framework governing non-prescription medicines.

-Market access for biosimilars was co-chaired by Denmark. The group took stock of the availability of biosimilar medicinal products in European national markets. They explored the conditions necessary to improve an informed uptake and adequate patient access to these products. Three deliverables are the final outcomes: 1) A Question & Answer document to provide comprehensive information on the concept of biosimilar medicinal products. This document touches upon scientific, regulatory and economic aspects. Its target audience are patients, health professionals and pricing and reimbursement authorities. 2)In addition an overview of reimbursement status in EU Member States and 3) a study on market penetration of biosimilars in EU was conducted.

All the deliverables of each of the five project groups will be made available at the following link :

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform_access/index_en.htm

The results of the Process will be completed in the second half of 2013 with the finalisation of the ongoing work regarding:

- Update of the Priority Medicines Report of the World Health Organisation

- Platform on Access to medicines in Africa.