Process on Corporate Responsibility in the field of Pharmaceuticals

Terms of reference for the Platform on access to medicines in Europe

The pharmaceutical sector contributes significantly to the health and well-being of our citizens, but also to economic growth and employment in Europe. Despite the many achievements of the past years, the European pharmaceutical sector is confronted today with major health, economic and scientific challenges.

Considering the contribution that medicines provide to the health of individuals, it is necessary to ensure that the pharmaceutical industry strategies are in line with the public health and societal needs and that all partners exercise their responsibilities. The Process on corporate responsibility in the field of pharmaceuticals will be set up to initiate a momentum among the Member States, industry and other relevant stakeholders by considering in a balanced approach societal and industrial challenges.

Given the experiences of the G10 process and of the High Level Pharmaceutical Forum, the Process on corporate responsibility in the field of pharmaceuticals should facilitate discussions on ethics and transparency of the sector but also on non-regulatory conditions for better access to medicines after their marketing authorisation. The process will therefore comprise three independent platforms.

- Transparency and ethics in the sector
- Access to medicines in Europe, in the context of pricing and reimbursement
- Access to medicines in developing countries with a focus on Africa

The Directorate General for Enterprise and Industry will manage this process in consultation with other relevant services of the Commission for a period of two years.

Platform on access to medicines in Europe

Scope

Given the diversity of pricing and reimbursement systems and the differences of availability and access to medicines across Europe, it is useful to put in place a European platform for political dialogue and consensus.

It is important to recall that pharmaceutical pricing and reimbursement policies fall within the competence of Member States. Each government is responsible for the organisation of its healthcare system and is free to take measures to ensure its financial stability. The principle of subsidiary applies in this field and must be fully respected.

The High Level Pharmaceutical Forum welcomed the development of a shared understanding that pricing and reimbursement policies need to balance timely and equitable access to pharmaceuticals for patients all in the EU, control of pharmaceutical expenditure and reward for valuable innovation within a competitive and dynamic market that also encourages research and development.

In this context, the platform on access to medicines in Europe will be dedicated to enhance voluntary collaboration among the Member States and relevant stakeholders in order, when appropriate, to find common non-regulatory approaches to enable timely and equitable access to medicines after their marketing authorisation. The platform on access to medicines in Europe will gather a number of concrete initiatives that could in particular facilitate pricing and reimbursement of innovative treatments after their marketing authorisation or that could contribute to a responsible environment for access.

Discussions of the platform should be bound by the present legal framework.

Process

The platform on access to medicines in Europe will be chaired by DG Enterprise and Industry. To support its work, DG Enterprise and Industry might also rely on experts and on organisations involved through the possible nomination of rapporteurs and if necessary, sub-group leaders.

Steering Group on Access to medicines in Europe

In order to steer the process in a given way, the platform will be driven by a Steering Group.

The Steering Group will generate momentum for effective development of the platform by:

- Overseeing the progress of its projects and by putting forward experienced-based recommendations when a project will be considered concluded.

- Exploring how to identify areas with the highest medical needs for a prioritarisation of medicines development in the context of pricing and reimbursement decisions[1] and how to characterise innovation[2].

Building on its discussions, on the outcomes of its work and on lessons learnt from its projects, the Steering Group should put forward recommendations at the end of its term which should be adopted on a consensus-based manner. Whenever possible, the recommendations should be targeted to specific stakeholders.

The Steering Group on access to medicines in Europe will be composed of representatives of the national competent authorities responsible for the pricing and reimbursement of pharmaceuticals and representatives of the stakeholders invited to take part to this platform.

DG Enterprise and Industry will chair the group in close collaboration with on going Presidencies of the EU. The meetings of the Steering Group should be organised in conjunction to the biannual meetings of the network of pricing and reimbursement authorities.

Projects on Access to medicines in Europe

Projects will be put in place for concepts to be developed and ideas to be tested. Projects will focus on concrete experiences of stakeholders and will explore non regulatory conditions which may impact upon access to medicines after their marketing authorisation. Lessons learnt in each project might feed into recommendations to the Steering Group concerning pricing and reimbursement of medicines.

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

[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 Belgium Presidency report *Innovation and Solidarity*

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 members of the platform on access to medicines in Europe will be proposed to contribute to the following projects:

1. **Mechanism of coordinated access to orphan medicinal products**

   Members will be invited to develop the concept of a coordinated access to orphan medicinal products based on the set up of programmes between companies and groups of competent authorities and results of the ongoing project on a mechanism for clinical added value on orphan medicinal products. A pilot project could be set up in a second stage.

2. **Capacity building on managed entry agreements for innovative medicines**

   The objective will be to map the various approaches employing managed entry agreements whose aim is to facilitate access to innovative medicines. Based on the initial mapping, members could pursue the exercise by developing further exchanges of practices and knowledge sharing.

3. **Facilitating the supply in small markets**

   The objective will be to clarify the specific non regulatory bottlenecks for the access of medicines in small markets with all concerned parties with a view to defining possible approaches on pricing and reimbursement of medicines and in particular with regards to the processes of launching, distribution and procurement..

4. **Promoting a good governance for non- prescription drugs**

   The objective will be to identify the necessary elements to ensure informed and adequate uptake of medicines after a change of their classification from being subject to medical prescription to not subject to medical prescription. The members will in particular investigate the role of competent authorities, pharmaceutical companies, consumers and patients and healthcare professionals.

5. **Market access for biosimilars**

   The upcoming emergence of biosimilars may create new market dynamics. The objective of this project will be to define what the necessary conditions within the pharmaceutical environment are to ensure informed adequate uptake of biosimilars.

Membership

DG Enterprise and Industry will chair the platform.

The Member States and EFTA countries will be invited to nominate representatives from their relevant competent authorities in charge of pricing and reimbursement of pharmaceuticals.

The following stakeholders' organisations would be invited to take part:

- European Patients Forum – EPF
- Bureau Européen des Unions de Consommateurs - BEUC
- Standing Committee of European Doctors - CPME
- Pharmaceutical Group of the European Union – PGEU
- European Hospital and Healthcare Federation - HOPE
- Association Internationale de la Mutualité - AIM
- European Social Insurance Platform – ESIP
- European Federation of Pharmaceutical Industries & Associations - EFPIA
- European Generic medicines Association - EGA
- European Self-Medication Industry - AESGP
- European Association for Bioindustries - EuropaBio
- European Association of Full-Line Wholesalers – GIRP

Academics might be invited to contribute to the platform.

Experts involved in their personal capacity (academics or others) will be requested to disclose possible conflicts of interest prior to meetings.