Process on Corporate Responsibility in the field of Pharmaceuticals

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Process on Corporate Responsibility in the field of Pharmaceuticals

- After G10 process and High Level Pharmaceutical Forum: Momentum for collaborative initiatives
- Societal and Industrial drivers
- From projects to recommendations… 2 years to deliver outside the regulatory decision making
- Competent authorities, public and private stakeholders:
  - Will be invited to become members of the process
  - Will be offered to participate in projects on voluntary basis
Areas of focus

• Transparency and deontology in the sector
• Access to medicines in Africa
• Access to medicines in Europe, in the context of pricing and reimbursement
Project on Transparency and Deontology

- To exchange information and potentially achieve a common understanding in terms of best practices when it comes to access to medicines:
  - Relation between industry and competent authorities
  - Relation between industry and healthcare professionals
  - Relation between industry and patients
Projects on Access in Africa

- Facilitate reflection on the contribution of European companies, their added value and the challenges they face.

- By looking at the needs of the concerned countries, the platform should identify how stakeholders, and in particular industry, could contribute further.
Platform Access to medicines in Europe

- Pharmaceutical pricing and reimbursement policies fall within the competence of Member States. The principle of subsidiary applies in this field and must be fully respected.

- The platform will be dedicated to enhance collaboration in order to find common non-regulatory approaches to ensure timely and equitable access to medicines after their marketing authorisation.
Structure - Platform Access to medicines in Europe

Steering Group

- To generate **momentum** for effective development of its projects and put **forward experienced-based recommendations**.
- **DG ENTR** will chair the group in **close collaboration with ongoing Presidencies** of the EU. The meetings could be organised in conjunction to the biannual meetings of the network of pricing and reimbursement authorities.

Projects

- for **concepts to be developed and tested**.
- Should focus on **concrete experiences** and will explore **non regulatory conditions for better access** to medicines after their marketing authorisation.
- The organisations will **volunteer experts**.
Members invited in the Platform Access to medicines in Europe

- **Member States**
  Relevant competent authorities of 27 Member States and EFTA countries

- **Stakeholders from the public and private sectors**
  - 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
Projects on Access in Europe

Encouraging access to innovative treatments

- Mechanism of coordinated access to orphan medicinal products
- Capacity building on contractual agreements for innovative medicines
Projects on Access in Europe

A responsible environment for access

- Facilitating the supply in small countries
- Promoting a good governance for non-prescription drugs
- Market access for biosimilars