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 on going 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 n**on 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**