18th ERTC Workshop "Corporate Responsibility in Improving Access to OMPs"

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Process on Corporate Responsibility in the Field of Pharmaceuticals

- It consists of three Platforms:
  1. Access to Medicines in Europe (6 sub-groups)
  2. Access to Medicines in Africa and
  3. Ethics and Transparency

- Process launched by VP Tajani in September 2010

- All activities should be finalised by mid 2013

- Results to identify areas for further cooperation in our future industrial policy initiative (Commission Communication on Industrial Policy - October 2012)
Access to Medicines in Europe
6 Working Groups

1. Access to biosimilars
2. Co-ordinated access to orphan medicinal products
3. Managed entry agreements
4. Facilitating supply in small markets
5. Good governance for non-prescription medicinal products
6. Priority medicines
Working group Mechanism of coordinated access to orphan medicinal products (MoCA-OMP)

• Aim: find innovative ways to provide real access to orphan drugs for patients with unmet medical needs, for whom these solutions would otherwise be out of reach, in an affordable and sustainable way

• Three workpackages:
  - Assessing orphan medicinal products (Italy and EFPIA)
  - Organising a structural access (Spain and ESIP)
  - Organising the individual access (Belgium and Eurordis)
Working group Mechanism of coordinated access to orphan medicinal products (MoCA-OMP) – state of play

Report of the group being finalised:

• the group agreed on the added value of a coordinated mechanism involving all stakeholders and using a European TVF, in view of delivering a report on the value of an OMP;

• the group intends to propose an ad hoc taskforce with voluntary collaboration of EU/EEA countries and stakeholders.
Such a task force could help competent authorities to determine access conditions by:

- evaluating the unmet medical needs;
- coordinating the preparatory steps (incl. horizon scanning, early involvement in the development of clinical development plans and patient registries);
- testing the mechanism through a concrete pilot, applying a European TVF.
Future

Future industrial policy in the field of pharmaceuticals will take into account the results of all working groups, to address in a comprehensive approach the current challenges in order to strengthen the competitiveness of the European pharmaceutical sector.