



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

**Brussels, 27 February 2013**

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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.

## **Working group Mechanism of coordinated access to orphan medicinal products (MoCA-OMP) – state of play**

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.