What is DG Enterprise and Industry doing to foster the Competitiveness of the European Pharmaceutical Industry?

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What's the Situation like?

- The European Union (EU) is still was by far the major world trader in medicinal and pharmaceutical products, with total trade amounting to EUR 141 800 million.
- Despite the ongoing economic crisis, the value of exports increased by 11 % in 2009, and by 16 % in 2010 reaching thus more than EUR 93 800 million in that year.
- This amount represented around 66 % of total trade and indicated a trade surplus of EUR 45 800 million. As in the years before, also in 2010 the United States was the main trading partner for exports, accounting for almost one third of all extra-EU-27 exports of medicinal and pharmaceutical products.
- As for imports, Switzerland was the main trading partner in 2010 with a share of 38 % of all extra-EU-27 imports of these products.

What's the Situation like?

- Singapore is a typical example of an emerging economy climbing up the value chain. It is to be assumed that Singapore will become an exporter of high-value medicinal products destined for Europe and the US in the foreseeable future.

Commission's General Objectives

Commitment to developing and maintaining a favourable environment for medicinal products in the European Union which:

1. guarantees a high level of protection of public health;
2. contributes to the completion of the single market in pharmaceuticals;
3. fosters a stable and predictable environment for pharmaceutical innovation and competitiveness.

Commission's Responses

EU activities formulated in the Communication on "Safe, Innovative and Accessible Medicines: a renewed vision for the Pharmaceutical sector" aim at:

1. making further progress towards a single and sustainable market in pharmaceuticals;
2. taking on the opportunities and challenges of globalisation;
3. making industry responsible and deliver for European patients;
4. restoring the EU's role as the natural home for pharmaceutical innovation.

DG ENTR's Responses

- Legislative
- Non-legislative

Legislative

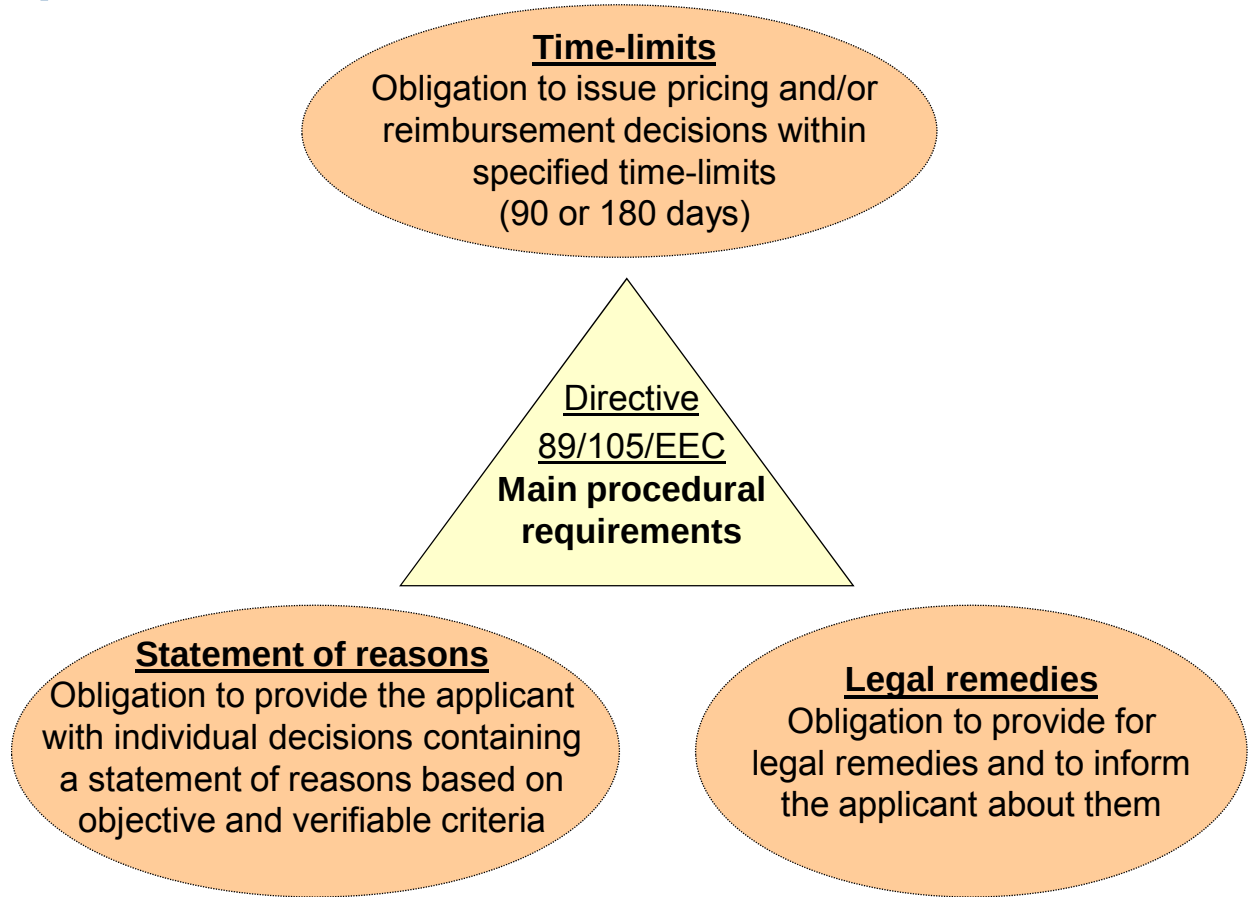
DIRECTIVE

relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

Context

- **Member States' competence** to organise national / regional health systems including pricing and reimbursement of medicines (Art. 168(7) TFEU)
- **Council Directive 89/105/EEC,** an internal market instrument **designed to facilitate the free movement of medicines (art 34-36 TFEU: no discrimination, no barrier, no distortion) in order to:**
  - contribute to **better patients' access to medicines**
  - **enhance the competitiveness of the pharmaceutical industry**

Main procedural requirements of current Directive 89/105/EEC



Rationale for the Revision of the Transparency Directive

- **Why ?**
  - Evolution of the pharmaceutical market (**Pharmaceutical Sector Enquiry**)
    - Increasingly complex/diverse pricing and reimbursement policies (innovative P&R procedures)
    - Significant disparities in time to market medicinal products
    - Excessive delays linked to P&R procedures (originators and generics)
  - Legal developments (**extensive interpretation by CJEU**)
    - Clarification of the scope of application
    - Interpretation in light of its objectives (effet utile)
- **How ?** The spirit of Directive 89/105/EEC is maintained (i.e. minimal procedural approach preserving the competence of Member States for the organisation of their health insurance system and pricing/reimbursement decisions)
- **What ?** The objective is to update the directive and improve its functioning and its effectiveness

Non-legislative

DG ENTR's Initiatives

- **Pharmaceutical Forum 2005-2008**: recommendations to ensure adequate balance between access to medicines, control of pharmaceutical expenditure and reward for innovation.

- Process created **momentum for collaborative initiatives** between stakeholders.

Process on Corporate Responsibility in the field of Pharmaceuticals

- After G10 process and High Level Pharmaceutical Forum: Momentum for collaborative initiatives.
- Competent authorities, public and private stakeholders.

What's going to be addressed?

Sept. 2010: V.P. Tajani launched stakeholder **Process on Corporate Responsibility in the field of Pharmaceuticals**

- **Access to medicines in third countries (focus on Africa)**
- **Access to medicines in Europe**
- **Ethics and Transparency**

Access to Medicines in Europe

- Objective: find **common, non-regulatory approaches** to ensure timely and equitable access to medicines after their marketing authorisation.
- Voluntary participation: Member States and representative organisations will volunteer experts for the projects
- Concrete projects to explore non regulatory conditions for better access to medicines after their marketing authorisation.
- Steering group to generate **momentum** for effective development of projects and put **forward experienced-based recommendations**.

Several workstreams…

- **… to encourage access to innovative treatments**

  1. Mechanism of coordinated access to orphan medicinal products
  2. Capacity building on contractual agreements for innovative medicines

- **… to promote a responsible environment for access**

  3. Market access for biosimilars
  4. Facilitating supply in small markets
  5. Promoting a good governance for non-prescription medicines
  6. Updating the WHO report "Priority Medicines"

Next Steps

- President Barroso underlined in his last State of the Union speech, on the 12th September, 2012, the pharmaceutical industry plays a significant role in contributing to the recovery of European economy growth and jobs (almost 2 % of total EU GDP).
- Communication "A Stronger European Industry for Growth and Economic Recovery – Industrial Policy Communication Update" of 10 October 2012. takes up this notion.

What does the Communication state?

- Commission points out that additional action is needed and announces a new "policy strategy agenda to strengthen the competitiveness of the pharmaceutical industry". The objective of the envisaged process is to secure the competitiveness and long-term viability of the EU pharmaceutical industry while ensuring the access to medicinal products for European citizens.

What does this Mean in Concrete Terms?

- Envisaged industrial policy should go beyond the ongoing work like the review of the Transparency Directive 89/105/EEC on pricing/reimbursement of medicinal products and the Process on Corporate Responsibility.

Comprehensive Approach

Comprehensive approach is needed addressing:

- distortions in the European internal market, notably stemming from diverging pricing and reimbursement practices in MS, and lately aggravated by the financial crisis and interim measures adopted in MS.
- the regulatory framework, which should ensure the development of a competitive European industry.
- issues related to the international dimension of competitiveness, i.e. ensuring a level-playing field in the international marketplace.