



**2<sup>nd</sup> Meeting of the Commission Expert Group  
on Safe and Timely Access to Medicines for  
Patients (STAMP)  
Brussels, 05.05.2015**

**The Network of Competent  
Authorities on Pricing and  
Reimbursement (CAPR)**

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## Treaty on the Functioning of the European Union (TFEU)

In accordance with Article 168(7) of the Treaty, Member States are responsible for the definition of their health policies as well as for the organisation and delivery of health services and medical care. **This includes measures regulating the prices of medicinal products and their inclusion in national health insurance systems.**



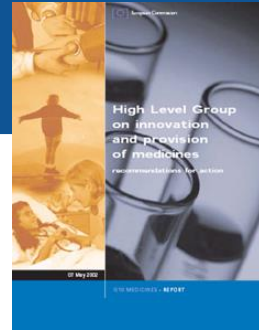
## The Commission's competence is restricted to

- initiate, amend and monitor the **implementation of legislation**
- organisational support and/or funding of **initiatives**, research, information tools, studies etc.
- support **cooperation and exchange of information** between Member States on prices and pricing policies



# Transparency Directive 89/105/EEC

- **Harmonisation as regards the transparency of measures regulating the pricing and reimbursement of pharmaceuticals**
- **Such measures should be based on objective and verifiable criteria and follow defined timelines.**
- **Commission to ensure that the current rules are fully complied with and that the existing problems related to the regulatory framework in place on pricing and reimbursement are appropriately addressed (via investigations and infringement procedures).**



# Pharma Forum (2008) and Process on Corporate Responsibility (2013)

- **Pharmaceutical Forum (2005-2008)**: high level ministerial platform adopted "Final conclusions & Recommendations".
- **Process on Corporate Responsibility in the Pharma Sector 2010-13**:
  - Objective: to **enhance collaboration** to find common non-regulatory approaches for more timely and equitable access to medicines after the Marketing Authorisation.
  - Focus:
    - Platform on Ethics & Transparency in the Pharma Sector.
    - Platform on Access to Medicines in Developing Countries.
    - Platform on Access to Medicines in Europe:
 

✓ Priority Medicines	✓ OTC
✓ Managed Entry Agreements	✓ Orphan Drugs
✓ Small Markets	✓ Biosimilars



All deliverables can be found at:

[http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process\\_on\\_corporate\\_responsibility/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/index_en.htm)





# CAPR



## The **Network of Competent Authorities on Pricing and Reimbursement** is

- an offshoot of the Pharmaceutical Forum (2005-2008) and has been installed during the Slovenian Presidency in 2008
- a platform offering the opportunity to **identify, share and discuss information, expertise and best practices/best policies** with other Member States on **high level issues** in the field of pricing and reimbursement of pharmaceuticals

# CAPR

- The Commission acts as a facilitator of these meetings providing administrative and financial support (grant agreement)
- Since 2008 fourteen meetings have been organised in Slovenia, France, Czech Republic, Sweden, Spain, Belgium, Hungary, Poland, Denmark, Cyprus, Ireland, Lithuania, Italy and recently in Latvia
- Register of Commission Expert Groups  
<http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2648>



## Many important topics of common interest have been tackled over the years in CAPR, e.g.

- cost-containment policies in times of economic crisis
- cost-management
- external reference pricing
- differential and value based pricing
- managed entry agreements
- generic substitution
- small markets and co-payment
- orphan drugs
- adaptive pathways
- collaboration between regulators, HTA bodies and payers





# CAPR meeting in Riga 16.-17.04.2015



# The future of CAPR

- Topics relating to pricing and reimbursement are more than ever high on political agendas
- Discussions take place in different political and technical fora, e.g. Working Party on Public Health at Senior Level, HTA, EUnetHTA, STAMP, PPRI
- There are 28 individual health systems with 28 different pricing and reimbursement policies
- The Commission emphasised the necessity of cooperation between authorities in its Staff Working Document of June 2014 (SWD(2014) 216 final/2): "Pharmaceutical Industry: A Strategic Sector for the European Economy\*"



## **Suggestions from the Working Party on Public Health at Senior Level (WPPHSL) (17.02.2015)**

*"The Network of Competent Authorities on Pricing and Reimbursement (NCAPR) could elaborate concrete pilot projects which could improve the access to valuable molecules by for instance limiting a multiplication of assessments, by testing and exploring pricing and financing models and by optimising data gathering."*



## CAPR has identified the

- paramount need for better co-operation between regulatory authorities and those being responsible for pricing & reimbursement (P&R) as well as to
- enhance mutual understanding and to learn from each other for the sake of improved access to medicines for patients



## CAPR will further discuss

- **how to be more strategic, integrated, concrete and accessible**



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**We intend to continue supporting financially, administratively and in any other possible way the organisation of the CAPR meetings and we look forward in engaging in close collaboration with future Presidencies as well as with other working groups.**





# THANK YOU