

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



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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
 - ✓ Managed Entry Agreements
 - ✓ Small Markets

✓OTC✓Orphan Drugs✓Biosimilars



All deliverables can be found at: <u>http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/</u> <u>process_on_corporate_responsibility/index_en.htm</u>



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









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 <u>high on political agendas</u>
- Discussions take place in <u>different political and</u> <u>technical fora</u>, 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 <u>necessity of</u> <u>cooperation between authorities</u> in its Staff Working Document of June 2014 (SWD(2014) 216 final/2): "Pharmaceutical Industry: A Strategic Sector for the European Economy*"

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmastrategy_en.pdf











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