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Subject : Draft Council conclusions on Innovation and Solidarity in Pharmaceuticals

Delegations will find in the Annex to this note draft Council Conclusions to be adopted by the Council (EPSCO) at its session on 7 December 2010.

DRAFT COUNCIL CONCLUSIONS

on

Innovation and Solidarity in Pharmaceuticals

THE COUNCIL OF THE EUROPEAN UNION:

1. **RECALLS** the Communication from the Commission of 10 December 2008 on Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector¹;
2. **RECALLS** its Resolution of 2 December 2003 "Pharmaceuticals and Public Health Challenges - Focusing on the Patients"²;
3. Further **RECALLS** its Conclusions of 22 September 2003 on Reinforcing The Competitiveness of the European-Based Pharmaceutical Industry³ and **REAFFIRMS** the need for a balance between competitiveness and public health policies;
4. **RECALLS** its Recommendation of 8 June 2009 on an action in the Field of Rare Diseases ⁴;

¹ COM(2008) 666 final

² OJ C20, 24.01.2004, p.2.

³ OJ C250, 18.10.2003, p.1.

⁴ OJ C 151, 3.7.2009, p. 7.

5. **RECALLS** the conclusions⁵ of the High Level Pharmaceutical Forum expressing a shared understanding that pricing and reimbursement policies of pharmaceuticals need to balance timely and equitable access, control of pharmaceutical expenditure and reward for valuable innovation within a competitive and dynamic market that also encourages research and development.
6. **RECOGNISES** that certain needs of patients remain unmet and that prioritisation of research investments based on criteria such as the debilitating impact of the disease on the patient and expected added value for the patients and for society is required;
7. **RECOGNISES** that Health Technology Assessment can be a relevant tool for assessing the relative efficacy⁶ and effectiveness⁷ as well as other relevant aspects of different health technologies, including medicinal products;
8. **NOTES** the problem analysis and recommendations expressed in the Commission's Communication on Europe 2020⁸, the Final Conclusions and Recommendations of the High Level Pharmaceutical Forum⁹, the reflections and recommendations contained in the various roadmaps for Joint Programming¹⁰ in the Health Sector (e.g. the Alzheimer roadmap¹¹), and **UNDERLINES** the need to continue to build on experience and expertise gathered together in initiatives that have already been put in place, such as the Innovative Medicines Initiative (IMI)¹², cooperation between Pricing and Reimbursement Authorities and in different research projects carried out under the seventh Framework Programme (FP7) 'Health'¹³;

⁵ <http://ec.europa.eu/pharmaforum/>

⁶ Relative Efficacy hereinafter means the extent to which an intervention does more good than harm under ideal circumstances, compared to one or more alternative interventions (source: Pharmaceutical Forum Topic "Core principles on relative effectiveness).

⁷ Relative Effectiveness hereinafter means the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of healthcare practice.

⁸ COM (2010) 2020 final

⁹ http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf

¹⁰ Towards Joint Programming In Research (European Commission, 15.07.2008)

¹¹ COM (2009) 379 final.

¹² <http://www.imi-europe.org/Pages/default.aspx>

¹³ http://ec.europa.eu/research/health/index_en.html

9. **WELCOMES** efforts to develop common and up-to-date knowledge and expertise in the assessment of innovative medicinal products, made within the context of cooperation networks between national HTA Agencies and the increasing collaboration between Competent Authorities for Medicinal Products and Pricing and Reimbursement Authorities;
10. **WELCOMES** the Commission's intention¹⁴ to consider a review of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems, in particular **CONSIDERING** the fact that since the implementation of that Directive new forms of pricing and reimbursement control mechanisms have been developed which are not clearly included within the scope of the Directive;
11. **DRAWS ATTENTION TO** the conclusions¹⁵ of the Conference on “Innovation and Solidarity in Pharmaceuticals” held in Brussels on 23 and 24 September 2010 and the background report “A call to make valuable innovative medicines accessible in the European Union”¹⁶, which contains recommendations for coordinated action to stimulate, measure and valorise pharmaceutical innovation.

CALLS UPON THE MEMBER STATES TO

12. Take initiatives to promote the rational and responsible use of valuable innovative medicinal products with regard to obtaining an optimal clinical outcome and an efficient management of expenditure (in terms of affordability, accessibility and sustainability), and to exchange best practice within existing networks of competent authorities utilising the input of relevant stakeholders, where appropriate.

¹⁴ http://ec.europa.eu/governance/impact/planned_ia/docs/2011_entr_005_national_health_insurance_en.pdf

¹⁵ http://www.health.belgium.be/eportal/Aboutus/eutrio/health/Innovation_and_Solidarity/index.htm?fodnlang=en

¹⁶ <http://presidency2010.famhp.be/public-documents/>

13. Further develop common methodologies for assessing core elements of relative effectiveness, in a way that permits an exchange of the information and knowledge gathered in these assessments between voluntarily cooperating Member States through collaboration frameworks established among the HTA bodies at EU level, e.g. the EUnetHTA.
14. Examine appropriate mechanisms for using the information and knowledge gathered in these assessments at Member State level.
15. Exchange information and experience on exceptional procedures aiming to improve early access and on procedures and methods used to allow access to specific indications in situations of unmet medical needs.

INVITES THE EUROPEAN COMMISSION AND THE MEMBER STATES TO

16. Take the initiative of updating the 2004 priority medicines report, in cooperation with WHO experts.
17. Continue to encourage the strengthening of coordination and prioritisation in the allocation of resources for pharmaceutical research to increase the probability of valuable innovations that meet unmet health needs, where appropriate through the development of partnerships.
18. Give priority to revising the clinical trials directive in dialogue with the European Parliament, with the aim of ensuring an improved regulatory framework for developing medicinal products and comparing alternative treatments with medicinal products in clinical research.
19. Avail themselves of the possibility of requesting post-marketing authorisation studies as foreseen in the recently revised legislation on pharmacovigilance¹⁷.

¹⁷ [Please insert reference to Directive 2010/.... amending as regards Pharmacovigilance Directive 2001/83/EC and Regulation/2010 amending as regards Pharmacovigilance Regulation (EC) No 726/2004.]

20. Use the results of cooperation between Member States to reduce, where feasible and appropriate, duplication of the assessments of relative efficacy and effectiveness as well as other relevant aspects of health technologies while respecting the principle of subsidiarity.
21. Continue to work on efficient ways to include information regarding relative effectiveness as early as possible in the development process of medicinal products, in parallel with, but clearly distinct from, the marketing authorisation process.
22. Foster dialogue with stakeholders on:
 - ethics and transparency in the sector,
 - access to medicines in Europe, and
 - access to medicines in developing countries, with a focus on Africa,particularly by cooperating in the process of corporate responsibility in the field of medicinal products.
23. Examine the possibility of enabling an efficient cross-border exchange of clinical data, and take appropriate initiatives to establish interoperable registries *e.g.* on rare diseases, while taking into account the directives on data protection and privacy.
24. Examine, based on the principles of solidarity, economically viable and efficient approaches to facilitate availability and access to valuable innovative medicinal products throughout the EU, while respecting the principle of subsidiarity and the competencies of Member States, *e.g.* on affordability and sustainability of health systems.

INVITES THE EUROPEAN COMMISSION TO

25. Support ongoing voluntary cooperation between Member States in Health Technology Assessment (HTA), including in the field of medicinal products.

26. Acknowledge in its forthcoming review of Council Directive 89/105/EEC the case law of the Court of Justice of the European Union, the ongoing development of innovative pricing and reimbursement mechanisms such as conditional pricing and reimbursement, contractual agreements, and specific procedures for early access.
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