Council of the European Union

PRESS
EN

**COUNCIL CONCLUSIONS**
Brussels, 1 December 2014

# Council conclusions on innovation for the benefit of patients

**Employment, Social policy, Health and Consumer affairs Council meeting**

**Brussels, 1 December 2014**

The Council adopted the following conclusions:

**"THE COUNCIL OF THE EUROPEAN UNION**

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, that Union action, which shall complement national policies, shall be directed towards improving public health, that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care and allocation of the resources to them;
2. RECOGNIZES that innovations in healthcare can contribute to health and well-being of citizens and patients through access to innovative products, services and treatments that have added value with regard to the existing ones and can also lead to more effective ways to organize, manage and monitor work within the health sector as well as to improve the working conditions for healthcare staff;
3. RECALLS the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
4. RECALLS the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;
5. TAKES NOTE that in order to stimulate development, there is a need to facilitate the translation of scientific advances into innovative medicinal products that meet regulatory standards, accelerate patients' access to innovative therapies with added value for patients and are affordable to the EU Member States' health systems;

6. TAKES NOTE that the EU pharmaceutical legislation already provides regulatory tools for the authorisation of medicinal products in order to meet unmet medical needs and facilitate timely access of patients to innovative treatments under certain circumstances and subject to certain conditions. Such mechanisms include “conditional” marketing authorisation, authorisation under “exceptional circumstances”, accelerated scientific review and compassionate-use programmes.

7. RECALLS that Regulation (EC) No 141/2000 on orphan medicinal products provides incentives for the development of medicinal products for rare diseases and resulted so far in the authorisation of a great number of such medicinal products and an equally important number of orphan designations.

8. RECALLS THAT the new Clinical Trials Regulation (EU) No 536/2014 aims to increase the EU’s competitiveness in clinical research and the development of new and innovative treatments.

9. NOTES THAT the Paediatric Regulation (EC) No 1901/2006 has contributed to better and safer research and more medicines for children on the EU market.

10. RECOGNISES that the development of innovative medicinal products is costly and time-consuming and includes risks; this may result in insufficient investment in research and development, thereby making it particularly difficult for smaller companies to bring innovative products onto the market;

11. RECOGNISES that early dialogue between technology developers, regulatory, health technology assessment (HTA) and, where relevant, pricing bodies may promote innovation and quicker access to medicines at affordable prices, to the benefit of patients;

12. RECALLS that Regulation (EC) No 1394/2007 on advanced therapy medicinal products is intended to ensure the protection of public health, the free movement of advanced therapies and the effective operation of the internal market in the biotechnology sector, whilst being innovation-friendly, proportionate and adapted to scientific progress;

13. TAKES NOTE of the ongoing European Medicines Agency’s "Pilot project on adaptive licensing";

14. TAKES NOTE of the Report from the Commission to the European Parliament and the Council in accordance with Article 25 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004[1];

15. RECALLS the Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, the Directive 93/42/EEC concerning medical devices and Directive 98/79/EC on in vitro diagnostic medical devices;

16. RECALLS the Council Conclusions on innovation in the medical device sector, adopted in 06 June 2011[2];

---

1 7310/14 - COM(2014) 188 final

2 OJ C 202, 08.07.2011

17. RECALLS the Council Conclusions on the reflection process on modern, responsive and sustainable health systems, adopted on 10 December 2013[3], and the Council Conclusions on the economic crisis and healthcare, adopted on 20 June 2014[4], which advocate the need for cooperation, while fully respecting areas of Member States' competence, on strategies to effectively manage expenditure on pharmaceuticals and medical devices, while ensuring equitable access to effective medicines within sustainable national healthcare systems;

18. NOTES WITH CONCERN that due to the very high prices of some innovative medicinal products in relation to their benefit to patients and to the public health expenditure capacities of some Member States, patients do not always have access to innovative treatments;

19. TAKES NOTE of the cooperation within the Network of Competent Authorities for Pricing and Reimbursement as well as the initiatives[5] for exchange of information and collaboration in the field of pricing and reimbursement facilitated by the European Commission between the competent national authorities and all relevant stakeholders, which may facilitate, inter alia, cost-containment, pharmaceutical innovation and patients' access to medicines;

20. TAKES NOTE that the European Union has supported cooperation on HTA since the late 1990s by co-funding projects and two Joint Actions (EUnetHTA I and II);

21. RECALLS that, while respecting the competencies of Member States, European cooperation on HTA can promote more consistent approaches to HTA as a health policy tool to support evidence-based, sustainable and equitable choices in healthcare and health technologies for the benefit of patients;

22. RECALLS that the objectives of the HTA Network[6] shall be to: i) support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short and long-term effectiveness, when applicable, of health technologies and to enable an effective exchange of this information between the national authorities or bodies; ii) support the analysis of the nature and type of information to be exchanged, and iii) avoid duplication of assessments;

23. UNDERLINES the importance of the strategy adopted by the HTA Network on 29 October 2014[7];

24. RECALLS the discussion in the Working Party on Public Health at Senior Level on cost effective use of medicines as part of the Reflection Process on modern, responsive and sustainable health systems.

---

3 OJ C 376, 21.12.2013, p.3 + Corrigendum OJ C 36, 7.2. 2014, p. 6

4 OJ C 2017,

5 Platform on access to medicines in Europe http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform_access/index_en.htm

6 COMMISSION IMPLEMENTING DECISION of 26 June 2013 providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment (2013/329/EU). OJ L 175/71, 27.6.2013.

7 http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

25. RECALLS the discussion at the Informal Meeting of Ministers of Health in Milan on 22-23 September 2014 on “innovation in health care for the benefit of patients”, which highlighted the need to support innovation for the benefit of patients with better use of the existing regulatory tools for marketing authorisation procedures and which highlighted the potential risks to the sustainability of some national health systems linked to very high cost pressures arising from some innovative products.

26. RECOGNISES that while these Conclusions mainly refer to medicinal products, given the specific nature of the sector, the same considerations regarding research and development and HTA are also applicable to medical devices, which play an equally important part in innovation for the benefit of patients.

**INVITES THE MEMBER STATES TO:**

27. Explore opportunities for cooperation on exchange of information between competent bodies in relation to a ‘life cycle approach’ for innovative medicinal products, including, where appropriate:

    (a) Early dialogue and scientific advice;

    (b) Pricing and reimbursement models;

    (c) Registries for monitoring the effectiveness of therapies and technologies;

    (d) Appropriate re-assessments;

    (e) Post-authorisation studies;

28. Implement the HTA strategy adopted by the HTA Network, taking into account national circumstances.

29. Increase the effective sharing of information on prices of and expenditure on medicinal products, including innovative medicinal products;

30. Continue to discuss and work further on innovations for the benefit of patients within the Working Party on Public Health at Senior Level, while recognising that a discussion on the relationship between the current legal framework for medicinal products and timely patient access to medicinal products has already started in the Pharmaceutical Committee.

**INVITES THE MEMBER STATES AND THE COMMISSION TO:**

31. Exchange views on how to make effective use of the existing EU regulatory tools of accelerated assessment, conditional marketing authorisation and authorisation in exceptional circumstances and on the effectiveness and impact of these tools while ensuring the high level of patient safety;

32. Discuss national initiatives for early patient access to innovative medicines and the possibility of increased information-sharing and cooperation in relation to compassionate use, so as to maximise the opportunities of patients across the EU to be supplied with innovative medicines;

33. Further enhance joint work on HTA;

34. Support collaboration between national regulators, HTA bodies, the European Medicines Agency and the HTA Network throughout the life cycle of the products, without compromising the independence and respective prerogatives of regulatory and HTA processes;

35. Use existing relevant fora to reflect on:

    a) possible developments in current national pricing policies and transparency from all relevant actors, including industry, on costs, that could contribute to increased availability and accessibility of innovative medicinal products to patients, while fully respecting that these are areas under Member States' competence;

    b) whether criteria are needed to take account of the added therapeutic value of new medicinal products in comparison with the existing ones for placing them on the market;

36. Continue the dialogue between stakeholders and competent authorities, including pricing and reimbursement authorities, and examine opportunities for potential cooperation on a voluntary basis in the field of pricing and reimbursement and facilitate the launching of pilot projects in that field;

**INVITES THE COMMISSION TO:**

37. Consider possible changes to the Regulation (EC) No 1394/2007 with a view to analysing and if necessary reducing regulatory burdens to increase incentives for SMEs and academia, while maintaining the principle of marketing authorisation based on quality, efficacy and safety;

38. Support the cooperation between Member States to implement the HTA strategy through a Joint Action under the third Programme for the Union's action in the field of health (2014-2020), while exploring options for continued and sustainable financing;

39. Propose measures to ensure the long-term sustainability of work on HTA, fully exploring all potential options, including considerations on how to make the best use of existing bodies which could facilitate cooperation, efficiency gains and scientific synergies;

40. While fully respecting the Member States' competencies, support the exchange of information between Member States on prices, pricing policies and economic factors determining the availability of medicinal products as well as, where appropriate, medical devices, with particular attention being paid to orphan medicinal products and small markets as they are particularly vulnerable to deferred or missed market launches, supply shortages and obstacles to achieving affordable prices of medicinal products;

41. Continue to support research and information tools that aim to provide a better understanding of how pharmaceutical pricing may be applied to maximise benefits for patients and Member States' health systems and, where relevant, to minimise possible unintended negative effects on patient access and health budgets."