IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COUNCIL

Council conclusions on Encouraging Member States-driven Voluntary Cooperation between Health Systems

(2017/C 206/02)

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 that Union action shall fully respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care as well as for the allocation of the resources assigned to them.

2. RECALLS that under Article 4(3) of the Treaty on European Union, the Union and the Member States shall, in full mutual respect, assist each other in carrying out tasks which flow from the Treaties, pursuant to the principle of sincere cooperation.

3. RECALLS the Communication from the Commission on effective, accessible and resilient health systems ([1]) which highlights the added value for Member States in further strengthening cooperation.

4. RECALLS the Council conclusions on the economic crisis and healthcare ([2]), adopted on 20 June 2014.

5. RECALLS the Council conclusions on investing in Europe's health workforce of tomorrow: Scope for innovation and collaboration ([3]), adopted on 7 December 2010.

6. RECALLS the Council conclusions on the Implementation of the EU Health Strategy ([4]), adopted on 10 June 2008, which amongst others, define the Working Party on Public Health at Senior Level as a forum for discussing major common strategic issues in health and strategic cooperation amongst Member States.

7. RECALLS the Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States ([5]), adopted on 17 June 2016.

8. RECALLS the Council Recommendation on an action in the field of rare diseases ([6]), adopted on 9 June 2009.

9. NOTES the Resolution of the European Parliament on Access to Medicines ([7]), adopted on 2 March 2017.

([1]) 8997/14 COM (2014) 215 final.
([2]) OJ C 217, 10.7.2014, p. 2.
([3]) OJ C 74, 8.3.2011, p. 2.
([4]) 16139/08.
([5]) OJ C 269, 23.7.2016, p. 31.
([6]) OJ C 151, 3.7.2009, p. 7.
([7]) European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI).

10. HIGHLIGHTS the importance that voluntary cooperation amongst Member States is encouraged in order to ensure continuity and sustainable and effective actions and to maximise the impact of the cooperation initiatives.

11. RECALLS Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare ([1]), and in particular Chapter IV thereof, relating to cooperation in healthcare.

12. Whilst REITERATING that health is valuable in itself, CONSIDERS that health systems deliver a wider social benefit that goes beyond human health protection and make a major contribution to social cohesion, social justice and economic growth.

13. CONSIDERS that strengthening European cooperation in selected areas can bring better outcomes for patients and health care professionals, whilst increasing the efficiency of health systems.

14. NOTES that 'health technology' means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare ([2]).

15. NOTES that reference herein to the term 'access to health technology' also incorporates the broader notions of procurement processes ranging from information gathering and sharing to purchasing and post-procurement monitoring, as well as pricing and reimbursement. This term is without prejudice to the implementation of Directive 2014/24/EU of 26 February 2014 on public procurement ([3]) and of Directive 2014/25/EU of the European Parliament and of the Council on procurement by entities operating in the water, energy, transport and postal services sectors ([4]).

16. CONSIDERS that quality of patient care is very important and that the health workforce is necessary to ensure high quality of care. Global shortages in the health workforce which seriously affect the capacity of the majority of the Member States, albeit to a higher degree in Central and Eastern Europe, may be tackled more effectively by increasing voluntary cooperation to improve the availability of skills and resources across the European Union.

17. REITERATES that cooperation between health systems involving Member States' competences should be exclusively Member State driven and voluntary in nature.

18. NOTES that voluntary cooperation between health systems may provide flexible structures adapted to the specific needs of the participating Member States, and that such cooperation may require the use of instruments defined by those Member States.

19. TAKES INTO ACCOUNT the differences that exist between health systems and the benefit of promoting rapid and efficient dissemination of innovative evidence-based practices.

20. NOTES that tackling the specific characteristics and challenges arising in the healthcare market for therapeutic innovations, in particular in the field of rare diseases, and the development of personalised medicine, may benefit from voluntary cooperation so as to ensure a balance between access, quality, affordability and sustainability of health systems.

21. NOTES that several Member States are engaging in models of cross-border and regional voluntary cooperation to improve access to health technologies and that valuable lessons may be learned from these experiences.

22. CONSIDERS that voluntary cooperation to improve access to health technologies is fully in line with common European values and principles.

23. NOTES that changes in health technology and market behaviour may require different approaches to improve access to health technologies than those applied in the past, amongst others through voluntary cooperation.

([1]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45.).

([2]) Point (l) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council.

([3]) Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

([4]) Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).

24. NOTES the demand from several Member States for increased voluntary cooperation between them, as a means of improving access to health technologies, including by:

— enhancing transparency through better sharing of information;

— enabling cross-country learning through sharing experience;

— strengthening bargaining power, particularly for smaller markets, through voluntary aggregation of demand;

— ensuring access to health technologies through cross-border exchange of information and products in short supply, especially in emergency situations.

25. NOTES that provision of highly specialised health care (HSHC) involves diagnosis, treatment and/or management of complex conditions with associated high costs, and can often only be provided by appropriately trained health professionals working within centres of expertise, thereby creating specific health workforce challenges.

26. NOTES that European Reference Networks (ERNs), when fully developed, present an opportunity for building capacity throughout Europe in the provision of specialised health services, in particular in the field of rare diseases, so as to ensure quality of care, and dissemination of knowledge and innovative practices.

INVITES THE MEMBER STATES TO:

27. Explore, through the exchange of information within existing relevant health fora, priority content areas and appropriate processes for the development of Member State-driven voluntary cooperation, as a way to increase the effectiveness, accessibility and resilience of their health systems, and to identify priority processes and product categories for which voluntary cooperation between the health systems of different Member States may add value as a means of ensuring greater affordability and better access to health technologies.

The discussions may also:

a) Explore the factors supporting and impeding voluntary cooperation to improve access to health technologies, within the context of health, which is a Member State competence;

b) Identify best practice frameworks for cross-border and regional voluntary cooperation to improve access to innovation, for those Members States willing to develop such approaches;

c) Explore solutions to increase the effectiveness of cooperation and to better anticipate the potential barriers to access, due to the emergence of new health technologies, including by actively contributing to joint horizon scanning;

d) Explore mechanisms for voluntary sharing of information in the post-marketing phase, with a view to evaluating the outcomes, including the impact, that adoption of innovative health technologies has on patients and on health systems;

e) Share information on criteria and processes used by Member States for disinvestment in health technologies that are no longer cost-effective;

f) Evaluate the progress made in the implementation of improved access to treatment for patients with rare diseases and chronic pain, while recognising the need to maintain a balance between innovation, availability, accessibility and affordability;

g) Explore areas in which voluntary cross-border collation of data and the development of common principles on data collection in compliance with data protection legislation [1] may provide added value, while fully respecting Member States' competences [2].

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, (OJ L 119, 4.5.2016, p. 1).

[2] Council conclusions on personalised medicine for patients, adopted on 7 December 2015 (OJ C 421, 17.12.2015, p. 2).

28. Identify areas of potential voluntary cooperation between Member States to strengthen and enhance the health workforce of the participating Member States, with a view to:

    a) Exploring possibilities and mechanisms for voluntary cooperation to enhance transfer of knowledge and skills and to further develop health workforce capacity;

    b) Making use of documented grassroots experience of voluntary cooperation in highly specialised healthcare to inform macro level policies, where appropriate;

    c) Promoting voluntary cooperation on ethical recruitment practices;

    d) Encouraging and supporting the generation of evidence on transferability of innovative practices, including voluntary cooperation, through structured mobility in highly specialised services, as a tool for disseminating innovative, high-quality health services.

29. Considering the existence of different information practices within the pharmaceutical market, and recognising the potential benefits of exchange of information between Member States on national pricing and reimbursement policies, share more information on and within pricing agreements relating to medicinal products on a voluntary basis, with a view to increasing transparency and improving the leverage of individual Member States in negotiations with industry and – consequently – enhancing the affordability of these products across the EU.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

30. Promote the acquisition of innovative and specialised skills for established professionals as well as post-graduate trainees through the implementation of voluntary cooperation activities between healthcare organisations geared to promoting better patient outcomes, continuity of care and strengthening of the health workforce.

31. Encourage the ERNs to attain their intended objectives of providing better access for patients requiring highly specialised healthcare, so that barriers to access are overcome and inequities between European citizens are reduced. This includes:

    a) Evaluating the readiness and capacity of ERNs to assume a role in highly specialised training and continuous professional development for health professionals, in particular through e-learning, e-training and short term exchanges to build health workforce capacity through ERN healthcare providers, and to develop their knowledge and expertise in diagnosis, treatment and care of patients;

    b) Reflecting on ways to stimulate innovative research on very rare diseases through ERNs, to pool evidence on the effectiveness of innovative technologies and to capture comparable and reliable data from interoperable patient registries, as well as other relevant information.

32. Facilitate and support the implementation of pilot projects for voluntary cross-border professional mobility as a means of building experience and the capacity to deliver innovative and highly specialised services, in collaboration with stakeholders, by building on the opportunities offered through existing structures.

33. Consider conducting a mapping exercise and reporting on voluntary national actions and voluntary European-level collaboration between Member States in the field of rare diseases in order to promote the exchange of best practices.

34. Examine the outcome of the evidence-based analysis of the impact of incentives on innovation, availability, accessibility and affordability of medicinal products, including orphan drugs.

35. Consider taking into account on a voluntary basis recommendations, best practices and outcomes based on the work carried out in relevant EU joint actions and expert working groups, and disseminating the results at various levels throughout the health system.

INVITES THE COMMISSION TO:

36. Facilitate a needs assessment, exchange and cooperation concerning cross-border post-graduate training and continuing professional development in the area of innovative and highly specialised services. In this regard, the mapping of the Continuing Professional Development in the EU (2014) [1] in consultation with Member States and the relevant European level stakeholder organisations, can be a valuable document to build on.

[1] https://ec.europa.eu/health/sites/health/files/workforce/docs/cpd_mapping_report_en.pdf

37. If requested by Member States, following submission of the needs assessment referred to in paragraph 36, reflect on the requirements for sustainable development and implementation of the options.

38. Inform the Council about the state of implementation of the Council recommendation of 8 June 2009 on an action in the field of rare diseases and on the follow-up to the Commission Communication of 11 November 2008 on rare diseases ([1]).

([1]) 15775/08 — COM (2008) 679 final.