OUTCOME OF THE COUNCIL MEETING

3737th Council meeting

Employment, Social Policy, Health and Consumer Affairs

Health

Brussels, 9 December 2019

President Krista Kiuru
Minister of Family Affairs and Social Services
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1 • Where declarations, conclusions or resolutions have been formally adopted by the Council, this is indicated in the heading for the item concerned and the text is placed between quotation marks.
• Documents for which references are given in the text are available on the Council's internet site (http://www.consilium.europa.eu).
• Acts adopted with statements for the Council minutes which may be released to the public are indicated by an asterisk; these statements are available on the Council's internet site or may be obtained from the Press Office.
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ITEMS DEBATED

HEALTH

Economy of Wellbeing – next steps in investing in health as its key component - public debate

On the basis of a presidency discussion paper (14303/19), ministers held a discussion entitled 'Economy of Wellbeing – next steps in investing in health as its key component'. They shared their views on the following questions:

– When developing concrete measures to advance the Economy of Wellbeing approach, what actions are needed to ensure a strong health-policy input while fostering cross-sectoral dialogue at EU level?

– More specifically, what critical elements should an EU mental health strategy include to best support the member states’ efforts?

– In the context of demographic change, what kind of actions should be put in place to promote active and healthy ageing, and to encourage prevention and anticipation-based ageing policies?

– Looking at the years to come, how could the member states and the Commission work towards the creation of a European Health Data Space through current and new initiatives to enable better use of health data in care, public health and research to benefit the wellbeing of all?

The debate followed on from the exchange of views on 24 October when the EPSCO Council also adopted conclusions on the economy of wellbeing. Those conclusions address several topics, some of which are related to health policy.

The focus of the discussion was on mental health, healthy ageing and the digital transformation of health and social services. Ministers agreed that national policies in these areas had to be supported by measures and policies at EU level, including through various EU programmes and data sharing. The debate highlighted the importance of raising mental health awareness, ensuring prevention and early intervention and improving mental health literacy. Participants agreed on the need to develop and implement an EU mental health strategy as well as a European health data space. The debate also highlighted the need to make health care systems more adapted to the digital age and to invest in technology, because of rapid digitalisation. The crucial role of cross-sectoral approaches and of cooperation at all levels was also stressed.

1 Council conclusions on the Economy of Wellbeing
European pharmaceutical policy – strengthened cooperation and coordination with the aim to improve access to medicines - public debate

Ministers held a debate on how to strengthen cooperation and coordination with the aim to improve access to medicines throughout the EU. The exchange of views was steered by a presidency discussion note (14307/19) setting out the following questions:

– What concrete measures could Member States and the Commission take to ensure access to both old and new medicines for national healthcare systems and patients, and to avoid problems caused by shortages?

– One of the reasons for shortages and supply disruptions is that the medicines’ supply chain has become longer, more complex and fragmented as companies have located a large part of production of medicines outside the EU. In order to ensure a reliable supply, is there a need to call for EU legislative measures to require back-up manufacturing capacity, earlier notification of interruptions and stronger measures to ensure continuity of supply? In your view, would this help reduce the risk of supply disruptions and shortages?

– Strengthened cooperation between Member States and related coordination of activities, such as monitoring, could contribute to mitigating the problems related to shortages of medicines and the sustainability of budgets. How could such cooperation be further strengthened?

The aim of the debate was to discuss solutions to the recurrent problem of securing access to medicinal products in the EU. Many delegations supported the idea to develop and implement an EU work agenda on pharmaceutical policy to avoid medicines shortages across the Union. The debate highlighted several possible measures to ensure easier access to medicinal products:

– encouraging the relocation of medicines production back to the EU

– transferring medicines from one member state to another with some exemptions concerning the requirements on the information accompanying the products concerned

– exchanging information on stocks

– using early warning mechanisms

– intensifying market surveillance

– strengthening cooperation at EU level
Any other business (09/12/2019)

1. The presidency informed ministers about the current work on the Regulation on health technology assessment and amending Directive 2011/24/EU (14619/19)

2. The Commission provided information about the state of health in the EU (14714/19)

3. The Commission also provided information on the state of play of the implementation of Regulation (EU) 2017/745 on medical devices and of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

4. Ministers were briefed on the outcomes of conferences organised by the Finnish presidency (14738/19)

5. The incoming Croatian presidency presented its work programme in the area of Health
OTHER ITEMS APPROVED

INTERNAL MARKET AND INDUSTRY

Amendment of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response*

The Council decided not to object to a Commission regulation concerning the amendment of regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures as regards information relating to emergency health response.

The regulation amends the wording of certain requirements for the submission of information relating to emergency health response and for the inclusion of a “unique formula identifier” in the supplemental information provided on the label of a hazardous mixture with a view to achieving for a more streamlined interpretation of these requirements, to improve internal coherence and to mitigate some unintended consequences. It also defers the first compliance date from 1 January 2020 to 1 January 2021 in order to allow sufficient time to develop the necessary solutions and make any necessary changes to the new rules.

The regulation is a delegated act pursuant to article 290 of the Treaty on the Functioning of the EU. It can now enter into force, unless the European Parliament objects.


The standards provide temporary exemptions to the hedge accounting requirements of International Accounting Standard (IAS) 39 Financial Instruments: Recognition and Measurement and International Financial Reporting Standard (IFRS) 9 Financial Instruments so that companies can continue to meet the requirements.

The Commission regulation is subject to the regulatory procedure with scrutiny. This means that now that the Council has given its consent, the Commission may adopt the regulation, unless the European Parliament objects.
TRANSPARENCY

Public access to documents

On 4 December 2019, the Council approved the reply to confirmatory application No 34/c/02/19 (13555/19).

On 4 December 2019, the Council approved the reply to confirmatory application No 36/c/01/19 (13650/19).

On 4 December 2019, the Council approved the reply to confirmatory application No 37/c/02/19 (13656/19).

ENERGY

EU position in the Energy Community

The Council decided on the position to be taken on behalf of the European Union in the Ministerial Council of the Energy Community and in the Permanent High Level Group of the Energy Community. The meetings will take place in Chisinau on 12 and 13 December 2019.

More information on the meetings on the website of the Energy Community.

FISHERIES

Opening of negotiations for a Sustainable Fisheries Partnership Agreement and Protocol with Denmark and Greenland

The Council decided to adopt a decision authorising the opening of negotiations with the Government of Denmark and the Government of Greenland for a sustainable fisheries partnership agreement (SPFA) and a protocol setting out the fishing opportunities and the financial contribution.

The SPFA was originally signed in 2007 and then extended. The current protocol was signed in 2015 and will expire at the end of 2020.

Both the agreement and the protocol need to be renegotiated to cover certain provisions of regulation 1380/2013 and establish fishing opportunities and financial contribution applicable as of 1 January 2021.
Corruption - special UNGASS session

The Council approved its contributions to the preparations of the special UNGASS session against corruption to be convened in the first half of 2021. These include in particular the contribution to the outcome document and the key elements of the EU UNGASS statement.