



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 20 June 2012

10790/12

**SAN 141
PHARM 45**

NOTE

from:	Presidency
to:	Council
Subject:	EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS COUNCIL MEETING ON 22 JUNE 2012

Results in the field of health during the Danish Presidency
- *Information from the Presidency*
(Other business item)

Delegations will find annexed an information note from the Presidency on the above-mentioned subject.

**Results in the field of health during the Danish Presidency
EPSCO (Health)
22 June 2012**

The Danish Presidency identified three main priorities in the field of health: the innovation agenda ‘Smart Health – Better lives’, chronic diseases with diabetes as a model and antimicrobial resistance (AMR).

Smart Health – Better Lives

Health and welfare technology has the potential to strengthen patient empowerment, improve quality and efficiency of care and thereby improve the quality of life of patients. At the same time, it can promote better use of resources and create favourable working conditions for the employees in Europe’s comprehensive public and private healthcare sectors, thereby continuously making healthcare smarter. This is crucial in a time of economic constraint and growing demographic pressure on European health systems.

The legislation regulating the European healthcare sector on both European and national level has significant impact on the scope for innovation. The same can be said for the methods applied in determining the use and dissemination of new technologies. Governing healthcare is governing innovation and vice versa.

Under the headline ‘Smart Health – Better Lives’, the Presidency has worked towards improving the room for innovation and the use of new technology in healthcare by raising awareness of the key question of how to create favourable conditions for innovation and how to make innovation a helpful tool in answering the substantial challenges facing tomorrow’s European health systems.

During the *Informal Meeting of Ministers for Health on 23-24 April 2012 in Horsens*, Ministers discussed how to promote favourable conditions for innovation – in both a national and a European setting – while keeping constant focus on patients’ needs and safety and on the effective use of resources. This also included a discussion of the role of Health Technology Assessment (HTA) and the future cooperation in the voluntary network on HTA established under the Directive on Patients’ Rights in Cross-border Healthcare (2011/24/EU). There was a general understanding of the important role played by EU legislation such as the Directives on medical devices and Good Clinical Practice and of the potential added value in the future cooperation on the assessment of new technologies – but also of the need for social and cultural innovation in healthcare alongside technological innovation.

The *eHealth Week 2012* included the *High Level eHealth Conference 2012* on 7-9 May 2012 in Copenhagen organised in cooperation with the Commission. The conference focused on “Smart Health – Better Lives” and the potential of eHealth in improving patient empowerment. The eHealth Task Force report ‘Redesigning Health in Europe for 2020’ was subject to a debate among Health Ministers, the European Commission and other high level representatives from the EU Member States, EFTA and EU candidate countries. The report focuses on how to achieve a vision of affordable, less intrusive and more personalised care by sharing the patient’s health data among the healthcare providers and with the patient. The report was published in May 2012 and

the European Commission will implement the relevant recommendations in the proposed eHealth Action Plan to be launched in the fall of 2012. The eHealth Week 2012 also included the first meeting of the eHealth Network established under Directive 2011/24/EU where a multiannual work programme was presented.

In November 2011 the Commission presented its' *Proposal for a Regulation of the European Parliament and the Council establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020*. The specific objectives of the proposed programme include the aims to contribute to innovation and sustainability of European health systems as well as to increase access to better and safer healthcare. Based on the discussions during the Danish Presidency, the proposal will be presented to the Council (Employment, Social Policy, Health and Consumer Affairs) on 22 June 2012 with a view to a partial general approach.

Chronic Diseases

The growing challenge of chronic diseases demands a broad approach ranging from population directed health promotion and disease prevention to the care for the individual person who already suffers from one or more chronic conditions. This is also the approach within the framework of the European reflection process on Innovative approaches for chronic diseases in public health and healthcare systems which was launched in December 2010 and is expected to be finalized in 2013.

At the *Informal meeting of Ministers for Health* on 23-24 April 2012, Ministers discussed patient empowerment focussing on principles and actions to support the self-management capacity of the patient. The debate showed broad agreement on the potential of 'patient empowerment' as a tool in the management of chronic diseases. Patient empowerment can increase life expectancy, enhance quality of life and give the patient more independence and autonomy. At the same time, Ministers pointed to potential pitfalls, such as the risk of increasing inequalities in health as a result of a more patient centered approach. Ministers agreed that patient empowerment is a key component in the ongoing European reflection process aiming to identify options to optimize the response to the challenges of chronic diseases.

Chronic diseases and the role of patient empowerment were also addressed during the *High Level eHealth Conference 2012* on 7-9 May 2012 in Copenhagen mentioned above.

The Presidency inaugurated the *European Year for Active Ageing and Solidarity between Generations 2012* with a conference in Copenhagen on 18-19 January 2012. The Conference focused on how innovation can bring new solutions to future challenges of an ageing society in Europe within the fields of employment, health and social affairs. The conference addressed how patient and citizen empowerment can contribute to the future of health and social care in Europe.

Antimicrobial Resistance (AMR)

Antimicrobial Resistance (AMR) does not respect national borders, and the rising level of resistance due to the increased use of antibiotics in both humans and animals is a challenge for most European countries. Building on the results already achieved under previous Presidencies, the Danish Presidency considered it important to keep the issue high on the agenda in the EU.

The Presidency's approach was to focus on promoting a more prudent and rational use of antibiotics and on strengthening and improving the surveillance of the use of and resistance to antibiotics. The Presidency also highlighted the need to reduce the use of antibiotics in both humans and animals, including in particular a decrease in the use of critically important antimicrobials (CIA's).

The conference: *Combating Antimicrobial Resistance – Time for Joint Action* took place on 14 - 15 March 2012 in Copenhagen. The conference was organised in close collaboration between the Danish Ministry of Health and the Danish Ministry of Food, Agriculture and Fisheries. The conference was co-financed by the European Commission, Directorate General Health and Consumers (DG SANCO).

The conference focused on the increasing global threat of antimicrobial resistance and the use of antimicrobials from a 'One Health' perspective and had the aim of exchanging best practices, raise awareness of the microbial threat and motivate Member States and stakeholders to instigate joint action. General information, materials and discussions from the conference are summarised in the conference report, which is available at the Presidency web-site: www.eu2012.dk/en

The Presidency prepared a set of council conclusions which focus on a prudent use of antimicrobials. The conclusions are in line with the Commission's strategy on Antimicrobial Resistance (AMR) from November 2011.

The conclusions invite the Member States to develop and implement national strategies or action plans for countering AMR, which among other things include national guidelines on the treatments with antimicrobial agents, to limit the use of critically important antimicrobials and to raise awareness among the public and professionals on the subject.

The Council conclusions will be presented for adoption at the meeting of the Council (EPSCO) on 22 June 2012.

Pharmaceuticals

In the area of pharmaceuticals, three legislative proposals were discussed during the Danish Presidency:

Information to the general public on medicinal products

In October 2011 and February 2012 the Commission presented its amended proposals for a Directive and a Regulation amending Directive 2001/83/EC and Regulation (EC) No. 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription.

In view of the widespread scepticism among Member States towards these proposals originally presented in December 2008, the Presidency decided to explore possible ways of taking the proposals forward through bilateral consultations with Member States. Eventually, bilateral consultations were carried out with 24 delegations. The Presidency was not able to identify common ground between Member States.

On request of the Presidency, the Committee of the Permanent Representatives on 23 May 2012 took note of the fact that there is no possibility to obtain a qualified majority in the Council in favour of adopting Common Positions based on these proposals¹.

Pharmacovigilance

The Commission proposals for a Directive and a Regulation amending Directive 2001/83/EC and Regulation (EC) No. 726/2004 as regards pharmacovigilance were presented in October 2011 and February 2012 with the aim to strengthen transparency and the reporting requirements in case of safety concerns about a medicinal product on the market. The proposals have been examined during the Polish and Danish Presidencies in the Working Party on Pharmaceuticals and Medical Devices.

After two informal trilogues on 7 and 19 June 2012, the Council reached an agreement at first reading with the European Parliament on these proposals. The political agreement is subject to formal approval by the European Parliament, the Commission and the Council.

Transparency Directive

The Commission proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems was presented in March 2012. The initial examination of the proposal has taken place in the Working Party on Pharmaceuticals and Medical Devices during the Danish Presidency.

Working Party on Public Health at Senior Level on 8 February 2012

The eighth meeting of the Working Party on Public Health at Senior Level was held on 8 February 2012². The agenda of the meeting consisted of four items:

Reflection process on Innovative approaches for chronic diseases in public health and healthcare systems

There was a general support to continue common work on chronic diseases. It was stressed that existing EU mechanisms should be used and duplication must be avoided, including in respect to the WHO. It was agreed to establish a "drafting group" led by the Commission and with the participation of the current (PL/DK/CY) and the future (IE/LT/EL) Trio Presidencies. The "drafting group" will submit a report to the Working Party's meeting in October 2012 under Cypriot Presidency focussing on two main elements:

- Health promotion and disease prevention with innovative methods and use of social media
- Chronic disease management and good practices exchange with the use of modern IT technologies, e.g. via Internet platforms.

¹ 10067/12 PHARM 38 MI 346 SAN 112 ECO 65 ENT 128 CODEC 1339

² 7311/12 SAN 47 (Outcome of Proceedings)

The role of the EU in international health fora

Delegations agreed that the Working Party should discuss strategic issues related to the WHO and expressed readiness to actively take part in discussions on WHO priorities setting. The need was stressed to avoid duplication with coordination taking place in Geneva. There was general support to the Presidency's suggestion to exchange information on EU candidacies for WHO governing bodies at global and regional level and to increase information exchange and consultations among Member States on matters related to WHO EURO.

The Commission informed delegations about its cooperation with the WHO Regional Office for Europe based on the Joint Declaration.

Reflection process - Towards modern, responsive and sustainable health systems

The Working Party decided to divide the sub-group 3 on "Adequate responses to society's growing and changing health needs and efficient and effective design of health sector investments" into two separate sub-groups on Cost-effective use of medicines (Coordinator: Netherlands) and on Integrated care models and better hospital management (Coordinator: Poland).

It was noted that the five sub-groups are now ready to start their work and that some of them were already in progress. All coordinators will by the end of August 2012 present a written status report (including timeframe, milestones and expected results) to be discussed at the next Working Party's meeting in October 2012 and possible input to the December 2012 Council (EPSCO) will be considered by the Cypriot Presidency.

The EU Health Strategy

The Commission gave an update on recent activities and informed about the state of affairs of Joint Actions co-financed from the Public Health Programme in 2008-2012.

The next meeting will be held on 3 October 2012 under Cypriot Presidency.
