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OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
Subject:	Working Party on Public Health on Senior Level on 17 February 2015

INTRODUCTION

The 14th meeting of the Working Party on Public Health at Senior Level (WPPHSL) held since the adoption of the Council Conclusions on the Implementation of the EU Health Strategy[1] was chaired by Ms Solvita Zvidrina, State Secretary, Ministry of Health, Latvia.

1. ADOPTION OF THE AGENDA

The provisional agenda for the meeting as set out in document CM 1096/1/15 REV 1 was adopted, with point 2.3 being taken at the beginning of the meeting. No ′Other business item′ was requested.

[1] 16139/08

2. COOPERATION ON HEALTH SYSTEMS

2.3. Health systems, economic crisis and sustainable public financing for health in Europe

Dr Hans Kluge, Director, Division of Health Systems and Public Health of the World Health Organisation Regional Office for Europe presented the results of the study "Economic crisis, health systems and health in Europe: impact and implication for policy"[2] elaborated by WHO Euro and European Observatory on Health Systems and Policies. In particular, he pointed the study's main findings and policy lessons as set out in chapter 9 of the summary of the study.

The Working Party noted the presentation and findings of the study.

2.1. Progress reports on cooperation towards effective, accessible and resilient health systems

The Commission informed the WPPHSL about the recent and forthcoming developments in the EU agenda on Health System based on 3 pillars set out in the Commission's Communication on effective, accessible and resilient health systems[3]:

- ***Strengthening effectiveness***
  - Co-operation in the area of HSPA in the framework of the HSPA Expert Group established in September 2014;
  - Patient safety and quality of care: follow-up to the Council Conclusions on patient safety and the quality of care[4];
  - Integration of care: European Innovation Partnership on Active and Healthy Ageing;
- ***Increasing accessibility***:
  - Planning of EU health workforce: Joint Action on health workforce planning and forecasting;
  - cost effective use of medicines: study on enhanced cross-country coordination in the area of pharmaceutical product pricing to be delivered by the end of 2015;
  - optimal implementation of the Directive 2011/24 on patient rights in cross-border healthcare;

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2 The summary is available at: http://www.euro.who.int/en/about-us/partners/observatory/publications/policy-briefs-and-summaries

3 8997/14 (COM(2014)215)

4 2014/C 438/05, OJ C 438, 6.12.2014, p. 7-11

- ***Improving resilience***
  - Health Technology Assessment (HTA): implementation of the Strategy for the EU cooperation on HTA[5] via the forthcoming 3rd Joint Action on HTA;
  - Health information systems: strengthening the health information system in consultation with the Expert Group on Health Information (EGHI);
  - e-health: Adoption of the ePrescription Guidelines (Nov 2014); new Joint Action on eHealth; deployment of two digital services: ePrescription and Patient Summary.

The Swedish delegation presented a progress report on the work of the HSPA Expert Group. The terms of reference for this group (co-chaired by Sweden and the European Commission) were agreed in September 2014. Since then, 2 experts meeting were convened. The works are now focusing along 2 main thematic strands dealt with by 2 dedicated sub-groups on the quality of care and the integrated care. An aim is to set up a forum for systematic exchange of views on HSPA. To that end, a dedicated web-based platform will be created.

The Belgian delegation presented a progress report on Joint Action on Health Workforce Planning and Forecasting. The Joint Action already brought up some tangible results, which will be presented in detail at the upcoming Plenary Assembly of the Joint Action on March 23rd and 24th in Madrid.
Belgium invited the WPPHSL to hold a more in-depth discussion on Health Workforce at the next meeting in July, based on the Joint Action results.

Delegations welcomed the presentation, underlining that data quality is of utmost importance in the context of HSPA and the work undertaken by the expert group shall not overlap with other initiatives in this area (e.g. work done by the OECD). Some delegations reiterated that co-operation on HSPA shall be carried out on voluntary basis.

The Working Party took note of the progress reports related to the work on health systems and expressed appreciation for the work accomplished so far by the stakeholders.

[5] HTA Strategy was adopted by the EU HTA Network on 29 October 2014

2.2. Cooperation with the Social Protection Committee under the European semester process: contribution of the Working Party on Public Health at Senior Level to the EPSCO Council conclusions on the Annual Growth Survey (AGS);

The Chair welcomed Ms Muriel Rabau, Vice-Chair of the Social Protection Committee (SPC). Ms Rabau presented a positive assessment of the consolidation of cooperation between the SPC and WPPHSL and called for its further strengthening. She noted that this was also reflected in the revised SPC mandate. The WPPHSL view on the Annual Growth Survey (AGS) 2015 will be for the first time directly integrated in the spring EPSCO Council. The joint SPC-WPPHSL session on the implementation of 2014 CSRs and adoption of new 2015 CSRs shall be held in April and June 2015 respectively.

The Chair shared the positive assessment of the cooperation between the two structures.

Delegations expressed their support for the continuation of the co-operation between the SPC and the WPPHSL. The Working Party approved the following text to be inserted in the draft Council Conclusions on AGS 2015 to be submitted to the EPSCO Council on 9 March 2015 for approval:

"Innovation in health care and long term care should focus on ensuring universal and equitable access to quality and safety in health services while securing their affordability, sustainability and cost-effectiveness. These innovations may include strengthening of health promotion and disease prevention in all relevant policy sectors, while ensuring integrated health care, enhancing primary health care, early diagnosis, optimising use of specialists and hospital care and securing an appropriate and skilled health workforce.

This may also include making better use of eHealth, Health Systems Performance Assessment and health technology assessment (HTA), while ensuring stable and continuous health financing."

2.4. Innovation for the benefits of patients

The Chair introduced the Presidency's paper (doc. 5511/15) related to the follow-up to the Council Conclusions on innovation for the benefit of patients adopted on 1 December 2014[6], in which Latvia and the next four Presidencies (LU, NL, SK and MT) invited the WPPHSL to continue steering the political discussions issues identified in the Council conclusions that can be clustered in three areas: broad range of aspects in the "pharmaceutical chain", which can be divided into three areas: (1) market access, (2) HTA, pricing and reimbursement and (3) prices of and expenditures on medicinal products, with the focus on innovative medicines.

Belgium submitted a non-paper proposing to transform the Working Group on cost effective use of medicines into a Working Group on innovation for the benefit of the patients, that could:

– develop of a horizon scanning on high cost specialized medicines challenges;
– insure guidance and governance of concrete pricing and reimbursement pilots based on the experience of the MoCA project (Mechanism of Coordinated Access to Orphan Drugs) aimed at fostering equal access to medicines;
– identify opportunities and barriers for coordinated action (especially regarding to information exchange, e.g. registries).

In addition, the Network of Competent Authorities on Pricing and Reimbursement (NCAPR) could elaborate a concrete pilot projects which could improve the access to valuable molecules by for instance limiting a multiplication of assessments, by testing and exploring pricing and financing models and by optimizing data gathering.

[6] 2014/C 438/06 (OJ C 438, 6.12.2014, p. 6)

Delegations in general welcomed the continuation of the discussion on innovation for the benefits of patients as proposed by the Presidency. Delegations also took note of the Belgian proposal, but stressed that any discussions shall be without prejudice to Member States' competencies, that they shall take place using existing fora, such as Pharmaceutical Committee, Network of Competent Authorities on Pricing and Reimbursement ('NCAP') or Commission Expert Group on Safe and Timely Access to Medicines for Patients ('STAMP'), and the participation of Member States shall be voluntary.
As other possible topics for consideration, the following has been mentioned by different delegations:

– prevention of shortages of medicines supply;
– market failures for treatment of dementia and development of AMR;
– re-export of medicines;
– EU level exchange on HTA;
– 'fair' pricing of medicines;
– cost/value ration for new medicines;
– reference pricing;
– 'therapeutical value' of innovative medicines;
– high prices of some medicines.

Luxembourg informed that it will organised a high level conference on innovative medicines on 8 July 2015 in Luxembourg.

The Commission expressed its readiness to support the discussions within the scope of its competence.

The Working Party invited the incoming Presidencies to continue the work in more detailed manner and define specific items for discussion by the WPPHSL at the forthcoming meetings.

3. THE EU HEALTH STRATEGY: UPDATE ON ACTIVITIES AND DEVELOPMENTS RELATED TO THE EU HEALTH STRATEGY

The Commission briefly reported on recent and forthcoming developments related to:

– the legislative files: implementation of Tobacco Products Directive, 50 years of EU Pharmaceutical Regulation - conference on 28 September 2015 in Brussels;
– cooperation on different topics, such as EIP on active and healthy ageing, health determinants (alcohol/nutrition); diseases: cancer, dementias, rare diseases; health information systems; health threats: Joint Procurement Agreement (JPA), Ebola, Anti-Microbial Resistance; Health Policy Forum;
– financing (Health Programme 2014-2020).

Some delegations expressed concerns about the timetable for adoption of delegated or implementing acts to be adopted according to the Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products ('Tobacco Products Directive'), which according to those delegations may pose a problem for timely transposition of the Directive. The Commission explained that the adoption of implementing or delegated acts should not slow down the transposition of the Directive by the Member States. Nevertheless, the Commission would, together with Member States, look into options how to speed up the process of their adoption while respecting all necessary procedural requirements and deadlines.

The Working Party took note of the information provided by the Commission.

4. THE ROLE OF THE EU IN INTERNATIONAL HEALTH FORA

The Presidency gave a debriefing on the 136th session of the WHO Executive Board (EB) that had taken place in Geneva between 26 January and 3 February 2015, the Executive Board special session on the Ebola emergency that took place on 25 January 2015, and the representation of the EU Member States in WHO governing bodies both at global and regional level.

The Presidency briefed also on preparations for the 68th World Health Assembly (WHA) on 18-26 May 2015. The agenda of this meeting will be charged i.a. with discussions on the draft air pollution resolution (not agreed at the 136th Session of the EB), the outcome of consultation process on the WHO engagement with non-State actors foreseen to take place between the EB and the WHA, and on the future of the global strategy and programme on access on medicines and intellectual property.
Attention was paid to two major global processes on health during 2015: management of the outbreak of the Ebola Virus disease and the place of health in the context of the post-2015 Development Agenda.

Delegations underlined that the EU co-ordination in Geneva has considerably improved, enabling the EU to pursue its agenda in much more efficient manner. Some important issues like lessons learned from the Ebola Crisis or Anti-Microbial Resistance were taken up as requiring a particular attention in the context of the EU role in the international fora.

The Working Party took note of the information[7] provided by the Presidency and confirmed that the EU positions on the EB agenda points and resolutions remain valid with a view to the preparation of the 68th WHA in May 2015.

5. TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP (TTIP): UPDATE ON ACTIVITIES AND DEVELOPMENTS RELATED TO HEALTH

The Commission informed about the current state of negotiations between the EU and the USA on TTIP, in particular on issues related to the health sector that are being discussed[8]:

- Pharmaceuticals - mutual recognition of each other's inspections of manufacturing plants carried out by the in the EU, the US and in third countries based on 'Good Manufacturing Practices', convergence of systems for the authorisation of biosimilars, strengthening co-operation on generics;
- Cosmetics - the US applies stricter regulation to over the counter cosmetics that treated as pharmaceuticals;

[7] 5512/15
[8] See also: http://ec.europa.eu/trade/policy/in-focus/ttip/

- On Sanitary and phytosanitary measures (SPS) the EU wants:
  - to set up a formal dialogue on animal welfare with US government regulators in order to promote the highest standards of animal welfare possible;
  - that the EU is recognised as a single entity for trade purposes, i.e. a single approval process for exports from all EU countries;

TTIP is not going to change the EU regulatory frameworks GMOs or growth hormones in livestock farming.

- Medical devices - the EU objective is that EU and the US regulators work better together to ensure faster access to life-saving devices, streamlining approval procedures and have better procedures for monitoring and recalling medical devices when necessary.

The Commission stressed that there public services are not subject to negotiations and the EU governments will remain free to decide what they consider to be public 'utilities' or services. It has also been clarified that pricing and reimbursement of medicinal products will not be affected by TTIP.

The Working Party took note of the information provided by the Commission. The Commission shall be invited regularly to give an update on TTIP negotiations.