Council of the
European Union

Brussels, 27 July 2016
(OR. en)

11351/16

SAN 298
SOC 469

OUTCOME OF PROCEEDINGS

From:	General Secretariat of the Council
To:	Delegations
Subject:	Working Party on Public Health at Senior Level on 15 July 2016

INTRODUCTION

The 17th meeting of the Working Party on Public Health at Senior Level (WPPHSL) was chaired by Mr. Boris Bánovský, General Director of Health Policy, Ministry of Health of the Republic of Slovakia.

1. ADOPTION OF THE AGENDA

The provisional agenda was adopted[1] with no additional 'Any other business' items.

2. COOPERATION ON HEALTH SYSTEMS

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

The Director-General of DG SANTE, Mr Xavier Prats Monné, informed the WPPHSL about the new developments in the EU agenda on health systems based on three pillars - strengthening effectiveness, increasing accessibility and improving resilience - as set out in the Commission's Communication on effective, accessible and resilient health systems[2].

1 CM 3107/16
2 8997/14 (COM(2014)215)

Several delegations raised concerns about the need for steering role of the Member States in initiatives concerning health systems, as well as the duplication of efforts at national and EU level; in that context was mentioned also the work of Social Protection Committee (SPC) and the preparation of the social protection performance monitoring (SPPM) report.

The Presidency informed about the departure of Ms Olivia Wigzell, Director General of the National Board of Health and Welfare of Sweden, from the position of the co-chair of the expert group on Health System Performance Assessment (HSPA) and her replacement by Dr Daniel Reynders, the Head of the International Relations Service, the Ministry of Health of Belgium. Some delegations expressed concern on the transparency of the procedure for selection of the new Vice-Chair of the expert group on HSPA. It has been explained that an expert group has been informed about the change and the necessity to ensure the continutiy of work. All Member States which took the floor expressed their appreciation to the work done by Sweden as co-chair of the HSPA expert group and confirmed their support and engagement in its work. On behalf of the WPPHS, the Chair thanked Olivia Wigzell for her commitment and work accomplished. The Chair concluded that in the future the selection of new the vice-chair by the expert group shall be better communicated in advance of the WPPHSL meeting.

The WPPHSL took note of the information from the Commission, the selection Dr Daniel Reynders as a new co-chair of an expert group on HSPA and the interventions of delegations.

2.2 State of Health in the EU

The Commission informed delegations on its new initiative - the "State of Health in the EU". It will consist of analytical products, established in partnership with the OECD and with the European Observatory on Health Systems and Policies, to support Member States in their efforts for better knowledge and stronger evidence-based policy making. It comprises four deliverables and builds on existing data and knowledge thereby avoiding additional burden on Member States.

The first deliverable will be a revised "Health at a Glance: Europe", to be published in November 2016, prepared by the OECD in cooperation with the Commission. The second will be a set of twenty-eight individual country health profiles developed by the OECD and the Observatory in cooperation with the Commission (foreseen for November 2017), providing complementary data and indicators, and emphasising the particular characteristics and challenges for each Member State. The third will be the Commission analysis of the twenty-eight country health profiles linking them to the broader EU agenda (also foreseen for November 2017). Finally, these three deliverables will allow for a voluntary exchange of best practice between the Member States to discuss concrete aspects of their respective country situations (it can be launched as of November 2017).

Several delegations took the floor and welcomed the initiative, underlining however that it shall be conducted strictly within the limits of Article 168 TFEU, avoiding duplication of work (e.g. with the OECD) and processes (e.g. JAF) and the Member States should be consulted on data used to ensure their correctness and validity.

The WPPHSL took note of the information provided by the Commission.

2.3 EU Joint Action on Health Workforce

The Belgian delegation presented the work and outcomes of the Joint Action (JA) on Health Workforce Planning and Forecasting, underlining the necessity to address its sustainability in the future. The JA has already achieved tangible results, notably in the area of forecasting workforce needs, anticipating future skill needs in the health professions and sharing good practice on effective recruitment and retention strategies for health professionals. The JA is coming to an end and there are several lessons to be learned from its outcomes, demonstrating how the EU cooperation can deliver added value. The main recommendation for the future is to further co-operate on applied research on data, mobility, labour market, economic drivers and on skills of the health workforce.

Some delegations participating in the JA praised the JA and highlighed that it is important to ensure the sustainability of its outcomes given the great impact of workforce planning for the future of the MS health systems. Commission mentioned the follow up action put in place through the Health programme 2016 and invited MS to a further dialogue in order to find long term sustainable solutions which would not rely on the health programme financing.

The Working Party took note of the information provided by Belgian delegation and expressed appreciation for the work accomplished.

2.4. Availability of human medicines in the European Union

The Presidency introduced the subject, focusing on the questions outlined in the doc. 10144/16 submitted to delegations before the meeting. It was also emphasized that on 17 June 2016 the Council (EPSCO) adopted Conclusions on Strengthening the balance in the pharmaceutical systems in the EU and its Member States[3], inviting, among others, the Member States to consider development of exclusively Member States driven voluntary cooperation between relevant authorities and payers from Member States and to explore possible areas in which such voluntary cooperation can contribute to higher affordability and better access to medicinal products[4].

Delegations in general welcomed the debate on this subject and considered that the availability of human medicines is an important topic. The comments were mainly on the following issues:

- a need to take closer look at various causes of shortages and ways to address them;
- production shortages and ways/incentives to avoid them;
- limits of a possible regulatory intervention and ways to reinforce exceptional regulatory status of pharmaceuticals;
- possible action at national level (e.g. planning adequate stocks, especially for critical medicines);
- need to exchange best practices about the national management /regulatory measures on medicines shortages;
- parallel export and ways to restrain it;
- lack of a definition of “shortages of medicines” or “unavailability of medicines” nor of “critical and / or irreplaceable medicines”;
- potential work fora and databases; role of European Medicine Agency (EMA) (e.g. establishing a web based platform where individual marketing authorization holders could “feed” in data about shortages due to manufacturing/ Good Manufacturing Practice (GMP) issues));

[3] OJ C 269, 23.7.2106, p.26.
[4] 10315/16, point 33.

– Joint Procurement Agreements (JPA) as a way to prevent medicine shortages - delegations were generally sceptical to use JPA as a general solution for shortages, although it could be considered for very specific products; the role of regional and cross-border co-operation between Member States and joint negotiations were also mentioned;
– relevance of the involvement of the stakeholders in the identification of the medicines shortages;
– a possible system for exchange of medicines lacking in some Member States but available in larger quantities in others.

The Commission acknowledged the complexity of the issue and expressed its willingness to support Member States, stressing however that at this stage it would be premature to change the regulatory framework what could lead to unintended effects. The Commission reminded that even in the existing regulatory framework, the Member States can impose certain restrictions (e.g. to curb parallel trade), as long as they are justified and proportionate (not going beyond what is strictly necessary).

The Chair concluded that the initial exchange of views on this topic will serve as a basis for the preparation by the Presidency of the debate at the Informal Meeting of the Ministers of Health in Bratislava on 3-4 October 2016.

3. Towards the end of tuberculosis in the European Region

The Presidency presented its document 10145/16 and suggestions contained therein, namely (1) to develop a comprehensive integrated EU Policy Framework addressing Tuberculosis, HIV/AIDS and Hepatitis C, (2) to broaden the scope of the Member States' HIV/AIDS Think Tank as well as HIV/AIDS Civil Society Forum to include TB and Hepatitis C, (3) to establish cooperation in the field of evaluation of cross-border measures and (4) to strengthen political collaboration at the highest political on TB and MDR-TB with countries from the Eastern Neighbourhood.

Delegations in general welcomed the fact that Presidency put the issue of MDR-TB on the agenda, especially because it is linked to the problem of antimicrobial resistance (multidrug resistant tuberculosis being a typical example of how AMR develops and how dangerous it is). A number of Member States supported the establishment of the integrated EU Policy Framework addressing Tuberculosis, HIV/AIDS and Hepatitis C. Hepatitis B, and possibly other diseases, should be added to such a framework. Member States also supported broadening of the scope of HIV/AIDS Think Tank and HIV/AIDS Civil society forum to include TB and Hepatitis B and C.

The co-operation with Eastern Neighbourhood countries where this problem is persistent as well as targeting risk groups is of utmost importance, so is an effective addressing co-morbidity and investing in MDR-TB research.

The Chair noted the support for further work on MDR-TB, espcially for the 'Integrated EU Policy Framework' and concluded that this discussion will feed into the debate at the informal meeting of the Health Ministers in Bratislava on 3-4 October 2016.

4. THE EU HEALTH STRATEGY: UPDATE ON ACTIVITIES AND DEVELOPMENTS

The Commission updated the WPPHSL on the main developments related to the EU Health Strategy, highlighting the following:

– Chronic Diseases: international objectives in UN and WHO, actions with EU added value called for by Member States and stakeholders at the conference on chronic diseases in April 2016; new joint action on chronic diseases in 2017 (27 countries, 5 million Euro co-funding) - focus on health promotion and integrated care;
– Joint procurement agreement: state of play: 23 MS signed and approved, 1 MS has signed and is ratifying, 2 MS are preparing the approval/ratification, 2 MS will not participate; on-going procedures include: personal protective equipment, BCG vaccine and Tuberculin; Diphtheria and Botulinum anti-toxins, pandemic vaccines;
– AMR: external evaluation of EU AMR Action Plan 2011-2016 completed in May 2016; UNGA special session on AMR – 16 September 2016;

– Tobacco Products Directive (TPD): implementation by the Commission is on track, 18 Member States have notified the transposition of TPD (9 complete + 9 partial notifications);
– Scientific Committees: new organisation (merger) of work of the Committees on Consumer Safety and on Health, Environmental and Emerging Risks;
– EU Health Policy Platform: launched on 21 April 2016 with 3 thematic networks already open.

To question by several MS on the patient safety expert group, the Commission responded that its intention is to focus more on the work on AMR and hospital acquired infections.

The WPPHSL took note of the information provided by the Commission.

5. THE ROLE OF EU IN INTERNATIONAL HEALTH FORA

5.1. EU in international health fora.

The WPPHSL took note of the information provided by the Presidency in document 10146/16.

5.2. AMR in the global context including the UN General Assembly

The WPPHSL was informed about the preparatory work underway in New York in the run up to the High Level meeting on AMR to be held in the margins of United Nations General Assembly in September 2016. It is important that given its expertise and political commitment, the the EU and its Member States will ensure a global commitment to this issue at the highest political level and work for the ambitious outcomes of the High Level meeting. The recently adopted Council conclusions[5] provided basis for the EU input.

[5] OJ C 269, 23.7.2106, p.26.

There was support from several MS, which refered to the findings of the recently published "Review on AMR" by Jim O'Neill [6]. Delegations underlined the need for the EU to lead the way in the area of combating AMR and speak in a single voice during the upcoming High Level Meeting on AMR in New York. In that context expectations were raised about the Commission's new Action Plan on AMR.

6. ANY OTHER BUSINESS

None.

---

[6] See, Review on AMR by Jim O'Neill, May 2016: http://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf