



Brussels, 31 July 2015  
(OR. en)

11039/1/15  
REV 1

SAN 240  
SOC 462

## OUTCOME OF PROCEEDINGS

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From: General Secretariat of the Council  
To: Delegations  
Subject: Working Party on Public Health on Senior Level on 15 July 2015

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## INTRODUCTION

The 15th 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 was chaired by Ms Anne Calteux, Senior Political Advisor - EU Coordination, Ministry of Health, Luxembourg.

### 1. ADOPTION OF THE AGENDA

The provisional agenda for the meeting<sup>1</sup> was adopted. No 'other business' items were requested.

### 2. COOPERATION ON HEALTH SYSTEMS

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

The Commission informed the WPPHSL about the new developments in the EU agenda on health systems. As usual, the information was based on the three pillars set out in the Commission's Communication on effective, accessible and resilient health systems<sup>2</sup>:

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<sup>1</sup> CM 2997/15

<sup>2</sup> 8997/14 (COM(2014)215)

- ***Strengthening effectiveness***
  - Cooperation in the area of HSPA<sup>3</sup>: the Expert Group has met three times since its establishment in September 2014 (10 November 2014, 6 February and 5 May 2015)<sup>4</sup>; the next meeting will take place on 9 October 2015;
  - Integrated care: a HSPA subgroup on integration of care has been established following the HSPA meeting on 6 February 2015 to share knowledge and report on performance assessments of integrated care in 2016; there has been a scaling up of good practices in the European Innovation Partnership on Active and Healthy Ageing (an online repository of innovative practices is under development).
  
- ***Increasing accessibility:***
  - Planning the EU health workforce: the Joint Action on health workforce planning and forecasting is delivering results in its final year (end of Joint Action: June 2016); the report on Effective Strategies for Recruitment and Retention of health professionals has been published recently (July 2015);
  - Cost-effective use of medicines: a study on enhanced coordination between Member States in the area of pharmaceutical product pricing is under preparation and its final delivery is planned by the end of 2015;
  - Implementation of Directive 2011/24/EU on patient rights in cross-border healthcare: the check by the Commission on Member States' transposition is nearly completed and the Commission's report to the Council and EP is planned for September 2015; the first call for European Reference Networks will be launched by the end of 2015; a study on better cross-border cooperation for high-cost capital investments in health is to be published by March 2016.

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<sup>3</sup> HSPA - Health Systems Performance Assessment

<sup>4</sup> [http://ec.europa.eu/health/systems\\_performance\\_assessment/policy/expert\\_group/index\\_en.htm](http://ec.europa.eu/health/systems_performance_assessment/policy/expert_group/index_en.htm)

- ***Improving resilience***

- **Health Technology Assessment (HTA)**: the HTA Network adopted a paper on 'reuse of joint work in national HTA activities' to complement the Strategy for EU cooperation on HTA<sup>5</sup>; preparation of the EUnetHTA Joint Action 3 is ongoing with the Member States (EUR 12 m budget for 2015-2019);
- **eHealth**: the eHealth Digital Services Infrastructure (eHDSI) will create conditions for the deployment of ePrescriptions and Patient Summary in cross-border care and will support the functioning of European Reference Networks (ERNs) to be established in accordance with Article 12 of Directive 2011/24/EU; the eHDSI will be supported by EUR 15 m from the Connecting Europe Facility; there was a kick-off meeting for the new Joint Action supporting the eHealth Network (JAseHN) at the end of May 2015 and the action will run until the end of 2018.

The Commission also informed the meeting about the renewal (as of spring 2016) of the mandate for an expert panel on effective ways of investing in health. Some delegations inquired about the mandate, working methods and added value of the expert panel. It was also suggested that its functioning should be evaluated before deciding on a renewal of the mandate. The Commission informed that the expert panel is an advisory body to the Commission established under Commission Decision 2012/C 198/06, which provides it with an independent, scientific and non-binding advice<sup>6</sup>.

The WPPHSL took note of the information provided by the Commission and comments by delegations.

The Chair concluded that the Presidency would come back to questions raised by delegations at an appropriate forum.

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<sup>5</sup> The HTA Strategy was adopted by the EU HTA Network on 29 October 2014

<sup>6</sup> [http://ec.europa.eu/health/expert\\_panel/index\\_en.htm](http://ec.europa.eu/health/expert_panel/index_en.htm)

## 2.2 Cooperation with the SPC under the European Semester

The Chair welcomed Ms Muriel Rabau, Vice-Chair of the Social Protection Committee (SPC) and underlined the effective cooperation between the WPPHSL and SPC in the 'second phase' of the European Semester, namely (1) WPPHSL contribution to the Council Conclusions on the social and employment aspects of the Annual Growth Survey (beginning of March), (2) 'joint WPPHSL -SPC review' of the implementation of the country-specific recommendations in the area of health (April) and (3) 'joint consideration' of new proposals for country-specific recommendations in the area of health (end of May - June).

The Chair introduced two proposals for joint SPC-WPPHSL work in the 'first phase' of the European Semester, namely (1) the WPPHSL contribution to the health-related chapter of the annual SPC report on recent social policy reforms (October/November) and/or the possible future Joint Employment and Social Report<sup>7</sup> and (2) the WPPHSL contribution to the SPC thematic review of health policy reforms (as identified by the Social Protection Performance Monitor) to be conducted by the SPC in November 2015 and focusing on access to healthcare.

The SPC Vice-Chair clarified that the SPC thematic review of health policy reforms with a focus on access to healthcare was selected by the SPC because access to healthcare is considered by the SPC as part of the social situation and social protection policies that it is called upon to monitor pursuant to Article 160 of the TFEU. Furthermore, the work on access to healthcare should counter-balance the focus on cost-effectiveness and sustainability under which healthcare systems reforms are assessed under the European Semester. The WPPHSL's involvement and the participation of representatives of health ministries in this debate is welcomed.

Delegations supported ongoing cooperation with the SPC with respect to the 'second phase' of the European Semester, as well as further WPPHSL involvement in its 'first phase', as set out above. It was underlined that the Member States should ensure adequate representation of the 'health' sector at SPC meetings.

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<sup>7</sup> As proposed in the five presidents' report entitled 'Completing Europe's Economic and Monetary Union' published on 1 July 2015

The Chair stressed the importance to increase cooperation and coordination with the SPC to enhance adequate representation of health in the 'Europe 2020' Strategy and the European semester, as stated in the work programme of the WPPHSL. The Chair concluded that the WPPHSL endorsed the further deepening of cooperation with the SPC in relation to the 'first phase' of the European Semester.

### **2.3 Innovation for the benefit of patients: Follow-up to the Council conclusions**

As a follow-up to the conclusions of the WPPHSL meeting on 18 February 2015, the Presidency, in close cooperation with the BE, NL, MT and SK delegations, prepared a discussion paper setting out concrete actions to support the implementation of the Council conclusions on innovation for the benefit of patients adopted on 1 December 2014<sup>8</sup>. The future work will be based on three basic principles:

1. respect of Member States' competence for organising health systems, including the pricing and reimbursement of medicinal products;
2. voluntary participation by Member States in any activity proposed;
3. work within existing structures.

The WPPHSL should be a forum that will steer activities and ensure synergies with ongoing work.

Large majority of Member States intervened on this topic, nearly all of them reiterating the subsidiarity principle and the need to respect exclusive competence of the Member States, in particular as regards the pricing and reimbursement of medicinal products.

Most of the Member States supported the content of the document as a comprehensive basis for future work. On the other hand, some Member States asked that its content should be further discussed by the WPPHSL. A few Member States asked for deletion of point related to "development of joint approaches on pricing and access schemes". A few also expressed reservation about the involvement of the Commission in elaboration of a "long-term integrated approach", because issues to be covered fall under Member States' competence.

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<sup>8</sup> OJ C 438, 6.12.2041, p.12

The Chair reconfirmed that what was proposed was a 'Member States-led process', in which the Commission would play a supportive role in accordance with Article 168 of the TFEU. The Chair suggested that the document shall be seen as a general basis for future discussions to be conducted under incoming Presidencies, allowing for flexibility as concerns the concrete modalities of further voluntary cooperation. Participation of Member States is voluntary and the "roadmap" outlines ongoing as well as possible activities that will be prioritized by incoming Presidencies. It should be kept in mind that the WPPHSL received a mandate from the Council to discuss and work further on innovation for the benefit of patients.

A number of Member States pointed out the importance of the financial sustainability of health systems and the need to find the right balance between accessibility of innovative medicinal products, taking into consideration ethical issues linked to fast access to innovative medicines, and sustainability of healthcare systems. Several stressed the need to work further on the definition of innovation, notably as regards its therapeutic added value.

A number of Member States specifically supported work on medicine shortages.

The Commission expressed its readiness to support the work of the Member States.

The Chair concluded that:

1. no activity would have any impact on the competence of Member States which is clearly laid down by the TFEU;
2. the impact of high medicine prices on Member States' health budgets, the therapeutic added value of innovative medicines and the sustainability of Member States' health systems should be also reflected in future activities;
3. incoming Presidencies will use document 9869/15, in particular the roadmap in the Annex, and the remarks expressed by the Member States during the discussion to guide their work.

### 3. The EU Health Strategy: update on activities and developments

The Commission briefly reported on recent and forthcoming developments, namely:

- the third EU Health Programme 2014-2020: the Annual Work Plan for 2015 was adopted on 2 June 2015 (call for project proposals by 15 September); the 2013 implementation report has been published; the preparation of the mid-term evaluation (to be submitted in autumn 2015) is ongoing; the ex-post evaluation of the second PHP has been finalised and the report will be submitted soon;
- Substances of Human Origin: implementation reports (on blood, tissues and cells) are being prepared and should be submitted to the Council and the EP in due course.
- Tobacco Products Directive: the Commission referred to the recently published Special Eurobarometer 429 on attitudes towards tobacco, to the stakeholder consultations on the feasibility study for an EU system for traceability and security features are ongoing (to July 2015) and the fact that ten implementing acts will have to be adopted by May 2016 (e.g. on labelling, ingredients, e-cigarettes).
- Health Investments: The Commission highlighted the possibilities of using European Structural and Investment Fund (ESIF) in support of health systems in EU Member States, including the guide for effective use of ESIF in health and a toolkit accompanying the guide<sup>9</sup>.

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

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<sup>9</sup> See: <http://www.esifforhealth.eu/>

#### 4. The EU's role in international health fora

After the presentation by the Chair of the recent health related activities in international health fora, the Finnish representative, in her capacity as Chair of the Standing Committee of the WHO Regional Committee for Europe, informed the Working Party about the preparations for the Regional Committee for Europe meeting in Vilnius in September 2015. 'The promotion of intersectoral action for health' will be one of the main issues on the agenda. Under the agenda item 'Partnerships for health', cooperation with the European Commission will be discussed. The final documents for the meeting will be available soon.

Concerning the elections to WHO Governing bodies, the Standing Committee has developed the nomination process, for which criteria have been clarified. One new feature is the letter of intent from the nominating Member States, to ensure commitment. A shortlist for nominations was drafted in May by the Standing Committee and the applicants have already been informed.

The WPPHSL took note of the information<sup>10</sup> provided by the Presidency and the Finnish representative.

#### 5. Transatlantic Trade and Investment Partnership (TTIP): update on health-related activities and developments

The Commission (DG Trade) informed the meeting about the current state of negotiations between the EU and the USA on TTIP and the 10th round of negotiations on 13-17 July 2015.<sup>11</sup>

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<sup>10</sup> 9870/15

<sup>11</sup> See: [http://ec.europa.eu/trade/policy/in-focus/ttip/documents-and-events/index\\_en.htm#\\_documents](http://ec.europa.eu/trade/policy/in-focus/ttip/documents-and-events/index_en.htm#_documents)



On issues related to the health sector, the Commission stressed the following:

- public services: TTIP will fully preserve the right of public authorities to choose the manner in which they deliver and run the public services offered to their citizens, especially education, health and social services. Public services are not subject to negotiations and EU governments will remain free to decide what they consider to be public 'utilities' or services<sup>12</sup>.
- pharmaceuticals: there is not yet a legal text to be discussed. During the preparatory work the possibility of reinforcing regulatory cooperation between EU and US was highlighted, in particular the mutual recognition of good manufacturing practices (GMP) for inspection purposes, biosimilar approval, streamlined authorisation systems for generics, a review of requirements for paediatric authorisations as well as cooperation on joint assessment approaches. The pricing and reimbursement of medicinal products will not be affected by TTIP;
- medical devices: work is focusing on unique device identification (UDI) and regulatory product submission.
- cosmetics: This area more difficult to negotiate due to different regulatory approaches, whereby several products classified as cosmetics in the EU are classified as over-the-counter drugs in the USA.

More detailed information on the different sectors can be found on the 'EU negotiating texts and factsheets' web page of DG TRADE<sup>13</sup>.

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

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<sup>12</sup> <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1115>

<sup>13</sup> <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1230>