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From:	General Secretariat of the Council
To:	Delegations
Subject:	Working Party on Public Health at Senior Level on 12 February 2018

The 20th meeting of the Working Party on Public Health at Senior Level ("WPPHSL") was chaired by Ms. Zlatimira Dobreva, the Presidency representative responsible for Healthcare, Pharmaceutical Products and Medical devices at the Permanent Representation of the Republic of Bulgaria to the European Union.

1. ADOPTION OF THE AGENDA

The provisional agenda was adopted as set out in document CM 1203/18.

2. HEALTH AT THE EU LEVEL – FUTURE PERSPECTIVES

The Chair briefly introduced the Presidency background note intended to serve as a basis for the discussion[1]. In that note, the Presidency, against the background of the ongoing debate on the future of Europe, initiated through the publication in March 2017 of the Commission White Paper[2], sets the goal to explore the possibility for a Member State driven agenda in the area of health.

1 Doc. 5431/18.
2 Doc. 6952/17.

The Commission representative welcomed this timely debate on **Health at the EU level** stressing that health should not be seen as an isolated sector as it is of horizontal importance for helping the EU to achieve its key objectives. After drawing the attention to the important contribution of the *acquis*[3], when properly implemented, to advancing health in the EU, he stressed that the decisive criterion when deciding on future action at EU level should not be the intrinsic importance of the issue - all health issues being important - but whether an "EU added value" could be identified. In order to get a better understanding of which tools have been truly useful for the Member States a number of assessments are currently undertaken by the Commission:

- the Mid-term evaluation of the 3rd Health programme 2014-2020[4];
- a consultation open until 9 March 2018 on EU funds in the area of investment, research and innovation, SMEs and single market[5];
- an upcoming impact assessment of the Health Programme.

As examples of actions with "EU added value" the Commission representative mentioned:

- EU assistance to Member States in co-ordinating economic, social and fiscal policies with resilient, effective and accessible healthcare systems[6] as one of its goals;
- that no other Region in the world has organised an exchange and transfer of best practises comparable to that that takes place between Member States with support from the EU budget;
- the European Reference Networks[7] that support research for better diagnosis and new treatments of rare diseases for which critical mass is a key factor; also here Europe could become a global player;
- e-Health as part of the Digital Market, which requires standards to achieve interoperability among the national systems and cybersecurity;
- the Steering Group on Prevention and Promotion[8], set up to support Member States in reaching international health targets.

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3 In particular the legislation on medicinal products and medical devices, on tobacco control, on cross-border healthcare and on serious cross-border threats to health.

4 Doc. 13147/17 + ADD1 + ADD 2.

5 https://ec.europa.eu/info/consultations/public-consultation-eu-funds-area-investment-research-innovation-smes-and-single-market_en.

6 He recalled that about 15% of public expenditure goes to healthcare.

7 https://ec.europa.eu/health/rare_diseases/european_reference_networks_en

8 https://ec.europa.eu/health/non_communicable_diseases/steeringgroup_promotionprevention_en

Referring to the upcoming negotiations on the Multiannual Financial Framework (MFF) and recalling the small size of the EU health budget (about 1 € per citizen to be used over several years) the Commission representative finished by once again stressing the need for "EU added value" in the actions to be selected for the future.

Most delegations shared the view that cooperation in the health policy area is **of great importance for the EU**. Some delegations in addition stressed that health is one of the areas that illustrate how EU action is in the interest of citizens; actions in the health sector can bring Europe closer to citizens. On the other hand, some delegations emphasised that the organisation of healthcare services falls within national competence.

Delegations in general agreed with the analysis that points to the role of health policy for ensuring citizens' well-being and for the achievement of goals in other policy areas such as economic growth and employment and for the social dimension of the EU. In this context several delegations mentioned the need for an increased consideration of health concerns in other policy areas (*e.g.* social policy, budget, taxes, *etc.*) at all decision-making levels as an example of where it is possible to **improve current practices**.

For all those reasons most delegations found the Council (EPSCO) to be the **most appropriate forum for the debate on the future of Europe from a health perspective**[9]. Some delegations drew the attention to regional agreements in the Pharmaceuticals sector (see Chapter 5) as examples of possible closer cooperation between Member States that agree on needs and goals.

With respect to key areas with a potential for **useful cooperation** with **added value** from working together at EU level, delegations identified, in particular:

- the fight against cross-border threats from communicable diseases, including through vaccination, and antimicrobial resistance[10];
- access to efficient medicines of high quality and the surveillance of the use of medicines[11];
- research and development of innovative treatments;

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9 Some delegations referred to Scenario 4 in the White Paper "Doing less more efficiently" as a starting point for discussion.

10 Some delegations pointed to the role of the European Centre for Diseases Prevention and Control.

11 Some delegations pointed to the role of the European Medicines Agency.

- diagnostics for and treatment of rare diseases[12];
- patients' rights in cross-border healthcare;
- e-Health (including e-prescription);
- mental health;
- the fight against chronic diseases and mitigation of their risk factors, such as poor nutritional habits and use of alcohol and tobacco;
- patient safety.

Many delegations expressed that the currently available EU funding sources, including the specific Health programme, should be maintained. Some of them, however, emphasised the need for better coordination between different funding programs in order to avoid duplication. Moreover, while recognising the benefits of synergies created by collaboration between different actors, some delegations underlined the need to avoid overlap between actions taken by the EU and activities already undertaken at other levels, notably by the WHO or by the OECD.

In the closing remarks, the Commission representative noted the convergence of views on the added value of action at EU level that respects the limitations set by the Treaties and stressed the need for coordination with other policy areas at national level.

The Chair concluded that the debate had given lots of food for thought as regards cooperation among Member States and noted that both areas where most delegations saw such cooperation as positive and areas were cooperation was less useful could be identified. She also undertook to reflect on the follow-up of this discussion at the forthcoming meeting of the Council (EPSCO).

[12] Some delegations pointed to the role of the European Reference Networks.

3. EUROPEAN STANDARDISATION IN THE HEALTH AREA

The Presidency briefly explained that European standardisation was on the agenda following concerns expressed by some delegations at the Council (EPSCO) on 17 June 2016[13]. The objective was to inform about the state of play and future plans of the Commission and of the European Standardisation Organisation (CEN/CENELEC) concerning any possible European Standards relating to healthcare services.

The Commission representative started his intervention by clearly stating that, despite the increasing relevance of the services sector as a sustainable driver for growth of the EU economy and the resulting need for development of European Standards applicable to service activities, healthcare services, which is an area of exclusive national competence, cannot legally[14] be included in any Commission initiative in the area of standardisation. Thus, it was never included in and it is not planned to be included in the Union work programme for European Standardisation[15]. Furthermore, the Commission has actively discouraged the private sector from taking any industry-driven initiatives in this field[16].

The representative of CEN/CENELEC briefly explained the role and work of CEN/CENELEC, in particular in the field of European Standardisation in the health sector.

CEN and CENELEC are two private non-profit organisations with more than 45[17] members (national standardisation organisations in: the EU Member States, Turkey, Macedonia, Serbia and three EFTA countries). The working programme is driven by industry needs. Standards represent consensus among all interested parties (national standardisation bodies, national authorities, industry, SMEs, social stakeholders). Only 2 or 3% of European Standards are for services, the main objective of standardisation being to remove technical barriers to trade. Standards are applied on a voluntary basis.

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13 Doc. 5430/18.
14 See Recital (12) of Regulation (EU) No 1025/2012 (OJ L 316, 14.11.2012, p. 12)
15 See Article 8 of Regulation (EU) No 1025/2012
16 Reference was made to a letter to CEN/CENELEC of 27 September 2016.
17 34 National Standardisation bodies plus eleven "affiliates".

With respect to the health sector, CEN/CENELEC activities are mainly focused on medical devices, following a request by the Commission. CEN, however, in June 2016 established a Focus Group on Healthcare Services[18]. The Focus Group is currently performing a mapping of ongoing standardisation activities regarding healthcare services at national, European and international levels. It thereby explores how standards could support healthcare services, but does not develop standards.

The representative of CEN/CENELEC expressed the view that standards for healthcare services can, bearing in mind the increased mobility of patients, contribute to patient safety, improved continuity and quality of care, improved communication and dissemination of best practices, and to supporting innovation, notably in the context of cross-border healthcare.

A number of delegations stressed that, in spite of the growing relevance of standards in a technologically complex and digital society, they are inadequate to address the specific characteristics of healthcare services.

Delegations further underlined that in areas where they could be useful, for instance for ensuring safety of devices and healthcare premises or for facilitating interoperability of systems (e-Health), standards should only be used for technical specifications. Even in this case, the whole process of standardisation should be performed in a transparent way and should be evidence- and multidisciplinary-based, with the involvement not only of industry, but also of the academic sphere, of other scientists, of healthcare providers and of patient organisations. It should also take into account national competent authorities' views.

Referring to the organisation and delivery of health services being a responsibility of the Member States according to the Treaty on the Functioning of the EU, many delegations suggested that CEN/CENELEC should not engage in standardisation relating to healthcare services**.**

[18] https://www.cencenelec.eu/News/brief_News/Pages/TN-2017-066.aspx
The mapping also has as an aim to develop a manual for standard writers in healthcare services. See also doc. WK 1716/2018.

The representative of the Commission suggested that national health authorities should liaise with their peers responsible for national standardisation (industry area).

The Chair concluded the discussion by noting the concerns expressed by many delegations regarding standardisation in the area of healthcare services, underlined that the development of such standards would fall outside the mandate defined by the annual Union work programme for European standardisation and suggested that the topic should be discussed at political level.

4. COOPERATION WITH THE SPC UNDER THE EUROPEAN SEMESTER PROCESS: CONTRIBUTION OF THE WPPHSL TO THE COUNCIL (EPSCO) CONCLUSIONS ON THE ANNUAL GROWTH SURVEY (AGS)

The Chair invited the Vice-Chair of the Social Protection Committee (SPC) to present a brief overview of the European Semester process[19].

The WPPHSL endorsed its contribution to the draft Council Conclusions on the 2018 Annual Growth Survey (AGS) on the basis of the text proposed by the Presidency[20] with an addition suggested by the Italian delegation (in bold) as follows:

"*Access to affordable preventive and curative health care of good quality is also key to fostering a healthy and active population and achieving economic prosperity. **Attention should be placed towards the dissemination of information, to encourage appropriate and equal access to healthcare***.".

The text has been communicated to the SPC and will be included in the draft Council conclusions on the 2018 AGS, which will be submitted via the Working Party on Social Questions to the Council (EPSCO) for adoption on 15 March 2018.

19 See doc. WK 1699/2018.
20 Doc. 5736/18.

5. PHARMACEUTICAL POLICIES IN THE EU – AVALABILITY, AFFORDABILITY, EFFICIENCY: POSSIBLE SOLUTIONS

The Chair invited the Italian, Polish, Netherlands and Latvian delegations to present regional schemes of voluntary cooperation among Member States intended to improve access to medicines.

The Italian delegation presented the political and administrative cooperation based on the "**Valletta Declaration**" signed by Ireland, Greece, Spain, Croatia, Italy, Cyprus, Malta, Portugal, Romania and Slovenia. Those Member States have 31,5% of the EU population (160 million EU citizens).

The agreement aims to guarantee patients' access to new and innovative medicines and therapies, while ensuring the sustainability of the national health systems. The cooperation is based on strong political will but, as there is no legal basis for action, any joint outcome must be implemented in each country in accordance with the respective national legal framework.[21]

The Polish delegation presented the "**Fair Pricing Initiative**" which is a mutual cooperation between Member States of the (enlarged) Visegrad Group: Poland, Lithuania, Slovakia, Hungary. The Czech Republic has currently the status of observer. The agreement is based on a memorandum of understanding that serves as its legal basis.

The aim of the initiative is to ensure patient access to medicines, especially oncological and orphan medicines. The fact that the participating Member States face similar problems make it easier to agree on solutions. The initiative has some challenges, linked to *e.g.* differences between the healthcare systems of the participating Member States.[22]

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21 See WK 1710/2018.
22 See WK 1709/2018.

The Netherlands delegation presented the scheme for cooperation among the Benelux countries and Austria (**BeNeLuxA**), which together have more than 37 million EU citizens. The cooperation is based on a letter of intent signed at Government level. The cooperation covers:

- horizon scanning,
- sharing of HTA,
- information exchange (covering policies and data),
- and pricing and reimbursement.[23]

It was underlined that there is strong political support for this cooperation that is based on a pragmatic approach, one very important element being to learn from each other, thereby taking into account differences between participating Member States, and not to duplicate work done elsewhere.

The Latvian delegation presented a **joint procurement system** that is shared with Lithuania and Estonia and which has as its aim to reduce the costs of medicinal products and of medical devices.

The participating Member States have had to make some adjustments of the national legislation in order to make the system succeed. Lessons learnt from the failure of a first attempt to jointly procure TBC vaccines for babies contributed to building experience. Since then, two successful joint procurements each involving two of the three Member States have been carried out. It is expected that the cooperation between the three Member States will continue.

All the speakers recalled that the schemes are open to accession of other Member States on a voluntary basis.

Following the presentations, the Chair invited delegations to share their views on pharmaceutical policies in the EU Member States, with the aim to increase awareness about Member State experiences and to prepare for future discussions on this topic.

[23] See WK 1715/2018.

In his introductory remarks, the Commission representative drew particular attention to the ongoing assessment of the **system of incentives**, notably the **evaluation of the legislation on paediatric medicines and on orphan medicines**. The Commission is carrying out a number of studies[24] with a view to assess positive and negative effects of the incentives to stimulate innovation, in particular their impact on the sustainability of healthcare systems and on improving access to treatment in order to be able to decide if any adjustments of the current system are needed.

The Commission representative also pointed to health technology assessment (HTA). He said that HTA is used in all Member States but that the tool used for this purpose at EU level, the EUnetHTA Joint Action 3 is a pilot project that despite being successful can by definition not continue indefinitely and will expire in 2020. In order to secure the sustainability of the HTA cooperation beyond 2020 the Commission has presented a legislative proposal[25] that focuses on the clinical aspects of HTA but allows interested Member States to go further.

The Commission representative furthermore indicated that a study of the effectiveness of the EU law imposing obligations on economic operators to guarantee continuous supply[26] of medicinal products was in preparation and in this context mentioned the possibility of national rules on parallel exports.

The Commission representative finished by reminding delegations that the new systems for verifying the safety features intended to prevent falsified medicines from reaching patients must be ready for use in most Member States from 9 January 2019[27]. He in this context specifically drew the attention to the obligation for hospitals to verify that medicinal products are not falsified before giving them to patients and offered technical advice from the Commission to Member States in need thereof.

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24 Reports on the implementation of the Regulations on paediatric medicines (2017) and on orphan medicines (planned for this year) and a study on the supplementary protection certificates.

25 Doc. 5844/18.

26 Article 81 of Directive 2001/83/EC.

27 See Commission Delegated Regulation (EU) 2016/161.

Most delegations considered access to highly **innovative, safe and efficient medicines** at **affordable prices** a very important topic, essential to the **sustainability of the health systems** and underlined the need to act in full respect for the principles of subsidiarity and proportionality.

Delegations noted the important role that **regional cooperation** could play in strengthening the negotiating powers of national authorities and agreed that challenges other than the negotiation of prices of medicines could also be tackled through such cooperation.

Some delegations while supporting the existing EU system of incentives stressed that it must contribute to stimulate useful innovation and expressed their interest in the forthcoming outcome of the ongoing review of this system. Some delegations also called for a revision of the Regulation on supplementary protection certificates (SPC) to provide for a SPC manufacturing waiver which would allow EU manufacturers to start producing generics either for export or for storing before the SPC expires.

Some delegations expressed concern regarding shortages in the supply of medicinal products and drew the attention to the role of parallel exports in causing such shortages.

With respect to a possible participation of a representative of EMA in the discussions, most delegations considered that this should be determined on a case by case basis and be limited to specific points under discussion.

Most delegations expressed their willingness to continue an exchange of views on pharmaceutical policies in the WPPHSL, but some of them stressed that despite the need to discuss similar topics also in other fora, unnecessary duplication should be avoided. Several delegations also held that the topic should be brought to higher political level and therefore be included not only on the agenda of future meetings of the WPPHSL but also be discussed at future Council (EPSCO) meetings.

The Chair closed the debate by stressing the importance of continuing discussions on this topic at all levels, including at the level of governments, and underlined that the discussion should not focus only on supporting innovation but also on effectiveness, affordability and patients' needs.

6. ANY OTHER BUSINESS

a) Update on the current activities at the EU level in the health area

The Co-Chair of the Health Systems Performance Assessment ("HSPA") Expert group[28] briefly presented the analysis undertaken by the group dealing with assessment of primary healthcare. The analysis will be presented in a report (to be published very soon) proposing ***possibilities to improve*** primary care in Europe. Focusing on rethinking the assessment tools and methodologies, the HSPA Expert group would point to the following preconditions for a successful HSPA regarding primary healthcare:

- Improve primary care information systems;
- Embed performance assessment in policy processes;
- Institutionalize performance system;
- Ensure accountability;
- Consider patients experience and values;
- Take advantage from adaptability;
- Support goal-oriented approach through a better use of professional and contextual evidence.[29]

The Commission representative informed the WPPHSL about the following:

- a Communication on digital health to be submitted in April and addressing secure access to health records, personalised medicine and citizen empowerment;
- the e-Health Network involving nine Member States that will start this summer and *inter alia* allow exchange of prescriptions;
- the European Reference Networks intended to help sharing knowledge about rare diseases that now consist of 24 reference networks that cover 900 healthcare units in 331 hospitals, where a first patient panel has recently been created (around 50 patients participate) and where a new call for tenders is under preparation;

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28 https://ec.europa.eu/health/systems_performance_assessment/policy/expert_group_en

29 See document WK 1704/2018.

- the proposal for a Council recommendation on vaccines for preventable diseases (under open consultation for public comments until April 2018);
- actions intended to combat infectious diseases under the "One Health Approach" including early warning systems and research and innovation;
- new tools for tracking and tracing of tobacco products that would help to implement the WHO Framework Convention on Tobacco Control (FCTC).

b) Bulgarian Presidency events

The Chair recalled that, on 6 February 2018, the Presidency organised a Conference on "The healthy future of Europe: healthy nutrition for children" in Sofia and thanked delegations for the interest shown. The outcome of the conference would be reflected in conclusions to be adopted by the Council (EPSCO) on 22 June 2018.

The Chair also announced the future events in the field of health scheduled to take place under the Bulgarian Presidency:

- a conference on pharmaceuticals (Sofia, 6 March 2018);
- the Informal Meeting of Health Ministers (Sofia, 22 and 23 April 2018);
- the Council (EPSCO) meeting (Luxembourg, 22 June 2018).