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From:	General Secretariat of the Council
To:	Delegations
Subject:	Working Party on Public Health at Senior Level on 15 March 2019

The agenda of the 21st meeting of the Working Party on Public Health at Senior Level (WPPHSL) was agreed as set out in CM 1231/2/2019 REV 2, with the addition of an information item on 'Cooperation between the WPPHSL and the Social Protection Committee in the context of the European Semester process' at the request of the German delegation.

The discussions at the WPPHSL meeting can be summarised as follows:

1. TRIO WORK PROGRAMME FOR THE WPPHSL

When starting the presentation of the Trio Presidency programme for January 2019 - July 2020[1], the Chair clarified that the two first main areas of work referred to in the Programme, namely, how to achieve a coherent, visible and sustainable approach to improve **patient safety**, and, on the other hand, how to minimise the **barriers to vaccination** in the EU would be addressed at this meeting. The Chair stressed that patient safety is relevant in hospitals but also in primary care and ambulatory settings and in order to improve it, the involvement of patients and their families is necessary. The Chair also noted that barriers to vaccination are often due to lack of information and misperceptions, but that, in some cases, an insufficient level of vaccination is due to discontinuities in vaccine provision.

[1] 6091/19.

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Referring to the fact that many of the 17 Sustainable Development Goals of the United Nations Agenda 2030 (UN SDGs) are related to health, the Finnish delegation announced their intention to, thereby building on the work already carried out during the Estonian Presidency in 2017, kick off a long-term process aimed at strengthening the role of the EU Member States in the **global health arena**. Moreover, the Finnish delegation would initiate a discussion aiming at a better understanding of the interplay between **economic dynamics and wellbeing**, covering multiple health, social, employment, education and gender equality dimensions, based on the perspective that resources spent on human well-being should be considered a profitable investment rather than an expense.

With regard to the perspectives for its Presidency, the Croatian delegation explained that, at this stage, it wanted to retain the necessary flexibility to cover future political priorities and ensure the continuity of the work developed at senior level. Nevertheless, the Croatian delegation mentioned the intention to explore ways of meeting the challenges of an **ageing population** from the perspective of the sustainability of lifelong health care.

The Commission representative welcomed the topics highlighted by the trio Presidency. With reference to the work that had been developed in those areas at EU level with a view to achieve the UN SDGs, the Commission representative mentioned, in particular:

– the prevention of **infectious diseases** through action against antimicrobial resistance (AMR), and the promotion of vaccination coverage[2], including at global level[3],
– the prevention of **non-communicable diseases**, through the promotion of healthy lifestyles, namely within the framework of the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases,
– incentives to **research**.

The Commission representative was also of the opinion that enhanced preparation at EU level of work in **international fora** in the field of health could increase the EU's influence on action undertaken at the global level.

[2] See for instance the Joint Action on vaccination (EU JAV);.

[3] See for instance the participation in the World Health Organization (WHO) Global Vaccine and Immunization Research Forum (GVIRF) and the organisation of the Global Vaccination Summit, in cooperation with the WHO, which this year will take place on 12 September in Brussels

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Recalling that health is a policy area where cooperation between the Member States could bring an added value to initiatives they take within the scope of their national competence, delegations welcomed the Trio programme, stressing the importance of the topics presented. Certain delegations also called for greater involvement of the WPPHSL, in its key role as a forum for exchange of views on subjects of concern for all Member States, in other challenges that lay ahead, such as:

a) '**access to medicines**'[4], particularly access to innovative treatments at affordable prices, mentioning the budgetary implications but also stressing the importance for improving patients' health;

b) the consequences of **digitalisation** (*e-health*) for healthcare systems; and

c) regular **horizon scanning** of the discussions in other policy areas with relevance for health (*Health-in-all-policies approach*), with the objective, *inter alia*, of making the best use of the synergies between decisions and actions under different Union policies.

A number of delegations agreed that, when the Commission is preparing its working programme for the next five years, the WPPHSL should seize the opportunity to fulfil its role as a '*forum for discussing major common strategic issues in health*'[5] and connect all the relevant objectives to set out a long-term agenda in the area of health to guide the work of the Commission and other Union institutions.

2. PATIENT SAFETY AS A GLOBAL CHALLENGE AND PRIORITY OF ACTION

The Chair briefly introduced the subject of discussion: how cooperation between Member States or support from the EU could add value to Member States' national initiatives aimed at achieving the worldwide objective of increasing the level of safety for patients receiving healthcare[6].

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[4] In this regard, the Italian delegation pointed out that, on 1 February 2019, Italy submitted a draft resolution on transparency to the World Health Organization (WHO) which should be discussed in May 2019 at the 72nd session of the World Health Assembly (WHA).
The Presidency informed that 'access to medicines' would be a topic on the agenda of the informal meeting of Health Ministers on 15 April 2019.

[5] See the Annex to the Council conclusions on a cooperation mechanism between the Council and the Commission for the implementation of the EU Health Strategy (16139/08).

[6] See WHO action: organisation of Global Ministerial Summits on patient safety (2016, 2017, 2018 and the next one planned for 2020) and the 71st World Health Assembly 2018 Side Event.
See OECD action: setting indicators and providing reports to the Global Ministerial Summits.

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As an introduction to the debate, some delegations were invited to share their views and experiences about possible solutions or successful national initiatives aimed at overcoming patient safety failures.

The German delegation underlined the advantages of **collaboration between Member States** addressing the same kind of issues (*e.g.* problems arising from highly complex healthcare treatments) and drew the attention to the potentially high profitability of investing in **preventive measures** in this area[7] (*e.g.* authorisation required for medicines, register of implants, minimum levels of staff in healthcare premises, investment in research, empowerment of patients and training of professionals), also within the context of the EU budgets for the next years.

The Finnish delegation explained how the national **medicines information system** helps to improve the safety of patients by focusing efforts on: (a) developing **research**; (b) creating **education and training opportunities** for healthcare professionals and for patients; (c) providing **guidance** for self-medicated and multi-medicated patients and for the public in general (for instance through a dedicated website page); (d) **recording problems and risks** associated with pharmaceutical treatments[8].

The United Kingdom delegation described how the **national safety strategy** aims at improving patient safety mainly through **preventive** measures, on the basis of three driving principles:

a) moving away from a culture of blame to the promotion of a system training staff to operate safely[9];

b) promoting an open and transparent 'adverse events report system'[10], based on harmonised measurement tools and methodology;

c) keeping in mind that there is always room for improvement[11].

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7 '*Investments in safety among most profitable of health care investments*' – WK 3292/2019.

8 For further details, see WK 1638/2019 + ADD 1.

9 The UK supports work programmes such as Getting it right first time, National Quality Improvement programmes and Learning from deaths - guidance for NHS trusts on working with bereaved families and carers. In response to the WHO's Medication without harm challenge, the UK launched the National Medicines Safety Programme.

10 The UK has established the Health Safety Investigation Branch to investigate serious patient safety incidents.

11 The UK has launched a consultation on proposals for a national patient safety strategy.

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Taking into account the cross-border dimension of patient safety (for example, the cross-border spread of infections, the global dimension of anti-microbial resistance), the UK delegation also advocated strengthening patient safety through close collaboration between Member States, particularly in the context of WHO[12] [13].

The Czech delegation mentioned some of the advantages of **involving patients in healthcare policies and decision-making** (*inter alia*, patients know what is in their own best interests, healthcare treatments which are well understood and accepted are more likely to be correctly applied, patients are also a valuable source of information about the impact of healthcare solutions on their personal lives). The Czech delegation considered that **educated and well-informed patients** who are aware of their own rights and responsibilities can play an active role at individual level[14], but further stressed that in its view a systemic approach should also involve **patient organisations**, preferably led by patients and aiming at protecting the rights or interests of patients in a transparent and independent manner[15].

Following these presentations, delegations held a general discussion focussing on the specific issues suggested by the Presidency[16].

As regards ways to improve the **safety of patients in non-hospital settings**, several delegations referred to possible **preventive** measures, such as:

- increasing the level of **skills and qualifications of healthcare providers** (general practitioners, nurses) through lifelong training programmes and easier accessibility of relevant information (for instance, disseminated through electronic means of communication),
- adopting a **multidisciplinary** approach, involving social care providers, pharmacists, etc.;
- providing support to **research** intended at improving the quality of treatment protocols, in particular concerning safety procedures (adequate medicines packaging and information, hygiene of medical instruments).

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12 The UK established the Global Patient Safety Collaborative via the WHO.
13 For further details see WK 2447/2019.
14 With this in mind, the Czech Republic invests in training courses and maintains an updated web page with relevant information.
15 In the Czech Republic Ministry of Health, a 'Patient Council', composed of 24 members from patient organisations, works as a permanent advisory body which is consulted on ministerial proposals and has a proactive role in proposing solutions.
16 For further details, see 5517/19.

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Delegations generally agreed that **empowering patients, families and their representatives** can contribute to safer healthcare. It was stressed that patients must be consulted, informed of the risks and outcomes of possible treatments and called to participate in the feed-back system as they are the ones who can best report experiences and outcomes. With these aims in mind, specific attention should be paid to the level of public knowledge in the domain of health through **education** and suitable advice from **trained healthcare professionals**[17].

On the availability of **tools for measurement** and on the **performance of feedback systems**, delegations referred to the possible means for further **collaboration between the Member States**, notably with the objectives of: (a) allowing for a wider exchange and comparability of **recorded data** on serious incidents[18]; (b) sharing information on the **effectiveness of measurement tools**; and (c) establishing **harmonised guidelines** on indicators, traceability of treatments and analysis of mistakes. However, delegations underlined that, at least in some areas of medical practice (for instance provision of suitable advice on healthy lifestyles), counselling methods and standards should be tailored to local, regional or national needs, cultures and habits of the patients.

While recognising the advantages of involving the **private sector**, for instance in training or education activities, some delegations pointed out that patient safety is also a question of trust in the system, requiring transparency and independence from economic interests.

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17 The delegations pointed out that participation of the public, feedback and transmission of information were now facilitated by the use of electronic means of communication.

18 In this respects and as a lesson to learn, the delegations also pointed to the new approach to the way mistakes are recorded and monitored: detecting errors should no longer be seen as a way of blaming or penalising health carers, but as a positive contribution to the quality of the treatment. Records should be anonymous and confidential and the evaluation should be based on independent expert analysis.

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Finally, the Commission representative referred to the actions that could be financed by the Union budget, using as an example the Joint Action on patient safety[19] and its network for sharing good practices (web-based platforms on patient safety and quality of care), which was funded until 2016 by the Union budget[20], as well as other initiatives including two Commission projects on self-care (*Pilot project on the promotion of self-care systems in the European Union* and *Pilot project on Promoting Self-management for Chronic Diseases in the EU*), and collaboration with the OECD on patient safety indicators[21]. The Commission representative also reminded the Working Party of the proposed network reporting to the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases – which could serve as a stable structure for cooperation and a network for the sharing of information on best practices and of recorded outcomes[22] – and also suggested that a professional network for patient safety be set up within the EU Health Policy Platform. Given the diversity and complexity of the topic, the Commission representative invited the Member States to identify the actions to be prioritised for future EU action.

Closing the debate, the Presidency concluded from the interventions that:

- patient safety was acknowledged as a priority at EU level, including for the sector of primary and ambulatory care;
- key preconditions for developing patient safety at national level include a regulatory framework, clinical and political leadership, competent professionals, learning from medical errors by means of a transparent notification system and blame-free analysis, and empowerment of patients as advocates for healthcare safety;

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[19] See on http://www.pasq.eu/ - 'The European Union Network for Patient Safety and Quality of Care, PaSQ Joint Action is co-funded and supported by the European Commission within the Public Health Programme, which focus is to improve Patient Safety and Quality of Care through sharing of information, experience, and the implementation of good practices. These platforms are organised around PaSQ National Contact Points (NCPs), who are also the contact persons for PaSQ matters in their respective countries.'

[20] However, the Commission needs to receive more information on the benefits obtained from the implementation of these good practices to be able to justify seeking new funding.

[21] For further details, see Appendix to the Annex to document 5517/19.

[22] Proposal drawn up in response to the invitation from the Council to the Member States and to the Commission to '*Finalise by December 2016 a framework for a **sustainable EU collaboration** on patient safety and quality of care, also taking into account the results of the "Joint Action on patient safety and quality of care" (PaSQ);*' in the Council conclusions on patient safety and quality of care, including the prevention and control of healthcare-associated infections and antimicrobial resistance (OJ C 438, 6.12.2014, p. 7).

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- a more coherent and systematic approach at EU level to patient safety was considered essential and should continue to be developed, with EU funds being used to support Member State initiatives, particularly in the following areas: re-training of health professionals; development of infrastructures; promotion of patients' participation; dissemination of evidence-based information on patient safety[23]; development of valid, transparent and blame-free patient safety feedback systems; improved tools for patient safety measurement[24]; supporting digital health initiatives for patient safety; combating antimicrobial resistance (AMR);
- the WPPHSL took note of the Commission's willingness to support all concrete initiatives which could bring added value to patient safety at EU level and to explore the opportunities to continue the efforts on patient safety in the future.

3. POSSIBLE SOLUTIONS FOR MINIMISING THE BARRIERS TO VACCINATION[25]

The Chair briefly introduced the subject for discussion: how to improve vaccination coverage to support the Member States in fulfilling the Sustainable Development Goals and the WHO targets, bearing in mind that vaccination is one of the health measures with the best cost/benefit ratio. As was the case for the previous topic, one of the objectives of the debate was to explore which ways of cooperation between Member States or support from the Union could bring added value to national efforts, in particular to implement the *Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases*[26].

In their interventions, all the delegations agreed that the Council Recommendation should be put into practice and that cooperation between the Member States was justified by the **cross-border** nature of the threats and the need to ensure the implementation of the 'free movement of people' pillar of the internal market. Some of the delegations participating in the Joint Action for Vaccination initiative highlighted the benefits of the inter-State cooperation developed in its framework and invited other Member States to adhere to the consortium. Nevertheless, delegations recognised that plans for fighting vaccine hesitancy require a national approach, as they must take into account local/regional/national factors such as the prevalent illnesses, the levels of exposure, the most vulnerable population groups and the cultural and societal environment.

[23] Patient safety research continues to be developed, including on some insufficiently explored areas (primary care and ambulatory).
[24] OECD patient safety indicators, patient-reported outcomes, patient-reported experience.
[25] For further details see 6092/19.
[26] OJ C 466, 28.12.2018, p. 1.

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Among the **national measures** aimed at ensuring wide vaccination coverage, delegations mentioned:

- increased **number of** mandatory or recommended[27] **vaccinations** where there is a need[28];
- **ensuring compliance** with vaccination requirements, by sanctions for non-compliance or – more effective in some cases – incentives for compliance (for instance, by making vaccination a condition access to social benefits);
- electronic **data records**[29], to be completed by the public healthcare system or by the private sector, which can form the basis for **monitoring** vaccination coverage (in particular of schoolchildren) and even for automatic notifications for vaccine boosters;
- **free administration** of vaccines, with simplified procedures (for instance by nurses or pharmacists);
- specific protocols for more **vulnerable people** (pregnant women, elderly people, people with chronic diseases and also low-income citizens, who are more vulnerable to diseases);
- enhanced **family awareness**, with a key role attributed to specifically trained healthcare professionals (general practitioners, nurses and pharmacists, who are closer to the patients); and
- fighting fake news on social media.

On the establishment of an **EU vaccination Passport**[30], seen by many delegations as a useful tool for facilitating the exchange of information and the free movement of people, some delegations declared that they needed more information on the objectives of the system and the implementation arrangements adopted in Member States, and also insisted on the need to avoid duplication of work at national level. Several delegations also called on the Commission to facilitate the implementation of the system by keeping updated lists of the vaccines administered in the different Member States, including identification of the administered products and of the treated diseases, so that equivalences can be easily established.

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[27] In the Member States where vaccines are not mandatory, recommendations may be accompanied by incentives.

[28] For example, for children, adolescents (Human Papilloma Virus), elderly people and healthcare professionals.

[29] Work developed in collaboration with the WHO, UNICEF and the OECD.

[30] See paragraph 16 of the Council Recommendation: '*(...) examining the feasibility of developing a common vaccination **card/passport** for EU citizens (that takes into account potentially different national vaccination schedules and) that is compatible with electronic immunisation information systems and recognised for use across borders, without duplicating work at national level*.'

Several delegations considered the **Coalition for Vaccination**[31] to be an important step in involving healthcare professionals and non-governmental organisations in the exchange of best practices and recommendations to healthcare staff.

Delegations generally welcomed the establishment of the **European Vaccination Information Sharing system** (EVIS)[32] as a network for increased cross-border exchange of medical data, including on indicators for measurement of the coverage and results of monitoring activities, and welcomed the fact that its platform for evidence-based information would be available to the public in a user-friendly and easily understandable way, although they moreover considered that it would be useful for awareness-raising campaigns to be disseminated also through the social media.

Many of the delegations deemed **shortage of vaccines** as one of the (major) causes of insufficient coverage. To help overcome the problem, some delegations recommended: (a) more accurate forecasting of needs; (b) the establishment of a network for sharing information on storage and possible transfer to Member States in need; (c) identification of the population groups more in need of scarce vaccines; (d) incentives and support for producers who comply with the Good Manufacturing Practices and to opt for a market-driven strategy.

Noting with concern that, due to inadequate vaccine coverage, the EU was 'exporting' diseases to third countries[33], the Commission representative pointed out that some problems were also linked to organisational weaknesses[34]. The Commission representative agreed that the fight against vaccine hesitancy should take into account national specificities but added that the messages transmitted to the public must be coherent, and pointed to three areas for **EU cooperation**: **communication** and promotion of trust; **research** and investment in new vaccines; issues linked to global coverage and **relations with third countries**.

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31 See paragraph 18 of the Council Recommendation: '*Convene a **Coalition for Vaccination** to bring together European associations of healthcare workers as well as relevant students' associations in the field, to commit to delivering accurate information to the public, combating myths and exchanging best practice.*'

32 Information sharing system, coordinated by the ECDC, involving the national public health authorities.

33 As it was the case for measles.

34 For instance, vaccination campaigns mainly addressed to children do not take enough account of adults who were not vaccinated in their childhood.

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The Chair closed the debate by concluding that:

- the Member States are developing good and concrete vaccination plans for implementing the Council Recommendation, but vaccination still represents a challenge in terms of achieving the recommended coverage level, in particular for children, health professionals and vulnerable groups (elderly people, migrants);
- collaboration between the Member States and with the EU institutions is essential to minimise the barriers to vaccination in the future; many actions supported by the EU (for example within the framework of the Joint Action on Vaccination) could contribute substantially to the implementation of the Council Recommendation; further support from the Commission would be very much welcomed, especially as regards joint procurements, raising awareness (among healthcare professionals), supporting professional networks and implementing digital solutions;
- the EU agencies, namely the European Centre for Disease Prevention and Control and the European Medicines Agency, should play an important role in supporting the Member States in improving vaccination coverage;
- the WPPHSL took note of the Commission's readiness to support not only EU initiatives but also national initiatives through the *EU Coalition for Vaccination*: healthcare professionals, who are the most trusted source of information for members of the general public, should be equipped to transmit suitable information;
- the *European Vaccination Information Sharing* (EVIS) system was welcomed as an ambitious project that would allow increased coordination among the Member States;
- the EU *vaccination passport* project should be further developed on a voluntary basis and in full compliance with data protection rules, since it must avoid duplication of work at the level of the Member States;
- with regard to vaccine shortage: the EU institutions could act as an intermediary, but the solutions must take into account national priorities and market strategies.

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4. ANY OTHER BUSINESS

a) The system for Tobacco Traceability[35]

The Commission representative drew attention to the fact that Directive 2014/40/EU[36] requires Member States to put in place their parts of the EU traceability system for cigarettes and roll-your-own tobacco by 20 May 2019. The Commission representative stressed the urgency for Member States to implement one of the key elements of that system – the appointment of the so-called 'ID issuer' – in time, in order to ensure the proper functioning of the system.

b) Future European priorities in the field of health[37]

The Netherlands delegation proposed that discussions be held in the framework of the WPPHSL to establish priorities for EU action in the field of health that should be reflected in the Commission agenda for the next five years.

c) Update on current activities at EU level in the field of health[38]

The Commission representative outlined the major initiatives undertaken in 2018. Regarding the use of EU sources of funding, the Commission representative added that keeping a fair balance in the distribution of funds among the Member States was a constant concern.

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35 For more details, see 7246/19.

36 Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 40, 06.01.2015, p.1).

37 For more details, see 7419/19.

38 For more details, see WK3891/2019.

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d) **Cooperation with the Social Protection Committee in the context of the European Semester process**

The German delegation received support from other delegations for its request for strengthened cooperation between the WPPHSL and the Social Protection Committee (SPC) to ensure that health related matters are better taken into account in the European Semester process.[39]. In this respect, some delegations suggested that, as an initial step, the Commission should be invited to prepare an assessment of the achievements and weaknesses of the ongoing cooperation and outline possible prospects for future cooperation.

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[39] See the Council conclusions on the Reflection process on modern, responsive and sustainable health systems: '*INVITES THE COMMISSION AND THE MEMBER STATES TO: […] (b) ensure the necessary coordination at national and EU level in order to adequately represent the health sector in the process of the European Semester, and to streamline the on-going healthcare assessments at EU level, in particular through strengthened coordination and cooperation with the Social Protection Committee and the Economic Policy Committee, and by examining and establishing a working relationship between the Working Party on Public Health at Senior Level and the Social Protection Committee*;' (OJ C 376, 21.12.2013, p. 3).