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NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: **Employment, Social Policy, Health and Consumer Affairs** Council meeting on 1 December 2014
Draft Council conclusions on Patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance
- Adoption
(Public debate in accordance with Article 8(2) of the Council's Rules of Procedure [proposed by the Presidency])

1. The Working Party on Public Health discussed and agreed the draft Council conclusions as set out in the Annex.
2. COREPER is invited to confirm the Working Party's agreement and submit the draft conclusions for adoption by the Council (EPSCO) at its meeting on 1 December 2014.
3. The Council is invited to adopt the draft conclusions and forward them for publication in the Official Journal.

**Draft Council conclusions on
Patient safety and quality of care, including the prevention and control
of healthcare associated infections and antimicrobial resistance**

THE COUNCIL OF THE EUROPEAN UNION

1. RECALLS that under Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities, that Union action, which shall complement national policies, shall be directed towards improving public health, that the Union shall encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action, and fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care;
2. RECALLS the Council conclusions on common values and principles in European Union Health Systems adopted on 2 June 2006¹, and particularly the overarching values of universality, access to good quality care, equity and solidarity;
3. RECALLS that the Annual Growth Survey 2014 highlights the need for the development of active inclusion strategies that include broad access to affordable and high-quality health services, also with regard to achieving the objectives of Europe 2020;
4. RECALLS the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections²;
5. RECALLS the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine³ and the Commission Action plan against the rising threat from antimicrobial resistance⁴;

¹ OJ C 146, 22.6.2006, p.1

² OJ C 151, 3.7.2009, p.6

³ OJ L34, 5.2.2002, p.13

⁴ 16939/11 (COM (2011)748)

6. RECALLS the Council conclusions of 22 June 2012 on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a “One Health” perspective⁵;
7. RECALLS that antimicrobial resistance and healthcare associated infections are subject to epidemiological surveillance in accordance with Articles 2.1(a)(ii) and 2.2 of the Decision 1082/2013 on serious cross border health threats⁶;
8. RECALLS World Health Assembly Resolution WHA67.25 on Antimicrobial Resistance adopted on 24 May 2014;
9. RECALLS that Council Recommendation 2009/C 151/01 and Directive 2011/24⁷ request that patients receive healthcare in accordance with safety and quality standards and guidelines and clarify the right to receive information, in a clear and transparent way, as regards safety and quality measures in place and complaints procedures and redress mechanisms;
10. NOTES that policy-making and decision-making processes should be evidence-based, and supported by systematic data collection that uses appropriate health information and communication technology (ICT) tools;
11. NOTES that the current trend of shifting care from hospitals to outpatient care, including primary care and home care, can result in an increased amount of care provided by non-hospital healthcare workers, social workers and carers, including informal caregivers;
12. RECOGNISES that education and training on patient safety and infection prevention and control should be embedded in training for health professionals and carers and be included in continuous professional development;
13. RECOGNISES that just and blame-free reporting and learning systems have proven to be excellent tools to increase patient safety culture;

⁵ OJ C 2011, 18.7.2012, p.2

⁶ OJ L 293, 5.11.2013, p.1⁶ OJ L 88, 4.4.2011, p.45

⁷ OJ L 88, 4.4.2011, p.45

14. TAKES NOTE of the conclusions of the two reports⁸ from the European Commission on the implementation of the Council Recommendation 2009/C 151/01;
15. RECOGNISES that the implementation of effective measures to prevent and control healthcare-associated infections at regional and national level is critical in curbing the further spread and rise of antimicrobial resistance and that addressing healthcare associated infections is one of the cornerstones of the EU Action Plan on combating the rising threat from antimicrobial resistance, adopted in 2011⁹;
16. RECALLS that approximately 3.2 million patients¹⁰ are estimated to acquire a healthcare associated infection in the EU every year, with 20-30 % considered to be preventable¹¹, and that a percentage between 5% and 10% of adverse events are expected to occur, with nearly half of these potentially avoidable;¹²
17. TAKES NOTE of the fact that according to the special Eurobarometer survey “Patient Safety and Quality of Care”¹³ just over half (53%) of all EU citizens think that patients could be harmed by hospital care in their country, while half of the respondents think that they can be harmed by non-hospital healthcare and that these percentages have not significantly decreased since 2009;

⁸ 17982/12 (COM(2012) 658 final) and 11266/14 (COM(2014)371 final)

⁹ http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

¹⁰ Prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals 2011-2012, ECDC, 2013.

<http://www.ecdc.europa.eu/en/publications/Publications/healthcare-associated-infections-antimicrobial-use-PPS.pdf>

¹¹ Harbarth S, Sax H, Gastmeier P. The preventable proportion of nosocomial infections: an overview of published reports. J Hosp Infect 2003;54:258-266.

¹² De Vries EN et al. The incidence and nature of in-hospital adverse events: a systematic review Qual Saf Health Care 2008;17:216-223.

¹³ http://ec.europa.eu/health/patient_safety/eurobarometers/ebs_411_en.htm

18. NOTES WITH CONCERN that according to the most recent data published by the European Centre for Disease Prevention and Control (ECDC)¹⁴, healthcare-associated infections caused by multi-drug resistant microorganisms are on the rise;
19. TAKES NOTE of the work of WHO and OECD on patient safety and quality of care, which is also supported by the EU;
20. WELCOMES progress made by the Member States since 2009 in including patient safety in public health policies as specified by the Council Recommendation 2009/C 151/01;
21. WELCOMES the work of the Patient Safety and Quality of Care Working Group on practical guidelines on education and training and on reporting and learning systems;
22. NOTES that patient empowerment and involvement are recognised as an essential part of good quality and safety of care and require an effort by Member States to exchange cross-country knowledge and effective tools;
23. WELCOMES the work of the European Network for Patient Safety and Quality of Care (Joint Action PaSQ) on the implementation of the Council Recommendation 2009/C150/01 as regards the exchange and implementation of good practices in Member States;
24. RECOGNISES a need for continued and sustainable collaboration at EU level on patient safety and quality of care;
25. NOTES that the implementation of the general patient safety provisions of the Council Recommendation 2009/C 151/01 has a positive contribution to the health of the population and the economy of health systems, and that this requires continued attention;
26. RECALLS that harm associated with adverse events represents an additional cost to health systems;

¹⁴ Antimicrobial resistance surveillance in Europe 2012. Annual Report of the European Antimicrobial Resistance Surveillance Network (EARS-Net). ECDC, 2013.
<http://www.ecdc.europa.eu/en/publications/Publications/antimicrobial-resistance-surveillance-europe-2012.pdf>

27. CONSIDERS that health system performance assessment can contribute to achieving progress in patient safety and quality of care;
28. INVITES THE MEMBER STATES TO:
- a) Intensify their efforts in implementing the Council Recommendation 2009/C 151/01, taking into account the priority areas identified in the conclusions of the two Commission's implementation reports and the reports on education and training and on reporting and learning systems produced by Patient Safety and Quality of Care Working Group;
 - b) Identify, if not already done, the authorities in charge of the implementation and monitoring of integrated patient safety strategies, including the prevention, surveillance and control of healthcare associated infections;
 - c) Consider the implementation of guidelines, recommendations and good practices on patient safety, the prevention and control of healthcare associated infections and antimicrobial resistance, and the use of the WHO taxonomy on patient safety to help improve clinical and organisational performance;
 - d) Promote the education and training of healthcare staff on patient safety and healthcare associated infections, taking into account the relevant work of the ECDC, including the ECDC's technical document "Core competencies on infection control and hospital hygiene professionals in the European Union"¹⁵, as well as relevant WHO recommendations, with a view to promoting the availability of appropriately trained staff, including specialised infection control staff, in healthcare settings;
 - e) Encourage health professional organisations to build an inter-professional patient safety culture which allows integrated and high-quality processes of care;

¹⁵ European Centre for Disease Prevention and Control. Core competencies for infection control and hospital hygiene professionals in the European Union. Stockholm: ECDC; 2013 <http://www.ecdc.europa.eu/en/publications/Publications/infection-control-core-competencies.pdf>

- f) Develop measures that allow just and blame-free reporting by health professionals or patients and support blame-free handling of errors and adverse events as well as learning from them;
- g) Encourage the participation and empowerment of patients, families and their informal caregivers, as well as patient organisations, through evidence-based and unbiased provision of information and education, and promote patients' participation in decision-making in the healthcare process in order to contribute to the prevention of adverse events;
- h) Consider the opportunity of developing cost-effective evaluation of patient safety programmes, also on the basis of the results of "Programme for the Union's action in the field of health (2014-2020)";
- i) Reinforce programmes and plans for infection prevention and control throughout the care and cure process, including tailored programmes for nursing homes and long-term care facilities;
- j) Step up the prevention, diagnosis, monitoring and control of healthcare associated infections, also by adopting, implementing and monitoring professional guidelines at national level, where appropriate in close cooperation with the ECDC;
- k) Share experience on strategies to ensure patient safety and quality of care between and across all settings of care;
- l) Develop professional guidelines on the prudent use of antibiotics, including the monitoring of prescriptions;
- m) Continue to devote special attention to antimicrobial resistance as stated in the Council Conclusions of 22 June 2012, as well as monitor the consumption of antimicrobial agents and implement the surveillance of antimicrobial resistance, including participation in EU surveillance networks on these issues as coordinated by the European Centre for Disease Prevention and Control and the European Medicines Agency;

29. INVITES THE MEMBER STATES AND THE COMMISSION TO:

- a) Promote patient safety culture, that comprises just and blame-free reporting on adverse events at healthcare setting level and work towards measuring and improving patient safety culture;
- b) Regularly review the practical guidelines on the education and training of health professionals and on reporting and learning systems;
- c) Promote the collection of information on adverse events;
- d) Promote the uptake of guidelines and evidence-based policy by exchanging best practices on the prevention and control of antimicrobial resistance;
- e) Develop EU guidance for patient/citizens' involvement in strategies on patient safety, taking into account the work of the World Health Organisation;
- f) Develop voluntary guidelines on how to establish standards and guidelines on patient safety, taking into account existing methodologies as regards setting standards and guidelines used both by national competent authorities and by health professional and scientific associations;
- g) Develop further work on the dimensions of quality in healthcare, taking into account existing knowledge, including the work of the "Joint Action on patient safety and quality of care" (PaSQ);
- h) 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);
- i) Take into account research results while developing policies and programmes and promoting further research on patient safety and quality of care;

- j) Work towards a better understanding of the cost-effectiveness of patient safety policies under the principles of efficacy, efficiency, appropriateness, safety and quality of care;
- k) Further strengthen the cooperation between the human health and the veterinary sectors in order to address the rising threat from antimicrobial resistance;
- l) Strengthen and coordinate research and innovation efforts to address antimicrobial resistance, in particular by providing support to the Joint Programming Initiative on Antimicrobial Resistance.
- m) Improve strategies for patient safety based on the outcomes of the Action called "Study on costs of unsafe care and cost-effectiveness of patient safety programmes" launched by the Commission in collaboration with the Patient Safety and Quality of Care Working Group;

30. INVITES THE COMMISSION TO

- a) Continue supporting Member States in improving strategies and programmes for patient safety in all settings of care based on the findings of the two Commission's implementation reports of the Council Recommendation 2009/C 151/01;
- b) Ensure coordination of EU activities on patient safety and quality of care, including treatment errors and healthcare-associated infections and antimicrobial resistance with the scientific support of relevant EU agencies, and taking into account the work of international organisations such as WHO and OECD;
- c) Continue monitoring developments in patient safety and healthcare associated infections in Member States and at EU level and report its findings on the trends of patient safety policies, the main causes of adverse events and the areas requiring further actions;
- d) Explore the feasibility to present a proposal for Council Recommendation on the provision of information to patients on patient safety following the Council Recommendation 2009/C 151/01, and following further preparatory work with the Member States on the dimensions of quality of healthcare;

- e) Monitor the implementation of the EU case definitions of healthcare associated infections and participation of Member States in EU surveillance of healthcare associated infections as coordinated by the ECDC;
 - f) Ensure a continuation of the EU Action Plan on Antimicrobial Resistance post 2017, including an emphasis on the prevention and control of healthcare associated infections.
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