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#### 'I/A' ITEM NOTE

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From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

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11107/19 FIN 500 SAN 342 SOC 544

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Subject: Draft Council conclusions in response to the European Court of Auditors' Special Report No 07/2019: "EU actions for cross-border healthcare: significant ambitions but improved management required"  
- Adoption

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1. On 4 June 2019, the European Court of Auditors published Special Report No 7/2019 entitled "*EU actions for cross-border healthcare: significant ambitions but improved management required*"<sup>1</sup>.
2. Under the rules laid down in the Council conclusions on improving the examination of special reports drawn up by the Court of Auditors<sup>2</sup>, the Permanent Representatives Committee on 16 July 2019 instructed the Working Party of Public Health to examine the report in accordance with those rules<sup>3</sup>.

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<sup>1</sup> This special report is available in 23 EU languages on the Court's website:  
<http://eca.europa.eu>.

<sup>2</sup> Doc. 7515/00 + COR 1.

<sup>3</sup> Doc. 11107/19.

3. The Working Party on Public Health examined the report at a meeting on 11 September 2019, at which representatives of the ECA presented their main findings.
  4. Based on that examination, the Presidency prepared a set of draft Council conclusions<sup>4</sup>, that was circulated to delegations.
  5. Following informal consultations, revised sets of draft Council conclusions were prepared<sup>5</sup> and a meeting of the Working Party was organised on 11 October 2019. At that meeting, the Working Party reached a tentative agreement on the text set out in the Annex to this note<sup>6</sup>.
  6. Consequently, the Permanent Representatives Committee is invited to confirm the agreement reached at Working Party level and to recommend to the Council to adopt, as an "A" item at one of its forthcoming meetings, the draft Council conclusions set out in the Annex to this Note.
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<sup>4</sup> WK 10495/2019

<sup>5</sup> See documents WK 10495/2019 REV1 + ADD 1 and WK 10495/2019 REV 2.

<sup>6</sup> The text of the draft conclusions was circulated in document WK 10495/2019 REV3. In that meeting some delegations entered scrutiny reservations that have meanwhile been lifted.

**Draft Council conclusions in response to the European Court of Auditors' Special Report  
No 7/2019:**

**"EU actions for cross-border healthcare:  
significant ambitions but improved management required"**

THE COUNCIL OF THE EUROPEAN UNION:

1. WELCOMES the Special Report of the European Court of Auditors No 7/2019: "EU actions for cross-border healthcare: significant ambitions but improved management required";
2. RECALLS that Directive 2011/24/EU on the application of patients' rights in cross-border healthcare ("the Cross-border Healthcare Directive")<sup>7</sup> provides rules for facilitating the access to safe, high-quality healthcare across national borders within the EU and promotes cooperation in a number of actions including, *inter alia*, treatment of rare diseases and the cross-border exchange of patients' data;
3. FURTHER RECALLS that the Cross-border Healthcare Directive lays down rules for patients<sup>8</sup> to be reimbursed for treatments received in cross-border healthcare, establishes National Contact Points responsible for providing patients with information on their rights to cross-border healthcare and facilitates access to the European Reference Networks (ERNs), in particular for patients with rare diseases;
4. NOTES that according to the Special Report annually approximately 200 000 patients take advantage of the systems put in place under the Cross-border Healthcare Directive to receive treatment abroad and that the majority of patient mobility occurs between neighbouring Member States;

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<sup>7</sup> OJ L 88, 04.04.2011, p. 45

<sup>8</sup> In these Council conclusions "patient" is a term used in conformity with the Cross-border Healthcare Directive.

5. UNDERLINES that the Member States have the main responsibility for health policies and that EU action in this area should be designed to complement and support Member States' activities;
6. TAKES NOTE of the main findings of the Court presented in the Special Report and of its recommendations to the Commission, in particular those that concern the need to provide further support and guidance for National Contact Points towards better communication on cross-border healthcare to patients, better preparation for cross-border exchanges of patients' health data and improved support to Member States to facilitate patients' access to treatment for rare diseases, in particular by continuing the development of ERNs;
7. ACKNOWLEDGES the Commission's intention to further facilitate and expand the cross-border exchange of electronic health records, as stated in its Communication of 25 April 2018<sup>9</sup> on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society;
8. DRAWS ATTENTION TO the fact that cross-border healthcare is regulated not only by the Cross-border Healthcare Directive but also by Regulation (EC) No 883/2004 on the coordination of social security systems<sup>10</sup>, and that it involves a multitude of actors and structures that vary between Member States;
9. TAKES NOTE of the Commission's reply to the findings of the Court and the initiatives already taken to implement those recommendations, in particular providing comprehensive guidance to the National Contact Points, supporting the deployment of cross-border exchanges of patients' health data and also addressing different challenges faced by the ERNs;

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<sup>9</sup> Doc. 6451/18 (COM(2018) 233 final).

<sup>10</sup> OJ L 166, 30.4.2004, p. 1

10. ENCOURAGES the Commission and the Member States to continue to cooperate closely towards the full implementation of the Cross-border Healthcare Directive by:
- further developing the EU-wide eHealth Digital Service Infrastructure (eHDSI), which enables the voluntary cross-border exchanges of patients health data such as e-prescriptions and patient summaries and, in particular, the establishment of connections between national eHealth systems and the eHDSI through dedicated National Contact Points for eHealth (NCPeH);
  - providing further support to the development of the ERNs, while fully respecting the responsibilities of Member States for the organisation of health services and medical care as laid down in Article 168(7) of the Treaty on the functioning of the European Union;
11. ENCOURAGES the Commission to:
- further support the work of National Contact Points established by the Directive to improve the information provided to patients on their right to cross-border healthcare, including a comprehensive and systematic information on the ERNs;
  - simplify the financial and administrative procedures for the ERNs at EU level and reduce their administrative burden;
  - assess the results of the 2008 strategy on rare diseases<sup>11</sup> and consider whether it needs to be updated, adapted or replaced;
  - further develop the ERNs' platforms providing guidelines, sharing knowledge and best practices, including the European Platform for Rare Diseases Registries, aimed to connect registries in the EU and thus facilitate *inter alia* epidemiological and clinical research on rare diseases;
  - continue its financial support to the ERNs with a view to their long-term sustainability;
  - continue monitoring and assessing the results achieved by the 2012 eHealth Action Plan and implementation of the 2018 eHealth strategy in terms of cost-effectiveness of the taken actions and their sustainability;

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<sup>11</sup> Doc. 15775/08 (COM(2008) 679 final).

12. WELCOMES the regular reporting by the Commission to the Council on progress in the implementation of Cross-border Healthcare Directive, in particular on patient flows and on the functioning of the ERNs and National Contact Points, and ENCOURAGES Member States to assist the Commission by providing information that is relevant for the preparation of those reports.
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