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To:	Delegations
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Subject:	Health in the Digital Society - making progress in data-driven innovation in the field of health
	– Council conclusions (8 December 2017)

Delegations will find in the annex the Council conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health, adopted by the Council at its 3583rd meeting held on 7 and 8 December 2017.

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Council conclusions on

Health in the Digital Society – making progress

in data-driven innovation in the field of health

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THE COUNCIL OF THE EUROPEAN UNION

RECALLS

1. That under Article 168 of the Treaty on the Functioning of the European Union a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities, and that Union action should complement the national policies, while respecting the responsibilities of the Member States in the definition of their health policy and for the organisation and delivery of health services and medical care. The Union should encourage cooperation between the Member States in the field of public health and, if necessary, lend support to their action and in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

2. That the Council has emphasised on several occasions[1] that in response to the common challenges related to health systems' sustainability, it is important to consider innovative approaches and models of healthcare, moving away from hospital-centred systems towards integrated care, strengthening health promotion and disease prevention and implementing personalised medicine, while recognising the potential of eHealth tools and services.

3. The Council conclusions of 1 December 2009 on a safe and efficient healthcare through eHealth[2].

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[1]   See: Council conclusions: Towards modern, responsive and sustainable health systems of 6 June 2011, OJ C 202, 08.7.2011, p. 10; Council conclusions on the "Reflection process on modern, responsive and sustainable health systems" of 10 December 2013, OJ C 376, 21.12.2013, p. 3; Council conclusions on the economic crisis and healthcare of 20 June 2014, OJ C 217, 10.07.2014, p. 2; Council conclusions on personalised medicine for patients adopted on 7 December 2015, OJ C 421, 17.12.2015, p. 2

[2]   OJ C 302, 12.12.2009, p.12

4.	The European Parliament resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance[3] calling for the opportunities of eHealth in improving patient safety to be explored, inter alia via electronic health records and mobile health tools, and for reinforced cooperation to exchange experiences and knowledge between Member States.

5.	The Communication from the Commission on 'A Digital Single Market Strategy for Europe' adopted on 6 May 2015[4] and the Communication from the Commission on the EU eGovernment Action Plan Accelerating the digital transformation of government, adopted on 19 April 2016[5].

6.	The Communication from the Commission 'EU eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century' adopted on 6 December 2012[6] and the European Parliament resolution of 14 January 2014 on the eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century[7].

7.	The Communication from the Commission 'On effective, accessible and resilient health systems'[8] adopted on 4 April 2014, recognising the important role of eHealth in supporting the resilience of health systems.

NOTES THAT

8.	Member States are facing common challenges related to the increase in chronic diseases prevalence and limited human and financial resources for ensuring sustainability of their health systems and meeting the growing demands of ageing populations. They are also facing common challenges related to cross-border health threats.

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[3]	P8_TA(2015)0197
[4]	COM(2015) 192 final
[5]	COM(2016) 179 final
[6]	COM(2012) 736 final
[7]	P7_TA-PROV(2014)0010
[8]	COM(2014) 215 final

9.	Owing to global trends in digitization, modern societies are becoming increasingly information driven with people relying on digital tools in their personal as well as their professional lives. This is also changing the attitudes and expectations of people towards the way healthcare is delivered.

10.	New opportunities are arising from big data[9] and improved data analytics capabilities[10], as well as from personalised medicine, use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions. New knowledge and skills are needed in the health sector to be able to utilise this potential.

11.	Different digital solutions and information systems currently in use in the health and social care systems are often not compatible with each other and do not support data exchange and sharing within national systems as well as across borders[11]. This impedes the usability and user-friendliness of these solutions, increases development and maintenance costs and hinders the continuity of care.

12.	Barriers to scaling up the potential in digital health and connected care, such as dominance of data silos, lack of interoperability and of common standards for measuring clinical and patient reported outcomes, limited access and use of large databases for research and innovation purposes, lack of funding and financial incentives, fragmented markets across the EU and across the spectrum of services, still exist and progress in implementing the data-driven digital solutions in the health sector remains limited.

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[9]	Big Data for Advancing Dementia Research. An Evaluation of Data Sharing Practices in Research on Age-related Neurodegenerative Diseases
[10]	Data-driven Innovation for Growth and Well-being, October 2015, OECD

[11]	Benchmarking Deployment of eHealth among General Practitioners 2013 (SMART 2011/0033)

EMPHASISES THAT:

13.   The health systems need to be continuously adapted to meet the expectations of the citizens and their health and care needs. In this context, it is important to embrace the possibilities of the digital society, to enable people to better understand and manage their own health with easier access to information and digital tools.

14.   Citizens' needs should be at the centre of data-driven healthcare innovation, acknowledging people as active agents in their own health journey and providing them more precise and personalised treatments as well as a more participatory healthcare experience, while supporting the role of health professionals and enhancing their interaction and communication with the patients.

15.   Citizens' right to have access to their own health data is a core principle of the Union data protection acquis. Without prejudice to the national legislation and legal grounds for health data processing, flexible systems and tools are needed enabling citizens to access their own data and information on the use of their data, as well as to manage their consent to processing and sharing their health data, including for secondary use. This will help to give people insight into and better control over the use of their health data, thus promoting trust and transparency, taking into account different attitudes and preferences of people when it comes to accessing and managing their data online[12].

16.   Digital solutions should contribute both to more efficient use of healthcare resources and to better targeted, more integrated and safer healthcare. Information sharing between health professionals leads to improved patient safety, reducing the number of avoidable mistakes and adverse events and improving the coordination and continuity of care and better adherence to treatment[13].

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[12]   According to the Special Eurobarometer 460 "Attitudes towards the impact of digitisation and automation on daily life" (2017), over half of all respondents would like online access to their medical and health records (52%) and seven in ten respondents (70%) would be willing to give their health and personal wellbeing data to others. They are the most likely to be willing to share their data with their doctor or health care professional (65%)

[13]   Improving Health Sector Efficiency. The role of Information and Communication Technologies (OECD, 2010)

17. It is important to enable cross-border exchange of health data within the EU to ensure the continuity of care also across borders, in accordance with the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare[14].

18. Availability of comparable and high-quality health data for research and innovation enables the creation of new knowledge to prevent diseases, to achieve earlier and more accurate diagnosis and to improve treatment, in particular supporting personalised medicine, and thus contributing to healthcare system development. The possibility to combine data sets from different data sources and across borders is especially important in the field of rare and low-prevalence complex diseases.

19. Cross-border exchange of health data and supporting data infrastructure is fundamental to combating cross-border health threats of biological, chemical, environmental and unknown origin[15] – as well as antimicrobial resistance and healthcare-associated infections. Sharing of quality data and analytics has enormous potential to assist the prevention, early detection, and control of infectious disease outbreaks.

20. A digital single market for information technologies (IT) used in the field of health and the free movement of data can boost the development and implementation of innovative data-driven technological solutions that will result in better health outcomes and improved quality of life for patients, ensuring that services and products are user-friendly, interoperable and safe.

21. The health systems also have a potential as engines for economic growth, offering economic opportunities, especially for the small and medium-sized enterprises developing innovative data-driven digital solutions.

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[14] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

[15] As set out in Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC Text with EEA relevance. OJ L 293, 5.11.2013, p. 1–15; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013D1082

22. Overcoming barriers to scaling up the potential in digital health and connected care requires a comprehensive set of actions building on the opportunities offered by the digital single market and on the principle of free movement of data and the underlying principles outlined in the EU eGovernment Action Plan.

23. In the design and implementation of digital tools in healthcare due consideration needs to be given to quality, safety, security and data protection requirements, as well as ethical aspects and the differences in digital and health literacy, in order to avoid creating further health inequalities. Furthermore, the use of digital tools is important aid to enhancing health literacy, inter alia by supporting communication between health professionals and patients.

24. Data protection and information security are of the utmost importance to maintain public trust in digital health services. Therefore, swift implementation of the EU legal framework for data protection[16], network information security[17] and secure electronic identification[18] is needed.

25. To maintain confidence and trust in digital health services it is important to raise awareness by developing communication strategies for policymakers, health professionals and citizens regarding the benefits digital health can bring for enhanced quality of healthcare and to provide transparency regarding the use of the health data.

26. Coordination and cooperation in the field of digital health will enable Member States to speed up the implementation of digital innovations in their health systems, to learn from each other and to benefit from the harmonised approaches, in full respect of their national competences. Thus, there is a need to step up practical cooperation among Member States.

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[16] REGULATION (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

[17] Directive (EU) 2016/1148 on security of network and information systems (NIS Directive).

[18] Regulation (EU) N°910/2014 on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation)

27. The EU funding mechanisms play an important role in supporting EU-wide data infrastructures for research and in developing health IT solutions and leveraging Member States' investments to support their large-scale implementation.

WELCOMES:

28. The good progress made in Member States with the implementation of eHealth and the fact that electronic health record systems and e-prescriptions are already deployed or in the process of being deployed in most Member States [19] [20].

29. The work carried out within the eHealth Network[21] set up under Directive 2011/24/EU and the EU Joint Action to support the eHealth Network, which has proven to be very valuable in coordinating Member States' efforts in eHealth, facilitating the cross-border exchange of health data within the EU.

30. The progress achieved in the establishment of the European eHealth Digital Service Infrastructure (eHDSI)[22] funded by the Connecting Europe Facility[23] for cross-border exchange of e-prescriptions and patient summaries.

31. The work undertaken by the European Reference Networks[24] to establish a dedicated IT platform for pooling expertise, information exchange and mutual learning, acknowledging the potential of these networks for enhanced data sharing for the purposes of improved diagnosis, as well as for research and innovation, in particular in the area of rare and low prevalence complex diseases.

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[19] From innovation to implementation – eHealth in the WHO European Region (2016, WHO)
[20] Overview of the national laws on electronic health records in the EU Member States (2014)
[21] See https://ec.europa.eu/health/ehealth/policy/network_en
[22] See https://ec.europa.eu/cefdigital/wiki/display/CEFDSIS/eHealth+2.0
[23] Established by Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 (OJ L 348, 20.12.2013, p. 129)
[24] https://ec.europa.eu/health/ern/policy_en

32. The partnerships and bottom-up initiatives on eHealth launched as part of the European Innovation Partnership on Active and Healthy Ageing[25], which are very important in supporting the transfer of knowledge and best practices between regions and engaging stakeholders across public and private sectors to work together.

33. The Commission Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy[26], which emphasises the importance of digital transformation in health and care.

34. The engagement and commitment of the stakeholders underlined by the Digital Health Society Declaration adopted at the high-level "Health in the Digital Society. Digital Society for Health" conference, which took place on 16-18 October 2017 in Tallinn, launching multi-stakeholder task forces to work on actions addressing the main challenges of large-scale deployment of digital innovation in the field of health.

INVITES THE MEMBER STATES TO:

35. Continue to implement policies that support digital innovation in the health sector, invest in and make active use of data-driven tools and methodologies which enable the provision of safe and high-quality healthcare services and support sustainable health systems.

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[25] See Communication from the Commission on Taking forward the Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing from 29.2.2012 – COM(2012) 83 final and the European Innovation Partnership on Active and Healthy Ageing https://ec.europa.eu/eip/ageing/home_en

[26] Commission Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All (COM(2017) 228 final)

36.   As part of their national strategies and action plans related to digital health:

−   provide appropriate digital tools for personal health information management to enable citizens to access and use their own health data, in accordance with the principles laid down in the General Data Protection Regulation, and where appropriate enable secure sharing of health data, as well as integration of user-generated data with medical data.

−   implement actions to improve the comparability, accuracy and reliability of health data and to encourage the use of health data to enable more transparent and patient-centred health systems focusing on health outcomes and evidence-based health policy and decision-making, as well as to promote data-driven innovation.

−   Review, where relevant and appropriate, existing national legal and administrative frameworks, both to remove obstacles to data exchange and sharing between health professionals for the safety and continuity of care and to enable the use of health data for research and innovation, in full compliance with data protection requirements.

−   implement actions to improve the digital skills of citizens and health professionals, inter alia through offering training to health professionals on the use of digital tools while engaging with citizens and civil society to build public trust and support for data sharing for the benefit of health.

37.   Set up sound and robust health data governance frameworks, as outlined in the OECD Recommendations on Health Data Governance[27], to ensure privacy and integrity of health data.

38.   Work together to facilitate the necessary convergence in regulatory and governance approaches to the use of health data for research and innovation purposes, by identifying and promoting best practices in the use of appropriate data protection safeguards and in health data governance within the Union, and, if appropriate, engaging with the bodies responsible for data protection for example in the framework of the European Data Protection Board provided for in the General Data Protection Regulation.

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[27]   adopted at the 17 January 2017 OECD Health Ministerial Meeting

39. Make use of regional and bilateral or multilateral collaboration among Member States and, as appropriate, engage with other stakeholders on initiatives that have a clear cross-border nature and can have a significant impact on the implementation of digital solutions in the field of health.

INVITES THE MEMBER STATES AND THE COMMISSION TO:

40. Work together, in particular within the eHealth Network, with the aim of achieving interoperable and user-friendly health information systems which allow connectivity of personal health devices and better interaction and information exchange between health and care providers and patients.

41. Continue and streamline existing work on eHealth standards and interoperability, further developing and extending the European eHealth Interoperability Framework[28], promote the use of international and open standards to avoid proprietary solutions creating vendor lock-in[29], which raises IT development and maintenance costs, and support the exchange of information on governance models to reinforce compliance to standards.

42. Promote the use of common data structures, coding systems and terminologies, as well as common standards for measuring clinical and patient reported outcomes, in order to improve semantic interoperability, quality and comparability of data.

43. Reinforce actions to improve data security, by promoting the development and use of privacy-enhancing technologies and privacy by design, exchanging information on available technical tools and methodologies for secure data exchange between authorised individuals and organisations and for the management of personal health data.

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[28] Refined eHealth Interoperability Framework adopted by the eHealth Network in November 2015

[29] See Communication from the Commission "Against lock-in: building open ICT systems by making better use of standards in public Procurement" adopted on 25.6.2013 COM(2013) 455 final

44.	Exchange experiences, transfer good practices and develop common approaches to ensure safety, quality, security and interoperability of mobile health tools and applications, while providing appropriate safeguards to increase trust and to support the uptake of these solutions for better health promotion, disease prevention and chronic disease management, taking into account the applicable Union legislation on medical devices, as appropriate.

45.	Continue the efforts to successfully implement the European eHealth Digital Service Infrastructure (eHDSI) and consider extending the scope of the cross-border exchange of health data to support exchange of electronic health records accessible to citizens across borders, by identifying and analysing new use-cases that support cross-border healthcare and contribute to the continuity of care.

46.	Building on the existing initiatives under the Digital Single Market Strategy such as the European Cloud Initiative[30], the EuroHPC[31] and the European Open Science Cloud, work together with the aim of improving access to larger European datasets, longitudinal data and world-class high performance computing infrastructure for health research and innovation purposes, while ensuring a high level of data protection.

47.	Building on the existing national and EU initiatives and public-private partnerships[32], consider creating decentralised data networks and common platforms to enable data integration and analysis in a secure environment, while avoiding unnecessary data storage at a central Union repository, and supporting large-scale cross-border implementation projects, for example in the field of personalised, including genomic, medicine.

48.	Continue collaborating on common disease registries and platforms, such as the European Platform for Rare Diseases Registration and the Orphanet database,[33] providing crucial interoperability tools for rare diseases research.

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[30]	Communication from the Commission on European Cloud Initiative – Building a competitive data and knowledge economy in Europe adopted on 19.4.2016 – COM(2016) 178 final

[31]	https://ec.europa.eu/digital-single-market/en/news/eu-ministers-commit-digitising-europe-high-performance-computing-power

[32]	Such as IMI2 Big Data for Better Outcomes programme (http://www.imi.europa.eu/), BBMRI ERIC (http://www.bbmri-eric.eu/) and others

[33]	www.epirare.eu/ www.orpha.net

49. Work together to improve data infrastructure, analytics and decision support to predict, prevent and control serious cross-border health threats.

50. Make better use of Union funding mechanisms such as the European Fund for Strategic Investments (EFSI)[34], the EU Structural Funds, the Connecting Europe Facility and Horizon2020[35] to support large-scale digital health implementation, by improving synergies in the cost-efficient use of EU and national funds and identifying common priorities and investment needs, and develop appropriate funding mechanisms and incentives to support interoperability of digital health infrastructure.

51. Consider agreeing on common criteria and indicators that Member States could use to monitor the progress of digital health adoption and to assess the impact of digital solutions, taking into account existing frameworks[36].

INVITES THE COMMISSION TO:

52. Continue supporting Member States efforts by collecting and assessing good practices and evidence to support the transfer of such practices and by raising awareness with regard to digital health.

53. Support the implementation of the existing EU legislation on data protection, electronic identification and information security in the health sector, inter alia by identifying good practices and facilitating the exchange of information between Member States, in order to facilitate cross-border data exchange and to take into account the specific needs and requirements of the health sector, while fully respecting Member States' competences.

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[34] Regulation (EU) 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, the European Investment Advisory Hub and the European Investment Project Portal

[35] See http://ec.europa.eu/programmes/horizon2020/en

[36] See the Monitoring and Assessment Framework for the EIP on Active and Healthy Ageing (MAFEIP) https://ec.europa.eu/jrc/en/mafeip and the Nordic Council of Ministers report "Nordic eHealth Benchmarking"

54. Continue supporting the extension of the eHealth Digital Services Infrastructure to all Member States and to implement new cross-border services, while reinforcing existing work to overcome the technical, semantic and legal challenges and ensuring consistency between different IT infrastructures, in particular the eHDSI and the European Reference Networks' dedicated IT platform.

55. Continue to support research and innovation in the field of digital health and provide support to scientific institutions and innovative companies developing digital health solutions, especially small and medium-sized enterprises (SMEs).

56. Support the Member States in the development and deployment of interoperable national infrastructure for sharing and exchanging health data, focusing especially on primary and integrated care models, supporting the delivery of efficient and high-quality health services and on the adoption of cross-border data exchange services under the eHDSI at national, regional and local levels.

57. Continue to support Europe-wide public-private partnerships and stakeholder engagement activities such as the European Innovation Partnership on Active and Healthy Ageing, aimed at empowering citizens and facilitating the implementation of the digital single market for digital health and care.

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