



Plenary sitting

B9-0239/2019

12.12.2019

MOTION FOR A RESOLUTION

further to Question for Oral Answer B9-0000/2019

pursuant to Rule 136(5) of the Rules of Procedure

on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2019/2804(RSP))

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on behalf of the Committee on the Environment, Public Health and Food Safety

B9-0239/2019

European Parliament resolution on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2019/2804(RSP))

The European Parliament,

- having regard to the Commission communication of 25 April 2018 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018)0233),
- having regard to the Commission communication of 30 April 2004 entitled ‘e-Health - making healthcare better for European citizens: an action plan for a European e-Health Area’ (COM(2004)0356),
- having regard to the Commission staff working document of 21 December 2007 entitled ‘Action plan of the lead market initiative in the area of eHealth - Annex I to the communication - A lead market initiative for Europe’ (COM(2007)0860, SEC(2007)1730),
- having regard to the Commission recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (notified under document number C(2008) 3282)¹,
- having regard to the Commission communication of 4 November 2008 on telemedicine for the benefit of patients, healthcare systems and society (COM(2008)0689),
- having regard to the Commission communication of 6 December 2012 entitled ‘eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century’ (COM(2012)0736),
- having regard to Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union²,
- having regard to Special report No 7/2019 of the European Court of Auditors, entitled ‘EU actions for cross-border healthcare: significant ambitions but improved management required’,
- having regard to Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format³,
- having regard to 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 healthcare⁴,

¹ OJ L 190, 18.7.2008, p. 37.

² OJ L 194, 19.7.2016, p. 1.

³ OJ L 39, 11.2.2019, p. 18.

⁴ OJ L 88, 4.4.2011, p. 45.

- having regard to 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 (the General Data Protection Regulation, hereinafter GDPR)⁵,
 - having regard to the Council conclusions of 8 December 2017 on ‘Health in the Digital Society – making progress in data-driven innovation in the field of health’⁶,
 - having regard to the question to the Commission on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (O-00000/2019 – B8-0000/2019),
 - having regard to Rules 136(5) and 132(2) of its Rules of Procedure,
 - having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas the emergence of new technologies creates both opportunities and challenges for the development of better healthcare; whereas Europe’s health and care systems face serious challenges in the context of an ageing society, higher life expectancy and consistently lower birth rates, creating concerns about the sustainability of the future provision of healthcare; whereas on the other hand, the emergence of new technologies is creating new opportunities; whereas, in this context, a paradigm shift is needed towards proactive and responsive healthcare systems where the maintenance of good health is the primary focus rather than disease management;
- B. whereas spending on healthcare is growing fast and accounts for 9.6 %⁷ of GDP in the EU as a whole; whereas health systems need to maximise the effectiveness and efficiency of accessible, resilient and sustainable health services and long-term care, and ensure fair access to them, as well as to provide new services in line with the evolution of society, deliver seamless care across services and providers, and deliver improvements that matter to patients and their changing and growing health and care needs, well-being and quality of life, while taking account of the differences between patients in terms of internet connectivity, digital skills and health literacy;
- C. whereas innovative digital solutions for health and care can boost the prevention of diseases and the promotion of healthy lifestyles, improve citizens’ quality of life, and pave the way for more efficient ways of organising and delivering health and care services;
- D. whereas data concerning the health of EU citizens is a key enabler for the digital transformation, and must be strictly protected against misuse; whereas the availability of data varies greatly across Member States, and whereas, owing to the lack of interoperability and market fragmentation across health systems, citizens cannot yet fully benefit from the digital single market;

⁵ OJ L 119, 4.5. 2016, p. 1.

⁶ OJ C 440, 21.12.2017, p. 3.

⁷ In 2017; OECD/EU (2018), *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, OECD Publishing, Paris.

- E. whereas healthcare digitalisation will not be limited to greater use of mobile health apps, but will also include data mining, i.e. the analysis of large data sets that serve as a foundation for artificial intelligence (AI) and machine learning;
- F. whereas the organisation and delivery of health and social care is the responsibility of the Member States; whereas the Union can support cooperation between Member States in promoting public health and the prevention of disease, in improving the complementarity of their health services on a cross-border basis, and in supporting and enabling research and development in the field of smart health in Europe;
- G. whereas patients' expectations and desire to monitor their own health are increasing, and the need to empower citizens in relation to their health through the provision of user-centred services and more preventive, personalised and responsive ways for people to interact with health services and health professionals is also becoming correspondingly greater;
- H. whereas the progressive digitalisation of society will increasingly lead patients, caregivers, healthcare professionals and potentially all the actors in the healthcare chain to face the challenges of using information technology and the digital infrastructure of patient records, raising questions of personal data security and privacy;
- I. whereas personal health data are of a particularly sensitive nature and should be subject to strict ethical requirements and citizens' informed consent with regard to their collection, processing, use and storage;
- J. whereas citizens' trust in the safety and confidentiality of the collection, processing, use and storage of their personal health data is of the utmost importance;
- K. whereas the implementation and use of digital health systems are at different levels in each Member State, regarding for example the use of updated technology, support infrastructures for the digital transformation, and the use of electronic health records in healthcare services;
- L. whereas the creation of a European Health Data Space is included in the mission letter to the Commissioner for Health, with a view to promoting health data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes;
- M. whereas science, research and innovation play a vital role in Europe's competitiveness and resilience; whereas exponential leaps in data availability and computing spur research initiatives to understand, prevent, and treat diseases and medical conditions; whereas data management techniques can help identify care gaps, risks, trends and patterns in a complementary or more effective way;
- N. whereas people along lower social gradients tend to have higher health needs and are also more vulnerable to becoming excluded by the digitalisation of healthcare;

General remarks

1. Welcomes the Commission communication on enabling the digital transformation of

health and care in the Digital Single Market, which aims at the promotion of health and the prevention and control of disease, and at helping address citizens' unmet needs, as well as representing an opportunity to improve the sustainability of health systems and make it easier for citizens to enjoy equal and affordable access to high quality care through the meaningful use of digital innovations;

2. Points out that while digital health holds considerable potential, it nevertheless has many unresolved issues when it comes to privacy, security and safety;
3. Underlines that in order to fully benefit from the potential of digital health tools it is of the utmost importance to implement digital health components taking full account of data privacy, security and accuracy and in a manner that integrates patient needs;
4. Notes that compliance with EU legislation on data protection should be a precondition of the digital transformation of health and care in the Digital Single Market;
5. Considers that the actions proposed by the Commission have the potential not only to contribute to providing more preventive, personalised and responsive healthcare to European citizens, to strengthen the efficiency of, equitable access to, and the sustainability and resilience of Europe's health and care systems, but also to stimulate growth and promote European industry in the domain, in particular by helping to maximise the potential of the Digital Single Market with a wider deployment of digital products and services in health and care, as well as the deployment of new services, especially for isolated and inaccessible areas which now have inadequate medical staffing levels and provision of services;
6. Is of the opinion that the digital transformation of health and care needs to support citizen-centred services, as well as empowering citizens to play a more active role in disease prevention and the promotion of health, including in health and care services and responding to citizens' needs; is also of the opinion that this transformation should allow for the exchange of information among the healthcare personnel involved, in accordance with the relevant EU framework on data protection, in dealing with patient records, electronic prescriptions, laboratory test results, medical imaging and discharge summaries; stresses, at the same time, that the needs of patients who are unable to keep up with the digital transformation must not be disregarded; stresses also that digital health should not be a gateway to dehumanised care;
7. Believes that there is a need to ensure a key role for citizens' organisations and networks and public health systems in the governance of and policymaking on digital health and care, at regional, national and European level; stresses, in this context, the importance of cooperation and interconnectedness between the databases of healthcare establishments;
8. Believes that public health systems are the best-placed authorities to manage and/or supervise the collection, anonymisation and pseudonymisation, custody and exploitation of health data while protecting patients' privacy, as well as the efficiency, accessibility and sustainability of the health and care sectors; considers that anonymisation and pseudonymisation enable sensitive data to be used in health research, also noting that pseudonymisation techniques allow the re-identification of the data donors in cases where their health is at risk; calls on the Commission to support projects aimed at

developing these techniques, as well as the technologies needed to create synthetic data for AI algorithm training;

9. Stresses that anonymised and pseudonymised health data could be used for scientific health research, to implement evidence-based health policies and to achieve a better understanding of diseases and the early detection of events that threaten public health, while complying with the principles of patient confidentiality;
10. Stresses that a Commission proposal on sharing information and data governance is necessary to tackle the implications for national health systems;

The need to guarantee access to and sharing of personal health data while applying the GDPR rules meticulously

11. Stresses that citizens have the right to access and share their personal health data in accordance with the GDPR in order to obtain better healthcare, and should be able to expect that this data be available in a timely manner and in a format that is layperson-friendly; points out that the recently adopted GDPR enhances the right of patients to access information on aspects of their health and protect their privacy; regrets, however, that the regulation does not go further on the issue of personal data as personal property or on creating other new rights for patients; observes that the aim of a patient-based system is to improve citizens' health, and that the national health services must guarantee such systems for the sake of the common good;
12. Considers that, owing to the sensitive nature of health data, the right to protection of privacy must be specially regulated, and that this requires special measures to avoid not only cyberattacks, but also the inappropriate use of such data by services;
13. Acknowledges that there are significant economic interests involved in the exploitation of data from the health and care sectors; calls, therefore, on the Commission and the Member States to clearly define responsibilities in relation to data governance, putting in place a new public-private paradigm;
14. Regrets that, at present, many citizens in Europe have either limited or non-existent electronic access to their personal health data, especially in the case of cross-border medical care;
15. Calls on the Commission to continue improving cybersecurity and thus reducing the risk of privacy breaches and the unauthorised use of health data across the Union;
16. Agrees with the Commission that citizens should have secure access to a comprehensive electronic record of their health data, and should remain in control of and be able to share their personal health data securely with authorised parties, while unauthorised access should be prohibited in accordance with the data protection legislation;
17. Calls on the Commission to continue promoting cooperation between Member States' health authorities in order to connect to a public eHealth digital infrastructure so as to extend its use to cover the interoperability of Member States' electronic record systems by supporting the development and adoption of a European electronic health record exchange format, taking account of multilingualism in the EU as well as users with

disabilities, particularly when patients have recourse to cross-border medical care, which, in order to serve the patients' interests, should ensure the most comprehensive information possible concerning health status;

18. Stresses the importance of monitoring the application to health of the GDPR and of the regulation on electronic identification and trust services for electronic transactions in the internal market⁸;
19. Calls on the Commission and the Member States to exchange best practices on the sharing of health data, such as those which already exist for medical treatment, preventive services or research, while placing a strong focus on citizens' privacy, as well as to develop standards and mutually recognised certification/accreditation schemes at European level, including data security and security audits;
20. Calls on Member States' health authorities to make use of EU financing instruments, such as the European Structural and Investment Funds and the European Fund for Strategic Investments, for the deployment of interoperable electronic health records at national and regional level, which will enable citizens to access their personal health data, and for investment in building solid and more reliable infrastructure which supports the digital transformation, and helps to reduce the digital divide between all Member States; calls for the benefits brought by the digitisation and digitalisation of health records to be used to help improve access to and quality of medical care in both urban and rural areas;
21. Calls on the Commission and the Member States to support projects that use real-world data and to develop criteria for the quality of data gathered in a non-controlled environment in order for real-world data to help achieve favourable health outcomes; in this context, further calls on the Commission to develop guidance to promote the secondary use of data for research and to ensure fair, transparent and non-discriminatory access to data throughout Europe;
22. Calls for the Commission and Member States' use of real-world data for regulatory decisions on medicines to complement evidence from randomised-controlled clinical trials;
23. Calls on the Commission to launch a broad European reflection on the ethical aspects of the digital transformation of health and care, actively involving citizens and all other actors in the healthcare chain, with a view to developing ethical standards and regulations to protect citizens' rights while providing security to researchers and the medical technology industry, in particular with regard to the exploitation of health data and the use of AI;
24. Calls on the Commission and the Member States to ensure the establishment of appropriate training and skills development in privacy and security measures, which are in line with prevailing standards and data processing techniques, for those processing personal health data; further calls on the Commission to launch an EU-wide educational

⁸ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257, 28.8.2014, p. 73.

campaign on the benefits of and mechanisms for health data sharing in order to break down misconceptions and support the actions put forward in its communication on enabling the digital transformation of health and care in the Digital Single Market;

The need for better health data

25. Considers that there is a need to increase the quality of health data, standardise data collection, promote the interoperability of European disease registers and advance the analysis of data using high-performance computing and modelling, as well as ensuring the protection of confidential or sensitive data;
26. Stresses the importance of standardising the regulation of healthcare devices, such as mHealth and eHealth devices, thus ensuring their accuracy and precision in the data context;
27. Calls on the Commission to set up a platform for competent authorities, notified bodies and the pharmaceutical and medical technology industries on the application of the Medical Devices Regulation⁹ to digital therapeutics and combination products, with specific attention to the needs of start-ups and SMEs;
28. Calls on the Commission to step up European coordinated action to support the secure exchange and linkage in practice of genomic and other health data in order to advance the progress of researchers and personalised medicine, and thereby identify the best treatments, while ensuring full compliance with data protection legislation and ethical principles;
29. Calls on the Commission, together with the Member States and accredited institutions, to proceed with the testing of specific applications for high-security cross-border health data exchange for research and health policy, in order to improve the prevention, diagnosis and treatment of diseases so as to help health systems to meet current and future challenges;
30. Considers that the move towards digitalisation is an opportunity to launch an ambitious capacity-building programme for citizens, to improve access to medical care, especially in rural areas, and to strengthen industrial opportunities in the field of healthy ageing technology and innovation; further considers that promoting the development of skills for the uptake and effective use of smart health products and services is of the utmost importance at all levels in the health value chain (patients, health professionals, regulatory bodies, payers and authorities);
31. Is of the opinion that ensuring a fit-for-purpose regulatory environment is a key element in protecting public health and providing access to high quality medicines; is also of the opinion that the effective use of IT systems will improve regulatory efficiency across Europe; urges the Commission, therefore, to optimise the European regulatory framework by harmonising regulatory telematics projects with a focus on data quality,

⁹ Regulation (EU) 2017/45 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1.

interoperability and the interdependency of the European regulatory framework;

32. Believes that the development of a shared framework to harmonise the collection of health data and its storage and use in the EU could improve the quality of research and the health services provided to citizens, also facilitating universal access;

The need for better digital tools

33. Considers that there is a need to better advance health promotion, prevent disease and deliver integrated services based on people's needs, especially in the event of pandemics, and that the European Centre for Disease Prevention and Control (ECDC) should play a central role in these efforts; calls for the development of digital solutions and adapted tools linked to more cooperation across Member States in order to avoid situations in which medicine shortages arise;
34. Considers that digital healthcare tools, such as portable patient information cards, could address the challenges of accessibility regarding health information and health literacy, both of which are essential for health promotion, better disease prevention and more effective disease management; considers that such tools, provided they are created with input from the appropriate health professionals, citizens and end-users and are in conformity with all the relevant legislation, permit more accurate and fuller information enabling the promotion of healthy habits and prevention activities, as well as support for decisions on health-related matters and patient adherence to treatments;
35. Stresses the importance of retaining the national/regional role in the organisation of health and care systems, including by using digital solutions and tools, since these have great potential for improving not only the quality, equity and sustainability of health services, but also people's health and wellbeing, while also increasing patient empowerment;
36. Stresses the importance of providing information to patients and supporting them in making meaningful decisions about their health; points out that digital platforms must be user-friendly and digitally accessible and must provide barrier-free information for patients and healthcare professionals in multiple languages;
37. Calls on the Commission to support the digitalisation of regulatory agencies and to work with the relevant actors, especially national health systems, in order to support more cooperation across borders and enlarge the deployment of digitally enabled care models, home care models and assistive home technologies suitable for the elderly, and to do so without encroaching on Member States' competences; considers, in this context, that the European Reference Networks can be excellent vehicles for showing how digital health can contribute to improving health outcomes and wellbeing across borders, as they provide a trusted environment in which health professionals and patients are already working together and exchanging health data across borders to achieve their goals;
38. Calls on the Commission and the Member States to ensure that health professionals upgrade the competences and skills necessary to collect, analyse and protect health data, including by defining requirements for digital health curricula for healthcare professionals, creating life-long training centres of excellence for specific digital skill

sets, stepping up exchanges of relevant good practice, and considering harmonising training and building up the capacity of regulatory bodies to assess smart health products and services in a rapidly evolving technology environment;

39. Calls on the Commission to work with the Member States and the relevant regional and local authorities to develop networks to educate citizens in the use of digital healthcare, enabling universal and equitable access; considers that if this goal is to be achieved there is a need to improve systems' interoperability and users' skills, with the highest levels of protection of sensitive data and with tools and mechanisms provided by the public health systems;
40. Calls on the Commission and the Member States to ensure that all measures to improve citizens' digital skills and access to and use of their health data take into consideration sensitive groups such as older citizens, people who are excluded from the information society and persons with disabilities;
41. Considers that a positive balance for citizens should be struck between the use of digital tools and direct consultation with health professionals; considers further that secure access to and cross-border sharing of health data would mark a positive step forward;
42. Considers that patients should benefit from the most up-to-date information about their medicines; urges the Commission, therefore, to develop further electronic product information, including use of e-leaflets, in order to improve regulatory efficiency and empower patients with up-to-date information on medicines;
43. Calls on the Commission to assist Member States and regional authorities in raising awareness about innovative procurement and investment opportunities for digital transformation in public health and care, and in leveraging public and private investment for the large-scale deployment of digitally enabled, integrated and person-centred care;
44. Calls on the Commission and the Member States to support the scaling-up of smart health pilot and demonstration projects so as to accelerate learning curves;
45. Calls on the Commission to examine the possibility of setting up a European smart health innovation hub to assess and promote smart health initiatives and provide a platform for all actors in the health chain to establish consortia to realise ambitious large-scale projects;
46. Calls on the Commission and the Member States to promote the sharing of best practices and evidence from early adopters of innovative solutions in healthcare, in particular by making full use of INTERREG Europe's projects and its Policy Learning Platform;
47. Calls on the Commission to continuously monitor, benchmark and promote the sharing of good practices between Member States and regions in order to create incentives for effective reforms and track progress towards value-based healthcare and sustainable healthcare systems;
48. Calls on the Commission to assist Member States in creating and implementing

contingency strategies to address any potential temporary or permanent unavailability of health data resulting from an accident or attack on the infrastructure, systems or software used for the collection, processing or storage of such data;

49. Supports the efforts of the ECDC to develop strategies to make better use of existing computerised systems, to use data to limit the spread of infectious diseases, and to help Member States gather and process data;
50. Stresses that a successful digital healthcare transition will require strong political leadership, a long-term vision, and sustained investment at both national and European level;
51. Calls on the Commission and the Member States to establish a clear timetable for the changes planned in order to create a digital health Europe, with mid-term assessments and the setting of targets;
52. Calls on the Commission and the Member States to implement the Commission's recommendations of February 2019 on a European Electronic Health Record exchange format;
53. Calls on the Commission to include these recommendations in the proposal for a European Health Data Space;

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54. Instructs its President to forward this resolution to the Council and the Commission.