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European Commission

ROADMAP			
TITLE OF THE INITIATIVE	Transformation of health and care in the Digital Single Market		
LEAD DG – RESPONSIBLE UNIT	DG CNECT UNIT H3 / SANTE UNIT B3	DATE OF ROADMAP	19/07/2017
LIKELY TYPE OF INITIATIVE	Communication		
INDICATIVE PLANNING	Adoption expected Q4_2017		
ADDITIONAL INFORMATION	https://ec.europa.eu/digital-single-market/en/policies/ehealth http://ec.europa.eu/health/ehealth/policy_en		

This Roadmap aims to inform stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have. The Roadmap is provided for information purposes only and its content may change. This Roadmap does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content.

A. Context, Problem definition and Subsidiarity Check

Context

- *The Digital Single Market Mid-term review (COM(2017) 228 final) announced that the Commission will adopt a Communication on digital transformation in health and care in 2017.*
- *The Communication will address future policy goals and actions in the area of digital health and care. To make borderless European healthcare a reality, citizens need secure access to their electronic health records - also when they travel or live abroad - as well as to e-prescriptions. With a secure supporting infrastructure, digital health data can significantly advance research, improve safety, disease prevention and personalised health and care. Data analytics can be applied to enhance efficiency of health systems and reduce waste. Moreover, mainstreaming digital health and care solutions empowers citizens; it facilitates patient feedback, and interaction / cooperation between patients and healthcare providers. Thanks to digital health tools citizens look after their health and benefit more from person-centred care focused on promotion of good health and prevention and management of chronic diseases.*
- *The Communication will also address how these policy options can be developed in line with legislation on the protection of personal data, patient rights and electronic identification.*

Problem the initiative aims to tackle

- *Digital technologies can help improve people's health and tackle shortcomings in the organisation and financing of health and social care. Digital tools and data can put the patients at the centre of care and offer them integrated services, better safety, quality and access to care everywhere in the EU, health promotion solutions and an empowered relationship with their doctor or carer. Digitisation can also support a more sustainable health and social care system and creates an environment ready to adapt to new technologies. However, the adoption into mainstream health and care is still slow and fragmented across Europe.*
- *With an ageing population, a rise in chronic diseases, health workforce shortages and increasing pressure on government budgets, Europe faces major challenges to keep its healthcare efficient, accessible to all and financially sustainable. The White Paper on the Future of Europe notes that by 2030 Europe will be the oldest region in the world. Life expectancy has increased, but this has not translated into benefits in terms of the average healthy life years of citizens across EU28 since 2010. Public expenditure on health and long-term care has been increasing in all EU Member States over the last decades, and is expected to rise even further in the face of increasing demand for care. In 2015, it accounted for 8.7% of GDP in the EU and could reach up to 12.6% of GDP in 2060.*
- *There is currently substantial fragmentation of the access to significant data-sets and advanced computing capacity between Member States, which is needed to advance personalised medicine or to demonstrate the efficacy and safety of medical products and therapies before and after being placed on the market. Acting at EU level by pooling data, sharing infrastructures and expertise in developing advanced digital solutions will be crucial in order to deliver benefits to citizens (patients and users), health care professionals, industry and Member States' health care authorities:*

➢ *Electronic health record (EHR) systems developed at national or regional level need to become compatible and readable (interoperable) everywhere in the EU, allowing an increasingly mobile EU population to receive the*

same level of care when traveling or living in another EU Member State. This will also increase the potential of the research community to gain access to large data-sets from EHRs required for development of new personalised treatments and medicines.

- *Developing and assessing new medical products and therapies for treating patients is challenging in the European Union. Equally challenging is to ensure that such treatments are accessible and cost-effective for healthcare systems. An enormous amount of data is needed to demonstrate the efficacy and safety of products before and after being placed on the market, with the ultimate goal of protecting public health and supporting Member States in their efforts to ensure sustainable healthcare systems.*
- *A coordinated cross-border sharing of expertise and distributed access to health data sets, can allow the EU and its Member States to provide their population with the most advanced medical and health care solutions and exploit the potential of innovation to support the future sustainability and resilience of healthcare systems.*
- *Efficiencies generated by innovative digital solutions can be accelerated and deployed more widely across the EU, helping to tackle health inequalities between Member States, supporting scalable markets and stimulating innovation.*

Subsidiarity check

- *The legal basis of the Digital Single Market lies with articles 4(2)(a), 26, 27, 114 and 115 of the Treaty on the Functioning of the European Union (TFEU). The legal basis for the Directive on patients' rights in cross-border healthcare lies with Articles 114 and 168 of the Treaty on the Functioning of the European Union (TFEU).*
- *The Communication will outline actions to support voluntary cross-border cooperation mechanisms with Member States in order to advance digital health and care transformation. The EU coordination mechanisms outlined in the Communication will be based on a clear EU added value and take into account the need for EU coordination action identified notably by the eHealth Network, set up under Article 14 of Directive 2011/24/EU on patients' rights in cross border healthcare. It includes national authorities responsible for eHealth policy designated by the Member States.*
- *The challenges to be addressed by the Communication were outlined in the Staff Working Document accompanying the Digital Single Market mid-term review Communication (SWD(2017) 155 final pages 60-66). They are cross-border challenges and can only be addressed through EU coordination with the Member States. Notably, while the majority of citizens wish to have electronic access to their health records when they are traveling or living in another EU country, only 9% of hospitals in Europe allow citizens to access their own patient records online and most of those only give partial access. Few Member States (less than 10) have e-prescriptions that can be used in another Member State. The percentage of hospitals exchanging clinical care information about patients electronically with other healthcare organisations within the same country ranges from 33% to 39%, whereas exchange with health and care providers in another Member State is only 4%.*

B. What does the initiative aim to achieve and how

The Communication will outline further measures in the area of digital health and care, to achieve the following outcomes:

1. Enable citizens´ secure access to electronic health records and e-prescriptions and the possibility to share them across borders when traveling, working or living in another Member State, building in particular on the Digital Service Infrastructure (DSI) currently being developed with support from the Connecting Europe Facility and the contribution from the eHealth Network. On the basis of the public consultation, the Communication may outline possible options to facilitate the exercise of the right of citizens to access electronically personal data concerning health.

2. Advance research, disease prevention and personalised health and care in key areas by enabling access to data sets and medical expertise across borders. A European decentralised digital infrastructure will enable the analysis of aggregated health data gathered and stored in different locations. The infrastructure will be developed through three initial and subsequent pilots; (i) Development of a data strategy for rare and complex diseases including a digital infrastructure in order to facilitate the transfer of knowledge from the lab to clinical care. (ii) Develop a comprehensive data exchange platform that will integrate different data-sets to develop new risk prediction models that will help anticipating epidemics and accelerate EU-wide identification of infectious threats within days; and (iii) Test solutions for the use of real word data notably for the purpose of pharmacovigilance and assessment of the effectiveness of products placed on the market. (iv) Subsequently further pilots will cover other diseases, such as cancer and brain related diseases.

3. Promote widespread uptake of digital tools to facilitate patient feedback and better interaction/ cooperation between citizens and healthcare providers, leading to better health care services and empowered citizens. This goal will be achieved through alignment of existing EU instruments to support for large-scale implementation of

interoperable digital services that support health system reforms and capacity-building towards more patient-centred and integrated care.

The Communication will outline the following type of actions combining different instruments:

- ✓ *Provide **policy orientations** for the optimal use of different funding instruments currently in place (eg. CEF, H2020, EFSI etc.);*
- ✓ *Outline possible **EU coordination actions** in cooperation with the Member States where there is a clear EU added-value; and*
- ✓ *Explore the need for **clarification of legislative and regulatory issues** related to the application of EU law in the field of digital health and care, or for further proposals.*

C. Better regulation

Consultation strategy

- *The launch of an Open Public Consultation related to this initiative will take place in the second half of July 2017 and close after the period of 12 weeks. The purpose of the consultation is to identify the need and scope of further policy measures and actions supporting the use of digital innovation to improve people's health and address systemic challenges of healthcare systems, in line with legislation on the protection of personal data, patient rights and electronic identification.*
- *The consultation will collect information from stakeholders on access to and use of personal data concerning health, making use of personal data to advance health research, disease prevention, treatment and personalised medicine and measures to promoting uptake of digital innovation to support interaction between citizens and health care providers.*
- *The consultation will build on an ongoing dialogue with stakeholders (as part of the eHealth Stakeholders Group, Digitising European Industry and the European Innovation Partnership on Active and Healthy Ageing) and Member States (eHealth Network).*
- *Dedicated discussions on the transformation of health and care in the DSM will also take place with Member States on the ministerial level, including in the EPSCO-Health Council formation (July 20-21 Informal Council of Health Ministers envisages half-day session dedicated to digital transformation of health and care in the context of the DSM).*
- *The results of the consultation will be published in https://ec.europa.eu/digital-single-market/en/consultations*

Impact assessment [max 10 lines]

- *No impact assessment is being prepared to support this initiative as no direct impacts are expected at this stage.*
- *The Communication will provide policy orientations for the implementation of different instruments currently in place (e.g. CEF, H2020, EFSI etc.) and will explore the possibility of EU coordination actions in cooperation with the Member States where there is a clear EU added-value.*
- *The intervention logic is based on the following chain of effects divided into input, outputs and changes sought:*

CHANGE SOUGHT

Widespread adoption of digital technology to make borderless European health and care a reality benefiting citizens, economic operators and health care systems, through (a) enacting the citizens' right to securely access their electronic health records - also when they travel or live abroad - as well as e-prescriptions, (b) support use of cross border data-analytics to advance research, improve safety, disease prevention and personalised medicine and (c) widespread uptake of digital solutions which facilitate patient feedback, and interaction between citizens, health and social care providers in a way that improves services and increases efficiencies of health care service provision.

EXPECTED IMPACTS

CITIZEN IMPACT > More personalised treatment, earlier diagnosis and prevention of diseases
ECONOMIC IMPACTS > A digital single market for personalised medicine and health innovation
SYSTEMS IMPACT > More efficient and resilient health and social care systems supported by people-centred digital tools.

OUTPUTS

(1) Complete the eHealth Digital Service Infrastructure currently under development
(2) Develop a European Electronic Health Record format accessible to citizens and readable / interoperable across the EU.
(3) Deploy and expand initial application pilots, starting with rare diseases, infectious diseases and assessment of medical products; then extend to other diseases, eg cancer, brain
(4) Fully operational European Reference Networks matching areas in (3)
(5) Develop a de-centralised European Health Data Infrastructure for personalised health research and treatment.
(6) Develop Capacity Building and Technical Assistance Scheme for digital health solutions in Member States and regions
(7) Launch a Digital Health and Care Deployment Program and mobilise investments at regional and national level
(8) Incorporate user feedback components in digital systems supported in (2) and (5).

OBJECTIVES

(1) Citizens can exercise their right to manage and share their health data (patient summaries, e-prescriptions and full electronic health records) across the DSM, though an interoperable exchange system.
(2) Researchers and health professionals can pool resources (data-sets, scientific expertise and computing capacity) across the DSM, supported by a decentralised digital infrastructure.
(3) Citizens and health care systems benefit from innovative digital tools that empower people to look after their health, stimulating prevention, enabling feedback and interaction with health care providers and support innovative care models to address rising demand for health and social care.

INPUTS AND ACTIVITIES

(1) Build on the current CEF eHealth DSI to develop a European Electronic Health Record (HER) exchange format accessible to citizens and interoperable / readable across the EU. This will involve making EHR systems developed at national or regional level accessible to citizens and ensuring that they become readable (interoperable) everywhere in the EU, allowing an increasingly mobile EU population to receive the same level of care when traveling or living in another EU Member State.
(2) Build on the European Open Science Cloud and Euro High Performance Computing initiatives to support cross-border sharing of scientific expertise, access to health data-sets and advanced computing capacity, allowing researchers in the EU to develop innovative personalised treatments, early diagnosis of disease and prevention solutions.
(3) Build on H2020 and other EU instruments (e.g. European Structural and Investment Fund and European Strategic Investment Fund to accelerate uptake of digital health solutions widely across the EU, enabling feedback between users and providers of health and social care services and helping to tackle health inequalities between Member States.

Evaluations and fitness checks

Further to the evidence provided in the SWD accompanying the midterm review of the Digital Single Market strategy (SWD(2017) 155 final pages 60-66) this communication will be accompanied by a Staff Working Document with a detailed problem definition and monitoring scheme based on evidence collected from studies and previous evaluations.