Public Consultation: Transformation Health and Care in the Digital Single Market

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Introduction

The purpose of this consultation is to define the need and scope of policy measures that will promote digital innovation in improving people's health, and address systemic challenges to health and care systems. Those measures must be aligned with legislation on the protection of personal data, patient rights and electronic identification. The consultation collects views on:

- Cross-border access to and management of personal health data;

- A joint European exploitation of resources (digital infrastructure, data capacity), to accelerate research and to advance prevention, treatment and personalised medicine;

- Measures for widespread uptake of digital innovation, supporting citizen feedback and interaction between patients and health care providers.

The European Commission reserves the right to publish all contributions to the consultation unless non-publication is specifically requested in the general information section of the questionnaire.

The public online consultation will close on the 12th of October 2017.

In case your response includes confidential data please provide a non-confidential version.

About you

1 – You are welcome to answer the questionnaire in any of the 24 official languages of the EU. Please let us know in which language you are replying.

English

*2 – You are replying

- as an individual in your personal capacity

- in your professional capacity or on behalf of an organisation

*10 – Respondent's first name

Ava

*11 – Respondent's last name

Lloyd

*12 – Respondent's professional email address

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*13 – Name of the organisation

American Chamber of Commerce to the European Union

*14 – Postal address of the organisation

Avenue des Arts 53, 1000 Brussels, Belgium

*15 – Type of organisation

Please select the answer option that fits best.

- Health and care organisation (e.g. hospitals, clinics, social and community care)

- Service provider (e.g. digital health services, data and technology services, insurance providers)

- Private enterprise (other)

- Professional consultancy, law firm, self-employed consultant

- Trade, business or professional association

- Non-governmental organisation, platform or network

- Research and academia

- Churches and religious communities

- Regional or local authority (public or mixed)

- International or national public authority

- Other

*18 – Please specify the type of organisation.

- Chamber of commerce

- Business organisation

- Trade Union

- Representative of professions or crafts

- Other

*24 – Is your organisation included in the Transparency Register?

In the interests of transparency, organisations, networks, platforms or self-employed individuals engaged in activities aimed at influencing the EU decision making process are invited to provide the public with relevant information about themselves, by registering in Transparency Register and subscribing to its Code of Conduct.

Please note: If the organisation is not registered, the submission is published separately from the registered organisations (unless the contributors are recognised as representative stakeholders through Treaty provisions, European Social Dialogue, Art. 154-1)

If your organisation is not registered, we invite you to register here, although it is not compulsory to be registered to reply to this consultation. Why a transparency register?

- Yes

- No

- Not applicable

*25 – If so, please indicate your Register ID number.

5265780509-97

*26 – Country of organisation's headquarters

- Austria

- Belgium

- Bulgaria

- Croatia

- Cyprus

- Czech Republic

- Denmark

- Estonia

- Finland

- France

- Germany

- Greece

- Hungary

- Ireland

- Italy

- Latvia

- Lithuania

- Luxembourg

- Malta

- Netherlands

- Poland

- Portugal

- Romania

- Slovak Republic

- Slovenia

- Spain

- Sweden

- United Kingdom

- Other

*28 – Your contribution,

Note that, whatever option chosen, your answers may be subject to a request for public access to documents under Regulation (EC) N°1049/2001

- can be published with your organisation's information (I consent the publication of all information in my contribution in whole or in part including the name of my organisation, and I declare that nothing

- can be published provided that your organisation remains anonymous (I consent to the publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that it is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent the publication.) Respondents should not include personal data in documents submitted in the context of consultation if they opt for anonymous publication.

Access to and use of personal data concerning health

A major change in the way we receive and provide health and care services is giving citizens the possibility to effectively manage their health data i.e. to grant access to this data to persons or entities of their choice (e.g. doctors, pharmacists, other service providers, family members, insurances) including across borders, in compliance with EU data protection legislation.

29 – Regarding the statement "Citizens should be able to manage their own health data", do you...

- Strongly agree

- Agree

- Neither agree nor disagree

- Disagree

- Strongly disagree

30 – Comments on previous question (e.g. what kind of information, obligatory self-management of data access vs optional, delegated management only to certain persons or organisations – e.g. doctors, pharmacists, other service providers, family members, others):

1000 character(s) maximum

AmCham EU believes that the ability to effectively manage data about one's health – as well as data about one's family members, as relevant, e.g. elderly parents or children – is a key factor in ensuring more empowered citizens and better health outcomes. Citizens' active management of their health data should complement effective data use by health and social care workers and institutions to improve the quality and effectiveness of both prevention and care. Increased levels of health and digital literacy in some parts of the population should be supported to this end.

EHRs should include all health data that would empower the individual, and any data that would be useful for healthcare professions to make informed decisions about their patients. When it comes to delegation, the decision should be left to the individual, including in the eventuality that the induvial is unable to take that decision. The individual should be able to access and remain fully in control of her or his health data, including moving that data across borders, regardless of data localisation restrictions.

31 – Regarding the statement "Sharing of health data could be beneficial to improve treatment, diagnosis and prevention of diseases across the EU", do you…

- Strongly agree

- Agree

- Neither agree nor disagree

- Disagree

- Strongly disagree

32 – Comments on previous question:

1000 character(s) maximum

> AmCham EU believes that sharing of health data – both concerning individual patients and at population level, using appropriate safeguards in compliance with EU data protection legislation – is an essential precondition for better prevention, diagnosis and treatment. Innovation along the continuum of care critically depends on data's ability to gain a fuller patient profile over longer periods of time, with the aim to support timely intervention, assist in diagnosis, personalise treatment plans and help contribute to the goal of improving patient outcomes; the sharing of anonymised, population-level data can tremendously improve research and public health.

33 – What are the major barriers to electronic access to health data?

- Risks of privacy breaches

- Legal restrictions in Member States

- Lack of infrastructure

- Cybersecurity risks

- Lack of awareness

- Lack of interest

- Others

34 – Please specify:

> - Motivating patients to take a more active role in their healthcare can be a challenge, as cultural norms about the provision of healthcare services have traditionally seen patients delegate most of the responsibility for improving health outcomes to a formal healthcare practitioner.
>
> - Patients must become more engaged with their healthcare in order to achieve the desired outcomes.
>
> - Technical barriers imposed by certain systems effectively prevent data interchange with other systems and tools from other vendors, even where a healthcare organisation and individual patients are satisfied with data sharing provisions.

35 – What are the major barriers to electronic sharing of health data?

- Heterogeneity of electronic health records

- Risks of privacy breaches

- Legal restrictions in Member States

- Lack of infrastructure

- Cybersecurity risks

- Lack of technical interoperability

- Data quality and reliability

- Lack of awareness

- Lack of interest

- Others

*36 – Please specify:

- Difficulty of managing authorisations and consents

- In some Member States, there's a lack of coordination and technical interoperability of data collected in hospitals, social security, and primary care providers, while others are still working to implement a governance framework that strikes an appropriate balance between patient-level consent and sharing of large-scale, anonymised population datasets.

- Systems that cannot adequately communicate with one another will prevent health data sharing before legal concerns can be considered

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37 – What should the EU do to overcome barriers to access and sharing of data?
The EU should:

- Standardise electronic health records

- Propose health-related cybersecurity standards

- Support interoperability with open exchange formats

- Support health care professionals with common (EU-level) data aggregation

- Support patient associations with common (EU-level) data aggregation

- Provide the necessary infrastructure for Europe-wide access to health data

- Develop standards for data quality and reliability

- Increase awareness of rights on data access under European law

- Focus on access in cross-border areas

- Propose legislation setting the technical standards enabling citizen access and exchange of Electronic Health Records amongst EU Member States

- Other

38- Please specify

- Standardisation generally helps to overcome barriers to access and sharing health data and can improve upon existing formats designed to stimulate access and sharing. However, broadly standardising electronic health records across the EU Member States may prove challenging.

> • Interoperability with open exchange formats, common data aggregation, the establishment of infrastructure to adequately support Europe-wide access to health data, standards – technical or otherwise – for quality and reliability, are all ways to help achieve the goals of improved health outcomes.

Making use of personal data to advance health research, disease prevention, treatment and personalised medicine

The increasing amount of data on the health and lifestyle of individuals has the potential to advance research, improve disease management and support health policy, notably if exploited in a coordinated way across Europe and in compliance with EU data protection legislation.

39 – Would you agree with the principle that personal health data should be made available for further research, on a case-by-case basis, in a secure way, and in compliance with data protection legislation?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

40 – For which purpose would you agree to make your health data available provided this is in compliance with data protection legislation? (Choose as many as you wish)

- Improving health care organisation
- Improving clinical practice
- Improving social care organisation
- For your own treatment
- Progressing research and innovation
- Developing health insurance schemes
- Informing public health programmes
- Supporting public health policy making
- Helping products development
- Increasing efficiency of health and social care
- Helping developing countries' health care systems
- None of the above
- Other

44 – Should high-performance computing, big data analytics and cloud computing for health research and personalised medicine be advanced?

- Yes

- No

- Do not know

45 – What would be the most important application areas?

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> Cloud data management – including data normalization and aggregation – and big data analytics need to be applied across the continuum of research, prevention and care. Notable application areas may be:
>
> - Predictive analytics to identify risk patients and appropriate treatment recommendations
>
> - Improving risk management for common diseases
>
> - Medical profile creation to improve personalised diagnosis and treatment

46 – Would it be useful to further develop digital infrastructure to pool health data and resources securely across the EU (linking and/or adding to existing infrastructure capacity)?

- Strongly agree

- Agree

- Neither agree nor disagree

- Disagree

- Strongly disagree

47 – What, if anything, should the European Commission do to stimulate the use of data and digital tools to advance research, disease prevention and personalised medicine?

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> AmCham EU believes the European Commission can play a unique role in using its broader Digital Single Market initiatives to ensure more interoperability and sharing of health data can be achieved in the individual Member States as well as cross-border. Moreover, the Commission could:
>
> 1) Prioritise guidance on the application of the GDPR to health data, including positive examples of the potential of data sharing in EU Member States;
>
> 2) Strengthen existing initiatives that allow for large-scale health data curation, exchange and processing; and
>
> 3) Engage and support Member States in large-scale programs that leverage data analytics across networked data pools.

48 – Do you / Does your organisation encounter barriers to using big data analytics for personalised medicine?

- Yes

- No

- Do not know

49 – Please explain what prevents the use of big data analytics:

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> AmCham EU believes that the same barriers apply to the use of big data analytics as those identified in our answers above for electronic access to, and sharing of, health data. European health systems and databases are

diverse and fragmented and there is a lack of harmonization of data formats, processing, and analysis which leads to a lack of interoperability. Moreover, the Commission could:

Promoting uptake of digital innovation to support interaction between citizens and health care providers

This section looks at the current status of digital services in health and care. It also addresses the role that individual citizens, health and care providers, industry, public policy authorities and the EU can play in the improvement of disease prevention and treatment in Europe.

53 – Please indicate to what extent you agree with the following statement: Citizen / patient feedback to health care providers and professionals on the quality of treatment is essential to improve health and care services.

- Strongly agree

- Agree

- Neither agree nor disagree

- Disagree

- Strongly disagree

54 – Please describe other factors you consider essential or more important than citizen feedback in order to improve health and care services (e.g. statistics and other evidence collected by public authorities and insurers, research, public health initiatives, education, cost-efficiency, the sharing of best practices…).

1000 character(s) maximum (1000 characters left)

AmCham EU believes that effective collection, management and sharing of health data across individual patients and at population level can create better outcomes than patient-generated triggers. For example, chronic disease can be treated more efficiently thanks to remote monitoring of patients through the collection and analysis of biometric data.

55 – What should the EU do to support the goals of disease prevention, better treatment and giving citizens the means to take informed decisions on health issues (by means of digital innovation)?

- Provide support for knowledge transfer between member states and regions

- Support regions and municipalities in rolling out new services

- Support EU associations of patients and clinicians to improve clinical practices

- Support further research

- Promote common approaches for feedback mechanisms about quality of treatment

- Other

56 – Please specify

1000 character(s) maximum (1000 characters left)

AmCham EU believes that these objectives will be a natural by-product of the EU's actions to overcome barriers to access and sharing of data described in previous sections of this consultation