EU initiative on a European Health Data Space (EHDS)

Public Consultation Factual Summary Report

1. Introduction

The European Commission conducted a public consultation to gather the views of the public on an EU initiative for a European Health Data Space (EHDS). The purpose of the consultation is to inform the Commission's work to support the impact assessment accompanying the EHDS proposal on the problems to be tackled, the policy options to be considered and their likely impacts. It was conducted to ensure that all possible views are considered in the design of a legal framework for an EHDS and to ensure transparency and accountability. The consultation was open from 03 May 2021 – 26 July 2021

The purpose of this document is to provide a summary of the feedback received as part of the public consultation on an EU initiative for a European Health Data Space (EHDS)[1].

The remainder of this summary is organised as follows: Section 2 provides an overview of the public consultation respondents according to their stakeholder category and country of establishment. Section 3 provides a summary of responses in three areas: a) access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making; b) digital health services and products; and c) Artificial Intelligence (AI) in healthcare.

Public consultations are not, by nature, statistically representative of the population. Therefore, their purpose is not to find answers that could be generalised, but rather to gain in-depth insights that can shed new light on a range of issues.

2. Respondents

The public consultation received a total of 382 valid responses (not counting duplicates from two organisations[2], and one contribution not respecting the Commission feedback rules). Of the 382 respondents, 64 provided additional documentation.

A range of stakeholders responded to the consultation. EU citizens were the most common type of stakeholders among respondents (26%), followed by non-governmental organisations (NGOs) (21%), academic/research institutions (14%), companies/business organisations (11%), business associations (8%), public authorities (5%), non-EU citizens (2%), trade unions (1%) and consumer organisations (1%). About a quarter of respondents represented European or international organisations. The rest of respondents represented national organisations or individual people coming from 23 EU Member States and eight non-EU countries. The most represented countries were Belgium, Spain, France, Germany and Italy.

3. Summary of findings

a. Access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making

i. Access to and exchange of health data for healthcare

The main change that respondents said they had been aware of in the last five years in relation to health data sharing across borders was an increase in the development of methods for enabling the use of

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space/public-consultation_en

[2] DG SANTE consulted with these two organisations to check which submissions should be considered, and only one consolidated answer was kept for each organisation.

medical information for public health and research (51%). Respondents also noticed increases[3] in the: exchange of health data such as patients' summaries and ePrescriptions (47%); access of patients to an electronic copy of the electronic health record (46%); and development of common identification and authentication measures to facilitate transferability of data (45%). A large proportion said they did not know how to answer the question or that they did not have an opinion (between 26% and 38% of the total respondents).

There were many objectives that respondents said a European framework on the access and exchange of personal health data should aim to achieve. The most important ones across all stakeholder types included: supporting and accelerating research in health (89%); promoting citizens' control over their own health data, including access to health data and transmission of their health data in electronic format (88%); and facilitating the delivery of healthcare for citizens across borders (83%). There were differences across stakeholder types when asked about other objectives. For instance, 88% of companies/business organisations said that 'facilitating the delivery of healthcare for citizens at national level' should be an objective, while only 53% of public authorities said this had been the case. In addition, 88% of business associations said that 'promoting private initiatives (e.g. for innovation and commercial use) in digital health' should be an objective, compared with only 31% of NGOs.

Several rights were deemed important by respondents, including the right to access one's health data in electronic format, including those stored by healthcare providers (88%), followed by the right to transmit one's heath data in electronic format to another professional/entity of one's choice (84%), the right to request healthcare providers to transmit one's health data in one's electronic health record (83%), and the right to request public healthcare providers to share electronically one's health data with other healthcare providers/entities of one's choice (82%).

By far, the element that respondents considered the most appropriate for controlling access and sharing your health data with healthcare professionals was ensuring the infrastructure or personal digital storage for accessing the data are secure and prevent cyberattacks (90%). The options of accessing one's health data that is exchanged between health professionals or with other entities either at national level via a digital infrastructure or cross-border via an EU electronic infrastructure also received strong support from respondents (respectively 72% and 69% of the total sample). There was also support for accessing health data through a personal digital storage and sharing it with health professionals (68%) or accessing health data through a mobile app and sharing data with health professionals (64%).

Respondents were divided between those who thought national digital health bodies cooperating at EU level are best suited to develop standards and technical requirements at EU level to support exchange of data in healthcare (40%), and those who thought an EU body might instead be best suited to do this (34%) (several mentioned such a body should meet some requirements, e.g. involve certain types of stakeholders such as scientific experts, representatives from patient organisations, etc.).

Respondents were asked how standards and technical requirements (e.g. to support the exchange of data in healthcare or to ensure the interoperability of health data exchanges) should be made applicable at national level and across the EU. Overall, respondents believed either an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority) or a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level) would be appropriate (respectively 39% and 37%). The option of using a voluntary labelling scheme was the least popular (10%). There were some differences across stakeholder types. For instance, business associations were the most likely type of stakeholders to believe standards and technical requirements should be made applicable through a labelling scheme (34%, compared with only 1% of NGOs for

[3] Based on respondents who answered "greatly increased" and "slightly increased"

instance), and the least likely to believe they should be made applicable by authorisation scheme (14% only, compared with 42% of NGOs and 47% of public authorities for instance).

According to respondents, the most likely cost impact of measures facilitating access to, control and transmission of health data for healthcare would be implementation costs for national healthcare providers (setting up infrastructure, complying with defined standards, etc.) (56% of respondents said the impact would be high). All stakeholder groups said this was the most likely impact, even though there were some differences between the groups (62% of academic/research institutions and 53% of public authorities said the impact would be high, compared with only 21% of business associations and 23% of companies/business organisations). Other possible impacts might be costs for healthcare professionals and providers (human resources, finances, etc.) (38%), as well as costs related to information and monitoring (36%). Again, academic/research institutions were more likely than companies/business organisations to say the impacts would be high. For all three types of costs considered in this question, a large proportion of respondents said they did not know how to answer the question or that they did not have an opinion (between 19% and 21% of the total sample).

Respondents also said such measures would have benefits in terms of facilitated access to healthcare across borders in the EU (72% of respondents said the impact would be high), as well as benefits for patients (e.g. transparency of the processing of their health data – 73%), and benefits on healthcare systems efficiencies (e.g. technological progress – 79% – and better healthcare provision – 74%). On average, across all eight types of benefits considered in this question, business associations and companies/business organisations were the most likely to say the impact would be high, and academic/research institutions and EU citizens were the least likely.

ii. Access and use of personal health data for research and innovation, policy-making and regulatory decision

The mechanism that respondents thought most appropriate to facilitate the access to health data for research, innovation, policy-making and regulatory decision was the mandatory appointment of a national body that authorises access to health data by third parties (ranked as "most preferred option" by 37% of respondents) (deemed more appropriate than the voluntary appointment of such a body – 11%). This was followed by the use of a public body which collects the consent of individuals to share their health data for specified societal uses (“data altruism”) and manages their health data (25%). For all four types of mechanisms considered in this question, just above one in ten respondents said they did not know how to answer the question or that they did not have an opinion (between 11% and 13% of the total sample).

Overall, respondents thought additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decision would be needed at EU level, mainly for research purposes, and for policy and regulatory purposes (when asked about health data categories, format, eligibility and security).

The two options that respondents said were most appropriate in facilitating access to health data held by private stakeholders for research, innovation, policy-making and regulatory decision was to have access to health data granted by a national body (rather than by the data holder), either subject to the agreement of data subjects, or in accordance with national law (respectively 48% and 46%).

Only a small proportion of respondents said a fee would facilitate the sharing of health data held by private stakeholders (20%), and 43% said a fee would not facilitate data sharing or only to a limited extent. Respondents highlighted the limitations of using this incentive (e.g. difficult to manage, not stimulating enough to share data etc.) and said it might even have a negative impact (e.g. potentially endangering patient interest by commercialising health data). Many respondents said that other types

of incentives would facilitate the sharing of health data held by private stakeholders (46%), such as: legal/mandatory obligations, legislations, laws, etc.; and greater interoperability between systems, databases and registries or a more transparent system for sharing data.

A large majority of respondents said an EU body could facilitate access to health data for research, innovation, policy making and regulatory decision if it had a number of functions, the most important ones being: setting standards on interoperability together with national bodies dealing with secondary use of health data (86%); bringing together the national bodies dealing with secondary use of health data, for decisions in this area (79%); and facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data (78%).

Overall, 67% of the respondents believed that the stakeholders participating in EHDS for research, innovation, policy-making and regulatory decision infrastructure should be subject to mandatory use of technical requirements and standards.

A smaller proportion (59%) of respondents said the participants in such an infrastructure would need to undergo an audit, certification or authorisation before participating in EHDS cross-border infrastructure. With regards to stakeholders participating in EHDS infrastructure using a voluntary labelling scheme to show compliance with data quality and interoperability technical requirements and standards, this was the least popular (25%).

Respondents also said such measures would have benefits in terms of providing access to cutting-edge, efficient and safe care (e.g. thanks to faster innovation in health – 77% of respondents said the impact would be high – and increased safety of healthcare and of medicinal products or medical devices – 75%), as well as benefits on healthcare systems efficiencies (e.g. better informed decision-making – 77% – and technological progress – 76%).
Respondents were asked about the most important impacts of a future EHDS allowing for the access and use of personal health data for research, innovation, policy making and regulatory decision-making. Several stakeholders mentioned possible economic impacts, such as an increase in productivity and efficiency improvements. They also noted possible social impacts, such as greater levels of research and innovation or increased transparency in population health across EU which would lead to rising overall health standards. However, there were mixed opinions on whether a future EHDS would lead to equity in the EU (noting that access to more data could foster inclusion through increased knowledge, while also creating a risk of possible discrimination in future policy-making and regulatory decision-making). In terms of impacts on fundamental rights, several respondents highlighted the risks related to data breaches in medical confidentiality and professional secrecy, as well as misuse of health data.

b. Digital health services and products

Respondents were asked about how to ensure access to, and sharing of, health data nationally and across borders through digital health services and devices. Overall, a majority of respondents said that it would be useful if citizens were able to transmit the data from m-health and tele-health into their electronic health records (77%), or, to a smaller extent, into the EU health data exchange infrastructure (67%). A majority of respondents also said that it would be useful if healthcare professionals could request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patient (68%), or, to a lesser extent, if healthcare professionals had the right to access patients' digital health records and data pertaining to the patient's use of digital health products or services (62%).
When asked about the most important impacts of the deployment and use of digital health products and services, several stakeholders mentioned possible economic impacts, such as an increase in both

the effectiveness and efficiency of healthcare systems. They also noted possible social impacts. For instance, there were mixed opinions on whether this would lead to more or less personalised care (and therefore to better or poorer health outcomes). Respondents also mentioned an effect might be the increased accessibility and availability of healthcare, diagnosis and treatments, leading to a reduction in health inequalities. In terms of impacts on fundamental rights, respondents said the deployment and use of digital health products and services could empower patients, but could also create risks related to data privacy and protection.

A majority believed tele-health could entail additional risks for the patients and for the doctors (65%), such as: risks linked to data security, risks of misdiagnosis, issues linked to unclear reimbursement systems; and dehumanisation and depersonalisation of medical treatment.

Respondents said that such risks should be addressed at the EU level, either through minimum standards for tele-health equipment (63%), through protocols/rules for tele-health (60%), or, to a smaller extent, through liability rules (56%).

Overall, respondents believed a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level) would be most appropriate to foster the uptake of digital health products and services at national and EU level (52%). A smaller proportion of respondents said an authorisation scheme managed by national bodies would be appropriate (43%). The option of using a voluntary labelling scheme was the least popular (19%).

Respondents believed that the most appropriate measure to support reimbursement decisions by national bodies would be a framework where EU funds support/top up cross-border digital health services that comply with interoperability standards and ensure patient access to, and control over, their health data (71%). Respondents said that other measures would also be appropriate, such as the use of an EU repository of digital health products and services assessed according to EU guidelines to aid national bodies to make reimbursement decisions (64%), a framework which facilitates reimbursement of all tele-health services (62%) or a framework where national authorities make available lists of reimbursable digital health products and services (62%).

A large majority of respondents believed access to EU funds for digitalisation in healthcare by Member States should be conditional upon ensuring interoperability with electronic health records and national healthcare systems (81%).

c. Artificial Intelligence (AI) in healthcare

To facilitate the sharing and use of data sets for the development and testing of AI in healthcare, respondents recommended allowing access to health data by AI manufacturers for the development and testing of AI systems in a secure way (including compliance with GDPR rules), by bodies established within the EHDS (65%).

A majority of respondents believed the introduction of AI in healthcare is creating a new relationship between the AI system, the healthcare professional and the patient (69%). While some thought this relationship was positive (bringing positive changes such as acceleration and optimisation of care as well as the fostering of research and discoveries), others said this would have downsides (e.g. worsening the level of trust between physicians and patients, or decreasing patient confidence in the solutions proposed). There were differences across stakeholder types. For instance, NGOs were the most likely to believe the introduction of AI in healthcare is creating a new relationship between the AI system, the healthcare professional and the patient (81%, compared with only 63% of business associations or 58% of EU citizens for example).

To ensure collaboration and education between AI developers and healthcare professionals, a large majority of respondents agreed that healthcare professionals and/or providers should demonstrate understanding of the potentials and limitations in using AI systems (83%). There were some differences across stakeholder types (e.g. only 66% of business associations agreed, compared with 89% of NGOs and 82% of public authorities). Another large majority aid that AI developers should be obliged to train healthcare professionals on the use of AI systems provided (77%). There were again some differences across stakeholder types (e.g. only 71% of business associations agreed, compared with 89% of NGOs and 88% of public authorities).

Many respondents believed there are specific ethical issues involved in the use of AI in healthcare (80%). For example, they said that the use of AI creates risks related to the possibility that AI might draw the wrong conclusions, or create biases which might reinforce discrimination and inequalities. They also mentioned concerns over the confidentiality of health data and health data protection, the dehumanisation of medicine as well as transparency issues.