EUROPEAN
COMMISSION

Strasbourg, 3.5.2022
SWD(2022) 132 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

{COM(2022) 197 final} - {SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final}

A. Need for action

What is the problem and why is it a problem at EU level?

The evaluation of the digital aspects of the Cross Border Healthcare Directive (2011/24/EU) (CBHD) shows low effectiveness of the current voluntary system. The main problems are that individuals have limited control over their health data at national and cross-border level, digital health solution producers face barriers when entering other Member States' markets and individuals cannot benefit from innovative treatments due to limited access to health data by researchers, innovators and policy makers.

What should be achieved?

Ensure that individuals have control over their own health data (nationally and cross-border) can benefit from a range of health-related products and services and that researchers, innovators, policy-makers and regulators can make the most of the available health data.

What is the value added of action at EU level (subsidiarity)?

Despite possibilities offered by GDPR, fragmentation persist at Member States level, when accessing health data. Moreover, the access and portability provisions of the GDPR do not fully meet the needs of the health sector. This hampers interoperability, data access and sharing, provision of digital health services and products in the internal market, as well as research, innovation and policy-making, including responses to health crises.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

Option 1: Intervention with low intensity: It relies on a reinforced cooperation mechanism and voluntary instruments that would cover digital health products and services and reuse of health data. It would be supported by improved governance and digital infrastructure.

Option 2 and 2+: Intervention with medium intensity: It would strengthen the rights of citizens to control digitally their health data and provide an EU framework for re-use of health data. The governance would rely on national bodies (for primary and secondary use of data) that would implement the policies nationally and, at EU level, would support the development of appropriate requirements. A digital infrastructure would support cross border sharing and re-use of health data. Implementation would be supported by certification and labels, thus ensuring transparency for authorities, procurers and users.

Option 3 and 3+: Intervention with high intensity: It would go beyond Option 2 by assigning the definition of EU level requirements and access to cross country health data to an existing or new EU body and would extend the coverage of certification.

The preferred option is **Option 2, with elements of 2+** ensuring a certification of electronic health records, data intermediation services comprising electronic health records and medical devices that feed data into EHRs, as well as a voluntary label for wellness apps. This would ensure the best balance between effectiveness and efficiency in reaching the objectives. Option 1 would improve the baseline marginally, as it remains voluntary. Option 3 would also be effective, but would have higher costs, may impact more on SMEs and may be less feasible politically.

What are different stakeholders' views? Who supports which option?

There was consensus overall among stakeholders that the EHDS should promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format and facilitating cross-border healthcare provision. Researchers and regulators are concerned about the current fragmented procedures for health data reuse and welcome EU action. Industry

representatives support common EU interoperability requirements, but stressed the need for a proportionate approach. A third-party certification scheme has more support than authorisation or labelling, but support varies between stakeholders. National representatives support the rollout of MyHealth@EU and the creation of a network of Health Data Access Bodies, but warned about the need to respect national specificities.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?

The preferred option would ensure that citizens are able to access and transmit digitally their health data and enable access to it, irrespective of healthcare provider and data source. MyHealth@EU would become mandatory and individuals could exchange their health data cross-border in a foreign language. Mandatory requirements and certification (for electronic health records, data intermediation services providing EHRs and medical devices feeding information into EHRs), and a voluntary label for wellness apps would ensure transparency for users and procurers and reduce cross-border market barriers for manufacturers. Researchers, innovators, policy-makers and regulators would be able to have access to quality data for their work in a secure way, with a trusted governance and at lower prices. The total economic benefits of this option are expected to be above EUR 11 billion, over 10 years.

What are the costs of the preferred option (if any; otherwise of main ones)?

The main costs stem from the deployment of the digital infrastructure supporting the EHDS. This includes completing the coverage of MyHealth@EU and the full rollout of the necessary digital infrastructure connecting Health Data Access Bodies, research infrastructures and EU bodies. Actions on promoting interoperability through mandatory certification and voluntary labels are also expected to trigger costs. The overall costs for the preferred option are expected to be between EUR 0.7-2.5 billion above the baseline over 10 years.

What are the impacts on small and medium-sized enterprises (SMEs)?

SMEs would have to comply with mandatory requirements on interoperability, security for electronic health records and some medical devices that feed information into EHRs. Producers of wellness apps could elect to ensure transparency for users through voluntary labels. While these measures may increase the burden on SMEs, common requirements across EU will increase the chances to be selected in procurements or reimbursement schema and will reduce the entry barriers to the markets of other Member States, partially or totally offsetting such costs. The common network of Health Data Access Bodies would facilitate the access of SMEs to health data, for research and innovation purposes. The preferred option is expected to lower the barriers for SMEs to reuse quality health data, contributing to their competitiveness.

Will there be significant impacts on national budgets and administrations?

The rollout of digital infrastructures for use and reuse of health data and the set up of health data access bodies are expected to impact national budgets and administrations. The preferred option allows Member States to choose their organisational arrangements, building on Data Governance Act. Parts of the costs will be offset through fees charged by Health Data Access Bodies. The setting up of data access bodies is expected to lower the costs to access data for regulators and policy makers and would increase transparency concerning medicinal products, allowing additional savings. Digitalisation can also reduce unnecessary tests and ensure transparency in spending, allowing savings to the health budget. EU funds will provide support for digitalisation.

Will there be other significant impacts?

Citizens would be able to enforce their rights to access and transmit digitally their health data to user-selected third parties from the health/social sector, without hindrance from manufacturers or healthcare providers. Participation in MyHealth@EU within a certain timeframe would reduce disparities when

accessing healthcare services in the cross-border context. The preferred option defines a common EU framework for accessing health data for research, innovation policy making, regulatory purposes and personalised medicine, building on GDPR, with a trusted governance and high security. It can reduce costs to access health data, with a higher level of transparency, accountability and security for citizens. The analysis of health data may lead to new medical discoveries.

Proportionality?

The initiative is limited to aspects that Member States cannot achieve satisfactorily on their own, as shown by the evaluation of Article 14 of the CBHD. The preferred option is proportionate, given the medium intensity of the proposal and the expected benefits for citizens and industry.

D. Follow up

When will the policy be reviewed?

The Commission will review the monitoring indicators periodically and evaluate the impacts of the legislative act after 7 years.