EUROPEAN COMMISSION

SEC(2022) 196

26.1.2022

REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space

COM(2022) 197
SWD(2022) 131
SWD(2022) 132

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Digital health data and services – the European health data space

Overall 2nd opinion: POSITIVE

(A) Policy context

The European Health Data Space (EHDS) aims to enhance health data interoperability by facilitating access to and control by citizens of their own health data. It also aims to promote the national and cross-border exchange of health data for healthcare provision and the re-use of such data for research and policy decisions. The regulatory framework covers governance and access rules, data quality and interoperability as well as digital infrastructure and their compatibility with GDPR provisions.

A voluntary eHealth Network is already in place. This uses the MyHealth@EU platform, which was set up by the Cross-Border Healthcare Directive 2011/24/EU. The articles of this Directive related to digital health were evaluated for this impact assessment.

(B) Summary of findings

The Board notes that its previous recommendations have been addressed to a large extent.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) The rationale for having a specific sectoral initiative on health data is not sufficiently explained.

(2) The difference between secondary use and data altruism is not clear and this leads to confusion in the different consent mechanisms.

(3) The report does not sufficiently reflect different stakeholder views.

(C) What to improve

(1) The report should better explain the rationale behind having a sectoral initiative on health data, in particular whether this is due to its peculiarity and related security issues, and the reason why other horizontal initiatives like the Data Act may increase the risks of

This opinion concerns a draft impact assessment which may differ from the final version.

inappropriate use of health data.

(2) The report should clarify what data altruism could add to secondary use of data. It should clarify the application of different consent mechanisms regarding data altruism and secondary use. It should explain better why another consent mechanism (opt-in) would be applied compared to opting-out for secondary use when no explicit individual consent is required.

(3) The report should clarify if the benefits from data governance by Health Data Access Bodies are related to obtaining individual consent or rather originate from the need to safeguard the rights and freedoms of the data subjects when no explicit consent is required.

(4) The report should better differentiate the stakeholder views throughout instead of providing majority views.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for Regulation [tbc] on the European Health Data Space, digital health services and products and the use of new technologies, including artificial intelligence (AI) in health
Reference number	PLAN/2020/8701
Submitted to RSB on	21 December 2021
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

Table 1. Overview of Benefits for the Preferred Option (above the baseline and over 10 years).

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	Amount	Comments
Direct benefits		
Cost savings and efficiency gains in the healthcare sector	*EUR 5.4 billion (EUR 58.9 saved per patient per year)*	*Savings stemming from higher uptake of telemedicine assuming traditional medicine costs EUR 68.9 per patient per year while only EUR 10 if using telemedicine*
Cost savings in the cross-border provision of health services	*EUR 173-232 million*	*Savings originating from faster deployment of cross-border ePrescription and medical imaging services through MyHealth@EU*
Efficiency gains in accessing health data by researchers and innovators	*EUR 0.8 billion*	*The use of real world evidence in policy-making in health can yield substantial savings thanks to greater transparency of the effectiveness of medicinal products resulting in more efficient regulatory processes*
Cost savings in the reuse of health data access	*EUR 3.4 billion*	*Savings for researchers, innovators, regulators and policy-makers, originating from not having to reach directly the data subjects to further process their health data and from instead relying on access granted by national health data access bodies*
Increased value of health data	*EUR 1.2 billion*	*Value generated thanks to more intensive and extensive health data sharing supporting data-driven innovation and regulatory and policy-making processes in health*
Indirect benefits		
Contribution to the growth of the digital health and wellness applications markets	*Faster growth expected at 20%-30% and 15%-20% per year, respectively*	
Reduction of non-dispensation rate for cross-border prescriptions	*26%*	*Based on the estimate of the current non-dispensation rate (46%)*
Availability of innovative medical products based on health data use and reuse	*Non-quantifiable due to lack of data*	*Citizens, healthcare professionals and providers would be able to benefit from innovative medical products based on health data use and reuse*

Table 2. Overview of costs for the Preferred Option (above the baseline).

II. Overview of costs – Preferred option							
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Governance of the EHDS (including preparation of requirements, assessment frameworks and guidelines, both for primary and secondary uses of health data)	*Concerned parties*	*National digital health authorities and the Commission (primary uses)*		*Health Data Access Bodies and the Commission (secondary uses)*			
	Direct costs	-	*EUR 1.3-2.0 million/year*	-	*EUR 1.3-2.0 million/year EUR 1.0-3.0 million/year invested for actions promoting interoperability, data altruism and the development of AI in health*		
	Indirect costs	-	-	-	-		
Establishment and operation of health data access bodies	*Concerned parties*	*Member States' authorities*					
	Direct costs	*EUR 1-3 million for each health data access body (not considering secure clouds and infrastructure, which may be shared with other bodies under Article 7 of the DGA)*	*EUR 0.5-1.5 million/year for each health data access body*				
	Indirect costs	-	-				
Expansion of the EU infrastructure for primary uses of health data	*Concerned parties*	*National digital health authorities and European Commission*					
	Direct costs	*EUR 0.8-2.5 million for the*	*EUR 0.5-1 million for the*				

(MyHealth@ EU)		*deployment of each new NCPeH (for new Member States only; shared) EUR 0.3-1.0 million for the implementation of each new service for at a NCPeH (shared)*	*maintenance of each MyHealth@ EU generic service EUR 7 million for the central services of MyHealth@ EU (Commission only)*				
	Indirect costs	-	-	-	-		
Mandatory third-party certification for EHR systems	*Concerned parties*	*Citizens, healthcare professionals/providers*		*Digital health products manufacturers obtaining the label*		*Digital health authorities*	
	Direct costs	-	-	*EUR 20,000-50,000*	*(Recertification estimated at 80% of certification cost every 5 years)*	-	*Monitoring of market and guidance on label (included in governance costs)*
	Indirect costs	-	-	-	-	-	-
Mandatory third-party certification for digital health products (medical devices feeding into EHRs)	*Concerned parties*	*Citizens, healthcare professionals/providers*		*Digital health products manufacturers obtaining the label*		*Digital health authorities*	
	Direct costs	-	-	*EUR 20,000-50,000*	*(Recertification estimated at 80% of certification cost every 5 years)*	-	*Monitoring of market and guidance on label (included in governance costs)*
	Indirect costs	-	-	-	-	-	-
Voluntary self-declared quality label for wellness applications	*Concerned parties*	*Citizens, healthcare professionals/providers*		*Mobile wellness applications developers obtaining the label*		*Digital health authorities*	
	Direct costs	-	-	*EUR 1,500-3,000*	*Non-quantifiable costs due to lack of data*	-	*Monitoring of market (non-quantifiable) Guidance*

							on label (included in governance costs)
	Indirect costs	-	-	-	-	-	-
Development and deployment of the EU infrastructure for secondary uses of health data	*Concerned parties*	*Health Data Access Bodies*		*European Commission*			
	Direct costs	*EUR 0.8-2.8 million for the deployment of infrastructure required per data access body to connect to the EHDS infrastructure*	*EUR 0.2-0.8 million for yearly maintenance*	*EUR 3 million for the deployment of a node for an EU body* *EUR 25 million for the deployment of central services*	*EUR 6-7 million for the maintenance for central services and nodes of EU bodies*		
	Indirect costs	-	-	-	-		
Data quality label	*Concerned parties*	*Data holders*		*Health data access bodies*		*Data reusers*	
	Direct costs	*EUR 7,000-17,000 for obtaining the data quality label*	-	-	*Monitoring and enforcement costs (non-quantifiable due to lack of information)*	-	*Increased costs in data access due to increased data quality (non-quantifiable due to lack of information)*
	Indirect costs	-	-	-	-	-	-

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Digital health data and services – the European health data space

Overall opinion: NEGATIVE

(A) Policy context

The European Health Data Space (EHDS) aims to facilitate access to and control by citizens of their own health data. It also aims to promote national and cross-border exchange of health data for healthcare provision and re-use of such data for research and policy decisions. The regulatory framework covers governance and access rules, data quality and interoperability as well as digital infrastructure.

A voluntary eHealth Network is already in place. This uses the MyHealth@EU platform, which was set up by the Cross-Border Healthcare Directive 2011/24/EU. The articles of this Directive related to digital health were evaluated for this impact assessment.

(B) Summary of findings

The Board notes the information provided in advance of the meeting.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report is not clear on the coherence with other related initiatives.
(2) The justification of the legal basis is not sufficient and does not reflect the core objectives targeted by the initiative.
(3) The objectives regarding secondary use are not sufficiently specified in their scope. They are not sufficiently clear on the coherence and consistency with the legal principles on the extent of personal data use, set out in related initiatives.
(4) The report is not clear on the issue of data control and consent in the proposed options.
(5) The report does not sufficiently justify the combination of measures in the different options. It does not sufficiently explain the choice of the preferred option.
(6) The report is not clear on how the different groups of stakeholders will be affected by the proposal. Their views are not well reflected throughout the report.

(C) What to improve

(1) The report should clearly identify the gaps and overlaps with existing and planned initiatives, in particular the General Data Protection Regulation (GDPR), the Data Governance Act and the upcoming Data Act. Coherence with those initiatives should be ensured, in particular on the issues of the use of data for public purposes as well as data altruism, consent, portability and ownership. This is especially in relation to secondary uses and the creation of a single personal data driven market for digital health products and services.
(2) The legal basis for this proposal should be better justified and linked to its main objectives. The report should clarify why Article 168(1) of the TFEU is not the main legal basis given that the proposal's core objective is better healthcare for citizens, while Article 114 relates to establishment of a single market for digital health data that is more focused on the potential commercial exploitation of this data.
(3) The report should clarify the main objectives of the proposal, in particular related to the secondary use of health data. It should be explicit on the possible secondary uses of health data and which private and public markets would be affected. It should clarify how these uses would comply with the principles and objectives on data access, control and use, as outlined in related initiatives. In this respect, it should differentiate between use of health data for commercial purposes and use of health data for improving health care.
(4) The proposed options should be clearer on the issue of consent on data use and data portability, as distinct from interoperability rules, especially with reference to the property and liability rules regimes that would apply.
(5) The report should assess whether it is possible that a different combination of measures would lead to a better result. It should justify each measure that appears in the preferred option and demonstrate that it contains the best performing combination.
(6) The report should provide justification for all assumptions used when estimating the costs and benefits and should acknowledge limitations and uncertainties in these estimates when proposing a best performing option. The report should be clearer on the costs and benefits for different groups of stakeholders.
(7) The report should introduce the views of different stakeholder groups in the main report and explain how they affect the choice of the combination of measures in the preferred option. It should clarify and discuss the possible divergent views of stakeholders.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Proposal for Regulation [tbc] on the European Health Data Space, digital health services and products and the use of new technologies, including artificial intelligence (AI) in health
Reference number	PLAN/2020/8701
Submitted to RSB on	27 October 2021
Date of RSB meeting	24 November 2021

Electronically signed on 26/01/2022 10:06 (UTC+01) in accordance with article 11 of Commission Decision C(2020) 4482

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Digital health data and services – the European health data space

Overall opinion: NEGATIVE

(A) Policy context

The European Health Data Space (EHDS) aims to facilitate access to and control by citizens of their own health data. It also aims to promote national and cross-border exchange of health data for healthcare provision and re-use of such data for research and policy decisions. The regulatory framework covers governance and access rules, data quality and interoperability as well as digital infrastructure.

A voluntary eHealth Network is already in place. This uses the MyHealth@EU platform, which was set up by the Cross-Border Healthcare Directive 2011/24/EU. The articles of this Directive related to digital health were evaluated for this impact assessment.

(B) Summary of findings

The Board notes the information provided in advance of the meeting.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report is not clear on the coherence with other related initiatives.

(2) The justification of the legal basis is not sufficient and does not reflect the core objectives targeted by the initiative.

(3) The objectives regarding secondary use are not sufficiently specified in their scope. They are not sufficiently clear on the coherence and consistency with the legal principles on the extent of personal data use, set out in related initiatives.

(4) The report is not clear on the issue of data control and consent in the proposed options.

(5) The report does not sufficiently justify the combination of measures in the different options. It does not sufficiently explain the choice of the preferred option.

(6) The report is not clear on how the different groups of stakeholders will be affected by the proposal. Their views are not well reflected throughout the report.

(C) What to improve

(1) The report should clearly identify the gaps and overlaps with existing and planned initiatives, in particular the General Data Protection Regulation (GDPR), the Data Governance Act and the upcoming Data Act. Coherence with those initiatives should be ensured, in particular on the issues of the use of data for public purposes as well as data altruism, consent, portability and ownership. This is especially in relation to secondary uses and the creation of a single personal data driven market for digital health products and services.

(2) The legal basis for this proposal should be better justified and linked to its main objectives. The report should clarify why Article 168(1) of the TFEU is not the main legal basis given that the proposal's core objective is better healthcare for citizens, while Article 114 relates to establishment of a single market for digital health data that is more focused on the potential commercial exploitation of this data.

(3) The report should clarify the main objectives of the proposal, in particular related to the secondary use of health data. It should be explicit on the possible secondary uses of health data and which private and public markets would be affected. It should clarify how these uses would comply with the principles and objectives on data access, control and use, as outlined in related initiatives. In this respect, it should differentiate between use of health data for commercial purposes and use of health data for improving health care.

(4) The proposed options should be clearer on the issue of consent on data use and data portability, as distinct from interoperability rules, especially with reference to the property and liability rules regimes that would apply.

(5) The report should assess whether it is possible that a different combination of measures would lead to a better result. It should justify each measure that appears in the preferred option and demonstrate that it contains the best performing combination.

(6) The report should provide justification for all assumptions used when estimating the costs and benefits and should acknowledge limitations and uncertainties in these estimates when proposing a best performing option. The report should be clearer on the costs and benefits for different groups of stakeholders.

(7) The report should introduce the views of different stakeholder groups in the main report and explain how they affect the choice of the combination of measures in the preferred option. It should clarify and discuss the possible divergent views of stakeholders.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Proposal for Regulation [tbc] on the European Health Data Space, digital health services and products and the use of new technologies, including artificial intelligence (AI) in health
Reference number	PLAN/2020/8701

Submitted to RSB on	27 October 2021
Date of RSB meeting	24 November 2021

Electronically signed on 26/11/2021 10:53 (UTC+01) in accordance with article 11 of Commission Decision C(2020) 4482