

Establishing the European health data space

Impact assessment (SWD(2022) 131 final, SWD(2022) 132 final (summary) accompanying a Commission proposal for a regulation of the European Parliament and of the Council on the European health data space, COM(2022) 197 final

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above-mentioned [proposal](#), adopted on 3 May 2022 and referred to the European Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE).¹

The proposal, included in the [Commission's 2021 work programme](#) (see [Annex I](#) – New initiatives) and in the [EU legislative priorities for 2022](#) (see the Commission's [working document](#)), aims to increase *natural persons'* (i.e. private individuals') *control* over their health data (i.e. allow individuals' health data to be accessible and transmittable), and to facilitate their 'primary use' (or 'use', see IA, p. 32, and Table 2, p. 33), i.e. the use of health data in the delivery of healthcare, including at cross-border level, and for ensuring continuity of care. In addition, the proposal aims to facilitate the use of personal or non-personal health data with the purpose for instance of supporting health research, policy-making, and innovation ('secondary use' or 're-use' of health data – see IA, [Part 1/4](#), p. 35, and Table 3, p. 34). Finally, it aims to contribute improving the conditions for the establishment and functioning of the internal market for digital healthcare products and services.

The proposal 'establishes the European health data space by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of health data' (Article 1). In addition, it sets out 'essential requirements [for interoperability and security] for electronic health record systems ['EHR systems'] and products claiming interoperability with EHR systems' (Annex II explanatory memorandum) in order to promote interoperability and data portability. The proposal is grounded in the [European strategy for data](#), [COM\(2020\) 66](#), which envisages establishing nine European common data spaces, including regarding health. In its [resolution](#) of 24 November 2021 on a pharmaceutical strategy for Europe, the Parliament welcomed the establishment of a European health data space (EHDS) as an interoperable digital infrastructure.

Problem definition

Based on the evaluation of the provisions regarding eHealth contained in Article 14 ('eHealth') of the cross-border healthcare [Directive 2011/24/EU](#) (CBHD) (IA, [Part 4/4](#), Annex 12, and supporting [study/annexes](#)), which was carried out in parallel with the IA rather than sequentially, the IA identifies **four problems** (IA, [Part 1/4](#), pp. 18-25):

1. **individuals have difficulties exercising their right to control their health data**, i.e. to access and transmit their health data at national and cross-border level. According to the IA, this hampers their access to health services, and causes ineffectiveness and inefficiencies in healthcare systems, e.g. unnecessary repeated tests;
2. **providers of digital health services and manufacturers of digital health products face barriers and additional costs when entering other Member States' markets**, hampering their competitiveness and causing lock-in effects (i.e. the vendors' tendency to provide proprietary health IT solutions), which the IA neither illustrates nor quantifies;



3. **individuals cannot benefit from innovative treatments based on health data use and re-use**, although the problem tree of Figure 5 (IA, [Part 1/4](#), p. 18) identifies this problem in a slightly different way ('individuals have access to limited innovative health products and services');
4. **policy-makers and regulators** (e.g. European and national health agencies) **cannot access health data easily for their tasks**, hampering optimal decision-making and effective crisis management, with the IA also mentioning researchers and innovators among the categories whose tasks are affected by health data re-use issues.

The IA identifies **three problem drivers**, the third underlying both problems 3 and 4, namely (IA, [Part 1/4](#), Figure 5, p. 18, and pp. 25-27):

1. **fragmented and limited tools available enabling citizens to access their own health data in electronic format in a timely manner and transmit them digitally**. As regards the aforementioned 'fragmented tools', the IA refers to the 'current fragmentation and patchwork of incompatible health data exchange formats and networks'. Similarly, under this driver, the IA mentions also the existence of divergent regulations at Member State level that 'do not enable sustainable data-sharing';
2. **limited legal** (regarding rules) **and technical** (regarding applications and IT infrastructure) **interoperability** (see also IA, [Part 3/4](#), Annex 10, pp. 3-26), **including cybersecurity and data protection aspects**, which according to the IA are fundamental for ensuring the secure flow of health data;
3. **differing administrative rules and procedures** (e.g. regarding data anonymisation), **divergent national legal frameworks, different specifications and standards** (e.g. for collecting data), **and fragmented infrastructures** (structured around health-specific subdomains) **for health data re-use** (see also IA, [Part 3/4](#), Annex 10, pp. 3-26). The IA states that one of the reasons can be attributed to the way the General Data Protection Regulation (GDPR) has been implemented in the health sector at Member State level. This is illustrated in its Annex 8 (IA, [Part 2/4](#), pp. 66-71; see also [study](#)).

Overall, the IA describes the scope of the problem satisfactorily, although it is unclear what the innovative treatments that would benefit patients referred to under problem 3 are. However, the IA would have benefited from quantifying the magnitude and EU dimension of the problems identified better, for instance as regards the costs for healthcare systems resulting from problem 1, or the additional costs sustained by providers and manufacturers when entering the markets of other Member States (problem 2). In addition, cybersecurity and data protection aspects appear to be insufficiently illustrated and clarified. Finally, it is unclear why driver 3 does not mention data use, in the light of problem 3 mentioning innovative treatments based on 'health data use and re-use'. In its Annex 3 (IA, [Part 2/4](#), pp. 23-24) the IA provides a summary table indicating the stakeholders affected (patients, citizens, healthcare professionals, health researchers, policy-makers, regulators, and the industry) and providing examples of primary and secondary uses of health data. The IA describes the evolution of the problem clearly but without providing any supporting evidence (IA, [Part 1/4](#), p. 27). In addition, it does not mention any existing or upcoming legislation and actions at EU or national level that might influence it, although stating that the retained options would build upon current and planned horizontal and sectorial legislative frameworks (see below the section on the range of options considered).

Subsidiarity / proportionality

According to the IA (p. 27), based on the explanations provided (IA, [Part 1/4](#), p. 28), the 'possible legal bases' for the initiative are [Article 16](#) and [Article 114](#) of the Treaty on the Functioning of the European Union (TFEU), the former regarding the protection of personal data, the latter allowing the EU to regulate those elements of private law creating obstacles to trade in the internal market. In addition, the IA states that the initiative would build on the provisions of Article 9(2)(h)(i)(j) GDPR ('processing of special categories of personal data'), although they cannot be implemented for every

individual. Finally, the IA provides a concise explanation as to why [Article 168](#) (TFEU), regarding the protection of public health, has not been selected as a potential legal basis (IA, p. 28). The IA deals with subsidiarity in a short dedicated chapter (IA, [Part 1/4](#), p. 29), explaining briefly, but convincingly, the need for EU action, and the explanatory memorandum includes a [subsidiarity grid](#). Proportionality is also mentioned (IA, [Part 1/4](#), p. 29), but the IA does not appear to have dealt with it in any depth. The IA, in fact, simply states that the 'the content and form of Union action that does not exceed what is necessary to achieve the objectives of the Treaties'. No reasoned opinions were submitted by national parliaments by the deadline of 2 September 2022.

Objectives of the initiative

The **general objective** of the initiative is '**to establish a genuine single market for digital health and to ensure that individuals have ... control over their own health data, can benefit from ... innovative health products and services** based on health data use and re-use, **and that researchers, innovators, policy-makers and regulators can make the most of the available health data for their work**, while preserving trust and security' (IA, p. 30). In addition, the IA identifies **three specific objectives**, namely (IA, pp. 30-31):

1. to '**empower citizens** through increased control of their personal health data **and support their free movement** by ensuring that health data follows them';
2. '**unleash the data economy** by fostering a genuine single market for digital health services and products'; and
3. '**ensure a consistent and efficient framework for the reuse of individuals' health data** for research, innovation, policy-making and regulatory activities'.

There seems to be a degree of overlap between the descriptions regarding the general objective and specific objectives 1 and 2. As regards specific objective 1, the IA clarifies that supporting the free movement of citizens means allowing health data to be used when and where individuals need it (IA, p. 30). However, the statement that 'this empowerment of individuals will also help build confidence of society in the use and re-use of health data' (IA, p. 30) is neither explained nor supported by evidence. For specific objective 3, the IA clarifies that it would be aimed at ensuring, in particular, the handling of health data requests, access procedures and secure infrastructure, and common governance mechanisms.

Although the specific objectives are largely consistent with the drivers identified in the Figure 5 problem tree (IA, p. 18), the objectives comply only partially with the SMART criteria, as they are not sufficiently specific or time-bound. In addition, the IA does not define any operational objectives to illustrate what the deliverables of the specific policy actions would be, contradicting the Commission's [Better Regulation Guidelines](#) (Tool #15 of the [Better Regulation Toolbox](#), pp. 108-110). Nevertheless, the IA identifies monitoring indicators for the specific objectives (IA, Table 9, p. 72).

Range of options considered

In addition to the baseline option 0 (no change), the IA retains for assessment **three options, and two sub-options** regarding the primary and secondary use of health data (see Tables 1 and 2 below, respectively). For both primary and secondary use of health data, the IA envisages increasing regulatory intervention. The IA states that the retained options would build upon current and planned horizontal and sectoral legislative frameworks such as, for instance, the GDPR, the [Data Governance Act](#) (see [Legislative Train Schedule](#)), the proposed [data act](#) (see [Legislative Train Schedule](#)), and the proposed establishment of a [European digital identity \(eID\) framework](#) (see [Legislative Train Schedule](#)), which are illustrated in the IA (IA, [Part 1/4](#), pp. 12-16, and [Part 2/4](#), Annex 6, pp. 53-59), although very succinctly as regards the data act and the eID framework. In addition, it states that 'all three options benefit from a horizontal set of safety and security measures to ensure individuals trustworthiness on the European Health Data Space'. However, these measures are not further specified as the text following this statement is missing from the IA report (IA, [Part 1/4](#), p. 35).

Table 1 – Range of retained options for the *primary* use ('use') of health data

MEASURE / DIMENSION	OPTION 0 VOLUNTARY COOPERATION (BASELINE)	OPTION 1 STRENGTHENED EU COORDINATION AND SOFT-LAW MEASURES	OPTION 2 REGULATORY INTERVENTION WITH MEDIUM INTENSITY	OPTION 3 REGULATORY INTERVENTION WITH HIGH INTENSITY
Individuals' and health professionals' right of control over electronic health data (SO1)	<ul style="list-style-type: none"> Based on the <i>general provisions</i> granted in the GDPR (Articles 15 and 20) and in the proposed data act 	<ul style="list-style-type: none"> Based on <i>guidelines</i> developed by a <i>mandatory</i> network of national authorities responsible for eHealth (<i>strengthened</i> eHealth Network – eHN) 	<ul style="list-style-type: none"> Established at EU-level by an expert group on digital health 	<ul style="list-style-type: none"> Same as Option 2
Scope of data domains (DDs) (SO1, SO2)	<ul style="list-style-type: none"> DDs covered in the Recommendation EU (2019)/243 on an European electronic health record exchange format (EEHRxF)* 	<ul style="list-style-type: none"> Same as Option 0 and additional DDs in the area of digital health (e.g. data streams generated by mobile health applications) 	<ul style="list-style-type: none"> Same as Option 1 and additional DDs in the area of digital health (<i>to be defined in delegated acts</i>) 	<ul style="list-style-type: none"> Same as Option 2
Interoperability requirements (IR), quality aspects (QA) and policy tool (PT) (SO2, SO3)	<ul style="list-style-type: none"> IR: established nationally QA: interoperability of DD covered in the Recommendation EU (2019)/243 PT: <i>guidelines / recommendations</i> on interoperability of DD covered in the Recommendation EU (2019)/243, and on identity management 	<ul style="list-style-type: none"> IR: same as Option 0 QA: <i>voluntary</i> self-declared quality label on the level of interoperability of electronic health record (EHR) systems, medical devices that can feed health data into EHRs, and wellness applications not classified as medical devices PT: <i>guidelines</i> on interoperability of DD covered in the Recommendation EU (2019)/243, on identity management, and on other digital health domains 	<ul style="list-style-type: none"> IR: established at EU-level QA: <i>mandatory</i> self-declared quality label for manufacturers and service providers of EHR systems, and medical devices that can feed health data into EHRs as regards their level of interoperability; <i>voluntary</i> self-declared quality label on the level of interoperability of wellness applications <i>not classified as medical devices</i> PT: minimum <i>EU mandatory</i> IR for EHR systems, and medical devices that can feed health data into EHRs (<i>that would become binding through implementing / delegated acts</i>); <i>recommended</i> EU specifications for wellness applications 	<ul style="list-style-type: none"> IR: same as Option 2 QA: (minimum) <i>mandatory third-party certification</i> on the level of interoperability of EHR systems, medical devices that can feed health data into EHRs, and wellness applications <i>not classified as medical devices</i> PT: as Option 2 but also covering certain wellness applications (<i>not specified in the IA</i>)

MEASURE / DIMENSION	OPTION 0 VOLUNTARY COOPERATION (BASELINE)	OPTION 1 STRENGTHENED EU COORDINATION AND SOFT-LAW MEASURES	OPTION 2 REGULATORY INTERVENTION WITH MEDIUM INTENSITY	OPTION 3 REGULATORY INTERVENTION WITH HIGH INTENSITY
			[SUB] OPTION 2+ (see ** below)	
Digital infrastructure for cross-border sharing of health data (SO1, SO2)	<ul style="list-style-type: none"> Voluntary deployment of the eHealth digital service infrastructure (eHDSI), which is recognisable to EU citizens with the brand name of MyHealth@EU Guidelines 	<ul style="list-style-type: none"> Voluntary deployment of MyHealth@EU Voluntary guidelines on specific aspects (see IA, Part 1/4, p. 40), developed by the strengthened eHN (see below) 	<ul style="list-style-type: none"> Mandatory deployment of MyHealth@EU; timeline for implementing existing services. Voluntary deployment of cross-border services enabling the interoperability and mutual recognition of health professionals' registries 	<ul style="list-style-type: none"> Mandatory deployment of MyHealth@EU; <i>stricter timeline</i> for implementing existing services; possibility of extending services to data domains beyond those covered in the EEHRxF Mandatory deployment of ... etc. (see Option 2)
National governance (NG) and EU cooperation (EUc) (SO1, SO2)	<ul style="list-style-type: none"> NG: Member States, supported by the eHN, implementing Article 14 of Directive 2011/24/EU EUc: voluntary network connecting national authorities responsible for eHealth (eHN) 	<ul style="list-style-type: none"> NG: national decision-making process EUc: <i>mandatory</i> network connecting national authorities responsible for eHealth (<i>strengthened</i> eHN) 	<ul style="list-style-type: none"> NG: national authorities responsible for eHealth supporting the implementation and enforcement of rights and EU-wide requirements (see IA, Part 1/4, p. 41) EUc: expert group, made of experts from national authorities responsible for eHealth 	<ul style="list-style-type: none"> NG: same as Option 2 EUc: existing EU regulatory body tasked to define requirements <p>[SUB] OPTION 3+ (see § below)</p>

SO1=specific objective 1; **SO2**= specific objective 2; **SO3**=specific objective 3 (referred to in the following Table 2).

* Patient summaries, ePrescriptions / eDispensations, laboratory reports, medical images and reports, hospital discharge reports.

** The IA considers a [sub] **Option 2+**, which envisages a mandatory *third-party certification* for EHR systems and medical devices that can feed data into EHR systems, instead of a *mandatory self-declared quality label*, while keeping *voluntary* the self-declared quality label for wellness applications. Additionally, Option 2+ envisages the enrolment of the labelled and certified products in an EU database § The IA considers [a sub] **Option 3+**, which envisages establishing a new EU coordination body.

Table 2 – Range of retained options for *secondary* use ('re-use') of health data

MEASURE / DIMENSION	OPTION 0 NO EU COOPERATION FRAMEWORK (BASELINE)	OPTION 1 STRENGTHENED EU COORDINATION & SOFT- LAW MEASURES	OPTION 2 REGULATORY INTERVENTION WITH MEDIUM INTENSITY	OPTION 3 REGULATORY INTERVENTION WITH HIGH INTENSITY
Access to health data by re-users (SO3)	<ul style="list-style-type: none"> Data processing based on subject's consent or national legislation Guidelines on research issued by the European data protection board 	<ul style="list-style-type: none"> Same as Option 0 <i>Guidelines</i> on health data re-use issued by a voluntary network of competent bodies on health data re-use 	<ul style="list-style-type: none"> Data processing not based on subject's consent <i>Common European legal basis</i> on re-use 	<ul style="list-style-type: none"> Same as Option 2
Types of data in scope for re-use (SO3)	<ul style="list-style-type: none"> Defined in separate national legal bases GDPR and proposal on harmonised rules on fair access to and use of data (data act) 	<ul style="list-style-type: none"> Same as Option 0 Guidelines on types of health data in scope for re-use and on voluntary sharing 	<ul style="list-style-type: none"> Specific categories of health data in scope for re-use set out in the common European legal basis Other data, including commercial data obtained from enterprises under the data act, managed by health data access boards (HDABs) 	<ul style="list-style-type: none"> Same as Option 2
Data altruism** (DA) (SO3)	<ul style="list-style-type: none"> DA mechanisms set out in Regulation (EU) 2022/868 – European Data Governance Act (DGA) 	<ul style="list-style-type: none"> Same as Option 0 (therefore not addressing the specificities of the health sector) 	<ul style="list-style-type: none"> DA is an opt-in system for individuals; where DA is managed by non-for profit / non-public entities, DA supervised by HDABs* 	<ul style="list-style-type: none"> Same as Option 2
Digital infrastructure for health data re-use (SO3)	<ul style="list-style-type: none"> No common EU infrastructure: thematic or disease-specific infrastructures would continue to be developed by Member States in an uncoordinated manner 	<ul style="list-style-type: none"> <i>Common</i> EU infrastructure: extension of MyHealth@EU to health data re-use Voluntary participation to its deployment (criteria set out in guidelines) 	<ul style="list-style-type: none"> New <i>decentralised</i> EU-wide infrastructure (i.e. peer-to-peer network) <i>Mandatory</i> participation in its deployment 	<ul style="list-style-type: none"> New <i>centralised</i> EU-wide infrastructure (i.e. centralised network) <i>Mandatory</i> participation to its deployment
Data quality (DQ), i.e. quality of data source (SO3)	<ul style="list-style-type: none"> No common assessment framework 	<ul style="list-style-type: none"> <i>Common</i> assessment framework Voluntary self-declared DQ label Codes of conduct 	<ul style="list-style-type: none"> Common assessment framework <i>Mandatory</i> self-declared DQ label No minimum DQ requirements 	<ul style="list-style-type: none"> <i>Mandatory DQ certification</i>, prepared by an existing institution or agency <i>Minimum mandatory</i> DQ requirements prepared by an existing institution or agency

MEASURE / DIMENSION	OPTION 0 NO EU COOPERATION FRAMEWORK (BASELINE)	OPTION 1 STRENGTHENED EU COORDINATION & SOFT- LAW MEASURES	OPTION 2 REGULATORY INTERVENTION WITH MEDIUM INTENSITY	OPTION 3 REGULATORY INTERVENTION WITH HIGH INTENSITY
Support (S) for AI development and verification (V) (SO3)	<ul style="list-style-type: none"> ▪ S: <i>quality criteria</i>, based on separate national legal bases ▪ V: none 	<ul style="list-style-type: none"> ▪ S: <i>codes of conduct</i>, in line with Article 69 ('Codes of conduct') of the artificial intelligence act (AIA), drawn up on quality criteria for data used for developing AI in healthcare ▪ V: verification of their implementation by AI system developers 	<ul style="list-style-type: none"> ▪ S: <i>standards / common specifications</i>, to be adopted under the AIA, developed by the bodies envisaged under the AIA, with the support of the HDAB ▪ V: verification of implementation supported by the HDAB, in addition to measures envisaged in the AIA 	<ul style="list-style-type: none"> ▪ S: as Option 2, with an additional obligation to structure health data according to requirements of semantic interoperability ▪ V: verification of implementation by the HDABs
National governance (NG) and EU cooperation (EUc) (SO2, SO3)	<ul style="list-style-type: none"> ▪ NG: separate governance frameworks focused on specific initiatives ▪ EUc: HDABs in some Member States 	<ul style="list-style-type: none"> ▪ NG: national HDABs (voluntary designation) ▪ EUc: voluntary European network of national HDABs 	<ul style="list-style-type: none"> ▪ NG: national HDABs (<i>mandatory</i> designation - see IA, Part 1/4, pp. 46-47, for the envisaged <i>harmonised</i> tasks) ▪ EUc: expert group on health data reuse supporting the Commission in adopting further rules to facilitate the re-use of health data (i.e. <i>reinforced</i> cooperation) 	<ul style="list-style-type: none"> ▪ NG: as Option 2 ▪ EUc: existing EU regulatory body or agency tasked to act as a European HDAB, and coordinate the work of national HDABs <p>[SUB] OPTION 3+ (see para. below for the envisaged difference with respect to Option 3)</p>

* See IA, [Part 2/4](#), Annex 9, pp. 70-82.

** Data altruism means the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them, or permissions of data holders to allow the use of their non-personal data without seeking or receiving a reward that goes beyond compensation related to the costs that they incur where they make their data available for objectives of general interest as provided for in national law, where applicable, such as healthcare, combating climate change, improving mobility, facilitating the development, production and dissemination of official statistics, improving the provision of public services, public policy making or scientific research purposes in the general interest – Article 2(16) DGA;

§ The IA considers (a sub-) **Option 3+**, which envisages the establishment of a *new* EU body responsible for coordinating national bodies and for providing access to cross-country and EU data.

Source: Compiled by the author, on the basis of the IA ([Part 1/4](#), Tables 2 and 3, pp. 33-34), and on the [study](#) supporting the impact assessment of policy options for an EU initiative on a European health data space.

The **baseline scenario regarding the primary use of health data** is illustrated succinctly, and the IA would have benefited from a better explanation of some of the measures/dimensions considered under the baseline (IA, [Part 1/4](#), pp. 35-36). The same shortcoming applies to the **baseline scenario regarding the secondary use of health data** (IA, [Part 1/4](#), p. 36), as the IA does not illustrate some of the measures/dimensions envisaged. According to the IA ([Part 1/4](#), pp. 36-37), **Option 1** consists of soft-law measures aimed at supporting the coordination and adoption of voluntary mechanisms among Member States. In addition, this option envisages expanding the work on interoperability of those data domains included in Commission [Recommendation EU \(2019\)/243](#) on an EEHRxF, by covering other data domains in digital health (e.g. domain of data streams generated by wearable health devices), and by extending the scope to secondary uses of health data.

Option 2 (and 2+) envisages a regulatory framework establishing a system of joint decision-making at European level on requirements concerning interoperability, security and other related aspects on Member States and market operators in the Single Market, supported by national implementation. In addition, it envisages strengthening the rights of citizens to control (i.e. access and portability) their health data and establishing an EU framework for the re-use of health data. The governance would fall to national bodies brought together at EU level in an expert group that would implement and enforce EU-level mandatory requirements nationally.

Option 3 (and 3+) envisages a legislative intervention whereby an EU body, together with competent national authorities, would be tasked with implementing and enforcing requirements on interoperability and cybersecurity. In addition, compared to Option 2, it envisages establishing a European health data access body. The IA provides an analytical and comprehensive explanation – albeit not always very clear – of the individual measures/dimensions identified for the retained options (IA, [Part 1/4](#), pp. 37-47, and (IA, [Part 3/4](#), Annex 11, pp. 27-28).

Assessment of impacts

The IA analyses the impact of the retained options, including the baseline, focusing mainly on the economic dimension, quantifying comprehensively and extensively the costs and benefits of the governance structures envisaged for the primary and secondary use of data, the infrastructure for the re-use and cross-border sharing of health data, and aspects regarding the level of interoperability (primary use) and the quality of data source (secondary use) (IA, [Part 1/4](#), pp. 49-59).

The analysis regarding the impact on addressing barriers for digital services and products when entering the markets of other Member States (problem 2) is dealt with qualitatively but seems unconvincing because it is very limited and based on a few statements not supported by any evidence (IA, [Part 1/4](#), pp. 60-61).

As regards social impacts, the IA quantifies the benefits for healthcare providers and patients, in terms of savings in health costs, resulting from an increased uptake of telemedicine and from a faster deployment of cross-border ePrescription and medical imaging services. Furthermore, it quantifies the savings for researchers and innovators resulting from the reuse of health data (IA, [Part 1/4](#), Tables 4-6, pp. 53-57). The IA considers that the environmental impacts will be limited. Although it does not substantiate this statement further, it appears justified, based on the problem definition and the objectives identified (IA, [Part 1/4](#), pp. 62-64).

The IA considers the impact of the retained options on fundamental rights relating to the protection of personal data and the freedom of movement (IA, [Part 1/4](#), pp. 61-62), and expects the preferred option 'to have a significant positive impact', although it would be greater for option 3. However, the IA would have benefited from analysing those issues further.²

Overall, the IA appears to have dealt with some aspects of the economic impact satisfactorily, while others are assessed in a very limited and unconvincing way. This is the case for the impact on innovation, although increasing innovation in health products and services is part of the general and specific objectives. Options are scored against the criteria of effectiveness, efficiency,

coherence, feasibility, EU added-value, and proportionality (IA, pp. 65-71). Looking at Table 7 of the IA (p. 65), it is however unclear why policy options 2 and 3 are scored the same as regards their effectiveness in supporting the free movement of people, given that the features envisaged for the cross-border sharing of health data appear to be more stringent under Option 3.

As regards efficiency, the IA does not explain convincingly why Option 3 'risks stifling innovation' (IA, [Part 1/4](#), p. 68). As regards coherence, the IA does not explicitly distinguish between internal and external coherence, although this distinction is included in the above mentioned Table 7 of the IA, and therefore it is not possible to understand how the scoring of the options was obtained.

The scores regarding legal and political feasibility and added-value are not explained. On the basis of effectiveness, efficiency and coherence criteria, the IA concludes its assessment, considering **Options 2+ and 2 to be the preferred options in the area of primary and secondary use of health data** respectively, for the reasons illustrated ([Part 1/4](#), pp. 69-71).

In addition, the IA provides a useful table quantifying the estimated distribution, by main categories of stakeholders, of the overall costs and benefits of the preferred option, distinguishing between primary and secondary uses of health data (IA, [Part 1/4](#), Table 8, p. 69). According to the IA, the highest benefits would be for healthcare service providers (between €4 436 million and €4 482 million), while manufacturers, suppliers of EHR systems, digital health products/services and wellness applications would bear the highest costs (between €271 million and €1 683 million). The choice of the preferred options would have gained further in persuasiveness had the IA provided more supporting evidence for some of the statements made. Furthermore, the IA would have benefited by avoiding some inconsistencies between the content of the two tables referring to the use and re-use of health data (IA, [Part 1/4](#), pp. 33-34), and the corresponding explanatory text of the IA report. Finally, a more user-friendly description of some of the envisaged measures/dimensions would have improved readability.

SMEs/ Competitiveness

The IA illustrates briefly the impacts of the retained options on small and medium-sized enterprises (SMEs), mentioning the 'prohibitive costs' (not quantified) of re-using health data and the barriers they face when entering new markets (IA, [Part 1/4](#), p. 60). Although they are not explicitly identified as affected stakeholders, the IA mentions SMEs several times when comparing the policy options, but the statements regarding them are not supported by any evidence and are only qualitative. Competitiveness is mentioned several times across the IA report but it is dealt with unsatisfactorily, because after stating that most of the effect on competitiveness depends on the effect of measures on costs structure, productivity and innovation, the IA does not provide any analysis regarding how these variables compare across the retained options (IA, [Part 1/4](#), pp. 60-61). In light of problem 3, and also considering that 95 % of the companies operating in the medical technologies sector are SMEs ([SWD\(2018\) 41](#), Annex V, p. 128), perhaps the IA would have benefited from analysing the impact on SMEs comprehensively.

Simplification and other regulatory implications

As regards the regulatory implications of the initiative, the IA simply states that the proposal 'ensures compliance with regulatory frameworks in the areas of cybersecurity, pharma and cross-border health threats' (IA, p. 12, and pp. 16-18). However, specific objective 3 is aimed precisely at ensuring 'a consistent and efficient framework for the reuse of individuals' health data for ... regulatory activities'. As such, it is unclear why the IA does not comment on the regulatory implications of the proposal, if any.

Monitoring and evaluation

The initiative would be evaluated 7 years after the regulation's entry into force. Table 9 of the IA (p. 72) provides an overview of the monitoring indicators envisaged for the three specific objectives

identified, including their sources, the data collection frequency, and the targets to be achieved. Overall, the monitoring framework appears to be comprehensive and convincing.

Stakeholder consultation

The Commission performed a standard 12-week open public consultation (OPC) from 3 May until 26 July 2021 that gathered [382 replies](#) from 23 EU countries and 8 non-EU countries, predominantly from EU citizens (26 %), followed by non-governmental organisations (21 %), academic/research institutions (14 %), and companies/business organisations (11 %) (IA, [Part 2/4](#), Annex 2, p. 9). In addition, 64 stakeholders provided additional documentation, e.g. position papers, reports, policy briefs, which are available on the [consultation webpage](#) of the Have your say portal. The IA includes, in the majority of cases, a breakdown of stakeholders' views, although only Member State feedback is illustrated as regards the protection of personal data, the possible features of the EHDS, and how standards and technical requirements should be made applicable at national level and across the EU. Stakeholders were also consulted via workshops and stakeholder surveys within three of the studies supporting the IA. Annex 2 is informative, providing an in-depth insight into stakeholders' views regarding the individual measures/dimensions. Their feedback is also summarised when the IA illustrates the retained options. According to the IA ([Part 1/4](#), pp. 47-48) 'there is overall widespread support for the different policy options (particularly policy Options 2-3)'.

Supporting data and analytical methods used

The IA is supported by several comprehensive external studies (IA, [Part 2/4](#), Annex 1, pp. 7-8), all but one of which are available from the EU Publications Office, making the analysis well-grounded and convincing, considering also additional evidence included in the endnotes (IA, [Part 1/4](#), pp. 73-85). In detailing comprehensively the methodological approach used (IA, [Part 2/4](#), Annex 5, pp. 35-52), the IA does not mention any particular analytical model, although modelling assumptions are included for calculating labelling and certification costs (IA, [Part 2/4](#), Annex 5, pp. 43-44).

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

On 26 November 2021, the Commission's Regulatory Scrutiny Board (RSB) adopted a [negative opinion](#) on a draft version of the IA report submitted on 27 October 2021, because it contained significant shortcomings. On 26 January 2022, the RSB adopted a [positive opinion](#) on a revised version of the IA report resubmitted on 21 December 2021, suggesting improvements to the explanation regarding the rationale for having a specific sectoral initiative on health data, and a greater effort to reflect stakeholders' views. The IA explains in its Annex 1 ([Part 2/4](#), pp. 3-7) how the comments in the RSB's opinions were addressed. The IA appears to have addressed the two RSB comments mentioned above, while the comments regarding the unclear difference between the secondary use of health data and data altruism, and the benefits to data governance relating to establishing health data access bodies do not appear to be tackled convincingly, based on the text included under paragraph 5.2.2.2 of the IA ([Part 1/4](#), p. 43).

Coherence between the Commission's legislative proposal and IA

The proposal appears to be consistent with the analysis carried out in the IA as regards the envisaged measures included in the preferred options, which have been taken up in the corresponding articles of the proposed new regulation. The monitoring indicators are not included among the articles of the proposed regulation.

Overall, the IA describes the scope of the problem sufficiently well, and explains briefly, but convincingly, the need for EU action, although proportionality does not appear to have been dealt with in any depth. The IA does not define any operational objectives, which would illustrate what the deliverables of the specific policy actions are, although it identifies monitoring indicators for the specific objectives. The sufficient range of retained policy options is structured according to increasing levels of regulatory intervention, and appears to be convincing. However, the IA would have benefited from providing a more user-friendly description of some of the envisaged measures.

On the whole, the IA appears to have analysed aspects of the economic impact satisfactorily, while the analysis regarding environmental impacts is very limited, although this appears justified based on the problem definition and the objectives identified. As regards social impacts, the IA quantifies the benefits, expressed in terms of savings in health expenditure, for healthcare providers, patients, researchers and innovators. The analysis regarding the impact on SMEs is rather weak, not least considering that 95 % of the companies operating in the medical technologies sector are SMEs. The analysis of the impact on innovation is not dealt with comprehensively, whereas this would perhaps have been warranted considering that increasing innovation in health products and services is part of the general and specific objectives, while the analysis regarding competitiveness is almost non-existent.

The IA appears to have addressed the RSB's comments only partially. The proposal appears to be consistent with the analysis carried out in the IA as regards the envisaged measures included in the preferred options.

ENDNOTES

¹ See C. Evroux, [European health data space](#), EPRS, European Parliament, 2022. See also the [preliminary opinion](#) of the European data protection supervisor.

² On potential legal issues arising from a European health data space, see A. Kiseleva and P. de Hert, '[Creating a European health data space. Obstacles in four key legal areas](#)', *European Pharmaceutical Law Review*, Vol. 5 (1), 2021, pp. 21-36.

This briefing, prepared for the LIBE committee, analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

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