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The impact of EU Digital Services Act and Digital Markets Act on health information systems

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Abstract

The European Parliament has approved new legislation, the Digital Services Act (DSA) and Digital Markets Act (DMA) to improve the functioning of the internal market of intermediary services in the European Union (EU) where there is a risk that the major so-called gatekeeper companies can exercise unfair control of core platform services. The purpose of this study was to investigate, what health information systems could be in the scopes of these acts and what requirements the acts may have for the production, the sale and the use of health information systems.

The act texts were examined bearing in mind what types of health information systems exist and what their user bases are. Those health information systems that can belong or do not belong to the groups of systems regulated by the DMA and DSA were identified. The most relevant requirements for these systems were also identified from these acts.

The result of the study is that these acts have only minor consequences for the healthcare information systems sector as they are not often intermediary (hosting) services in the meaning of the DSA or gatekeepers in the meaning of the DMA. The emerging digital healthcare platforms are most affected by the new DSA and secondly such peer support patient portals where patients can supply content for others to see. Apparently, no digital healthcare platform has yet reached such a size or a dominant role within the EU that it would fall under the scope of the DMA.

The two above mentioned healthcare related intermediary services have due diligence obligations to remove illegal contents from their services and to treat their business and consumer customers fairly. The obligations include clear and fair terms and conditions, the provision of a single point of contact for users and authorities, content moderation, complaint handling, marking advertising clearly, annual reporting, and responding to the contacts from the authorities. The obligations increase when the size of the enterprise increases.

It is still too early to produce healthcare information systems specific guidance to support the implementation of these two acts as the acts themselves and potential upcoming general guidance documents can serve the health information systems community sufficiently well.

Keywords: electronic services, healthcare, laws, markets, health informatics

Introduction

In addition to the existing General Data Protection Regulation [1], the European Union (EU) is also preparing other regulations which apply to information systems. The recent information society regulations, approved in July the 5th, 2022 are the Digital Services Act (DSA) [2] and the Digital Markets Act (DMA) [3]. The background to the DSA is that the new internet-based digital services although providing new possibilities for businesses and a wider choice for consumers, also come with new risks which need to be controlled similarly within the European Union. The DSA, referring to the Treaty on the Functioning of the European Union [4], mentions that the diverging national laws negatively affect the internal market in managing these risks and therefore EU wide regulation is necessary. These risks are related to the freedom of expression and consumer protection, but also to the freedom to conduct business without discrimination by the providers of intermediary services. The background of the DMA is to protect consumers and business users from the very large core digital platform providers exercising their very strong role as "gatekeepers" to services in a way that is harmful for the functioning of the internal market and consumers' rights.

These acts apply when the services within scope are offered to consumers and businesses within the EU. The DSA requires the EU member countries to establish a Digital Services Coordinator (DSC) to each member country to act as a national authority to take actions in their territory with respect to the DSA. The European Commission is assigned this role in controlling the very large online platforms and very large search engines with an average annual user base of 45 million people. Although the EU Commission may get help from national authorities in enforcing the DMA, it is the main actor in its enforcement.

The purpose of this study was to investigate, what health information systems could be in the scopes of these acts and what requirements the acts may have for the production, the sale and the use of health information systems. Additionally, this study aims at finding out if it is necessary to support the acts with healthcare specific guidance.

According to ISO/TR 14639-2:2014, a health information system is a system that combines vital and health statistical data from multiple sources to derive information and make decisions about health needs, health resources, health costs, uses of health services, and outcomes of healthcare [5]. The range of health information systems is quite wide. Literature has varying categorizations of types of health information systems [6-9]. New innovations and the market growth [10] of these systems increase the variety of the offering.

Hospital information systems are perhaps the most significant subgroup of health information systems. In Reichertz's classification in 2006 [6], the common data base system of patient data (now electronic health record system EHR), the admission, discharge and transfer system and the communication system form the core of hospital information systems. Hospital information systems include also various departmental information

systems such as intensive care unit patient monitoring systems, medical imaging and image management systems, laboratory systems, and systems for the cardiology and neurological departments, to name a few. These and many other systems such as electronic prescription systems can be accompanied with decision support systems to improve the quality of care. The direct patient care related systems can be connected to the second main category of health information systems, the so-called back-office systems such as billing and accounts management systems. Additional support systems include supplies management, personnel scheduling and management systems, and insurance related information systems.

To support regional care, health information exchange systems [11] enable the sharing of patient data from different care units in the region. Population health management systems are yet in a higher level collecting, e.g. epidemiological and capacity use information from several regions to give decision makers information for national decision making.

The patient interaction systems are the newest main category of health information systems. These include patient portals and online tutorials and various forms of telemedicine, e.g., remote patient monitoring. Personal health record (PHR) systems give the control of the contents and access to the record to the patient herself/himself. Mobile health apps and personal health information systems leveraging wearable sensors are systems which are not necessarily under the control of traditional health delivery organisations. These can be connected to digital health platforms [12] which offer a connection point to several service providers and patients. They can also incorporate social media functions such as peer discussion fora for patients of the same disease.

In many cases, the health information systems, particularly the hospital information systems, are hosted on-site in hospitals. Information systems that are related to particular medical devices reside quite naturally near these devices. In some cases, hospital information systems services are hosted in the premises of the health information systems provider or in the cloud. The cloud service can be a private cloud arrangement or a public cloud service with appropriate security arrangements. The administrative, back-office systems are more likely to apply software as a service model because a sudden break in communications is not as life critical as it would be in the acute patient care departments. Patient interaction systems can be hosted on-site of the health delivery organisations, but they can be hosted outside the organisation as well. The social media types of systems are typically hosted outside the hospital environments.

The governance of the on-site systems is typically within the health delivery organisation or within a trusted service provider. The governance of the back-office systems can be both within the health delivery organisation or in the hands of a service provider. The patient interaction systems are most likely to be under the governance of an outside service provider. This study reveals what consequences the DSA and DMA have to the development and use of some health information systems.

Material and methods

The regulation texts were downloaded from the EU website after they had been approved in the European Parliament. The texts were examined bearing in mind the nature, scale, users, governance model and manufacturers of the various cat-

egories of health information systems. The first matter to study was the scope of the act, i.e. which health information systems fall under the act in question. It was considered which ones of the health information systems have the intermediary service nature defined by the DSA and the DMA. The second object of the study was the identification and listing of the requirements for those health information systems that are within the scope of the act. The most important findings are explained in the following section.

Results

The Digital Markets Act

The scope of the act

The Digital Markets Act is intended to control the major gatekeeper companies against discriminatory practices to other businesses and taking unfair advantage of their strong position towards consumers. A gatekeeper is defined as an undertaking providing core platform services. Core platform services include online intermediation services, online search engines, online social networking services, video-sharing platform services, number-independent interpersonal communications services, operating systems, web browsers, virtual assistants, cloud computing services, and online advertising services [3]. To be designated as a gatekeeper, an enterprise needs to have a significant impact on the internal EU market and "it provides a core platform service which is an important gateway for business users to reach end users". A significant impact is defined by having a turnover of more than EUR 7.5 billion, or a market value of EUR 75 billion and it has at least 45 million monthly consumer users or 10000 business users. The EU Commission may designate an enterprise as a gatekeeper even if it does not reach all these numeric measures if the enterprise appears to be in a too strong position to control its customers indicated by additional criteria mentioned in the DMA. The gatekeepers typically have access to "big data" of their customers which, when applied against the spirit of the DMA, can give unfair competitive advantages towards their business users.

There can be health information systems which could be considered falling into the scope of the DMA: Digital online health platforms can belong to the class online intermediation services. These platforms, studied by the Digital healthcare ECOsystem research and innovation capability building (DiHECO) project [13], provide the possibilities for businesses and health care professionals to offer their services to consumers. Patient online social networks and health counselling virtual assistants are also within the scope of the services covered by the DMA. It is, however, quite unlikely that digital health service enterprises reach anywhere near the numeric thresholds mentioned in the DMA in their business operation within the EU. Some true gatekeeper companies may have health related operations, too, but these operations alone would not have brought the gatekeeper status to these companies. All in all, current health-focused information system service providers can more or less ignore the DMA.

Requirements

The main requirements of the DMA are given in articles 5 to 7 and space does not allow to describe them here exhaustively. It is forbidden to the gatekeepers to cross-use personal data held by the gatekeeper collected for a different purpose to other purposes to gain unfair advantage with respect to its business users. The gatekeeper cannot forbid business users to offer their services through other channels with different prices. The terms of the gatekeeper can't disallow business

users and consumers to raise any issues of non-compliance of the gatekeeper with relevant EU or national law. The gatekeeper can't require that all financial transactions between consumers and business users use only its own payment systems. The gatekeeper must allow and support the portability of user's data from its service to other services. The gatekeeper has to demonstrate that it complies with the requirements in these articles and provide an overall report about it in six months after having been identified as a gatekeeper. If the gatekeeper tries to avoid fulfilling the requirements by using some sort of a loophole, the EU Commission has the power to act rapidly, too. The gatekeeper needs to deliver an independent auditor's report about its consumer profiling activities to the EU Commission. Gatekeepers need to establish a compliance function to monitor themselves about the compliance to the DMA and to communicate with the EU Commission. The DMA does not pose requirements to the design and development phase of the health information system; only the end result and its governance is decisive.

The Digital Services Act

The scope of the act

The Digital Services Act covers "intermediary services". The intermediary services are divided into three classes, 'mere conduit', 'caching' and 'hosting' services. The mere conduit services are typically related to the technical infrastructure which does not make decisions based on the content of the data such as wireless local area networks, domain name system (DNS) services etc. An example of the caching services could be a content delivery network applying a cloud service which stores a copy of the original data object for faster access by its end users. These two classes are not health information systems, but health information systems may use such technical infrastructure. The third class, hosting services is the class that some health information systems may fall into. In the context of the DSA, a hosting service "consists of the storage of information provided by, and at the request of, any natural or legal person who uses an intermediary service, in particular for the purposes of seeking information or making it accessible". It needs to be mentioned that general purpose web hosting services and general-purpose cloud services are not considered as hosting services covered by the DSA.

How the definition of hosting applies to health information systems requires some imagination. As digital online platforms are covered by the DSA in general, so are digital online health platforms. The DSA calls the service providers in these platforms as "traders". A private health care provider would not qualify as a hosting service provider if all the health care personnel listed on its website are employed by the company. The company is then providing health care services directly. If, however, at least one of the professionals is offering his or her services through his or her (or somebody else's) enterprise (here: a trader), the company then provides intermediary services to this enterprise and falls under the DSA.

Section 3 about online platforms does not mostly apply to micro and small enterprises defined by the EU Commission Recommendation 2003/361/EC [14] which means companies that employ fewer than 50 people and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. Even a small enterprise can be a provider of a very large online health platform, if the user base exceeds the mentioned 45 million users and the more demanding requirements begin to apply to this enterprise.

Some patient portals may fall under the scope of the DSA if they provide information, e.g. links to health services requested by those health service providers. This becomes even clearer if the portal provides recommendation services which suggest or prioritize content, typically products or services, to the user as described in article 24a of the DSA. Those health information systems where patients can exchange information with their peers are within the scope of the DSA, but they are not online platforms if this function is not in a major role in the system.

It is easy to recognize some health information systems which are clearly not within the scope of the DSA. Those systems which are under direct control of the health delivery organisation and offer services to the personnel and patients of the organisation are not within scope because the intermediary element is missing from the service even if the governance of the platform is given to an outside service provider. The medical devices containing embedded software are clearly not within scope also due to the missing intermediary element. Electronic health record systems or the information systems of medical specialities do not make information available to the general public in an open form and do not fall under the DSA. Public health information systems, if they also provide information for the general public do not qualify as intermediary services because there does not exist a similar provider – service recipient relationship between the providers of the public health information and its publisher as the DSA specifies. Online health guidance systems are typically out of scope unless they mediate services or products as well.

Some providers of back-office systems for health delivery organizations could fall under the scope of the DSA. This happens if their service offering includes services from other service providers in a marketplace fashion. The back-office system itself would not fall under the scope of the DSA.

Requirements

The DSA is important to the intermediary service providers in two ways. First, it requires due diligence of these service providers to make the internet a safer place to do business for consumers and businesses. On the other hand, it sets the limits of liability of the service providers when they have implemented the DSA requirements, protecting them from punishments of actions that illegal actors have performed using their services.

The requirements the DSA imposes on the providers of the intermediary services covered by the act increase with the size of the service provider. Husovec, and Roche Laguna call these universal, basic and advanced obligations [15]. The emphasis is on the protection of consumers but the rights of the copyright holders of intellectual property are considered as well. One of the main requirements is to remove illegal content from the services. This can include e.g., hate speech, sexual harassments or other discriminatory actions in a discussion platform or copies of copyrighted material made openly available on a file sharing platform against the will of the copyright holder. Others than small enterprises need to report about the removal using a standardized reporting interface to the authorities. All providers also need to make available an electronic point of contact and make their terms and conditions publicly available. These terms should inform how the content on their services is moderated, including automatic methods.

The digital online health platforms operated by at least medium size enterprises need to provide an annual report targeting the transparency of opera-

tions. Even the smaller enterprises need to adhere to reporting their average number of customers to the DSC or the EU Commission upon request. Even they need to maintain a sufficient level of traceability of the traders operating in their platform and to react appropriately if misconduct of the traders is observed in their platforms. The service must also enable the traders to fulfil their legal "obligations regarding pre-contractual information, compliance and product safety information under applicable Union law". The services should not nudge the users to decisions which are harmful to them. Advertising should be clearly indicated. The service should be impartial and not favour certain businesses over others. If the service recommends goods or services to the users, the logic behind the recommendations should be publicly available. Extra caution needs to be exercised in privacy and security if the platform users are minors.

The requirements for very large providers of intermediary services are so many, dozens of pages in the DSA and apply to so few enterprises that they are not listed here in detail. These enterprises even need to have a crisis response mechanism in place for cases where there is a serious threat to public security or public health. Like with DMA, the DSA does not pose requirements to the design and development phase of the health information system; only the end result and its governance is decisive.

Discussion

The DMA is intended to control the global gatekeeper companies and to provide a more even playing field for smaller businesses to compete even with the gatekeepers. The definitions of the gatekeepers rule out typical health information system service providers at the moment. If, however, one of the digital online health platforms grew to a dominant position in the EU, it might find that the EU Commission begins to treat them as gatekeepers although the EUR 7.5 billion annual turnaround threshold is not exceeded. At that point at the latest, the platform needs to fully comply with the DMA or risk having to pay a significant sum of money in fines.

Although the DMA does not apply to most health information systems, it has an indirect effect on them. If the large gatekeeper companies comply with this act, their services will be a better and fairer playing field also to health information service companies. For example, mobile health app producers can assume to have their product available to consumers in the dominant app stores even though the gatekeeper company brought a similar health app available as well. Akman [16], although criticizing the DMA of some of its weaknesses, underlines that the DMA is different in comparison with previous EU competition laws in a sense that the resolution to a case of unfair practises by a gatekeeper can come faster. This is important to the smaller companies, and it fits better to the nature of the rapidly evolving digital markets. Another question is, can the EU Commission truly act with the necessary speed if it is flooded by complaints against the practises of the current gatekeepers.

Like Akman, Kerber [17] also criticizes the vagueness of some obligations of the DMA. This gives the EU Commission flexibility to act but on the other hand makes it difficult for the gatekeepers to prepare to perform according to the act. Anticipating these problems, article 47 already refers to the possibility for the EU Commission to adopt guidelines to facilitate the effective implementation of the DMA. As digital health platforms have not existed for a long time yet, nor have the potential gatekeeping problems yet emerged which

would warrant the creation healthcare specific guidance documents in the near future.

The name of the Digital Services Act is somewhat misleading because the act does not cover all digital services. A better name would have been Digital Intermediary Services Act because the scope of the act is limited to intermediary services. The definition of the intermediary services is vague to the extent that it is not obvious to the average reader what services are covered. The act excludes those services where intermediary service is not the main part of the service which may lead to discussions in borderline cases.

Most health-related services which are within the scope of the DSA are so small that the most difficult requirements of the act do not apply to them. Normal fair business practices are often sufficient to comply, but it is necessary to study the act, particularly the reporting requirements. The systems should also support the estimation of the average numbers of monthly users of the service in the way that the DSA determines.

The DSA encourages the creation of voluntary codes of conduct to support the act. Before the act has been in force and general guidance to support it is not yet available, it would be too early to issue healthcare specific guidance to support the DSA. The act itself and the upcoming general guidance may be sufficient for the successful compliance to the act by digital health service platforms as well.

All scholars are not convinced that these acts provide sufficient protection for consumers in general. Cauffman and Goanta [18] state that "the DSA appears to be more concerned with providing legal protection and certainty for intermediary service providers than for consumers using their services". As health information systems typically have not been the most problematic from the consumer protection point of view, this is not a major problem.

Savin [19] considers the introduction of the DSA as positive development despite its minor weaknesses. He mentions the increasing need for the moderation of the content in the platform as a consequence of the DSA. As the moderation cannot be based solely on automatic methods, the platforms need to employ people to make the decisions of service suspension and termination and to complaint handling. Savin concludes that the combination of DMA and DSA can become a standard solution for platform regulation also outside the EU like the European privacy and consumer laws have become.

Summarizing, if the health information system is considered being within the scope of the DMA or DSA, the key issue is to arrange the governance [20] of the system in such a way that the requirements of the act are fulfilled. This may introduce costs [21] which need to be accounted for in the business planning.

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Conflict of interest statement

The author has no conflicts of interests with the topic areas of this study.

References

[1] EUR-Lex. Consolidated text: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). European Parliament and European Council; 2016 [cited 9 October 2022] Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679

[2] European Parliament. Digital Services Act. European Parliament; 2022 [cited 29 July 2022]. Available from: https://www.europarl.europa.eu/doceo/document/TA-9-2022-0269_EN.html

[3] European Parliament. Digital Markets Act. European Parliament; 2022 [cited 29 July 2022]. Available from: https://www.europarl.europa.eu/doceo/document/TA-9-2022-0270_EN.html

[4] EUR-Lex. Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union. Official Journal of the European Union, C 202, 7.6.2016 [cited 27 February 2023]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2016:202:TOC

[5] ISO. ISO/TR 14639-2:2014 Health informatics - Capacity-based eHealth architecture roadmap - Part 2: Architectural components and maturity model. ISO; 2014 [cited 26 February 2023]. Available from: https://www.iso.org/obp/ui/#iso:std:iso:tr:14639:-2:ed-1:v1:en:term:2.24

[6] Reichertz PL. Hospital information systems - Past, present, future. Int J Med Inform. 2006 Mar-Apr;75(3-4):282-99. https://doi.org/10.1016/j.ijmedinf.2005.10.001

[7] Wager KA, Lee FW, Glaser JP. Evolution of health care information systems in the United States. In: Wager KA, Lee FW, Glaser JP. Health Care Information Systems: A Practical Approach for Health Care Management. 5th ed. John Wiley & Sons Inc.; 2022. ISBN: 978-1-119-85386-2.

[8] Pagliari C, Sloan D, Gregor P, Sullivan F, Detmer D, Kahan JP, Oortwijn W, MacGillivray S. What Is eHealth (4): A Scoping Exercise to Map the Field. J Med Internet Res. 2005 Mar 31;7(1):e9. https://doi.org/10.2196/jmir.7.1.e9

[9] Roys J. What are the main types of health information technology? SDV International; January 24, 2022 [cited 26 February 2023]. Available from: https://www.sdvinternational.com/insights/types-of-health-information-technology

[10] Mordor Intelligence. Healthcare it market - growth, trends, covid-19 impact, and forecast (2023-2028). Hyderabad, India: Mordor Intelligence; 2023 [cited 26 February 2023]. Available from: https://www.mordorintelligence.com/industry-reports/global-healthcare-it-market-industry

[11] HealthIT.gov. Health Information Exchange. Washington: Office of the National Coordinator for Health Information Technology (ONC); 2023 [cited 26 February 2023]. Available from: https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/health-information-exchange

[12] Pundziene A, Gutmann T, Schlichtner M, Teece DJ. Value Impedance and Dynamic Capabilities: The Case of MedTech Incumbent-Born Digital Healthcare Platforms. California Management Review. 2022;64(4):108-134. https://doi.org/10.1177/00081256221099326

[13] Värri A, Nieminen H, Helander N, van Gils M. DiHECO – Digital healthcare ecosystem research and networking. FinJeHeW. 2022;14(2):256–260. https://doi.org/10.23996/fjhw.114944

[14] EUR-Lex. Commission Recommendation Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises. EUR-Lex; 2003 [cited 10 October 2022]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003H0361

[15] Husovec M, Roche Laguna I. Digital Services Act: A Short Primer. In: Husovec M, and Roche Laguna I. Principles of the Digital Services Act. Oxford University Press; Forthcoming 2023. https://doi.org/10.2139/ssrn.4153796

[16] Akman P. Regulating Competition in Digital Platform Markets: A Critical Assessment of the Framework and Approach of the EU Digital Markets Act. European Law Review. 2022;47(1):85-114. https://doi.org/10.2139/ssrn.3978625

[17] Kerber W. Taming Tech Giants with a Per-Se Rules Approach? The Digital Markets Act from the 'Rules vs. Standard' Perspective. Concurrences 2021(3):28-34. https://doi.org/10.2139/ssrn.3861706

[18] Cauffman C, Goanta C. A New Order: The Digital Services Act and Consumer Protection. European Journal of Risk Regulation. Dec 2021;12(4):758 – 774. https://doi.org/10.1017/err.2021.8

[19] Savin A. The EU Digital Services Act: Towards a More Responsible Internet. Copenhagen Business School, CBS LAW Research Paper 2021;21-04. Journal of Internet Law. https://ssrn.com/abstract=3786792

[20] Gorwa R. What is platform governance? Information, communication & society. 2019;22(6):854-871. https://doi.org/10.1080/1369118X.2019.1573914

[21] Keller D. The EU's new Digital Services Act and the Rest of the World. VerfBlog. 2022/11/07. https://verfassungsblog.de/dsa-rest-of-world/, DOI: 10.17176/20221107-215642-0