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*Regulation of Artificial Intelligence in Healthcare within the European Union**

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ABSTRACT The use of artificial intelligence (AI) is spreading rapidly in healthcare. AI systems have no regulation of their own in the European Union, but are subject to a growing set of overlapping regulations that are difficult to identify and systematize. This paper provides an orderly analysis of all these regulations at the European level in order to clarify the cardinal points of the regulation of AI systems in healthcare, as it is not homogeneous, but depends on the specific use of the system. The new EU's Regulation on AI and the Regulation on Medical Devices are the two key points that should complement each other. However, they are insufficient as the AI Regulation is too generic and the Medical Devices Regulation is outdated. Therefore, a specific regulation is needed to regulate the use of AI in healthcare.

1. *Artificial intelligence in the European Union's new digital policy*

Nearly a decade ago, the European Union shifted its strategy in digital policy.[1] Previously, the Union favored a non-regulatory approach to digital innovation, allowing technological progress to develop freely. Regulation was basically based on corrective, negative, reactive and *ex post* measures. This approach facilitated significant advances such as the personal computer and the Internet, which developed under minimal intervention on specific issues such as privacy, intellectual property and consumer rights.[2]

At the beginning of the last decade, a shift in the model was initiated due to the increasing significance of the digital transformation for both economic growth and social development, as well as the imperative to foster an environment of trust and security. This change stemmed from the emergence of a new generation of data-protection regulation.[3] This regulation introduced proactive, *ex ante* measures aimed at prevention, actively engaging individuals in compliance (proactive responsibility). It adjusted the level of intervention based on the scale and severity of the risks (risk-oriented approach) and incorporated obligations from the outset (protection by design and by default). Additionally, it introduced supplementary measures such as self-regulation (codes of conduct) and co-regulation (certifications).

These new measures were applied across the entire digital sector, marking a departure from the traditional laissez-faire approach to digital policy. This shift is evident in the regulation of large platforms, such as the Digital Services Act and the Digital Markets Act, which introduce *ex ante* regulations.[4] However, the most notable change can be observed in the regulation of artificial intelligence (AI). For the first time, restrictions and limitations are imposed on the use of a digital innovation. AI regulation includes the most innovative and intensive instruments within the new EU digital policy as a response to its penetration

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[1] On the origin of this change see U. Beck, *The Digital Freedom Risk: Too Fragile an Acknowledgment*, in *Quaderns de la Mediterrània*, no. 22, 2015, 141-144. Also see J. Vida, *The Risk of Digitalization: Transforming Government into a Digital Leviathan*, in *Indiana Journal of Global Legal Studies*, vol. 30, no. 2, 2023, 3-13. On the peculiarity of the European strategy for regulating digital innovation and its impact on innovation see A. Bradford, *The False Choice Between Digital Regulation and Innovation*, European University Institute, 2024.

[2] This explains why there has not been a piece of legislation like a Personal Computer Act or an Internet Act. The closest thing to the latter has been Directive 2000/31/EC on certain legal aspects of information-society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), which states that Member States may not restrict the freedom to provide information-society services of another Member State (art. 3).

[3] Specifically, Regulation (EU) 2016/679 of 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

[4] These are Regulation (EU) 2022/2065 on a single market for digital services (Digital Services Act) and Regulation (EU) 2022/1925 on contestable and fair markets in the digital sector (Digital Markets Regulation), and other regulations that make up the new digital-services package.

and disruptive potential.

According to the legal definition contained in the Regulation on Artificial Intelligence (RIA), [5] AI systems are software based on new forms of programming[6] that endow them with hitherto unknown functionalities, such as the capacity to generate predictions, contents, recommendations or decisions.

These systems are no longer linear, proposing solutions in a deterministic way, but have a certain autonomy although they are not independent, since they solve specific problems according to previously defined objectives.[7] AI systems are structured in various modalities, spanning from foundational models (generative AI) capable of executing multiple tasks (such as summarizing, responding, supervising, etc.) to highly specialized programs tailored for specific functions (like e-mail spam filters). Additionally, AI systems can be manifested in different forms. They can either function directly as software or be incorporated into robotic devices (such as articulated arms or vehicles), enabling them to translate their actions into physical responses by interacting with the environment.

The distinct attributes of AI, coupled with its rapid advancement and increasing ubiquity, have led to the implementation of various regulatory strategies at both the international and national levels.[8] The EU has been at the forefront of this movement, issuing a series of documents that have culminated in the Regulation on Artificial Intelligence (RIA) and the proposal for a Directive on AI liability[9] within a particularly short timeframe. These initiatives will be complemented by additional regulations addressing matters such as intellectual property rights, military applications, and more.

The European strategy on AI is unique as it does not solely rely on regulations but incorporates several soft-law instruments that provide a more flexible, agile and precise approach. They contain policy declarations on digital rights, which although not directly enforceable, offer guidance and serve as interpretative frameworks. Additionally, ethical guidelines, which preceded the Regulation now complement it. Furthermore, standardization plays a crucial role as a private and voluntary tool essential for managing this specialized and changing sector.

AI governance encompasses a comprehensive package of measures, comprising both traditional regulations and soft-law approaches. This comprehensive approach stands in contrast to the limited initiatives taken in the governance of other disruptive technologies such as blockchain, cloud computing, virtual reality, quantum computing, etc.

2. *The impact of artificial intelligence on healthcare*

The healthcare sector is experiencing a surge in the adoption of AI. This is due in part to the vast amount of data generated within the healthcare systems, which allows AI to be trained on a wealth of scientific evidence.[10]

[5] Regulation (EU) 2024 laying down harmonized rules on artificial intelligence defines AI systems as "a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" (art. 3 RIA). Although the Commission's proposal referred to "software" and the final version opts for "machine-based systems" – probably to make it more generic –, AI system will generally consist of software. For an approach to AI legal definition see J. Vida Fernández, *Artificial Intelligence in Government: Risks and Challenges of Algorithmic Governance in the Administrative State*, in *Indiana Journal of Global Legal Studies*, vol. 30, no. 2, 2023, 73-75.

[6] Specifically, these are techniques based on machine-learning strategies, logic-based strategies, statistical strategies, etc. Unlike classical programming, in which systems receive data and rules to obtain results, AI systems receive data and results to define the rules that solve the problems posed, which gives them new functionalities.

[7] This specific AI (or narrow AI) is different from general AI (or strong AI) that characterizes human beings, which is not yet far from being achieved. See A. Zlotnik, *Artificial Intelligence in Public Administrations: Definitions, Project Feasibility assessment and Application Areas*, in *Boletic*, no. 84, 2019, 27–28. See also S. C. Kantheti and R. Manne, *Application of Artificial Intelligence in Healthcare: Chances and Challenges*, in *Current Journal of Applied Science and Technology*, no. 40, 2021,78-89.

[8] In the United States, President Biden issued Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence on October 30, 2023. Section 8 is specifically dedicated to the protection of patients (Sec. 8. Protecting Consumers, Patients, Passengers, and Students).

[9] The Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) COM/2021/206 final was submitted on April 21, 2021 and has been adopted in three years. As for the Proposal for a Directive from the non-contractual liability rules to artificial intelligence (AI Liability Directive) COM/2022/496 final was submitted on September 28, 2022 and continues to be processed.

[10] In this sense, William Osler stated that "Medicine is a science of uncertainty and an art of probability". There

This, in turn, empowers the development of AI-powered tools that can significantly impact patient care.

The integration of AI is driving a profound transformation across all levels of the healthcare sector. This integration enables advancements in disease prevention, treatment, and management. AI facilitates a deeper understanding of both individual and population health, leading to innovations that improve effectiveness and efficiency within healthcare delivery.

EU and its Member States are increasingly interested in integrating AI into healthcare. Their primary goal is to enhance the health of their citizens and deliver top-quality healthcare services. Moreover, they are facing a rising healthcare expenditure, which they hope to mitigate through efficient resource management made possible by digitization.

This explains the extraordinary momentum of AI in healthcare, which promises to introduce substantial changes that will take the digital transformation of the sector to the next level. Until now, digital healthcare (e-Health) was limited to the provision of remote healthcare services via the Internet (telemedicine) and the digitization of management (electronic medical records).[11] IA introduces a qualitative change that affects substantive issues and is transforming the practice of healthcare professions and the organization and management of healthcare services, leading to intelligent healthcare (i-Health).[12]

Although the transformative potential of AI extends to all sectors, it is essential to recognize that healthcare is a particularly sensitive area. Here it intersects with crucial legal values such as physical human life, privacy and human dignity. These values must be carefully balanced with the advancement of public and private activities. Consequently, intense public intervention has emerged aimed at safeguarding health and related principles and values while ensuring that healthcare delivery remains reliable and accessible.

In this context, the integration of AI into the healthcare sector is expanding across all its dimensions, with varied implications for the public interest and the rights and freedoms of citizens. These implications differ depending on the specific field in which AI is applied.

A distinction must be made between the use of AI in healthcare at the individual level and its professional application for healthcare purposes. In the first case, AI is used to monitor and improve health in the private sphere, both by citizens and companies, as evidenced by the proliferation of health apps in mobile devices (smartphones, smartwatches) that collect body data (Internet of Bodies, IoB). The management of a massive volume of citizens' health data, conveniently processed through AI systems, can contribute to the improvement of public health both at the individual level, promoting healthy habits and monitoring health status, and at the collective level, analyzing the health of the population, identifying problems or threats and allowing the planning and management of health strategies and policies in both the private and public spheres.

However, our focus here will be on the use of AI for healthcare purposes, which is governed by a complex legal framework comprising numerous overlapping and complementary rules. The applicable regulations vary depending on the scope and application of AI, thus necessitating the distinction and systematization of the various contexts in which AI can be employed within the healthcare setting:[13]

are innumerable reports from consulting firms that highlight the potential of AI in the field of healthcare, such as McKinsey Technology Trends Outlook 2022.

[11] Digital transformation for healthcare has so far been limited to so-called online government (e-Health), which essentially consists of putting healthcare online, as it is based in one specific technology, such as the Internet, and its sole purpose is to enhance interaction by eliminating the spatial and temporal barriers that separate healthcare services from patients. e-Health is purely instrumental, but not substantial, as it is limited to considering interactions between the healthcare systems and patients by streamlining information distribution and service provision, but without the ability to change the model or essence of healthcare. For an overview of e-Health see M.N. Moreno Vida, *Impacto de la medicina 4.0 en el sistema de salud*, in R*evista de derecho de la seguridad social. Laborum*, no. 6 (extra), 2024, 345-375.

[12] According to the characteristics of AI, digitalization will no longer be instrumental but substantive, as it affects decision-making and service-delivery processes. AI will lead to a real transformation of healthcare as detailed below.

[13] A summary in T. Davenport and R. Kalakota, *The potential for artificial intelligence in healthcare,* in *Future Healthcare Journal*, 2019, vol 6, no. 2, 2019, 94-98. Also see N. Terry, *Of Regulating Healthcare AI and Robots*, in *Yale Journal of Law and Technology*, no. 21, 2019, 3-20 and F.J. Estella Pérez and N. Escobedo Ortega, *La inteligencia artificial en el sector salud: aplicaciones e impacto*, in *I+S: Revista de la Sociedad Española de Informática y Salud*, no. 158, 2024, 21-24. A more detailed tour of the various applications can be found at *Artificial Intelligence in Healthcare: Applica-*

a) On the one hand, AI is playing an increasingly important role in research, becoming an indispensable factor in healthcare innovation. Thus, AI reduces the time and cost for the discovery of new drugs and makes it possible to identify new therapies for certain diseases.
b) In medical practice, AI systems find application across various segments of healthcare:
   1. Prevention: They enable the identification of future disease trends or health issues at both the individual and collective levels. For instance, software that forecasts cancer risk years in advance or detect suicide risk by analyzing behavior on social networks.
   2. Diagnosis: This is an area where significant progress has been achieved. For example, AI aids in diagnosing diabetic retinopathy from imaging or even COVID-19 from analyzing the sound of the voice.
   3. Treatment: AI is increasingly applied in treatments, ranging from precision surgery assisted by AI to personalized drug treatments or precision medicine.
   4. Patient Monitoring: AI systems are also utilized in monitoring patients, such as predicting epileptic seizures or assessing the success of rehabilitation for patients with addictions.
c) In healthcare management, AI software is increasingly used in the organization, management and delivery of healthcare services at different levels:
   1. Micro Level: AI systems optimize the scheduling of individual patient visits, enhancing efficiency in patient management.
   2. Middle Management Level: AI systems are employed for organizing services, including the coordination of urgent ambulance transport or the management of primary care services.
   3. Macro Level: AI systems play a role in structural decision-making within healthcare policies. This includes determining the locations of healthcare facilities, managing personnel policies, and making decisions regarding the authorization and financing of drugs.

As it can be seen, the use of AI systems occurs in very different domains, each presenting specific challenges and subject to distinct legal frameworks. Apart from these differences in the areas in which AI is used, two additional factors modulate the legal regime and implications of AI usage.

On the one hand, the role of AI systems in decision making must be taken into account. The implications are not the same when the AI system is used in an auxiliary way to support the decisions of healthcare professionals, and when they act in an automated way without direct human intervention in decision making.

Another relevant factor is the context of use of AI systems, whether it is the private sector or whether they are used by public institutions subject to additional obligations and guarantees such as Public Administrations.

3. *The European Union strategy for artificial intelligence in healthcare*

The significant potential presented by the integration of AI into healthcare systems, along with its strategic importance for the future of healthcare, has positioned it as a priority in EU's digital transformation policies. It is essential to recognize that the drive for the digital transformation of healthcare and the integration of AI into the EU stems from two distinct policies: digital policy and health policy.

Regarding digital policy, successive general strategies of the Union have increasingly emphasized the importance of AI, as evidenced in the current strategy outlined in the 2020 Communication "Shaping Europe's Digital Future," which includes generic mentions of AI. The 2021 Communication "Digital Compass 2030," goes further by establishing objectives for the incorporation of AI.[14] However, regarding the digitization of healthcare, these documents maintain a traditional perspective of e-Health, associating it primarily with the transition to electronic formats and

tions, risks, and ethical and societal impacts, EPRS | European Parliamentary Research Service, Scientific Foresight Unit (STOA) PE 729.512 – June 2022.

[14] The first reference to AI was included in the strategy "Shaping Europe's Digital Future" [Commission Communication COM(2020) 67 final, 19.2.2020] in which AI is mentioned generically as a relevant innovation and a White Paper is indicated as an action but without much pretension.
In the current strategy Digital Compass 2030: Europe's approach for the Digital Decade (Commission Communication COM(2021) 118 final 9.2.2021), references to AI are multiplied, although no specific section is dedicated to it, but reference is made to intelligent IT applications and a target is set for 75% of companies to have incorporated AI by 2030.

the implementation of telemedicine,[15] without providing specific references to the application of AI within healthcare.

On the other hand, European AI strategies have indeed recognized the healthcare sector as one of the most susceptible to transformation, and promoting AI in healthcare has been proposed as an objective.[16] However, this specific objective is not included in the European policy for Digital Administration, which maintains the traditional e-Health approach without explicit reference to the incorporation of AI.[17]

The Union's health policy is much more limited in scope, since it lacks competence over the organization and management of national health systems. Although there is no comprehensive EU health strategy as such, there has been a notable emphasis on digital-health initiatives. This involves primarily transitioning to electronic formats, with a strong focus on the significance of accessing health data to advance research, prevent diseases, and enhance personalized health and care.[18]

Indeed, it is within the Union's data policy where the most significant impetus for AI is indirectly occurring. Progress is being made towards establishing a genuine European health-data space, which serves as the fundamental basis for the operation of AI applications in healthcare.[19]

Beyond political directives, the EU's substantial drive for AI, specifically in healthcare, is evident through its funding programs.

The Union's long-term budgets and the NextGenerationEU recovery plan are dedicated to promoting a green and digital transition across all sectors, including healthcare. A substantial portion of the €750 billion allocated will be directed towards healthcare, facilitated through mechanisms established at the national level. This funding aims to enhance healthcare systems to better address future crises.

In addition to the Next Generation EU plan, the EU launched the EUproHealth 2021-2027[20] program in response to the COVID-19 pandemic, aiming to strengthen national health systems. With a budget of €5.3 billion, the EUproHealth program encompasses several action lines.[21] These include strengthening the use and reuse of health data for healthcare delivery and research and innovation, as well as encouraging the adoption of digital tools and services. Moreover, the program emphasizes the digital transformation of healthcare systems, which involves the integration of AI.

Indeed, it is evident that the Union is strongly dedicated to advancing the transformation towards digital healthcare. With a significant economic allocation, the Union aims to promote the digitalization of healthcare services, including integrating AI systems.

[15] The 2020 Communication "Shaping Europe's Digital Future" refers to the promotion of electronic health records, while the 2021 Communication "Digital Compass 2030" points to online interaction, paperless services, electronic transmission and access to data instead of paper and promotes access to digital health services.

[16] The Communication "Coordinated plan on artificial intelligence", 7 December 2018 [COM(2018) 795 final] pointed to this potential and prioritized the health-data space. For its part, the White Paper on Artificial Intelligence-A European approach aimed at excellence and trust, 19.2.2020 [COM(2020) 65 final] also highlights the transformation of AI in healthcare and, as established in action 6, promotes AI by the public sector and, as a priority, in healthcare.

[17] The Berlin Declaration on the digital society and value-based digital administration at the ministerial meeting during the German Presidency of the Council of the European Union on December 8, 2020 talks about improving health systems and medical care through interoperable digital solutions in the eHealth Network, such as the exchange of medical records or mobile health applications.

[18] On this issue see the Commission Communication on achieving the digital transformation of health and care services in the Digital Single Market; empowering citizens and creating a healthier society, COM(2018) 233 final, 25.4.2018. It makes hardly any mention of AI which is logical considering that at the time this technology was not yet too well known.

[19] The Communication "Towards a common European data space" COM(2018) 232 final of 15.4. 2018 containing the guidelines of the European data strategy pointed to the access and exchange of health data which is developed in the Communication on digital transformation of healthcare COM(2018) 233 final and leads to the proposal for a Regulation of the Parliament and the Commission on the on the European Health Data Space presented on May 3, 2022 and which will allow the massive exchange of health data at European level for both primary (medical use) and secondary (research) use that only make sense and prove useful because of their incorporation into AI systems.

[20] Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a program of Union action in the field of health ("EUproHealth program") for the period 2021-2027 and repealing Regulation (EU) 282/2014.

[21] The lines of action include improving and promoting health, protecting the population, providing access to medicines, health products and relevant products in the event of a crisis, ensuring that these products are available, accessible and affordable, and strengthening health systems.

4. *A map of the regulation of the artificial intelligence in healthcare within the European Union*

The current moment provides a favorable context for increased utilization of AI in healthcare at the European level. This calls for the urgent identification and systematization of the legal framework for AI in healthcare. Stakeholders, both public and private, in the sector are grappling with a complex web of regulations, including both existing laws and those pending approval. These regulations do not seamlessly align due to their differing bases, resulting in overlapping and disorderly arrangements.

As a starting point, it should be borne in mind that the European Union intervenes based on the principle of attribution of competences. Therefore, it is necessary to identify the competences through which it regulates the use of AI in healthcare.

On one hand, the Union holds competence over the single market, allowing it to intervene on AI as a "product". On the other hand, by virtue of this same competence over the single market, it can also regulate medical devices incorporating AI.

On the other hand, the Union has no competence to regulate the organization and management of national healthcare systems. It is therefore up to the Member States to regulate the use of AI in their healthcare systems taking into account the regulations on AI and medical devices.

Thus, the Union has a wide scope for action to regulate the use of AI in healthcare, but limited to AI as a technology and as a medical device – when used in medical practice –. On the other hand, its competence will be very limited when it comes to regulating how national healthcare systems should acquire, manage and use AI.

Taking into account the competencies of the Union, it is easier to systematize the regulations governing the use of AI in healthcare at the European level. It is useful to distinguish several blocks according to their purpose, which include specific rules on AI, healthcare-related rules applicable to AI systems and other general rules regulating the activity of these systems. The following sections analyze these regulatory blocks, outlined as follows:

a) A first block of specific measures on AI as a technology that includes both standards and soft-law measures:
   1. The Artificial Intelligence Regulation of 2024.
   2. The proposal for a Directive on liability for artificial intelligence.
   3. The European Declaration on Digital Rights and Principles for the Digital Decade 2023.
   4. The Ethical guidelines for trustworthy AI adopted by the Expert Group in 2019.
   5. Technical standards (ISO, IEC, CEN, CENELEC, ETSI, SIST).
b) The second block consists of health-sector regulations affecting the use of AI.
   1. Regulation of medical devices.
   2. National regulations on the organization and functioning of health systems.
c) The third block includes the general rules that apply to complementary issues that frame the use of AI in the healthcare setting:
   1. Data regulations.
   2. Regulations on digital services.
   3. Regulations on cybersecurity.
   4. Product safety regulations.
   5. Fundamental Rights.

4. *Artificial Intelligence Regulations that condition AI use in healthcare*

4.1. *European Union Regulation on artificial intelligence*

Among the specific regulations governing AI, the Regulation on Artificial Intelligence (RIA) takes center stage. Once approved in 2024, the RIA will not be fully applicable until two years after its entry into force. Nonetheless, it has already emerged as the cornerstone of regulating this new technology. It will serve as the pivotal framework that shapes the utilization of AI across all sectors, with particular significance in healthcare.

However, it is essential to note that the RIA does not provide a comprehensive and detailed regulation of AI as a technology. Instead, it focuses on setting specific restrictions of varying degrees depending on the particular use case. The regulation is based on the principle of freedom of use of AI systems, with limitations imposed only when there is an impact on rights, freedoms, and values. The primary objective of the RIA is to prevent fragmentation of the legal framework for AI by Member States that could impede free across-borders movement of goods and services

based on this technology.[22]

Therefore, the RIA sets forth a framework of minimum standards, including prohibitions and requirements, aimed at preventing harm that may arise from certain uses of AI. However, it also permits unrestricted development and use in all other cases. In essence, it serves as a foundational regulation that prohibits Member States from imposing additional prohibitions and requirements that may impede the free movement and use of AI systems.

This does not imply that there is no room for further development of the legal framework outlined in the RIA. Currently, it resembles more of a directive than a regulation, as it is crafted using a unique legislative technique that blends principle-based regulation with limited specific requirements. Additionally, it refers to further development through delegated and implementing acts by both the Commission and the Member States.

Furthermore, in addition to the general regulations on AI outlined in the RIA, sector-specific regulations will remain applicable. For instance, regulations on medical devices or the organization of healthcare systems may contain requirements that impact AI systems in those areas. This creates an additional regulatory framework that supplements the legal regime on AI, as will be further discussed in the following section.

The scope of application of the RIA is broad, encompassing a horizontal and comprehensive range that extends across the entire healthcare sector. Specifically, it includes all uses of AI within healthcare.

Specifically, concerning its objective dimension, the RIA encompasses all potential uses of AI systems across all sectors – with some exceptions[23] – regardless of whether their utilization is professional or private. This includes all AI systems utilized in healthcare, ranging from apps promoting healthy habits to those employed with medical purpose and for healthcare-service management.

Similarly, according the subjective dimension, the RIA applies to all entities involved in the development, deployment, and utilization of AI systems, whether individuals or legal entities, public or private.[24] This is particularly pertinent in the healthcare sector, as it implies that there is no differentiation based on whether the AI system is employed by private professionals or organizations or by the public health services of the Member States. Even if they are considered Public Administrations, they are not exempt from compliance with the RIA.

At this point, to understand how stakeholders in the healthcare sector fit into this framework, it is necessary to delineate the various parties bound by the RIA. The RIA distinguishes between providers – who develop an AI system or commission its development – and deployers, who professionally utilize an AI system under their authority. Lastly, there are the individuals affected by AI systems, known as the "persons concerned".[25] According to this configuration, healthcare professionals, companies, and organizations primarily fall into the category of deployers, as they typically do not develop AI systems but rather acquire them from vendors.[26] This distinction is significant because providers bear greater obligations, being responsible for ensuring the safety and reliability of AI systems as developers, while deployers are tasked with complying to the conditions of use. As for patients, they are the ones impacted by AI systems, benefiting from the security and assurance measures put in place, but their rights are relatively limited under the RIA.[27]

Finally, concerning the territorial dimen-

[22] Recital 1 states that the objective of the RIA is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, the placing on the market, the putting into service and the use of AI systems in the Union, in accordance with Union value. Article 1 adds that the objective of the RIA is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy AI, while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter of Fundamental Rights.

[23] Certain uses related to transportation (art. 2.2) and to national security (art. 2.3) are excluded.

[24] "Provider" is defined as a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge; while the "deployer" a natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity.

[25] Article 3 of the definitions refers to all the parties involved, which are the provider, deployer, authorised representative, importer and distributor.

[26] In any case, to the extent that they can be considered to develop these AI systems – for example, by adapting an acquired AI system – they will be considered providers.

[27] Specifically, the right to an explanation of decisions taken individually (art. 86 RIA).

sion, it should be noted that the RIA applies to AI system-providers and deployer, regardless of whether they are established or located in third countries, as long as the output information generated by the AI system is utilized within the Union.[28] This extraterritorial reach of the RIA holds significance in digital activities, as they might be conducted from outside the Union but remain subject to its regulation.

The RIA sets forth prohibitions and requirements based on a risk-oriented approach that is open, proportionate, and adaptable, allowing for flexible intervention based on the level of risk posed by various AI uses. It delineates four risk levels: unacceptable-risk uses, which are prohibited; high-risk uses, subject to requirements verified through a conformity assessment; limited-risk uses, with minimum transparency obligations; and zero-risk uses, which are exempt from restrictions.

For systems intended for use in the healthcare sector, the classification as high-risk systems is particularly relevant, as they have a significant impact on public health, safety, and fundamental rights. AI systems are classified as high-risk in two main ways:

a) Firstly, high-risk AI systems include those utilized as safety components of products subject to conformity assessment under specific legislation, such as medical devices. Therefore, reference must be made to Regulation (EU) 2017/745, discussed below, to determine if an AI software can be considered a medical device. Among medical devices, those subject to a conformity assessment are classified as high-risk, while those subject to a declaration of conformity are excluded.
b) Secondly, all AI systems listed in Annex III of the RIA are considered high-risk. Among the systems listed that are relevant to healthcare are the following in order of importance:
    1. AI systems used to access public health services encompass all those involved in the management of health services.[29] This reference is particularly pertinent for AI systems not directly related to medical activities, as they are automatically classified as medical devices and thus deemed high-risk. Non-medical systems determining access to and utilization of health services, such as those scheduling medical appointments or calculating patient co-payments, fall into this category. Additionally, Annex III specifically mentions AI systems intended for assessing and categorizing emergency calls from individuals, as well as those utilized in dispatching or prioritizing first responders during emergency situations, including medical assistance services and emergency triage systems.
    2. Biometric identification systems utilized for biometric categorization[30] based on sensitive or protected attributes, such as race or ethnicity, represent another category, which may be used, for instance, in routine triage processes. Moreover, biometric identification systems employed for emotion recognition, serving purposes like identifying pain or addressing mental-health concerns, could be pertinent. If intended for medical applications, these systems would fall under the classification of high-risk medical devices and systems.
    3. Lastly, healthcare-provider companies and the national healthcare systems can use AI systems for personnel recruitment and decision-making processes concerning labor relations and performance evaluations that are also considered high-risk.[31]

    AI systems in Annex III will not be considered high-risk if they do not pose a significant risk of causing harm to the health, safety or fundamental rights of natural persons, especially when they do not substantially influence the outcome of decision making, i.e. when they are used as a complement to human decision making.[32] This exception does not

[28] As provided in Article 2.1 c).

[29] Annex III in paragraph 5(a) specifically refers to AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public-assistance benefits and services, including healthcare services, as well as to grant, reduce, revoke, or reclaim such benefits and services.

[30] Included in Annex I, section I, which includes other cases.

[31] Annex III refers to them in paragraph 4 as an IA system for "employment, management of workers and access to self-employment".

[32] Article 6.3 RIA indicates that this is the case when the AI system is intended to perform a limited procedural task; improve the outcome of a previously performed human activity; detect patterns of decision making or deviations and is not intended to replace human evaluation; or when it performs a preparatory task for an eval-

apply to AI software for medical purposes, only to the AI system used in the management of healthcare benefits.

High-risk systems must meet a series of requirements, mainly subject to a risk-management system that allows them to be identified and analyzed, assessed and evaluated and subjected to the appropriate risk-management measures. In addition, there are other requirements related to data quality, documentation and traceability, transparency, human supervision, accuracy and robustness. Compliance with these requirements must be demonstrated by a conformity assessment conducted by an independent body designated by the Member States. Once the assessment has been passed, it is entered in a European register and the CE marking is affixed for placing on the market.

Furthermore, the RIA sets forth particular transparency requirements for AI systems designed to engage with individuals or to discern emotions, typically classified as limited-risk systems.[33] It mandates the disclosure of the use of an AI system in such interactions, as well as when employing emotion-recognition or biometric-categorization systems, which can be fulfilled through verbal notification or displaying a logo. This transparency mandate will impact numerous AI systems used in healthcare, particularly those involved in patient interactions, whether medically or administratively.

Apart from the mentioned cases, all other AI systems are free to use without any prohibition or requirement. However, these AI systems can voluntarily comply with the requirements applicable to high-risk systems through Codes of Conduct, even though they are not obligated to do so.

In healthcare, free-use AI systems will be less common, especially for medical purposes. Only those AI systems not considered high-risk, such as those not classified as medical devices or those subject to a declaration of conformity – not a conformity assessment –, will be available for free use. However, in health management, there may be a greater number of freely available systems, as only those directly impacting access to healthcare benefits will be considered high-risk.

uation relevant to the listed use cases.

[33] Article 50 RIA refers to transparency obligations of providers and users of certain AI systems.

5.2. *Other relevant artificial-intelligence Regulations*

In addition to the RIA, other European-level regulations on AI are emerging, with relevance to the utilization of AI systems in healthcare.

A case in point is the proposal for a Directive on AI liability, put forth by the Commission in September 2022.[34] The primary objective of this Directive is to harmonize certain national non-contractual fault-based liability rules, so as to ensure that persons claiming compensation for damage caused to them by an AI system enjoy a level of protection equivalent to that enjoyed by persons claiming compensation for damage caused without the involvement of an AI system. The Directive introduces two mechanisms aimed at overcoming this imbalance and facilitate tort-liability claims that may be frustrated by the complexity of AI systems and their opacity when dealing with black-box systems.

To this end, the Directive imposes the disclosure of evidence on high-risk AI systems to enable a claimant to substantiate a non-contractual fault-based claim for damages. Furthermore, it introduces a rebuttable presumption regarding the causal link between fault (failure of performance) and damage (system performance), thereby shifting the burden of proof in the case of non-contractual fault-based claims brought before national courts for damages caused by an AI system.[35]

It is, therefore, an initiative that will be absolutely essential to determine the patrimonial liability in the event of damage derived from IA systems in the healthcare field, making it easier for patients to claim against both healthcare providers and IA-system providers. In these cases, there seems to be no difference between a public or private healthcare provider, since, although the regulation refers to cases of civil liability, it is understood that this regulation is applicable to cases of liability of

[34] Proposal for a Directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final, 28.09.2022. The liability of robots is a relevant issue see F. Ramón Fernández, *Inteligencia artificial y la atención médica: pacientes, diagnóstico y robots*, in *Revista de derecho y genoma humano: genética, biotecnología y medicina avanzada*, no. 56, 2022, 125-156.

[35] This is regulated in Article 4 of the proposed Directive, which refers to the rebuttable presumption of causality in case of fault.

administrations.[36] This however will be one of the issues to clarify.

Therefore, this initiative is crucial for finding liability in cases of damages caused by AI systems in healthcare, aiming to simplify the process for patients to seek compensation from both healthcare providers and AI-system developers. In these scenarios, the distinction between public and private healthcare providers seems negligible. While the regulation primarily focuses on civil-liability cases, its applicability to instances of administrative liability requires further clarification.

At present, the RIA (Regulatory Impact Assessment) and the proposed Directive on AI liability represent the EU's specific regulations concerning AI. However, it is likely that additional initiatives will arise at the European level, addressing specific facets, such as intellectual property. Moreover, sectors like transportation or national security, which are beyond the scope of the RIA, may also see dedicated regulatory efforts in the future. While it may seem logical to establish specific rules for the use of AI in sensitive sectors such as healthcare, the EU's approach is to apply a single general regulation, the RIA, to all AI applications. This does not preclude each Member State from applying its own regulations within its jurisdiction, including those relating to AI in sensitive sectors such as healthcare.

5.3. *Soft law on artificial intelligence*

The EU's strategy for governing AI goes beyond traditional regulation by incorporating various soft-law instruments to complement its legal framework.

A) Firstly, there are political documents recognizing digital rights, such as the European Declaration of Digital Rights and Principles for the Digital Decade, approved by the European Parliament, the Council, and the Commission on 23 January 2023. Chapter III addresses interactions with algorithms and AI systems, laying down principles applicable across various domains, including healthcare. These principles advocate for human-centered, reliable, ethical, transparent, and non-discriminatory AI systems. Moreover, they emphasize the importance of human oversight in AI-generated outcomes affecting people's safety and fundamental rights, cautioning against using AI to preempt decisions, particularly in healthcare.

While non-binding, these policy documents codify existing rights and indicate the emergence of new ones. They also serve as an interpretative criterion for existing regulations that may not yet fully encompass these principles.

B) Secondly, with the 2018 Ethical Guidelines for Trustworthy AI, established by the High-Level Expert Group, the European Union seeks to establish itself as a leader in promoting trustworthy and ethical AI practices.

While non-binding, these guidelines hold significant legal weight, serving as a reference for both the Union and its Member States in the development and interpretation of AI regulation. Additionally, they provide guidance for AI providers and users (deployers), outlining principles, requirements, and procedures for ensuring the reliability of AI systems.

C) A final important soft-law instrument with considerable influence is the standardization or technical normalization systems. These standards are not legally binding but are widely acknowledged by providers and users as benchmarks for quality and legal compliance. Due to their technical depth, detail, and adaptability, they effectively address the specifics left by mandatory hard-law regulations.

Notably, standardization is poised to play a crucial role, evident in the latest ICT Standardization Plans of the European Union,[37] which are paving the way for the development of the initial technical standards on AI.

[36] The term "civil liability" does not exclude the liability of the Administration. In addition, the proposal of Directive uses the RIA definitions of provider and user (deployer), which include both public and private parties. In addition, the explanation accompanying the proposal states that: "While this Directive does not apply with respect to criminal liability, it may be applicable with respect to state liability. State authorities are also covered by the provisions of the AI Act as subjects of the obligations prescribed therein."

[37] AI standards have been an important part of the successive EU Rolling Plan since 2018 and specific committees already exist (such as UNE Committee CTN 71/SC 42 Artificial Intelligence and Big Data) and specific standards have been adopted, such as: AI concepts and terminology (ISO/IEC 22989: 2022), biases in AI systems and AI-assisted decision making (ISO/IEC TR 24027:2021), guidelines for the implementation of AI systems (ISO/IEC 42001:2023), AI risk management (ISO/IEC 23894:2023).

6. *Health Regulations affecting the use of artificial intelligence*

6.1. *European Union Regulation on Medical Devices*

In addition to the general regulation on AI that conditions its uses, some sectoral regulations also affect the use of AI systems integrated in certain products and subject to specific regulations, such as toys, elevators, precision equipment, radio equipment and, as far as we are concerned here, medical devices that are subject to Regulation 2017/745 (EU).[38]

The definition of medical devices encompasses AI systems, as it expressly includes "software" intended by the manufacturer to be used by individuals for "specific medical purposes" such as:[39]

a) Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
b) Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
c) Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
d) Providing information by means of in vitro examination of specimens derived from the human body.

Therefore, general-purpose software used within healthcare but lacking a medical purpose is excluded, as is software designed for wellness or lifestyle purposes.[40] The criterion is not whether the software directly impacts the human body, but rather whether its intended purpose aligns with that of a medical device.[41] Consequently, any software used for health services management unrelated to medical functions would also be excluded from being considered medical devices.

Finally, it should be noted that computer software can qualify as medical devices when it is used directly and independently, but also when used as an accessory when it serves to operate a medical device – for example, software that controls an insulin pump.

Medical-device software is categorized into different classes depending on the level of risk it poses to people's health. This classification dictates the extent of the requirements such products must meet before they can be commercialized, ranging from less stringent to more stringent standards.[42]

Thus, software intended to provide information for making decisions for therapeutic or diagnostic purposes is classified in class IIa, unless these decisions have an impact that could cause death or an irreversible deterioration of a person's state of health (in which case it would be class III), or a serious deterioration of a person's state of health or a surgical intervention (in which case it would be class IIb). On the other hand, software intended to monitor physiological processes is classified as class IIa, unless it is intended for monitoring vital physiological parameters, in which case it is classified in class IIb. All other software is classified as class I.

This classification of software as medical device responds to the classical programming paradigm, since they are limited to the typical functions of this type of software that complements – but does not replace – the activity of healthcare professionals, providing information for decision making or facilitating the observation of physiological processes. Therefore, automated medical-device software is

[38] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[39] Article 2 of Regulation (EU) 2017/745 which defines "medical device" as any instrument, device, equipment, hardware, software, implant, reagent, material or other article intended by the manufacturer to be used on humans, separately or in combination, for any of the following specific medical purposes. See S. Jabri, *Artificial Intelligence and Healthcare: Products and Procedures*, in *Regulating Artificial Intelligence*, in T. Wischmeyer and T. Rademacher (eds), Cham, Springer, 2020, 328-335.

[40] Recital 19 refers to general-purpose programs (e.g., a word processor used in a hospital) although the distinction is not so simple. It also leaves out computer programs aimed at wellness or lifestyle goals (such as health, sleep, diet, etc. apps) that do not have the status of a medical device.

[41] For an analysis of AI systems in medical devices in the United State see W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Issues*, in *SciTech Lawyer*, no. 14, 2017, 15-17. Also see N. Terry, *Of Regulating Healthcare AI and Robots*, in *Yale Journal of Law and Technology*, no. 21, 2019, 15-17. For an overview of the regulation of medical devices and a comparison between the EU and the USA see F. Pesapane, C. Volonté, M. Codari e*t al.*, *Artificial intelligence as a medical device in radiology: ethical and regulatory issues in Europe and the United States,* in *Insights Imaging*, vol. 9, 2018, 745-753.

[42] As provided in Rule 11 of Annex VIII of Regulation (EU) 2017/745. On the classification of AI software see A. Kiseleva, *AI as a Medical Device: Is It Enough to Ensure Performance Transparency and Accountability in Healthcare?,* in *European Pharmaceutical Law Review*, no. 1, 2020, 8-10.

not conceivable without direct human intervention, limiting the scope and potential of AI systems in medical practice.

All medical-device software needs a declaration of conformity – which is common to all classes – with which manufacturers guarantee that their products conform to the essential requirements. Depending on the classification, they must obtain a certificate of conformity – classes IIa, IIb, III and others – issued by a notified body that verifies the conformity of the products corresponding to different class requirements.

Regulation 2017/745 (EU) on Medical Devices and the RIA operate concurrently in the regulation of AI systems utilized for medical purposes. Their simultaneous application is not redundant, as each serves distinct objectives. The Medical Devices Regulation is primarily concerned with safeguarding health, whereas the RIA aims to protect other rights and interests of patients.[43]

Thus, AI systems that are considered medical devices will be classified, firstly, according to the classification of the Regulation on Medical Devices depending on the risk they pose to health. They are also classified through the RIA which, by default, classifies them as high-risk systems, regardless of the level of risk to health they pose.[44]

This implies that AI systems for medical purposes will have to undergo three conformity assessments: one based on their classification as medical devices and obtain a conformity-assessment certificate from a notified body at national level; one as high-risk AI systems from another notified body under the RIA; and an impact assessment, in cases involving high risks to the rights and freedoms of individuals under the RGPD data-protection regulation.

To avoid duplication and reduce burdens, the RIA integrates the supervision of the requirements relating to high-risk IA systems within sectoral regulations, resulting in a single conformity assessment that will be, in the case of medical software, the one applicable to medical devices.[45]

Although this solution is pragmatic, it has significant drawbacks. First, the criteria for evaluating AI systems – including transparency, impartiality, data integrity, traceability, oversight and robustness – are diluted within the sectoral procedure. This dilution occurs because the sectoral regulations primarily prioritize health protection, but do not fully address other values in the evaluation of AI systems. There is also a major organizational problem, as the incorporation of IA-system requirements into sectoral procedures exceeds the health expertise of the sectoral-assessment body, which will need to be restructured.[46]

6.2. *National Regulations governing Public Healthcare Systems*

Another sectoral regulation governing the use of AI in healthcare are the regulations of national public healthcare systems. In this re-

[43] Thus, the AI software with medical purpose ensures that it does not cause physical harm, but, in addition, that it does not affect privacy or equality. Recital 64 of the RIA highlights the different risks faced by the RIA with respect to sectoral regulation: "The hazards of AI systems covered by the requirements of this Regulation concern different aspects than the existing Union harmonisation legislation and therefore the requirements of this Regulation would complement the existing body of the Union harmonisation legislation. For example, machinery or medical devices products incorporating an AI system might present risks not addressed by the essential health and safety requirements set out in the relevant Union harmonised legislation, as that sectoral law does not deal with risks specific to AI systems."

[44] Therefore, an AI system for body temperature measurement will always be a high-risk AI system under the RIA, but may be classified as a Class I medical device which is the lowest level of risk.

[45] This is provided for in Article 74(4) RIA, which states that the supervisory procedures for IA systems do not apply when those legislative acts already provide for procedures ensuring an equivalent level of protection having the same objective. Recital 64 explains this solution: "This calls for a simultaneous and complementary application of the various legislative acts. To ensure consistency and to avoid an unnecessary administrative burden and unnecessary costs, providers of a product that contains one or more high-risk AI system, to which the requirements of this Regulation and of the Union harmonisation legislation based on the New Legislative Framework and listed in an annex to this Regulation apply, should have flexibility with regard to operational decisions on how to ensure compliance of a product that contains one or more AI systems with all the applicable requirements of that Union harmonised legislation in an optimal manner. That flexibility could mean, for example a decision by the provider to integrate a part of the necessary testing and reporting processes, information and documentation required under this Regulation into already existing documentation and procedures required under existing Union harmonisation legislation based on the New Legislative Framework and listed in an annex to this Regulation. This should not, in any way, undermine the obligation of the provider to comply with all the applicable requirements". In a similar sense, see recital 81 with respect to quality-management systems.

[46] Thus, national authorities for the evaluation of medical devices will have to adapt in order to be able to verify the compliance of AI systems with the requirements related to aspects such as respect for the principles of equality, transparency, respect for fundamental rights, among others.

gard, it should be noted that the organization and management of public services is an exclusive competence of the Member States.[47] Additionally, since a significant portion of healthcare systems operate as public administrations, it is important to understand that the Union does not have competence over the organization and functioning of national administrations either.

Therefore, Member States have room to define the conditions for integrating AI systems into their healthcare system. This can be accomplished through regulations governing healthcare systems as well as through regulations governing the organization and operations of public administrations.

Member States must limit themselves to regulate the use of AI in the organization and management of healthcare systems. They should not interfere in matters relating to medical AI systems, as the Union's competence over the single market – exercised over both AI systems and medical devices – prevents Member States from adopting measures that would hinder the movement of these products.

To date, Member States have not enacted regulations specifically addressing the use of AI in healthcare systems.[48] This is likely because AI technology is not yet widely adopted, and there is anticipation for the European Regulation on AI, which is expected to establish the foundation and boundaries for any further national regulation. However, some Member States are taking steps by enacting measures on the use of AI in public administrations but more focused on their legal activity formalized in procedures, and less on the material provision of public services.[49]

7. *General Regulations framing the use of artificial intelligence*

The final regulatory block to consider encompasses general regulations that govern the use of AI. These regulations serve various purposes and do not specifically mention AI but nonetheless condition its use. They constitute the legal framework with which AI systems must comply and will be complemented, rather than replaced, by the RIA. It is useful to make a systematic list of all the regulations currently governing AI in healthcare. This list demonstrates that AI in healthcare is already regulated, even if not by specific regulations. Therefore, compliance with all these regulations is essential when using AI in healthcare, with the specific circumstances of each case determining the extent of its application.

Firstly, data regulations have increased significantly due to the European Data Strategy. This strategy is designed to maximize data potential and make their reuse and share easier within the market, while still protecting citizens' rights, especially their privacy. For this reason, the strategy relies on the General Data Protection Regulation, which will be applied whenever personal data are processed in AI operations.[50] Among the measures established to promote the free flow of data in the Union are the Open Data Directive, the 2022 Data Governance Act and the 2023 Data Act.[51]

[47] Article 168(1) TFEU provides that "7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."

[48] In Spain, the regulations that shape the National Health System, such as the General Health Act, the Cohesion and Quality Act and the regional regulations, contain provisions referring to digitalization – as in the case of the digital medical record or the electronic prescription –, but there are no specific provisions regarding AI.

[49] In the case of Spain, the provision applicable to the use of AI solutions by Administrations in general is Article 41 of 40/2015 Act on the Legal Regime of the Public Sector on "automated administrative actions" but it is not applicable to material activity as it is limited to actions taken in the framework of a procedure. On the other hand, Article 23 of Act 15/2022, on equal treatment and non-discrimination, which requires Administrations to promote mechanisms to ensure transparency, explainability, accountability and minimize biases in the algorithms involved in decision making; impact assessments following the principles set forth in the European Union regulations; and a seal of quality of the algorithm. In any case, there is no mandatory requirement, nor is it specified what these measures consist of, so that, in the end, it is a referral to the RIA. See J. Valero Torrijos, *The Legal Guarantees of Artificial Intelligence in Administrative Activity: Reflections and Contributions from the Viewpoint of Spanish Administrative Law and Good Administration Requirements,* in *European Review of Digital Administration & Law – Erdal*, 2020, vol. 1, issue 1-2, 55-61.

[50] On the application of automated decisions by AI systems in healthcare see J. Meszaros, J. Minari and I. Huys, *The future regulation of artificial intelligence systems in healthcare services and medical research in the European Union*, in *Frontiers in Genetics*, no. 13, 2022.

[51] The EU's data strategy is outlined in the Commission Communication "A European Data Strategy" COM(2020) 66 final, February 19, 2020. Within the data regulatory package are:
- General Data Protection: Regulation (EU) 2016/679 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;
- Judicial Data Protection Directive: Directive (EU)

Furthermore, when AI systems are incorporated into online services, they fall under the scope of digital-services regulations. Specifically, this includes the Information Society Directive and the Digital Services Act when they are integrated into intermediary services such as online platforms and marketplaces. In addition, the Digital Markets Act applies to "gatekeepers," which are large-scale companies that operate key-platform services.[52]

Of particular relevance to the use of AI in healthcare are cybersecurity regulations. Among them, the NIS 2 Directive, which establishes measures for the coordination and management of security protocols for networks and information systems. Also, the Cybersecurity Regulation and the proposed Cybersecurity Products Regulation. In addition, the regulation on critical infrastructures affecting national health services.[53]

Furthermore, as AI systems are products, they are subject to general product-safety and product-liability regulations, including the General Product Safety Regulation and the Machinery Regulation, as well as to product-liability and general consumer and user regulations.[54]

Last but not least, AI systems will have to respect the system of fundamental rights, both those recognized at the European level in the Charter[55] and the European Convention on Human Rights, and those recognized at the national level in each of the Constitutions of the Member States.

This complete and dense set of rules applies to IA systems in general, regardless of their use. In any case, as these are generic rules, they are specified and/or displaced by the special rules that will be issued specifically on IA systems, namely the RIA and the proposed Directive on Liability on IA, to which other specific rules will be added.

8. *A critical overview of the European Union regulatory landscape of artificial intelligence in healthcare*

This review of the regulations governing AI in healthcare highlights the challenges posed by its regulation, as there is no specific regulation of its own, but rather different layers of rules regulating different aspects such as the use of AI, medical devices, national healthcare systems and multiple related aspects such as data, cybersecurity, etc.

In the case of Regulation on AI, it should be noted that although the RIA applies to all AI systems used in healthcare, it establishes requirements of varying intensity depending on the use in question. Thus, all AI systems used for medical purposes will be considered high-risk and must pass a conformity assessment. The same applies to AI systems used for healthcare management that affect the access

2016/680 of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data;
- Re-use Directive: Directive (EU) 2019/1024 on open data and re-use of public sector information;
Data Governance Act: Regulation (EU) 2022/868 of 30 May 2022 on European data governance;
- Data Act: Regulation (EU) 2023/2854 of the Council of 13 December 2023 on harmonised rules on fair access to and use of data.

[52] The Digital Services Package contains the following legislation:
- Directive on electronic commerce: Directive 2000/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market;
- Digital Services Act: Regulation (EU) 2022/2065 of the Council of 19 October 2022 on a Single Market For Digital Services;
- Digital Markets Act: Regulation (EU) 2022/1925 of 14 September 2022 on contestable and fair markets in the digital sector.

[53] Cybersecurity regulation applicable to AI systems include:
- NIS Directive 2: Directive (EU) 2022/2555 of 14 December 2022 on measures for a high common level of cybersecurity across the Union;
- Cybersecurity Act: Regulation (EU) 2019/881 of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification;
- Proposal for a Regulation on horizontal cybersecurity requirements for products with digital elements COM/2022/454 final;
- Critical Infrastructure Directive: Directive (EU) 2022/2557 of 14 December 2022 on the resilience of critical entities.

[54] Product and consumer-protection regulations include:
Consumer protection Regulation: Regulation (EU) 2017/2394 of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws.
- Product Safety Regulation: Regulation (EU) 2023/988 of the Council of 10 May 2023 on general product safety;
- Machinery Regulation: Regulation (EU) 2023/1230 of the Council of 14 June 2023 on machinery;
- Proposal for a Directive on liability for defective products COM/2022/495 final;
- Consumer Protection Regulation: Regulation (EU) 2017/2394 of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws.

[55] Charter of Fundamental Rights of the European Union of 2000 (2016/C 202/02).

to healthcare benefits. Otherwise, all systems that interact with people or recognize sentiments will be subject to transparency obligations. All other AI systems used in healthcare are free to use and will not be subject to any limitations or requirements.

As for the Regulation on medical devices, it covers a large part of the AI systems used in healthcare since it applies to all those AI-products that have a specific medical purpose – diagnosis, prevention, monitoring, prediction, prognosis, treatment or disease alleviation – and will be classified according to the risk they present to health, so they must, in all cases, make a declaration of conformity, and in cases of greater risk to health they must obtain a conformity assessment.

The national regulations on the organization and operation of public health services can specify how AI systems can be used into the public system in terms of access to health benefits. The problem is that it can lead to two modes of AI use by establishing unjustifiable differences between use of AI in public healthcare, which would be subject to stricter rules, and the use of AI in private healthcare, which would be subject to general requirements.

Finally, there are the numerous general data, digital services, cybersecurity, consumer and fundamental rights regulations to comply with, in addition to AI and medical device-specific regulations that may modulate or shift their content.

The unique structure of the legal framework regulating AI in healthcare suggests that it may be insufficient due to the lack of specific legislation tailored to this context.[56] While measures such as the RIA, together with the proposed Directive on AI liability and soft-law measures, help mitigate the risks associated with AI systems in healthcare, they do not fully address the risks associated with their medical use. Conversely, the Regulation on Medical Devices ensures the safety of AI systems for medical purposes, but does not cover other non-health-related aspects, such as equality, transparency, etc.

Therefore, it is crucial that all these regulations are applied in a complementary and coordinated manner to ensure effectiveness without imposing excessive burdens on individuals. Without proper coordination, an AI system intended for medical use might need to undergo multiple conformity assessments, including those for medical devices, high-risk AI, and data protection. Hence, the RIA, in the case of AI software considered to be medical devices, refers to sectoral assessment procedures, although this solution is questionable due to the lack of specialization of the body that must carry out this assessment.

Moreover, the Regulation on medical device may be outdated to cope with the peculiarities of AI systems, as they were developed to ensure the safety of classical programming software with medical purpose. This raises difficulties, on the one hand, for the classification of AI systems as medical devices, since many of them are used as decision-support systems and, although the CJEU has adopted a functional criterion in the definition of medical devices based on medical purpose, this may be difficult to apply in some cases. On the other hand, the use of AI systems in healthcare also poses problems, since their autonomous software is not allowed and no reference is made to the relevance that these systems can have in decision-making, which, in some cases, can even replace them.

These shortcomings highlight the importance of adopting a strategy regarding the use of AI in healthcare. The European Parliament has proposed some alternatives[57] such as:

a) Extend AI regulatory frameworks and codes of practice to address healthcare-specific risks and requirements; Promote multi-stakeholder engagement and co-creation throughout the whole lifecycle of medical AI algorithms;
b) Create an AI passport and traceability mechanisms for enhanced transparency and trust in medical AI;
c) Develop frameworks to better define accountability and monitor responsibilities in medical AI;
d) Introduce education programmes to enhance the skills of healthcare professionals and the literacy of the general public.
e) Promote further research on clinical, ethical and technical robustness in medical AI;
f) Implement a strategy for reducing the European divide in medical AI.

[56] For a similar critic see H. van Kolfschooten, *EU Regulation of Artificial Intelligence: Challenges for Patients' Rights*, in *Common Market Law Review*, no. 59, 2022, 81-112.

[57] See *Artificial Intelligence in Healthcare: Applications, risks, and ethical and societal impacts*, EPRS | European Parliamentary Research Service, Scientific Foresight Unit (STOA) PE 729.512 – June 2022, 46-53.

The most straightforward solution may be the enactment of specific regulation at the European level to address the unique characteristics of AI systems in healthcare. Such regulations should integrate the requirements outlined in the RIA and update those of the Regulation on Medical Devices. The growing relevance of AI systems in healthcare and their profound impact makes it advisable to adopt a comprehensive regulation to ensure the safe and responsible use of these technologies in such a critical and sensitive area as healthcare, which involves numerous rights, health and human life.