

The national impact of the European AI Act

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Abstract: *L’Impatto nazionale dell’AI Act europeo* – This article examines the Italian Law on artificial intelligence (Law No. 132/2025) within the regulatory framework established by the EU AI Act. It argues that the Italian legislation establishes a model grounded in accountability and human oversight, reaffirming the primacy of human agency in decision-making in the deployment of AI systems across sensitive domains, including healthcare, employment relations, professional activities, and judicial functions. The paper further addresses governance choices, regulatory sandboxes, the regulation of health data for scientific research, and delegated legislative powers, examining their systemic implications within a multilayered European legal order.

Keywords: AI Act; Italian implementation; Sandboxes; AI Governance; Health data processing

1. Introduction: the relationship between the European Regulation and the Italian Law

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Italy has enacted legislation on artificial intelligence, i.e. the Italian «Law on Provisions and Delegations to the Government in the Field of Artificial Intelligence»¹, which necessarily operates within the scope afforded to national legislators by the European Union Artificial Intelligence Regulation².

¹ Law No. 132 of 23 September 2025, published in the Italian Official Journal No. 223 of 25 September 2025. It is also worth recalling that seventeen bills (three in the Senate and fourteen in the Chamber of Deputies) had been introduced in Parliament with a view to regulating artificial intelligence, as reported by *Il Sole 24 Ore* on 26 January 2025. Among the recent commentaries on the Italian AI Law, G. Finocchiaro, *Diritto dell’intelligenza artificiale*, Bologna, 2025; V. Franceschelli, A. Sirotti Gaudenzi (Eds), *La legge Italiana sull’Intelligenza Artificiale – Commento alla Legge 23 settembre 2025, n. 132*, Santarcangelo di Romagna, 2025; M. Iaselli, *Commentario alla legge sull’intelligenza artificiale. Principi, governance e applicazioni settoriali. Legge 23 settembre 2025, n. 132*, Rome, 2025.

² Reference is, of course, to Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 «laying down harmonised rules on artificial intelligence», the so-called «AI Act». Among the now numerous commentaries on the AI Act, C. Casonato, G. Olivato, *AI Regulation in Europe: Exploring the Artificial Intelligence Act*, in A. Fabris, S. Belardinelli (Eds), *Digital Environments and Human Relations. Ethical Perspectives on AI Issues*, Cham, 2024, 87–112; L. Feiler, N. Forgó, M. Nebel, *The EU AI Act: A Commentary*, Surrey, 2025; G. Cassano, E. M. Tripodi (Eds), *Il regolamento europeo sull’Intelligenza Artificiale. Commento al Reg. UE n. 1689/2024*, Santarcangelo di Romagna, 2024; L. De Biase, R. Viola, *La legge dell’intelligenza artificiale. L’AI Act europeo per trovare un senso nel futuro della tecnologia*, Milan, 2024; G. Finocchiaro, *Intelligenza Artificiale. Quali regole?*, Bologna, 2024; A. Mantelero, G. Resta, G. M. Riccio (Eds), *Intelligenza artificiale. Commentario*, Milan, 2025;

It is widely recognised that one of the principal objectives of the European Regulation is to affirm the digital sovereignty³ of the European Union, both internally and externally⁴. Within this framework, artificial intelligence plays a pivotal role. Therefore, no internal fragmentation within Europe can be tolerated, nor any divergent national interpretation or implementation of the legal rules governing the digital sector, which aim to establish a European digital market, while reconciling market purposes with the protection of fundamental rights.

The Italian Law, as its title indicates, contains both substantive provisions and legislative delegations in the field of artificial intelligence. It

S. Calzolaio, A. Iannuzzi, E. Longo, M. Orofino, F. Pizzetti (Eds), *La regolazione europea dell'intelligenza artificiale nella società digitale*, Turin, 2025; F. Donati et al., *La disciplina dell'Intelligenza Artificiale*, Milan, 2025; U. Ruffolo, *AI Act. La regolamentazione europea dell'Intelligenza artificiale*, Rome, 2025. However, the contributions addressing the Regulation at the proposal stage remain noteworthy, in particular: G. Alpa, *Quale modello normativo europeo per l'intelligenza artificiale?*, in *Contr. e impr.*, 2021, 4, 1003; L. Floridi, *The European Legislation on AI: a Brief Analysis of its Philosophical Approach*, in 34(2) *Philos. Technol.* 215 (2021); M. Mcfadden, K. Jones, E. Taylor, G. Osborn (Eds), *Harmonising Artificial Intelligence. The role of standards in the EU AI Regulation* *Harmonising Artificial Intelligence*, Oxford, 2021; J. Mökander, M. Axente, F. Casolari, L. Floridi (Eds), *Conformity Assessments and Post-market Monitoring: A Guide to the Role of Auditing in the Proposed European AI Regulation*, in 32 *Minds & Machs.* 241-268 (2021); B. Townsend, *Decoding the Proposed European Union Artificial Intelligence Act*, in 25(20) *Insights* (2021); M. Veale, F. Z. Borgesius (Eds), *Demystifying the Draft EU Artificial Intelligence Act*, in 22(4) *Comput. L. Rev. Int'l* 97 (2021); M. Ebers, *Standardizing AI – The Case of the European Commission's Proposal for an Artificial Intelligence Act*, in L. Di Matteo, M. Cannarsa, C. Poncibò (Eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge, 2022, 321-344.

³ In this regard, L. Floridi, *The Fight for Digital Sovereignty: What It Is, and Why It Matters, Especially for the EU*, in 33(3) *Philos. Technol.* 369-378 (2020); F. Casolari, L. Floridi and others, *Safeguarding European Values with Digital Sovereignty: an analysis of statements and policies*, in 10(3) *Internet Pol'y Rev.* (2021); G. Finocchiaro, *Digital Sovereignty: A European Perspective on Public and Private Powers*, in G. De Gregorio, O. Pollicino, P. Valcke (Eds), *The Oxford Handbook of Digital Constitutionalism*, Oxford, 2026; S. Fratini, E. Hine, C. Novelli, H. Roberts, L. Floridi, *Digital Sovereignty: A Descriptive Analysis and a Critical Evaluation of Existing Models*, in 3(59) *Digit. Soc'y* 58 (2024); H. Roberts, E. Hine, L. Floridi, *Digital Sovereignty, Digital Expansionism, and the Prospects for Global AI Governance*, in M. Timoteo, B. Verri, R. Nanni (Eds), *Quo Vadis, Sovereignty?: New Conceptual and Regulatory Boundaries in the Age of Digital China*, Cham, 2023, 51-75.

⁴ The objective is to promote the European model in relation to the other principal global actors, namely China and the United States. The most recent policy programmes published by the two reflect divergent geopolitical strategies: on the one hand, the U.S. document «Winning the Race: America's AI Action Plan»; on the other, the Chinese «Action Plan on Global Governance of Artificial Intelligence». Whereas China calls for a global governance framework for artificial intelligence, the United States adopts a more competitive and leadership-oriented approach, as also confirmed by President Trump's most recent Executive Order «on Ensuring a National Policy Framework for Artificial Intelligence», aimed at outlining a predominantly “soft” regulatory framework. On the matter, J. Guo, Z. Duan, C. Flanigen, E. Hsu, V. Simon, L. Floridi, *Energy Consumption Ramifications of U.S.-China AI Competition*, in SSRN, 19-6-2024, available at papers.ssrn.com/sol3/papers.cfm?abstract_id=4839772; G. Finocchiaro, *Le diverse strategie di Usa e Cina per la leadership*, in *Il Sole 24 Ore*, 2025; E. Hine, L. Floridi, *Winning the AI Race? The US AI Action Plan in Context*, in SSRN, 17-9-2025, available at papers.ssrn.com/sol3/papers.cfm?abstract_id=5494858.

may be divided into four principal areas: general principles, reaffirmed and further elaborated; the implementation of the choices entrusted by the European legislator to the national legislator; newly introduced provisions; and delegated legislative measures.

2. General principles

Article 1, paragraph 1, of the Italian Law on artificial intelligence, as an opening provision, sets out the objectives of the new regulatory framework, which pursues a dual aim: to seize the opportunities offered by artificial intelligence while, at the same time, ensuring protection against its risks.

Article 1 stipulates: «This law [...] promotes the proper, transparent and responsible use of artificial intelligence, within an anthropocentric framework, with a view to harnessing its opportunities. It ensures oversight of the economic and social risks and of the impact of artificial intelligence on fundamental rights».

This dual objective is reflected in numerous provisions concerning artificial intelligence. In particular, Article 1 of the European Regulation states that its purpose is to «promote the uptake of human-centric and trustworthy artificial intelligence (AI), while ensuring a high level of protection of health, safety, fundamental rights enshrined in the Charter [of Fundamental Rights of the European Union], including democracy, the rule of law and environmental protection, against the harmful effects of AI systems in the Union and supporting innovation».

The wording of the Italian Law necessarily reflects that adopted in the European Union where the debate on artificial intelligence was launched as early as 2018, with the establishment by the European Commission of the High-Level Expert Group on Artificial Intelligence, and a terminology that constitutes an essential cultural reference framework has been progressively articulated.

Indeed, beyond the markedly different regulatory choices adopted by various countries worldwide, which, in this specific context, do not appear to support the extension of the so-called «Brussels effect»⁵, the language of the debate has developed within the European context⁶.

The promotion of innovation and the safeguarding of fundamental rights thus represent the core terms of the regulatory equation for both the European and the Italian legislators. Likewise, the anthropocentric

⁵ For a comprehensive analysis, A. Bradford, *The Brussels Effect: How the European Union Rules the World*, New York, 2020.

⁶ As noted in the Senate Report accompanying the Law of 20 May 2024, p. 3: «the European Expert Group identifies the following principles as grounded in fundamental rights: i) respect for human autonomy; ii) prevention of harm; iii) fairness; iv) explicability. The latter term, explicability, widely used in the specialised literature on artificial intelligence, constitutes a fundamental requirement for fostering trust among citizens and users of artificial intelligence systems: both the processes and the outcomes of such systems must be transparent, understandable and explainable to the user. The Expert Group further identified the following as 'requirements' derived from the four aforementioned principles: 1) Human agency and oversight; 2) Technical robustness and safety; 3) Privacy and data governance; 4) Transparency; 5) Diversity, non-discrimination and fairness; 6) Societal and environmental well-being; 7) Accountability».

dimension of artificial intelligence occupies a central position in both legal texts.

The principles set out in Article 1 of the Italian Law are subsequently elaborated throughout the entire text. They amount to a declaratory restatement of principles already embedded in both the Italian and the European legal orders, which are expressly recalled and reaffirmed.

Article 3 enumerates the principles governing the research, experimentation, development, adoption, deployment and use of artificial intelligence systems and models, with regard, in particular, to data quality and the limitations on their use; to human oversight and intervention; and to the protection of democratic life. Article 4 then emphasises the protection of personal data, while Article 5 focuses on promoting the use of artificial intelligence and encouraging the creation of a market.

With regard to research, experimentation, development, adoption, deployment and use of artificial intelligence systems and models, they must be carried out in compliance with fundamental rights and freedoms guaranteed by the Constitution, European Union Law, and the principles of transparency, proportionality, security, personal data protection, confidentiality, accuracy, non-discrimination, gender equality and sustainability⁷.

As to the development of artificial intelligence systems and models, the Law reiterates that such development must be based on lawful, complete, reliable, secure, of quality, appropriate, transparent, supervised data and processes, in accordance with the principle of proportionality, i.e. in relation to the sectors in which the systems and models are deployed⁸.

According to the anthropocentric approach embraced by the European Union, artificial intelligence systems and models must be developed and applied respecting human autonomy and decision-making, the prevention of harm, transparency and explainability, as well as the principles previously referred to⁹.

Notably, the Law provides that the use of artificial intelligence systems must not interfere with the functioning of institutional and political processes nor impair «the freedom of democratic debate from unlawful interference, regardless of its source, safeguarding the interests of State sovereignty as well as the fundamental rights of every citizen»¹⁰. A link emerges between this provision and the later introduction in the text of the criminal offence of deepfake dissemination¹¹.

Finally, the Law expressly recognises that cybersecurity constitutes an «essential precondition» for ensuring compliance with the rights and principles laid down by it¹²: without security, not only from a technological point of view, but also in organisational terms, the effective protection of

⁷ Thus, Article 3, paragraph 1.

⁸ Thus, Article 3, paragraph 2.

⁹ Thus, Article 3, paragraph 3.

¹⁰ Thus, Article 3, paragraph 4.

¹¹ More precisely, reference is made to the offence of «Unlawful dissemination of content generated or altered by means of artificial intelligence systems» introduced by Article 26 of Law No. 132/2025 through the insertion of a new Article 612-*quater* of the Criminal Code, which will be examined below.

¹² Thus, Article 3, paragraph 6.

rights in the online environment cannot be guaranteed. Indeed, security has received increasing attention, including at legislative level.

2.1. The Anthropocentric Approach: the instrumental nature of artificial intelligence and human liability

As previously noted, the anthropocentric approach lies at the core of both the Italian and the European regulatory frameworks and is expressly affirmed as early as Article 1.

The Italian Law further articulates this approach within specific sectors, such as healthcare, employment, intellectual professions¹³, judicial activity, and public administration.

The fundamental principles are once again affirmed: artificial intelligence currently constitutes a tool designed to assist individuals, not to replace them. Therefore, physicians, lawyers and other professionals, as well as judges and public authorities, may avail themselves of artificial intelligence systems, but always under their supervision and control, remaining responsible for the use of such tools.

The Law imposes a duty of transparency and information upon those who make use of artificial intelligence and confirms their responsibility, expressly excluding any autonomous liability of artificial intelligence itself. Two principles are established (or reaffirmed): on the one hand, the duty to inform; on the other, that artificial intelligence is purely instrumental and cannot be granted decision-making authority.

In the healthcare sector, Article 7 provides that physicians must inform their patients of the use of an artificial intelligence system and remain responsible for its use.

Article 11 establishes that artificial intelligence in the workplace must be employed with a view to improving workers' conditions, and that «the employer or principal is required to inform the worker of the use of artificial intelligence». Accordingly, the use of artificial intelligence in the employment context¹⁴ must be safe, reliable and transparent. Workers must

¹³ It is stated, in particular, in the aforementioned Senate Report, p. 7: «particular significance, in view of the role they play within the Italian economy and social fabric, is attributed to the intellectual professions, whose general regulation is set out in the Civil Code, under Chapter Two “Of Intellectual Professions”, of Title Three “Of Self-Employment”, of Book Five “Of Labour”, Articles 2229 to 2238. In relation to these professions, [Article 13] (“Provisions concerning Intellectual Professions”) lays down principles intended to safeguard the intellectual professions against a use of artificial intelligence that would distort their function (which consists in placing at the disposal of clients one’s specific expertise and intellectual resources) and undermine the relationship of trust between client and professional. Accordingly, it is provided that within the intellectual professions human critical thinking must always prevail over the use of artificial intelligence tools, which may concern only activities supportive of professional practice. Furthermore, to ensure the fiduciary relationship between professional and client, it is established that information concerning the artificial intelligence systems used by the professional must be communicated to the client in clear, simple and comprehensive language».

¹⁴ On this issue, see the recent «Guidelines for the Implementation of AI in the Workplace» adopted by the Ministry of Labour and Social Policies by Ministerial Decree No. 180 of 17 December 2025, aimed at providing operational guidance to enterprises, SMEs and self-

be informed whenever artificial intelligence is used to process their data. In this respect, the Law requires workers to be informed, according to Article 1-*bis* of the Legislative Decree No. 152 of 26 May 1997 (paragraph 2), namely regarding:

- «a) the aspects of the employment relationship affected by the use of the systems [...];
- b) the purposes and objectives of the systems [...];
- c) the logic and functioning of the systems [...];
- d) the categories of data and the main parameters used to programme or train the systems [...], including performance evaluation mechanisms;
- e) the monitoring measures adopted in relation to automated decision-making, any corrective processes, and the person responsible for the quality management system;
- f) the level of accuracy, robustness and cybersecurity of the systems referred to in paragraph 1, the metrics used to measure such parameters, and the potentially discriminatory impacts of those metrics».

Similarly, Article 13, entitled «Provisions concerning the intellectual professions», reiterates the instrumental nature of artificial intelligence, stating, in paragraph 1, that «the use of artificial intelligence systems in the intellectual professions shall be limited to activities that are instrumental and supportive of professional practice». This means, for example, that a lawyer may employ artificial intelligence as a tool to assist in legal research or in drafting an initial version of a pleading, provided that artificial intelligence does not replace the lawyer in making decisions or determining the legal strategy.

The following paragraph further states that, «in order to ensure the relationship of trust between professional and client, information concerning the artificial intelligence systems used by the professional shall be communicated to clients in clear, simple and comprehensive language».

Unlike the provisions governing the use of artificial intelligence in the workplace, the Law does not specify the content of the information to be provided, nor does it set out the modalities by which such information must be conveyed: for instance, it could be incorporated into the privacy policy, by including a reference to the use of artificial intelligence and specifying that further information is available. However, the right to an explanation in relation to decision-making processes involving artificial intelligence, as enshrined in the AI Act, as well as the right established under Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (the «GDPR»), continue to apply.

In recent years, case-law, including in Italy, has addressed the use of artificial intelligence by lawyers. These cases concern, *inter alia*, the citation of non-existent case law¹⁵ and the drafting of pleadings entrusted to artificial intelligence, which produced «a conglomerate of abstract statutory and case-law references, lacking logical order and largely irrelevant, without any submissions concretely related to the factual circumstances of the case»¹⁶,

employed workers, with particular emphasis on algorithmic transparency, human oversight, non-discrimination and the protection of personal data.

¹⁵ Thus, Court of Florence, Business Section, Order of 14 March 2025, No. 945.

¹⁶ Court of Turin, Labour Section, Judgement of 16 September 2025, No. 2120.

resulting in submissions characterised «above all by the poor quality of the defence briefs and by the total lack of pertinence or relevance of the arguments relied upon»¹⁷.

The Regional Administrative Court of Lombardy¹⁸, after once again noting that all the case-law cited in the application were manifestly unrelated to the grounds advanced, held that the inclusion of erroneous references introduces «elements potentially capable of influencing the adversarial proceedings and the decision-making phase», making the review by the Court and the opposing parties «unnecessarily burdensome». The Court further reiterated that «the signature of procedural documents serves the function of attributing responsibility for the content and consequences of the defence submissions to the signatory, irrespective of whether they were drafted personally or with the assistance of collaborators or artificial intelligence tools».

Beyond this, it is essential that no exemption from liability is recognised in favour of those who use artificial intelligence systems. Such systems are extremely powerful and highly beneficial, yet they require proper training, critical judgment and, above all, responsibility. On this matter, the Italian Law adopts a clear and unequivocal stance.

Comparable cases have already arisen in the United States¹⁹.

Professional associations worldwide have undertaken to draft policies governing the use of artificial intelligence within law firms, and all emphasise the continuing responsibility of the lawyer. From Florida to California, bar associations have issued guidance, including the «Practical Guidance for the Use of Generative Artificial Intelligence in the Practice of Law» which expressly requires human review of any output generated by artificial intelligence.

In Europe, the New Technologies Commission of the *Fédération des Barreaux d'Europe* (the association of European bars), in June 2023, adopted the «Guidelines for Lawyers on Leveraging the Opportunities Offered by Large Language Models and Generative Artificial Intelligence» emphasising that responsibility for the outcomes must ultimately rest with the lawyer. The same principles underpin the «Charter of Principles for the Informed Use of Artificial Intelligence Tools in Legal Practice» published in December 2024 by the Milan Bar Association.

Turning to the judicial sphere, according to Article 15, entitled «Use of Artificial Intelligence Systems in Judicial Activity», «when artificial intelligence systems are used in judicial activity, all decisions concerning the interpretation and application of the law, the assessment of facts and evidence, and the adoption of judicial measures shall remain exclusively reserved to the judge». The underlying principle remains unchanged: artificial intelligence is merely instrumental, it may provide support, but it

¹⁷ Court of Latina, Labour Section, Judgement of 23 September 2025, No. 1034.

¹⁸ Reference is made, in particular, to the Judgment of the Regional Administrative Court of Lombardy (Section V), 21 October 2025, No. 3348.

¹⁹ It is worth referring to the order, now widely known, issued on 22 June 2023 by Judge Castel, which sanctioned the lawyers who had used ChatGPT in the proceedings by citing non-existent judicial precedents.

cannot replace human decision-making. Just as lawyers remain responsible, judges do as well.

The Italian Superior Council of Judiciary addressed the matter in its «Recommendations on the Use of Artificial Intelligence in the Administration of Justice», adopted on 8 October 2025, identifying the activities that may be carried out by judges with the assistance of artificial intelligence. All activities relating to the interpretation and application of the law, the assessment of facts and evidence, and the adoption of judicial decisions remain, of course, excluded.

It should further be noted that the European Regulation on artificial intelligence classifies as high-risk «AI systems intended to be used by a judicial authority or on their behalf to assist a judicial authority in researching and interpreting facts and the law and in applying the law to a concrete set of facts, or to be used in a similar way in alternative dispute resolution»²⁰.

This classification entails several consequences. While it evidently permits the use of such systems, it also requires compliance with a set of requirements laid down in the Regulation, which adopts a risk-based approach, classifying AI systems according to the level of risk they present: systems presenting an unacceptable risk, high-risk systems, and systems posing low or minimal risk.

Since AI systems intended for use by judicial authorities are classified as high-risk systems, to be placed on the European market, they must meet specific requirements in terms of performance, accuracy and robustness and must be subject to appropriate conformity assessment. Moreover, the decisions must be sufficiently transparent, explainable and documented.

Italian case law has had occasion to address decisions adopted through algorithms. It is worth recalling it, even though it does not strictly concern the functioning of artificial intelligence systems. The Council of State²¹ articulated several fundamental principles. First, that «the mechanism through which the automated decision is implemented (namely, the algorithm) must be “knowable”, according to an enhanced understanding of the principle of transparency, which also entails full disclosure of a rule expressed in a language different from the legal one [...]. In other words, the “multidisciplinary nature” of the algorithm (a construct that undoubtedly requires not only legal expertise, but also technical, IT, statistical and administrative knowledge) does not dispense with the need for the “technical formula”, which in practice constitutes the algorithm, to be accompanied by explanations capable of translating it into the underlying “legal rule” and of rendering it readable and comprehensible, both for citizens and for the judge». Second, that «the algorithmic rule must not only be knowable in itself, but must also be subject to the full cognisance and full review of the administrative court. This requirement responds to the indispensable need to scrutinise how public power has been concretely exercised and ultimately constitutes a direct expression of the citizen’s right of defence, who cannot be denied knowledge of the modalities, even if

²⁰ See Annex III, paragraph 8, (a), of the AI Act.

²¹ Council of State (Section VI), 8 April 2019, No. 2270.

automated, through which a decision affecting his or her legal sphere has been adopted».

The Council's reasoning was subsequently confirmed and further developed. In 2019, the Council itself clarified²²: the «minimum safeguards required in any instance of the use of algorithms in public decision-making: a) full ex ante knowability of the model employed and of the criteria applied; b) attribution of the decision to the authority vested with the relevant power, which must be in a position to carry out the necessary review of the logic and legality of the choice and of the outcomes generated by the algorithm».

The Italian Law now expressly provides that public administrations must ensure «that the persons concerned are able to understand the functioning of artificial intelligence systems and that its use is traceable»²³.

Furthermore, the general principle prohibiting fully automated decisions was already enshrined in the European Data Protection Regulation, where Article 22 requires human intervention in the adoption of decisions, which may not be left entirely to an “automated system,” save for specific exceptions.

Decisions and the corresponding responsibility remain vested in the human agent, which, for the time being, neutralises, from a legal perspective, the debate on the legal subjectivity of artificial intelligence²⁴.

²² Council of State (Section VI), 13 December 2019, No. 8472. The Council of State upheld the judgment of the Regional Administrative Court, albeit on different grounds. The decision states: «It cannot therefore be held that the entire law on administrative procedure, conceived at a time when public administration had not yet been affected by technological revolution, applies indiscriminately to algorithmic administrative activity, as suggested in the reasoning of the first-instance judgment; nor are literary references to Orwellian scenarios, however well-known and appreciable, persuasive (they should be treated with caution, as the matter requires not an emotional approach but one capable of defining a new balance, in the workplace, between human and machine, differentiated according to each field of activity). The issue of the risks associated with the tool cannot be resolved through the rigid and mechanical application of all the detailed procedural rules set out in Law No. 241 of 1990 [...] rather, it must be held that the fundamental safeguard required in connection with the use of so-called algorithmic tools is transparency, in the terms previously outlined, referable to the principle of reasoning and/or justification of the decision». In the same terms, see Council of State (Section VI), 13 December 2019, Nos. 8473 and 8474.

²³ Thus, Article 14, paragraph 1.

²⁴ The issue of the legal subjectivity of artificial intelligence concerns whether AI can be regarded as possessing consciousness and, consequently, whether it may be recognised as a legal subject. The matter was raised by the European Parliament in its Resolution of 16 February 2017 «recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL))», which, at paragraph 59, (f), invited the Commission to consider «creating a specific legal status for robots in the long run, so that at least the most sophisticated autonomous robots could be established as having the status of electronic persons responsible for making good any damage they may cause, and possibly applying electronic personality to cases where robots make autonomous decisions or otherwise interact with third parties independently». It should be noted that the debate has been expressly superseded by the abandonment of the proposal to confer legal personality on AI systems by the European Parliament itself, which, in its Resolution of 20 October 2020 containing «recommendations to the Commission on a civil liability regime for artificial intelligence», observed, at point 7, that: «all physical or virtual activities, devices or processes that are driven by AI-systems may technically be the direct or indirect cause of harm or damage, yet are nearly always the result of someone building, deploying or

3. Choices Reserved to the National Legislator

The Italian Law also makes use of the options left to the Member States by the European Regulation, most notably the designation of the national competent authority for artificial intelligence and the implementation of regulatory sandboxes.

3.1. Governance

One of the most critical issues addressed by the Regulation concerns governance, which is entrusted to the Member States²⁵. In Italy,

interfering with the systems; [it] notes in this respect that it is not necessary to give legal personality to AI-systems». The European Commission subsequently addressed the issue of liability in its «Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence», COM(2022) 496, adopting a minimum harmonisation approach focused on fault-based liability rules. By Communication COM(2025) 45 and the related Annex I of 11 February 2025, within the framework of its Work Programme 2025, the European Commission announced its intention to withdraw the AI Liability Directive, citing the absence of a «foreseeable agreement» and indicating that further assessments would be carried out regarding a possible new proposal or an alternative approach. The proposal was definitively withdrawn on 6 October 2025 by Notice C/2025/5423. In legal doctrine, with regard to the recognition of legal personality, a favourable position appears to be adopted by G. Sartor, *Cognitive automata and the law: electronic contracting and the intentional of software agents*, in 17(4) *A.I. & L.* 253 (2009); U. Pagallo, *The Laws of Robots*, Cham, 2013; D. Vladeck, *Machines without Principals: Liability Rules and Artificial Intelligence*, in 89 *Wash. L. Rev.* 117 (2014); G. Teubner, *Rights of Non-Humans? Electronic Agents and Animals as New Actors in Politics and Law*, in 33 *J.L. & Soc'y* 497 (2016); Id., *Soggetti giuridici digitali? Sullo status privatistico degli agenti software autonomi*, Naples, 2019. A contrary position is instead taken by A. Bertolini, *Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules*, in 1 *Law Innov. & Technol.* 214 (2013); A. Amidei, *Il quadro normativo europeo*, in U. Ruffolo, *Intelligenza artificiale e responsabilità*, Milan, 2017, 98 and, in the same volume, also F. Di Giovanni, *Intelligenza artificiale e rapporti contrattuali*, 127; A. Bertolini, G. Aiello, *Robot companions: A legal and ethical analysis*, in 34(3) *Info. Soc'y* 130 (2018). More recently, see, U. Ruffolo, A. Amidei (Eds), *Diritto dell'Intelligenza Artificiale*, Rome, 2024, 137 and E. Palmerini, *Soggettività e agenti artificiali: una soluzione in cerca di un problema?*, in *ODCC*, 2020, 2, 445-474. May I also be permitted to recall my own contributions: G. Finocchiaro, *La conclusione del contratto telematico mediante i "software agents": un falso problema giuridico? Brevi considerazioni*, in *Contr. e impr.*, 2002, 500; *Intelligenza artificiale e responsabilità*, in *Contr. e impr.*, 2020, 713 and *La proposta di regolamento sull'intelligenza artificiale: il modello europeo basato sulla gestione del rischio*, in *Diritto inform.*, 2022, 303.

²⁵ The AI Act requires, in particular, the establishment or designation as national competent authorities for the purposes of the Regulation of «at least one notifying authority and at least one market surveillance authority» (Article 70). While the role of the market surveillance authority is self-explanatory, it is worth clarifying that the notifying authority is the authority «responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring» (Article 3, no. 19). Conformity assessment bodies, in turn, are the entities entrusted with assessing the compliance of certain high-risk artificial intelligence systems with the Regulation, in accordance with the conformity assessment procedures set out in Article 43 of the AI Act. The national governance framework is embedded within a complex system of European governance, composed of several newly established bodies: the AI Office, through which the European Commission «develops» its expertise and capabilities in the field of artificial intelligence (Article 64 of the AI Act), the European Artificial

considerable debate arose as to whether to establish an independent administrative authority for artificial intelligence, following the example of other countries, such as Spain²⁶. It was also questioned whether these functions might instead be assigned to the Data Protection Authority.

The Law ultimately provides that the national strategy for artificial intelligence is to be prepared by the Presidency of the Council of Ministers²⁷. Governance is therefore political in nature and situated at the highest level of executive authority, namely the Presidency of the Council.

The designated national authorities for artificial intelligence are the Agency for Digital Italy (*AgID*) and the Agency for National Cybersecurity (*ACN*).

The structure of the Presidency of the Council responsible for technological innovation and digital transition is entrusted with coordinating and monitoring the implementation of the strategy, acting in cooperation with *AgID* and *ACN*, and after consulting the Bank of Italy, the National Commission for Companies and the Stock Exchange (*CONSOB*), and the Insurance Supervisory Authority (*IVASS*).

Furthermore, a «Coordination Committee» is established, as provided by Article 19, paragraph 6, «for activities relating to entities, bodies, and foundations operating in the field of digital innovation and artificial intelligence, and chaired by the President of the Council of Ministers».

The competences established in the Regulation, which are essential for its implementation, are, as noted, allocated between national agencies, namely *ACN* and *AgID*. The functions assigned to *ACN* and to *AgID* consist of supervisory, monitoring and certification activities, i.e., functions of an administrative nature. While *AgID* is designated as the notifying authority, *ACN* is designated as the market surveillance authority and single point of contact with the institutions of the European Union, pursuant to Article 70 of the Regulation.

According to Article 20, paragraph 1, *AgID* is responsible for promoting innovation and the development of artificial intelligence. It is entrusted with defining procedures and exercising functions and tasks relating to notification, assessment, accreditation and monitoring of the entities responsible for verifying the conformity of artificial intelligence

Intelligence Board, composed of one representative per Member State and two permanent subgroups (for the structure and tasks of the Board, see Articles 65 and 66 of the AI Act); an Advisory Forum, «to provide technical expertise and advise to the Board and the Commission» (Article 67 of the AI Act), and a Scientific Panel of Independent Experts (for the composition and tasks of the Panel, as well as access thereto by Member States, see Articles 68 and 69 of the AI Act).

²⁶ Other countries have instead opted for the establishment of new *ad hoc* bodies. Spain, the first European country to take such a step, established, by *Real Decreto* 729/2023 of 22 August 2023, the *Agencia Española de Supervisión de Inteligencia Artificial*, entrusted with supervisory, advisory and training functions aimed at ensuring the proper application of national and European legislation on artificial intelligence. In February 2025, France established the *Institut national pour l'évaluation et la sécurité de l'intelligence artificielle*, with the mission of bringing together national stakeholders possessing expertise in the field of artificial intelligence.

²⁷ Thus, provided by Article 19.

systems. Accordingly, all accreditation, assessment and certification activities provided for under the European Regulation are carried out by *AgID*.

ACN, on the other hand, is responsible for the supervision of artificial intelligence systems, including inspection and enforcement activities, and, naturally, for safeguarding cybersecurity aspects. Pursuant to Article 20, paragraph 1, (c), *AgID* and *ACN*, each within their respective spheres of competence, ensure the establishment and joint management of regulatory sandboxes aimed at the development of artificial intelligence systems.

The governance framework thus assigns to the Presidency of the Council of Ministers responsibility for defining the national strategy and establishes the two national authorities competent in the field of artificial intelligence for the performance of the functions provided for in the Regulation. At the same time, the sector-specific competences of *CONSOB*, the Bank of Italy and *IVASS* remain unaffected, as do those of independent authorities such as the Data Protection Authority, the Competition and Market Authority (*AGCM*) and Communications Regulatory Authority (*AGCOM*).

For this reason, a second Coordination Committee is established pursuant to Article 20, paragraph 3. The Italian Law thus outlines a complex governance structure, characterised by a strong central role of the Government in the field of artificial intelligence.

3.2. Regulatory Sandboxes

Among the choices entrusted to the national legislator are those concerning the regulation of sandboxes.

Sandboxes allow for experimentation, including from a regulatory point of view²⁸. Within the space left to the Member States by the European legislator²⁹, the legislature appropriately takes the opportunity to regulate experimental environments, which are particularly significant in the AI sector, given that regulation is being developed for a technology whose evolution remains uncertain. In this context, and to reduce regulatory complexity, it is essential to acknowledge the need for experimentation so

²⁸ It is worth mentioning Article 20, paragraph 1, (c), which provides that *AgID* and *ACN*, each within their respective spheres of competence, shall ensure the establishment and joint management of experimental environments aimed at the development of artificial intelligence systems compliant with national and European Union Law. With regard to regulatory sandboxes, reference must also be made to Article 9, which governs the processing of personal data, including special categories of personal data, for research and experimental purposes «including through artificial intelligence and machine learning systems, as well as through the establishment and use of special experimental environments for research purposes»; as well as to Article 24, paragraph 2, (l), (1), which delegates to the Government the adoption of provisions designed to facilitate the involvement of the university and research system «in the promotion, development and use of regulatory sandboxes in collaboration with the productive sector».

²⁹ Reference is made to Article 57, paragraph 1, of the AI Act, which requires Member States to ensure that their competent authorities establish at least one regulatory sandbox for artificial intelligence at national level, to be operational by 2 August 2026.

that the law may accompany technological development without abdicating its role in steering innovation.

Article 58 of the European Regulation provides that the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation and supervision of regulatory sandboxes. The Italian Law specifically provides for the establishment of sandboxes in the healthcare sector for research purposes, including through the secondary use of personal data, and entrusts their detailed regulation to a decree of the Minister of Health to be adopted³⁰.

4. New Provisions

Thirdly, the Law regulates areas in which the European legislator does not possess specific competence. New criminal offences are introduced or penalties for existing ones increased³¹, while substantial innovations are enacted in specific sectors, such as healthcare.

Among the innovations, those concerning scientific research and experimentation aimed at the development of artificial intelligence systems in the healthcare sector are noteworthy: Article 8 recognises the public interest as a legal basis for the processing of personal data carried out for scientific research purposes, implementing, as the provision expressly states, Articles 32 and 33 of the Italian Constitution³².

Accordingly, alongside the most frequently relied upon legal basis, namely, the data subject's consent, and the other legal bases sometimes invoked under provisions governing specific research projects, as well as

³⁰ Thus, Article 9.

³¹ On this point, particular reference must be made to Article 24, paragraph 3, (f), of the Law under discussion, which confers a delegation upon the Government for the purpose of «adapting and specifying the regulatory framework governing cases of unlawful development and use of artificial intelligence systems». Among the guiding principles and criteria for the exercise of the delegation is the provision of «remedies, including interim measures, aimed at preventing the dissemination and ensuring the removal of content unlawfully generated, including by means of artificial intelligence systems, supported by a system of sanctions that are effective, proportionate and dissuasive». Reference should also be made to Article 26, which introduces new criminal offences and aggravating circumstances connected with the use of artificial intelligence tools.

³² Article 8, paragraph 1 of the Law stipulates, more precisely: «processing of data, including personal data, carried out by public bodies and non-profit private entities, by Scientific Institutes for Research, Hospitalisation and Care (*IRCCS*), as referred to in Legislative Decree No. 288 of 16 October 2003, as well as by private entities operating in the healthcare sector within research projects involving public bodies, non-profit private entities or *IRCCS*, for scientific research and experimentation aimed at the development of artificial intelligence systems for the purposes of disease prevention, diagnosis and treatment, the development of medicines, therapies and rehabilitative technologies, the production of medical devices, including prostheses and interfaces between the human body and support instruments for the patient's condition, public health, personal safety, health and healthcare security, as well as the study of physiology, biomechanics and human biology, including in non-healthcare contexts, where necessary for the creation and use of databases and foundation models, are declared to be of significant public interest in implementation of Articles 32 and 33 of the Constitution and in compliance with Article 9, paragraph 2, (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016».

Article 110-*bis* of the Italian Data Protection Code, which provides a more flexible framework for research projects promoted by Scientific Institutes for Research, Hospitalisation and Healthcare (*IRCCS*), an additional and significant ground of lawfulness is introduced: that of the public interest, which can now be invoked in research projects conducted by public bodies, by *IRCCS*, and by private entities in collaboration with *IRCCS*.

This is all the more significant given that facilitating scientific research in the healthcare sector, including through the processing of personal data, benefits not only researchers and patients, but the country as a whole by strengthening its research competitiveness.

Furthermore, in the healthcare sector and again with regard to scientific research, the Law provides that the obligation to inform data subjects may also be fulfilled through a general privacy policy published on a website, that the secondary use of personal data without direct identifying elements is permitted and that processing for the purposes of anonymization, pseudonymization, or synthesis is always authorized³³.

Article 9 devotes particular attention to the establishment of regulatory sandboxes in the healthcare sector for scientific research purposes, referring their detailed regulation to a decree to be adopted by the Minister of Health, to be guided by the criterion of the «maximum degree of simplification».

Two concluding remarks should be made. Scientific research in the healthcare sector appears to be overregulated. Significant overlap exists among the aforementioned provisions, further compounded by the applicable European legislation.

In this regard, reference should be made to the «European Health Data Space – EHDS» established by Regulation (EU) 2025/327, which provides for the free use of health data for research purposes, based on an opt-out mechanism, as well as on the submission of access applications to designated bodies, which will grant access to anonymised or pseudonymised health data depending on the purpose pursued.

Similarly, the «Ecosistema dei dati sanitari – EDS», established by the Decree of the Ministry of Health of 31 December 2024, also provides for the processing of health data for scientific research purposes, specifically in the medical, biomedical and epidemiological fields.

The underlying trend is clear: to enhance the value of health data and to promote its circulation. This represents a new and certainly positive development, following a period often characterised by excessive data protection, and gives effect to what is already envisaged by the GDPR itself. Indeed, as its very title indicates, the GDPR seeks both to protect personal data and to facilitate its free movement, as had already been intended, albeit unsuccessfully, by the parent Directive in 1995.

On the other hand, however, the overlap of Italian and European rules in the same field undermines legal certainty and does not benefit operators or researchers. It suffices to consider the regulatory paradox whereby scientific research in the healthcare sector may ultimately be subject to fewer compliance burdens when conducted through artificial intelligence systems.

³³ Thus, Article 8, paragraphs 2 and 3.

Overregulation, at both the Italian and the European level, has now become an issue that must be addressed: the time has come to consider a legislative simplification process, including in the relatively recent field of digital regulation³⁴. In this respect, the signal sent by the European Commission's very recent proposal to simplify the GDPR³⁵ appears insufficient. Greater courage would be required, and such an initiative could well begin with the provisions governing scientific research in the healthcare sector.

The Italian Law also addresses copyright. In line with the case law trend that has emerged at the global level, it emphasises that authorship remains a human prerogative, even where a work has been created with the assistance of artificial intelligence³⁶. As in the provisions already discussed concerning the liberal professions, judicial activity and healthcare, and following the path traced by the European regulator, by case law and by doctrine, artificial intelligence is essentially characterised as a tool. Accordingly, Article 25, paragraph 1 of the Law amends Law No. 633 of 22 April 1941 and clarifies that protected works are works of «human» creativity, «even when created with the assistance of artificial intelligence tools, provided that they constitute the result of the author's intellectual work».

With the introduction of new Article 70-*septies*, it is provided that «reproductions and extractions from works or other materials available

³⁴ In this regard, reference must also be made to the considerations set out in the Report presented by Mario Draghi to the European Commission, *The Future of European Competitiveness*, although addressed to EU-level regulation: M. Draghi, *The future of European competitiveness*, in *European Commission*, 9-9-2024, available online at: commission.europa.eu/topics/competitiveness/draghi-report_en#paragraph_47059.

³⁵ Reference is made to the legislative package known as the «Digital Omnibus» presented by the European Commission with the objective of simplifying the existing regulatory framework in the fields of artificial intelligence, cybersecurity and data protection. Of particular interest, even more than the reform of the GDPR itself, is the «Digital Omnibus on AI», which introduces a new provision including the deployers of high-risk systems and the providers and deployers of other categories of AI systems and models as authorized to process, on an exceptional basis, special categories of personal data for the purpose of identifying and correcting «bias» in AI systems, under specific conditions and in compliance with the safeguards laid down in the GDPR.

³⁶ The judicial proceedings involving Stephen Thaler, the creator of certain software designed for image generation, are particularly well known. At his initiative, courts in the United States and Australia held that copyright may vest only in a human being and not in software (see US District Court of Columbia, *Stephen Thaler v. Register of Copyrights and Director of the United States Copyright Office*, 18 August 2023 and Australian Federal Court, *Commissioner of Patents v. Thaler*, 13 April 2022). In the same vein, the Beijing Internet Court ruled that an image produced by an artificial intelligence system may be protected under copyright law in light of its originality and the creative contribution of the author, understood as a natural person. In Italy, the issue has been addressed only incidentally by the Court of Cassation, in Order No. 1107 of 16 January 2023, concerning the unlawful exploitation of a work of art created with the assistance of an artificial intelligence system. Although the Court did not rule on the merits as to whether the work qualified for copyright protection, it held that the use of software in the creative process of producing an image is not sufficient, in itself, to exclude the creative character of a work and merely calls for a more rigorous assessment of the level of creativity, aimed at «verifying whether and to what extent the use of the tool has absorbed the artist's creative elaboration».

online or in databases to which lawful access has been obtained, for the purposes of text and data mining through artificial intelligence models and systems, including generative systems, shall be permitted subject to compliance with Articles 70-ter and 70-quater». Accordingly, text and data mining is authorised, subject to compliance with the aforementioned provisions, unless the rightholder has expressly reserved such use³⁷.

The final part of the Law is devoted to certain criminal offences created, expanded or aggravated through the use of artificial intelligence systems³⁸. Among these is the so-called «deepfake offence», introduced by new Article 612-*quater* of the Criminal Code, entitled «Unlawful dissemination of content generated or altered by means of artificial intelligence systems», which provides:

«Anyone who causes unjust harm to another person by transferring, publishing or otherwise disseminating, without that person's consent, images, videos or voices that have been falsified or altered through the use of artificial intelligence systems and are capable of misleading others as to their authenticity shall be punished with imprisonment from one to five years. The offence shall be prosecutable upon complaint by the injured party. Proceedings shall, however, be initiated *ex officio* where the act is connected with another offence for which prosecution must be initiated *ex officio*, or where it is committed against a person who is incapable, by reason of age or infirmity, or against a public authority by reason of the functions exercised».

5. Delegated legislative powers

The Italian Law confers extensive delegated powers to the Government.

First, Article 16 provides for a delegation to the Government concerning data, algorithms and mathematical methods for the training of artificial intelligence systems. A specific regulatory framework is to be adopted governing the modalities and limits applicable to the training of AI systems. Pursuant to Article 16, paragraph 3, the guiding criteria of the delegation are: a) to identify the cases in which legislative intervention is required; b) to provide for protective remedies, including compensatory or injunctive relief, as well as sanctions; and c) to assign jurisdiction to the specialised business courts.

Further delegations are laid down in Article 24, which authorises the Government to adopt one or more legislative decrees to align the Italian legal framework with the European Regulation on artificial intelligence. Among the most significant objectives: conferring supervisory, inspection and sanctioning powers to the AI authorities; introducing the necessary

³⁷ Much will depend, on this issue, on the forthcoming ruling of the Court of Justice of the European Union in Case C-250/25, *Like Company v. Google Ireland Limited*, the first preliminary ruling to bring directly before the Court the question of the applicability to generative AI systems of the Union copyright framework in the publishing sector, including the «text and data mining» exception provided for in Directive (EU) 2019/790. By contrast, the provisions that had envisaged, inter alia, the affixing of a specific label indicating that a work, artistic or otherwise, had been created with the use of artificial intelligence were ultimately removed from the Italian law.

³⁸ As previously noted, Article 26 of the Law No. 132/2025 governs this matter.

amendments and additions to the legislation governing banking, financial and insurance services; and providing literacy and training courses in various contexts.

Of particular significance is the delegation conferred to the Government to adapt and further specify the regulatory framework governing the unlawful development and use of artificial intelligence systems. The guiding criteria of the delegation in this area include, for example: a) the provision of remedies, including interim measures, aimed at preventing the dissemination and ensuring the removal of content unlawfully generated, including with artificial intelligence systems, supported by a system of effective, proportionate, and dissuasive sanctions; b) the introduction of autonomous criminal offences, punishable on the basis of intent or negligence, centred on the failure to adopt or adapt security measures for the production, circulation and professional use of artificial intelligence systems, where such omissions give rise to a concrete risk to life, public or individual safety, or to State's security; c) the clarification of the criteria for attributing criminal liability to natural persons and administrative liability to legal entities for offences relating to artificial intelligence systems, taking into account the actual level of control exercised by the agent; d) in cases of civil liability, the provision of instruments for the protection of the injured party, including through a specific regulation of the allocation of the burden of proof, taking into account the classification of artificial intelligence systems and the corresponding obligations as set out in Regulation (EU) 2024/1689.

6. Conclusions

The regulatory framework governing artificial intelligence appears highly complex and multi-layered.

The overarching framework is established by the European Regulation, which provides a detailed regime governing market access for artificial intelligence systems and models, based on a procedural and compliance-oriented approach.

The space available to the national legislator therefore lies primarily in refining the instruments for the protection of substantive rights. However, such intervention does not occur on a blank slate: considering the extensive legislative output of the European legislator, the Italian framework operates within an already densely regulated environment. Suffice it to refer to the rules on personal data protection, as well as those concerning copyright and liability.

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