

On 17 September 2025, the Italian Parliament approved the first national law on artificial intelligence (AI), thereby making Italy the first country in the European Union to adopt a domestic legislation governing the use of AI.

On 25 September, the relevant law – Law No. 132/2025 (the AI Law) – was published in the Official Gazette of the Italian Republic (*Gazzetta Ufficiale della Repubblica Italiana*) and will become effective after a 15-day vacancy period from its publication therein (i.e. 10 October 2025).

The AI Law, composed of 28 articles drafted in compliance with and following the guidelines of EU Regulation no. 2024/1689 (the EU AI Act), aims at providing a legal framework for the principles governing, *inter alia*, the use of AI in different sectors (e.g. healthcare, employment, professional services, intellectual property, etc.). In addition to the above, as expressly mentioned in the AI Law, the relevant law shall be construed and applied according to the EU AI Act, and it does not introduce additional obligations other than those already set forth under the relevant European regulation.

The fundamental principles on the use of AI provided for under the AI Law and which constitute the basic rules of its application are set forth under Article 3 of the AI Law, namely (a) transparency, (b) proportionality, (c) security, (d) protection of data, (e) accountability, (f) gender equality and (g) nondiscrimination.

The AI Law devotes specific attention to “human-centric, transparent and safe AI use”. Substantially, the use of AI cannot substitute the ultimate decisional power of the individual using AI-based systems/software. The AI Law clearly states that it aims at promoting AI in an anthropocentric dimension, clearly underlining the need of human oversight over the use of AI (see Article 1).

There will be harsher penalties for using AI technology to commit crimes, including fraud and identity theft, and stricter transparency and human oversight rules.

Further to the above, the AI Law also aims at protecting minors who use AI, providing that children under the age of 14 may use AI only under consent of their parents.

The Italian Parliament was particularly focused on the data protection-related issues linked to the use of AI-based systems and thus included specific principles and obligations to safeguard the data used by and/or fed to AI-based systems, especially in the healthcare sector. Indeed, pursuant to Article 8 of the AI Law, the processing of personal data by AI-based systems in the healthcare sector is considered to be of significant public interest.

As mentioned above, the AI Law introduces the principles governing the use of AI in certain sectors; in particular:

### Healthcare

AI is deemed as an important tool in the healthcare sector, which may be valuable for the diagnosis and treatment of health conditions. However, AI shall not be used in a discriminatory manner; the patients have the right to know when AI is used; and the ultimate decisional authority always falls upon the medical team.

The National Agency for Regional Health Services – *Agenzia nazionale per i servizi sanitari regionali* (AGENAS) – will develop an AI platform that will be used to support the medical staff in the diagnostic and treatment process; however, its suggestions shall not be considered as binding for the medical team who is entrusted with the ultimate decisional authority.

The processing of personal data (including sensitive data pursuant to Article 9 of the GDPR) by AI-powered medical databases will be governed by a dedicated decree of the Ministry of Health.

### Employment

AI may be used in the employment sector in order to improve employees’ work conditions as well as physical and mental integrity. However, the use of such technology in the employment sector needs to be safe, reliable, transparent, nondiscriminatory and not in violation of the employees’ data-protection rights. In any case, the employees are entitled to know when AI-based systems are used.

Article 12 of the AI Law also provides for the creation of an observatory on the use of AI in the employment sector, which will have to define the strategy and monitor the use of AI in this sector.

### Professional Services

AI may be used to assist and support professionals in their work activities. Nonetheless, intellectual work shall prevail over AI’s input, and clients need to be informed, in a clear, simple and complete manner, when AI is used. The obligation set forth by the AI Law on the information obligation upon the professional is quite generic; however, it is likely that such information will be provided to clients through a dedicated information notice, which will include which AI systems will be used and how.

Professional associations will most likely provide certain guidelines, but in any case it would be appropriate for professionals to amend and adapt the relevant engagement documentation.

## Intellectual Property

The AI Law amends, *inter alia*, the Italian intellectual property code by ensuring that a work of art produced with the use of AI is protected as long as it is the result of human creativity. Thus, human contribution is essential, and AI may be used but only as a supporting tool.

## Judicial System

AI may be used as a tool in the judicial system, but nonetheless, the activities of interpretation and enforcement of the law, as well as the analysis of evidence, must always be carried out by the judge.

However, until the full implementation of the EU AI Act, the use and experimentation of AI-based systems in the courts shall be approved by the Ministry of Justice, which is also entrusted to issue dedicated decrees on the use of AI in courts

Finally, the AI Law authorises up to €1 billion from a state-backed venture capital fund to support companies active in AI, cybersecurity and telecommunications.

The oversight and coordination activities linked to the implementation of the provisions set forth in the AI Law will be subject to (a) a special committee established within the Presidency of the Council of Ministers and (b) two national agencies: Italy's Digital Transformation Agency (AgID) and National Cybersecurity Agency (ACN).

As mentioned, the AI Law constitutes a legal framework by the means of which the Italian Parliament, in addition to shaping the fundamental principles that will govern the use of AI, has also assigned specific powers to the government and ministries for the adoption of legislative decrees and specific decrees that will govern the use of AI in practice.

In addition to the above, please consider also that, even though the AI Law, inspired by the EU AI Act, is an important step towards regulating this complex matter, it will be necessary to undertake a concrete harmonisation and coordination process at European level involving all EU member states.

Despite the need to wait for detailed legislation with respect to certain aspects, the imminent entry into force of the AI Law (10 October 2025) requires companies and public administrations to take immediate action for compliance therewith. In particular, both such entities will have to conduct specific audits and mappings of AI systems currently in use (assessing the legal basis for their use, the levels of transparency, and the risks associated with the operative use of such systems), adopting appropriate measures to comply with the new legal framework.

## Contacts



**Daniela Sabelli**

E [daniela.sabelli@squirepb.com](mailto:daniela.sabelli@squirepb.com)



**Sara Belotti**

E [sara.belotti@squirepb.com](mailto:sara.belotti@squirepb.com)



**Francesco Cadelli**

E [francesco.cadelli@squirepb.com](mailto:francesco.cadelli@squirepb.com)