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ITALY'S PNRR DECREE 2026 CONVERSION LAW: KEY HEALTHCARE REFORMS INTRODUCED BY LAW NO. 50/2026

*In the Italian Official Gazette No. 91 of 20 April 2026, Law No. 50/2026 converting Decree-Law No. 19/2026 (the "**2026 PNRR Decree**") was published, which introduces measures for the implementation of the National Recovery and Resilience Plan (PNRR) in the field of cohesion policies.*

Law No. 50/2026 introduced several significant developments in the healthcare sector. Some of the most significant are the following:

- **Services aimed at improving the management and continuity of care for oncology patients.** Article 4-*bis* provides that the **Regions must establish**, where not already in place, **telemonitoring and teleconsultation services for oncology patients**, with the objective of ensuring prompt intervention and continuity of care. The measure falls within Mission 6 "Health" of the PNRR, particularly in the area of territorial telemedicine, in accordance with the Ministerial Decrees of 21 September 2022 and 30 September 2022. The initiative is intended to reduce inappropriate hospital admissions and improve patients' quality of life.
- **Simplification measures benefiting patients suffering from chronic and rare diseases.** Article 15 authorises the Regions to use **negotiated procedures without prior publication of a tender notice for the procurement of patented medicinal products with exclusive therapeutic indications**, including orphan drugs and innovative medicines supplied by a sole Marketing Authorisation Holder (MAH). The measure is aimed at preventing delays in the availability of medicines and ensuring continuity of treatment by leveraging digital infrastructures already financed under the PNRR, particularly for patients lacking alternative therapeutic options.
- **Targeted measures to address precarious employment within the National Health Service (SSN).** Healthcare authorities will be permitted, until 31 December 2026, to launch extraordinary recruitment procedures reserving up to 50% of available positions for personnel with prior experience acquired under flexible employment arrangements. In addition, in order to address the shortage of physicians, the possibility of retaining contracted medical personnel in service on a voluntary basis up to the age of 72 has been extended until 31 December 2027. These employment relationships may also be further extended for a limited period beyond the applicable retirement age thresholds.

- **Introduction of enhanced transparency obligations for supplementary healthcare and social-health funds.** The Law also introduces a stricter transparency framework applicable to supplementary healthcare and social-health insurance funds, imposing more stringent disclosure and reporting obligations on such entities.

SUPPLEMENTARY HEALTHCARE UNDER THE SPOTLIGHT: NEW TRANSPARENCY RULES INTRODUCED BY LAW NO. 50/2026

*Pending a comprehensive reform of the sector, the law converting the 2026 PNRR Decree also introduces significant measures concerning supplementary healthcare, imposing stringent transparency obligations for supplementary and complementary healthcare and social-health funds linked to the National Health Service ("**Supplementary Healthcare Funds**") (Fondi Sanitari Integrativi).*

The scope of the new regulatory framework includes:

a. **Supplementary healthcare funds of the National Health Service** established pursuant to Article 9 of Legislative Decree No. 502/1992, for which registration with the Ministry of Health's Register of Healthcare Funds is mandatory;
b. **Supplementary assistance schemes** established by entities, welfare funds and mutual aid companies operating exclusively for welfare purposes, pursuant to national collective bargaining agreements or company regulations, which are likewise required to register with the Ministry of Health's Register of Healthcare Funds for the purpose of tax deductibility of contributions;
c. **Other forms of supplementary or complementary assistance**, including those established on a contractual basis, provided that they are organised on a permanent basis, have managerial autonomy and are aimed at providing healthcare, social-healthcare or long-term care services to employees, self-employed workers, pensioners and their family members.

Insurance undertakings and insurance products supervised pursuant to the Italian Private Insurance Code remain outside the scope of the reform.

As regards the content of the measure, the 2026 PNRR Decree provides that:

- Supplementary Healthcare Funds must **prepare and publish their financial statements and accompanying reports on their institutional websites**, within three months following the end of each financial year, and must submit the same documentation within the same timeframe to the competent supervisory authorities. Such documentation must include data relating to members, contributions, benefits provided and asset management activities, including reports issued by supervisory and auditing bodies. **Financial statements and related documentation are expressly deemed to constitute**

"corporate communications" for the purposes of Articles 2621, 2621-*bis*, paragraph 1, and 2621-*ter* of the Italian Civil Code concerning false corporate disclosures;

- Failure to comply with the above-mentioned obligations concerning preparation, publication and filing results in the impossibility of obtaining, renewing or maintaining registration with the Ministry of Health's Register of Healthcare Funds, as well as the loss of access to the incentives and tax benefits currently provided under applicable legislation;
- The new regime will apply starting from the financial year following the one in progress as at 31 December 2025.

Finally, during the parliamentary conversion process, paragraphs 9 to 11 of Article 29 of the 2026 PNRR Decree were repealed. Those provisions would have granted COVIP, the Italian Pension Funds Supervisory Authority regulatory and supervisory powers over supplementary healthcare and social-health funds.

THE SCHILLACI REFORM: RESHAPING TERRITORIAL PRIMARY CARE AND GENERAL PRACTICE IN ITALY

On 28 April 2026, the Italian Minister of Health presented a draft law decree concerning the reorganisation of territorial primary care and general practice, with the objective of making the "Community Health Clinic" (Case di Comunità) fully operational.

- **Dual-track model.** The key innovation of the draft legislation is set out in Article 2, which formally introduces a "dual-track" model consisting of: (i) a "reformed" contractual arrangement as the ordinary framework for general practitioners and paediatricians, and (ii) a selective, planned and voluntary employment channel for structured territorial functions, particularly aimed at staffing Community Health Clinics, within the framework of regional healthcare planning and predefined workforce allocations.

- **Reformed contractual framework: maintaining relationship of trust alongside new organisational obligations.** The reformed contractual framework, governed by Article 3, is designed to preserve the fundamental patient-oriented features of the current system - namely patient freedom of choice and extensive territorial coverage - whilst introducing more stringent organisational obligations.

  Under the proposed framework, general practitioners and family paediatricians would continue to operate as trusted primary care providers while also being integrated as providers of territorial healthcare functions within an organised network. Minimum requirements would include digital interoperability, structured management of chronic and vulnerable patients, audit and monitoring mechanisms, multidisciplinary teamwork, and a scheduled portion of healthcare activities to be carried out within Community Health Clinics.

- **Remuneration: towards a national per-patient tariff system**. The proposed remuneration structure would be based on multiple components, including basic compensation, chronic care management, preventive care, organisational and technological support, activities performed within Community Health Clinics, and performance-related results. This reflects a gradual shift away from a system predominantly based on the number of registered patients towards one increasingly linked to organisational performance and healthcare outcomes. The technical and financial section of the draft provides a 2023 cost baseline and outlines a prospective national tariff estimated at approximate-

ly €128 per patient per year.

- **Community Health Clinic as a structural component of the healthcare system.** Article 4 introduces a national minimum "organisational commitment", subject to regional adjustment, covering participation in the territorial healthcare network, organised presence within Community Health Clinics, use of shared information systems, participation in audits and performance indicators, and integration into multidisciplinary care paths.

  Activities carried out within Community Health Clinics are expressly defined as a structural element — rather than a merely incentivised activity - of the new territorial healthcare model. The detailed allocation of working hours and operational procedures set out in the National Collective Agreement (*Accordo Collettivo Nazionale* - ACN) and regional healthcare planning.

- **Selective employment model for highly organised territorial functions.** Article 5 establishes a selective employment channel for territorial primary care functions aimed at ensuring constant coverage, shift organisation, continuity of care and multidisciplinary collaboration for highly organised healthcare services, with Community Health Clinics identified as the primary operational setting.

  Priority implementation scenarios include Hub Community Clinics, selected Spoke facilities, urgent continuity-of-care needs, and structured care coordination functions. The draft therefore permits pilot implementation in priority areas identified through regional and local healthcare planning.

- **Permanent recruitment and mandatory choice between salaried employment and the reformed contractual model.** Article 6 governs a transitional mechanism allowing the voluntary permanent recruitment of general practitioners currently practising - and, according to the draft, includes paediatricians - holding a specialist qualification, through simplified selection procedures to be established by ministerial decree within sixty days from the date of entry into force of the conversion law of the decree. The draft further provides for a mandatory choice, six months after approval of the reformed contractual framework, between the salaried employment channel and the reformed contractual arrangement, in order to prevent the indefinite continuation of the transitional regime.

- **Central role of the Regions in healthcare planning.** The Regions will play a decisive role in defining operational needs relating to Community Health Clinic activities, priority geographical areas, healthcare functions, minimum organisational and digital standards, adjustment of organisational obligations, and workforce allocations and deployment of staff under the employment-based channel. Local Health Authorities (*Aziende Sanitarie Locali*) will be responsible for implementing these measures through operational acts and ongoing monitoring activities.

- **Digitalisation and administrative simplification.** Article 8 links the new healthcare model to broader administrative simplification measures, interoperable digital tools and automated data flows, alongside the gradual strengthening of administrative and nursing support services and the implementation of telemedicine, telemonitoring and minimum technological standards.

- **Training, equivalence of qualifications, new contractual arrangements and implementation timetable.** Article 9 provides that, within 90 days of the date on which the law converting the decree comes into force, a ministerial decree shall establish criteria concerning the equivalence and recognition of qualifications, supplementary training courses and methods, coordination between specialist training in general practice and the new regulatory framework, as well as procedures governing the involvement of physicians in training within structured territorial healthcare activities.

  Article 10 establishes two contractual deadlines: within sixty days of the date on which the law converting the decree comes into force, negotiations for the amendment of the National Collective Agreement for general practice must commence; within 120 days of the date on which the law converting the decree comes into force, a dedicated contractual section - or a separate employment agreement - must be introduced for salaried physicians working in territorial primary care. Monitoring activities under Article 11 will be based on indicators including hours effectively worked within Community Health Clinics, shift coverage, the number of chronic and vulnerable patients under structured care management, use of the Electronic Health Record system, telemedicine uptake, prescribing and organisational suitability, inappropriate emergency room admissions, and overall system costs and savings.

  The implementation timetable is particularly ambitious: the review of regional supplementary agreements and mapping of healthcare needs shall be completed within 30 days; the draft reformed contractual framework and employment channel shall be prepared within 60 days; transitional arrangements, workforce allocations and standards must be defined within 90 days; and the first implementation measures and monitoring activities shall commence within 180 days.

THE ACTIVE INGREDIENT IS AN ALGORITHM: THE DIGITAL THERAPIES BILL BETWEEN THE MDR, AI ACT AND DATA PROTECTION

*On 7 May 2026, the Social Affairs Committee of the Chamber of Deputies decided to issue a favourable opinion on the consolidated text of Bills Nos. 1208, 2095, and 2220 concerning "**Provisions on digital therapies**". The Committee's approval represents a significant milestone in the legislative process, which is expected to provide Italy with a comprehensive regulatory framework for digital therapies.*

According to the text currently under discussion before the Chamber of Deputies, Article 1 defines digital therapeutics as software-mediated therapeutic interventions, with a specific therapeutic indication, designed to prevent, manage or treat a medical condition or disease by modifying the patient's behavior in order to improve clinical outcomes. Known internationally as digital therapeutics ("**DTx**"), they are based on scientific evidence from rigorous clinical trials and are not simply health-related applications nor exclusively telemonitoring interventions. Digital therapeutics consist of a **core digital function** and **supporting components aimed at improving the patient's experience, adherence** and **adoption**, and may **function independently or in combination with pharmacological therapies, medical devices** or **clinical interventions**. DTx are, for example, apps used for the management of insomnia, the monitoring of patients affected by Parkinson disease, or gaming applications for children affected by ADHD.

From a regulatory perspective, DTx qualify as medical devices under Regulation (EU) 2017/745 ("**MDR**") and must bear CE marking following a conformity assessment. Moreover, as DTx fall within the category of medical devices, they are subject to the scope of the *National Health Technology Assessment Program – Medical Devices* (PNHTA-DM).

Within thirty days of the law coming into force, a **National Committee for Digital Therapies** must be established within the Ministry of Health, including a representative of the Data Protection Authority.

The draft bill would pave the way for the recognition of DTx by the national healthcare system and their inclusion in the Essential Levels of Care ("**LEA**"), subject to clinical validation compliant with evidence-based medicine standards, with preference given to randomised controlled trials. Although the text does not introduce specific data

provisions, large-scale processing of health data is intrinsic to these devices and will require a qualified legal basis — generally inclusion in healthcare plans — alongside compliance with the principles of data minimisation and storage limitation.

The MDR classification also places DTx among high-risk AI systems **under Annex II of the AI Act** (Art. 6), **triggering the requirements of Annex IV: technical documentation, transparency, human oversight, robustness and cybersecurity across the system lifecycle. The AI Act's additional requirements over the MDR specifically concern the quality and governance of training data and the traceability of algorithmic decisions.**

For health tech and medtech companies operating in Italy, **the draft bill introduces** an **additional national level of qualification and assessment on top of the MDR requirements**; the draft bill does not yet impose immediate compliance obligations, but **defines the scope within which such obligations will take shape**: a signal that it is advisable to initiate a regulatory dialogue on algorithmic documentation, data quality and safety requirements promptly.

HEALTH DATA FOR SCIENTIFIC RESEARCH: THE EDPB GUIDELINES AND THEIR IMPLICATIONS FOR THE PHARMACEUTICAL SECTOR

*On 22 January 2026, the European Data Protection Board ("**EDPB**") **published its Guidelines on the processing of personal data for scientific research purposes**, currently under public consultation until 25 June 2026 (the "**Guidelines**"). For pharmaceutical companies, Contract Research Organisations ("**CROs**"), hospital networks and biotechnology players, the Guidelines carry direct operational relevance across the full spectrum of clinical and translational research activity.*

The Guidelines establish a set of indicative criteria to assess whether a given activity constitutes "scientific research" under the GDPR and therefore benefits from the specific regime applicable to it. These include:

- a methodical and systematic approach;
- adherence to ethical standards;
- verifiability and transparency;
- autonomy and independence; and
- a contribution to the advancement of knowledge.

The EDPB explicitly illustrates the application of this concept in the pharmaceutical field: a company developing a treatment for a rare disease that initiates a clinical trial, appoints vetted researchers, follows Good Clinical Practice standards ("**GCP**") and submits its protocol to an ethics committee shall, in principle, satisfy the relevant criteria.

One of the most significant clarifications from a practical standpoint provided by the Guidelines, concerns the **informed consent obtained from a patient prior to their participation in a clinical trial** — as required by the Clinical Trials Regulation ("**CTR**") — **this does not automatically constitute a legal basis for data processing under the GDPR.** The two instruments operate on distinct levels and must be clearly distinguishable in the consent documentation: **sponsors and CROs must identify their GDPR legal basis separately and document it accordingly.**

In this regard, the Guidelines confirm that it is possible to rely on **legitimate interest** under Article 6(1)(f) GDPR, even in the case of commercial **pharmaceutical research, provided the balancing test is satisfied.** However, given that **health data constitutes a special category under Article 9, a legal basis under Article 6 is never sufficient on its own**: a separate derogation under Article 9(2) must always be identified. In this regard, the Guidelines specifically point to **Article 53(1)(e) of the EHDS Regulation** as a relevant option, enabling **the secondary use of health**

data for scientific research within the European Health Data Space as a valid alternative to explicit consent — a particularly significant route for large-scale data programs.

Regarding **biobanks and long-term follow-up studies, where research purposes cannot be fully specified at the time of data collection**, broad consent remains admissible, provided the scope of research is clearly delimited and appropriate ethical safeguards — such as ethics committee oversight — are in place.
Further processing for scientific research purposes is presumed compatible with the original collection purpose under Article 5(1)(b) GDPR, **without requiring a separate compatibility assessment** — a provision of material relevance for real world evidence ("**RWE**") programs and post-authorisation studies. **The Guidelines also confirm that data may be retained beyond the conclusion of a clinical trial when intended for use in future research projects.**
On the **allocation of responsibilities**, the **sponsor is considered a controller** as it determines the purposes and essential means of processing through the trial protocol, while a **CRO operating under the sponsor's instructions shall in general qualify as a processor** — **joint controllership** may arise in **public-private research consortia** combining pharmaceutical companies, university hospitals and research institutes.

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