TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

In Italy, the placing on the market, wholesale distribution, retail sale, import and export of medicinal products are primarily governed by Legislative Decree No 219/2006[1] (the 'Code'). The Code transposes the European Union pharmaceutical framework into national law and establishes the regulatory requirements applicable to medicinal products for human use.

The Code designates the Italian Medicines Agency (Agenzia Italiana del Farmaco or AIFA) as the competent authority for: (1) granting marketing authorisations (MAs) for medicines marketed in Italy; (2) issuing manufacturing and import authorisations for medicines and active substances; (3) supervising pharmacovigilance, quality and regulatory compliance activities; and (4) managing procedures relating to parallel import and export certifications.

The Ministry of Health is responsible for the wholesale distribution and brokerage of medicinal products, overseeing advertising and distance selling of non-prescription medicines, supervising the retail pharmacy network and related public health functions.

The Regions and Autonomous Provinces hold administrative competence for issuing authorisations to wholesale distributors and depositaries, as well as for granting pharmacies the authorisation to provide distance selling of medicinal products. The operational management of these authorisation procedures has been delegated to the competent local health authorities.

With regard to both medical devices and in vitro diagnostic (IVD) medical devices, Legislative Decree No 137/2022[2] and Legislative Decree No 138/2022[3] align the national framework with Regulation (EU) 2017/745 (the 'Medical Device Regulation' or 'MDR') and Regulation (EU) 2017/746 (the 'In Vitro Diagnostic Medical Devices Regulation' or ''IVDR''), respectively, and designate the Ministry of Health as the competent authority for compliance, market surveillance and related administrative functions.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use and risk classes for devices) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Medicines are classified for supply purposes into prescription-only ('RX') and non-prescription

[1] See www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2006-04-24;219!vig= accessed 14 May 2026.
[2] See www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2022-08-05;137 accessed 14 May 2026.
[3] See www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2022-08-05;138 accessed 14 May 2026.

medicines. The latter are further divided into over-the-counter (OTC) and non-prescription (*senza obbligo di prescrizione* or SOP) products. The key distinction is that only OTC products may be placed on open shelves for direct access by patients in pharmacies, while SOP medicines must be dispensed by pharmacists. Both SOP and OTC medicines can be advertised to the public and sold online.

No medicinal product may be placed on the market without an MA issued by AIFA or an EU centralised authorisation issued by the European Medicine Agency. Simplified procedures exist for generic medicines, well-established use applications (bibliographic dossiers) and homeopathic medicinal products.

Medicines are also classified according to their reimbursement status: (1) Class A encompasses essential medicines and those for chronic conditions, covered by the National Health Service (NHS); (2) Class C includes medicines fully paid by the patient; and (3) Class H covers medicines for hospital use, supplied exclusively within hospitals or healthcare facilities and reimbursed by the NHS within that setting.

For medical devices and IVD devices, MDR and IVDR – as implemented by national legislation – govern the conditions for placing products on the market, define the obligations of manufacturers, importers and distributors, and set out comprehensive requirements for vigilance and post-market surveillance.

Devices are classified according to their risk level and degree of invasiveness, ranging from Class I to Class III for medical devices and from Class A to Class D for IVD medical devices. Conformity is demonstrated through assessment procedures involving notified bodies, where necessary, followed by CE marking. The conformity assessment procedure depends on the device's risk class: for medical devices, only Class I non-sterile, non-custom and non-reusable-surgical devices may be self-certified; all other devices require a notified body; and for IVD medical devices, only Class A non-sterile devices may be self-certified, while Class A sterile, B, C and D require notified-body involvement.

Unlike medicinal products, devices do not undergo a marketing authorisation process; once conformity is demonstrated, CE marking is affixed and the product may be placed on the EU market.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance or financial guarantees) attach to them?

Wholesale distribution of medicines requires authorisation issued by the local health authority, specifying the premises from which the activity is carried out. This authorisation is not required if the entity already holds manufacturing authorisation covering the same products. Applicants must: (1) have suitable premises, installations and equipment; (2) employ a qualified person holding a degree in pharmacy, chemistry, pharmaceutical chemistry or industrial chemistry; and (3) have systems and procedures in place to ensure compliance with all applicable obligations. The responsible person must be continuously present at the authorised site. Wholesalers must comply with Good Distribution Practice (GDP).

In addition to wholesalers, the Code also refers to an entity that may be entrusted with the commercialisation of a medicinal product in Italy under a specific agreement with the marketing authorisation holder (MAH). Such an entity is known as the sales concessionaire (*concessionario di vendita*). The appointment of concessionaires is optional, and MAHs must notify AIFA of their

concessionaires through a dedicated online system.

The Code also identifies operators who participate in the distribution chain without engaging in the sale of medicines. Depositaries store medicinal products on behalf of third parties and must comply with GDP requirements applicable to storage activities. Medicine brokers, by contrast, negotiate the sale or purchase of medicinal products independently and on behalf of others, without taking physical possession of the products. Entities established in Italy performing brokerage activities must register with the Ministry of Health and promptly notify it of any changes to their details.

For medical devices and in vitro medical devices, the regulatory framework for wholesale distribution is less prescriptive, focusing on market surveillance and database registration. Distributors making devices available in Italy must register in the national database maintained by the Ministry of Health, providing their corporate details and the device identifiers. At the EU level, the European Database on Medical Devices (EUDAMED) is the European database established under the MDR and IVDR to centralise information on devices, economic operators, vigilance and market surveillance. EUDAMED is only partially operational, but the use of its first four modules – including the Actor Registration Module relevant for distributors – will become mandatory on 28 May 2026. From that date, distributors will also be required to register in EUDAMED, and it remains to be clarified how this new EU-level requirement will interact with existing national systems, particularly the database listing medical devices that may be purchased by the NHS (the Repertorio).

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions attach to them?

In Italy, community pharmacies may dispense all medicinal products, including prescription-only medicines, and may also sell other health-related products, operating on the basis of an authorisation issued by the local health authority under Law No 475/1968.

Para-pharmacies (non-pharmacy retail outlets) may sell only non-prescription medicines (SOP/OTC) and other categories of health products such as medical devices, food supplements and cosmetics. Unlike community pharmacies, they do not require a pharmaceutical authorisation and may operate on the basis of a Segnalazione Certificata di Inizio Attività (SCIA) (certified notice of commencement of activity) submitted to the competent municipality under general commercial rules. Pursuant to Article 5 of Law Decree No 223/2006, the sale of non-prescription medicines in para-pharmacies is permitted, provided that prior notification has been submitted to the Ministry of Health and to the competent region, and that sales are carried out under the supervision of a qualified pharmacist.

Distance selling of non-prescription medicines to the public is permitted for community pharmacies and para-pharmacies under Article 112-quater of the Code, subject to prior authorisation by the local health authority (see Question 5). Distance selling of medical devices and IVD medical devices is also permitted, and does not require specific authorisation

5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?

In Italy, online sales of medicines to consumers are strictly regulated. Prescription-only medicines cannot be sold at a distance; only non-prescription medicines (SOP/OTC) may be supplied online. Under Article 112-quater of the Code, online sales are permitted exclusively to pharmacies and para-pharmacies authorised by the competent local authority. Authorised sellers must notify the authority of their entity details, VAT number, logistics address, start date of

distance sales, website URL and identifiers. Their websites must display the authority's contact details, a link to the Ministry of Health's webpage and the national common logo on every page, hyperlinked to the Ministry's public list. Only entities included in this list may lawfully sell medicines online. The distance sale of any medicinal products through a marketplace is forbidden.

For medical devices, Italian law does not impose specific conditions on online sales, beyond general consumer protection rules on distance selling. Devices may therefore also be sold through social media channels and marketplace platforms.

In both sectors, the Ministry of Health has the authority to order the immediate cessation of unlawful online practices and block access to infringing websites.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

Italy's import control framework for therapeutic products originating from non-EU countries operates within the broader EU regulatory system and is further defined by Articles 50 et seq of the Code, as well as by AIFA's resolutions and guidelines.

Importers of medicinal products and active pharmaceutical ingredients (APIs) must hold an AIFA-issued manufacturing authorisation, which also covers importation activities, or obtain specific import authorisation from AIFA for the individual case. A qualified person (QP) must certify that each imported batch complies with EU quality standards, including Good Manufacturing Practice (GMP), before it can be released to the market.

The importation of medicinal products that are authorised abroad (within the EU or in non-EU countries), but not authorised for marketing in Italy, when requested by the treating physician for the treatment of named patients, is governed by the Ministerial Decree of 11 February 1997[4] and authorised by the Uffici di Sanità Marittima, Aerea e di Frontiera ('USMAF-SASN') offices, which operate under the Ministry of Health.

At Italy's external borders, the USMAF-SASN performs sanitary checks on medicinal products and APIs arriving from non-EU countries, ensuring that any applicable public health requirements linked to the nature of the shipment are met.

The importation of medical devices follows a different regulatory pathway. Within the EU, devices that comply with the MDR/IVDR and bear CE marking may circulate freely without additional import licences. Devices arriving from non-EU countries are instead subject to customs controls and USMAF-SASN sanitary inspections, which verify compliance with EU conformity assessment requirements and applicable safety standards.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Italy permits the personal importation of medicinal products for non-commercial, personal

[4] See www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=1997-03-27&atto.codiceRedazionale=097A2390&elenco30giorni=false accessed 14 May 2026.

therapeutic use under Article 158(8) of the Code and the Circular of the Ministry of Health dated 23 March 2017.[5] Travellers may bring medicinal products intended for their own therapy, provided that they are for personal use and correspond to a therapeutic treatment not exceeding 30 days. Customs authorities may carry out checks to verify compliance with these conditions.

The personal importation of medical devices follows a different framework. CE-marked devices that comply with EU legislation may circulate freely within the EU and may be brought into Italy by travellers for personal use without quantitative limits or prior authorisation. Devices originating from non-EU countries remain subject to standard customs controls, even when carried or shipped for personal use.

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?

According to Article 112-quarter of the Code and the guidelines issued by the Ministry of Health, only pharmacies and para-pharmacies authorised in Italy are permitted to sell medicinal products to Italian consumers online (SOP/OTC). Distance selling is allowed only upon specific authorisation from the competent local authority, under the responsibility of the pharmacist in charge, and is strictly linked to the physical premises of the pharmacy or para-pharmacy located in Italy, including the warehouse where the medicinal products intended for shipment must be stored. Consequently, the supply of medicinal products from abroad (whether from EU or non-EU countries) directly to Italian consumers is not permitted.

A different approach applies to medical devices. CE-marked devices may be sold online within the EU under the general rules of the MDR/IVDR, without requiring a local presence in Italy. Conversely, suppliers located outside the EU cannot supply devices directly to Italian consumers, as non-EU operators may not place devices on the EU market without an EU-based importer and full compliance with applicable conformity assessment and labelling requirements.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product relabelling or repackaging, and requirements to maintain original quality, safety and traceability?

Parallel importation of medicinal products in Italy operates within the EU free-movement framework and is authorised by AIFA. It applies to medicinal products that are authorised and marketed in another EU Member State and are imported into Italy when an equivalent product already holds Italian marketing authorisation. Parallel importers must be authorised wholesale distributors and must hold an AIFA-assigned identifier required for the commercialisation of medicinal products in Italy (Sistema Informativo Sanitario or SIS code). AIFA verifies such requirements and, if satisfied, issues a parallel import licence.

Parallel importers must ensure that the product is relabelled or repackaged to comply with Italian regulatory requirements. Packaging must be in Italian and must include the Italian summary of product characteristics (SmPC) and patient information leaflet (PIL). Repackaging operations must be carried out in an AIFA-authorised manufacturing site, ensuring that the product's original quality and integrity are preserved. Quality and safety obligations include complying with GDP and ensuring full traceability throughout the supply chain.

From an intellectual property perspective, parallel importation is permitted under the EU

[5] See https://storagehub.homnya.net/cmsimage/allegati/allegato8106969.pdf accessed 14 May 2026.

principle of the exhaustion of trademark rights. However, when repackaging is carried out, the importer must notify the trademark holder before placing the repackaged product on the Italian market and, if requested, provide a sample of the modified materials and packaging. In line with case law of the Court of Justice of the EU (CJEU) (Joined Cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb), the trademark holder may oppose parallel imports only in limited circumstances.

With regard to medical devices, CE-marked products that have been legally placed on the market in one EU Member State may circulate freely within the EU without the need for a national import authorisation. Where relabelling or repackaging is carried out, these activities must preserve the original condition of the device, clearly identify the importer on the packaging and require prior notification to the manufacturer. The importer must also comply with all applicable traceability and post-market obligations under EU medical device legislation, and ensure that labelling, instructions for use and any other mandatory information provided to the user are supplied in Italian, in accordance with national language requirements.

EXPORT

10. Are there quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?

Italy does not operate a system of quantitative export quotas or export-permit requirements for medicinal products. However, to protect public health and ensure the continuous availability of therapeutic products on the national market, AIFA is empowered under the Code to adopt any measures necessary when shortages occur or are likely to occur, or in the context of public health emergencies. This statutory authority enables AIFA to intervene rapidly and flexibly to safeguard adequate national supply.

In practice, when AIFA identifies a shortage or other risks, it may issue a resolution temporarily prohibiting the export or parallel distribution of specific medicinal products. Export bans are the measure most commonly used, but AIFA may also adopt other appropriate emergency measures where needed to ensure continuity of supply.

AIFA also maintains publicly accessible lists that support the administration of these measures. The shortage list identifies medicinal products currently unavailable or at risk and is updated on an ongoing basis. Separately, AIFA publishes and regularly updates the list of medicinal products subject to temporary export bans. Following a legislative amendment to Article 148 of the Code adopted in December 2025, AIFA is also required to maintain and keep updated an additional list identifying medicinal products for which specific measures have been adopted to prevent or mitigate shortages or temporary unavailability, including in situations where no suitable therapeutic alternatives exist.

Enforcement is carried out through coordinated oversight. Wholesalers and distributors must comply with AIFA's prohibitions and retain the affected products within Italy. Regional health authorities monitor distribution flows and stock levels, while the Customs Agency may block outbound shipments of products included in AIFA's export-ban list. Non-compliance may result in administrative and criminal sanctions, as well as regulatory action.

With regard to medical devices, Italy likewise does not apply export quotas or permit requirements. In situations of actual or potential shortage, the Ministry of Health may adopt temporary measures to safeguard national availability, and the customs agency may intervene to prevent the outbound shipment of affected devices.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the

manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling or record-keeping obligations apply?

Manufacturers authorised by AIFA may legally produce medicinal products exclusively for export, even when those products are not authorised for marketing in Italy. The key requirement is that the manufacturing site holds a valid AIFA manufacturing authorisation and operates in full compliance with EU GMP standards. Products manufactured solely for export may bear labelling and packaging compliant with the requirements of the destination country.

A central instrument for exports is the Certificato di Prodotto Farmaceutico (CPP), issued by AIFA. The CPP confirms that the manufacturer is authorised and GMP-compliant and specifies whether the product is authorised in Italy or produced exclusively for export. Many importing countries require the CPP as part of their registration process. Manufacturers must maintain full GMP documentation, QP certification and traceability records demonstrating that the product is intended solely for export. For medical devices, there is likewise no 'export-only' or 'dual-labelling' authorisation regime. Manufacturers may produce devices exclusively for export provided that the manufacturing site is duly authorised and compliant with applicable EU quality-system requirements. Labelling and packaging follow the rules of the destination country. To support exports to non-EU jurisdictions, manufacturers may obtain a Certificato di Libera Vendita (CLV) from the Ministry of Health, which confirms that the device is legally manufactured in the EU and may be marketed or exported.

LABELLING, TRACEBILITY AND PRODUCT INFORMATION

12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Imported medicinal products must comply with the Code and all applicable EU pharmaceutical rules. Medicines placed on the Italian market must bear labelling in Italian and include the PIL and SmPC in Italian. Any relabelling or repackaging must be performed in an AIFA-authorised manufacturing site to ensure preservation of product quality and integrity. Italy applies the EU Falsified Medicines Directive (2011/62/EU) and Delegated Regulation (EU) 2016/161 that have been implemented by Legislative Decree No 17/2014:[6] prescription medicines must carry safety features, including a two-dimensional (2D) data matrix with a unique serial number and a tamper-evident seal, and the corresponding data must be uploaded to the National Medicines Verification System (NMVS). These requirements apply equally to imported products.

For exports, medicinal products must comply with the labelling and regulatory requirements of the destination country. Manufacturers must maintain complete GMP documentation, QP batch certification and full traceability records.

Imported medical devices must bear labelling in Italian and comply with the unique device identification (UDI) system before being placed on the Italian market. Importers must verify the CE marking, ensure that the EU declaration of conformity is available, and register themselves and the device in the national medical device database. UDI-based traceability obligations apply to all devices placed on the EU market, including imported products.

For exports, medical devices must comply with the regulatory and labelling requirements of the destination country. Manufacturers must maintain full technical documentation, quality-system

[6] See www.normattiva.it/uri-res/N2Ls?urn:nir:stato:decreto.legislativo:2014-02-19;17 accessed 14 May 2026.

records and traceability information. Devices manufactured exclusively for export outside the EU are not required to bear CE marking or UDI.

PRICING, REIMBURSEMENT AND MARKET ACCESS

13. Are there any price control, reimbursement, public procurement or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

Italy applies several mechanisms that, while not trade measures in the strict sense, materially influence distribution channels and the availability of therapeutic products.

For reimbursed medicines, AIFA's price-setting and reimbursement decisions significantly affect market penetration: lower regulated prices and reimbursement status drive demand through both retail and, in particular, hospital channels, shaping which products are widely supplied within the NHS. Medicines are generally purchased by the NHS through regional tender, which concentrates purchasing on selected suppliers.

Manufacturers and wholesalers are subject to statutory supply-obligation rules requiring continuous and adequate supply to the national market. These obligations, combined with AIFA's power to impose temporary export restrictions during shortages, limit the diversion of stock to other markets and directly affect domestic availability. Pharmacists must also comply with dispensing and generic-substitution rules (ie, mandatory substitution with the lowest-priced equivalent), which influence which products are actually supplied to patients.

For medical devices and IVD devices, pricing and market access are largely determined at the regional level through public procurement procedures. Regions and local health authorities conduct a tendering process that selects specific devices or suppliers for hospital and outpatient services, which significantly influences market structure and distribution channels.

Unlike medicinal products, medical devices do not generally have a nationally administered price governing NHS reimbursement and procurement; instead, they are typically supplied as part of the healthcare service in which they are used. Public procurement authorities rely on reference tariffs and other benchmark price tools that guide contracting entities and help to define the maximum amounts payable for specific categories of devices. As a result, procurement mechanisms play a central role in shaping availability, pricing and market access.

ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

Italian regulators have extensive investigative and enforcement powers to address non-compliance with trade and distribution rules for therapeutic products. For medicinal products, AIFA, the Ministry of Health, regional authorities, the Nuclei Antisofisticazioni e Sanità (NAS) Carabinieri and the Customs Agency conduct inspections of manufacturers, importers and wholesalers, verify GDP and GMP compliance, review documentation, and perform sampling and laboratory testing. They may also investigate illegal imports, falsified medicines and breaches of distribution or export ban rules.

Administrative measures include fines; suspension or revocation of manufacturing or wholesale licences; orders to withdraw or recall products; and mandatory corrective actions. AIFA may prohibit the export or parallel distribution of specific medicines in case of shortages and can require companies to implement remedial measures. Civil liability may arise where

non-compliance causes harm to patients or contractual partners. Criminal sanctions apply to serious offences, such as the manufacture or distribution of falsified medicines, illegal importation or violations of narcotics legislation, and may involve imprisonment, fines and product seizure.

For medical devices and IVD devices, enforcement is primarily carried out by the Ministry of Health, regional authorities and the NAS. Their powers include market-surveillance inspections, verification of CE marking and conformity documentation, and sampling of products. Administrative measures may include orders to bring devices into conformity, withdrawal or recall of non-compliant products, suspension of economic operators and administrative fines. Criminal sanctions may apply in cases involving unsafe or falsified devices or fraudulent conformity documentation.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?

At the national level, a notable anticipated development concerns the expected regulation of home delivery services for prescription medicines, which are distinct from the online sale of prescription-only products, the latter being prohibited under Italian law (see Question 5). These services expanded significantly in Italy during the Covid-19 pandemic and remain currently available nationwide. Such platforms typically allow users to reserve medicines from a selected pharmacy; transmit the prescription to the pharmacist; and delegate to third parties the in-pharmacy collection and delivery of the products, so that the patient receives them at home. However, there is currently no specific legislative framework governing these services. As a result, operators have been operating in a grey area. For these reasons, the Ministry of Health has established a working group involving other authorities and relevant stakeholders, and a regulatory framework for home delivery services is expected to be introduced going forward.

A further development concerns the recent adjustment of the statutory wholesale margin applicable to reimbursed medicinal products distributed through community pharmacies. Article 1, paragraph 324 of Law No 207/2024 (the 'Budget Law 2025') increased the mandatory wholesale margin from three per cent to 3.65 per cent of the ex-factory price for reimbursed medicines (Class A). AIFA subsequently issued an implementing determination to clarify the operational criteria for its application. Several pharmaceutical companies – particularly manufacturers of off-patent medicines – challenged the determination before the Regional Administrative Court, arguing that the methodology adopted by AIFA exceeded the scope of the legislative mandate and resulted in a disproportionate economic impact on marketing authorisation holders. While a number of companies have withdrawn their challenges, others remain pending, and a decision from the Court is expected in the coming weeks. The outcome may influence future pricing and distribution dynamics within the reimbursed medicines supply chain.

Furthermore, the Italian Government has initiated a comprehensive reform of the national pharmaceutical framework through a draft legislative delegation aimed at consolidating and modernising existing legislation into a new Unified Medicines Code. The draft delegation – approved in preliminary form by the Council of Ministers on 18 September 2025 – empowers the Government to adopt, by 31 December 2026, one or more legislative decrees reorganising and rationalising the rules governing medicinal products. The draft sets out general and sector-specific guiding principles, covering areas such as access to medicines, pricing and expenditure control mechanisms (including payback), distribution, digitalisation of prescribing and dispensing processes, pharmacovigilance and the role of community pharmacies within the territorial care network. The draft law will be submitted to Parliament for examination and

approval. Once enacted and implemented, the resulting legislative decrees are expected to affect various aspects of the regulatory framework for medicinal products in Italy.