# Legal 500
# Country Comparative Guides 2025

## Italy
## Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Italy.

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# Italy: Life Sciences

## 1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

Medicinal products are currently regulated by Legislative Decree No. 219/2006 (Code of Pharmaceuticals) implementing Directive 2001/83/EC and Directive No. 2003/94/EC. Medical devices were previously regulated by Legislative Decree No. 46/1997.

Following the adoption of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) the existing framework was respectively overhauled by Legislative Decrees No. 137/2022 (MD) and No. 138/2022 (IVD). Food supplements are regulated by Legislative Decree No. 169/2004 implementing Directive 2002/46/EC (and by ministerial decree of the Ministry of Health dated 9 July 2012), alongside other secondary sources.

## 2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

The regulatory process for medicinal products in Italy follows a structured pathway involving various stages. Generally, while research activities must be carried out in accordance with relevant legislation on preclinical and clinical trials, the Legislative Decree No. 219/2006 (Code of Pharmaceuticals) sets out instead the discipline concerning the development of pharmaceuticals.

To obtain the relevant marketing authorization (MA), the applicant must submit to Italian Medicines Agency (AIFA) the relevant information on pharmaceutical, preclinical and clinical trials collected in a standardized dossier. AIFA can issue the MA after verifying the regularity and the compliance with the discipline of the submitted dossiers. Following the approval, AIFA also approves package and labels of the marketed medicine and the summary of the relevant characteristics.

Then, post-marketing vigilance is conducted by AIFA in collaboration with pharmaceutical companies. The MA holder is, in particular, required to record and report suspected adverse drug reactions and must also specifically appoint a person responsible for pharmacovigilance.

With regard to medical devices, manufacturers must ensure that the design and production of devices fully address safety and quality requirements. In particular, medical devices must respect the discipline on EC marking, which certifies conformity with EU standards. Manufacturers are also obligated to comply with the General Safety and Performance Requirements as outlined in EU Regulations 2017/745 (MDR) and 2017/746 (IVDR). Within the context of the regulatory framework of the just mentioned regulations, the Ministry of Health is appointed as the Italian competent authority and the National Institute of Health (ISS) operates as a Notified Body.

## 3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Food supplements regulatory process are governed in Italy by Legislative Decree No. 169/2004. Prior to the first market placement, manufacturers are required to submit a specific notification form to the Ministry of Health, including a copy of the product's label. For food supplements imported from non-EU countries, a 90-day waiting period is observed to enable the Ministry of Health to raise any objections.

After assessing the submitted documentation to ensure compliance with safety and health standards, the Ministry of Health approves the product and includes it in a registry of authorized food supplements, which it publishes and periodically updates.

The Ministry of Health annually defines a surveillance plan for food supplements with regional authorities, considering emerging issues in the sector, under the coordination of the Italian National Institute of Health (ISS).

 

## 4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Following the issuance of the MA (marketing authorization) by the Italian Medicines Agency, the MA holder of a pharmaceutical product is required to keep a record of suspected adverse reactions observed in Italy, the European Union, or third countries pursuant to Legislative Decree No. 219/2006 (Code of Pharmaceuticals).

The MA holder must record and report to AIFA, with the utmost urgency, and in any event, no later than 15 days, any suspected serious adverse reaction to medicinal products for which it holds a MA that occurred in Italy of which they have become aware, including those reported by healthcare professionals to their healthcare facilities. AIFA must ensure that all reports received by it are promptly made available to the MA holder.

The MA holder must designate a person responsible for pharmacovigilance within its organization and must initially submit periodic safety update reports (PSUR) to AIFA at least every six months.

## 5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

The Italian Medicines Agency (AIFA) is the Italian competent authority for regulatory oversight over medicinal products pursuant to Legislative Decree No. 219/2006 (Code of Pharmaceuticals). AIFA grants the MAs for medicines through national, decentralized and mutual recognition procedures. Medicinal products falling within the scope of the centralized procedure are assessed instead by the European Medicines Agency (EMA). AIFA is also in charge of the National Pharmacovigilance System and oversees the respect of post-marketing surveillance obligations and medicinal product safety.

Legislative Decrees No. 137/2022 (MD) and No. 138/2022 (IVD) introduced safety and vigilance obligations for medical devices. The Ministry of Health is the Italian competent authority for both medical devices (MD) and *in vitro* diagnostic devices (IVD). The Italian National Institute of Health (ISS) operates as a Notified Body responsible for EC certification activities and conformity assessment of medical devices pursuant to Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR).

With regard to food supplements, the Ministry of Health is the Italian competent authority designated for granting MAs and for examining the labels submitted through the notification procedure prior to the first market placement. The Ministry of Health is also responsible for defining the surveillance plan for food supplements pursuant to Legislative Decree No. 169/2004.

## 6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

In Italy, regulatory decisions adopted by competent authorities, including the denial of marketing authorization for medicinal products, medical devices, and food supplements, can be challenged within 60 days from the communication of the measure through an administrative judicial process before the Administrative Court (*Tribunale Amministrativo Regionale – TAR*) and, in second instance, the Administrative Court of Appeal (*Consiglio di Stato*).

Alternatively, regulatory decisions could be challenged by means of an extraordinary petition before the President of the Republic (*ricorso straordinario*), which is an alternative dispute resolution instrument, to be lodged within 120 days of the communication of the measure.

## 7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

Legal framework for clinical trials in Italy is primarily governed by Regulation (EU) 536/2014 (Clinical Trials Regulation). See the EU Section for the relevant descriptions.

National implementing legislation includes Law No. 3/2018 and ministerial decrees, including the Ministey of Health Decree of 26 January 2023, which designated 40 territorial ethics committees for the evaluation of clinical trials on medicinal products and medical devices.

 

## 8. Is there a public database for clinical trials in your country, and what are the rules for publication?

Yes, clinical trials must be registered and published in a public database managed by the the Italian Medicines Agency (AIFA) pursuant to Regulation (EU) 536/2014 (Clinical Trials Regulation).

The National Observatory on Clinical Trials (OsSC) manages the authorization process of clinical trials (Phase I-IV) and provides a picture of the clinical research progress in the country. OsSC operates also as an interface for transferring information to the European EudraCT database.

## 9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

For medicinal products, the EU "8+2+1 year" framework governs clinical data protection. Data submitted by the originator for authorization purposes is protected for eight years from the date of initial authorization of the reference product, during which time applicants for generic marketing authorization cannot rely on the originator's preclinical and clinical trial data. Moreover, generic products cannot be placed on the market until ten years have elapsed from the initial authorization of the reference product. Under specific circumstances, this ten-year period may be extended to a maximum of eleven years. For more details, see the EU section relevant question and answer.

## 10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

Currently, there are no legislative proposals in Italy aimed at further digitalizing the clinical trial process, that has digitalized since the 2022 introduction of the Clinical Trials Information System (CTIS), which facilitates information exchange between clinical trial sponsors, EU Member States, EEA countries, and the European Commission.

However, in August 2024, the Italian Medicines Agency (AIFA) released the 'Guideline on regulatory simplification and decentralized elements for conducting clinical trials of medicinal products in accordance with Regulation (EU) 2014/536'. This guideline addresses organizational aspects and provides clarifications on incorporating decentralized elements in clinical trials, such as the use of third-party service providers, reimbursement of participant expenses, and delivery of investigational medicinal products to participants' homes.

## 11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

Legal requirements for the authorization of manufacturing plants for medicinal products are set by Legislative Decree No. 219/2006 (Code of Pharmaceuticals) and EU legislation. The manufacturing process must comply with the requirements of Directive (EU) 2017/1572 and the Good Manufacturing Practice (GMP) guidelines published by the European Commission. The Italian Medicines Agency (AIFA) carries out periodic on-site inspections of the manufacturing facilities, including those belonging to suppliers and subcontractors. Unannounced inspections are carried out at least every five years to check the compliance of the manufacturing process with the technical documentation.

Manufacturers of medical devices must meet the requirements set by Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), which include compliance with safety and performance standards. The Ministry of Health can conduct on-site inspections and impose restrictions on the manufacture and use of any specific type of marketed device pursuant to the EU Regulations. Additionally, the Minister of Health can impose, by decree, limitations on the use of the medical device regarding aspects not covered by the EU Regulations.

Production and packaging of food supplements must be carried out in facilities authorized by the Ministry of Health, in accordance with the provisions of Legislative Decree No. 111/1992. The list includes the facilities authorized for the production and packaging of food supplements, along with the corresponding type of production. The Minister of Health defines by decree technical requirements and general criteria for the authorization to produce and package food supplements.

## 12. Please briefly describe the typical process of distributing medicinal products, medical devices,

 

## and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Distribution of medicinal products is regulated by Legislative Decree No. 219/2006 (Code of Pharmaceuticals) and concerns only drugs for which a MA has been granted. The wholesale distribution of medicinal products must be authorized by the competent authorities (regions or autonomous province) and must comply with the best practices to ensure proper storage and transportation.

Medical devices distributors are required to register in the national database operated by the Ministry of Health and to provide relevant information, including the EU device information necessary for the "Eudamed" database. They must also ensure that both storage and distribution of the devices meet the health requirements set by Legislative Decrees No. 137/2022 (MD) and No. 138/2022 (IVD).

Food supplement distributors must submit the product's label to the Ministry of Health before the first commercialization. Extra-EU food supplements can be made available only 90 days from the receipt of the product label, unless objections are raised. Food supplements successfully approved are listed in a register operated by the Ministry of Health pursuant to Legislative Decree No. 169/2004.

For all kind of the just mentioned products, the manufacturers in Italy typically avail itself of wholesalers and distributors, while, in more limited cases, engage in direct distribution.

## 13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Pricing rules for medicinal products depend on their classification into one of three different categories for the purpose of reimbursement. *Fascia A* and *Fascia E* medicinal products comprise respectively essential drugs, including those for chronic diseases, and medicine for hospital use only that are fully reimbursed by the National Health System. The category of *Fascia C* medicinal products instead includes medicines with and without a prescription requirement, that are fully paid for by the patient.

Prices for *Fascia A* and *Fascia E* medicinal products are determined through negotiations between the Italian Medicines Agency (AIFA) and the pharmaceutical companies pursuant to Law No. 326/2003. Prices for *Fascia C* medicinal products are freely set by the pharmaceutical companies and are valid across the entire national territory.

Medical devices prices are generally not subject to regulations and depend on the specification and technical features of the device concerned. However, the pricing of medical devices must factor in public spending control mechanisms as the payback system. The newly established National Observatory on Medical Device Prices is responsible for verifying the consistency of tender prices of Medical Devices.

The Ministry of Health promotes the implementation of the National Health Technology Assessment (HTA) Program for medical devices to facilitate their approval, identification, and evaluation, focusing on innovative features critical for reimbursement purposes. HTA is a process based on scientific evidence, as set out by Regulation (EU) 2021/2282, and it aims to assess the effectiveness of new or existing health technologies.

Food supplements in Italy are not subject either to specific pricing regulation or reimbursement rules.

## 14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

The advertising of medicinal products in Italy is regulated by a multilayer framework, including Legislative Decree No. 219/2006 (Code of Pharmaceuticals), directed to both the public and healthcare professionals. In the case of medical devices, advertising is regulated by Legislative Decrees No. 137/2022 (MD) and No. 138/2022 (IVD). Food supplements advertising is governed by Legislative Decree No. 169/2004. Relevant legislation is often supplemented by secondary sources and codes of self-regulation adopted by associations of companies.

Additional legislation includes, Legislative Decree No. 206/2005 (Italian Consumer Code) and Legislative Decree No. 145/2007 (misleading advertisement) establishing provisions related respectively to consumer protection and the advertisement of goods, including medicinal products and medical devices.

Medical devices advertising is regulated by both EU and national legislation. Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) prohibit the use of misleading claims regarding the intended use, safety, and performance of the device. Legislative Decrees No.

 

137/2022 (MD) and No. 138/2022 (IVD) further restrict advertising to the public for some categories of medical devices.

Advertising for other devices is subject to a 24-month authorization issued by the Ministry of Health, following the opinion of a specific Health Technical Committee as outlined in Presidential Decree No. 44/2013.

Food supplement advertising is regulated by Legislative Decree No. 169/2004, which prohibits attributing therapeutic properties to food supplements, claiming they prevent or cure human diseases, or otherwise referring to such properties.

In the case of products for which warnings are required, the message must include an explicit invitation to read them carefully. More generally, advertising of food supplements must also comply with the rules set by EU Regulations 1924/2006 (Claims), 432/12 and 1169/2011.

## 15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

In Italy, patents for medicinal products, medical devices, and food supplements are regulated by a combination of national laws, European regulations and international agreements: (a) Italian Industrial Property Code (Legislative Decree No. 30/2005 and subsequent amendments); (b) European Patent Convention (EPC), which allows obtaining a European patent that can be validated in Italy and in other member countries of the European Patent Organisation (EPO); (c) Regulation (EU) 1257/2012 and Council Regulation (EU) 1260/2012 concerning the implementation of a Unitary Patent offering uniform protection in all EU member states participating in the Unitary Patent system.

In addition with regard to medicinal products, also applies Regulation (EU) 2019/933 amending Regulation (EC) 469/2009 concerning the Supplementary Protection Certificate (SPC) for medicinal products. The SPC extends the patent term to compensate for the time taken to obtain a marketing authorization for the specific medicinal product. In Italy, the patent protection term for medicinal products can be extended up to a maximum of five years.

Distinctive signs related to products and services in the field of medicinal products, medical devices, and food supplements in Italy can be protected through registration: (a) as a national trademark under the Italian Industrial Property Code; or (b) as a European Union trademark under the Trademark Regulation (EU) 2017/1001 and its implementing regulations; or (c) as international trademark under the Madrid System, in accordance with the Madrid Agreement and the Protocol relating to that Agreement.

In the case of pharmaceutical trademarks, it is also necessary to take into account the provisions on naming contained in Legislative Decree No. 219/2006, which implemented the Directive 2001/83/EC on the Community code relating to medicinal products for human use, as well as Directive 2003/94/EC.

With reference to food supplements reference must also be made to Legislative Decree No. 169/2004, which implements Directive 2002/46/EC on food supplements, and Regulation (EC) 1924/2006 (Claims), which concerns the use of nutrition and health claims.

## 16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Typically, a cease-and-desist letter is sent directly to the infringer, asking them to stop the infringing activity without the need for court action.

In the event of non-compliance or in delicate and/or urgent cases, patent holders of medical products and medical devices can act against infringers according to the following twofold course of actions:

- *interim* proceedings (simplified and expedite) meant to provide the claimant with adequate *interim* measures to protect its rights, provided that two conditions are met: (a) *prima facie* case; (b) *danger in delay*. If these requirements are found to be particularly sound, the claimant could also obtain an *ex parte* order, which will then be confirmed or disregarded by the Judge after the resistant's appearance. Should the Court hold that there is no basis for an *ex parte* order, a hearing for discussion will be scheduled prior to the issue of any decision;
- ordinary proceedings (which may be commenced both simultaneously with or after *interim* proceedings and correspond to full trial procedures). These proceedings can address either infringement (and consequent damages compensation) and/or (in)validity (by way of counterclaim or declaratory judgment by the alleged infringer). The court may

 

order damages, taking into account various factors such as the owner's lost profits, the infringer's benefit, moral damages, or the royalty that would have been paid for the authorized use of the infringed right, or the return of profits.

There are also several specific IP measures that can be requested to stop infringement immediately. They may include injunctions, seizure, judicial searches, withdrawal from the market of the infringing goods, penalty due for any violation of or for any delay in executing the orders (astreintes), destruction of the infringing items, assignment of such items to the owner of the IP right infringed upon, publication of the decision in newspapers/magazines/media and damages compensation.

All civil disputes related to patents are handled in first instance by the IP Section of selected Courts. First instance decisions can be appealed before the Court of Appeal, the relevant appeal proceedings providing for a more expedite route (as e.g. evidentiary activity are hardly ordered). Second instance decisions can in turn be appealed before the Supreme Court on matters of law.

Furthermore, the Italian part of European Patents that have not been opted-out may be litigated either before the national courts or the Unified Patent Court (UPC), while the UPC is exclusively competent for Unitary Patents – for further details we refer to the European chapter of this guide.

## 17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

The use of trademarks for these product categories is strictly regulated to ensure that the information provided to consumers is accurate and not misleading as to the nature and characteristics of the products.

With respect to medicinal products, the use of trademarks that may suggest unproven therapeutic properties or that may confuse consumers with other existing medicinal products is prohibited. Trademarks must not be misleading as to the nature, composition or therapeutic effects of the medicinal product. The names of medicinal products must be approved by the competent authorities (such as the Italian Medicines Agency – AIFA) prior to marketing.

Under the MDR and IVDR regulations, medical devices must be CE-marked and comply with conformity rules before being placed on the market, and the relevant trademarks must not be misleading as to the intended use, safety and performance of the device.

For food supplements, Legislative Decree No. 169/2004 provides that labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties.

## 18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

The main product liability regime under Italian law is governed by Articles 114-127 of the "Consumer Code" (*i.e.* Legislative Decree No. 206/2005), whose provisions reflect in many aspects those contained in the relevant EU pieces of legislation, as summarized below.

The claimant is any individual who has suffered compensable damages (*i.e.*, health damages, as well as material damages to goods, other than the defective product itself, normally intended for private use or consumption), caused by a defective product, whilst the defendant is either the manufacturer and/or its authorized representative and/or the EU importer (if the manufacturer is based outside the EU), or the local distributor/supplier (if the above subjects are not identified).

The claimant must prove the defect, the damage and the causal link between defect and damage, whilst the defendant must prove the circumstances that exempt it from liability as provided for by Article 118 of the Consumer Code.

The limitation period is 3 years, running from the day on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the responsible party. The claimant is no longer entitled to compensation upon the expiry of 10 years after the day when the product was placed on the market.

The above main regime does not prevent the applicability of other relevant pieces of legislation, including for instance (a) the general Italian rules regulating civil tort liability, *i.e.* Articles 2043 and ss. of the Italian Civil Code, whose main rule sets forth that any claimant is entitled to seek compensation for damages proving that these were caused by a willful or negligent conduct of the counterpart, and (b) other rules potentially applicable to products' non-conformities, under the Consumer Code and/or the Italian Civil Code;

 

Moreover, according to the prevailing Italian case-law, with regard to drugs only, Article 2050 of the Italian Civil Code also applies, which provides a very stringent burden of proof for the allegedly liable party (who must demonstrate that all appropriate measures were taken to prevent the damage). A minority view also supports the application of said Article 2050 also to food supplements.

### 19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

With reference to civil product-liability, please see the answer to question no. 18 above. Civil liabilities may also include potential contractual liabilities, which may vary on a case-by-case basis, depending on the type of involved contracts, and thus will not be examined here.

With reference to administrative/regulatory risks of liability, please note that the violation of the administrative/regulatory obligations may imply the application of various administrative fines, including in particular, but not limited to, those set forth by the Consumer Code – amounting to minimum 1.500,00 – maximum 40.000,00 euros – applicable to manufacturers and/or distributors where they: (a) fail to provide the necessary cooperation to the competent national authorities for certain regulatory/safety/post-marketing vigilance activities outlined in Article 107, paragraph 2(a) of the Consumer Code, and/or (b) place on the market products that pose risks to consumer safety, in violation of Article 104 of the Italian Consumer Code.

With reference to criminal liability, the activities associated with the commercialization of defective and/or dangerous products may also constitute criminal offenses, including in particular, but not limited to, the following: (a) criminal offences set forth by Article 112, paragraphs 1-3, of the Italian Consumer Code, which cover liability for the offense of placing products on the market in violation of a prohibition imposed by the competent authorities, offense of placing dangerous products on the market, offense of failing to comply with the safety measures issued by the competent authorities; (b) personal injuries and/or death, as set forth by Articles 582, 589 and 590 of the Italian Criminal Code; (c) fraud in the exercise of trade under Article 515 of the Italian Criminal Code; (d) with regard to food products only, commercialization of counterfeit or adulterated and/or non-genuine foodstuffs under Articles 442 and 516 of the Italian Criminal Code; (e) with regard to drugs, trade in or administration of faulty medicines under Article 443 of the Italian Criminal Code.

With reference to enforcement practices, in addition to the answer given to question 5 about the competent national authorities, we also note that: (a) for medical devices, the Ministry of Health is responsible for the pre- and post-market surveillance and corrective actions (withdrawal, suspension of trade, etc.); (b) for medicinal products (including biologicals), AIFA (*i.e.* the Italian Medicines Agency), in cooperation with the European Medicines Agency and the Ministry of Health, is responsible for the supervision of the regulatory/surveillance activities and for taking urgent measures, such as prohibiting sales or seizing medicines; (c) for food supplements, food regulation is handled by the Ministry of Health, in cooperation with the European Food Safety Authority (EFSA). Key enforcement activities include official controls, product recalls and sanctions.

### 20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

The regulatory framework for digital health applications in Italy is mainly provided by EU Regulation (EU) 2017/745 (MDR). At national level, Legislative Decree No. 137/2022 completes the framework. Among other things, this decree mandates the creation of a national database for the registration of health devices and recognizes, within certain limits, the possibility of selling medical devices online.

Additionally, digital health applications processing personal data must comply with the provisions of the GDPR and the Italian Privacy Code under Legislative Decree No. 196/2003 (including, *inter alia*, with the principle of privacy by design).

Specifically on AI, in September 2023, the Italian Data Protection Authority released a set of principles known as the 'Decalogue' to provide preliminary guidance for the development of national health services through AI-based systems. Despite being primarily addressed to processing of health data carried out in the exercise of public interests, the Decalogue provides useful guidance to both public and private actors, marking a concrete policy effort to balance the expected benefits of AI in healthcare applications with the protection of fundamental rights.

 

### 21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

Legislative Decree No. 216/2006 (Code of Pharmaceuticals) sets out a public service obligation for wholesalers of medicinal products to ensure the continuous supply and delivery of requested medicines for a specific geographic area (Article 105). Medicines subject to measures preventing shortages or unavailability cannot be withheld from distribution and AIFA can issue a temporary export ban measure.

There are no specific provisions for medical devices on this issue. However, the Ministry of Health pursuant to Legislative Decrees No. 137/2022 (MD) and No. 138/2022 (IVD) can envisage the identification of the authorized sellers for each type of device and impose specific requirements to ensure that the storage and distribution of the devices comply with public health interests that include general safety and performance requirements.

### 22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

Pharmaceutical companies and companies active in the marketing of medicinal products or medical devices are subject to various, sometimes overlapping, compliance standards in the Italian legal system. Some of these are general and apply to corporations regardless of their business: one significant example is Legislative Decree No. 231/2001, which requires companies to assess the risks connected with their business and put in place systems and controls apt at preventing the commission of a wide array of crimes in all risk-sensitive areas. Failure to do so may, under certain conditions, entail corporate liability (to be assessed before criminal courts) if a relevant offence is committed in the interest or for the benefit of the company, potentially leading to the application of fines, disqualifications and debarment measures, reputational sanctions and confiscation of the profits of the alleged crime.

In addition to this general standard, and to the risks highlighted above, Italy has compliance rules specifically addressed to the pharma industry.

Legislative Decree no. 219/2006 subjects to punishment the owner or legal representative of a company that engages in the manufacture of medicinal products or active substances without the relevant authorization, as well as anyone who places on the market medicinal products for which the relevant authorization has not been issued or confirmed or has been suspended or revoked, or medicinal products with a declared composition different from the authorized one.

According Article 443 of the Italian Criminal Code anybody who holds for trade, markets or administers to patients defective or imperfect medicines shall be punished with imprisonment, in addition to fines. According to the well-established Italian case law, it is not needed that the medicine be dangerous for public health, but simply that it has naturally lost its qualities or it has defects – also in its production and control – impacting on its therapeutic effects. If the substances or medicinal products were deliberately adulterated, more serious penalties apply under Article 440 of the Italian Criminal Code.

As for the prohibition of bribery in the healthcare sector, Articles 170 et seq. of Royal Decree No. 1265/1934 punish anyone who gives or promises to a doctor, veterinary surgeon or pharmacist money or other benefits for the purpose of facilitating in any way the dissemination of medicinal specialties or any other product for pharmaceutical use (and, specularly, the doctor and the pharmacist are punishable). Moreover, Legislative Decree No. 219/2006 punishes the granting, offering or promising of rewards, pecuniary advantages or benefits in kind in connection with the activity of providing information on and presenting medicinal products carried out by doctors or pharmacists, unless they are of negligible value and are in any event connected with the activity carried out by the doctor and the pharmacist (who are likewise subject to punishment).

More recently, Law No. 62/2022, commonly known as the "Sunshine Act" mandates public disclosure of information relating to payments made and agreements entered into between pharmaceutical companies and health operators/organizations as well as of relevant shareholdings and licences granted to people and organizations in the healthcare sector. Omitted, incorrect, false, and misleading reporting are punished with administrative fines and, under certain conditions, may expose to criminal liability.

Although not mandatory by law, various domestic and international standards also contribute to provide guidance on compliance best practices within the healthcare and pharmaceutical sector, including those

 

developed by IFPMA (the International Federation of Pharmaceutical Manufacturers and Associations) and EFPIA (the European Federation of Pharmaceutical Industries and Associations), which published Codes of Practice collecting ethical rules for the promotion of medicinal products to healthcare professionals and the interactions with them, healthcare organisations and patients' organisations.

At domestic level, Farmindustria, the Italian Association of Pharmaceutical Industries developed a Code of Professional Conduct aimed at providing guidance on compliance with international standards for Italian players, a Code of Conduct focused on Antitrust Compliance, and Guidelines on the certification of procedures governing scientific information activities. AIFA, the Italian Medicines Agency, also developed a Quality Manual and several audit procedures and guidelines, mostly based on UNI EN ISO 9001:2015, orienting its oversight activity.

### 23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

During the course of 2024, the following significant rulings are noteworthy.

With two sentences (No. 139 and n. 140) published on 22 July 2024, the Constitutional Court intervened on the payback mechanism on medical devices, declaring it constitutionally legitimate, while the Supreme Court, with sentence No. 18372 of 5 July 2024, clarified that the rationale of the so-called 'Bolar clause is to facilitate the timely entry onto the market of generic drugs so as not to prolong, in fact, the duration of the exclusive right, allowing generic manufacturers to begin the administrative and experimental activities preliminary to obtaining an AIC, even while the reference patent is still valid.

### 24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

For several years, the Italian healthcare system has been undergoing significant digitalization, albeit not always at a constant pace. This drive is reinforced in the Italian National Recovery and Resilience Plan, which emphasizes the use of new technologies to improve hospitals and home healthcare, including the expansion of telemedicine.

One of the latest initiative that have furthered the digitalization of the healthcare system is the 'Electronic Health Record 2.0' introduced by Ministerial Decree of 7 September 2023. This digital infrastructure aims to address the shortcomings of the existing FSE by improving data sharing between national and regional health systems, allowing patients to upload personal health-related documents, and supporting advanced digital health services such as telemedicine and AI-driven health monitoring.

Regarding artificial intelligence (AI), in addition to the Decalogue released by the Italian Data Protection Authority mentioned under question 20 above, a bill on Artificial Intelligence is currently under review in the Senate. The draft bill currently includes *inter alia* (a) principles for the use of AI in the healthcare and disability sector, (b) provisions for the secondary use of personal data by public and private non-profit entities for research and scientific experimentations in AI systems in healthcare; and (c) the further enhancements to the FSE through the creation of an AI platform to support healthcare purposes and territorial assistance.

### 25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

With reference to key developments and trends in the Italian market, please refer to the report on the draft bill on artificial intelligence reported in question no. 24.

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