This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

Civil law

**National law database**

**Language:** Italian  
**Link:** [http://www.normattiva.it](http://www.normattiva.it)  
**Nature:** Official law database  
**Organisation responsible for the website:** Prime minister’s office, the senate of the republic and the chamber of deputies.

**Legal UHC start date**

1978

**Source:** [http://www.euro.who.int/__data/assets/pdf_file/0006/87225/E93666.pdf](http://www.euro.who.int/__data/assets/pdf_file/0006/87225/E93666.pdf)

**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
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2.8 Regulation

2.8.1 Regulation and governance of third-party payers

Until 1992, only the central government could raise taxes and allocate funds to the regions, while the regions funded the ASLs and their hospitals. Funding was based on past spending, and the ASLs had no incentives to contain costs. Therefore, most ASLs overspent their budgets, and the central government funded their deficits. In the 1990s, a series of reforms was introduced, underpinned by the principles of managerialism, regionalization and managed competition. Managerialism gave ASLs greater independence but required them to improve their performance and encouraged them to adopt governance techniques similar to those of private companies (Cantú, Ferré & Sicilia, 2010). It also made it possible for hospitals to become independent from ASLs by taking on the legal form of a Hospital Enterprise (Azienda Ospedaliera – AO), with their own managing board. Reimbursements to providers are based on activity-related funding: diagnosis-related groups (DRGs) for hospitals and a capitation (partially combined with fee-for-service) for GPs and outpatient specialist services (see Chapter 3).

Regionalization has progressively transferred full jurisdiction on health care to the regions. They carry out goal-setting and planning; fund their spending with regional taxes and user charges (even though a national equalization fund still compensates for cross-regional differences in fiscal capacity); and are free to decide whether to keep the purchasing role for themselves or transfer it to the ASLs. As a result, since the 1990s different regions have been experimenting with different organizational and funding models, thus resulting in great diversity.

- Most regions use an ‘ASL-centred template’, with each ASL acting as both provider and (to a limited extent) as purchaser of services from a limited number of AOs. This template partly resembles a quasi-market, as ASLs are financially penalized if residents seek care from providers other than theirs, as they have to pay them.
- A few smaller regions in northern and central Italy adopt a ‘region-centred template’, where most purchasing concentrates at the regional level, while ASLs act mostly as providers. These regions directly control most public providers and they accredit only a limited number of private providers.
- Lombardy is the only region that has carried out a complete purchaser–provider split. Most hospitals have been taken out of ASL control and established as AOs. ASLs purchase services from public and private providers, while the region has a regulatory role. The incentive for ASLs to ensure financial control by limiting provision balances the incentive for providers to increase volumes by attracting patients who have full freedom of choice. However, inadequate governance of demand makes ASLs act more often as third-party payers than purchasers, and volume-driven profits have led hospitals to increase demand artificially. Though a significant part of the reform that introduced the model was withdrawn in the early 2000s, Lombardy remains the region with the greatest emphasis on freedom of choice and a tendency towards a purchaser–provider split.

2.8.2 Regulation and governance of providers

Health-care providers can be either public or private. Public health-care providers are either under direct control of their ASL or are independent organizations (AOs, University Hospitals and Public Research Institutes – IRCCS), though under a regional planning, financial and control scheme. On the other hand, private providers, both for-profit or non-profit, cooperate with public ASLs and regional authorities in ensuring the supply of services. However, several provisions exist to ensure they meet minimum structural, organizational and operational standards; the main ones are: authorizations, institutional accreditation and contracts.

Authorization procedures concern the minimum structural, technological and organizational criteria required under Italian law to operate in the health-care sector and concerns individual professionals and facilities. Authorization applies to any subject operating in Italy, even if its activities are completely outside those of the SSN.
SSN accreditation is a form of public licensing necessary for providing health care on behalf of the SSN, which is quite different from voluntary accreditations issued by organizations such as the Joint Commission International or the International Organization for Standardization. SSN accreditation hinges on more extensive quality criteria than authorization. It encompasses management of human and technical resources, as well as consistency of the provider’s activity with regional health planning, and evaluation of the activities already conducted and the results achieved. The standards for the accreditation procedure were first set in 1997 by the National Accreditation Act. The Constitutional reform of 2001 gave regions the freedom to set their own accreditation criteria and procedures, as long as the LEA is guaranteed. At present, significant variability exists in regional accreditation policies.

Lastly, contracts between private providers and regional authorities (on behalf of the SSN) specify the financing conditions that will apply to that provider. Contracts qualify them as ‘SSN providers’, thus allowing them to begin to operate on behalf of the SSN, as authorization and accreditation alone are not enough for that purpose. Regional health authorities, in cooperation with ASLs, define the details of the contract agreements. Contracts also specify the operational and financial information the provider must supply to the ASL and region, the terms for supervision and monitoring, the maximum yearly volume or mix of care, and the financial and administrative sanctions if the provider exceeds or does not reach the targeted volume (Cantú, Ferré & Sicilia, 2010). These contracts for private providers are the equivalent of the formal agreements ASLs establish with public providers.

### 2.8.3 Registration and planning of human resources

Every region determines its annual requirements for medical specialists by means of an ad hoc algorithm. The algorithm combines, per specialty, the overall turnover rate of SSN doctors according to the latest annual state budget with the variation of the number of specialists that each region needs for that year. These data express regional needs for the three categories of medical specialties, surgical specialties and medical services specialties.

Every three years, the State-Regions Conference determines the number of medical residencies allotted to each region. The annual requirement for medical specialists turned in by each region is matched with financial resources made available by the Ministry of Finance. If these resources are not enough to finance all the residencies needed, the regions can fund the remaining ones through regional or private funds.

### 2.8.4 Pharmaceuticals

Governance of pharmaceuticals rests with the AIFA, the Italian Agency for Pharmaceuticals. AIFA approves the pharmaceuticals that can be produced, used and marketed in Italy, and authorizes clinical trials.

Pharmaceuticals are divided into three categories, with different reimbursement regimes. Class A (Classe A) includes pharmaceuticals that are reimbursed by the SSN with or without co-payment and distributed either by pharmacies or by hospitals. Regions are free to impose a share of co-payment on their price, mainly used for cost-containment purposes or as a disincentive against inappropriate drug use. These shares can be dependent on parameters such as the patient’s health status, income, age or employment status, and the number of regions introducing them has been on the increase over the last decade (see section 5.6). Class H (Classe H) includes pharmaceuticals that are fully reimbursed by the SSN, but can only be distributed by hospitals. Class C (Classe C) includes drugs that are entirely paid for by patients, except when regional health departments include specific drugs in reimbursement schemes. Class C pharmaceuticals are divided, in turn, into medicines with compulsory medical prescription and medicines not requiring a compulsory medical prescription. The latter are over-the-counter (OTC) pharmaceuticals against minor, mild or intrinsically transient conditions or symptoms, suitable for self-medication. Off-label use of a pharmaceutical – defined as the use in clinical practice of a registered pharmaceutical with a therapeutic indication or administration forms different from what the AIFA registration specifies – is strictly regulated. In principle, it is only allowed when no alternative exists and enough scientific evidence for its efficacy is available.

Until 1992, the Ministry of Health had a statutory power to decide which pharmaceuticals were publicly reimbursed and to determine their prices. After a series of corruption scandals, the role of reimbursement
and marketing regulation was taken up by several different independent committees, until AIFA was established in 2003. The prices of Class A and H drugs are determined by a negotiation process between AIFA and the producer. The producer must file an application, including evidence proving a positive cost–effectiveness ratio or otherwise show that the pharmaceutical is of interest to the SSN. The prices of all Class C drugs are determined by the producer but with some constraints. The price must be the same across the country; it can only be increased every two years; and the increase cannot be higher than expected inflation. AIFA monitors the market to check that these conditions are met. The prices of OTC drugs are freely determined by the producer.

Italian law distinguishes, for patent purposes, between branded pharmaceuticals and generic or equivalent pharmaceuticals. Branded drugs are pharmaceuticals sold with specific names and packages, either within patent or after the patent has expired. Generic or equivalent pharmaceuticals are not covered by patent but have the same composition, pharmaceutical form and dosing. Generic drugs are usually identified by the International Nonproprietary Name (INN). They can be produced and sold following an authorization to enter the market (Autorizzazione all’Immissione in Commercio – AIC) by the Ministry of Health. However, their price must be at least 20% lower than the price of the matching branded pharmaceutical previously covered by patent. Reimbursement of pharmaceuticals not covered by patent – that is, either with an expired patent or a generic – is regulated by national provisions that specify a minimum reduction in price and even leave single regions free to set their reimbursement price as the price of the cheapest matching generic pharmaceutical available under regional distribution.

An incentive exists for generic substitution: pharmacists have to ask patients whether they would like to replace a patented pharmaceutical with the cheapest equivalent drug. If the doctor explicitly states that the prescribed pharmaceutical cannot be replaced or the patient refuses the replacement, the patient must pay the difference between the price of the prescribed pharmaceutical and the price of the matching generic. Over the last few years, more cost-containment measures have been introduced. Since 2011, AIFA has set a maximum reimbursement price for equivalent Class A drugs. This reimbursement cap is based on a survey of current prices in other EU countries, and must be enough to determine a predetermined yearly saving for regions. The first deliberation (March 2011) used Germany, the United Kingdom, France and Spain as reference countries and determined a maximum reimbursement of 40%.

2.8.5 Regulation of medical devices and aids

Regulation of medical devices and aids falls within the remit of the Ministry of Health’s General Directorate for Medical Devices, Pharmaceutical Services and Care Safety. Its duties include surveillance of the production of medical devices, their commerce and their use within the SSN, in line with Italian and the European regulations. It oversees surveillance, provides the forms and the contacts for notifications of malfunctions or accidents connected to medical devices, and checks the requirements for correct notifications. With AGENAS and AIFA, it coordinates HTA activities (see section 2.7.2). Since 2010, an information system has been active to monitor medical devices bought or used by all public health providers. This information system is connected to the NSIS (see section 2.7.1). In 2012, the directorate began a reorganization, which is ongoing.

2.8.6 Regulation of capital investment

The first investment plan for buildings and technologies was introduced in 1988. In 1998, the investment framework for public resources was changed and since then health-care infrastructure is no longer regulated through the same administrative pathways that regulate other public spending. Instead, single ministries are responsible – mostly the Ministry of Health. For this purpose the ministry created the Centre for Evaluation and Verification of Public Investments. The regions also obtained the main responsibilities for planning. The centre consists of professionals drawn from the ministry, regions and ASLs, and its composition is changed every three years. It advises on all proposed investments, deliberates on the use of European Funds in health care, monitors annual data on infrastructure planning and implementation sent by the regions to the ministry, and supports projects that come across difficulties. The centre also cooperates with the European Health Property Network (EuHPN). The Inter-ministerial Committee for Economic Planning (CIPE) is a public agency that supervises all public capital investments, ensures financing and prevents illicit use of investments.