HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's-eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

Powers and responsibilities within the Italian healthcare system are divided among the national government and the regions.

The national government is responsible for the financing of the National Health Service (NHS) and determines the essential levels of healthcare that must be provided for all residents (known as the *Livelli Essenziali di Assistenza* – LEA).

The regions plan and manage the provision of healthcare within their respective territories in accordance with general national legislation. They define regional healthcare needs in order to grant the LEA and, together with local health authorities, carry out the procedures for authorising healthcare activities.

The Italian health system is essentially public: access to care is guaranteed without discrimination to all Italian residents and, under certain conditions, to foreign citizens (see Q6 below). Healthcare is provided by the NHS and its health facilities, including accredited private facilities. The provision of certain health services may be subject to a co-payment by citizens (the so-called *ticket sanitario*).

As an alternative to the NHS, citizens can access care provided by private facilities or professionals who are not accredited by the NHS. This will need to be self-funded by the individual, or they may rely on private insurance policies to cover the relevant costs.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Each year, national legislation sets the standard national health requirement, ie, the overall level of NHS resources, in accordance with the LEA and within existing financial constraints. The financing of the NHS is governed by Legislative Decree No 56/2000 and is essentially based on: (1) regional taxation; (2) financing from the national budget; and (3) direct contributions from citizens through the co-payment system.

The funds are allocated to the Italian regions according to the criteria established by the Decree of the Ministry of Health of 30 December 2022, namely:

- population and frequency of healthcare consumption by age (98.5 per cent of the funds);
- mortality rate of the population (0.75 per cent of the funds); and

- other indicators relating to specific territorial situations (incidence of poverty; level of education; unemployment rate) (0.75 per cent of the funds).

The Ministerial Decree of 12 January 2017 lists the health services provided by the NHS (the LEA) that these funds are intended to cover, according to pre-defined standard tariffs established at national level. Local facilities, both private and public, that provide health services on behalf of the NHS are reimbursed by central government in accordance with this tariff.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

The Ministry of Health is responsible for ensuring the protection of the right to healthcare and the effective funding and operation of the entire NHS. In particular, the Ministry, through an ad hoc committee (*Comitato permanente per la verifica dell'erogazione dei Livelli Essenziali di Assistenza*), monitors the provision of essential services throughout the country, the adequacy of the resources allocated and their correct use.

The Italian Medicines Agency (*Agenzia Italiana del Farmaco* – AIFA) is the national public body that manages pharmaceutical expenditure and monitors the life cycle of pharmaceuticals with the aim to ensure their efficacy, safety, appropriateness and access throughout the country. Specifically, AIFA is responsible for authorising the manufacture, import, export and distribution of pharmaceuticals as well as negotiating with pharmaceutical companies the price of pharmaceuticals reimbursed by the NHS.

The Italian Competition Authority (*Autorità Garante della Concorrenza e del Mercato* – AGCM) is responsible for ensuring an open and competitive market in the healthcare sector.

In this context, national courts play an important role in pricing matters when medical companies challenge decisions of public authorities. In particular, administrative courts review the legality of decisions taken by public authorities in light of the applicable legal and regulatory framework.

Finally, the main associations representing companies (*Farmindustria* for pharmaceuticals and *Confindustria Dispositivi Medici* for medical devices) ensure a constant dialogue with the authorities to promote the interests of their members in respect of healthcare financing matters.

4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Covid-19 pandemic has not changed the general system of healthcare financing, however a number of decrees have been issued and approved to implement emergency measures to increase the level of funding for the NHS.

As a general trend, the public expenditure for healthcare continues to increase even after the end of the emergency period due to the Covid-19 pandemic. According to the data provided by the Ministry, funding has increased from €119m in 2020 to €134m in 2024. However, according to the latest reports from the Organisation for Economic Co-operation and Development (OECD), health spending in Italy remains below the European average, both in terms of per capita expenditure and health spending as a percentage of gross domestic products.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Italian citizens are registered with the NHS and receive healthcare assistance without discrimination and on equal terms throughout the national territory. The same rights apply to citizens of the European Economic Area who hold the European Health Insurance Card.

Extra-EU nationals legally resident in Italy have different access to the NHS, depending on the purpose of their stay. Foreign citizens who are staying temporarily (for a maximum of 90 days, eg, as tourists) can only receive urgent healthcare assistance from the NHS by paying regional tariffs and they cannot register with the NHS (except for students and au pairs). On the other hand, foreign citizens who work regularly or who have applied for an extension of their residence permit for specific reasons (eg, family reasons, asylum or subsidiary protection) have the right to register with the NHS free of charge and their healthcare coverage is extended to their family members legally resident in Italy. Finally, foreign citizens legally residing in Italy for more than three months who do not have the right to register with the NHS free of charge are obliged to take out insurance against the risks of sickness, accident and maternity. They can do this either by taking out a private insurance policy or by registering voluntarily with the NHS by paying an annual contribution.

Private healthcare providers, such as hospitals, clinics and medical practices, that are authorised to operate in Italy, can access public funding for providing healthcare services to patients on behalf of the NHS by obtaining accreditation from the competent regional authority.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

As the healthcare system in Italy is public, private insurance is a residual way of accessing health services in Italy. In principle, insurance companies are privately financed, and premiums are determined according to criteria freely set by the companies themselves, without any governmental involvement.

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

Private insurers are free to determine the level of coverage offered to their policyholders, including differentiating between face-to-face and telehealth medical appointments. For NHS coverage of healthcare services provided by public or accredited private facilities, please see Q8.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

Services provided by public and private accredited hospitals within the LEA – both inpatient and outpatient – are financed by the NHS (see Q2). The Ministerial Decree of 12 January

2017 lists the health services covered by the NHS, while subsequent decrees indicate the corresponding national maximum tariffs for these services, according to which local health facilities providing care to patients on the Italian territory are reimbursed. To date, healthcare services delivered remotely are reimbursed to local health facilities at the same tariffs as the corresponding face-to-face healthcare services (this complies with the provisions of the national guidelines on telemedicine). However, Italian regions have started to issue decisions reporting the tariffs specifically applicable to services provided remotely such as tele-monitoring, tele-assistance, etc. Lombardy region was the first to issue such decision in December 2024.

Patients are generally required to contribute to the provision of certain health services through a co-payment, the amount of which may vary on regional basis.

9. How are the prices of such services determined? How is economic efficiency controlled?

When local health facilities provide health services to patients within the LEA, ie, at the NHS's expenses, they are reimbursed for each service according to the maximum tariffs set at national level, while patients may be asked to contribute through a co-payment.

National maximum tariffs are established to ensure that the costs incurred by the NHS are uniform throughout the national territory, on the basis of the standard cost of services with reference to facilities pre-selected according to criteria of efficiency, appropriateness and quality of care, as derived from data held in the health information system. On the other hand, the amount of co-payment that citizens may be asked to bear – as a percentage of the value of the individual prescription – may vary between regions, up to pre-determined maximum ceilings.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

Where private practices, laboratories and other service providers are accredited to the NHS, the funding and reimbursement of health services provided will follow the rules set out above (see Q2 and Q8). In other cases, funding is at the expense of private operators and the cost of health services is borne by patients.

11. How are the prices of such services determined? How is economic efficiency controlled?

Where private providers are accredited by the NHS, costs are set according to the criteria set out above (see Q8). In other cases, private operators are free to determine the cost of the services to be borne by patients (or private insurances).

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

Expenditure on pharmaceuticals and medical devices is funded by the NHS (see Q2).

Reimbursement of pharmaceuticals depends on their classification into one of the following bands:

- Class A: essential pharmaceuticals and pharmaceuticals for chronic conditions, which are reimbursed by the NHS (possibly with a co-payment by the patient). Class A pharmaceuticals are supplied by pharmacies.
- Class H: pharmaceuticals for hospital use, which can only be used in hospitals or distributed by health care facilities and are reimbursed by the NHS.
- Class C: pharmaceuticals not included in classes A or H are allocated to class C; they are fully paid for by patients.

While pharmaceutical companies are free to set prices for pharmaceuticals in class C, the price of class A and H pharmaceuticals is established following a negotiation process before the AIFA (see Q13). Italian legislation does not provide for a pricing and reimbursement mechanism for medical devices as it does for pharmaceuticals; however, under certain conditions (eg, products needed to ensure the provision of care within the LEA or when they are used to treat hospitalised patients), medical devices can be provided directly to patients at the expense of the NHS, which has previously purchased the device from private operators (see Q13).

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

The price of pharmaceuticals reimbursed by the NHS (class A and class H) is determined through a negotiation process before the AIFA, which is governed by the Ministerial Decree of 2 August 2019 and related guidance issued by the same authority. To obtain reimbursement, companies must support their negotiation requests with, in particular, (1) scientific documentation demonstrating the 'added therapeutic value' of the pharmaceutical compared to alternative treatments already on the market; (2) information on the consumption and reimbursement status of the pharmaceutical abroad, including its price; (3) the expected market share of the pharmaceutical over the next 36 months; and (4) the expected economic impact on the NHS. The negotiation procedure starts after the marketing authorisation has been granted.

As an exception, pharmaceutical companies may apply for reimbursement of their products prior to obtaining a marketing authorisation if the application concerns: (1) orphan pharmaceutical products; (2) pharmaceutical products of exceptional therapeutic and social importance; or (3) pharmaceutical products that can only be used in a hospital or similar setting. Generic or biosimilar pharmaceuticals are automatically placed in the same reimbursement class as their originator (without price negotiation) if the pharmaceutical company proposes a sales price that is clearly favourable to the NHS.

With regard to pharmaceuticals paid by patients (class C), in principle companies are free to determine the relevant price. Price of class C pharmaceuticals can only be increased in January of each odd-numbered year.

The price of medical devices is freely determined by private operators. When medical devices are provided free of charge to patients by the NHS in the context of the provision of health treatments included in the LEA, the prior purchase of such devices by public authorities

(such as single hospitals or regional central purchasing bodies) takes place by means of tendering procedures under public procurement legislation.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

Payback mechanism for medical devices

Payback is a health policy mechanism that requires companies supplying pharmaceuticals or medical devices to the NHS to reimburse each Italian region, under certain conditions, for a proportion of the expenditure incurred to procure such products. Specifically, the law sets annual spending ceilings for NHS purchases of pharmaceuticals and medical devices and requires the supplying companies to reimburse a proportion of the amounts in excess of these ceilings according to certain criteria. This mechanism for controlling health spending has been in place for a long time for pharmaceuticals while it has been recently introduced for medical devices. Against the application of the payback mechanism to medical devices, companies have lodged around 2,000 appeals with the Administrative Court of the Lazio region which then finally brought the case before the Italian Constitutional Court. In its ruling 140/2024, the Constitutional Court confirmed the legitimacy of this mechanism, arguing that it was a solidarity contribution necessary to support the financial stability of the NHS. In parallel, stakeholders are pushing the Ministry of Health and regional authorities to set up a technical committee to reform the payback mechanism.

Access to orphan drugs

In its ruling no. 2967/2024, the Italian administrative court of last instance (Council of State) confirmed the legitimacy of an AGCM's decision regarding prices for orphan pharmaceuticals. The authority found an abuse of dominant position in the behaviour of companies charging unjustifiably high prices for the supply of orphan pharmaceuticals to the NHS, although the companies acted in compliance with the applicable regulatory framework.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

The NHS has been underfunded for years: although the resources allocated have increased in absolute terms, they are still insufficient to guarantee citizens effective healthcare throughout the country (see also Q4). As a result, the role of private healthcare – where costs are borne entirely by patients (including through private insurance) – has increased and is likely to continue to do so in the coming years.

Among the most significant and recent legislative developments involving the provision of care, we mention the following.

Bill on digital therapeutics

Bill 1208, 'Provisions on digital therapies', was presented in June 2023 and is now currently under review before the Italian Parliament. The document aims to regulate digital technologies with therapeutic purposes in Italy – falling within the category of software as medical device, with a focus on reimbursement.

In order to evaluate digital therapeutics (DTx) with a view to their inclusion among the services that the NHS is obliged to provide to citizens free of charge (or with a co-payment), the final article of the bill stipulates that the Italian National Agency for Regional Health Services (*Agenzia nazionale per i servizi sanitari regionali* – AGENAS) must identify the digital therapies to be included in the LEA through a specific accelerated procedure, similar to what happens in other countries. It also states that each DTx must be the subject of at least two clinical trials 'with high quality evidence' in order to be included in the LEA. This bill is currently under parliamentary scrutiny.

Law on differentiated autonomy

In June 2024, Law No 86 on so-called 'differentiated autonomy' was adopted, which in implementing Article 116 of the Italian Constitution, aims to grant Italian regions, under certain conditions, greater autonomy and legislative powers in certain areas, including health. The law has been heavily criticised because its actual implementation risks widening the already existing gap between northern and southern Italian regions in the provision of essential services to citizens.

For these reasons, a number of Italian regions have appealed to the Constitutional Court, which, in judgment no 192 of 2024, declared several key points of the new law unconstitutional. The government will therefore have to amend the law in order to continue on this path.

New developments for innovative pharmaceuticals

The 2025 Budget Law (Law no. 207/2024) brings many changes regarding the funding of innovative pharmaceuticals intended for the treatment of serious pathologies, with a clear therapeutic added value compared to alternatives already on the market.

Firstly, as of 1 January 2025, pharmaceuticals that meet the conditional innovation requirement ('*innovatività condizionata*') will have access, under certain conditions, to the funds allocated for innovative pharmaceuticals, up to a maximum of €300m per year.

Furthermore, of particular note is the redefinition of the concept of innovation – previously granted on the basis of AIFA Resolution no 1535/2017 (ie, therapeutic need, therapeutic added value and quality of evidence) – which will now be assessed by taking into account 'the manufacturing technology of the active substance, the mechanism of action, the method of administration to the patient, the clinical efficacy and safety, the impact on quality of life and the impact on the organisation of healthcare' (the new criteria will be further detailed by AIFA by 31 March 2025).

It is also worth noting that, under the new rules, therapeutic indications that have lost patent protection or have never enjoyed such protection will not be taken into account in the assessment of innovation.