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

Authors:
Lluís Alcover, Joan Carles Bailach and Claudia Gonzalo, Faus Moliner
lalcover@faus-moliner.com, jcbailach@faus-moliner.com and cgonzalo@faus-moliner.com

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).

The public sector plays a major role in providing healthcare in Spain within the National Health System (NHS), which provides virtually universal coverage and is mainly funded from general taxation. The NHS comprises 17 regional health care systems with full responsibility for the planning and provision of health care services. Ceuta and Melilla (two Spanish autonomous cities located on the northern shores of Morocco) do not have their own healthcare systems, and the Ministry of Health (MOH) finances and governs healthcare there through the centrally managed National Institute of Health Management (INGESA). High-level coordination among all regional healthcare systems occurs through the NHS Interterritorial Council, which comprises the national Minister of Health and the 17 regional ministers of health. The NHS has two main levels: primary healthcare (with family doctors that act as gatekeepers) and specialised care.

Private actors also play an important role in the provision of healthcare. The private sector provides voluntary health insurance to individuals, which mainly plays a supplementary role offering people faster access to treatment. The private sector is also closely connected with the public sector, especially in the hospital care field where some services are contracted out, such as diagnostic tests (private intervention in the primary health care is marginal). Private entities also play an important role in the pharmaceutical area since pharmacies, and distributors/wholesalers are private providers.

An updated overview of the Spanish health system (2024) may be found[1] in the *Spain Health System Review* elaborated by the European Observatory on Health Systems and Policies, among others. Some data and references included herein are obtained from that publication.

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

Royal Decree Law 16/2012, which amends laws such as Law 16/2003 on the cohesion and quality of the NHS and the Law on Guarantees and Rational Use of Medicinal Products (LGRUM), regulates the benefits package provided by the NHS. This includes two main categories of services: the common package, which is the same in the 17 regional health services of the NHS, and the complementary package, decided under the rules of each region (financial

[1] Available at: https://eurohealthobservatory.who.int/publications/i/spain-health-system-review-2024

sufficiency and budget stability criteria must be accredited by regions before adding new benefits to their packages).

When it comes to the reimbursement of medicinal products, there are other specific rules to consider apart from the mentioned LGRUM. Royal Decree 271/1990, Royal Decree 83/1993, Order of 17 December 1990 and Order of 6 April 1993 on price and reimbursement regulate the reimbursement procedure. They establish a 'cost plus' system under which the maximum ex-factory price (PVL) should respond to the cost of the product plus a given margin. As a matter of practice, however, it is well known that the price-approval process entails a negotiation with the authorities where the cost and the profit margin are not really the variables that are considered. Royal Decree 177/2014 establishing the Reference Price System and Royal Decree-Law 8/2010 (amended by Royal Decree-Law 9/2011) regulating mandatory discounts on the PVL are also relevant rules for reimbursement purposes.

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

Key regulators and supervisory bodies are the MOH, the Interministerial Price Committee (CIPM), the Interterritorial Council of the NHS (CISNS), regional departments of health, and health technology assessment (HTA) bodies.

The MOH plays a coordination role with the assistance of the CISNS. The CISNS is a collegiate governance body that unites the Health Minister, health ministers of the 17 regions and the autonomous cities of Ceuta and Melilla. The MOH and the CISNS also have powers to determine the benefits package provided by the NHS, including the pharmaceutical provision.

The CIPM is the specific committee composed of members of the MOH, other ministries and representatives of the regions responsible for assessing applications and deciding on the maximum ex-factory price (PVL) for reimbursed medicinal products.

Regional departments of health primarily manage health service provision.

HTA is performed at both national and regional levels. At national level, there is no clear regulatory framework, and the Ministry of Health is in the process of drafting a Royal Decree to regulate this matter, which is expected to be approved during 2025. At regional level, some regions have HTA bodies which are grouped in a national network called RedETS.

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

No structural change regarding financing and reimbursement was adopted as a consequence of the Covid-19 pandemic. However, it is worth mentioning that the pandemic caused a substantial increase in health expenditure during the year 2020 and following, and placed the reinforcement of the public health system and the guarantee of the right to health as a priority of the administrations (see the Public Health Strategy 2022[2] approved by the Ministry as a reaction to the pandemic). The pandemic also led to an amendment of the LGRUM to allow price control of certain non-prescription medicinal products and medical devices during exceptional health situations, and the implementation of measures to ensure the availability of critical products for the NHS (such as face masks). Other aspects that were revised after the

[2] Available at: www.sanidad.gob.es/ciudadanos/pdf/Public_Health_Strategy_2022_Pending_NIPO.pdf

Covid-19 pandemic include, among others, robustness of supply chains, telemedicine regulations, mental health, expenditure increase for primary care, public health surveillance, and non-face-to-face dispensing of medicinal 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?

Since 2018 (Royal Decree Law 7/2018), the NHS provides coverage of a comprehensive benefits package to all Spanish residents, including citizens and foreign nationals who have established their residence in the Spanish territory. In practice, the NHS's coverage is virtually universal. Opting out from the NHS coverage is not possible, although the population can buy private insurance. Apart from the NHS, there are two other statutory health systems in Spain: mutual funds (MFs) catering for public servants and their beneficiaries; and the mutualities for accidents and occupational diseases (MAODs) which are specific for work-related accidents and occupational diseases. MFs affiliates may opt for public healthcare provision (NHS) or private provision.

Suppliers of medical goods

Public bodies in charge of the purchasing of medicinal products and medical devices are usually the regions, through their regional health services. Such services can purchase products from private entities considering the rules set out in the Spanish Procurement Act. This means that the contractor shall fulfil basic criteria to be able to enter contracts with the authorities (have legal capacity, certain economic and technical capacity, no records of pending amounts owed to the tax authorities, etc) and comply with the specific conditions set out in the tender conditions regarding the products (price thresholds, quality and technical requirements, etc).

Medical service providers

Public bodies may also contract health services from private providers (eg, high-technology diagnostic tests, or long-term care services and palliative care). Such providers must comply with the basic criteria mentioned in the preceding paragraph and regulated in the Spanish Public Procurement Act. The contracted health services may be formalised through service agreements (usually under a fee-for-service scheme) or concessions where the contractor fully manages a certain service and assumes its operational risk.

HEALTH INSURANCE FINANCING AND COVERAGE

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

In Spain, three statutory health systems coexist: the NHS, MFs for public servants and their beneficiaries, and MAODs.

Coverage within the NHS is financed through general taxation; no premiums apply. In some cases, co-payments may apply (eg, pharmaceutical prescriptions dispensed at retail pharmacies). MFs are funded – apart from transfers from the budget of the central government – by contributions of its affiliates set by the central government in the general budget law each year. MAODs are financed through social security contributions paid by employers and employees, which are also determined annually by budgetary and social security laws.

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?

The MOH and the CISNS have powers to determine the benefits package provided by the NHS, including provision of pharmaceuticals. Regions, however, can add benefits for their population provided that they comply with certain requirements, including financial sufficiency and budget stability criteria. When it comes to MFs and MAODs, the contract between the mutuality and the government may further define the scope of the coverage.

We are not aware of any differences in coverage for in-person medical appointments and telemedicine appointments within the NHS. Generally, both options are covered, although this may depend on the specific service.

HOSPITAL SECTOR

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

Public hospitals are normally funded through global budgets. Budgets are usually fixed by means of formulas which may comprise variables such as the population served by the hospital, number of discharges, case mix index (ie, metrics that reflect the diversity, complexity and severity of the patients treated at the healthcare facility) and structural-related tariffs (ie, tariffs that depend on structural features of the centre). From a patient perspective, all services performed at a hospital level, including stationary and ambulatory services, are reimbursed and provided free of charge.

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

Most of the publicly funded health services use global budgets as the funding mechanism. The system usually builds on framework agreements between regional healthcare services and providers (hospitals in this case). Such agreements regulate the quantity of services, the price of such services (usually established by means of formulas; see Q8) and the overall budget. They also may include quality-oriented elements (such as waiting list reduction) and outcome related variables (such as accessibility, responsiveness, etc). Efficiency controls rely mostly on budgetary caps and monitoring, so that hospitals are incentivised to meet efficiency targets.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

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

Regional healthcare services, in addition to using the public providers, may need to rely on private hospitals to deliver certain services (such as specific diagnostic tests, and long-term or palliative care). The reimbursement of the private provider is typically determined in contracts and tender conditions between the provider and the regional healthcare service. Such conditions are determined by the relevant Authority on a case-by-case basis and negotiated thereafter with the service provider.

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

The determination of the prices is set in the contracts mentioned in Q10. For surgical or diagnostic test provisions, private providers are usually remunerated by means of fees based on annually updated public tariffs. For long term or palliative care, *per diem* fees are the most common payment scheme and the unit depends on the condition of the patient, the therapeutic complexity and the characteristics of the hospital.

PHARMACEUTICALS AND MEDICAL DEVICES

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

Pharmaceuticals

The reimbursement proceeding of pharmaceuticals aims to determine whether the product should be reimbursed or not and, if yes, its PVL and other reimbursement conditions. Key actors are the MOH, the CIPM (see Q3 above), and HTA bodies, both at national (regulatory framework under construction, approval expected for 2025) and regional level.

Regarding the reimbursement decision, Spain follows a selective funding system, meaning that not all products are reimbursed. Reimbursement criteria are laid down in Article 92 of LGRUM and include aspects such as the seriousness of the pathology for which the product is approved, needs of special groups of people, incremental clinical benefit, cost-effectiveness, need to rationalise public expenditure, existence of alternatives at a lower cost, degree of innovation, etc.

Further, Article 92 of LGRUM provides that the following products will not be reimbursed:

- medicinal products not subject to medical prescription;
- medicinal products which are not used for the treatment of a clearly defined pathology;
- products for cosmetic or dietetic use;
- mineral waters, elixirs, toothpastes or other similar products;
- medicinal products indicated for the treatment of syndromes and/or symptoms of minor severity; and
- medicinal products which do not meet current therapeutic needs (this being understood as an unfavourable benefit/risk balance in the diseases for which they are indicated).

The MOH considers all of the above and determines which medicinal products are reimbursed and which are not. Reimbursed products are listed in a database run by the MOH called 'Nomenclator'.

For the reimbursement of products with high uncertainty (clinical or economical), risk sharing schemes are becoming frequent such as pay for performance schemes, price volume agreements, caps, etc.

Medical devices

The reimbursement of medical devices follows a different path. In general terms, the process is not as structured as the one for pharmaceutical products. Some of the devices to be used at hospital level are directly purchased through public procurement procedures with no actual reimbursement proceeding at a national level. Regarding medical devices for non-hospitalised patients, the proceeding and criteria for reimbursement are set out in Royal Decree 9/1996

and Royal Decree 1030/2006. Annex I and II of such Royal Decree include an exhaustive list of the products (including medical devices) for non-hospitalised patients that may be reimbursed (eg, bandages, gauze, catheters, urine collection bags).

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

The applicable rules (which are old but still in force, ie, Royal Decree 271/1990, Royal Decree 83/1993, Order of 17 December 1990 and Order of 6 April 1993) still contemplate a 'cost plus' system under which the PVL of medicinal products should respond to the cost of the product plus a given margin. This system, however, does not apply in practice. It is well known that the price-approval process entails a negotiation with the authorities where the cost and the profit margin are not really the variables that are considered. Companies should be prepared for prices mainly to be determined by issues such as (1) a comparative pharmaco-economic evaluation of the medicine in which the advantages of the new product should be quantified; (2) the price of the product in other European Union Member States, (3) the activities performed by the company in Spain (R&D, manufacturing, etc) or the relationship with a local company through a co-marketing or licensing arrangement.

Prices of reimbursed medical devices dispensed to non-hospitalised patients are fixed by the MOH/CIPM in accordance with the provisions of the LGRUM and Royal Decree 9/1996.

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.

In recent years, there has been some litigation in relation to access to medicinal products whose reimbursement has been explicitly denied by the MOH. Some hospitals offer such products, and others do not, generating a situation which sometimes is argued to be incompatible with Spanish constitutional rights such as the right to equality (Article 14), the right to life (Article 15) or the right to healthcare (Article 43). Several courts have ruled in favour of the plaintiffs, ordering regional authorities to cover the treatment. Judgements of the Supreme Court of 19 February 2024 and 11 April 2024, which mainly relate to the right to equality but include some *obiter dicta* references to the right to life, are the most recent ones regarding these matters.

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.

1. Important changes are expected to be approved in the upcoming months regarding the regulatory framework of medicinal products and medical devices. The Spanish Government is working on an amendment of the LGRUM with the objective, among others, to contemplate new measures to rationalise pharmaceutical expenditure and promote rational use of public funds. Such measures include the modification of the reference price system (RPS) to increase

competition, the recognition of the value of incremental innovation in the context of the RPS and reimbursement proceedings, or the application of additional paybacks to certain hospital use products. The government is also working on a new Royal Decree on health technology assessment and on a new Royal Decree regulating price and reimbursement proceedings for medicinal products.

2. The Spanish Government is considering (see *Annual Regulatory Plan for 2024)*[3] the possibility of preparing new laws prioritising public direct management in the NHS. This is relevant because within the NHS different management models coexist, including purely public models and other schemes that include some degree of private ownership/management. This law, as far as has been published, may have the effect of limiting private management schemes within the NHS.

3. In 2024, parliamentary discussions were held regarding new laws aiming to improve the foundational principles of the NHS. Matters discussed included the possibility to widen healthcare coverage in certain population subgroups; the amendment of the current distinction between the core, supplementary, accessory and complementary benefits, gathering benefits in a single package; the cancellation of the option of regions to offer complementary benefits; or reducing copayments. Although such laws were not finally approved because of the abrupt termination of last legislative term, the mentioned matters will most likely be in the public debate during the upcoming years.

4. A current hot topic in Spain affects MFs (see Q5). As said, public servants, armed forces and the judiciary are eligible to receive coverage under MFs, a statutory system differentiated from the NHS. MFs' affiliates may opt for public (NHS) or private healthcare. The provision of private healthcare in this scenario is performed through entities that are contracted by MFs under public procurement procedures. Such procedures end with the selection of certain service provider entities with whom contracts are signed ('Contracts'). The issue is that in October 2024, all Contracts expired (they are now running under exceptional extensions) and no entity has submitted offers in the open public procurement procedure to find service providers for the upcoming years. Entities claim that the business is not economically attractive for them. There is currently a debate about increasing the premiums that the central government pays per employee, or terminating the exceptional extensions mentioned above and transferring all insured civil servants under MFs' schemes to the NHS. If the agreements with insurers were to be terminated, it is estimated that more than one million people would have to be incorporated into the NHS, and this would have a significant budgetary impact.

[3] Available at: https://transparencia.gob.es/transparencia/dam/jcr:00e03e20-a2c7-46cb-a482-00f487896469/PAN_2024.pdf