# THE HEALTHCARE LAW REVIEW

Sixth Edition

**Editor**
Ulrich Grau

THE LAWREVIEWS

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SIXTH EDITION

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# PREFACE

The sixth edition of *The Healthcare Law Review* covers six new jurisdictions and a total of 17 jurisdictions from Europe, North and South America and Asia. All chapters have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues that are of interest for healthcare providers and related businesses.

The past two years have been dominated by the covid-19 pandemic. The pandemic not only affected all healthcare providers and staff working in health and social care but also scientists, public health officials and politicians throughout the world. Each country was hit hard by the pandemic, some countries were even overwhelmed, and major sources of the healthcare systems had to focus on maintaining the functioning of the health systems even in this exceptional situation. Therefore, all countries took additional exceptional measures to fight the pandemic. According to the reviews from the individual countries, these exceptional measures have now largely been scaled back or totally withdrawn, even though the pandemic is not yet over.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through greater digitisation and use of telemedicine. This is not only about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. The next few years will show whether these innovations can also be successfully implemented in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders. The European Union is already well on the way with the implementation of a European Health Data Space.

Even if individual countries solve their problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful the respective countries have been with their solutions in each case. I truly hope that the publication of *The Healthcare Law Review* will be particularly helpful in that respect.

I am more than happy to take over the editorship from Sarah Ellson from Fieldfisher LLP, London. I would like to sincerely thank her for her commitment over the past years. It is an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the

healthcare systems of the countries covered. We will continue our efforts to include more countries to this publication to be able to give a comprehensive worldwide approach to healthcare issues by each country.

**Ulrich Grau**
D+B Rechtsanwälte Partnerschaft mbB
Berlin
August 2022

**Chapter 12**

# SPAIN

*Beatriz Cocina*[1]

## I OVERVIEW

The Spanish national health system (SNS) is a mainstay of the state based on the rule of law defined by the Spanish Constitution. Article 43 of the Constitution guarantees the right to healthcare, which is a guiding principle for public authorities to define social and economic policies.

Spain is divided into 17 autonomous regions that have broad powers on health matters; the regions are responsible for providing public healthcare services and related funding. To ensure that all citizens are treated equally throughout Spain, some basic healthcare conditions are guaranteed for all Spanish citizens and it is the central authorities who set them, although autonomous regions do play a role in the central decision-making process regarding new benefits or technologies. They also have a big say on how they apply the system in their respective territories, and may even decide to provide additional healthcare services to their citizens. As a result, there are significant differences in how healthcare services are provided in the various regions and, more notably, in the provision of social and dependency care services, which are less regulated at a central state level.

Public policies for the provision of health services in Spain are exposed to the added difficulty of ensuring that the current healthcare system is sustainable and affordable in view of the ageing population, and of having new, expensive products and technologies in combination with patients' increasing demands for health and social benefits.

Nonetheless, the Spanish SNS is considered one of the best in the world, providing citizens free access to quality healthcare. For instance, according to a study published in 2019 by the Ministry of Health,[2] within the context of the EU, Spain has good indicators in terms of, among other things:

*a* life expectancy;
*b* healthcare spend;
*c* years of healthy life at birth and at age 65;
*d* mortality from cancer or cardiovascular diseases;
*e* the percentage of the population declaring their needs unsatisfied through medical attention;
*f* citizens' perception of personal health; and
*g* vaccination coverage and transplants.

1 Beatriz Cocina is a lawyer Uría Menéndez Abogados SLP.

2 Los sistemas sanitarios en los países de la Unión Europea. Características e indicadores de salud 2019. https://sanidad-ue.es/en/.

The coverage is also one of the widest in the EU, without co-payments. Dental coverage and mental health services are the main areas where there are still reported general shortcomings. In addition, private healthcare is also considered affordable and is quite widely used, coexisting with the public system.

## II THE HEALTHCARE ECONOMY

### i General

The SNS provides free access to comprehensive healthcare services. It provides close to universal coverage. It includes not only all Spanish citizens, but every resident in Spain (regardless of legal status), as well as their dependent relatives. Some limitations were introduced in 2012 to restrict the system to Spanish citizens and individuals who legally reside in Spain, but they were withdrawn in 2019, and full access to public healthcare is currently available to all who have been residing in Spain for at least three months, and for those who do not actually reside in Spain but are able to prove that they have no access to public healthcare in their country of residence, and no third party is obliged to provide funding.

In any event, everyone is entitled to receive emergency care and pre-natal and post-natal care regardless of their legal status. All minors (under 18) are entitled to healthcare as if they were Spanish citizens.

As an exception, the public healthcare system does not cover non-Spanish citizens whose income exceeds certain thresholds and who are not contributing or have not contributed to the country's social security, unless they adhere to a specific contract.

### ii The role of health insurance

Individuals who are not entitled to public healthcare (i.e., residents that do not contribute to the social security system and whose income exceeds €100,000 per year) have the option (but not the obligation) to adhere to a special arrangement with the SNS and thus receive public healthcare. The fee currently amounts to at €60 per month, or €157 per month for over 65s.

On the other hand, despite the public system providing universal coverage, many people in Spain also have a private healthcare insurance, and this trend is growing. This gives citizens quicker or more convenient healthcare assistance, especially in certain areas. Public employees (civil servants, the judiciary and army personnel) also have the option to adhere to the private healthcare system through mutual societies instead of benefiting from public healthcare services.

There are also well-established fully private healthcare services that are becoming more and more popular, even if they are not covered by any insurance, especially in certain niche sectors such as fertility treatments, eye surgery or dental care.

### iii Funding and payment for specific services

SNS coverage includes public health services; primary healthcare; specialist care; emergency care; medicines and medical devices; prosthetics; dietary products; and health transportation.

As to which specific services are included, the Ministry of Health defines the benefits and decides the 'portfolio of common services' (i.e., techniques, technologies and procedures) included in the public healthcare system, which constitute the minimum national standards.

The decision-making process to include benefits or services in the public healthcare system (i.e., in the corresponding catalogue or portfolio) is complex and requires assessing diverse public bodies. In general, including new services and benefits is largely based on the

assessment by the Interterritorial Council of the SNS, a body made up of representatives of the various autonomous regions whose role is to ensure that everyone in Spain receives the same healthcare services. The Spanish Ministry of Health, through technology evaluation agencies, assesses new techniques, technologies or procedures before including them in the portfolio of services. These decisions will establish when and how a new service or technology is eligible for public funding. For example, access to certain fertility treatments is limited by the patient's age or number of previous attempts; access to certain early diagnosis services or screening programmes is also limited to certain age groups.

As regards funding, except for limited patient co-payments, public healthcare in Spain is provided at no cost to the beneficiaries and funded through taxation.

Co-payments are in force for medicines and medical devices prescribed through the public system. Ordinary co-payments range from 40 to 60 per cent of the price of the medicines (with a cap) depending on beneficiaries' income. A chronic patient's co-payment is set at 10 per cent, and the unemployed and beneficiaries of public assistance have no co-payment obligations.

Patients generally have the freedom to choose between healthcare centres and professionals. However, the portfolio of common services may only be provided by centres, establishments and services of the SNS (its own, or subcontracted), except in life-threatening situations. Expenses incurred for urgent cases, and instant and life-threatening healthcare situations provided outside the SNS, will be reimbursed, provided the intention is not to unfairly benefit from this exception.

## III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The basic structure through which healthcare services are provided comprise health centres, which is the main comprehensive primary care centre. SNS beneficiaries can choose their health centre, but this freedom may be limited to guarantee that patients are equally distributed among the various health centres and professionals.

Beyond primary care diagnosis and treatment, SNS users have the right to be treated at specialised hospitals. Patients who need specialist care need a referral from their primary care doctor. Patients are free to choose which specialist hospital they want assigned to them in their health area. However, all SNS users can also access national reference services if they have exhausted all the diagnosis and treatment possibilities of the specialised services in the autonomous region where they reside.

There is no single electronic medical record within the SNS. Instead, each autonomous region operates an independent system. Since 2006, a project has been in place to gradually unify the medical record structure to guarantee that records from different regions can be accessed and managed, but each region is progressing at different rates (and in some cases different electronic records apply to primary care and hospital care within the same region). Managing the records from different regions is only possible currently in the electronic medicine prescription system, under which patients can get their publicly funded medicine from pharmacies outside their region.

## IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

### i Regulators

The central state establishes the basic legal framework, requirements and principles to provide healthcare services and operate healthcare centres. Implementation and enforcement are delegated to the autonomous regions. They are thus responsible for establishing the specific requirements and processes to authorise health centres and grant authorisations and permits and carry out inspections and audits. They are responsible for enforcing applicable healthcare regulations generally and have powers to initiate infringement proceedings and impose administrative penalties for non-compliance.

For specific topics, the health authorities are assisted and advised by consulting committees that include representatives from other regulatory bodies and independent professionals. The following are the main ones:

*a* The Spanish Bioethics Committee, which falls under the auspices of the Ministry of Health, is an independent, consultative professional body whose mission is to issue reports, proposals and recommendations for public authorities at the state and regional level on matters related to the ethical and social implications of biomedicine and health science, and establish the general principles to produce codes of good practice in connection with the provision of healthcare, social services and scientific research.

*b* The National Transplant Organisation is an independent coordinating agency of the Spanish Ministry of Health responsible for promoting and facilitating donation and transplantation of human organs, tissues and cells, and to guarantee their appropriate and correct distribution, according to technical knowledge and equity principles.

*c* Healthcare professionals providing healthcare services are bound by the applicable professional codes of ethics (i.e., the Spanish Medical Deontological Code and the International Code of Medical Ethics of the World Medical Association, jointly, the Codes). Pursuant to the Codes, healthcare professionals must always exercise their independent professional judgement and maintain the highest standards of professional conduct and, in particular, refrain from carrying out any non-ethical practices (the Codes include an exhaustive catalogue of said practices).

Medical societies also regularly issue opinions and guidance on topics of interest or contested matters such as, to name but a few, end-of-life care, access to fertility treatments and use of embryos for research purposes.

Although the instruments and policy documents these public and private bodies issue are not legally binding, they are undoubtedly pertinent to providing healthcare services.

### ii Institutional healthcare providers and healthcare professionals

All healthcare providers need to be authorised as health centres or health services by the relevant regional authority. Under the applicable regulations, all centres providing healthcare services must obtain an installation permit before they are set up, and a healthcare operating permit before they start operating, which the competent regional authority grants for five years. In order to grant the authorisation or extend it, the authorities will verify that the applicant has the facilities, means, procedures and adequate personnel to carry out the activities for which authorisation is being sought. Each separate service or unit must be specifically authorised; regional regulations have set out different requirements for different types of healthcare units

(e.g., surgery, oncology, lab analysis and primary care are subject to different requirements in terms of the physical space they need, the levels of hygiene or control protocols required, or even the minimum surface area for waiting rooms).

The authorities will require detailed documentation (evidence that the corresponding party owns or has a right to use premises, the layout of the premises and equipment, an organisational chart, its personnel's qualifications, facilities, resources and equipment, operational handbook, quality system, other relevant policies and procedures, etc.). The authorities will also generally inspect the premises.

The authorisation procedure for individual healthcare practitioners is basically the same, but the documentation they need to provide is naturally much simpler.

Once this permit is granted, the centre will be registered with the General Registry of Health Centres, Services and Establishments. The authorisation must be physically exhibited at the premises and the authorisation number included in any legal documentation.

Operating without the required permit is a severe infringement that may be sanctioned with penalties that range from roughly €15,000 up to €90,000, depending on the region. The authorities could also decree the closure of the premises until the situation is regularised. Naturally, in addition to the amount of the potential fines and risk of closure, the business impact of discontinuing a given practice, and the reputational risk, are important factors to be considered.

## V OWNERSHIP OF HEALTHCARE BUSINESSES

As a matter of principle, there are no restrictions on who owns a healthcare business, or any differences between for-profit and not-for-profit entities. There is no maximum number (*numerus clausus*) of healthcare centres and no specific requirements in terms of financial viability or governance, provided the minimum requirements to set up and operate a healthcare centre are met. The only limitation applies to owning pharmacies, which is a common practice in Spain, and entails that only individually licensed pharmacists can own and manage retail pharmacies. It is true that certain stakeholders (notably, some medical and dentist associations) have claimed that professionals must own or control healthcare institutions. This is based on a particular interpretation of the Spanish regulations on professional limited liability companies. The prevailing interpretation does not support this conclusion, but case law has not always been consistent. Although we are not aware of any recent attempts to try to enforce this interpretation, this risk cannot be entirely ruled out.

On the other hand, some limitations have recently been introduced to protect certain critical sectors. Since early 2000, Spanish foreign direct investment (FDI) regulations only required prior authorisation for a limited number of investments, such as those from tax havens, into activities related to national defence and security, and (for non-EU investors) into gambling, airlines and audiovisual media, among other sectors.

To address the covid pandemic, and following guidance from the European Commission, the government adopted urgent measures to avoid opportunistic investments into critical sectors by creating a new screening mechanism for certain FDI. The health sector is considered a critical sector.

The mechanism was introduced in March 2020 and amended in November 2020. It applies to non-EU and EFTA residents, and also, for certain investments, to EU or EFTA residents whose beneficial owner (more than 25 per cent of the share capital or voting rights)

is a non-EU or EFTA resident. It also applies if the investor is controlled by a third EU Member State government and if the investor is subject to ongoing judicial or administrative proceedings for engaging in illegal or criminal activities.

FDIs subject to the screening mechanism are those that result in the foreign investor reaching a stake of at least 10 per cent of the share capital of the Spanish company; or any transaction that enables effective participation in the management or control of a Spanish company.

Affected FDIs require a prior administrative authorisation from the Council of Ministers. It has six months to issue a decision – even though the time required for the authorisation is shorter in practice. The FDI authority also has a fast track 30-day procedure to authorise investments below €5 million. Investments below that figure are exempt from the mechanism.

Legislation does not provide the substantive criteria that are to be used to assess the foreign direct investment criteria. According to the authorities' guidance, the decision is based on the risk that the investment may pose to health, security, public order or national defence, and on the context and circumstances of the foreign investor. A draft royal decree is currently being processed to make this system more reliable, transparent and clear.

Gun-jumping will render the FDI null until authorisation is obtained, and in addition could entail fines up to the value of the investment.

The mechanism is not limited to the duration of the covid pandemic; rather, it will apply permanently and indefinitely unless subsequent legislation removes or amends it.

## VI MARKETING AND PROMOTION OF SERVICES

Legally, advertising and information about health centres or establishments, as well as the services they provide, is limited to the scope of the healthcare operating permit. Any other type of advertising in this regard requires the prior and express authorisation of the competent health authorities. In practice, however, all regions do not strictly enforce these regulations and only some of them have enacted and effectively applied a prior authorisation procedure for healthcare service advertising. The regulations also establish that advertising services offered by healthcare centres to the public must respect the scientific basis of the activities, and must be objective, prudent and truthful so as to not raise false expectations or disseminate misconceptions. Unauthorised medical activities or products, or those for which there is no evidence of their beneficial effects for human beings, cannot be advertised.

Apart from the above quite general principles, advertising of healthcare services is scarcely regulated in Spain. Several attempts to enact a specific healthcare advertising law have been made in the past, and Congress is currently considering a legislative proposal.

On the other hand, Spain has no specific anti-kickback legislation for healthcare services. Unlike incentives linked to prescribing medicines and medical devices, which are clearly prohibited, the regulations are silent on granting incentives to healthcare professionals to recommend specific healthcare services or refer patients to a given institution. Civil servants (which generally include all healthcare professionals that practise in the public healthcare system) are nonetheless prohibited from receiving any remuneration associated with exercising their legal duties. Note that the Spanish Medical Code of Ethics (and the International Code of Medical Ethics of the World Medical Association) prohibit certain commercial practices, such as referring patients to other institutions in exchange for remuneration, or remunerating the referral of patients to an institution (also known as fee-splitting); and disseminating false

or misleading promotional messages. Nonetheless, in practice, fee-splitting and payments to doctors for patient referrals are not unheard of in the medical sectors, especially in certain niche practices.

## VII PROCUREMENT OF SERVICES AND GOODS

The notion of commissioning the provision of care services does not apply as such in the Spanish national health service. We note, however, that there are several formulas that allow private healthcare providers to participate (obviously, for consideration) in providing publicly funded healthcare services. Spanish law establishes that the provision of public healthcare services does not necessarily need to be managed directly by the Spanish public administration but may also be indirectly procured through diverse collaboration schemes, in any form admitted by law, and notably through agreements with other (public or private) undertakings. This option has been used unevenly across regions; some, such as Valencia, Catalonia and Madrid, have made extensive use of these formulas, while others directly manage the provision of healthcare generally and only resort to agreements with third parties for specific needs.

## VIII REIMBURSEMENT OF SERVICES AND GOODS

The decision-making process to include benefits or services in the public healthcare regime (i.e., in the catalogue or portfolio) involves a complex procedure and requires assessing diverse public bodies. In general, whether new services and benefits are included depends largely on the assessment carried out by the Interterritorial Council of the National Health System, a body made up of representatives from different autonomous regions whose role is to ensure that healthcare in Spain is the same for everyone. New techniques, technologies or procedures must, in addition, be assessed by the Spanish Ministry of Health, through its technology evaluation agencies, if they are to be included in the portfolio of services. These decisions will set out the conditions for a new service or technology to be eligible for public funding. For instance, access to certain fertility treatments is limited by the patient's age or number of previous attempts; access to certain early diagnosis services or screening programmes is also limited to certain age groups.

The medicine reimbursement process is different and is governed by different principles. In general, the medicine pricing and reimbursement regulation is vague and scant – just some provisions in the Spanish Medicines Law (Royal Legislative Decree 1/2015) and a 30-year-old royal decree – which leaves many questions unanswered. Attempts over the years to give these matters more clarity and legal certainty by enacting a pricing and reimbursement regulation have not been successful. However, in the past couple of years, the Advisory Council for the Reimbursement of the Pharmaceutical Provision, a public advisory body created on 19 March 2022, has issued a series of consensus documents and recommendations, including making proposals to amend laws and approving developing regulations. It seems that the attempt to end the current uncertain situation has been taken seriously, although, needless to say, priorities over the past two years have shifted significantly due to the covid pandemic.

The criteria to adopt a reimbursement decision are expressed quite vaguely. They include:

*a* the seriousness, duration and secondary effects of the pathology;

*b* needs of certain population groups;

*c* therapeutic and social value, incremental clinical benefit and cost-effectiveness;

*d* the rationalisation of public expenditure and budgetary impact; and
*e* the existence of alternatives and degree of innovation.

A legal reform in 2012 stressed that the pricing decision must take into account, among other factors, cost-effectiveness and budgetary impact, the element of innovation, and, for innovative medicines, possible discount or rebate schemes.

In practice, cost is primarily assessed against the therapeutic alternatives available, and significant cost increases are unlikely unless there is a clear and considerable clinical advantage. The prices applied in other EU Member States are taken into account (the expectation being that the Spanish price will be in the low range).

Finally, as previously mentioned, in Spain, the autonomous regions are responsible for providing healthcare services. Although they are not entitled to deny access to medicines included in the pricing and reimbursement system, they are in charge of purchasing medicines and managing healthcare generally, which gives them some leeway to influence the medicines that are prescribed and dispensed. In practice, it is usual that after the central pricing and reimbursement process is completed, each region develops a market access strategy (although this is sometimes done per hospital).

## IX DIGITAL HEALTH DEVELOPMENTS

In December 2021 the General Secretariat for Digital Health, Information and Innovation for the National Health System approved the SNS digital health strategy. This strategy will be developed from 2021 to 2026 in the context of using the European funds associated with the recovery and resilience facility. As is generally known, the recovery and resilience facility is financing Member State reform and investment from the start of the covid pandemic until 31 December 2026. To benefit from this facility, Member States submit their recovery and resilience plans to the European Commission. Each plan sets out the reforms and investments to be implemented by the end of 2026, and Member States can receive a maximum pre-agreed financing allocation.

The strategy prioritises four main goals:

*a* enabling individuals and involving them in the healthcare they receive;
*b* optimising processes and communication between professionals as much as possible;
*c* adopting data management and governance principles that allow for the availability of quality and interoperable information and create a national health data space; and
*d* applying innovative policies aimed at the '5Ps': population, prevention, prediction, personalisation and participation.

Among other measures, the strategy attempts to reinforce the SNS' digital services, develop digital clinical records, the interoperability of information at both a national and international level, and establish conditions that allow massive data processing to generate and extract knowledge.

Specific projects to implement the strategy need stakeholder approval and funds from the recovery and resilience facility, which may also be complemented by additional funding from the Ministry of Health and the regions.

## X CORONAVIRUS

In the context of the covid pandemic, the government and regional authorities have approved multiple exceptional measures to guarantee the availability, or expedite the provision, of certain basic services through, among other things:

*a* controlling production and centralising supplies of critical goods (medicines, hygiene products, personal protection equipment);

*b* alleviating certain bureaucratic burdens (e.g., the approval process for clinical trials for covid medicines and for variations of existing clinical trials to adapt to the isolation measures and the limitation of resources);

*c* enabling emergency healthcare contracts (by derogation of general public procurement principles); and

*d* avoiding physical interactions (e.g., replacing visits to doctors with video communication or phone calls, providing in-home services and delivering medicines to patients' homes).

Many of these measures are no longer in force, as the critical stages of the pandemic seem to have been overcome. However, some of these measures are here to stay. Particularly, in many regions primary care doctor visits are still being conducted by telephone or, at least, patients have the choice to go to their doctor in person or get medical help and prescriptions by telephone. In addition, some regions are in the process of implementing projects to prolong the home delivery of medicines, which was an exceptional measure during the covid pandemic, although this will require changes in legislation. Finally, as previously mentioned, the screening mechanism for FDI in the healthcare sector is still in force and is not expected to be revoked in the short to mid-term.

## XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

In June 2022, the government produced a Bill (Law on Equity, Universality and Cohesion of the National Health System) that, among other measures, would limit public authorities' ability to collaborate with private operators in providing healthcare to exceptional duly justified cases where they cannot manage the services directly. This would effectively entail excluding private healthcare providers from the provision of public services, which is very widely extended, particularly in some regions. The Bill actually states that agreements currently in force would be terminated in advance, so that the public authorities start managing the services again. This has caused heated debate in Spain.

We expect 2022 and 2023 will also be crucial years for the pharmaceutical industry, as the EU pharmaceutical legislation is under review and proposed changes are expected to be made public by 2022 year-end. Companies, healthcare operators and regulators will also need to start to adapt to the new EU Regulation on health technology assessment,[3] which has been in force since January 2022 and which will apply from 2025. This Regulation aims to standardise health technology assessments that are used as a basis for health policy decisions.

There are also several ongoing initiatives, including the digital health strategy and the Bill Law on Equity, Universality and Cohesion of the National Health System, which advocate for creating a national health data space incorporating real world healthcare data that can be

3 Regulation 2021/2282.

used to maximise its value and generate opportunities for better healthcare, scientific research and growth. This is currently a big area of focus for many healthcare providers and other operators in the healthcare sector.

## XII CONCLUSIONS

In spite of the current economic uncertainty and global political scenario, Spain is the focus of much investment in the private healthcare sector. Even though Spain has a robust public healthcare system, it is regarded as a field of opportunity for private investors who see potential for scaling up, internationalisation and consolidation, leveraging on:

*a* highly trained healthcare professionals;

*b* low costs, as compared with international competitors;

*c* a liberal legal framework and social acceptance regarding research, use of genetic data, fertility treatments, donations of human cells and tissue, among others; and

*d* strong biotech clusters and university research groups, and opportunities for collaboration with the public research network.

We expect to continue seeing M&A transactions and other collaboration deals in the healthcare sphere in Spain in the coming months.

**Appendix 1**

# ABOUT THE AUTHORS


**BEATRIZ COCINA**

*Uría Menéndez Abogados SLP*


Beatriz Cocina is a lawyer in the healthcare and life sciences practice area of Uría Menéndez. She joined the firm in 2001 and became a counsel in January 2013.

Beatriz regularly advises national and multinational companies in the pharmaceutical, healthcare and food sectors on all contractual, commercial and regulatory aspects of their businesses.

She specialises in distribution policies, commercial agreements (manufacturing, supply, distribution, co-marketing, collaboration and licence agreements), R&D (clinical trials, co-development), pricing and reimbursement of medicines and medical devices, and promotional activities. She represents clients before administrative and contentious administrative courts in regulatory matters, and before civil courts in, among others, product liability and unfair competition claims. She also provides advice on M&A transactions in these sectors.

In recent years Beatriz has been involved in several matters related to the design and implementation of innovative medicine wholesale policies and defending the policies before regulatory and competition authorities and the courts. She has also worked extensively on the negotiation of commercial agreements and the design of compliance and anti-bribery programmes, and the monitoring of their practical implementation.

Beatriz is regarded as a leading lawyer in healthcare and life sciences by the main international legal directories, such as *Chambers Europe*, *Best Lawyers* and *The Legal 500*. In 2021 she was named healthcare lawyer of the year by *Best Lawyers*.


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