PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Brief: Spain 2020

Pharmaceutical Pricing and Reimbursement Information (PPRI) Pharma Briefs Series

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

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Final version

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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

About PPRI Pharma Briefs

This concise report on the pharmaceutical pricing and reimbursement policy framework in Spain is part of the series of PPRI Pharma Briefs launched by the Pharmaceutical Pricing and Reimbursement Information (PPRI) Secretariat in 2019.

PPRI networks

The PPRI network is a collaboration of **pharmaceutical pricing and reimbursement authorities** of 51 – mostly European – countries (as of December 2020) as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of this network is to facilitate exchange between public officials, supported by scientific evidence and a common understanding of pharmaceutical policy issues. Under the framework of PPRI, further regional PPRI networks (e.g. in Central Asia) and thematic PPRI networks (e.g. on medical devices) have been established. PPRI networks are coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG).

PPRI contributes to the international scientific evidence base, in particular in the areas of (comparative) **pharmaceutical systems research** and pharmaceutical policy analysis, by providing country information that is usually not published in other literature. This is of interest for policy-makers who want to cross-learn and benchmark as well as for researchers who perform policy analyses and require contextual information on national pharmaceutical systems.

PPRI country information

Well-established publications that offer pharmaceutical pricing and reimbursement information on a single PPRI country are the **PPRI Pharma Profiles** that are available as in-depth reports as well as short reports, see https://ppri.goeg.at/ppri_pharma_profiles. Furthermore, one-page graphical abstracts are provided in the **PPRI Posters**, see https://ppri.goeg.at/ppri_posters.

The new series **PPRI Pharma Briefs** responds to the interest and needs expressed by policy-makers and technical experts in public authorities responsible for the pricing and reimbursement of medicines to read concise reports of the pharmaceutical policies in other countries.

The PPRI Pharma Briefs draw upon the information and data that have been provided by the PPRI network members, in addition to literature and relevant documents, such as legal provisions.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (1 January 2020)	47,329,980 (provisional value)
Country size (2020)	499,564 km²
Gross domestic product / GDP (2019, provisional value)	GDP per capita: € 26,430
Health expenditure / HE (2019)	HE per capita: € 2,451 HE in % of GDP: 9.0% Public HE as % of total HE: 70.0%
Pharmaceutical expenditure / PE (2018)	PE per capita: € 366 PE in % of HE: 15.3% Public PE as % of total HE: 69%

GDP = gross domestic product, HE = health expenditure, PE = pharmaceutical expenditure
Pharmaceutical expenditure data relate to the outpatient sector only

Sources: population – Eurostat [1], country size – World Bank [2], GDP – Eurostat [3], health and pharmaceutical expenditure – OECD "Health at a Glance 2020" [4]

Provision of pharmaceuticals

Community pharmacies (end of 2019)	22,069
Dispensing doctors (2020)	Spain has no dispensing doctors
Wholesale (2020)	19 wholesale companies representing 97% of the pharmaceutical wholesale market
Pharmaceutical industry (2019)	141 research-based companies

Data on pharmaceutical companies relate to members of the industry association Farmaindustria

Sources: community pharmacies –data provided by the Ministry of Health, wholesale – Fedifar [5], pharmaceutical industry – Farmaindustria [6]

Pharmaceutical market

Pharmaceutical market (2019)	€ 16,190 million (expressed in value, at ex-factory price level, under consideration of the statutory discounts to the SNS
Medicines (2020)	14,666 medicines authorised (counted including different pharmaceutical forms and dosages), corresponding to 32,712 pack size 21,703 medicines (counted including different pharmaceutical forms and dosages) included in the outpatient reimbursement list (December 2020)
Generic market shares (2019)	22.93% in value 46.90% in volume

Sources: pharmaceutical market – data provided by the Ministry of Health, number of authorised medicines – AEMPS [7], number of medicines in the reimbursement list – data provided by the Ministry of Health, generic market shares – data provided by the Ministry of Health

Pharmaceutical pricing (2020)

Price regulation	In place for reimbursable medicines (i.e. medicines for use in the National Health Service (Sistema Nacional de Salud / SNS) in outpatient and inpatient sectors
Pricing authorities	**Outpatient**: Ministry of Health **Inpatient**: Ministry of Health
Key pricing policies	**External price referencing**: supplementary pricing policy for reimbursable medicines in outpatient and inpatient sectors (prices in other European countries to inform price negotiations) **Value-based pricing**: no primary pricing policy, but value-based pricing elements **Price negotiations**: key pricing policy for reimbursable medicines in outpatient and inpatient sectors **Managed-entry agreements (MEA)**: used for high-priced reimbursable medicines in outpatient and inpatient sectors, mainly financially-based MEA **Tendering**: for some high impact hospital-only medicines at central level, for other medicines done by hospitals; tendering-like systems for off-patent medicines in some regions **Cost-plus pricing**: no, but manufacturing costs are considered to inform price negotiations of reimbursable medicines in outpatient and inpatient sectors **Generic price link**: in place for reimbursable medicines in outpatient and inpatient sectors (generics and originator medicines to reduce the price) **Biosimilar price link**: applied on a case by case basis for reimbursable medicines in outpatient and inpatient sectors
Pricing in the supply chain	**Wholesale**: statutory regressive margin scheme for all outpatient medicines **Pharmacy**: statutory regressive margin scheme for all outpatient medicines **Value-added tax**: 4% for medicines (standard VAT: 21%)

Source: overview provided by PPRI Secretariat

Pharmaceutical reimbursement (2020)

Reimbursement authorities	**Outpatient:** Ministry of Health (decision-taking); regions (payers) **Inpatient**: Ministry of Health (decision-taking); regions (payers)
Reimbursement lists	**Outpatient:** a national positive list and a national negative list **Inpatient:** hospital pharmaceutical formularies (at hospital level) supplement the national positive and negative lists
Reimbursement criteria	**Outpatient**: added value of the medicine, place of the medicines in the treatment, cost-effectiveness, budget impact **Inpatient:** same as for outpatient medicines; hospitals may apply further criteria (e.g. lowest price in a tender)
Co-payments for medicines	**Outpatient:** percentage co-payments of 40%, 50% or 60% for working population (standard rates, linked to income) 10% or 60% for retired people (standard rates, linked to income) Always 10% for medicines for chronic diseases 100% reimbursement rates for unemployed people without benefits, people with the lowest social pension and people suffering from occupational diseases. **Inpatient:** no co-payments in place
Demand-side measures to enhance the uptake of off-patent medicines	**Reference price system:** yes, at active substance level **Prescribing by International Non-Proprietary Name (INN):** mandatory (prescriptions for acute treatments and chronic treatment for naïve patients), except for non-substitutable medicines which can be prescribed by trade name **Generic substitution:** mandatory **Biosimilar substitution:** not allowed

Source: overview provided by PPRI Secretariat

Key technical terms are defined in the glossary in Annex 3.

Summary

Spain has a national health service (Sistema Nacional de Salud / SNS), and the 17 autonomous regions have their own health service. With regard to medicines, key institutions are the Spanish Agency of Medicines and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios / AEMPS), which is responsible for marketing authorisation and for a clinical assessment of the medicine, and the Ministry of Health (MoH), which prepares pricing and reimbursement decisions. The final pricing and reimbursement decision is taken by the Inter-Ministerial Pricing and Reimbursement Committee (Comisión Interministerial de Precios de los Medicamentos / CIPM) affiliated to the MoH, which involves national public authorities and the regions. The regions pay for medicines.

Prices of medicines eligible for use in the outpatient and inpatient sectors of the Spanish SNS are regulated. The decision on the inclusion of a medicine into reimbursement and its ex-factory price is taken in the same administrative process. It is informed by an HTA which consists of two parts: The clinical assessment is conducted by the Medicines Agency AEMPS, which produces a Therapeutic Positioning Report. The second part of the HTA concerns an economic assessment which is provided by the MoH. This HTA considers the findings of the clinical assessment as well as the added value of the medicine (cost-effectiveness analysis), prices of that medicine in other countries, estimated manufacturing costs and the estimated budget.

Informed by the HTA, the MoH undertakes price (and reimbursement) negotiations with the marketing authorisation holder. In the case of high-priced medicines, a managed-entry agreement (either a financially-based or a performance-based MEA) can be concluded. The prices of medicines in other countries serve as additional information for the pricing and reimbursement decision; so external price referencing is used as a supplementary pricing policy.

In the case of generics, a price link policy is applied. A generic must be 40% lower than the price of the originator, which also has to reduce its ex-factory price at the market entry of the first generic. Biosimilar medicines tend to be priced 30% lower than the originator reference medicine but this price link is not mandatory.

In some regions (e.g. Andalusia), a tendering-like system is applied for off-patent outpatient medicines, in addition to the price setting at national level. The winning bid (lowest-priced medicine) will be selected for reimbursement.

Apart from this variant for off-patent outpatient medicines, tendering is usually applied for medicines used in hospitals. The MoH is responsible for tendering of some high-impact hospital-only medicines, in which regions can join on a voluntary basis. Requests for tenders may also be solicited by hospitals in their procurement of medicines.

The pharmacy purchase price (wholesale price) and pharmacy retail price of all outpatient medicines are regulated based on statutory regressive margin schemes. The value-added tax is 4% on medicines, compared to 10% on health products and 21% in general.

Spain applies two claw-back systems. Since the financial crisis in 2010, a mandatory discount of 7.5% for new medicines and of 4% for orphan medicines is charged on the pharmacy retail price of all medicines sold to the SNS for both outpatient and inpatient use. It equally impacts manufacturers, wholesalers and pharmacies. In a separate claw-back system, community pharmacies have to make payments to the SNS based on their annual sales to the SNS.

A national positive list and a national negative list are in place. They are supplemented by hospital pharmaceutical formularies applied by hospitals. No co-payments are charged on medicines administrated in hospitals. Outpatients have to co-pay in pharmacies when filling their prescription: Percentage co-payments depending on the income of the patient are applied (co-payment rates for 40%, 50% or 60% for working population and 10% or 60% for pensioners). Some socio-economic groups are exempt from co-payments (unemployed people without benefits, people with the lowest social pension and people suffering from occupational diseases). Medicines for chronic diseases always carry a co-payment of 10% of the pharmacy retail price, independent from the income of the patient and with a maximum of € 4.24 per pack.

Spain applies a reference price system at active substance level (based on the law of 28 November 2020, previously established at ATC-5-level). The reference price of a cluster of interchangeable medicines is determined based on the lowest-priced medicine in that reference group. Generic substitution is mandatory, and the lowest-priced generic is dispensed. Patients cannot obtain a higher-priced generic even if they would be willing to pay the price difference. Biosimilar substitution is not allowed. Doctors have to prescribe by the International Non-Proprietary Name (INN) for acute care and in the first prescription for chronic treatment, corresponding to the initiation of the first treatment. For chronic care whose prescription corresponds to the continuity of treatment, it is allowed to prescribe by trade name, as long as it is included in the reference price system or is the one with the lowest price within its reference group. Prescription by trade name is also possible for non-substitutable medicines and as long as the principle of "greater efficiency" is respected.

In May 2017, Spain joined as one of the founding members the newly established cross-country collaboration "Valletta Declaration" which aims to improve access to medicines through cross-country cooperation.

Keywords

Pricing, reimbursement, pharmaceutical policies, pharmaceutical system, Spain

Resumen

España tiene un Sistema Nacional de Salud (SNS) y las 17 Comunidades Autonómas (CCAA) tienen su propio servicio de salud. Con respecto a los medicamentos, las instituciones clave son la Agencia Española de Medicamentos y Productos Sanitarios / AEMPS, que es la responsable de la autorización de comercialización y la evaluación clínica de los medicamentos y el Ministerio de Sanidad (MS), que es responsable de las decisiones de precio y financiación. La decisión final de precio y financiación la toma la Comisión Interministerial de Precios de los Medicamentos / CIPM, órgano colegiado adscrito al Ministerio de Sanidad, compuesto por las autoridades públicas nacionales y de las Comunidades Autónomas. Las CCAA son los pagadores de los medicamentos.

Los precios de los medicamentos que se pueden usar en el Sistema Nacional de Salud tanto en el sector hospitalario como ambulatorio están regulados. La decisión de la inclusión de un medicamento en la financiación y su precio de venta del laboratorio se adopta en el mismo procedimiento administrativo. El proceso se informa por una evaluación farmacoeconómica que consiste en dos partes: Una evaluación clínica que lleva a cabo la AEMPS, que se recoge en un Informe de Posicionamiento Terapéutico. La segunda parte de la evaluación consiste en una evaluación económica aportada por el MS. La evaluación farmacoeconómica tiene en cuenta los hallazgos de la evaluación clínica así como el valor añadido del medicamento (análisis de coste-efectividad), los precios del medicamento en otros países, los costes estimados de producción y el impacto presupuestario estimado.

A través del informe de evaluación farmacoeconómica, el MS lleva a cabo las negociaciones de precio (y financiación) con el titular de comercialización. En el caso de medicamentos de alto precio, se puede acordar un acuerdo de acceso al mercado (bien basado en resultados o económico). Los precios de los medicamentos en otros países sirven como información adicional para la decisión de precio y financiación, por lo que el precio de referencia externo se usa como una política complementaria para fijación de precio.

En el caso de genéricos, se aplica una política de precio relacionada. Un genérico debe tener un precio un 40% inferior al del innovador, el cual tiene que reducir también su PVL a la entrada en el mercado del primer genérico. En los medicamentos biosimilares se tiende a fijar el precio en un 30% inferior al del innovador, pero esta relación no es obligatoria.

En algunas CCAAs (ej, Andalucía), se aplica un sistema de negociación para los medicamentos fuera de patente de dispensación con receta, además del precio fijado a nivel nacional. Se seleccionará para financiación el que haga la propuesta de menor precio del medicamento.

A parte de esta variante para medicamentos fuera de patente, la negociación se aplica normalmente a los medicamentos de uso en hospitales. El MS es responsable de la negociación de medicamentos de uso hospitalario, en las cuales las CCAAs se pueden unir de forma voluntaria. Las solicitudes de negociación conjunta pueden solicitarse también por los hospitales para su suministro de medicamentos.

El precio de compra de las farmacias (precio de distribución) y el precio de venta en la farmacia se todos los medicamentos con receta está regulado a base escalas de márgenes regresivos a nivel estatal. El IVA es del 4% para medicamentos, en comparación con el 10% de otros productos sanitarios y el 21% general.

España aplica dos sistemas de descuento. Desde la crisis financiera, en 2010, se aplica un descuento obligatorio del 7,5% para nuevos medicamentos y del 4% para medicamentos huérfanos sobre el precio de venta de la farmacia a todos los medicamentos vendidos al SNS tanto para uso hospitalario como ambulatorio. Este descuento impacta igualmente a fabricantes, distribuidores y farmacias. En un sistema de descuentos separado, las farmacias comunitarias deben realizar pagos al SNS en base a sus ventas anuales al SNS.

Existe una lista nacional positiva de medicamentos en vigor y una lista nacional negativa. Estas se complementan con los formularios farmacéuticos hospitalarios usados por los hospitales. No se cobra co-pago a los medicamentos administrados en hospitales. Los pacientes ambulatorios tienen que realizar co-pagos en las farmacias cuando retiran sus recetas: Los porcentajes de co-pago aplicados dependen de los ingresos del paciente (tasas de co-pago 40%, 50% o 60% para trabajadores en activo y 10% o 60% para pensionistas). Algunos grupos socio-económicos están exentos de co-pago (personas sin empleo que han perdido el derecho a percibir el subsidio de desempleo, personas perceptoras de rentas de integración social y personas con enfermedad profesional). Los medicamentos para enfermedades crónicas llevan siempre un co-pago del 10% del precio de venta en farmacia, con independencia de los ingresos del paciente y con un máximo de 4,24 € por envase.

Desde 28 de noviembre de 2020 España aplica un Sistema de precios de referencia a nivel de principio activo (en lugar de por ATC5). El precio de referencia de un grupo de medicamentos intercambiables se determina en base al medicamento de menor precio de ese grupo de referencia. La sustitución por genérico es obligatoria y se debe dispensar el medicamento de menor precio. Los pacientes no pueden obtener un genérico de mayor precio ni siquiera si están dispuestos a pagar la diferencia de precio. La sustitución de biosimilares no está permitida. Los médicos tienen que prescribir por principio activo (INN) en prescripciones de procesos agudos y en la primera prescripción de un proceso crónico, correspondiente a la instauración del primer tratamiento. Para los procesos crónicos cuya prescripción se corresponda con la continuidad de tratamiento, podrá realizarse por denominación comercial, siempre y cuando ésta se encuentre incluida en el sistema de precios de referencia o sea la de menor precio dentro de su agrupación homogénea. La prescripción por denominación comercial también será posible en el caso de los medicamentos considerados como no sustituibles, siempre y cuando se respete el principio de mayor eficiencia para el sistema.

En mayo de 2017, España se unió como uno de los miembros fundadores a la nueva colaboración entre países “Declaración Valetta” cuyo objetivo es mejorar el acceso a los medicamentos a través de la cooperación entre países.

Palabras clave

Precios, reembolso, políticas farmacéuticas, sistema farmacéutico, España.

Graphical summary

GOBIERNO DE ESPAÑA | MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

PPRI Pharmaceutical Pricing and Reimbursement Information

SPAIN

Ministry of Health

Directorate General (DG) of Services of the National Health System Common Portfolio and Pharmacy

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Pharmaceutical pricing and reimbursement policies in the in- and out-patient sector

Total population= 47.33 million (2020)
GDP per capita (€) =26,430 (2019)
Organisation of health care sector = NHS
Health expenditure per capita= 2,451 € (2019)
Health expenditure in % of the GDP= 9% (2019)
Pharmaceutical exp. (%current health exp.) = 15.3 % (2018)

PRICING

The Ministry of Health, Consumer Affairs and Social Welfare (MoH) is the competent authority for pricing and reimbursement in the outpatient and inpatient sector. Payers are the regional governments and decisions are made by a Price & Reimbursement Committee (P&R committee), whose members are representatives of the MoH, as well as representatives of the Ministry of Finance and Civil Service, Ministry of Industry, Trade and Tourism, Ministry of Economy and Competitiveness, and of all Regional Governments health representatives.

Pricing in the out-patient sector and in-patient/hospital sector

The ex-factory price is established by the P&R committee for all reimbursable medicines (both outpatient and inpatient). External price referencing is used as supportive pricing policy. Pricing policies for generics and biosimilars are in place. Conditional pricing is also applied (capping, MEAs). Reference price system (RPS) is also applied for outpatient price fixing. VAT for medicines is a reduced rate of 4%

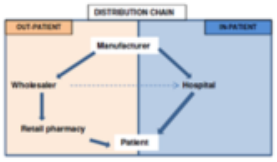
OUTPATIENT

Wholesale remuneration
Ex-factory price ≤91.63 €, wholesale margin is 7.6% of the wholesale price. Ex-factory price >91.63 €, fixed wholesale margin of 7.54 €
Pharmacy margins
Ex-factory price ≤91.63 €, 27.9% of pharmacy retail price. Ex-factory price >91.63 € and ≤ 200 €, fixed pharmacy margin of 38.37 €/pack. Ex-factory price >200 € and ≤ 500 €, fixed pharmacy margin of 43.37 €/pack. Ex-factory price is >500 €, fixed pharmacy margin of 48.37 €/pack.

A pharmacy claw-back system has been in place since August 2000, with pharmacies making payments based on a percentage of their annual sales of reimbursable medicines at manufacturer prices

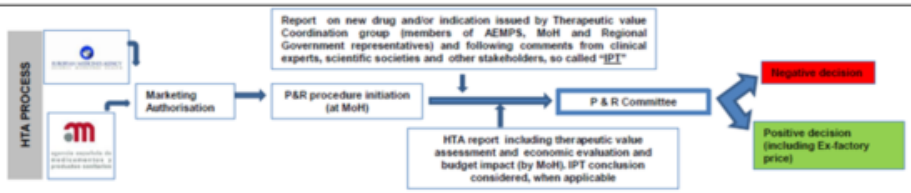
INPATIENT

Wholesale remuneration and pharmacy remuneration are not applicable in the in-patient sector
Tendering for medicines in the in-patient sector in addition to pricing policies is also applied.



Reforms: As cost-containment measures, mandatory discounts are in place. Discounts of 7.5% on originator medicines, 4% on orphan medicines and 15% for medicines reimbursed for more than 10 years and without a generic, granted jointed by manufacturers, wholesalers and pharmacies to the NHS for all reimbursable medicines since 2010. Exemption: Products included in the internal reference price system.

COVERAGE / REIMBURSEMENT



Coverage / reimbursement out-patient sector

There are both positive and negative lists. Medicines included in the positive list are updated monthly and available at:
http://www.mscbs.gob.es/profesionales/nomenclator.do

NEW: A new search tool informing on whether a medicine is reimbursed or not (including both out-patient and in-patient), is available at: https://www.mscbs.gob.es/profesionales/medicamentos.do .

Co-payment
60% of selling price of medicines for people earning ≥100,000 €/year; 50% for people earning ≥18,000 and <100,000 and 40% for the remaining employed citizens. Specific medicines for long term treatment have a reduced co-payment of 10% of the price with a maximum fee of 4.26 €/pack. Co-payment for retired people is 10% with a maximum monthly co-payment depending on earnings (6€, 18€ and 60€, respectively). Special vulnerable groups are exempt from co-payment.

Coverage / reimbursement in-patient sector: In terms of coverage and reimbursement, consideration of inpatient medicines is given to medicines dispensed only in hospitals regardless of whether or not the patient is formally admitted.

Co-payment:

There is full coverage of reimbursed medicines with no co-payment by patients in the in-patient sector.

1 Framework

Health care in Spain is organised based on a **National Health Service** (NHS; Sistema Nacional de Salud / **SNS**), and each of the 17 Autonomous Regions has its own health service.

The Spanish Constitution of 1978 established the right to health care for all citizens. The key legal document for medicines is the **Royal Decree 29/2006** on guarantees and rational use of medicines and health products [8] (as amended by Royal Legislative Decree 1/2015 of 24 July [9]). It is a comprehensive Medicines Act that regulates several aspects, including clinical research, ➲ marketing authorisation, prescription and dispensing, procedure for public funding and rational use of medicines; for terms with the ➲ sign consult the glossary in Annex 3 which can be easily accessed by clicking at the labelled terms). In 2012, during the global financial crisis, **Royal Decree 16/2012**, on urgent measures for the sustainability of the SNS, introduced cost-containment measures in the pharmaceutical sector [10].

As of 2020, key authorities at federal level are the Agency of Medicines and Medical Devices (**Agencia Española de Medicamentos y Productos Sanitarios / AEMPS**), which is responsible for marketing authorisation and also for clinical assessments of medicines and the Ministry of Health (**Ministerio de Sanidad**; the English abbreviation MoH will be used in the following text). The relevant unit of the MoH, which performs ➲ Health Technology Assessments (HTA) and prepares ➲ pricing and ➲ reimbursement decisions on medicines, is the Directorate General for Common NHS Services Portfolio and Pharmacy (**DG de Cartera Común de Servicios del SNS y Farmacia**). Final decisions on pricing and reimbursement of medicines are taken by the Inter-Ministerial Pricing and Reimbursement Committee (**Comisión Interministerial de Precios de los Medicamentos / CIPM**) affiliated to the MoH. The CIPM has representation of the MoH, other Federal Ministries (Ministry of Finance and Civil Service Ministry Industry, Trade and Tourism, Ministry of Economy and Competitiveness, and health representatives of all Regional Governments). CIPM decisions are applicable to all medicines used in the Spanish SNS (outpatient and inpatient sectors). **Regions** have some discretion to conduct some follow-up action on the pricing and reimbursement decision.

There are several **HTA institutions** at regional levels (e.g. Escuela Andaluza de Salud Pública, Agencia d'Avaluació de Tecnologies Sanitàries, Agencia de Evaluación de Tecnologías Sanitarias) which perform HTA on a broad range of health technologies sometimes including medicines. The information in this PPRI Pharma Brief refers to the year 2020, unless indicated differently.

2 Pricing

Pricing at manufacturer price level

The **ex-factory price of ➲ reimbursable medicines**, i.e. pharmaceuticals included for use in the outpatient and inpatient sectors of the Spanish SNS, is regulated (➲ price control). The decision on the price is taken in the same administrative procedure as the decision on the public funding

(reimbursement) of the respective medicines. For **non-reimbursable medicines** (i.e. those not included in the SNS) there is ➲ free pricing (i.e. the manufacturers may set the price at their own discretion).

The key pricing policy to set the **price of new (on-patent) medicines** is a ➲ price negotiation between the marketing authorisation holder (MAH) and the MoH. The Medicines Act defines several criteria for the pricing decision, including the severity of the disease, medical needs, therapeutic benefit, degree of innovation as well cost-effectiveness and budgetary impact.

The Spanish MoH bases its pharmaceutical pricing decisions on the outcomes of an **HTA process**, which is composed of a clinical part done by the AEMPS and an economic assessment performed by the MoH.

The **clinical HTA** is presented in the **Therapeutic Positioning Report** (Informe de Posicionamiento Terapéutico / IPT), which is prepared by the Therapeutic Value Coordination Group (TVCG) led by AEMPS. The TVCG also involves members of the MoH and the regional governments. The TPR is produced and made available after the MAH's submission of the dossier to request reimbursement and a price and is considered in the pricing and reimbursement decision. The purpose of the IPT is to inform about the therapeutic value of a medicine based on evidence on its effectiveness, safety and comparative effectiveness in the light of existing medicines for the same condition. The health gains identified are not mapped to a generic scale (e.g. QALYS) as in other countries [11]. AEMPS prepares a draft IPT and then produces the final report based on comments of the TVCG, further experts (e.g. scientific societies) and stakeholders (e.g. patients, the MAH).

Based on the IPT, the **MoH** prepares the full HTA, including an **economic evaluation** and a **budget impact analysis**. The HTA report investigates the following components:

» the added value of the medicine compared to equivalent alternatives (a cost-effectiveness analysis),
» the place of the medicine in the treatment of the indication as indicated in the IPT,
» the price requested by the MAH and the prices in other countries,
» the estimated manufacturing costs and
» the estimated budget.

Thus, the pharmaceutical pricing policy framework for new medicines is one that considers **value elements** (however, ➲ value-based pricing is no primary pricing policy).

The prices of the respective medicine in other countries are taken into consideration as complementary pieces of information to inform the price negotiations. In Spain, ➲ external price referencing (EPR) is applied as a supplementary pricing policy, in order to have a benchmark price as one component in the decision-making. EPR is applied on a case by case basis, and it is mainly used for new medicines, with no therapeutic equivalent. Spain considers the prices of 14 European countries (Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Slovenia, Sweden, Slovakia and UK). The Spanish price should not be higher than the lowest price of that medicine in the reference countries.

Similarly, information on **estimated manufacturing costs** that marketing authorization holders are requested to report in the pricing and reimbursement dossier serves as additional information. However, this approach does not qualify to be considered as a ➲ cost-plus pricing policy. Information on research and development (R&D) costs is also used as background information.

For new, high-priced medicines, ➲ **managed-entry agreements** can be concluded between the MAH and the MoH (see "Agreements").

Based on Royal Decree Law 8/2020 enacted in response to the global financial crisis (cf. chapter 1), Spain has been applying a **mandatory** ➲ **discount** (➲ claw-back) system applicable to all medicines sold to the SNS (both outpatient and inpatient sectors) that are not included in the reference price system, i.e. medicines without identical alternatives already marketed. The discounts amount to:

» 7.5% for new medicines,
» 4% for orphan medicines and
» 15% for medicines older than 10 years in the market and without a ➲ generic or ➲ biosimilar medicine.

These discounts of 7.5%, and 4% respectively, are charged to the pharmacy retail price but they equally impact the ➲ wholesale price and the ex-factory price.

Prices of generic and biosimilar medicines are linked to the prices of the originator and reference medicine (➲ **price link policy**). In addition, **prices of the originator and reference medicines** have to be reduced at the market entry of the first generic or biosimilar medicine, respectively.

When a generic first enters the market, its price must be 40% lower than the one of the originator medicine. As soon as a "homogeneous group" (i.e. a reference group that contains medicines of the same active ingredient, same dosage and pharmaceutical form) has been established, the price of the generic has to be lowered to the price of the (lowest) generic in that group. If its price is not reduced, the medicine will be substituted by the lowest priced generic when the pharmacist fills the prescription (see also the ➲ reference price system in the section "demand-side measures" in chapter 3).

For biological medicines, the price link is less explicit. Biosimilar medicines tend to be priced around 30% lower than the reference product. However, that price link is not mandatory, and it is decided on a case by case basis.

Procurement

Royal Decree-Law 8/2010 allowed **centralised** ➲ **procurement** of medicines (and medical devices) for use in the SNS. This is done by the *Instituto Nacional de Gestión Sanitaria (INGESA)* under the MoH, which functions as the national procurement agency and performs framework agreements and further procurement procedures at national level.

The MoH is in charge of performing ➲ **tendering** **for hospital-only medicines**. Regions can join in on a voluntary basis and they did so in the case of epoetins and monoclonal antibodies.

Otherwise, **hospitals procure** medicines on their own. Medicines of high budget impact are **purchased jointly** by the hospitals of the same region. For these regional procurement activities, regional procurement committees have been established, and all hospitals that are members of the joint purchasing group have to use the medicine which wins the tender. Key actors on behalf of the purchasing body are the purchasing committee (at hospital or regional levels), the hospital pharmacy, the main doctor in the field and hospital administration. Key **criteria** for awarding are the lowest price or the Most Economically Advantageous Tender (MEAT) which allows considering further award criteria [12].

A common procurement model in the outpatient sector is direct acquisition from pharmaceutical companies by pharmacies. Some pharmacies have been joining groups called "procurement centres" that had solely been created to strengthen purchasing power [12].

In the **outpatient** sector, some **regions apply tendering-like systems**. For instance, the region of **Andalusia** introduced an auction-like system for procuring off-patent medicines in the outpatient sector. The (maximum) prices are still set by the CIPM, but the tender with lowest price will be selected for inclusion in the SNS [13].

Pricing in the supply chain

Spain applies **statutory regressive** ➲ margin **schemes** to regulate the pharmacy purchase prices (**wholesale prices**) [14] and **pharmacy retail prices** [15] (for details see Annex 2). The wholesale and pharmacy margin schemes are applicable to all medicines used in the outpatient sector, independently of whether, or not, they are included in the SNS.

In addition, a **claw-back system** is in place **for** ➲ community pharmacies which have to provide payments to the SNS based on their annual sales of SNS medicines at ex-factory price level [14].

For medicines used in hospitals, prices are set at the ex-factory price level; no ➲ mark-ups are applied.

The value-added tax (**VAT**) is 4% while the VAT on health products (medical devices) is 10% and the standard VAT is 21%.

3 Reimbursement

Given the combined administrative procedure on pricing and reimbursement, the **same entities as for pricing** play a role with regard to reimbursement decisions in outpatient and inpatient sectors: the MoH, with its technical unit of Directorate General for Common NHS Services Portfolio and Pharmacy, the Inter-Ministerial Pricing and Reimbursement Committee CIPM, the Medicines Agency AEMPS to provide a clinical assessment, the regions and possibly regional HTA institutions. The regions are payers of reimbursable (i.e. publicly funded medicines), and they may impose restrictions on reimbursed medicines.

Reimbursement for outpatient medicines

With regard to ➲ reimbursement lists, Spain applies a combination of a **positive** list (i.e. a list of medicines eligible for reimbursement) **and negative list** (i.e. medicines that are excluded from public funding). The decision on the inclusion into reimbursement is based on an **HTA** provided by the MoH. The HTA is also informed by a clinical assessment performed by AEMPS (for details see chapter 2).

Reimbursable medicines for outpatient use are usually not fully covered by the SNS. Patients have to co-pay defined shares (**percentage** ➲ co-payments), whose extent is usually linked to their socio-economic status:

» **Active working population** have to co-pay **40%, 50% or 60%** of the pharmacy retail price gross, depending on the income (yearly income of < € 18,000; € 18,000 – € 100,000 and > € 100,000, respectively);

» **Retired people** have to co-pay **10%** of the pharmacy retail price with a ceiling of € 8.23 per month (yearly income of < € 18,000), of 10% of the pharmacy retail price with a ceiling of € 18.52 per month (yearly income of € 18,000 – € 100,000) **or 60%** of the pharmacy retail price with a ceiling of € 61.75 per month (yearly income of > € 100,000).

For **medicines to treat chronic diseases**, the co-payment always amounts to **10%** of the pharmacy retail price, with a ceiling of € 4.24 (no income criteria are applicable).

No further co-payments (e.g. a prescription fee or deductible) are charged. In addition, no co-payments are applicable under the reference price system since the patient must use the lowest-priced medicine dispensed by the pharmacist (mandatory ➲ generic substitution).

Some socio-economic groups (i.e. low-income pensioners, long-term unemployed without unemployment benefits, people with work accidents and occupational diseases) are **exempt** from any co-payments.

Reimbursement for inpatient medicines

In addition to the national positive and negative lists, which are also applicable for medicines used in inpatient care, separate hospital pharmaceutical formularies (HPF) are in place. There are individual HPF per hospital and joint HPF in some regions. There is no national HPF.

The decision on the inclusion of a medicine into a HPF is taken at hospital level by its Pharmaceutical and Therapeutic Committee (PTC) which is responsible for setting, developing and updating the HPF. The PTC is a multidisciplinary team composed of pharmacists, physicians and nurses. The PTC decides on the inclusion of a new medicine in the HPF following on an application by a doctor which should include information on efficacy, safety and expected expenditure. The hospital pharmacy reviews the evidence and drafts a review report (i.e. a kind of a "clinical HTA"), which informs the decision on a possible inclusion of the medicine in the HPF. These reports are based on reporting guidelines developed by the GENESIS (Grupo de Evaluación de Novedades,

EStandarización e Investigación en Selección de Medicamentos) working group of the Spanish Society of Hospital Pharmacy [16].

Medicines included in a HPF are administered to the inpatients **without any co-payments**. They are paid by the hospitals out of their hospital budgets, and thus fully funded by the respective regions.

Agreements

Since 2012, **managed-entry agreements (MEA)** between industry and payers have been concluded for new high-priced medicines in outpatient and inpatient sectors. They include financially-based MEA (flat discounts) as well as performance-based MEA.

Demand-side measures

Since 1996, Spain has had a ➲ reference price system. It includes medicines with therapeutic equivalent (e.g. a generic or biosimilar medicine or a non-generic medicine that was approved in the EU more than ten years ago). In the reference price system, medicines are clustered at **active substance** level (i.e. a reference group contains medicines of the same active ingredient and also the same route of administration). The reference price is determined based on the **lowest-priced** medicine (i.e. expressed in lowest daily treatment costs per defined daily doses / DDD) per cluster [9]. The Directorate General for Common NHS Services Portfolio and Pharmacy of the MoH is in charge of establishing the reference groups and determining the references prices. The latter are annually updated by a ministerial order.

➲ **INN** (International Non-Proprietary Name) **prescribing** is **mandatory**, including for biological medicines, for acute care and the first prescription for chronic treatment, corresponding to the initiation of the first treatment. For chronic care whose prescription corresponds to the continuity of treatment, it is allowed to prescribe by trade name, as long as it is included in the reference price system or is the one with the lowest price within its reference group. Prescription by trade name is also possible for non-substitutable medicines and as long as the principle of "greater efficiency" is respected.

Generic substitution at community pharmacy level is **mandatory**. Patients are always dispensed the lowest-priced alternative medicine even if they insist on a specific brand (included in in the same reference price group) and would be willing to pay out-of-pocket the price difference. **Biosimilar substitution** is **not allowed**. In contrast to substitution (i.e. at the community pharmacy level), switching (from the reference medicine to a biosimilar, and between biosimilar medicines) by a doctor is possible.

4 Developments

Spain undertook a lot of reforms (mainly cost-containment measures) in the pharmaceutical sector in response to the global financial crisis. In June 2014, Spain joined the Joint Procurement Agreement of the European Union to jointly procure medical countermeasures [17]. Spain was one of the signatory countries of the cross-country collaboration "Valletta Declaration", established in

May 2017 (today 10 member countries, mainly from Southern Europe). The "Valletta Declaration" aims to improve access to medicines, through collaboration in HTA and joint procurement, for instance [18].

The Order of 27 November 2020 [19] changed the methodology for building reference groups in the reference price system (from ATC-5 to active substances), and the review of the reference price system is expected to lead to lower prices and savings for the SNS and patients [20].

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Data provision

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6 Annex

Annex 1: Stakeholders

Role	Names in Spanish and English	Website(s)
Competent authority for marketing authorisation of medicines	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (Agency of Medicines and Medical Devices (	https://www.aemps.gob.es
Competent authority for pricing and reimbursement of outpatient and inpatient medicines	Ministerio de Sanidad / Ministry of Health Comisión Interministerial de Precios de los Medicamentos (CIPM) / Inter-Ministerial Pricing and Reimbursement Committee	https://www.mscbs.gob.es/sanidad/portada/home.htm https://www.mscbs.gob.es/profesionales/farmacia/CIPMyPS.htm
Public payers for outpatient and inpatient medicines	Comunidades Autónomas / Autonomous Communities (regions)	-
Patients organisations	Plataforma de asociaciones de pacientes/ Patients Associations Platform	www.plataformadepacientes.org
Consumers organisations	Organización de Consumidores y Usuarios (OCU)/ Organisation for Consumers and Users Consumidores en Acción (FACUA)/ Consumers in Action	www.ocu.org www.facua.org
Pharmacy associations	Consejo General de Colegios Farmaceuticos Farmaceuticos	https://www.portalfarma.com
Industry associations	Farmaindustria / National Pharmaceutical Industry Assocation	https://www.farmaindustria.es
Wholesale association	Federación de Distribuidores Farmacéuticos (FEDIFAR) / National Federation of Wholesalers	http://fedifar.net

Source: surveyed by the author

Annex 2: Regulation of wholesale and pharmacy remuneration (2020)

Wholesale remuneration scheme

Ex-factory price	Wholesale margin
Lower than or equal € 91.63	7.6% of the pharmacy purchase price
Above € 91.63	€ 7.54 (per pack)

Applicable to all medicines

Source: Decreto 823/2008, de 16 de mayo, por el que se establecen los márgenes, deducciones y descuentos correspondientes a la distribución y dispensación de medicamentos de uso humano [14]

Pharmacy remuneration scheme

Ex-factory price	Pharmacy margin
Lower than or equal € 91.63	27.9% of the pharmacy retail price
Above € 91.63 and lower than or equal € 200.-	€ 38.37 (per pack)
Above € 200.- and lower than or equal € 500.-	€ 43.37 (per pack)
Above € 500.-	€ 48.37 (per pack)

Applicable to all medicines

Source: Royal Decree-Law 4/2010 [15]

Annex 3: Glossary

biosimilar	A biological medicine that is developed to be similar to an existing biological medicine (the "reference medicine"). Biosimilar medicines can only be marketed following the patent expiry of the reference medicine.
claw-back	A policy where funds already paid by public payers to pharmaceutical companies, wholesalers or pharmacists have to be paid back to the third party payers under certain conditions (e.g. if a certain threshold is exceeded).
community pharmacies	Health care facilities which dispense medicines (prescription-only medicines and/or non-prescription medicines, reimbursable and/or non-reimbursable medicines) to outpatients.
co-payment	Insured patient's contribution towards the cost of a medical service covered by the health insurance. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
cost-plus pricing	Pricing policy that determines a medicine price by taking into account production costs, promotional expenses, research & development, administration costs, overheads and a profit that is considered 'reasonable'.
discount	A price reduction granted to specified purchasers under specific conditions prior to purchase.
external price referencing	The practice of using the price(s) of a medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
free pricing	Pricing policy, in which governments allow pharmaceutical companies to determine the price of the medicine they launch.
generic	A medicine which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicine, and whose bioequivalence with the reference medicine has been demonstrated by appropriate bioavailability studies.
generic substitution	Practice of substituting a medicine, whether marketed under a trade name or generic name (branded or unbranded generic), with a less expensive medicine (e.g. branded or unbranded generic), often containing the same active ingredient(s).
Health Technology Assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
INN prescribing	Requirements for prescribers (e.g. physicians) to prescribe a medicine by its International Non-Proprietary Name (INN), i.e. the active ingredient name instead of the trade name.

managed-entry agreement (MEA)	An arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms and are usually classified into financially-based and performance-based MEA.
margin	Percentage of the selling price that is profit. In the case of the pharmaceutical distribution, a wholesale or pharmacy margin is price-dependant type of remuneration awarded to distribution actors such as wholesalers and pharmacies for handling their services.
marketing authorisation	A licence issued by a medicines agency approving a medicine for market use based on a determination by authorities that the medicine meets the requirements of quality, safety and efficacy for human use in therapeutic treatment.
mark-up	Percentage of the purchasing price added on to get the selling price.
price link policy	Practice of setting the price of a medicine (e.g. a generic or a biosimilar) in relationship to the price of another medicine (e.g. originator, biological reference medicine), usually at a certain percentage lower.
pricing (price setting)	Act of determining the medicine price which is either taken by a pharmaceutical company (free pricing) or is the competence (responsibility) of a competent authority (price control).
price negotiation	A pricing procedure, in which medicine prices are discussed and agreed (e.g. between manufacturer and third party payer).
price regulation (price control)	Pricing policies where government authorities set the price of a medicine and/or indirectly influence it (e.g. statutory pricing, price negotiations, public procurement).
procurement	A process to purchase goods and services (e.g. medicines) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
reference price system	A reimbursement policy in which identical medicines (ATC 5 level) or therapeutically similar medicines (ATC 4 level) are clustered (reference group). The third party payer funds a maximum amount (= reference price), while the patient must pay the difference between the reference price and the actual pharmacy retail price of the medicine, in addition to any co-payments.
reimbursable medicines	Medicines which are eligible for reimbursement. Expenses of reimbursable medicines may be fully covered by third party payers, or only partially (a specific percentage).
reimbursement	Coverage of the expenditure by a third party payer (e.g. social health insurance/National Health Service).
reimbursement list	A list that contains medicines with regard to their reimbursement status. It may either include medicines eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).

tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.
value-based pricing	Policy of authorities to set the prices of a new medicine and/or decide on reimbursement based on the therapeutic value that a medicine offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly based on a value assessment.
wholesale	All activities consisting of procuring, holding, supplying or exporting medicines, apart from supplying medicines to the public.

Source: Glossary of Pharmaceutical Terms of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies [21]