

The Fenin logo consists of a teal circle containing the word "Fenin" in white, sans-serif font. It is positioned in the upper left quadrant of the slide, overlapping a large, light teal circular graphic that features a gradient from light to dark teal and a dark blue circular element at the bottom.

Fenin

SPANISH HEALTHCARE MARKET

June 2026

WEBINAR FENIN-MEDTECH EUROPE



FENIN

Spanish Federation of
Healthcare
Technology
Companies





What we do?

We represent the interests of companies that **manufacture, import, and distribute medical devices** that improve the **prevention, diagnosis, treatment, and monitoring of diseases.**

Our **purpose as a sector**

To improve people's health and quality of life by **helping healthcare institutions provide** healthcare professionals and patients with **innovative medical technology** in the most efficient way



Fenin is member of:

Nacional Associations



Europeas Associations





300 companies associates & 50 startups

Large enterprises

20%

COMPANY PROFILE

- National and international firms
- Manufacturers and distributors
- Dynamic and innovative
- Wide variety of products
- Products with high distribution costs
- Highly qualified professionals
- Heavily regulated



SME

80%

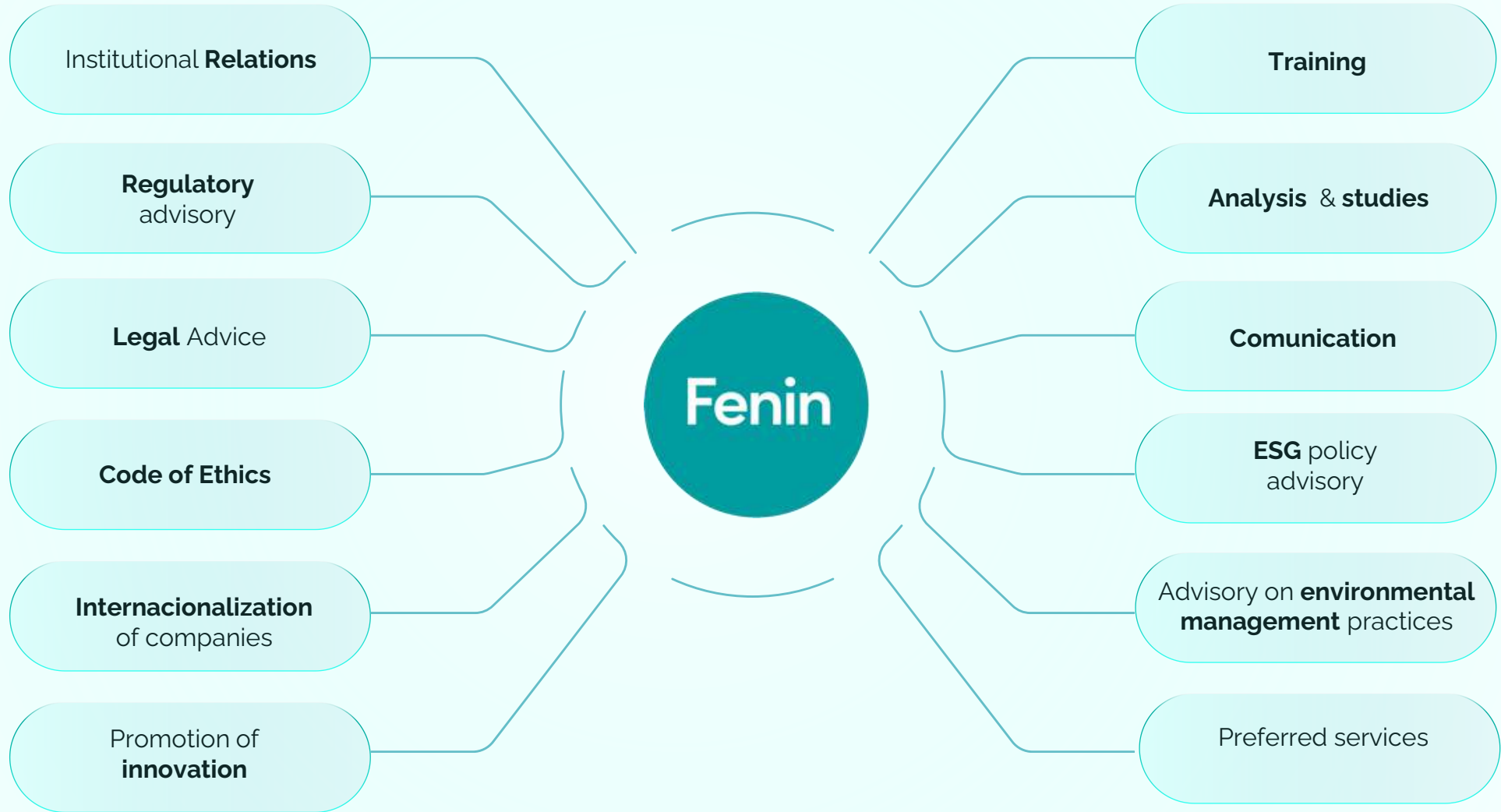
Manufacturers

39%

Startups

+50

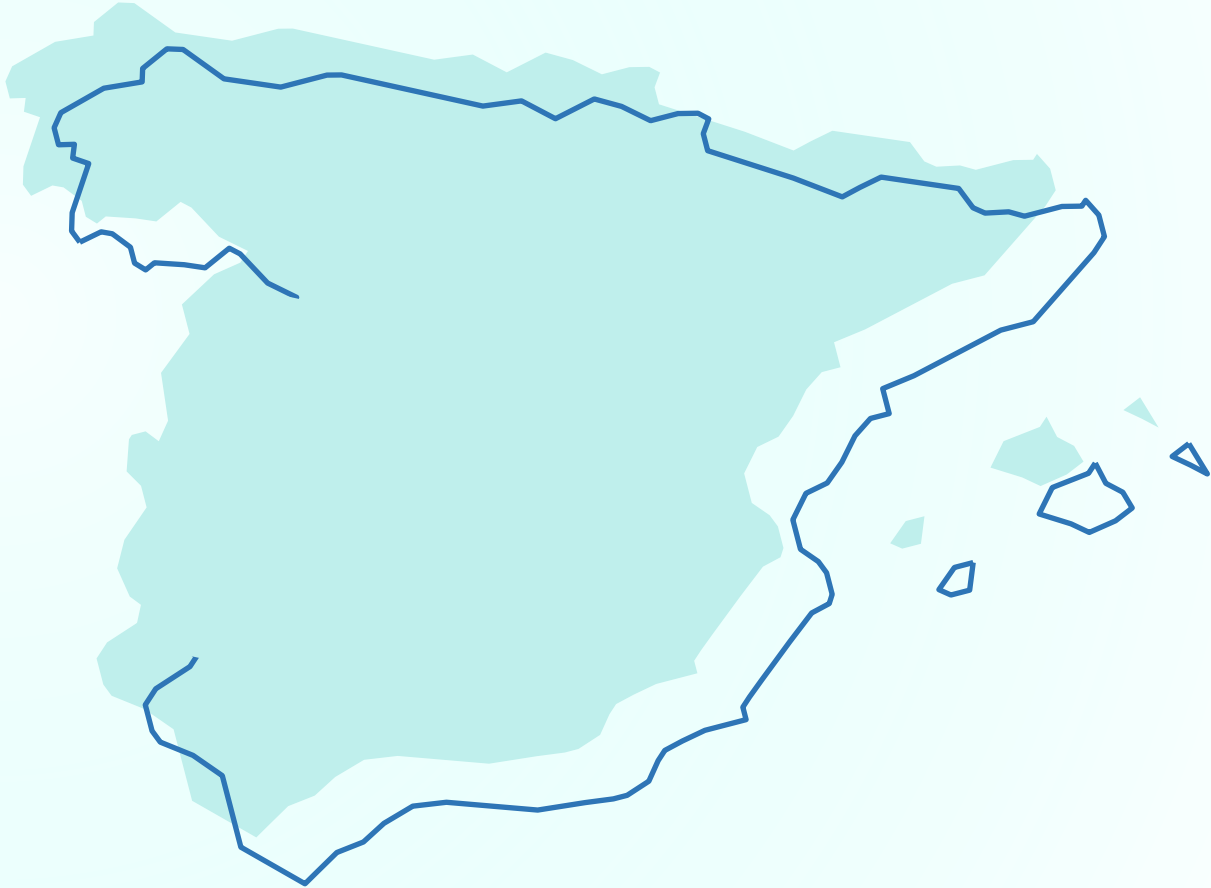
Our Services





SPAIN

at a glance



€ Modern and mature economy

- 5th economy of Europe
- Diverse economy



Working population: 23 million people

- High unemployment: 11%-13%



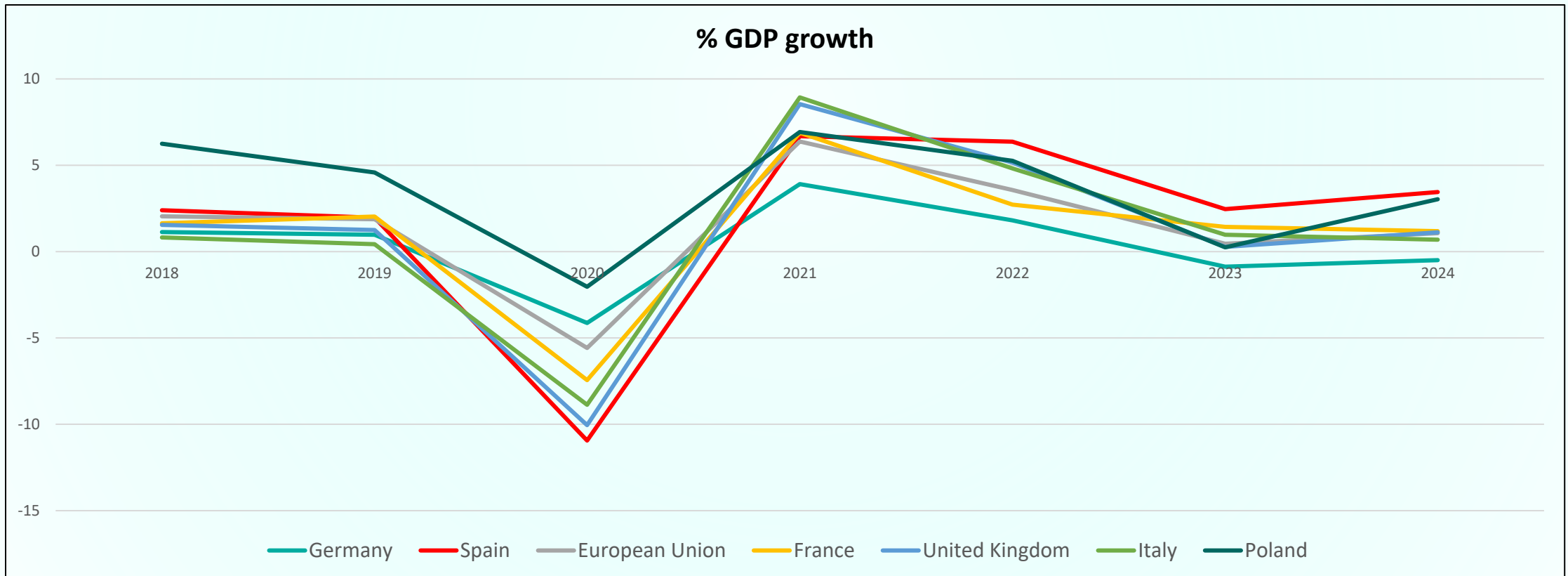
Modern infrastructure

- Transport infrastructure is one of the most developed in the world



Developed Health (eco)system

- Modern public health system
- universal coverage for all legal residents
- Wide range of services





Spanish Healthcare Technology Sector



Spanish Healthcare Technology sector in figures

5th market in Europe

Number of companies in Spain

933

Companies

Manufacturers

362

Companies

Revenue

17.700

Millions of euros

Exports

4.995

Millions of euros

+7%

Over Healthcare expenditure

8'7%

over total healthcare expenditure in 2024

Over GDP

1'11%

Direct Added Value

6.000

Millions of euros



Impact of the sector

Healthcare Technology in the labour market

Social Commitment



96%
permanent
employment (+10 pp. vs
total economy)



60.000 €
Total Investment
by employee (+30.000€
vs total economy)



3%
disability-inclusive
employment
(+0,3 pp. vs total
economy)



46%
female employment
(-1 pp. vs total economy)



23%
women on governing
bodies
(-12 pp. vs total economy)

Employment generator



55.600
Direct Employment



86.000
Indirect & induced
employment

Innovation Leader



264 M€
Expenditure in R+D+i



28%
of firms
invest in R+D+i



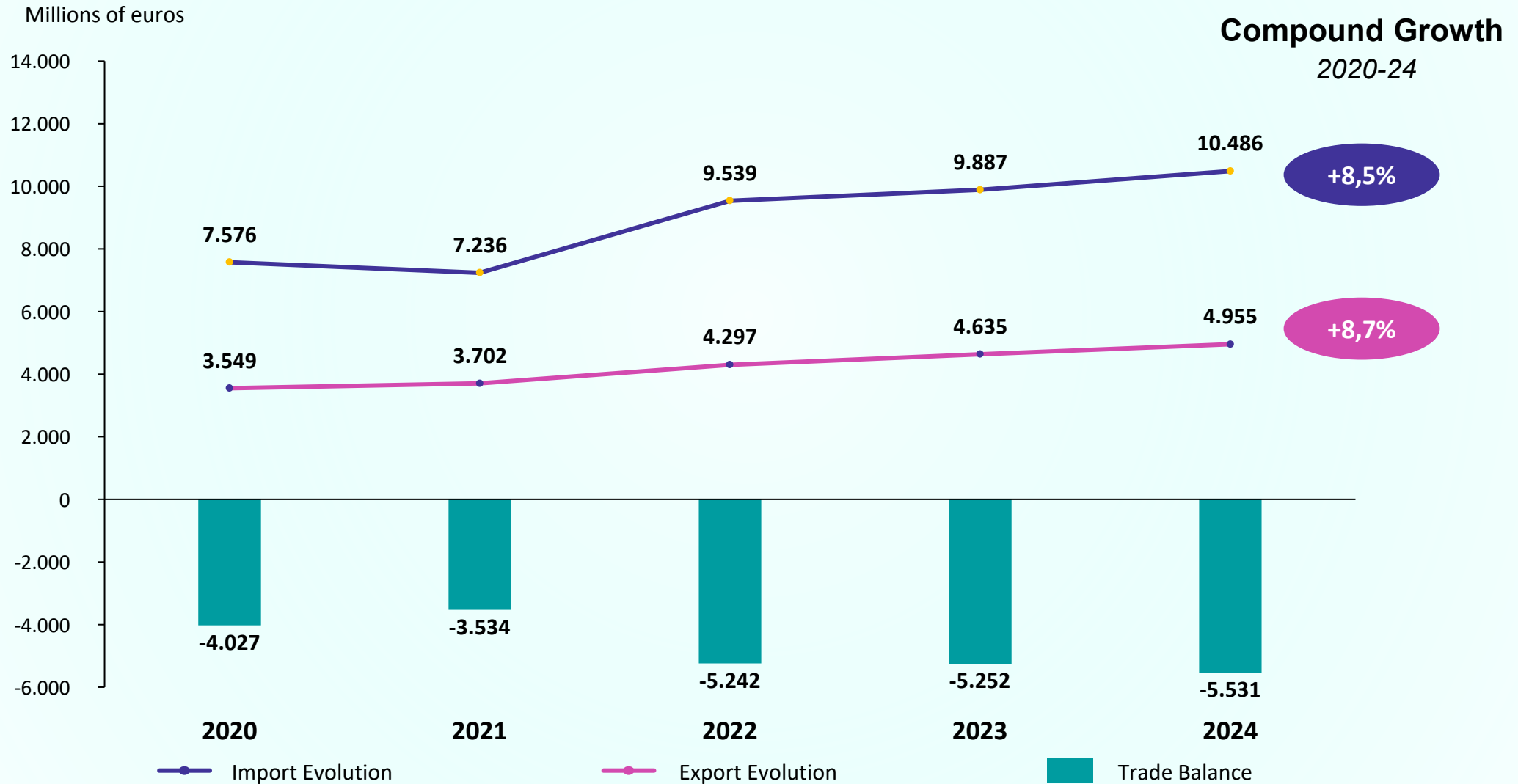
163
European patents
de Spanish origin
(+14% vs 2022)



**2º campo
técnico**
by number of
european patents



Trend in imports, exports, and trade balance of the healthcare technology sector in Spain, 2020–2024





Impact of healthcare technology manufacturers in Spain

(2024 Data only for manufacturers)

Driver of the economy



362
manufacturers
(92% are SMEs)



4.980M€
revenue



1.681M€
Direct added value



6.500M€
de valor añadido indirecto e inducido



+170
factories



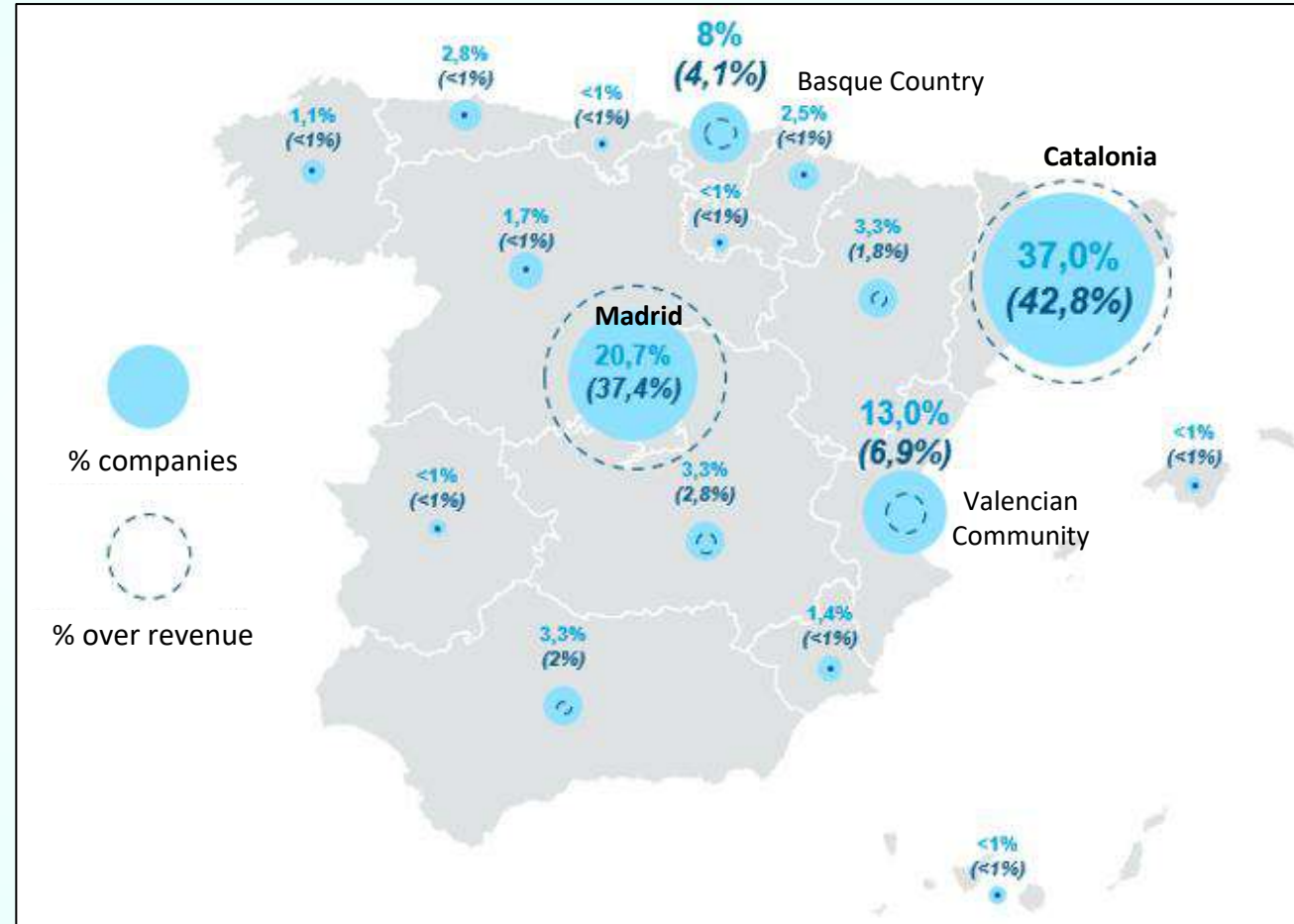
19.377
direct employment



60%
Open to industrially invest



57%
Collaborated in R+D projects



Source: Data for 2023



MONITOR FENIN

OVERVIEW AND TRENDS

of the Spanish healthcare system

OVERVIEW AND TRENDS

of the Spanish healthcare system

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1 Main figures of the National Health System

- Population and state of health
- Healthcare
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- Health spending
- Health expenditure on medical devices
- Trends in the expenditure on medical devices (without prescription or dispensing order)
- Variation in expenditure on medical devices and GDP (%)
- Expenditure on medical devices included in the Pharmaceutical Benefit 2025

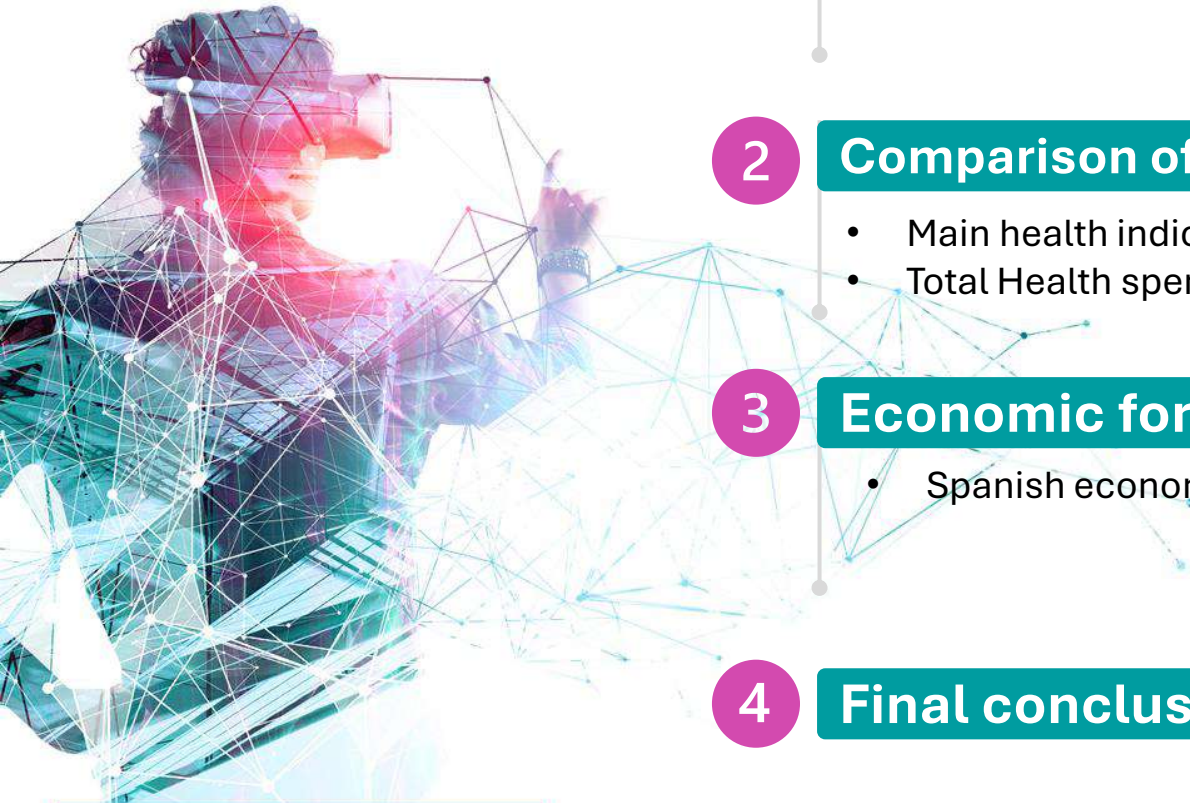
2 Comparison of the Healthcare System with the OECD figures

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Main figures of the National Health System

- Population and state of health
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Population and state of health



Inhabitants

49 millions
 21% are over the age of 65
 84 years is the life expectancy of a person born today
 80 years living in good health



State of health

7 out of 10 people think they are in good health

Obesity



15% in adults
 7% in children



Births

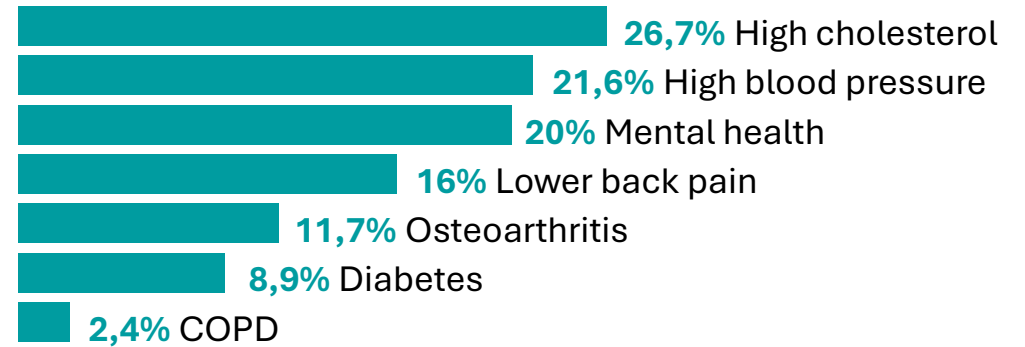
▶ 320.656



Deaths

▶ 436.124

Main chronic health problems



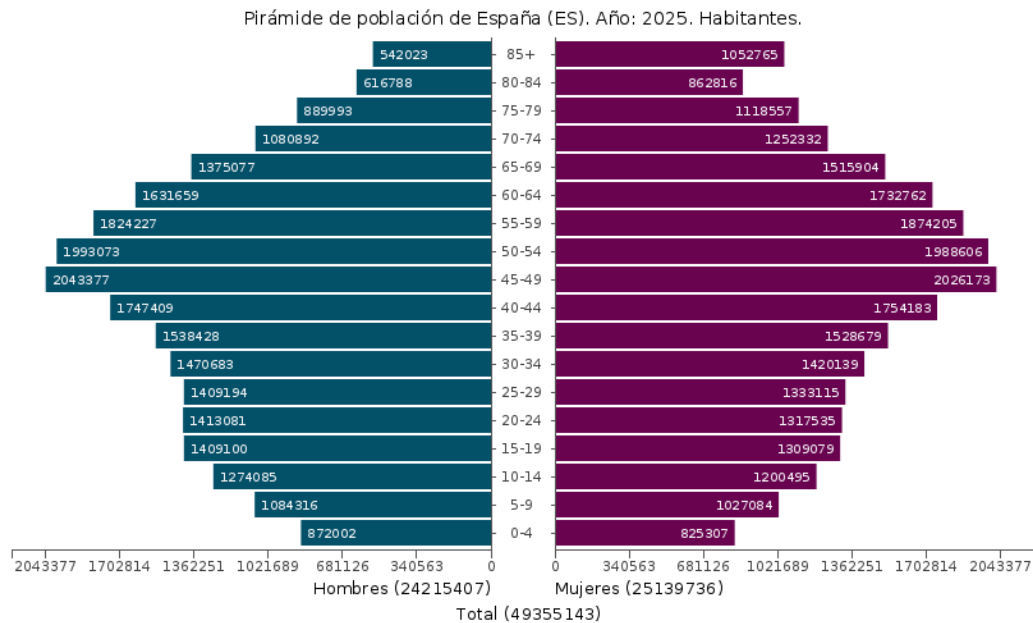
Main causes of death from cardiovascular diseases, tumors and respiratory diseases: porcentaje (%) of total deaths for each group. 2023

		Total	Hombres	Mujeres
Enfermedades cardiovasculares	Enfermedad isquémica del corazón	23,9	31,5	17,0
	Enfermedad cerebrovascular	20,2	18,9	21,4
Tumores malignos	Tumor maligno de pulmón	20,5	25,1	13,8
	Tumor maligno de colon y recto	13,4	13,4	13,5
	Tumor maligno de mama en la mujer	5,8	-	14,2
	Tumor maligno de próstata	5,4	9,0	-
Enfermedades respiratorias	Enfermedad pulmonar obstructiva crónica	27,1	34,6	18,0
	Neumonía e influenza	25,3	23,9	27,0

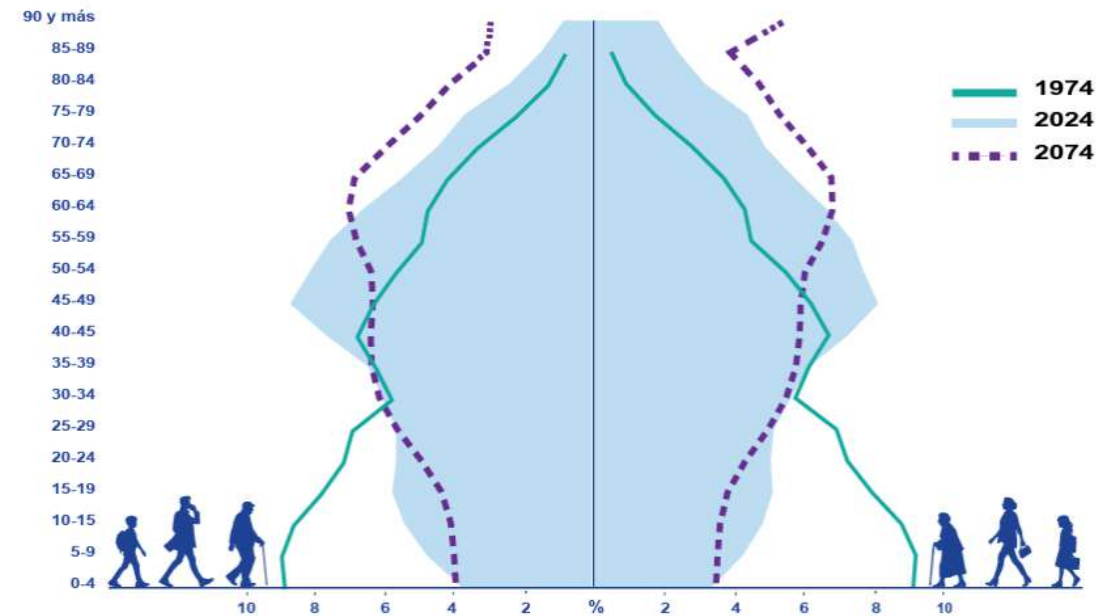
Population and state of health

Spain's population pyramid

Year 2025. Inhabitants



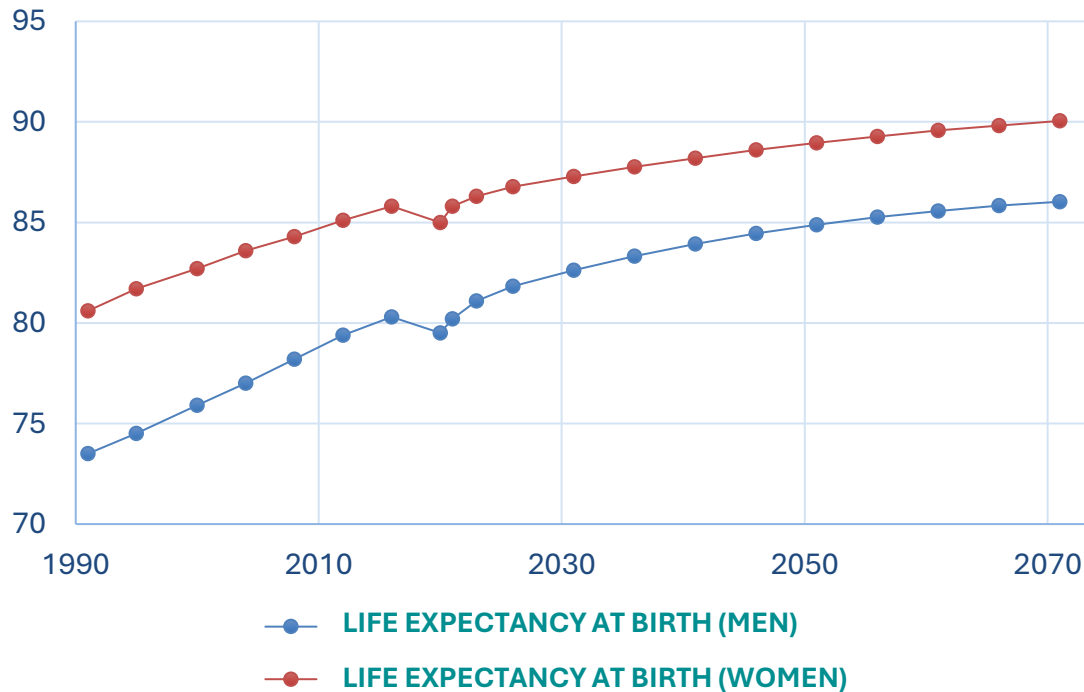
Spain's population pyramid 1974-2074



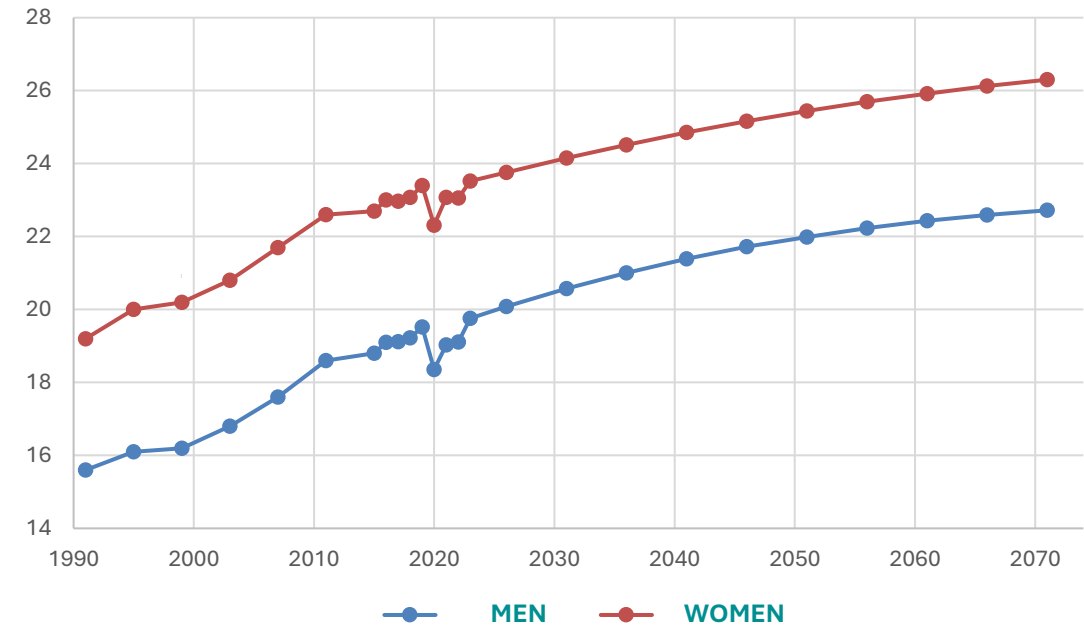
Population and state of health

Observed and projected life expectancy

LIFE EXPECTANCY (1991-2071)



LIFE EXPECTANCY 65 YEAR



According to these INE projections, life expectancy at birth would reach 82.5 years for men and 87.4 years for women, a gain of 1.7 and 1.2 years respectively compared to the current values. In 2073, these values would be 86 years for men and 90 for women.

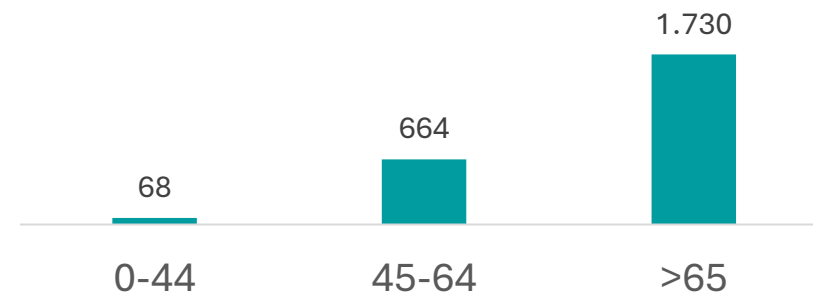
Population and state of health

Cancer figures in Spain (2026 Estimate)

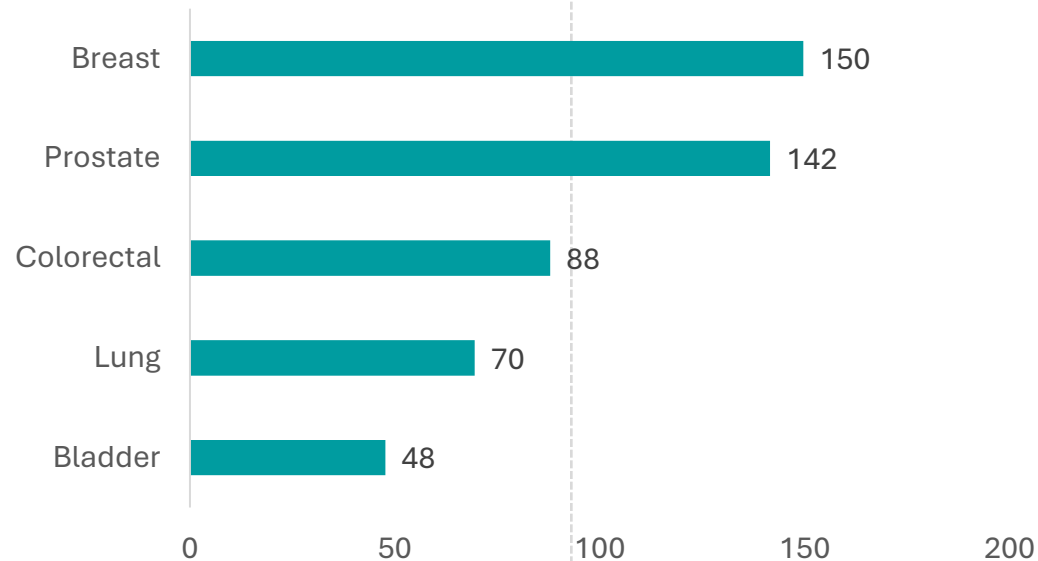
New Cases per 100.000 Inhabitants by Sex



New Cases per 100.000 Inhabitants by Age



New Cases per 100,000 Inhabitants by Cancer Type



Population and state of health

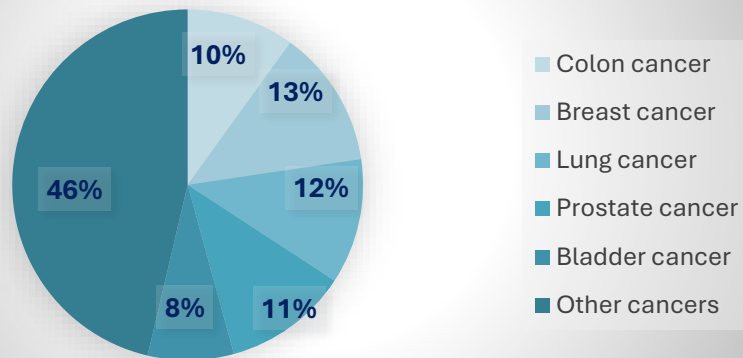
Cancer figures in Spain (New diagnosed cases)

	Year	DIAGNOSED CASES	ANNUAL CHANGE
	2015	258.834	
	2016	262.354	1,40%
	2017	265.918	1,40%
	2018	270.363	1,70%
	2019	276.246	2,20%
	2020	282.421	2,20%
	2021	279.980	-0,90%
	2022	278.729	-0,40%
	2023	284.081	1,90%
	2024	286.664	0,90%
	2025	296.103	3,33%
ESTIMATE	2026	301.884	1,95%
	2040	341.450	

Developments in incidence

Year	Crude rate (new cases por 100.000 inhab.)	Annual change %	Men Crude rate	Annual change %	Women Crude rate	Annual change %	
2015	555	1,60%	649	1,90%	464	1,30%	
2016	564	1,60%	660	1,70%	470	1,30%	
2017	571	1,20%	670	1,50%	475	1,10%	
2018	579	1,40%	681	1,60%	480	1,10%	
2019	587	1,40%	683	1,80%	486	1,30%	
2020	595	1,40%	704	1,60%	491	1%	
2021	591	-0,70%	692	-1,70%	494	0,60%	
2022	587	-0,70%	681	-1,60%	497	0,60%	
2023	591	0,70%	687	0,90%	499	0,40%	
ESTIMATE	2024	588	-0,50%	683	-0,60	506	1,00%
	2025	597	1,50%	533	-22,00%	658	10,00%
	2026	601	0,67%	541	-1,00%	659	0,15%
	2030	663		751		631	
	2040	691		845		691	
	2050	712		877		712	

FIGURES BY TYPE OF CANCER

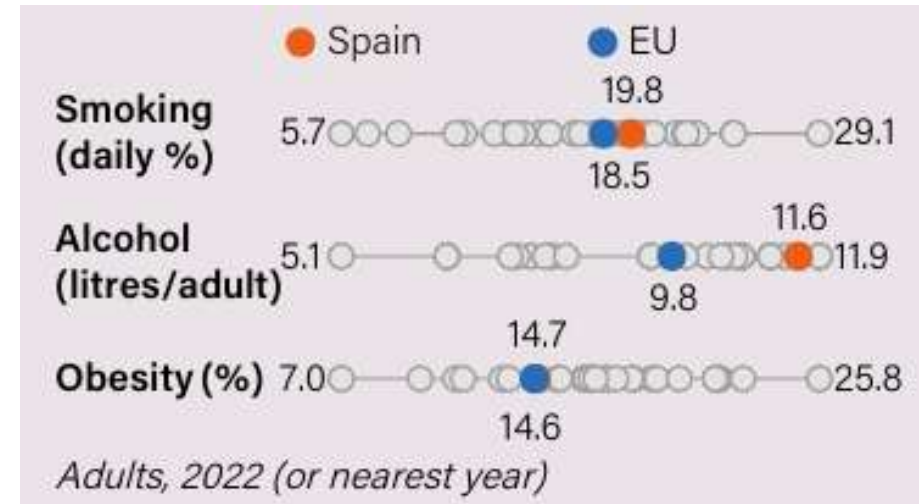


Breast cancer	38.318
Lung cancer	34.908
Prostate cancer	34.833
Colon cancer	30.035
Bladder cancer	23.929
Other cancers	139.861

Population and state of health

! Risk factors. Comparison with the EU figures

- In 2020, the proportion of adults who smoked daily remained higher than in most EU countries, although it has declined steadily since 2000.
- Alcohol consumption has increased since 2010, reaching 11.1 litres per adult in 2023, which is around 10% above the EU average.
- Obesity rates among the adult population have risen only slightly since 2017 and, in 2022, were at levels similar to the European average.

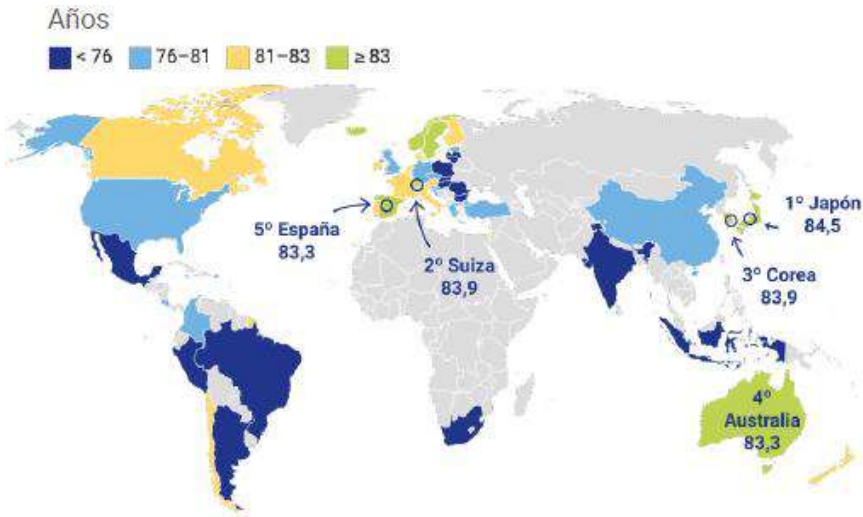


Country Health Profile 2025: Spain

Population and state of health

Some basic health indicators in Spain

Life expectancy at birth

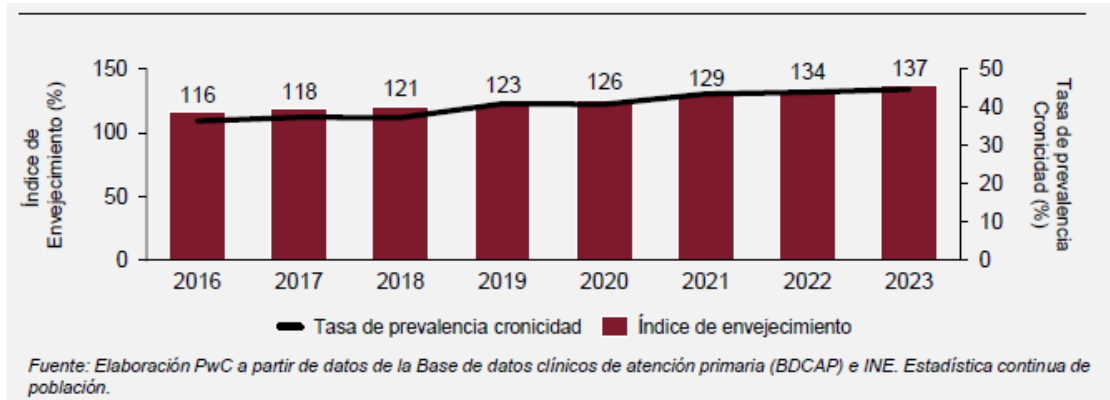


Capacity and resources during 2021

Por c/ 1.000 habitantes

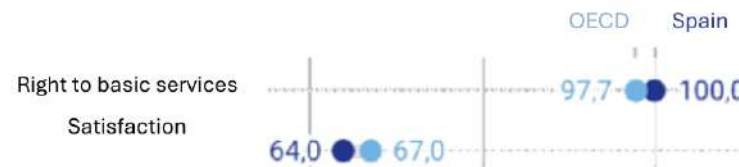


Trends in Chronic Disease Prevalence and the Ageing Index (2016-2023)



Access to healthcare services - Coverage

% population



Service coverage
1.1% of the population indicates that some of their healthcare needs are not covered, compared to the OECD average of 2.3%

Healthcare



476

Hospitals

- 117,000** Beds
- 22,000** Day hospital beds
- 358** Reference centres, services and units
- 47** Hospitals with authorised transplant programmes
- 4 million** Hospital admissions
 - *7,9 days in hospital (global average)*
 - *6,5 days in hospital (global average) for acute cases*
 - *€5.810 average cost of hospital stays*
- 95 million** Appointments
 - *96 days of waiting time before the first appointment*
- 3,9 million** Surgeries (with and without hospital stays)
 - *119 days of average waiting time for non-urgent surgeries*
- 6,335** Transplants
- 26 million** Emergency care visits
- 4.856** Surgical Rooms



Primary healthcare centres

- 3,000** Healthcare centres
- 10,000** Doctor's offices
- 2,000** Outpatient emergency service centres
- 243 million** Doctor's appointments
- 147 million** Nurse's appointments
- 78 million** Video appointments
- 14 million** Home visits
- 36 million** Emergency care visits

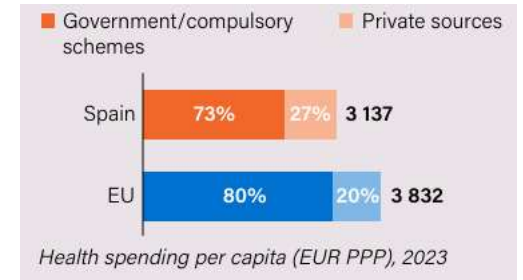


Emergency and urgent care

- 3,000** Ambulances
- 8 million** Requests for assistance
- 600** Ambulances handling 1,000 requests for care

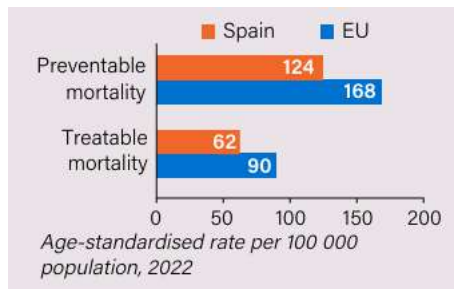
Characteristics of the Health System

- Universal coverage.
- Health spending per capita approximately one-fifth below the EU average.
- Public expenditure as the main source of financing, but in terms of out-of-pocket expenses (21%), it is higher than the EU average (16%).
- Decentralised system with regional jurisdiction in relation to operational planning, allocation of resources and purchase and supply decisions.



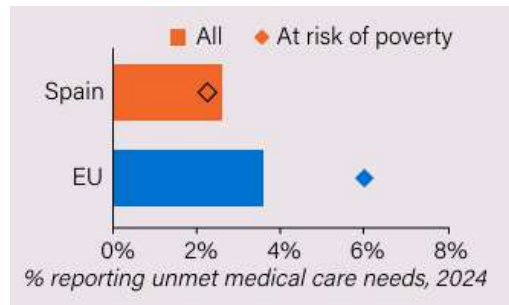
Efficacy

- Low preventable mortality rates.
- A range of policies address risk factors, while screening programs strengthen prevention efforts.
- Low hospitalization rates for heart failure and diabetes reflect the effective performance of primary care and integrated care services.
- Regional inequalities.



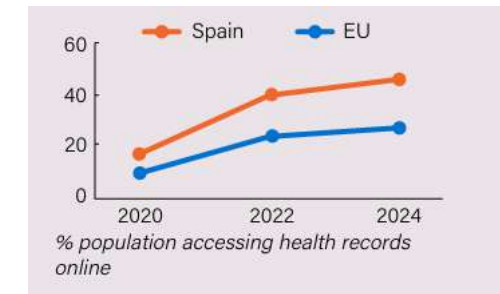
Accessibility

- Good access to healthcare services.
- Healthcare workforce shortages may affect accessibility.
- Expansion of dental health services.
- Waiting lists are the main barrier to accessing healthcare.



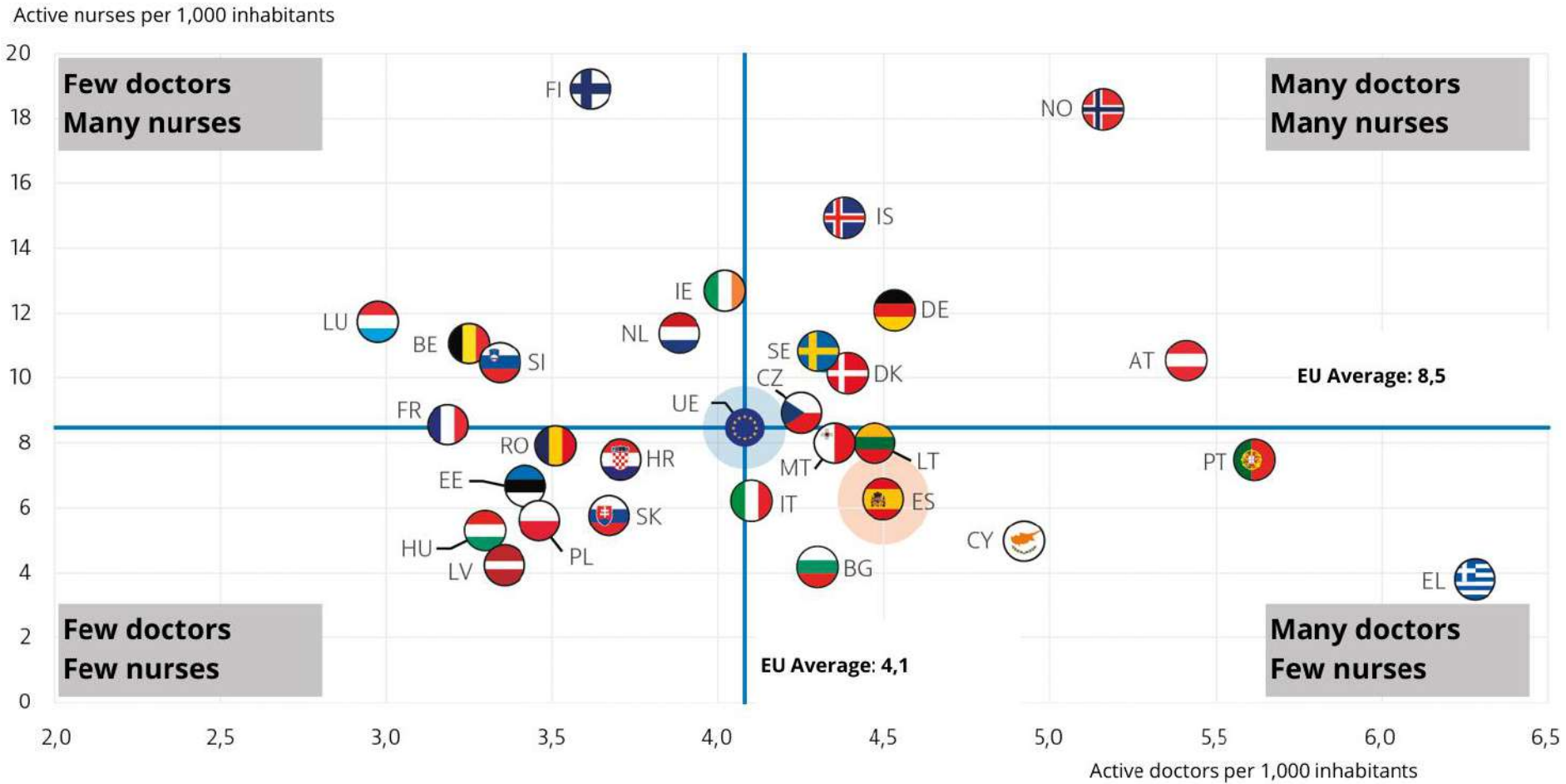
Resilience

- Digitalization is a key element in building a resilient healthcare system.
- Spain has launched strategic digital health initiatives and increased funding in this area.
- A high proportion of the population schedules appointments and accesses medical records online.
- Public healthcare expenditure has increased over time.



Characteristics of the Health System

Spain has more doctors than the EU average, but less nurses



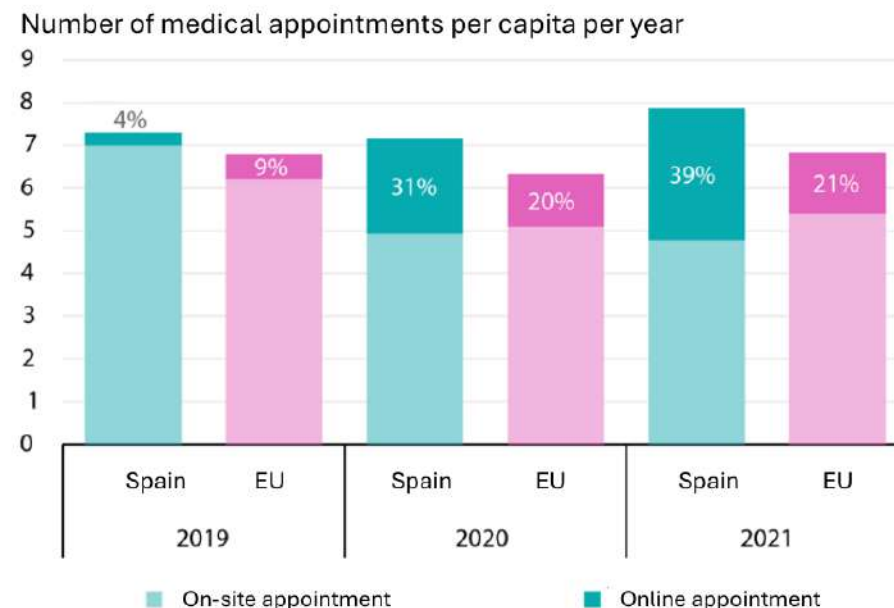
Notes: the EU average is not weighted. Data regarding the number of nurses includes all categories of this profession (not just those that meet the EU Directive on the recognition of professional qualifications). In Portugal and Greece, these figures include all licensed physicians, resulting in an overestimation of the number of active physicians (for example, around 30% in Portugal). In Greece, the calculation of the number of nurses is excessively low, since it only includes those working in hospitals. The number of nurses in Spain does not include assistant nurses, even though they have a similar role to those of nurses in other European countries.

Characteristics of the Health System

The use of digital technologies is more common after the COVID-19 pandemic

- **COVID 19** significantly accelerated the adoption of **telemedicine** as a key tool to ensure continuity of care.
- **Teleconsultations increased from 4% (2019) to 39% (2021)**, consolidating their use beyond the pandemic.
- This shift led, in **December 2021**, to the **launch of the National Digital Health Strategy**, aimed at strengthening the **SNS** through digital technologies.
- By **2025**, the Strategy is in an **advanced stage of implementation**, with **six action plans and €893 million in investment**, focused on interoperability, digital and personalized care, health data, genomics, and primary care.
- The Strategy **has been extended to 2024–2029**, with new programs to **consolidate and scale** digital health, reinforcing **AI**, interoperability, remote monitoring, and alignment with the **EHDS**.

The percentage of video appointments with doctors was almost twice the EU average in 2021.



Healthcare budgets per Autonomous Community. 2025

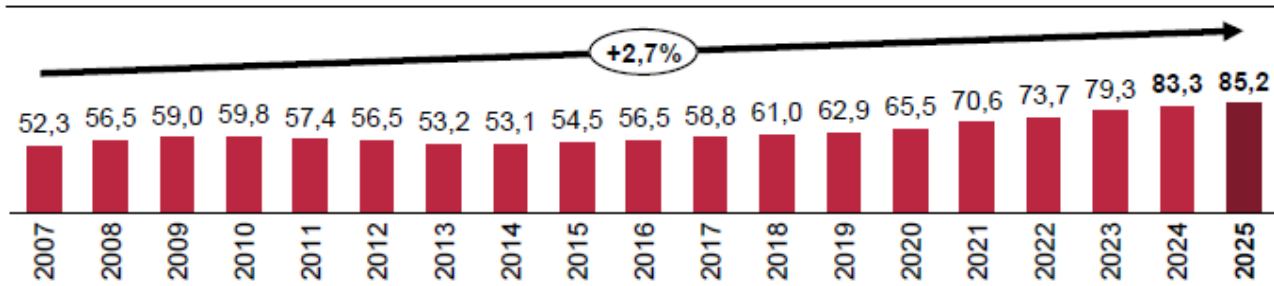
	2018	2019	2020	2021	2022	2023	2024	2025
COMUNIDADES AUTÓNOMAS	61.042.159	62.867.885	65.493.386	70.603.422	73.672.218	79.337.495	83.437.174	85.949.024
Andalucía	9.834.104	10.539.999	11.050.090	11.759.292	12.464.381	13.823.670	14.231.568	15.281.986
Aragón	1.991.285	2.000.557	2.072.958	2.328.735	2.243.830	2.549.043	2.780.150	2.780.150
Asturias (Principado de)	1.682.523	1.765.509	1.829.485	1.968.939	2.022.103	2.158.158	2.345.760	2.470.349
Balears (Illes)	1.584.351	1.730.482	1.730.396	1.935.433	2.029.072	2.222.505	2.331.402	2.482.082
Canarias	2.936.749	3.014.185	3.147.436	3.308.761	3.468.862	3.801.306	4.378.154	4.598.793
Cantabria	854.603	874.228	922.064	996.633	1.028.118	1.087.885	1.149.824	1.222.693
Castilla y León	3.597.144	3.592.949	3.583.993	4.376.339	4.376.339	4.763.575	4.892.524	4.892.523
Castilla-La Mancha	2.806.828	2.806.827	3.023.926	3.715.937	3.660.154	3.678.599	3.912.812	3.767.804
Cataluña	8.876.083	8.876.083	9.789.102	9.789.049	10.687.201	11.708.158	11.708.158	11.708.158
Comunitat Valenciana	6.390.695	6.635.407	6.765.083	7.530.056	7.837.688	8.258.826	8.504.180	8.638.480
Extremadura	1.631.546	1.718.749	1.770.476	1.905.926	2.037.137	2.241.579	2.316.643	2.378.513
Galicia	3.861.434	3.987.978	4.109.640	4.587.712	4.589.358	4.972.964	5.191.549	5.458.253
Madrid (Comunidad de)	7.870.552	8.108.966	8.165.992	8.187.538	8.786.758	9.124.872	10.161.794	10.462.571
Murcia (Región de)	1.861.698	1.919.543	1.922.870	2.187.455	2.212.365	2.336.698	2.508.496	2.503.550
Navarra (Comunidad Foral de)	1.059.988	1.086.649	1.163.219	1.253.822	1.261.404	1.332.763	1.466.157	1.511.159
País Vasco	3.763.542	3.770.794	3.978.458	4.219.379	4.414.504	4.689.612	4.947.248	5.162.494
Rioja (La)	439.037	438.983	468.198	552.416	552.942	587.281	610.754	629.466

Healthcare budgets per Autonomous Community. 2025

	2016/2015	2017/2016	2018/2017	2019/2018	2020/2019	2021/2020	2022/2021	2023/2022	2024/2023	2025/2024
COMUNIDADES AUTÓNOMAS	3,62	4,10	3,81	2,99	4,18	7,80	4,35	7,69	5,17	3,01
Andalucía	4,35	5,66	5,45	7,18	4,84	6,42	6,00	10,91	2,95	7,38
Aragón	12,61	5,33	4,89	0,47	3,62	12,34	-3,65	13,60	9,07	0,00
Asturias (Principado de)	1,80	10,49	-0,04	4,93	3,62	7,62	2,70	6,73	8,69	5,31
Balears (Illes)	5,62	7,21	6,15	9,22	-0,01	11,85	4,84	9,53	4,90	6,46
Canarias	0,37	2,87	8,01	2,64	4,42	5,13	4,84	9,58	15,17	5,04
Cantabria	2,15	2,38	3,60	2,30	5,47	8,09	3,16	5,81	5,69	6,34
Castilla y León	1,00	5,36	3,19	-0,12	-0,25	22,11	0,00	8,85	2,71	0,00
Castilla-La Mancha	8,77	3,54	2,85	0,00	7,73	22,88	-1,50	0,50	6,37	-3,71
Cataluña	-0,16	5,00	0,00	0,00	10,29	0,00	9,18	9,55	0,00	0,00
Comunitat Valenciana	7,58	2,96	5,04	3,83	1,95	11,31	4,09	5,37	2,97	1,58
Extremadura	12,30	-0,71	4,18	5,34	3,01	7,65	6,88	10,04	3,35	2,67
Galicia	3,03	2,86	6,85	3,28	3,05	11,63	0,04	8,36	4,40	5,14
Madrid (Comunidad de)	2,16	2,49	3,08	3,03	0,70	0,26	7,32	3,85	11,36	2,96
Murcia (Región de)	5,94	1,74	4,78	3,11	0,17	13,76	1,14	5,62	7,35	-0,20
Navarra (Comunidad Foral de)	5,89	6,00	1,17	2,52	7,05	7,79	0,60	5,66	10,01	3,07
País Vasco	0,80	3,53	3,94	0,19	5,51	6,06	4,62	6,23	5,49	4,35
Rioja (La)	3,19	2,25	4,04	-0,01	6,66	17,99	0,10	6,21	4,00	3,06

Healthcare budgets per Autonomous Community. 2025

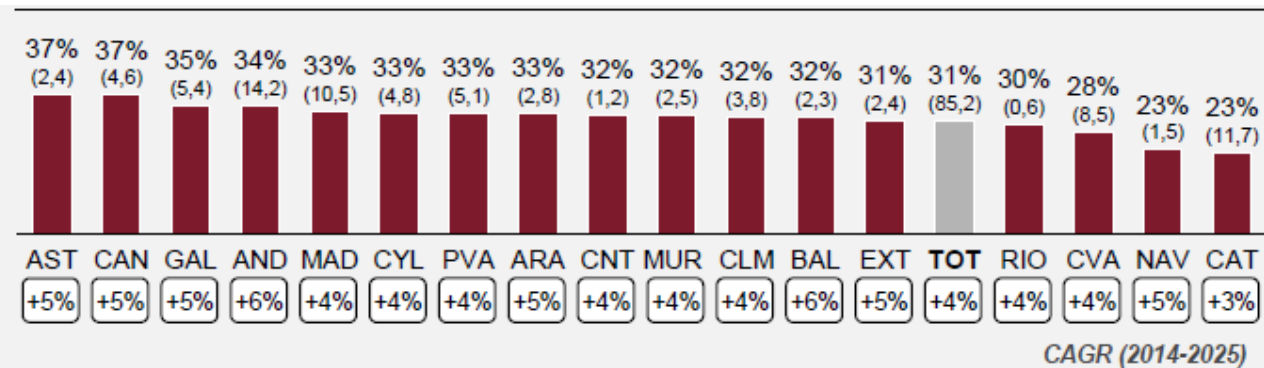
Evolution of initial health budgets per Autonomous Community.
Billions of euros. 2007-2025



Nota: En 2025, se ha cogido el dato de 2024 para aquellas comunidades cuyo presupuesto se prorroga: Aragón, Baleares, Castilla y León, Cataluña, R. de Murcia y Comunidad Valenciana.
Fuente: Ministerio de Sanidad 2024. Recursos económicos del Sistema Nacional de Salud y Ministerio de Hacienda (2024). Proyectos de presupuestos generales de las comunidades autónomas 2025.

The health budget, one of the main management tools of the Autonomous Regions, has exceeded 85,000 M€ in 2025, absorbing 31% of their total budgets.

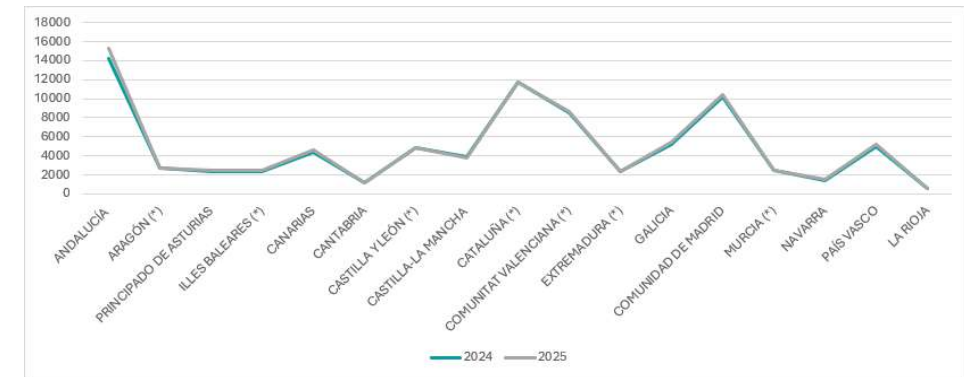
Share of Initial Healthcare Budget in Total Regional Budgets
% of Total Budget (billions euros, current prices), 2025



Nota: En 2025, se ha cogido el dato de 2024 para aquellas comunidades cuyo presupuesto se prorroga: Aragón, Baleares, Castilla y León, Cataluña, R. de Murcia y Comunidad Valenciana.
Fuente: Ministerio de Sanidad 2024. Recursos económicos del Sistema Nacional de Salud y Ministerio de Hacienda (2024). Proyectos de presupuestos generales de las comunidades autónomas 2025.

Healthcare budgets per Autonomous Community. 2025

CC.AA	% Change 2024/2025	2025 Budget	2025 Budget per Capita	% (CP.II+VI) 2025
TOTAL	3,0%	85.949,02	1.757,38	38,62%
ANDALUSIA	7,4%	15.281,99	1.764,02	37,12%
ARAGON (*)	0,0%	2.780,15	2.055,37	33,73%
ASTURIAS	5,3%	2.470,35	2.435,97	36,22%
BALEARIC ISLANDS (*)	6,5%	2.482,08	1.994,61	35,92%
CANARY ISLANDS	5,0%	4.598,79	2.036,47	33,87%
CANTABRIA	6,3%	1.222,69	2.060,53	38,62%
CASTILE & LEÓN (*)	0,0%	4.892,52	2.040,35	33,24%
CASTILE-LA MANCHA	-3,7%	3.767,80	1.777,05	29,25%
CATALONIA (*)	0,0%	11.708,16	1.441,97	60,65%
VALENCIAN COMMUNITY (*)	1,6%	8.638,48	1.595,49	35,92%
EXTREMADURA (*)	2,7%	2.378,51	2.258,80	31,44%
GALICIA	5,1%	5.458,25	2.010,09	38,49%
MADRID COMMUNITY	3,0%	10.462,57	1.468,31	37,32%
MURCIA (*)	-0,2%	2.503,55	1.579,73	17,80%
NAVARRA	3,1%	1.511,16	2.210,83	35,67%
BASQUE COUNTRY	4,4%	5.162,49	2.304,57	35,80%
LA RIOJA	3,1%	629,47	1.924,29	33,11%



DATA: € million

Note: (*) 2024 budgets carried forward

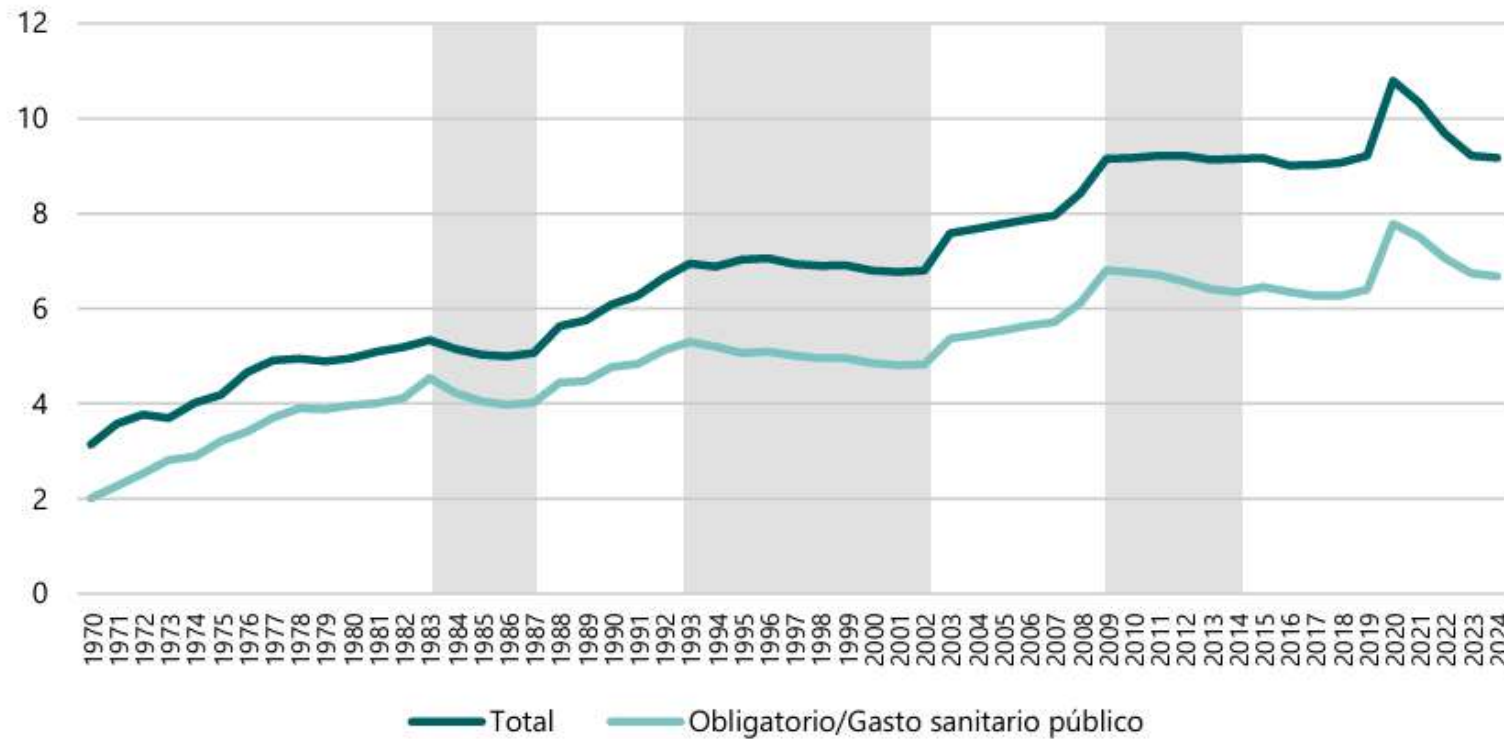
Source: Ministry of Health. Regional budgets (Autonomous Communities).

INE: Municipal Register, January 2025

Ministry of Health Note: As of the publication date (08/07/2025), the Central Government, the Social Security system, and seven autonomous communities (Aragón, Balearic Islands, Castile and León, Catalonia, Valencia, Extremadura, and Murcia) are operating with 2024 budgets carried forward into 2025.

Health spending

Spain, 1970–2024 (% of GDP)

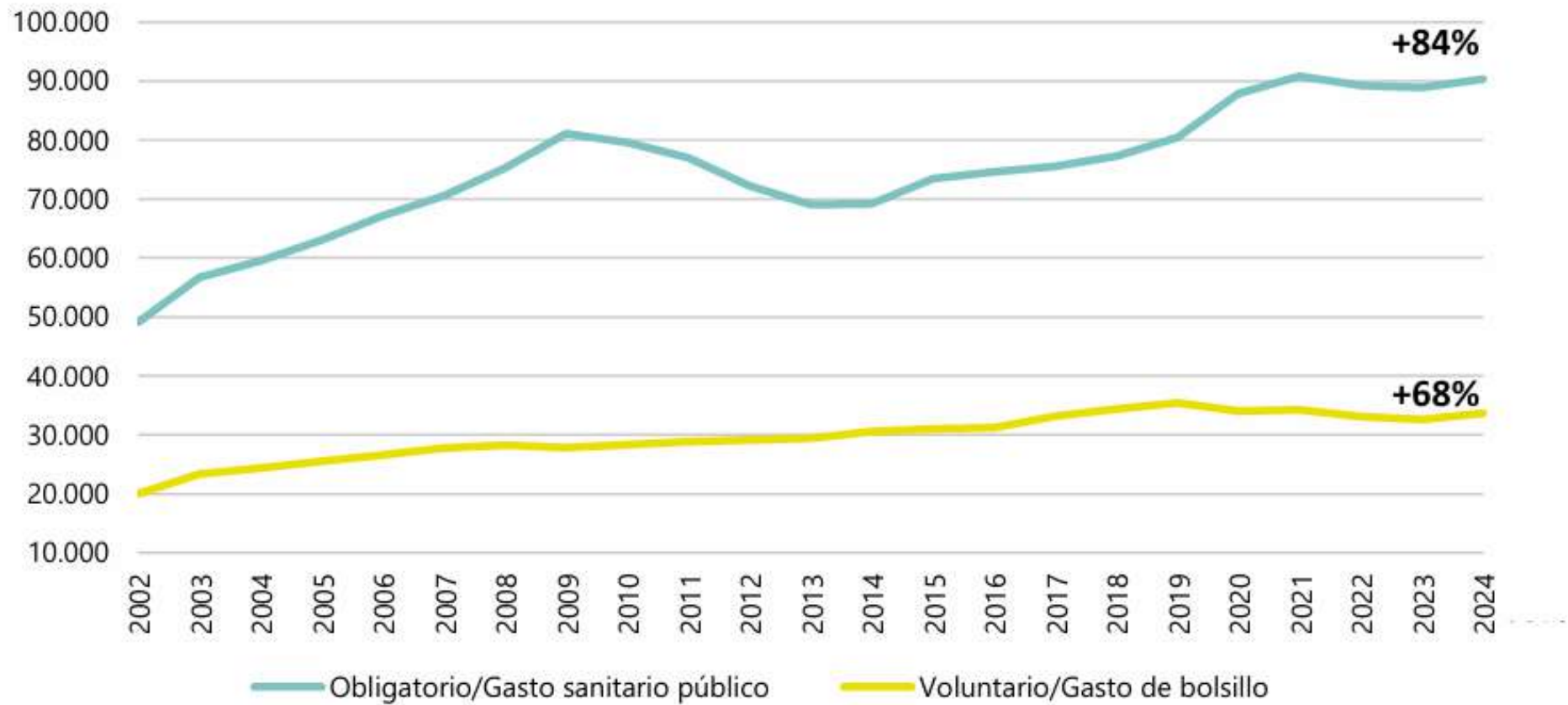


Fuente: OECD (2025a).

Healthcare expenditure in Spain has increased from around 3% of GDP in 1970 to nearly 10% today, reflecting a sustained upward trend.

Health spending

Healthcare Expenditure and Financing Spain, 2002–2024 (constant 2020 prices)



Fuente: OCDE (2025a).

Health spending

Comparison of Resources and Activity in the National Health System 2014–2024

Sistema Nacional de Salud	Incremento %
Médicos AP por 1000 hab. asignados	3,9
Enfermería AP por 1000 hab. asignados	16,9
Consultas medicina por habitante asignado	-3,2
Consultas enfermería por habitante asignado	7,0
Médicos Hospital por 1000 hab.	18,2
Enfermería Hospital por 1000 hab.	23,6
Camas SNS por 1000 hab.	3,1
Ingresos hospitalarios por 10.000 h	0,9
IQ por 10.000 hab.	0,1
Urgencias hospitalarias	18,7
Hospital Día uso por 1000 hab.	32,8
Angioplastia por 10.000 hab.	-11,4
Gasto Sanitario Público	56
Población	4,7

Fuente: Ministerio de Sanidad (2025a, 2025c).

Health spending



Public

€105,100 million/year
7,0% of GDP
€2,176/inhabitant
7 out of every 10 euros allocated to curative care, physical therapy and long-term care
14.641 million euros on prescription medicines
73,65 % total health spending



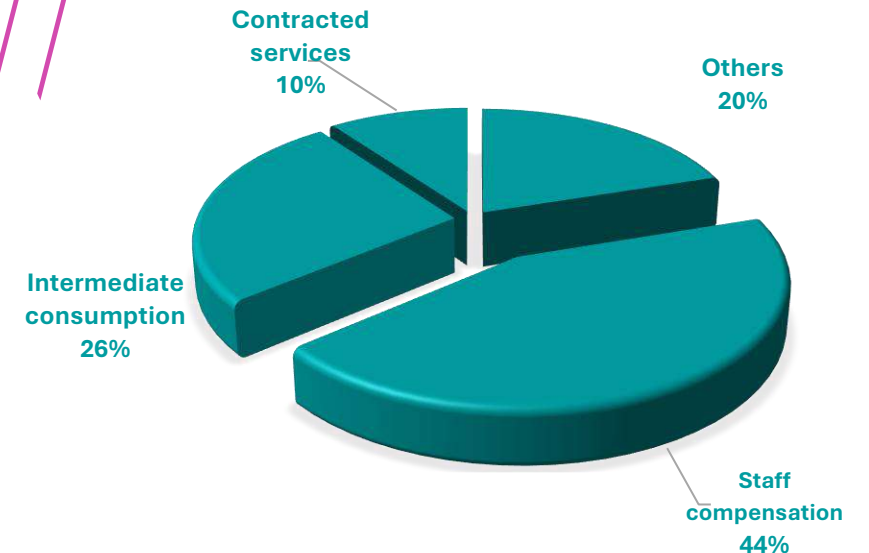
Private

€37.600 million/year
2,5% of GDP
€779/inhabitant
9 out of every 10 euros of direct household payments are allocated to curative care and physical therapy (including dental care), medication (including co-payments), lenses and hearing aids
26,35% total health spending

TOTAL

€142.700 million/year
9,5% of GDP
€2,955/inhabitant

Public health expenditure Spain 2023



<https://www.sanidad.gob.es/estadEstudios/sanidadDatos/home.htm>

<https://www.sanidad.gob.es/estadEstudios/estadisticas/docs/EGSP2008/egspPrincipalesResultados.pdf>

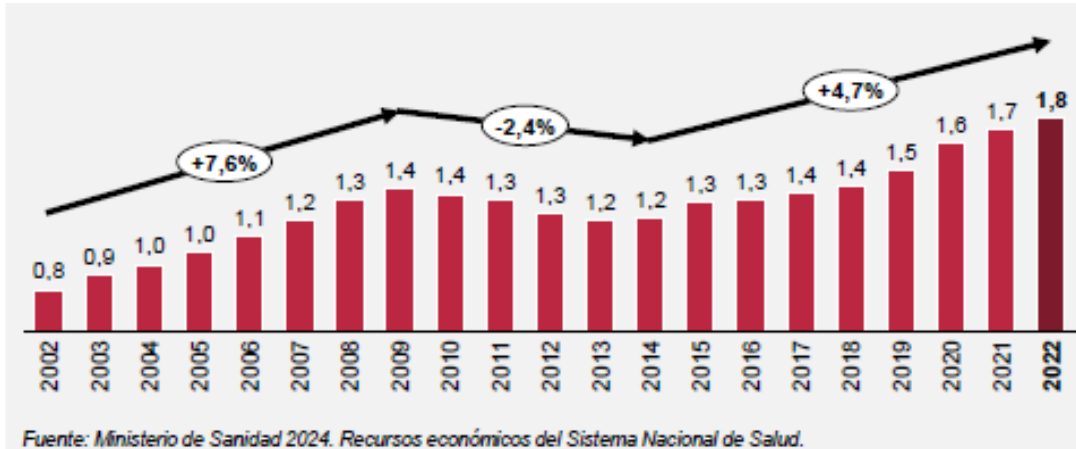
PUBLIC HEALTH EXPENDITURE, BY ECONOMIC CLASSIFICATION. Millions of euros. Spain 2000-2024

Year	Public Health Expenditure (% of Total Health Expenditure)	Public Health Expenditure (€ million)	Health Expenditure (% of Total Public Expenditure)	Public Health Expenditure (% of GDP)	Public Health Expenditure per Capita
2024	72,80%	106.331.900.000,0		6,70%	2.187 €
2023	73,18%	101.107.253.000,0	14,85%	6,75%	2.091 €
2022	72,94%	96.979.906.000,0	15,22%	7,06%	2.029 €
2021	72,61%	92.797.409.000,00	15,20%	7,51%	1.956 €
2020	72,09%	87.872.520.000,00	15,13%	7,78%	1.855 €
2019	69,44%	80.225.315.000,00	15,23%	6,40%	1.703 €
2018	69,18%	76.080.352.000,00	15,11%	6,28%	1.626 €
2017	70,51%	73.335.841.000,00	15,27%	6,31%	1.576 €
2016	71,56%	71.364.354.000,00	15,08%	6,40%	1.536 €
2015	71,32%	70.153.872.000,00	14,77%	6,51%	1.512 €
2014	70,27%	65.934.836.000,00	14,09%	6,39%	1.419 €
2013	71,01%	65.710.300.000,00	13,88%	6,44%	1.410 €
2012	72,11%	68.080.693.000,00	13,35%	6,60%	1.456 €
2011	73,48%	71.665.564.000,00	14,60%	6,74%	1.533 €
2010	74,45%	72.821.522.000,00	14,75%	6,79%	1.564

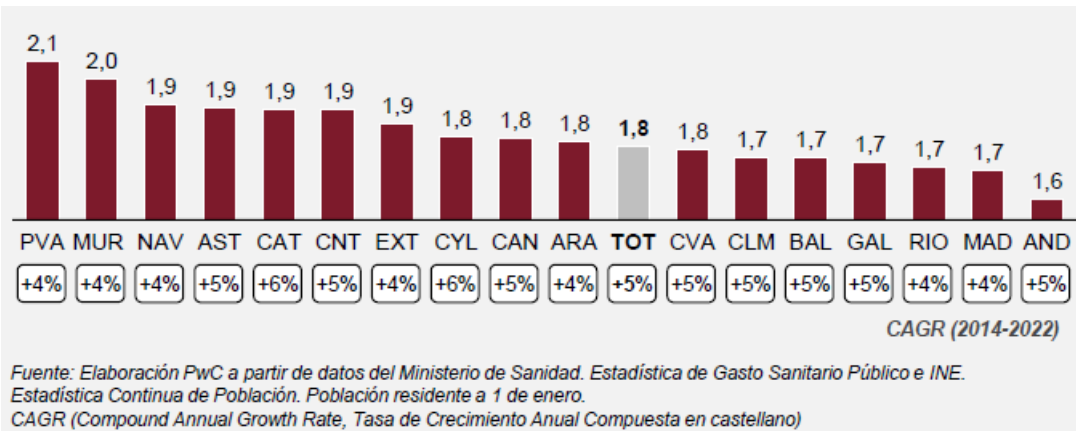
Health spending

Public health expenditure per inhabitant has grown steadily since 2014, reaching a peak in 2022 at €1,800 per inhabitant, with notable differences between regions

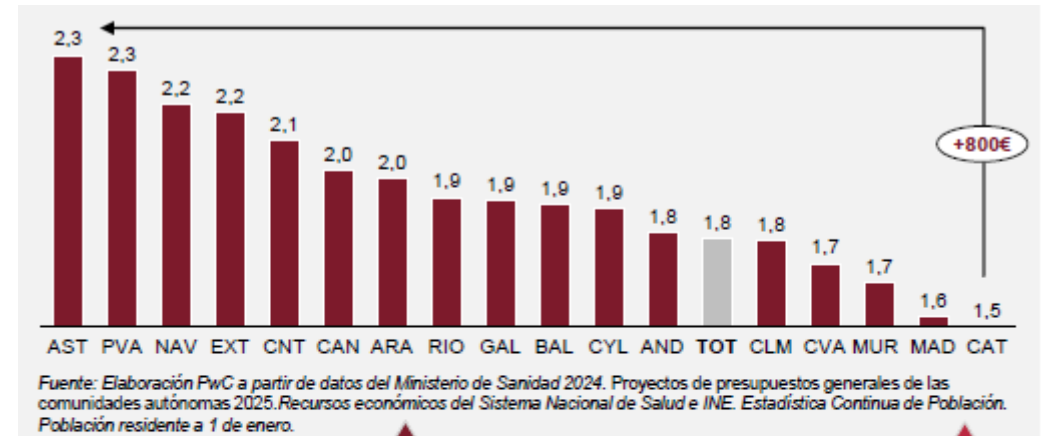
Trends in Adjusted Public Healthcare Expenditure per Capita in CC.AA
Thousand euros (current prices) per adjusted inhabitant, 2002 - 2022



Adjusted Public Healthcare Expenditure per Capita in CC.AA
Thousand euros (current prices) per adjusted inhabitant (2022) and CAGR (2014 - 2022)



Adjusted Per Capita Healthcare Budgets in CC.AA
Thousand euros (current prices) per adjusted inhabitant (2025)



1.800€

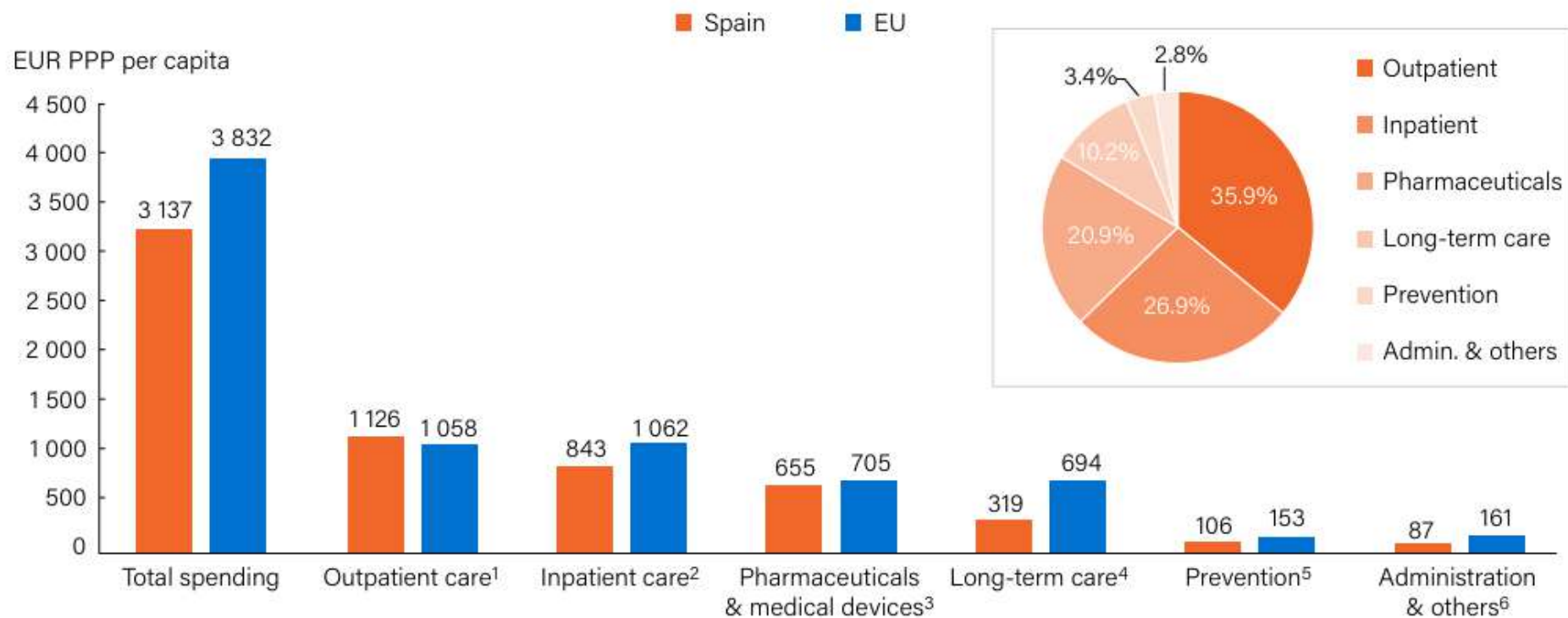
adjusted per capita healthcare budget across the Autonomous Communities, although with significant interregional differences

800€

per capita difference between the Autonomous Communities allocating the most and least resources and budget to healthcare

The differences in the allocation of health resources between autonomous communities are wide and significant, with a difference of approximately €800 per inhabitant.

Health spending



Spain spends less on health than the EU average

2023 data:

- The distribution of healthcare expenditure by function in Spain shows that, in 2023, 36% was allocated to outpatient care and 27% to inpatient care.
- 21% was spent on pharmaceuticals and other medical goods.
- Spain's spending on long-term care (10%) and preventive care (3%) is low compared with EU averages (18% and 4%, respectively).
- Given its lower overall health spending, Spain spends less per capita than the EU average across all healthcare categories.

Health expenditure on medical devices

Trends in Medical Device Expenditure

Net Accrued Expenditure. Cumulative Annual Total

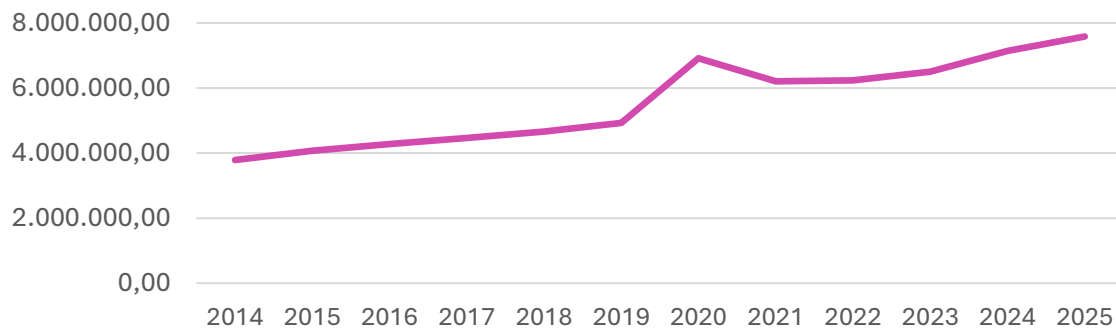
Trends in Medical Device Expenditure (Non Prescription / Non Dispensed) – € thousand –

ADMINISTRATION	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026 (Febrero)
TOTAL ADMINISTRATIONS	3.787.007,55	4.069.743,35	4.280.121,95	4.468.305,07	4.664.010,95	4.932.170,72	6.915.375,27	6.204.133,85	6.239.841,47	6.499.193,56	7.139.938,84	7.584.981,98	1.172.699,15
TOTAL CENTRAL GOVERNMENT (INGESA, MUGEJU, MUFACE, PRISON HEALTH SERVICES)	65.142,23	54.179,42	50.647,37	52.183,94	51.636,43	51.435,15	63.063,63	50.625,45	48.826,61	49.277,66	53.903,85	58.390,95	7.587,75
TOTAL AUTONOMOUS COMMUNITIES	3.721.865,32	4.015.563,93	4.229.474,58	4.416.121,13	4.612.374,52	4.880.735,57	6.852.311,63	6.243.507,40	6.191.014,86	6.449.915,90	7.086.034,99	7.526.591,03	1.165.111,40
YEAR ON YEAR GROWTH RATE (%) (%)		7,9	5,3	4,3	4,7	6,3	40,4	-9,0	-0,9	4,2	9,8	6,14	-0,23

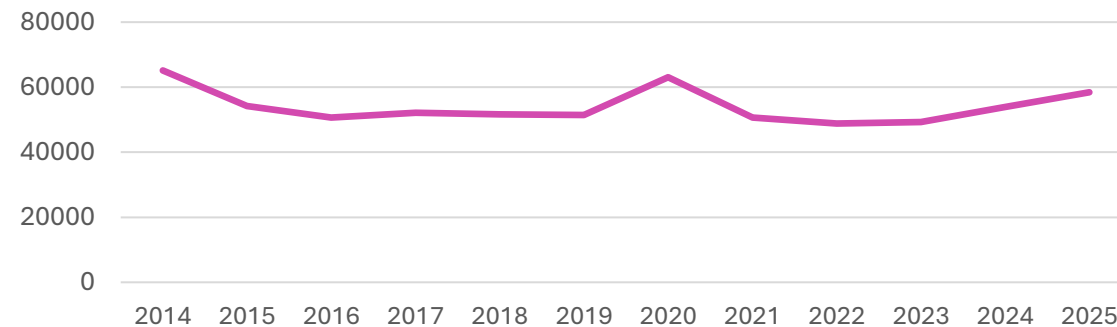
Medical device expenditure shows uneven growth or decline depending on the year and the region.

Trends in Medical Device Expenditure (Non Prescription / Non Dispensed) – € thousand –

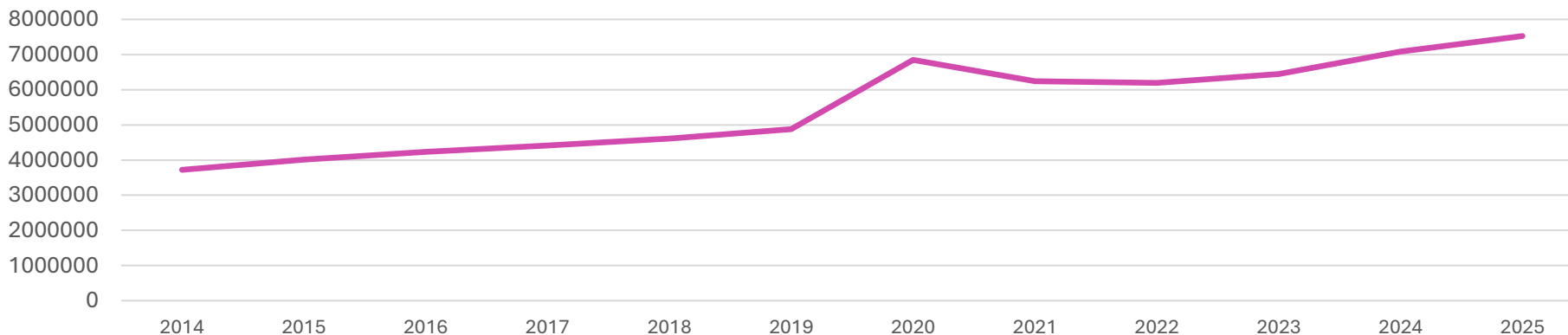
Total Administrations



Total Central Government



Total Autonomous Communities



Health expenditure on medical devices

Net accrued expenditure. Cumulative annual figures

Expenditure on medical devices without prescription or without an associated prescription form THOUSANDS OF EUROS

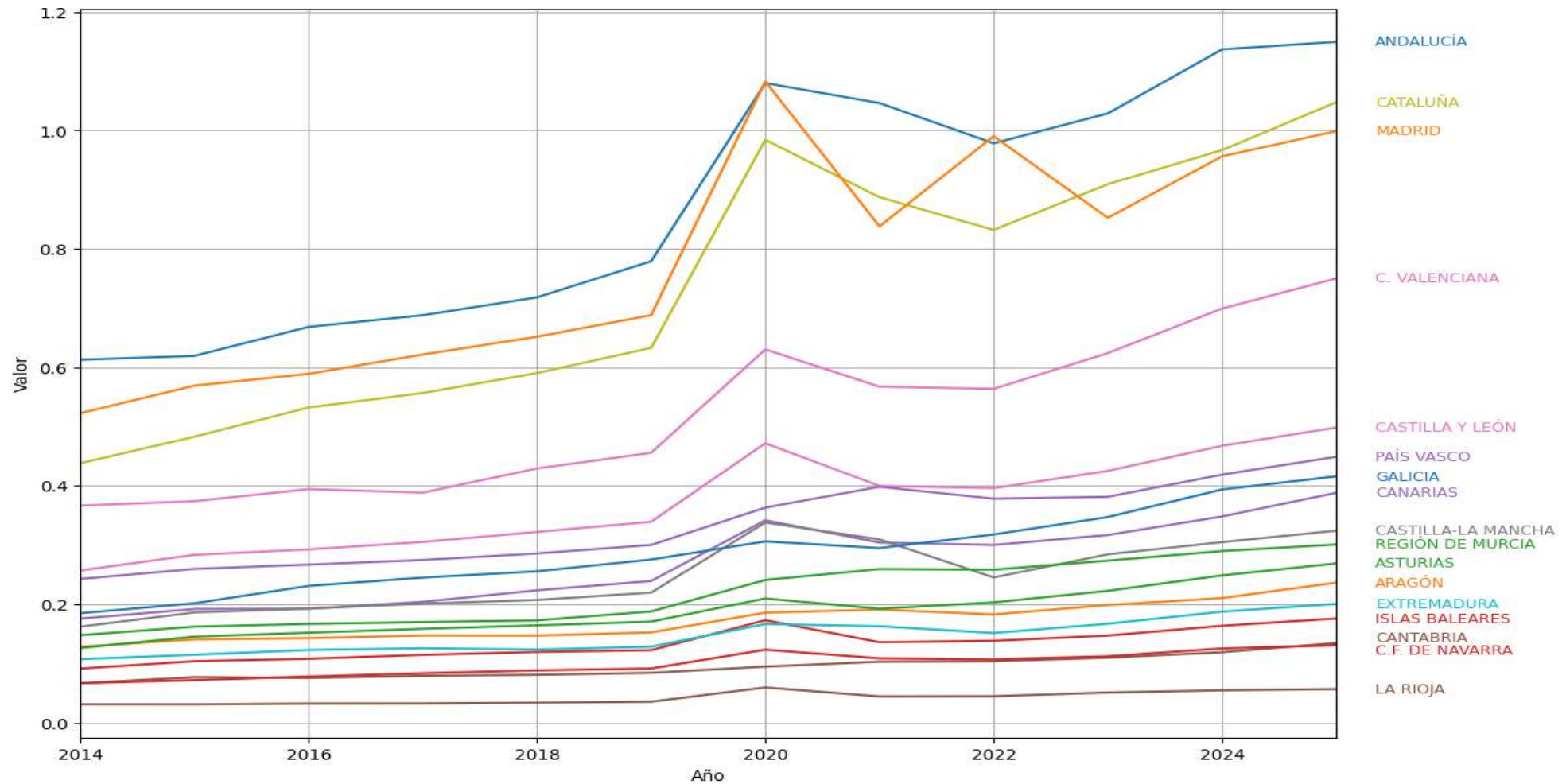
AUTONOMOUS COMMUNITIES	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
ANDALUSIA	612.829,23	619.349,96	668.297,10	688.062,21	718.182,23	779.169,54	1.079.972,64	1.046.237,44	978.311,82	1.034.008,88	1.136.855,82	1.149.642,9
ARAGON	128.238,25	140.706,57	142.778,41	147.235,04	147.085,10	152.475,37	185.864,68	191.019,84	182.786,54	198.125,89	210.978,05	236.444,12
ASTURIAS	126.174,23	145.288,19	151.937,24	158.536,69	164.436,53	170.727,45	209.719,44	192.346,70	203.099,59	222.646,21	248.727,63	268.850,14
BALEARIC ISLANDS	91.387,22	103.881,36	107.936,85	114.578,38	119.479,87	122.471,87	173.088,19	135.930,94	138.244,91	147.055,59	163.449,16	175.994,7
CANARY ISLANDS	175.792,57	191.966,37	192.411,73	204.046,00	223.526,49	239.314,87	341.798,25	304.197,35	300.091,08	316.446,83	348.183,10	388.114,17
CANTABRIA	66.556,64	76.919,38	75.472,49	79.327,60	80.808,29	84.210,34	94.694,87	103.042,26	103.747,42	109.786,02	118.990,77	134.636,09
CASTILLA Y LEÓN	257.051,65	283.467,88	292.482,65	305.220,96	322.013,18	339.290,82	471.842,91	399.837,89	395.994,36	423.553,41	465.909,69	498.352,41
CASTILLA-LA MANCHA	162.187,36	186.207,28	192.694,43	201.031,26	207.203,51	219.666,80	338.062,85	309.476,40	245.300,90	283.822,72	304.772,10	324.169,85
CATALONIA	438.143,50	482.859,55	532.264,80	556.693,02	590.326,69	632.816,61	984.219,65	887.311,19	832.043,31	908.479,42	966.245,60	1.047.547,04
EXTREMADURA	107.280,93	114.771,31	122.780,32	125.752,59	123.617,35	128.332,84	166.714,16	162.887,50	151.462,12	167.103,47	187.472,32	200.627,78
GALICIA	184.913,00	201.594,49	231.039,40	245.025,58	255.637,74	275.461,65	306.153,50	294.864,07	317.817,33	344.252,31	393.742,23	415.920,48
MADRID*	522.567,23	569.120,25	589.024,77	621.683,57	651.663,80	688.159,01	1.082.880,77	838.108,69	990.300,81	852.846,01	955.157,73	998.848,3
REGION OF MURCIA	147.704,39	162.204,52	166.881,06	169.915,35	172.781,97	187.861,08	240.970,03	259.468,53	258.311,20	273.617,11	289.778,15	300.831,4
A. COMMUNITY OF NAVARRE	66.801,32	71.904,41	77.899,50	83.547,96	88.300,61	91.502,26	123.298,86	108.673,47	106.953,74	112.149,88	125.389,95	130.688,64
BASQUE COUNTRY	242.728,66	259.681,95	266.916,05	274.769,15	285.696,32	300.127,61	363.178,31	398.346,44	378.249,93	381.410,98	418.783,94	449.004,49
LA RIOJA	30.986,47	30.924,36	32.280,73	32.466,86	33.806,11	35.435,01	59.559,47	44.354,97	44.653,17	51.075,96	54.840,93	56.799,44
A. COMMUNITY OF VALENCIA*	366.521,62	373.995,11	394.357,96	388.484,66	429.162,90	455.744,08	630.293,05	567.403,72	563.646,63	623.535,21	696.757,82	750.119,08
TOTAL AUTONOMOUS COMMUNITIES	3.727.864,27	4.014.842,93	4.237.455,49	4.396.376,88	4.613.728,69	4.902.767,21	6.852.311,63	6.243.507,40	6.191.014,86	6.449.915,90	7.086.034,99	7.526.591,03

Health expenditure on medical devices

Net accrued expenditure. Cumulative annual figures

Expenditure on medical devices without prescription or without an associated prescription form
THOUSANDS OF EUROS

Trends in Medical Device Expenditure (by Autonomous Community)



Health expenditure on medical devices

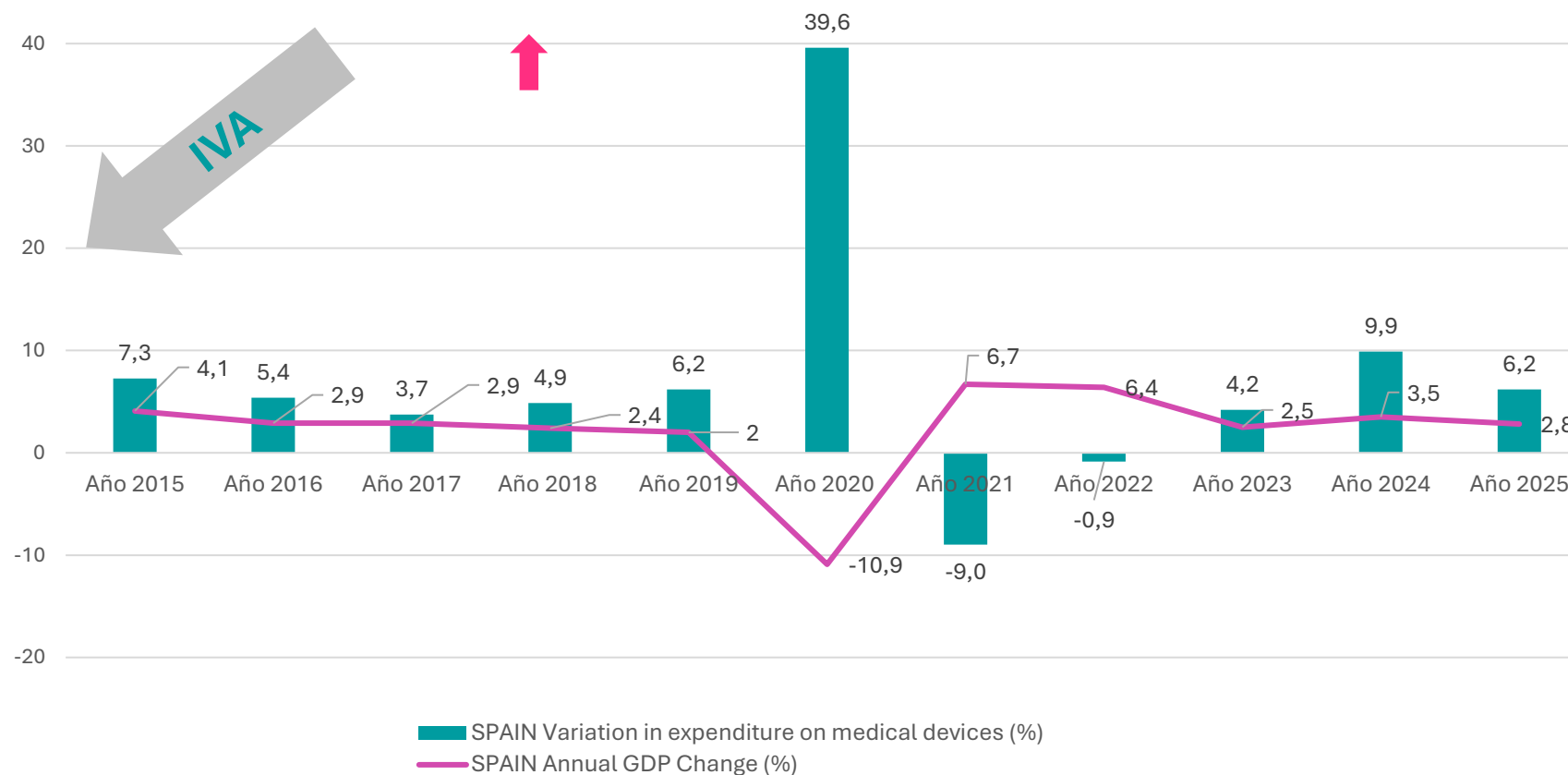
Net accrued expenditure. Cumulative annual figures

Expenditure on medical devices without prescription or without an associated prescription form Year-on-year Variation Rate (%)

AUTONOMOUS COMMUNITIES	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
ANDALUSIA	1,1	7,9	3,0	4,4	8,5	38,6	-3,1	-6,5	5,7	10,5	1,12
ARAGON	9,7	1,5	3,1	-0,1	3,7	21,9	2,8	-4,3	8,4	6,2	12,38
ASTURIAS	15,1	4,6	4,3	3,7	3,8	22,8	-8,3	5,6	9,6	11,7	8,09
BALEARIC ISLANDS	13,7	3,9	6,2	4,3	2,5	41,3	-21,5	1,7	6,4	11,1	7,58
CANARY ISLANDS	9,2	0,2	6,0	9,5	7,1	42,8	-11,0	-1,3	5,5	9,9	11,46
CANTABRIA	15,6	-1,9	5,1	1,9	4,2	12,5	8,8	0,7	5,8	8,4	13,15
CASTILLA Y LEÓN	10,3	3,2	4,4	5,5	5,4	39,1	-15,3	-1,0	7,0	9,6	6,59
CASTILLA-LA MANCHA	14,8	3,5	4,3	3,1	6,0	53,9	-8,5	-20,7	15,7	7,2	6,34
CATALONIA	10,2	10,2	4,6	6,0	7,2	55,5	-9,8	-6,2	9,2	6,3	8,35
EXTREMADURA	7,0	7,0	2,4	-1,7	3,8	29,9	-2,3	-7,0	10,3	12,2	7,02
GALICIA	9,0	14,6	6,1	4,3	7,8	11,1	-3,7	7,8	8,3	13,4	5,63
MADRID*	8,9	3,5	5,5	4,8	5,6	57,4	-22,6	18,2	-13,9	12,0	4,45
REGION OF MURCIA	9,8	2,9	1,8	1,7	8,7	28,3	7,7	-0,4	5,9	5,9	3,81
A. COMMUNITY OF NAVARRE	7,6	8,3	7,3	5,7	3,6	34,7	-11,9	-1,6	4,9	11,8	4,28
BASQUE COUNTRY	7,0	2,8	2,9	4,0	5,1	21,0	9,7	-5,0	0,8	9,8	7,22
LA RIOJA	-0,2	4,4	0,6	4,1	4,8	68,1	-25,5	0,7	14,4	7,5	3,90
A. COMMUNITY OF VALENCIA*	2,0	5,4	-1,5	10,5	6,2	38,3	-10,0	-0,7	10,6	11,7	7,28
TOTAL AUTONOMOUS COMMUNITIES	7,7	5,5	3,8	4,9	6,3	39,8	-8,9	-0,8	4,2	9,8	6,14

Trends in the expenditure on medical devices (without prescription or without an associated prescription form)

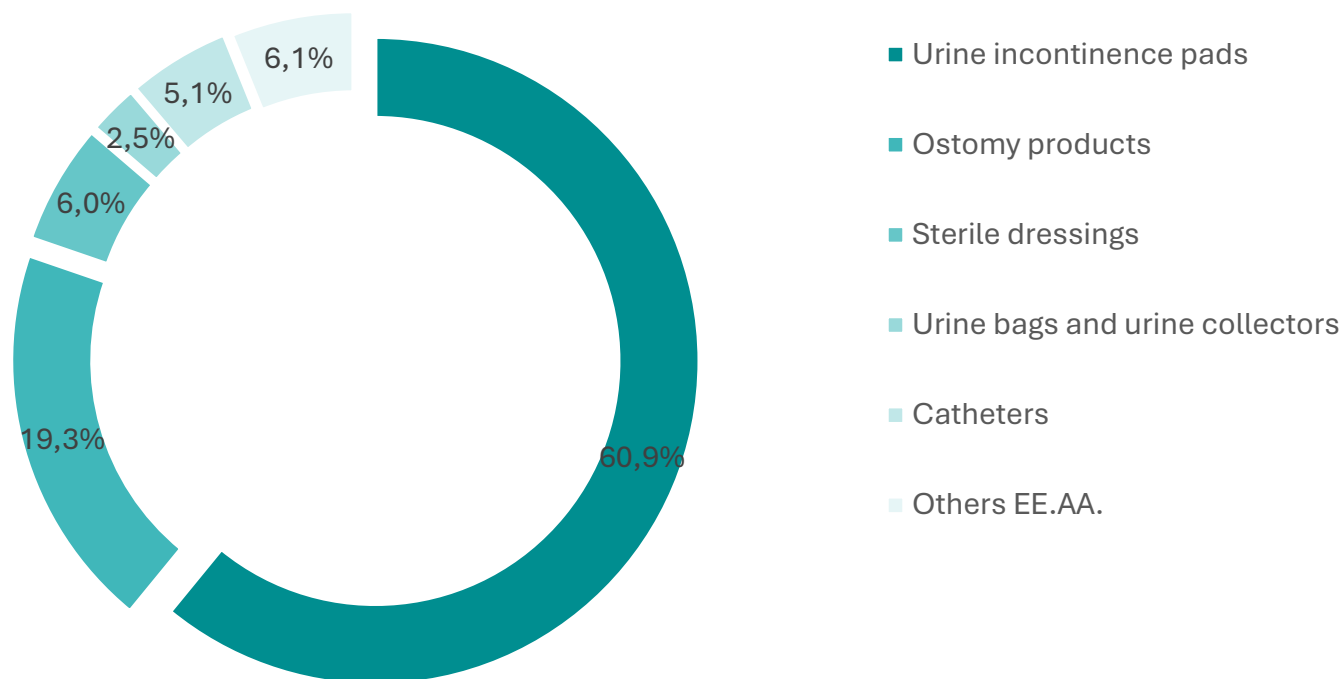
SPAIN: TRENDS IN THE EXPENDITURE ON MEDICAL DEVICES AND GDP (%)



Expenditure on medical devices included in the Pharmaceutical Budget 2025

MEDICAL DEVICES CONSUMPTION 2025

753,62 MILLIONS € → 5,4% of PPS*



(*) PPS: Public Pharmaceutical Spending on prescription medicines. Total 2025: €14,389.63 million

MONITOR FENIN

OVERVIEW AND TRENDS

of the Spanish healthcare system

2

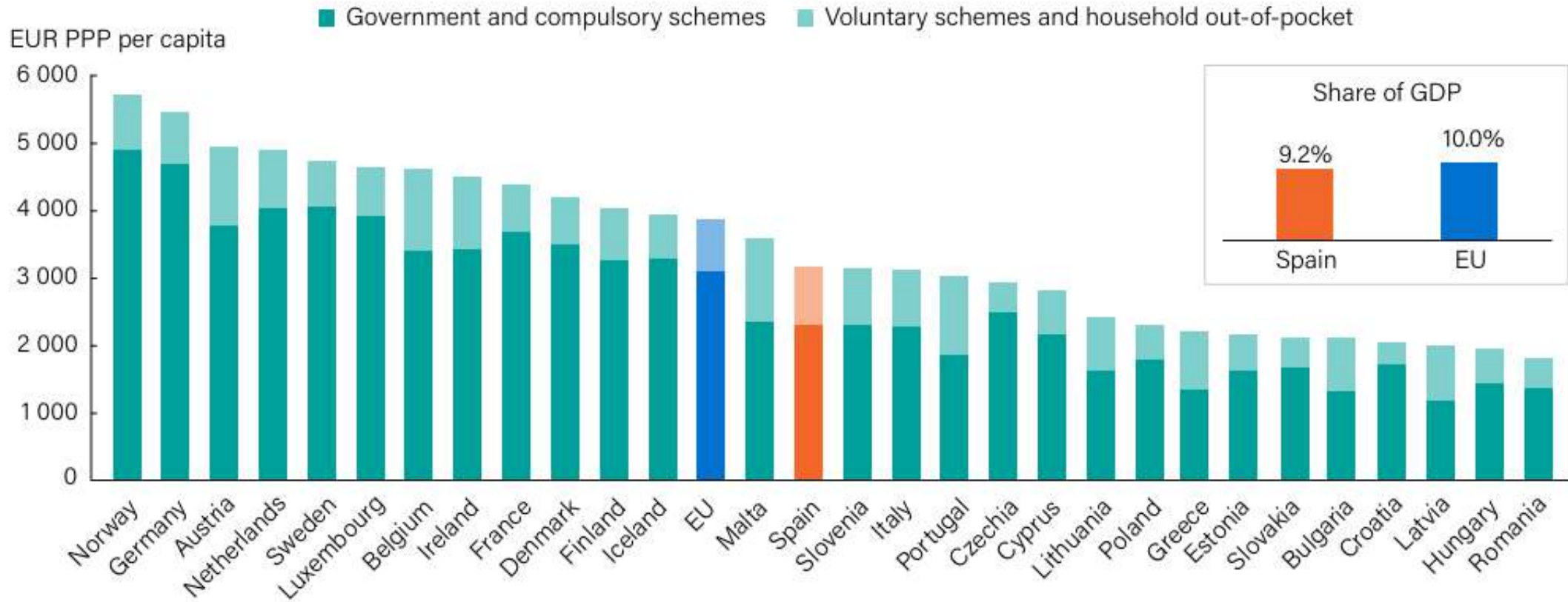
Comparison of the Healthcare System with the OECD figures

- Main health indicators in the EU
- Health spending in Spain and Europe, 2023

Fenin

Tecnología
Sanitaria

Total healthcare expenditure in Spain and Europe, 2023



Notes: The EU average is weighted (calculated by the OECD).
 Sources: OECD Data Explorer (DF_SHA); Eurostat (demo_gind); data refer to 2023.

MONITOR FENIN

OVERVIEW AND TRENDS

of the Spanish healthcare system

3

Economic forecasts

- Spanish economy

Fenin

Tecnología
Sanitaria

3 Spanish economy

- **Geopolitical tensions in the Middle East** have increased uncertainty in a context where the Spanish economy entered 2026 with solid growth, although signs of a **slowdown in activity** are already emerging.
- **GDP has grown by 0.6%** in the first quarter and remains above the European average, but growth has begun to lose momentum, mainly due to the **lower contribution of investment**. In addition, employment is showing signs of moderation and **unemployment has increased to 10.8%**.
- **Inflation has picked up again** in recent months due to rising energy costs and is now above 3%, which, together with **tighter financial conditions**, is beginning to affect consumption and investment.
- **Forecasts place growth at around 2.2% in 2026**, with slight downward revisions, while **inflation has been revised upwards**, in a still uncertain environment, albeit supported by factors such as tourism and fiscal policy.

MONITOR FENIN

OVERVIEW AND TRENDS

of the Spanish healthcare system

4

Final conclusions



Fenin

Tecnología
Sanitaria

Comparison of Spain with other EU27 countries

Key indicators and the frequency at which Spain is above the OECD average for the relevant indicators (when data for Spain is available) are shown.



STATE OF HEALTH

Spain's results are better than the OECD average in 74% of the indicators

- Life expectancy: 84 years, 3 years higher than the UE.
- Preventable mortality: 142 out of every 100,000 (less than the OECD average of 222).
- Treatable mortality: 51 out of every 100,000 (less than the OECD average of 79).
- 7.7% of people indicated that their state of health was bad or very bad (OECD average: 7.9%).
- The diabetes prevalence rate is higher than the OECD average.



RISK FACTORS

Spain's results are better than the OECD average in 50% of the indicators

- Smoking rate (20%): higher than the EU27 average (18.0%).
- Intake of alcohol: higher than the EU27 average, with 11.8 litres per capita vs 8,5 litres.
- Obesity incidence rate: 16%, lower than the EU27.
- 30 deaths caused by atmospheric contamination out of every 100,000. (OECD average: 27,57).



QUALITY OF CARE

Spain's results are better than the OECD average in 54% of the indicators

- Intensive care: The mortality rate 30 days after a stroke was 9.4% (OECD average: 7.8%) and 6.5% after a heart attack (OECD average: 6.8%).
- Primary healthcare: 356 admissions per 100,000 inhabitants, less than the OECD average (463).
- Safe prescriptions: Spain prescribed more antibiotics than the OECD average.
- Preventive care: 74% of women underwent breast cancer screening tests, higher than the OECD average (55%).

Comparison of Spain with other OECD countries

Key indicators and the frequency at which Spain is above the OECD average for the relevant indicators (when data for Spain is available) are shown.



ACCESS TO CARE

Spain's results are better than the OECD average in 44% of the indicators

- The entire population has access to basic services.
- 62% of the population is satisfied with the availability of quality healthcare services (OECD average: 64%).
- Financial coverage, with 73% of spending covered by mandatory co-payments, is lower than the OECD average (75%).
- Out-of-pocket expenses: 21% of health spending, higher than the OECD average (18%).
- 1.7% of the population indicates that some of their healthcare needs are not covered (OECD average: 3.4%)



HEALTH SYSTEM RESOURCES

Spain's results are better than the OECD average in 41% of the indicators

- Spain spent €3,000 per capita on health, (including private and public health), less than the OECD average, which is equivalent to 9,2% of GDP vs the OECD average of 9.2%.
- 4.4 practising doctors per 1,000 inhabitants (OECD average: 3.9); and 5.9 practising nurses (OECD average: 9.2).
- Spain has 2.9 hospital beds per 1,000 inhabitants, less than the OECD average (4.2 beds).



Spanish Federation of Healthcare Technology Companies

WEBINAR FENIN-MEDTECH EUROPE: MARKET ACCESS





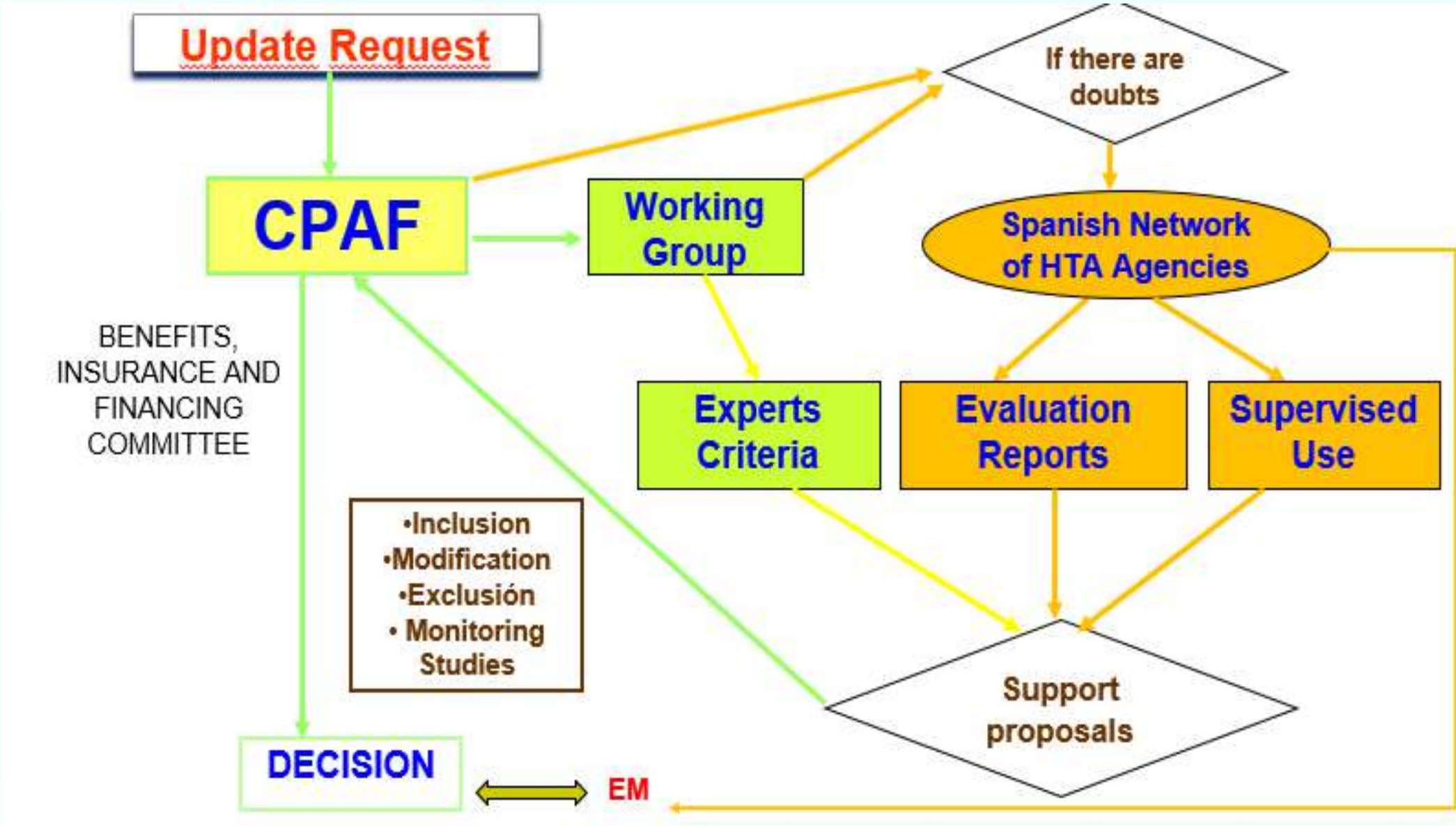
PURPOSE OF HTA

ASSESSMENT to introduce “rationally” in the market the technological innovations according to criteria of

- ✓ *Security*
- ✓ *Efficacy*
- ✓ *Effectiveness*
- ✓ *Efficiency*

The HTA is carried out through Health Technology Assessment Agencies (AETS), at the request of the Administration, and / or through academic and research entities with experience in the subject.

COMMON PORTFOLIO OF NHS SERVICES



HTA PROCESS IN SPAIN...until now

- Identify the issues to be evaluated: taking into account the health needs of the population, who is requesting the HTA and their reasons (why it is needed at that time, what type of decision supports the HTA, etc)
- Prioritize the identified issues: those factors that influence each of the issues and the potential impact of the HTA are evaluated.
- Assessment: Previously selecting the evaluation tools.
- Validate, internally and externally, the reports developed.
- Disseminate and communicate the results obtained.



Defining the point of view from which the evaluation will be carried out: patient, primary care / hospital, SNS or society



HTA AGENCIES - SPAIN

<p>Agència de Qualitat i Avaluació Sanitàries de Catalunya</p> <p>AQuAS. Catalunya, 1991</p>	<p>EUSKO JAURLARITZA GOBIERNO VASCO OSASUN SAIA DEPARTAMENTO DE SALUD</p> <p>Osteba</p> <p><small>Oficina Tecnològica d'Anàlisi i Avaluació de Tecnologies Sanitàries Osasun Office for Health Technology Assessment</small></p> <p>OSTEBA. País Vasco, 1992</p>
<p>Instituto de Salud Carlos III</p> <p>AETS. ISCIII-MSSSI, 1994</p>	<p>SERVICIO DE EVALUACIÓN Y PLANIFICACIÓN</p> <p>SESCS. Canarias, 1995</p>
<p>JUNTA DE ANDALUCÍA CONSEJERÍA DE SALUD Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (AETSA)</p> <p>AETSA. Andalucía, 1996</p>	<p>avalia-t</p> <p>AVALIA-T. Galicia, 1999</p>
<p>Dirección General de Planificación, Investigación y Formación CONSEJERÍA DE SANIDAD</p> <p>Comunidad de Madrid</p>	<p>IACS Instituto Aragonés de Ciencias de la Salud</p>

**Consulting
NON-BINDING
reports**



HTA AGENCIES - SPAIN



- ❑ Order SSI / 1833/2013, of October 2, which creates and regulates the Council of the Spanish Network of Technology Assessment Agencies and Benefits of the National Health System.
- ❑ Operating regulations: 8 agencies
- ❑ REDETS is represented by the Ministry of Health in the **Coordination Group (HTACG)** in the field of non-pharmacological health technologies under the EU Health Technology Assessment Regulation (Regulation (EU) 2021/2282)
- ❑ REDETS actively participates in the working subgroups derived from the HTAR Regulation, where key technical and methodological aspects for its implementation are discussed.

OPPORTUNITIES

- Standardize evaluation reports, clinical guidelines, etc.
- External review documents
- Regulation of work deadlines, documentary contribution and allegations management.
- Regulation dialogue with the healthcare industry



HTA AGENCIES – SPAIN- GOALS

To Base decision-making on the incorporation, financing or divestment conditions and appropriate use of health technologies, through their global application throughout the national territory through the corresponding health services, in order to promote equity and sustainability of the SNS.

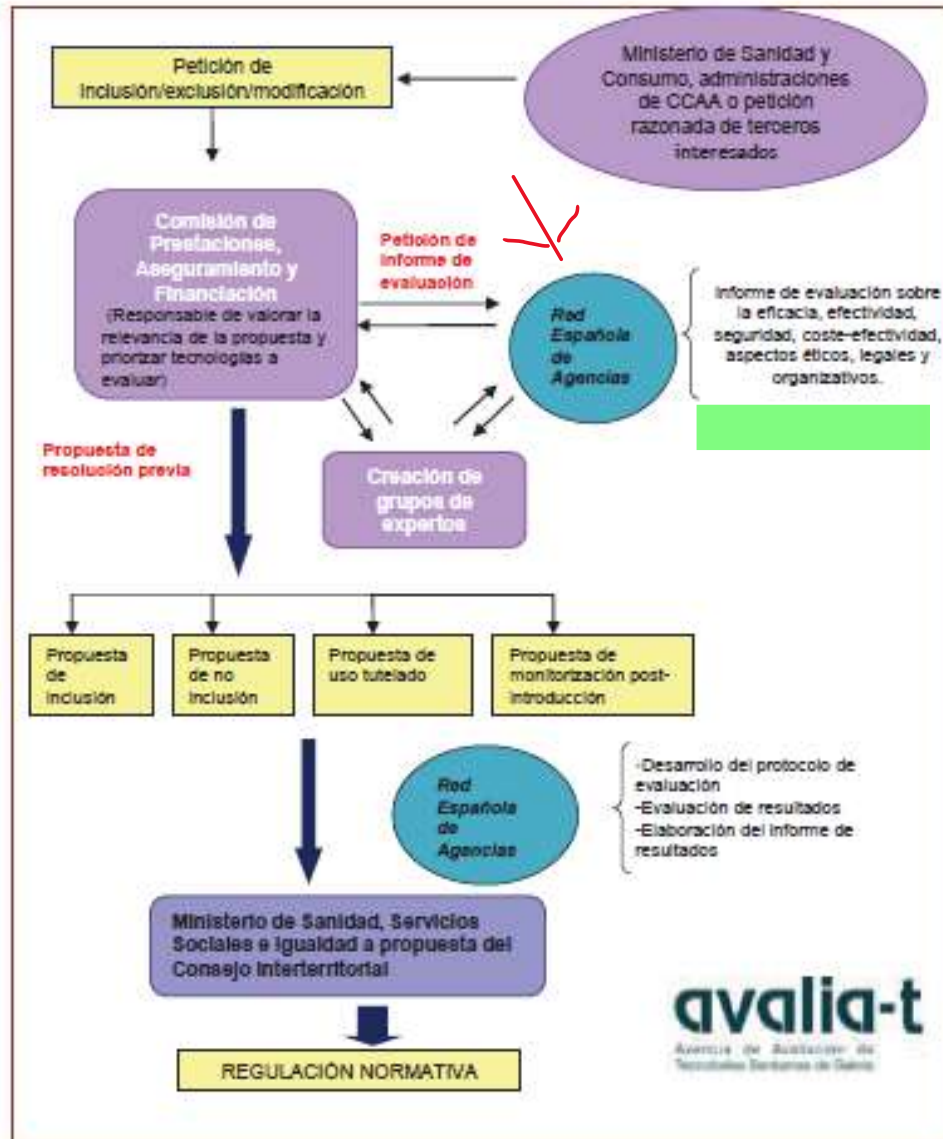
SPECIFIC GOALS



- Collaborating in updating and improving the Basic Portfolio of SNS Services
- Contributing to the rapid transfer of knowledge and dissemination of scientific evidence to clinical practice and to the different decision-making levels of the NHS.
- Ensure a common quality methodological framework in the evaluation and preparation of reports.
- Ensuring resources and methodological tools for HTA
- Promotin individual and collective training activities among health technology agencies and units.
- Generating an HTA culture on the collaborative network structure between all agencies and units.



HTA AGENCIAS – SPAIN- ANNUAL WORKING HTA PLAN



RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS
Y PRESTACIONES DEL SNS
RedETS

Plan de Trabajo 2026	Agencia/Unidad
Informes de evaluación de tecnologías sanitarias (IETS)	
Cribado de portadores de bacterias multirresistentes (EPC y SARM) en el ingreso hospitalario	AETSA
Evaluación de biomarcadores para el diagnóstico y manejo clínico de COVID persistente en el Sistema Nacional de Salud	AETSA
Enfoque multimodal de tratamiento del dolor neuropático	AETSA
Programas de tele rehabilitación domiciliaria en lesión medular	AETSA
Equipo multimodal de PET y RM simultáneo con gantry de 60 cm para estudios de alta resolución espacial	AETSA
Evaluación de la eficacia y seguridad de dispositivos quirúrgicos indicados para la evacuación controlada de tejido y/o fluido en una intervención quirúrgica del sistema cerebral o ventricular mediante cirugía mínimamente invasiva	AETSA
Evaluación de la efectividad y coste-efectividad del uso de la ecografía portátil en UVs móviles	AETSA
Evaluación de la eficacia, seguridad y coste-efectividad de los programas de tele rehabilitación en pacientes con movilidad reducida o que residen en zonas rurales o de difícil acceso	AETSA
Inteligencia artificial para la predicción de sepsis en el adulto	AETSA
Evaluación de cuidados conscientes del trauma en recursos sanitarios	IACS
Evaluación de la eficiencia de los sistemas de telemonitorización integral de pacientes ingresados en domicilio	IACS
Indicadores y estándares de calidad en salud mental comunitaria	IACS
Revisión de evidencia sobre criterios de indicación y priorización de la demanda en listas de espera para una gestión eficiente y el establecimiento de tiempos máximos de acceso a las prestaciones	IACS/SESCS
Evaluación de la eficacia, seguridad y coste-efectividad de la implementación de la terapia de presión negativa en el ámbito de la atención primaria	SESCS
Salud mental en emergencias y desastres naturales	SESCS
Actualización de la evaluación del cribado prenatal de toxoplasmosis	SESCS
Neuroestimulación medular para el tratamiento de dolor crónico del tronco y extremidades inferiores	SESCS
Transporte óseo transversal. Empleo en pie diabético complicado con úlceras crónicas.	SESCS
Efectividad, seguridad y coste-efectividad de los sistemas de monitorización continua de glucosa en tiempo real, sistemas de asa abierta y sistemas híbridos de asa cerrada (páncreas artificial) para pacientes con diabetes. Actualización.	SESCS

43 HTA reports

3 monitoring studies

1 clinical practice guideline

Digital health, screenings, mental health and highly complex technologies

Budget: > 14 M€



HTA AGENCIES – SPAIN- ACTIONS DEVELOPED BY FENIN

- HTA application to guarantee user access to new technological advances in equity and territorial equality
- Assessment considering the differences between health technologies and pharmaceutical products
- Single evaluation procedure for the entire NHS
- Standardized methodology; consensus indicators
- Transparency and responsibility of all agents
- **Active, systematic and transparent participation of companies in the HTA**
- Considerations beyond cost-effectiveness: product benefits, cost to the system, cost evaluation or investment in cooperation.

**IS Carlos III -
Canarias (2017):**
Methodological
Manual to standardize
procedures for
relations with the
industry in the
preparation of STD
reports in a
homogeneous way in
the Spanish Network
for the Evaluation of
Health Technologies and SNS Benefits





HTA PROCESS IN SPAIN...from now

BOLETÍN OFICIAL DEL ESTADO

Núm. 131 Viernes 29 de mayo de 2026 Sec. I. Pág. 73384

I. DISPOSICIONES GENERALES

MINISTERIO DE SANIDAD

11587 Real Decreto 415/2026, de 27 de mayo, por el que se regula la evaluación de tecnologías sanitarias.

El desarrollo y la incorporación a la práctica clínica de las tecnologías sanitarias constituye un elemento básico de la protección de la salud de las personas que, a su vez, aspiran a obtener oportunamente un beneficio de ellas cuando se enfrentan a problemas de salud que no están adecuadamente resueltos por las alternativas disponibles. Sin embargo, el desarrollo y el acceso a las tecnologías sanitarias tiene un importante impacto social que excede el ámbito exclusivo de la salud, ya que son una fuente de investigación, innovación y conocimiento, así como un motor del desarrollo industrial, de la creación de empleo, y del crecimiento económico.

El objeto de este real decreto es regular las actividades de evaluación de las tecnologías sanitarias (en adelante, ETS) en tanto estén dirigidas específicamente a informar decisiones de la administración competente relativas a la incorporación, financiación, precio, reembolso, modificación de las condiciones de uso o desinversión en tecnologías sanitarias.

Las tecnologías sanitarias incluyen medicamentos, productos sanitarios, pruebas para el diagnóstico *in vitro*, procedimientos clínicos, terapias y productos sanitarios digitales, modelos organizativos y medidas para la prevención, el diagnóstico o el tratamiento de enfermedades. Cada una de estas tecnologías tiene una regulación propia y unos requerimientos diferentes para ser aplicadas en la práctica clínica que aseguran la garantía de la calidad, la seguridad y la eficacia.

La ETS es un proceso científico basado en datos contrastados que permite determinar la eficacia relativa de tecnologías sanitarias existentes o nuevas. Por ello, se trata de una herramienta necesaria para informar las decisiones de las autoridades competentes estatales y autonómicas en el diseño e implementación de la cartera de prestaciones sanitarias con el objeto de promover un sistema sanitario equitativo, eficiente y de alta calidad. Es importante hacer notar que la evaluación de tecnologías sanitarias informa la toma de decisiones, pero no constituye la propia toma de decisiones.

Para cumplir con sus fines, la evaluación de cualquier tecnología sanitaria comprende tanto los aspectos clínicos como los aspectos no clínicos de la misma. Se han identificado nueve ámbitos para la ETS, de los que cuatro son clínicos y cinco son no clínicos. Los cuatro ámbitos clínicos son la identificación de un problema de salud y la tecnología sanitaria actual, el análisis de las características técnicas de la nueva tecnología sanitaria, su seguridad relativa y su eficacia clínica relativa. Los cinco ámbitos de evaluación no clínicos se refieren al coste y la evaluación económica de una tecnología, y a sus aspectos éticos, organizativos, sociales y jurídicos, tal y como se recoge en los considerandos del Reglamento (UE) 2021/2282 del Parlamento Europeo y del Consejo, de 15 de diciembre de 2021, sobre evaluación de las tecnologías sanitarias y por el que se modifica la Directiva 2011/24/UE. Dentro de los aspectos no clínicos, se incluye adicionalmente también el ámbito ambiental y es probable que puedan crecer en el futuro conforme se evalúen más terapias y productos sanitarios digitales.

Por otra parte, el procedimiento para la financiación pública de los medicamentos y productos sanitarios para su inclusión en la prestación farmacéutica debe tener en cuenta criterios generales, objetivos y publicados, según el artículo 92 del texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios, aprobado por el Real Decreto Legislativo 1/2015, de 24 de julio. Estos criterios se refieren a dimensiones que están incluidas en la esfera de la ETS y, en concreto y entre otros, al «valor terapéutico y social del medicamento y beneficio clínico incremental del

BOE-A-2026-11587
Verificable en https://www.boe.es

Royal Decree 415/2026 on Health Technology Assessment



26/05/2026

KEY ASPECTS

- ✓ Standardize how the National Health System evaluates medicines & medical devices for pricing, reimbursement and inclusion in public healthcare: *1 year to reach normative instructions and methodological guidelines*
- ✓ Adapts Spanish HTA to the EU HTA regulation: no duplication of clinical evaluation ((efficacy and safety)
- ✓ Measuring impacts “Economic, Organizational, Social, Environmental”, considering ethical aspects
- ✓ HTA will not binding, not mandatory



HTA PROCESS IN SPAIN...from now

Health technologies under the scope

- Class IIb and III medical devices subject to certain conditions under the MDR and selected in accordance with prioritization criteria
- Class D in vitro diagnostic medical devices under similar conditions
- Any other medical device, procedure, digital technology, or organizational measure/model agreed upon by the HTA Council
- Technologies that have already been evaluated and require updating or reevaluation
- Other non-pharmacological health technologies, including digital health and technologies with AI components

Prioritization Criteria

- ✓ Unmet medical need
- ✓ Being first-in-class
- ✓ Potential impact on patients, public health, or sustainability/implementation within the Spanish NHS
- ✓ Incorporation of AI, machine learning, or equivalent algorithms
- ✓ Cross-border dimension or significant added value at the EU level.



HTA PROCESS IN SPAIN...from now

Governance System: HTA vs HTA adoption

1. **Governance Council:** Oversees governance and methodology to align the national framework of health and pharmacy policies with EU
 - ** Approval of work programs and methodological guidelines
 - ** 21 Members: Ministry of Health (State Secretariat), AEMPS (Spanish Agency of Medicines and Medical Devices), CIPM (Interministerial Commission on Pricing), patient organizations, healthcare professionals, and 6 representatives from the autonomous communities
2. **HTA Offices:** comparative assessment of clinical and non-clinical areas
 - Office for the HTA of medicines: AEMPS (Spanish Agency for Medicines & Medical Devices)
 - Office for the HTA of non-pharmacological health technologies: REDETS (Spanish Network of Agencies for Health Technology Assessment)
3. **Adoption Group:** advisory body
 - Recommendations on the adoption of health technologies based on HTA reports
 - Representatives: Ministry of Health, autonomous regions, health professionals, patients & health economists




HTA PROCESS IN SPAIN...from now

HTA Timelines / Data

1. **Non-pharmacological technologies:** max. 180 days
2. Medicines: 90 days for clinical aspects + 90 days for non-clinical aspects
 - Times may be extended when re-assessments need to be
 - If EU JCA: national clinical report aprox. 15 days



1. **Using RWD from clinical practice & National Health Data Repository**
records, monitoring and pilot programs to manage uncertainties in the HTA
2. **Review of technologies in the system:**
If better alternatives **VS** adding value  **replacement**



HTA PROCESS IN SPAIN...from now

Stakeholders Participation

- ❖ **Voluntary scientific consultations before market entry:** Administration - Companies
Speeding evaluations and guide clinical research directly with the Spanish NHS
- ❖ **Participation of civil society in all phases of the evaluation:**
Patient organizations and civil society to ensure patient experience and real-world needs directly factored into the HTA of medicines and medical devices + alignment with EU Regulations
- ❖ **Transparency & Ethics:**
Strict management of any conflict of interest
Public reports with no confidential information restricted. Member profiles, meeting minutes, and declarations of interest published
- ❖ **Companies:** information regarding health technologies
Clinical Data: Core clinical evidence aligned with the EU JCA framework.
Economic Dossiers: Detailed information on funding (including public/non-profit sources) + data on production and development costs
Guidelines: Mandatory dossier models published by the Ministry of Health



HTA PROCESS IN SPAIN...from now

Expected Impact

- Accelerated Timelines
- Transparency
- Broader Participation
- Safe&evidence based innovation
- Framework for the incorporation, financing, pricing, reimbursement, and public decision-making regarding health technologies
- Reinforce the importance of clinical, economic, and organizational value assessments in decisions made **before or during the procurement process**

MEDTECH: SPANISH PUBLIC PROCUREMENT



Key Aspects

1) Decentralized public health procurement model

- Healthcare transferred to the 17 Autonomous Communities
- Coexistence of regional, provincial, hospital purchases and some centralized purchases at the NHS level



2) Regulation: Law 9/2017 on Public Sector Contracts (LCSP)

- Guides the awarding of contracts towards transparency and the best value for money, ***not just the lowest price.***

HCT SPANISH MARKET:
**70 % PUBLIC/
30% PRIVATE**

3) Medical devices must comply with the technical and safety regulations (Regulation (EU) 2017/745 & Royal Decree 192/2023), with requirements for safety, efficacy, technical documentation and CE marking

4) **INGESA:** centralized procurement body of the NHS for certain medicines, products and health services, usually through framework agreements to which the administrations voluntarily adhere

MEDTECH: SPANISH PUBLIC PROCUREMENT

LACK OF BUDGET

LATE PAYMENT

PUBLIC PURCHASING

INTRODUCTION OF NEW TECHNOLOGIES

COMODITIZATION

- Margin decreases: Strong pressure to reduce prices
- Heterogeneous and fragmented in 17 CCAA:
 - Different regulations, services and products catalogue
 - Low interoperability
 - Higher costs/inefficiency
 - Purchasing models based on price
- SNS. Insufficient financing; Payment delay
- Low productivity
- Increasing costs
 - Elderly population.
 - High level of chronicity and dependence.
 - Patients expectations
- Lack of perception of cost pressure; Universal coverage
- Slow and inefficient incorporation of new technologies; **Lack of clear and agile process**
- No integration between Public and Private Healthcare.

MEDTECH: SPANISH PUBLIC PROCUREMENT

PUBLIC PROCUREMENT TOOLS

1. **Standard Supply Tenders**

Usual procedure for medical devices, tendered by a health service, a regional authority, a logistics platform or a hospital

2. **Framework Agreements**

Regulated in Articles 218 to 222 of the Spanish Public Sector Contracts Law (LCSP): NOT a procurement procedure but a rationalization technique for consolidating purchases in 2 phases:

*INGESA selects the suppliers and sets the terms and prices of the framework agreement

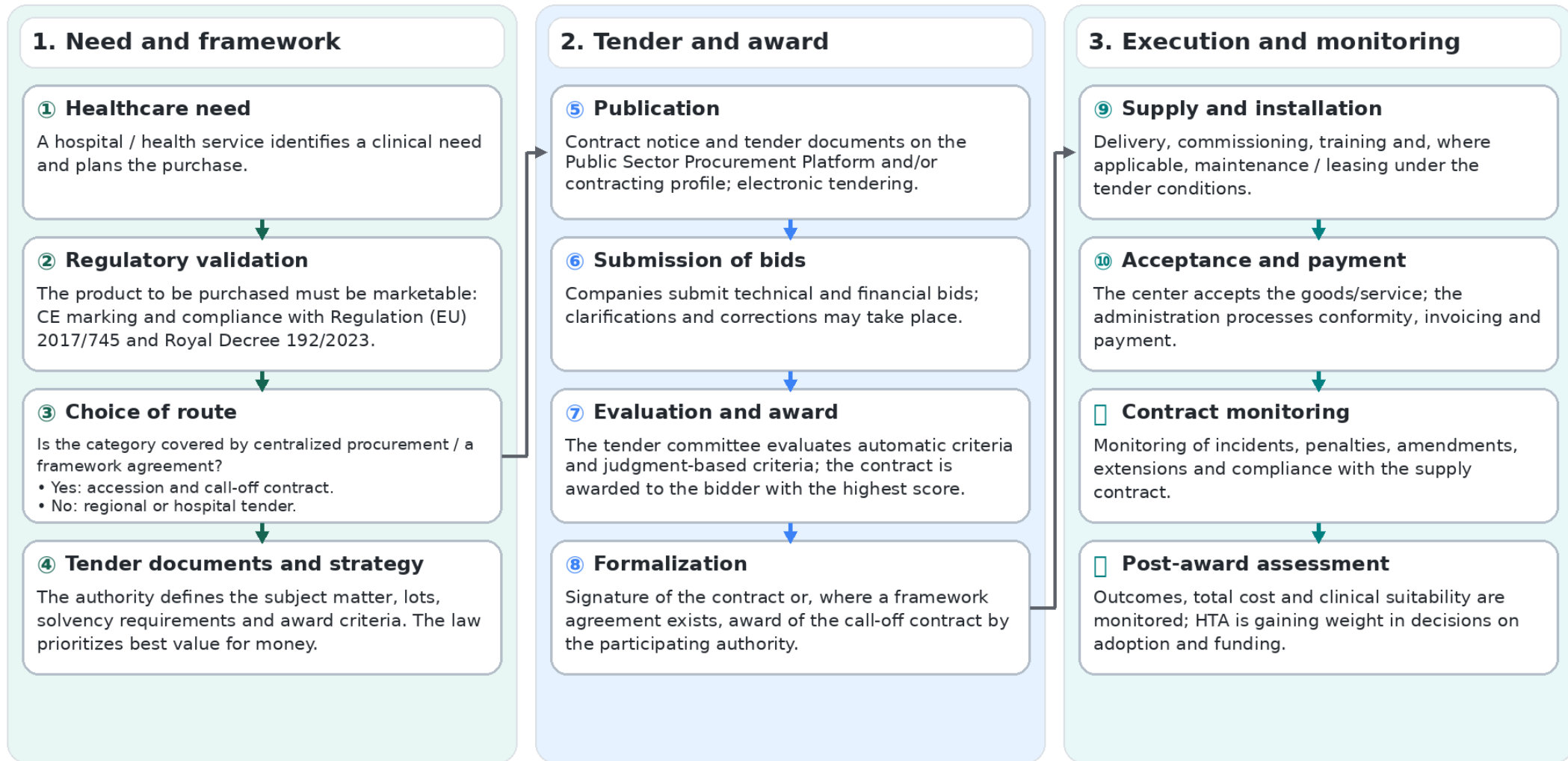
* Administrations participants award contracts based on these terms, specifying quantities, deliveries, and execution, and assuming responsibility for receipt and payment

3. **Electronic procurement and advertising**

- Tenders are published and managed through the **Public Sector Procurement Platform**.
- Searching for tenders, contracting authority profiles, specifications and announcements.
- Designed as the central component of electronic public procurement.



MEDTECH: SPANISH PUBLIC PROCUREMENT MAP

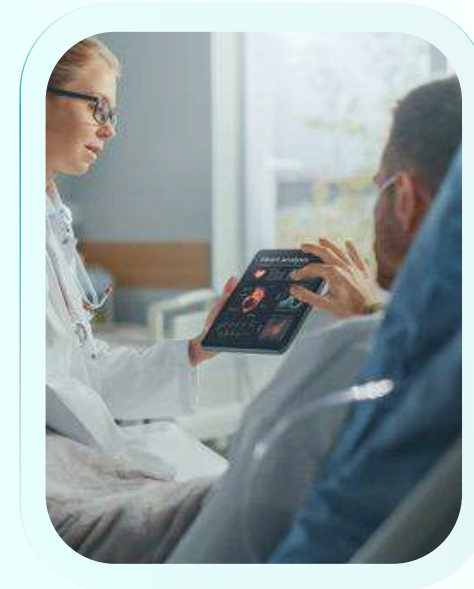


Current system highlights: decentralization across 17 regions + selective centralization (INGESA); the legal framework promotes value for money, although the sector still reports procedures strongly driven by price.

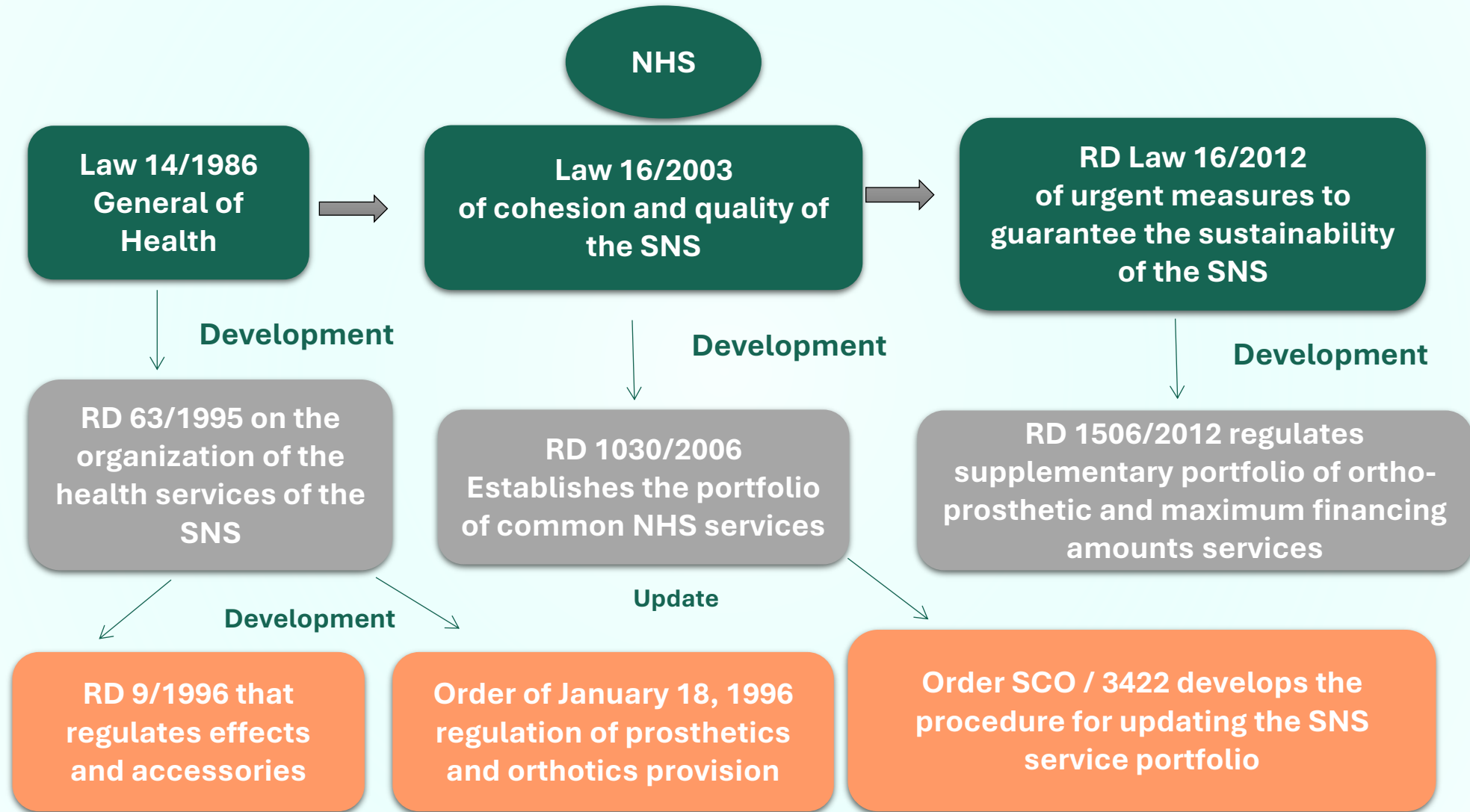
Spanish Federation of Healthcare Technology Companies

Fenin

Pharmaceutical benefit and
ortho-prosthetic benefit



REGULATION OF THE HEALTHCARE PORTFOLIO OF SERVICES





CONTENTS: COMMON SERVICES PORTFOLIO OF THE SPANISH NHS - ANNEXES TO ROYAL DECREE 1030/2006



Specialized care
Health transport
Public health
Emergency care
Primary care
Ortho-prosthetic benefit
Dietetic products
Pharmaceutical benefit

Contents

- **Basic common portfolio of healthcare services** (public health, primary care, specialized care, emergency care, urgent health transport, implants).
- **Supplementary common portfolio**
via outpatient dispensing
(pharmaceutical, ortho-prosthetic, dietetic products and non-urgent health transport)
- **Common portfolio of ancillary services**
(not considered essential and/or are complementary or support services to improve a chronic condition)

*NO USER
CO-
PAYMENT*



*USER
CO-
PAYMENT*





FORMS OF PUBLIC FUNDING

Public funding for medical devices is established through three different mechanisms:

- **At primary and specialized care level**
 - The Administration covers the costs of products and services, without patient intervention. Supply
 - Provision of contracted healthcare services under a fixed-budget model. Oxygen therapy and dialysis
- **At ortho-prosthetic benefit level**
 - The patient pays the cost directly and is then partially or fully reimbursed for the cost of the product. Orthopaedics
- **At pharmaceutical benefit level**
 - Through medical prescription with the involvement of the pharmacy. Depending on whether the patient is actively employed or not, they assume part of the product cost. Devices and accessories



FORMS OF PUBLIC FUNDING



- ❑ **At primary and specialized care level,**
 - through public procurement procedures in accordance with the Public Sector Contracts Law,
 - the technology must be included in the portfolio,
 - inclusion of the product in any list or catalogue is not requested
 - it includes the ortho-prosthetic benefit in the basic portfolio: surgical implants
 - in some cases, the definition of the technologies is very generic



ORTHO-PROSTHETIC BENEFIT





ANNEX VI ORTHO-PROSTHETIC BENEFIT

The ortho-prosthetic benefit consists of the use of medical devices, whether implantable or not, intended to replace, modify all or part of a body structure, or to modify, correct or facilitate its function. It includes the elements needed to improve the patient's quality of life and autonomy.

This benefit will be provided by health services or will give rise to financial support, in accordance with the regulations established by the competent health authorities.

The different Regional Health Services prepare their own product catalogues, which define the items funded within their scope of management.

The prescription of products included in the ortho-prosthetic benefit must be carried out by a specialist-care physician.

Annex VI to Royal Decree 1030/2006

- Basic: **Surgical implants**
- Supplementary: **External ortho-prostheses**
 - *External prostheses*
 - *Orthoses*
 - *Wheelchairs*
 - *Special ortho-prostheses*



FORMS OF PUBLIC FUNDING

□ At supplementary ortho-prosthetic benefit level,



- in orthopaedic and audioprosthesis centres that manufacture custom-made ortho-protheses and adapt them individually. They must meet the requirements established by the competent health administration
- Medical devices must meet the requirements set out in the applicable legislation in force.
- through catalogues developed at regional level based on the current legislative framework for the ortho-prosthetic benefit, which establishes the minimum criteria for this benefit.
- Depending on the autonomous community, reimbursement will be made directly to the patient/user or to the establishment.
- A model similar to the pharmaceutical benefit is being implemented, with an application for inclusion in the offering and the setting of a maximum funding price.



PHARMACEUTICAL BENEFIT



LAW 16/2003 OF COHESIÓN AND QUALITY



Pharmaceutical Reimbursement

Pharmaceutical reimbursement covers medicines, medical devices and actions needed to ensure appropriate, dose-adjusted and cost-effective treatment.

It is governed by Royal Decree Legislative 1/2015 on guarantees and rational use.

For outpatient care, it includes indication, prescription and dispensing.

Medical devices require CE marking and an NHS financing/dispensing decision.

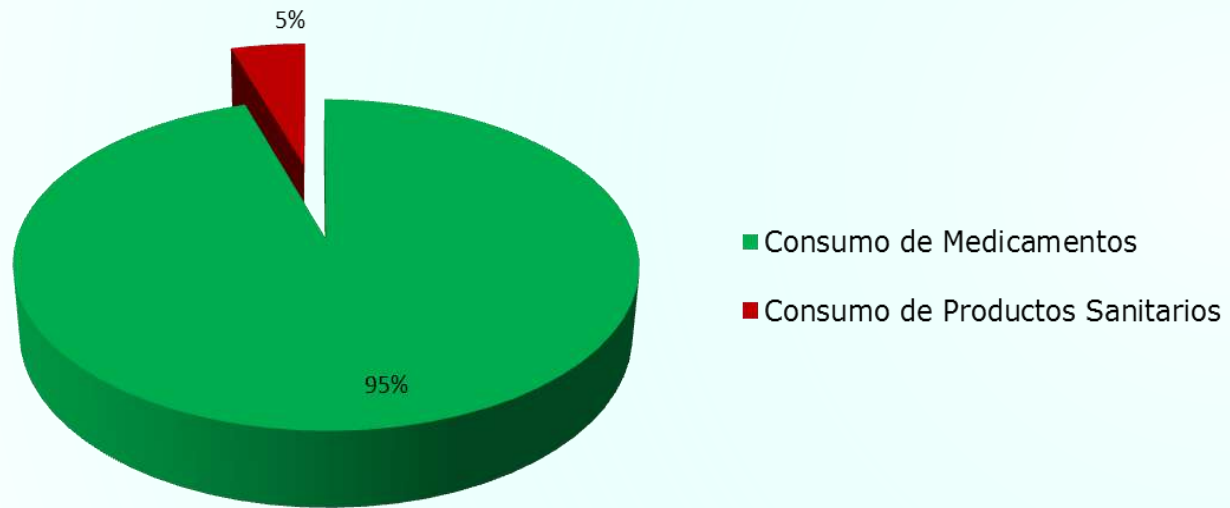


MEDICAL DEVICES INCLUDED IN PHARMACEUTICAL REIMBURSEMENT

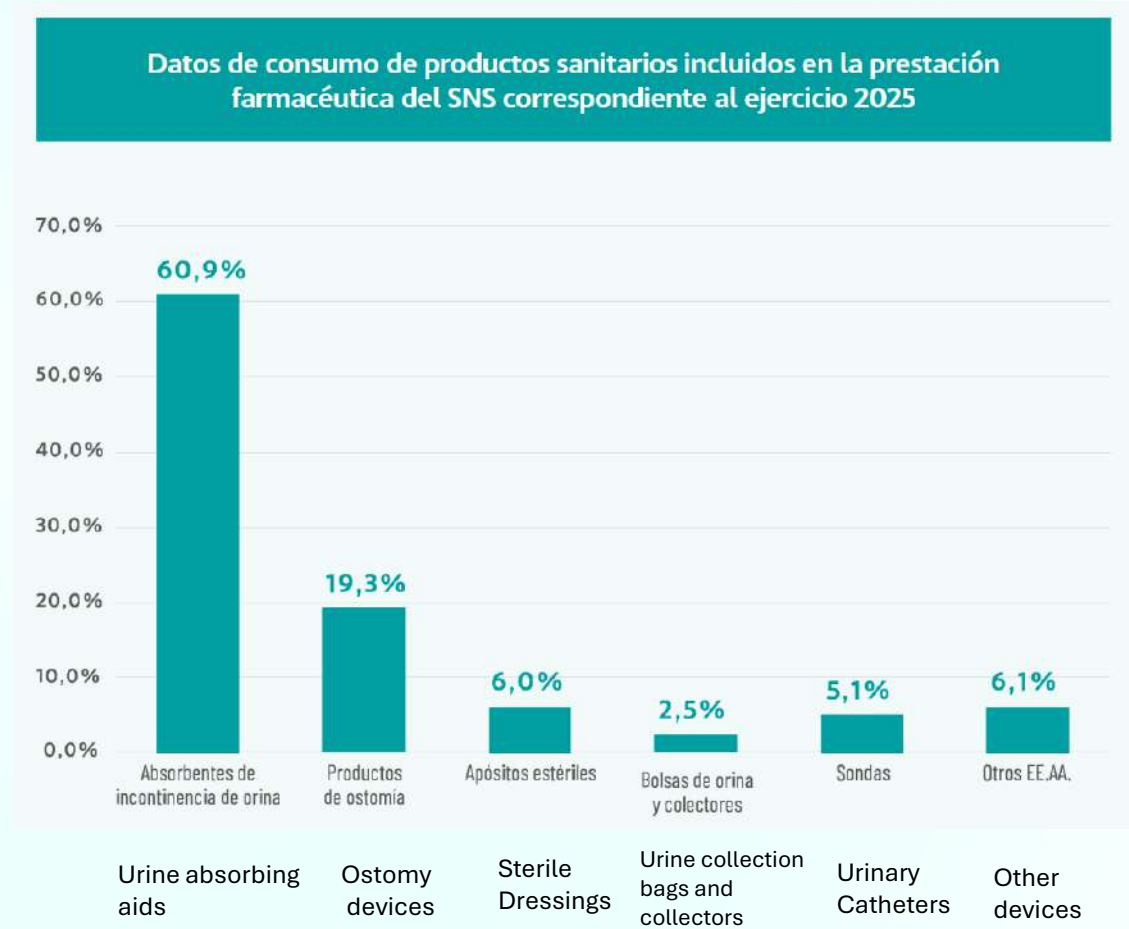


Total expenditure: 14.389.626.975 €

Medical device expenditure: 758.369.006,7€



Source: Ministry of Health. Year 2025



ROYAL DECREE 90/2026: SELECTIVE FUNDING OF MEDICAL DEVICES UNDER THE PHARMACEUTICAL BENEFIT



Current 2026 regulation

Royal Decree 90/2026 regulates selective funding and distribution margins for medical devices for non-hospitalised patients.

Repealed 1996 regulation

Royal Decree 9/1996 governed the funding and supply of health effects and accessories for non-hospitalised patients; it has now been repealed.

Legislative update 2006-2015

Law 29/2006 and Royal Legislative Decree 1/2015 updated and harmonised legislation on medicines and medical devices.

CONSEQUENCES OF 20 YEARS WITHOUT REGULATORY DEVELOPMENT AND BLOCKED INNOVATION

Lack of regulatory development

20 years without a pricing and funding procedure for medical devices.

Limited innovation

Services became less efficient; updates were mainly incremental.

Patient impact

Fewer innovative products available than in other European countries.

R&D impact

Lower business incentives and declining investment.



PURPOSE AND SCOPE OF THE ROYAL DECREE



Regulates funding, pricing, selection, procurement and dispensing of devices for non-hospitalised patients.

Defines how devices are included, modified or excluded from the NHS pharmaceutical benefit.

Sets distribution and dispensing margins.

Applies only to funded medical devices for non-hospitalised patients.

FORMS OF PUBLIC FUNDING



☐ At pharmaceutical benefit level,

- serially manufactured medical devices obtained on an outpatient basis and intended for therapeutic treatment or to help patients manage its adverse effects.
- in health centres or through pharmacies,
- with direct reimbursement following the medicines model (pharmacy),
- benefit criteria and the corresponding funding are established centrally by the Ministry of Health,
- inclusion in the offering is requested product by product and the price is set

CATEGORIES AND REQUIREMENTS FOR FUNDABLE MEDICAL DEVICES

ANEXO I

Grupos de productos sanitarios con aportación normal

Descripción del grupo

1. Algodones.
2. Gasas.
3. Vendas.
4. Esparadrapos.
5. Apósitos.
6. Parches oculares.
7. Tejidos elásticos destinados a la protección o reducción de lesiones o malformaciones internas.
8. Irrigadores y accesorios para irrigación.
9. Bragueros y suspensorios.
10. Absorbentes para incontinencia urinaria.
11. Otros sistemas para incontinencia.

ANEXO II

Grupos de productos sanitarios con aportación reducida

Descripción del grupo

1. Aparatos de inhalación (inhaladores, cámaras de inhalación, insufladores).
2. Sondas.
3. Bolsas de recogida de orina.
4. Colectores para bolsas de recogida de orina y accesorios.
5. Bolsas de colostomía.
6. Bolsas de ileostomía.
7. Bolsas de urostomía.
8. Accesorios de ostomía.
9. Apósitos de ostomía.
10. Sistemas de irrigación ostomía y accesorios.
11. Sistemas de colostomía continente.
12. Cánulas de traqueotomía, laringectomía y filtros.

Categories of medical devices

Fundable medical devices are divided into:

- **wound-care materials,**
- **medical devices intended for administering medicines,**
- **medical devices intended for collecting excreta and secretions, and**
- **devices intended to protect against or reduce injuries or internal malformations.**

Classification and groups

Groups are organised by co-payment level and by product characteristics/use.

Funding requirements

Only mass-produced products that meet specific requirements may be funded for non-hospitalised patients (custom made medical devices are excluded)

TYPES OF MEDICAL DEVICES INCLUDED IN PHARMACEUTICAL REIMBURSEMENT

Annex I:

- 1.- Cottons
- 2.- Gauze
- 3.- Bandages
- 4.- Adhesive plaster
- 5.- Dressings
- 6.- Eye patches
- 7.- Elastic tissues for the protection or reduction of injuries or internal malformations
- 8.- Irrigators and accessories for irrigation
- 9.- Trusses and jockstraps
- 10.- Urine absorbing aids
- 11.- Other systems for incontinence



TYPES OF MEDICAL DEVICES INCLUDED IN PHARMACEUTICAL REIMBURSEMENT

Annex II

- 1.- Inhalation devices (inhalers, inhalation chambers, insufflators)
- 2.- Urinary catheter
- 3.- Urine collection bags.
- 4.- Urine collection bags collectors and accessories.
- 5.- Colostomy bags.
- 6.- Ileostomy bags.
- 7.- Urostomy bags.
- 8.- Ostomy accessories.
- 9.- Ostomy dressings.
- 10.- Irrigation systems, ostomy and accessories.
- 11.- Continent colostomy system.
- 12.- Tracheostomy and laryngectomy tubes and filters.





TECHNICAL SPECIFICATIONS AND INCLUSION CONDITIONS



Inclusion in specific groups

Products must be included in the groups listed in Annexes I and II, including accessories needed for their use.

Compliance with current law

The criteria in Article 92.6 of the Law on guarantees and rational use of medicines and medical devices must be met:

- a) Severity, duration and after-effects of the different conditions for which they are indicated.
- b) Specific needs of certain groups.
- c) Diagnostic, monitoring, treatment, prevention, relief or disability-compensation value.
- d) Social value of the medical device and its incremental clinical benefit, considering its cost-effectiveness.
- e) Availability of medical devices or other therapeutic alternatives for the same conditions at a lower price or treatment cost.

Technical certificates and requirements

The Ministry of Health's technical specifications must be met, with certificates accrediting compliance.

CE marking and regulation

Products must bear CE marking and comply with the European rules applicable to medical devices.

Advertising restriction

Products must not be advertised to the general public in order to comply with the regulation.

APPLICATION, DOCUMENTATION AND ASSESSMENT PROCESS



Procedure starts with company registration and application.

- DG Services Portfolio maintains the register and assigns each company a number.

Application package: product description, requested maximum PVL, budget/price justification, 3-year sales forecast and sustainability proposal if applicable.

Regulatory evidence: EU conformity declaration, CE/Notified Body certificate when required, technical compliance declaration and assessment templates.

Companies must also provide **EU marketing status/prices and comparable prices.**

Samples must be submitted in person within 5 days of electronic filing.

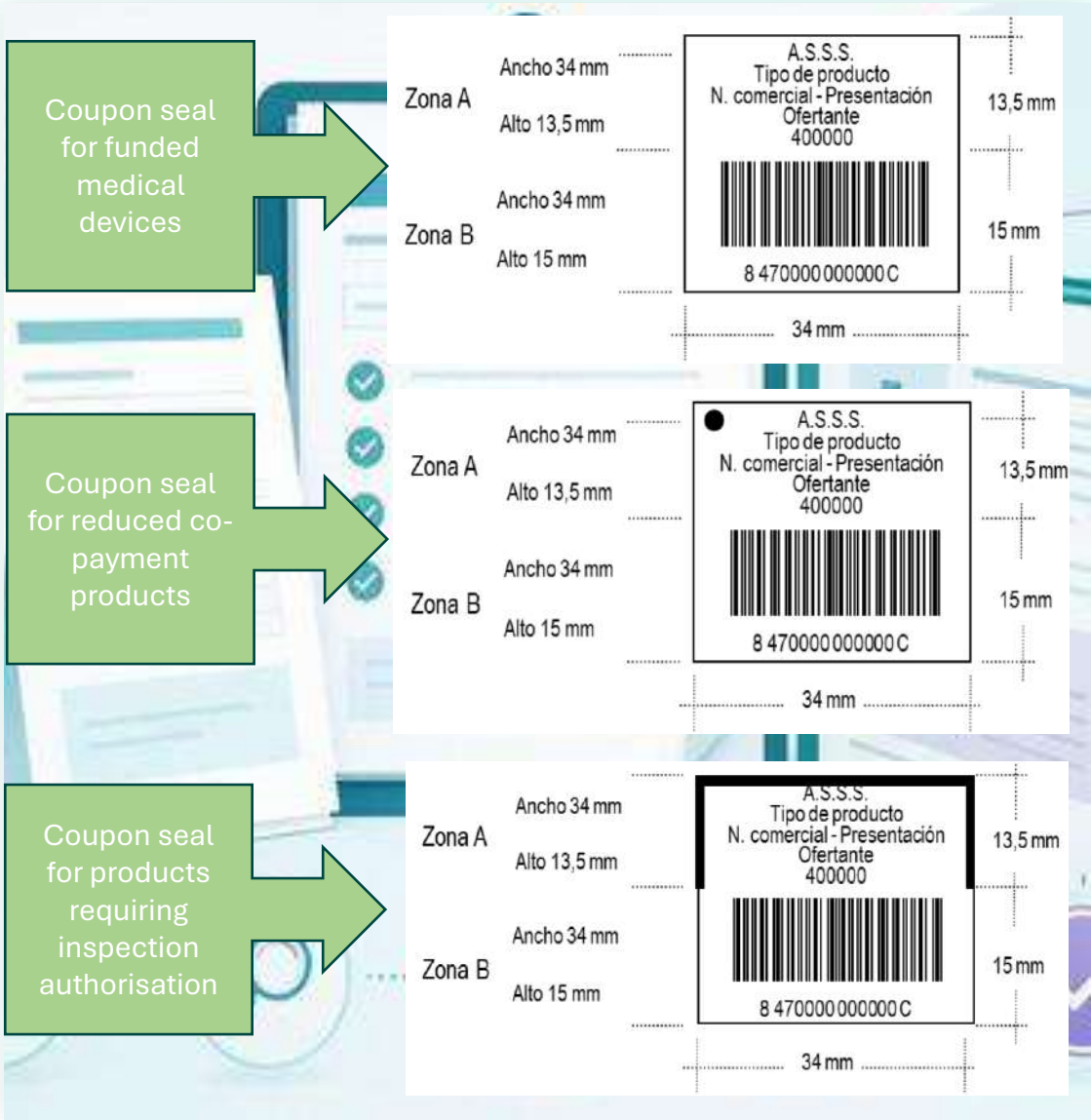
The technical report assesses clinical role, innovation, effectiveness, use conditions, durability, alternatives and NHS budget impact.

- Cost-effectiveness analysis may be added when needed.

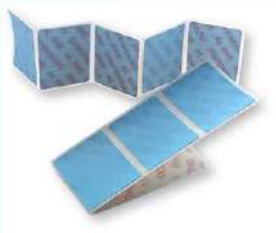
The report supports CIPM price setting.

The authority has up to 6 months to approve or reject the application.

COUPON SEAL



Coupon seal identifies funded devices and serves as proof of pharmacy dispensing.



The **funding decision** authorises use of the seal and sets the maximum PVL.

Pharmacies may remove the seal only to attach it to the official prescription or dispensing order.

Products supplied **via healthcare or social-care centres** must be delivered with the **seal cancelled or without coupon seal**.

EXCLUSION CRITERIA AND PROCEDURES



Devices may be excluded from NHS pharmaceutical benefit under legal or regulatory criteria.

- The procedure may start ex officio or at the company's request.
- Economic review compares price and treatment cost with available alternatives.
- Alternatives must have equivalent quality, safety, efficacy and effect.
- Comparisons use maximum PVL or cost of use, depending on product equivalence.

SETTING THE MAXIMUM EX-FACTORY PRICE AND RETAIL PRICE



CIPM sets a maximum laboratory selling price (maximum PVL) using objective criteria.

- Cost-effectiveness and budget impact are considered.
- Retail price = maximum PVL + distribution/dispensing margins + taxes.
- If a company markets below maximum PVL, it must notify the Ministry so the public price can be adjusted.

DISTRIBUTION AND DISPENSING MARGINS



Distribution margins

Margins for distribution of medical devices in pharmacies are regulated by the National Health System and specified in Annex IV.

Dispensing margins

The margins applicable to the dispensing of medical devices by pharmacies are also defined in Annex IV of the Royal Decree.

ANEXO IV

Márgenes correspondientes a la distribución y dispensación de productos sanitarios incluidos en la prestación farmacéutica del Sistema Nacional de Salud para pacientes no hospitalizados

Los márgenes correspondientes a la distribución y dispensación de productos sanitarios incluidos en la prestación farmacéutica del Sistema Nacional de Salud para pacientes no hospitalizados quedan recogidos de la siguiente forma:

PVL máximo del producto	Márgenes correspondientes a la distribución	Márgenes correspondientes a la dispensación
Igual o inferior a 59 euros.	6% del precio de venta del distribuidor sin impuestos.	21% del precio de venta al público sin impuestos.
Superior a 59 euros.	3,77 euros por envase.	16,69 euros por envase.

Margins by maximum PVL

PVL ≤ €59: 6% distribution margin; 21% pharmacy dispensing margin on retail price excluding taxes.

PVL > €59: fixed margins of €3.77 for distribution and €16.69 per package for pharmacy dispensing.

PROCEDURE FOR OFFER CHANGES AND PRICE REVIEWS



Companies may request changes to packaging data, trade/brand name, price, company/manufacturer, indications, use instructions or minor improvements.

- Changes **cannot reduce technical characteristics or compliance** with original specifications.
- **DG has up to 6 months** to decide; Nomenclator changes follow the launch date.
- Prior hearing is required; parties have 10 days for representations.
- Decision may approve or reject; appeal within 1 month; approving administrative silence applies.



APPLICATION, ASSESSMENT AND DECISION ON PRICE REVIEWS

Companies may request upward price review due to economic, technical or health changes, or revised therapeutic utility.

- Application includes product description, proposed PVL and supporting economic/technical justification.
- DG assesses the request and issues a technical report.
- CIPM decides upward or downward review, considering budget impact and lower-cost alternatives.
- Decision deadline: 6 months, with prior hearing and appeal rights.
- Companies may request voluntary PVL reductions at any time.

DISPENSING AND SUBSTITUTION PROCEDURE IN PHARMACIES



The **pharmacy dispenses the prescribed or authorised device.**

- **If the price exceeds the lowest in its homogeneous group, substitute with the lowest-price product.**
- **In shortage or urgency, the pharmacist may substitute a similar product** at the same or lower price and inform the patient.
- **Receipt must identify date, product, price and co-payment.**
- **Devices not charged to the NHS are still dispensed by pharmacies.**



Co-payment for products at the standard rate

Users of medical devices in Annex I pay as established in the Law on guarantees and rational use.

Co-payment for reduced-rate products

Users of products in Annex II have co-payment limited to the maximum caps defined for reduced co-payment medicines.

Co-payment exemptions

People exempt from co-payment under the categories defined in law do not have to pay for medical devices.



TECHNICAL SPECIFICATIONS FOR MEDICAL DEVICES INCLUDED IN THE PHARMACEUTICAL BENEFIT



DG will update requirements and technical specifications for each grouping, category, subgroup or type.

- It will define which **centres may issue compliance certificates for inclusion** or existing funded products.
- **Exceptional exclusion:** devices not marketed at entry into force and still unmarketed one year later without justification may be excluded.

REGISTER OF OFFERING COMPANIES

DG maintains the register of companies offering devices for NHS funding and assigns each an offer number.

- **New companies must register electronically** before submitting offers.
- **Companies already included at entry into force remain registered** but must update outdated data.
- **Specific assessment and pricing criteria** will be developed within 12 months of entry into force.





MEDICAL DEVICES THAT FORM PART OF THE PHARMACEUTICAL BENEFIT



Existing Annex I/II devices remain funded under the Royal Decree.

- Current funded devices receive a maximum PVL derived from retail price excluding taxes and margins, according to the periods established in section 3 of this transitional provision by product group.
- Devices outside the new annexes are excluded after a 3-month transition.
- Price-review windows run by product group following this schedule:
 - a) **First period: 1 July 2026 to 31 December 2026** for **urine collection bags, tracheotomy cannulas, laryngectomy products and filters.**
 - b) **Second period: 1 January 2027 to 30 June 2027** for **urine absorbing aids, other incontinence systems, catheters and collectors for urine collection bags and accessories.**
 - c) **Third period: 1 July 2027 to 31 December 2027** for **cotton wool, gauze, bandages, adhesive tapes, dressings, eye patches, inhalation devices, trusses and suspensories, and elastic fabrics intended to protect against or reduce injuries or internal malformations.**
 - d) **Fourth period: 1 January 2028 to 30 June 2028** for **colostomy bags, ileostomy bags, urostomy bags, ostomy accessories, ostomy dressings, ostomy irrigation systems and accessories, continent colostomy systems, and irrigators and irrigation accessories.**
- After the fourth period, any funded device may request an upward PVL review.

UPDATE OF PRODUCT GROUPS, COUPON SEAL AND MARGINS



The Ministry of Health may **update, by ministerial order, the groups of medical devices eligible for inclusion in the SNS pharmaceutical benefit for non-hospitalized patients, as listed in Annexes I and II**, when technical-health or economic reasons so require.



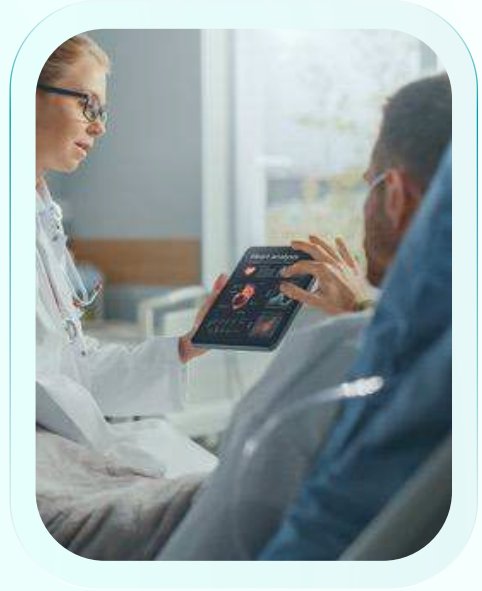
The Ministry of Health may issue the provisions required for the **updating and adaptation of Annex III to advances in information systems and technologies.**



The **margins for the distribution and dispensing of the medical devices provided for in Articles 16 and 17, and set out in Annex IV of this Royal Decree, will be updated by order of the Ministry of Health, following agreement by the Government Delegate Committee for Economic Affairs.**

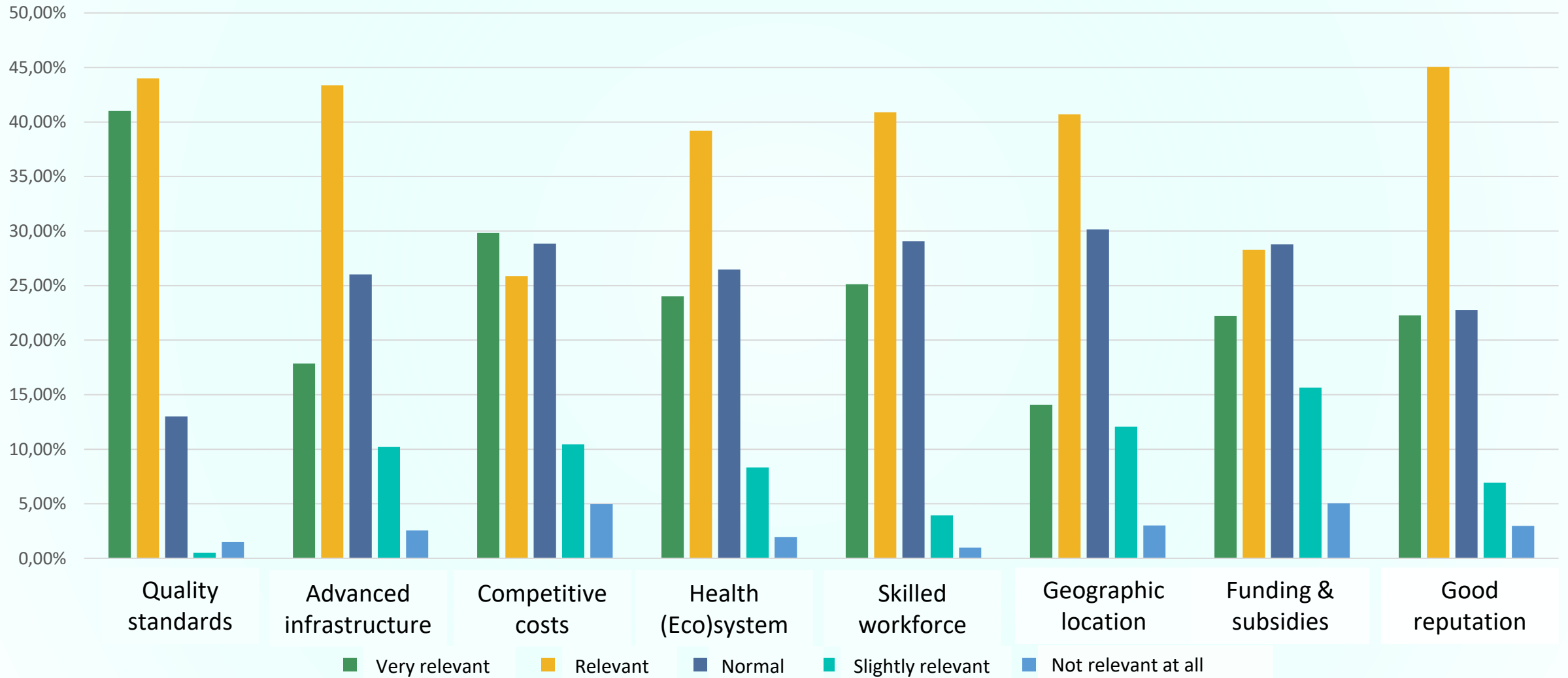


Key Topics to have to know for reaching the Spanish market



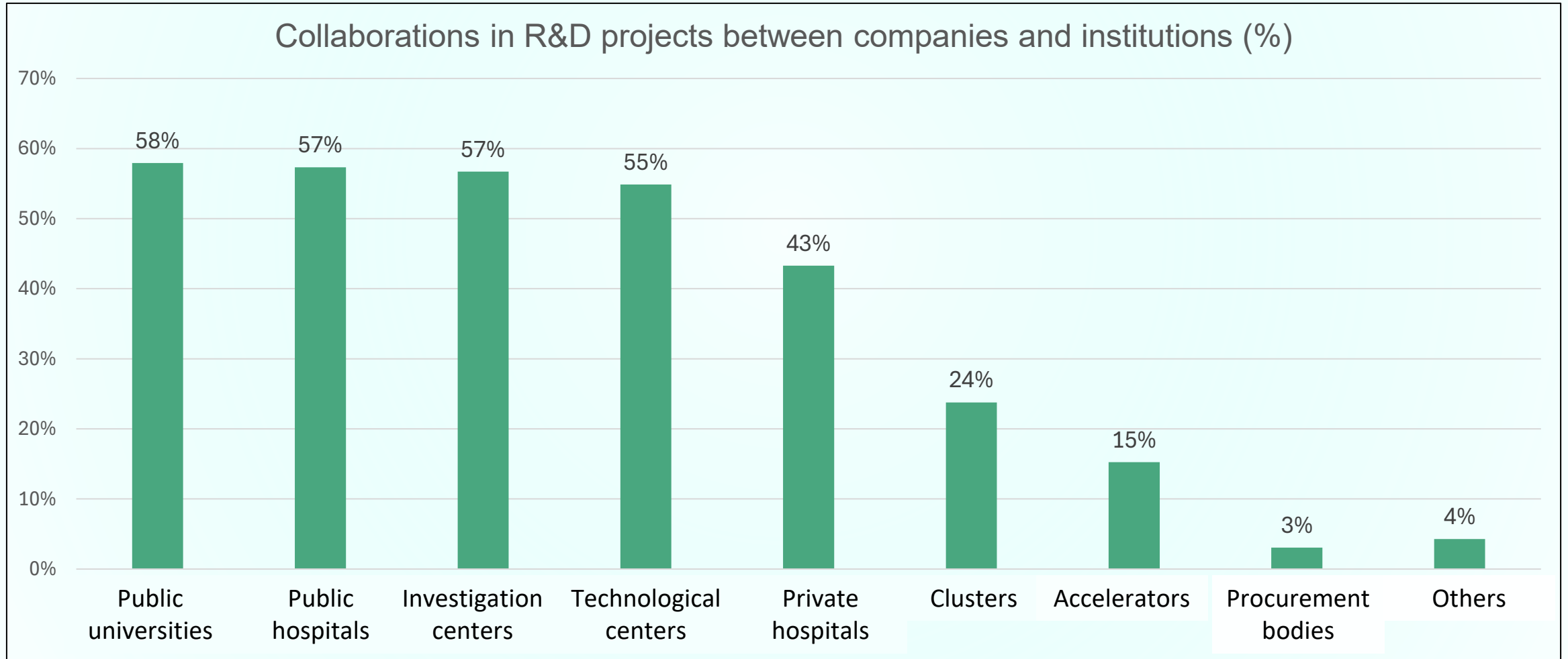


Advantages of manufacturing in Spain (%)





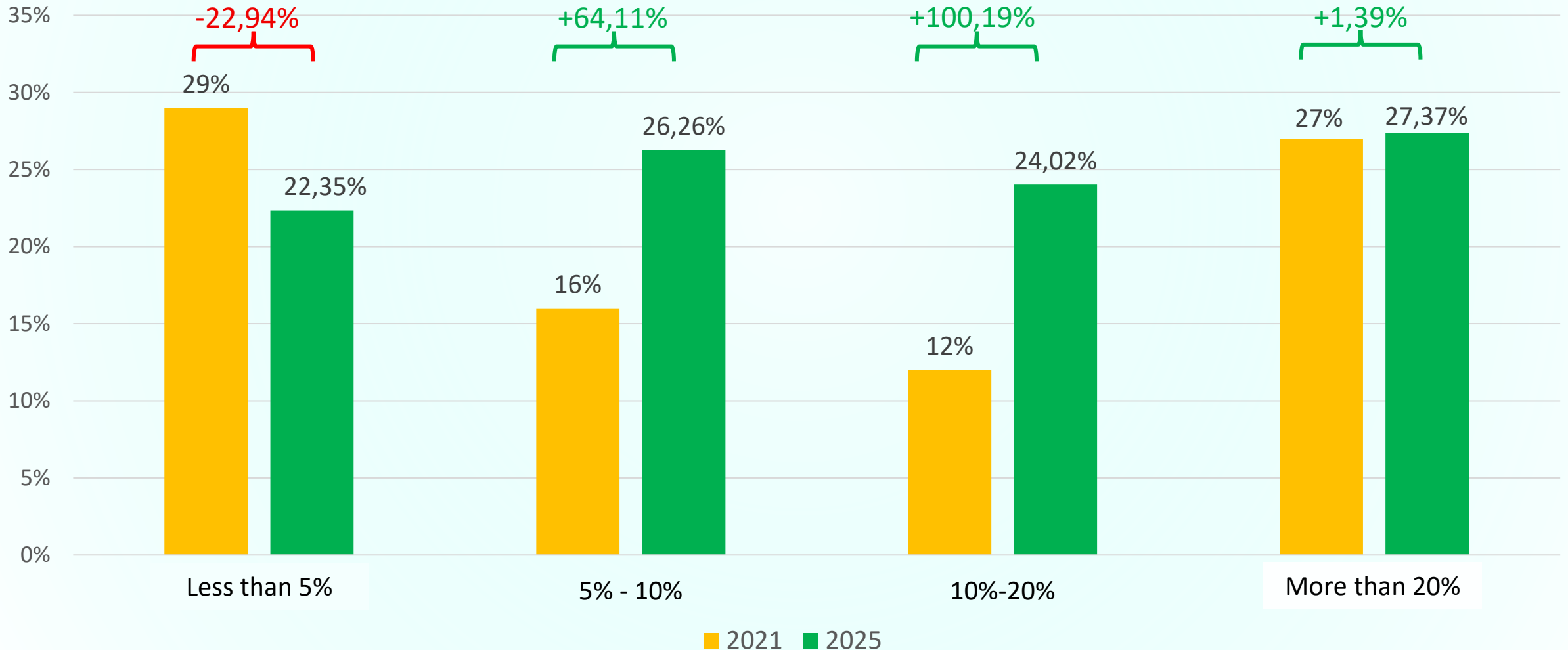
- +57% have engaged in R&D collaboration with institutions (+23.96% compared to 2021)
- Emerging role of the start-up ecosystem with disruptive innovations





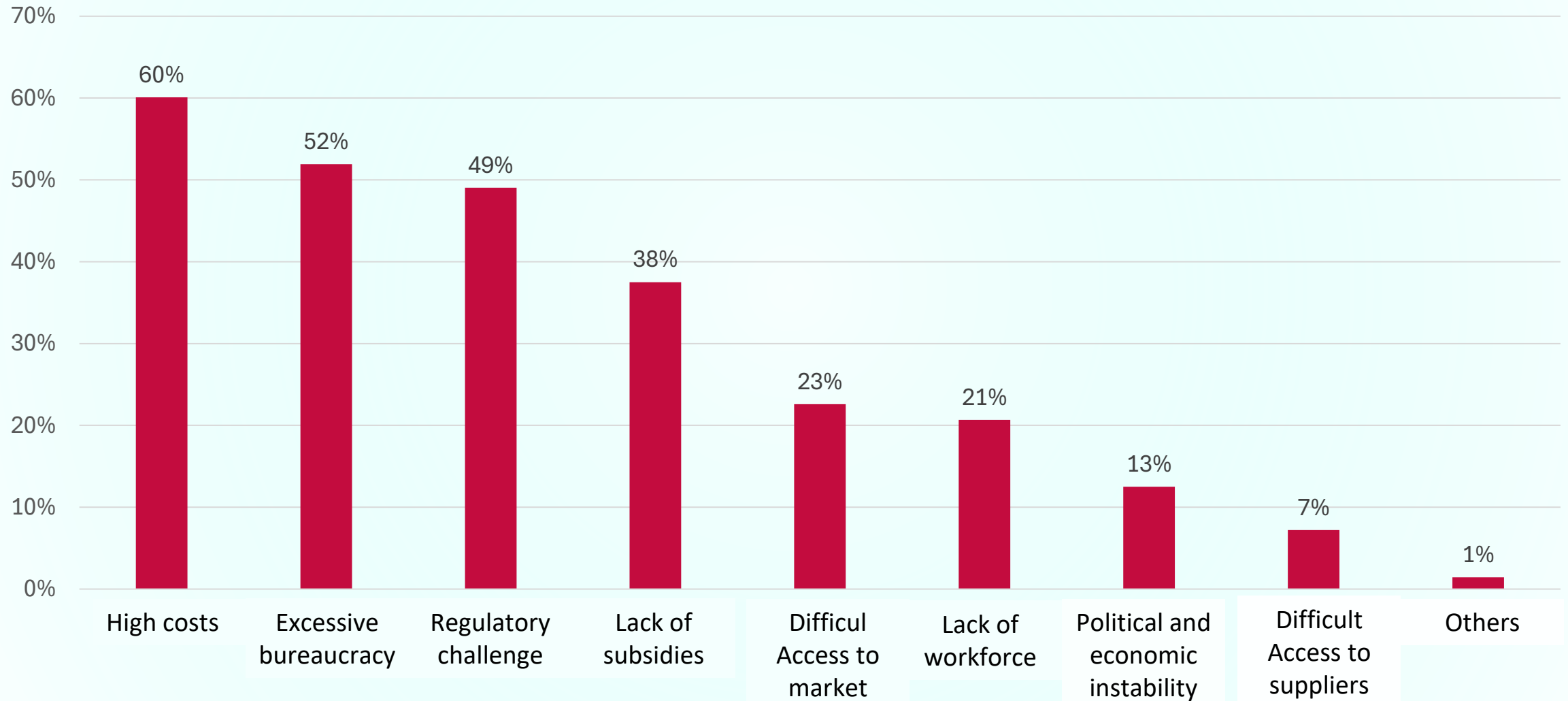
85% of companies have an R&D department

Manufacturers' investment in R&D relative to revenue 2025 vs 2021 (%)





Disadvantages of manufacturing in Spain (%)





Mature market with several characteristics and opportunities



Very decentralised market

- **Not one-single market**
- **17** autonomous communities (federal states)
- **Market Access is regional, not fully national**
- Different formularies, procurement practices



Price-driven approach

- Strong pressure via procurement & budget constraints
- Slowly moving toward
 - value-based healthcare
 - Innovation procurement (still developing)

Market Access Pathways are fragmented

- Depends on: product type, clinical value, budget impact...



Long payment times

- High variability across regions
- Administrative timelines
- High variability across regions



Developed Health (Eco)system

- Strong hospital infrastructure
- Increasing digitalization
- Opportunity for innovation and collaboration
- Lack of interoperability

Strong weight of public health

- **Tenders at regional or hospital level**
- Administrative timelines
- Strong infrastructure
- High variability across regions



Mature market with several characteristics and opportunities



Role of distributors and local partners

- **As decentralised market, presence if key:** market knowledge, tender management, contact with stakeholders...



Importance of stakeholders & decision-makers

- Key actors:
 - Regional Health Authorities
 - Hospital management
 - Procurement bodies
 - Spanish Agency for Medicines and Medical Devices (AEMPS – *Agencia Española del Medicamento y Producto Sanitario*)
 - Health Ministry
- Other key actors:
 - Industry Ministry
 - ICEX – Invest in Spain
 - Regional agencies for competitiveness and industrial development (Invest in Madrid, ACCIO in Catalonia, IVACE in Valencia...)
 - Innovation Ministry
 - Regional governments and departments

THANK YOU VERY MUCH!

