2022 Report

A Word from the President

Jesús Ponce

President of Farmaindustria

“We have to make strides together in our commitment: to keep innovating for people”

These were my first words on the day I took office as President of Farmaindustria in October 2022. And since then, I have continued to repeat it at the conferences, forums and debates that I have spoken at: we are here because we innovate for people. This is our purpose.

The difficult years of the pandemic are proof of this. The world expected – or rather, needed – a response from our industry; and we gave it to them. Society has confirmed this: we have been a key part of the solution. All this has strengthened our ties with the population. They understand us better now, they know our job and our purpose: they see that we are a valuable sector, and not only in healthcare. But in the economic and social spheres too.

A quick glance at the key milestones of this Farmaindustria Activity Report for 2022 backs this up. We are a sector open to listening and communicating with society, committed to good practices and transparency; a sector focused on collaborating with patients, to understand and try to meet their needs, and with healthcare professionals; we are leading the way in diversity and equality, and we are leaders in environmental sustainability. And all this, as shown by this Report, is achieved while maintaining continuous dialogue with the Government to seek solutions to improve healthcare and to reconcile patient access to innovation with the financial sustainability of the healthcare system. We are a strategic sector for Spain.

It is true that we are living in a difficult and continuously evolving context and face many challenges. One such challenge is the European Commission’s proposal to review Europe’s pharmaceutical legislation, which contains a number of measures that threaten the future of the pharmaceutical industry on this continent and constitute a further barrier to patient access to innovative treatments. The policies set out in this review weaken the incentives for investment in biopharmaceutical innovation, restricting the science, research and development of new

medicines in the European Union. This loss of competitiveness relative to markets such as the United States and Asia has direct implications for citizens, whose access to new medicines or the possibility of taking part in innovative clinical trials is reduced.

But there are also significant opportunities ahead. Turning now to Spain, we have spent some months working on the Strategic Plan for the Pharmaceutical Industry and we need to keep pushing forward to make it a reality soon. This plan should establish three key goals: ensure access to innovation by improving the timelines and availability of innovative medicines, drawing on a stable, clear, agile and predictable framework; consolidate Spain's biomedical R&D leadership, paying special attention to translational research and feeding this two-way path between laboratory and clinical practice, and, lastly, to strengthen production by boosting employment and growth and reducing external dependence.

This is a unique opportunity for Spain and Europe to strengthen their role as a global R&D and production hub, ensuring the strategic nature and driving force of the pharmaceutical industry. Indeed, we must leverage the opportunity created by the Spanish Presidency of the Council of the European Union in the second half of 2023 to place health, medicines and the innovative pharmaceutical industry that makes them possible among the priorities of this mandate and to promote a biomedical research ecosystem on the continent based on the protection of intellectual property and more resilient production and supply chains for medicines.

Society needs us and we want to help improve it. Because those of us working in biopharmaceutical companies all have a common goal: to keep innovating for people.

Letter from the Director General

Juan Yermo

Director General of Farmaindustria

These are the most exciting adventures of our time. In our hands, we hold the possibility of improving the lives of thousands of people, even saving many of them. And we cannot fail.

During my first year leading the Association, which brings together 140 biopharmaceutical companies in Spain, and in the aftermath of the COVID-19 crisis, I have been acutely aware of the scale of this endeavour. And I confess that the mere idea of being successful gives me the strength each day to drive, together with the Farmaindustria team, the transformation that society demands of us as an industry.

We have focused on coming up with solutions to bring innovative medicines to patients in Spain, and to do so as quickly as possible. We have worked closely with the national and regional authorities to increase the number of medicines authorised in our country (only 58% of those approved in Europe reach Spain) and to reduce patient waiting times (in excess of 20 months, which, if we include npmaspc k c l r delays at regional level, extend on average beyond two years). The patients and their families need it.

Aware of our commitment to society, in 2022 we launched specific proposals to increase the objectivity and predictability of pricing and pcgk`psqc k c l r procedures and to establish clear criteria and mechanisms for early access to new medicines. To consolidate this task, we designed an agenda of public events on the topic, culminating in our first high-level event on the social value of medicines in November last year, where the problem of access to medicines in Spain was the central topic of discussion.

During this time, we have reinforced collaboration, dialogue and our trust with both national and regional governments. Considerable efforts were directed toward the meeting held between a broad representation of global pharmaceutical industry executives and the President of the Government of Spain and three cabinet ministers, both before and after the event, to promote our future Strategic Plan. And we are currently finalising the technical discussions that will be the cornerstones of our roadmap for access to medicines and the sustainability of Spain's National Health System (*Sistema Nacional de Salud*, SNS), the research and development of new therapies, and the production of medicines in Spain.

At continental level, however, we have detected questions that pose a threat to our competitiveness compared to countries like the United States and China. The Commission's proposal for a review of European pharmaceutical legislation not only jeopardises investment in innovation in Europe, but could have an adverse effect on the population's access to the best and most innovative medicines. We have stepped

up talks with the Government and diverse parliamentary groups to explain these threats and try to reverse the direction of the reform. Nonetheless, the issue will undoubtedly be addressed during the Spanish Presidency of the Council of the EU during the second half of 2023.

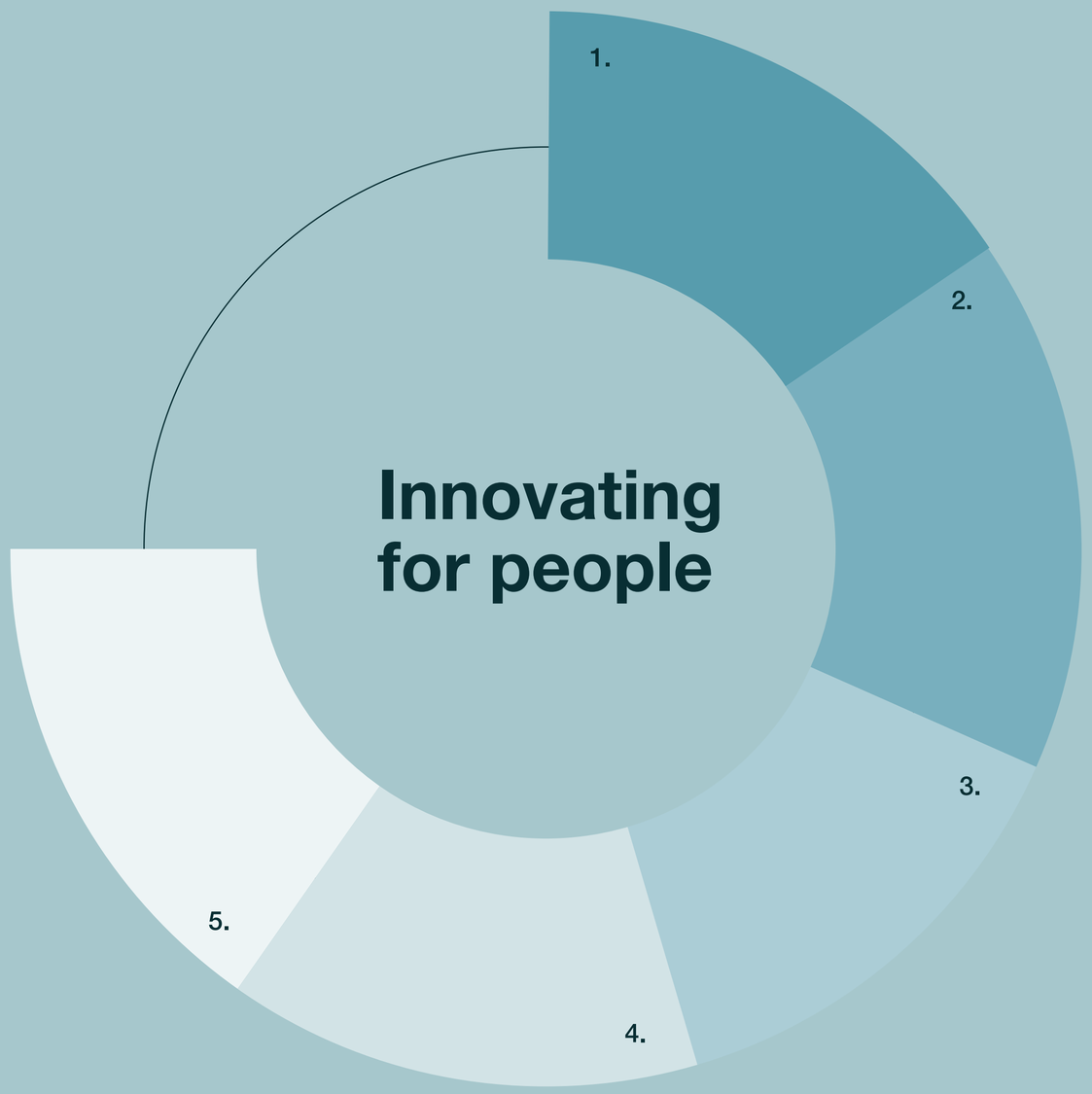
Spain is a global leader in clinical trials. And this is a heritage that we are bound to uphold as a country. Therefore, we have launched a number of parallel public-private initiatives in pharmaceutical R&D. We have worked alongside governments and diverse agents on critical initiatives for the future of biomedical innovation in Spain, including adaptation to European regulations on clinical trials, the development of networked clinical trials in different autonomous regions and mechanisms to transfer Spain's scientific excellence in basic research to pharmaceutical innovation. Public-private collaboration is key to realising our vision of Spain as a global benchmark and hub of biomedical innovation.

We must look to the future. Few industries can boast having such a stimulating purpose as the promotion of research, innovation and the production of medicines to improve people's lives, and doing so in an ethical and environmentally responsible way. We want to keep innovating for people. And we want to do it with the excellence that has always characterised us, with the good practices that we promote in our daily lives, with a robust social commitment and unity of purpose. This is the industry that we are building together. This is the strong Farmaindustria we want.

1.

Innovating for people

What We Do



1. Access and sustainability

Just 58%
of the medicines approved in Europe reach patients in Spain.

4 out of every 10 k cb g a g l cq
authorised in Europe are now for rare diseases.

2. Production

103 k_l sd_arsp c qgrcq for
medicines for human use.

Spain's third most exported product
is medicines, worth almost €27,000 million.

3. Research

ħ1*267 M
of R&D investment, of which
789 (62%)
were allocated to clinical trials.

4. Collaboration with the LFS

ħ592.7 M
allocated to research projects developed alongside hospitals, universities and public and private centres.

55 hospitals and 13 autonomous regions
have collaborated on the BEST clinical research excellence project.

5. Economic and social value

More than 44,000 jobs
53% held by women.

Almost 70% of the energy
used by plants manufacturing medicines is renewable.

2.

Pharmaceutical Industry Data

2.1 The pharmaceutical industry in Spain and worldwide

Spain's pharmaceutical industry generates a production to the value of €17,457 million, according to the latest available data for 2020.

Medicines are also Spain's third most exported product, as indicated by the latest data for 2022 from the Spanish Ministry of Industry, Trade and Tourism.

This is all developed at 103 manufacturing sites for medicines for human use, of which 11 manufacture biological medicines.

Pharmaceuticals is the second leading sector (after cars) in R&D&i investment. In 2021, the National Statistical Institute recorded investments to the value of €1,006 million.

Based on data from the Farmaindustria *R&D Activities Survey*, this figure amounted to €1,267 million, of which 62% was allocated to clinical trials to discover new medicines.

Pharmaceutical companies are also big drivers of wealth through jobs, employing more than 44,000 direct workers according to the *2021 Employment Survey* conducted by Farmaindustria and almost 49,000 according to EFPIA and Eurostat data. With the addition of indirect and induced jobs, the pharmaceutical industry generates a total of 210,000 jobs in Spain.

These figures place Spain as the ninth largest pharmaceutical market globally, accounting for around 1.9% of the world total and 7.8% of the total European market, according to 2021 data from consulting firm IQVIA.

In terms of pharmaceutical expenditure, OECD 2020 data show that public expenditure per capita in Spain (€255.9) was 34% lower than the eurozone average (€385.5) and around half of the investment of countries such as Germany (€580.4) and Ireland (€493.9).

Production

The pharmaceutical industry has high levels of industrial activity and a strong impact on Spain's economic configuration. This was highlighted by the *Study on the industrial implementation of the pharmaceutical sector in Spain*, conducted by the consulting firm ManageArt for Farmaindustria, which describes for the first time who Spain's pharmaceutical manufacturing sites are, the type of activity they perform and their impact.

The results of this study indicate that the pharmaceutical industry has a total of 103 manufacturing sites for medicines for human use in Spain, 11 of which are for biological medicines. If we add to these the manufacturing sites for active substances (46) and those for veterinary medicines (24), Spain's total number of manufacturing sites is 173, distributed among 122 different business groups.

The largest concentration of plants is in Catalonia, home to 79 of the 173 plants, followed by the autonomous region of Madrid, with 40; Castile and Leon, with 14; and Castile-La Mancha, with 8.

On the map

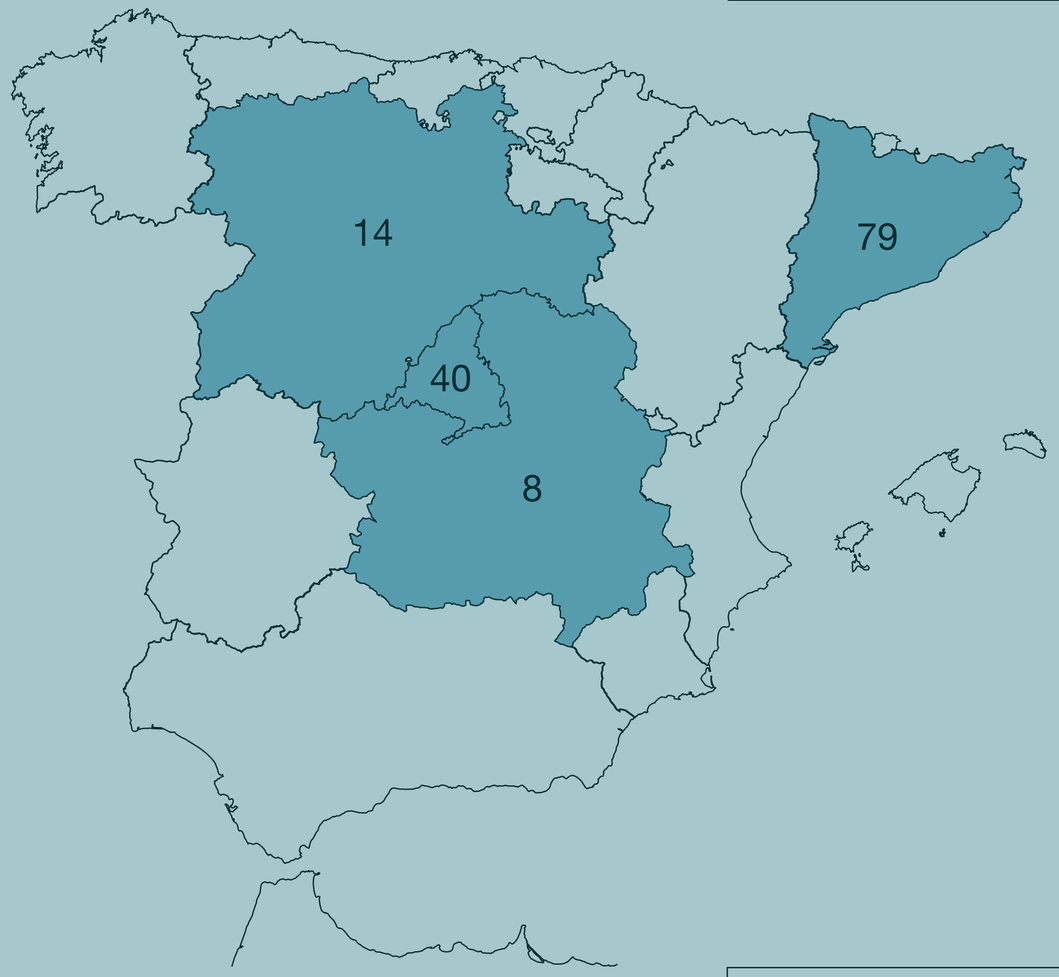
Spain's pharmaceutical industry manufacturing sites generated a production of €17,457 million in 2020, +5.2% more than in 2019.

The other major impact of the industry's manufacturing sites is in employment, both for its knock-on effect on other sectors of activity and for its classification. The report explains that industrial manufacturing sites of medicines in Spain directly employ more than 36,000 people, with a cumulative annual growth of +4.2% since 2019. And if we factor in the indirect and induced jobs generated by the industry due to its high number of suppliers and outsourced services, pharmaceutical manufacturing sites help to create over 180,000 total jobs in Spain.

1.

173

manufacturing sites

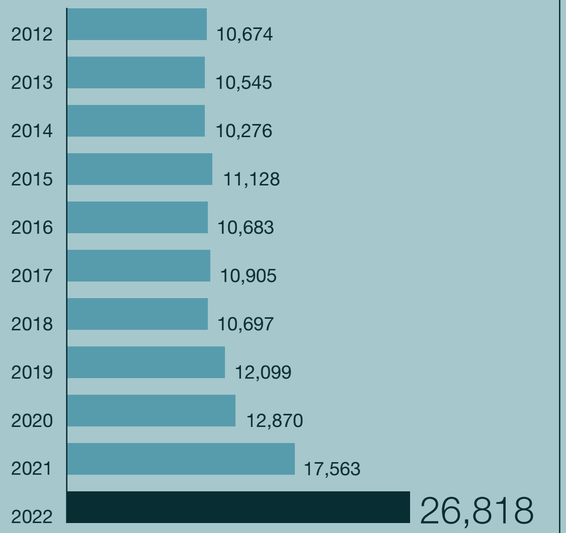


Pharmaceutical exports

In 2022, the pharmaceutical industry increased its foreign sales by +53% to €26,818 million.

2.

Trend in pharmaceutical industry exports over the last ten years (2012–2022)

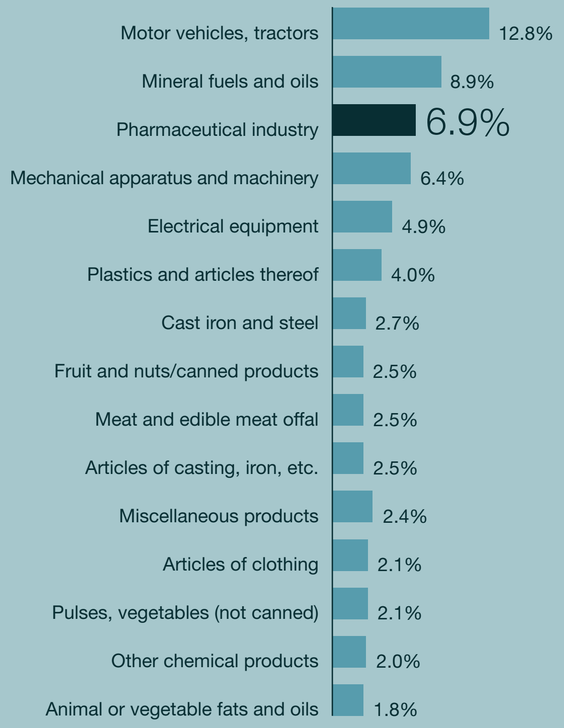


Source:
Ministry of Industry, Tourism and Trade

In 2022, Spain's third largest exporter was the pharmaceutical industry, behind only motor vehicles and mineral fuels and oils.

3.

Classification of the top 15 export sectors in 2022 (% of total country exports)



Source:
Ministry of Industry, Trade and Tourism Datacomex (data according to customs tariff schedule) (TARIC)

With regard to the geographical distribution of pharmaceutical foreign trade, in 2022, the European Union was still the chief buyer of medicines and vaccines manufactured in Spain, followed by Switzerland, the United States, China and the United Kingdom.

4.

Trend in pharmaceutical industry exports by country and geographical destination

	Exports	Imports	Exports	Imports
WORLD TOTAL	**100.0%**	**100.0%**	**100.0%**	**100.0%**
EU-27	**61.1%**	**41.3%**	**70.0%**	**42.2%**
Germany	9.4%	13.0%	6.4%	14.1%
Belgium	29.0%	6.7%	46.8%	7.5%
France	4.6%	4.7%	3.9%	4.4%
Netherlands	3.3%	5.6%	1.6%	4.1%
Ireland	2.6%	1.9%	2.5%	2.2%
Italy	3.9%	3.3%	2.9%	3.8%
REST OF EUROPE	21.6%	30.0%	16.1%	20.4%
United Kingdom	2.3%	1.9%	1.7%	2.9%
Switzerland	18.1%	27.9%	13.7%	17.2%
REST OF WORLD	17.3%	28.7%	13.9%	37.4%
China	2.1%	2.7%	2.6%	3.3%
United States	4.1%	15.7%	3.0%	23.8%
India	0.4%	0.8%	0.3%	1.1%
Japan	0.6%	0.3%	0.4%	0.3%

R&D&i

If we are to improve in this respect, and considering that the Spanish Strategy for Science, Technology and Innovation itself recognises that in the short term (2021–2023) “clear and robust support for R&D&i in healthcare will be vital”, it is essential to promote a climate and ecosystem that will harness the momentum of the leading research sectors, which include the pharmaceutical industry as a particularly strategic leading sector of research, as evidenced by the latest data from the Spanish National Statistical Institute (*Instituto Nacional de Estadística*, INE), which are summarised below:

— The pharmaceutical industry invested €1,006 million in research and development in 2021, representing 18.9% of Spanish industry's total R&D investment, making it by far the leading industrial sector by volume of research spending. (See Figure 5)

— Breaking down R&D spending by phases, the pharmaceutical industry yet again heads the industrial classification for volume of resources intended for basic or fundamental research, where it accounts for more than half of the total spend of the industrial sector in Spain (58%), and in applied research, where it represents 27% of the industrial total.

— With regard to the nature of the investments, the pharmaceutical sector also leads the industrial ranking, both in research conducted internally at company-owned centres (19.5% of the industrial total) and in research contracted from third parties (universities, hospitals, public or private centres, etc.), where it accounts for 15.8% of the Spanish industry total, the highest ratio together with the automotive industry.

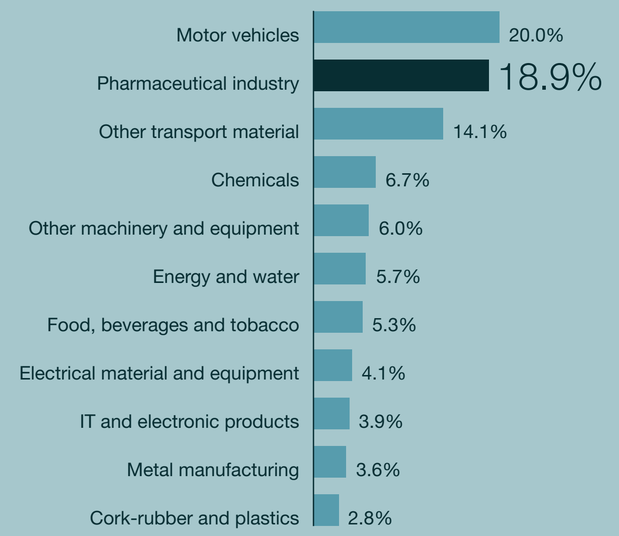
— The pharmaceutical industry is also the sector that generates the most research jobs, with 6,385 professionals dedicated to such tasks. Two-thirds of these posts (4,238) are also occupied by women. One in every four female researchers employed in Spanish industry now works at a pharmaceutical company.

— In relation to patent generation, according to the European Patent Office, the pharmaceutical industry was in 2022, for the third year running, the industrial sector filing the greatest number of patent applications in Spain (181), followed by the health technology industry. (See Figure 6)

— In turn, according to data from the *R&D Survey* conducted annually by Farmaindustria, almost two-thirds of the pharmaceutical industry’s entire R&D investment in 2021 (62.3%) was allocated to clinical research, making it one of Spain's finest examples of public-private partnerships. Specifically, €592.7 million, 47% of the total, was allocated to research projects developed alongside hospitals, universities and public and private centres. (See Figure 7)

5.

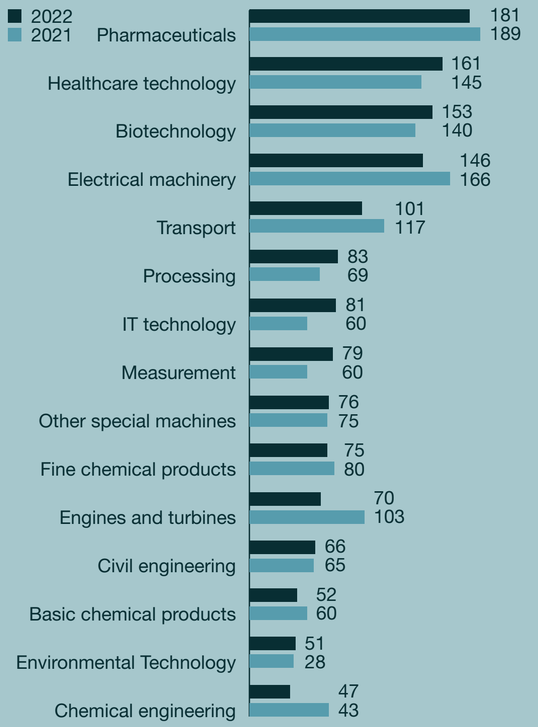
Main industrial sectors by R&D investment in Spain (2021)



Source:
Farmaindustria, based on statistics on R&D activities in 2021 (INE)

6.

Spanish patents 2022: the 15 fields of technology



Source:
Source: Farmaindustria, based on European Patent Office (www.epo.org)

7.

Pharmaceutical industry investment in R&D by research phase (2021)

Source:
Farmaindustria. R&D Survey (*Encuesta I+D,* EID) (2021)

Contextual data

— With 47.5 million inhabitants, Spain is the 4th most populous country in the EU-27 (after Germany, France and Italy) and the 7th of the 50 on the European continent (after the previous three and Russia, Turkey and the UK).

— In GDP terms, in 2021, Spain was the 14th global economy by size, accounting for 1.5% of global GDP and 6.1% of Europe's total.

— With regard to the pharmaceutical market, according to the latest data from the consulting firm IQVIA (2021), Spain is the 9th largest pharmaceutical market in the world and accounts for around 1.9% of the global total and 7.8% of the total European market.

Current situation

The data contained in the following tables allow some interesting conclusions to be drawn on the relevance of the pharmaceutical industry in Spain, compared to eurozone countries.

Highlights:

— Spain is the fourth leading country of the 20 in the Eurozone for direct job creation, accounting for 1 in 10 direct jobs created by the pharmaceutical industry in the euro zone.

— Spain is the fourth eurozone country with the largest investment in pharmaceutical R&D and the sixth largest manufacturer of pharmaceutical products (10% of the total value of eurozone medicine production is from our country).

8.

Key figures of the pharmaceutical industry in the leading eurozone economies of Europe (2020)

Country	Number of companies (01.)	Production (EUR million) (02.)	Employment	Internal sales (LSP) (EUR million) (03.)	Foreign trade (LSP) (EUR million) (04.)		Research (05.)
					Imports	Exports	
Germany	104	32,350	115,519	42,962	58,817	87,203	8,466
Austria	250	1,434	16,335	4,827	9,561	11,941	283
Belgium	125	20,245	40,464	6,303	46,261	56,210	4,964
Cyprus	12	253	1,755	177	356	381	85
Croatia	20	451	5,987	1,024	1,637	1,052	40
Slovakia	26	356	2,287	1,461	2,172	541	35
Slovenia	22	2,546	11,969	728	5,259	7,062	334
Spain	139	16,246	48,867	17,604	15,938	12,709	1,161
Estonia	27	N/A	380	355	565	95	N/A
Finland	40	1,895	6,178	2,762	2,112	833	258
France	270	23,558	99,310	29,552	28,974	34,065	4,451
Greece	59	1,653	26,500	5,381	3,227	2,883	102
Netherlands	42	6,180	20,000	6,185	30,650	45,000	642
Ireland	46	19,305	42,000	2,354	9,223	62,092	305
Italy	200	34,300	66,400	23,446	28,051	33,112	1,620
Latvia	20	255	2,232	275	681	456	N/A
Lithuania	39	N/A	1,220	829	1,292	874	N/A
Malta	N/A	N/A	1,033	196	288	367	N/A
Portugal	116	1,857	9,100	3,524	3,039	1,378	90
EUROZONE	1,557	162,884	517,536	149,945	248,103	358,254	22,836

01. Pharmaceutical companies that are members of EFPIA associations.

02. The data refer to production activities for medicines and raw materials for human and veterinary use, except in the cases of Germany, Spain and Ireland, for which they relate only to activity intended for human use.

03. Includes sales through retail pharmacies, hospitals and other distribution channels.

04. Foreign trade in pharmaceuticals (SITC 54).

Includes veterinary products.

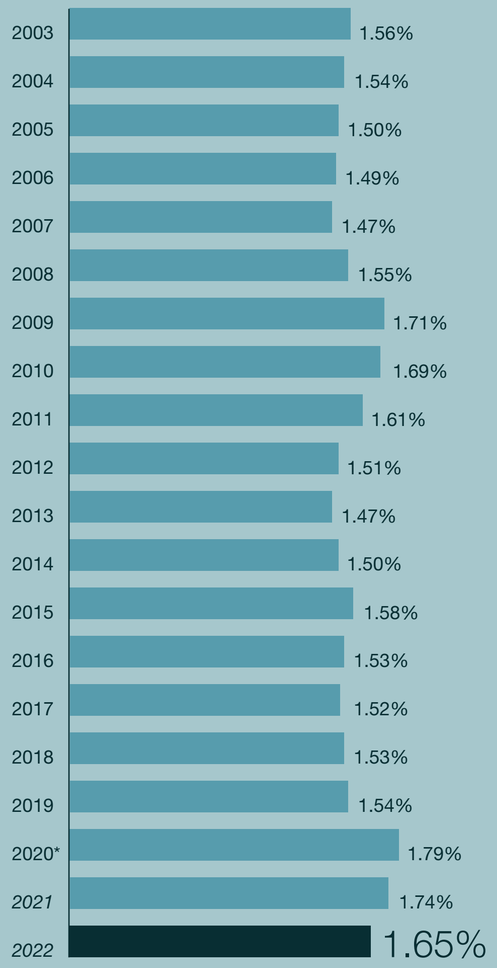
05. Research and development by each country's pharmaceutical industry

Note: this relates to data from 19 of the 20 countries that have formed the Eurozone since 1 January 2023, with the sole exception of Luxembourg whose information is not included in the table (the data for this country was unavailable).

Source:
Farmaindustria, based on EFPIA and Eurostat.

9.

Public pharmaceutical investment as a percentage of GDP



*2020 was heavily impacted by the sharp decline in GDP in 2020 (-10%)

Note: 2021–2022, Farmaindustria estimates, based on Ministry of Finance data

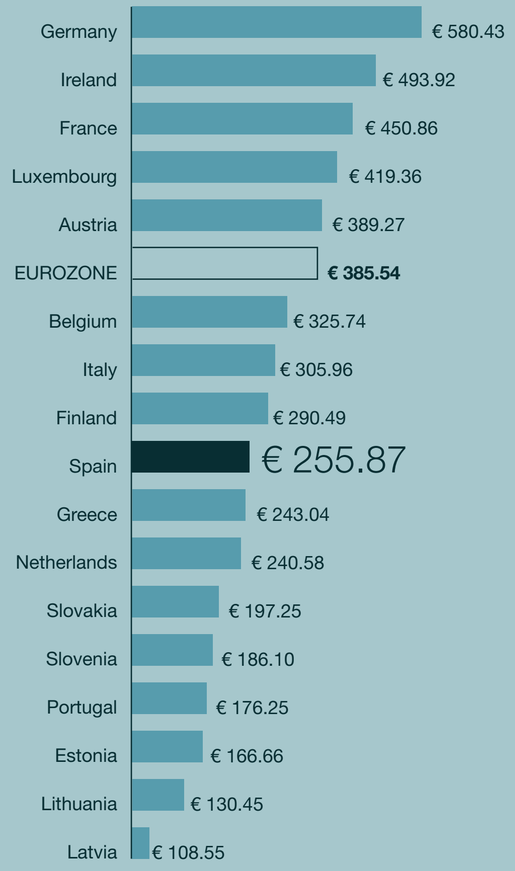
Source: Farmaindustria, based on data from the Ministry of Health (Health Accounting System) and the INE

Highlights:

- Based on OECD data, in 2020 public pharmaceutical expenditure per inhabitant in Spain (€255.9) was 34% lower than the eurozone average (€385.5) and around half of what countries like Germany (€580.4) and Ireland (€493.9), invested.
- Spain is also below the eurozone average if we analyse public pharmaceutical spending in terms of GDP: pharmaceutical investment in Spain (1.08% of GDP) is 7% lower than the eurozone average (1.16%), 25% lower than in Germany (1.43%) and 20% lower than in France (1.32%), for example.

10.

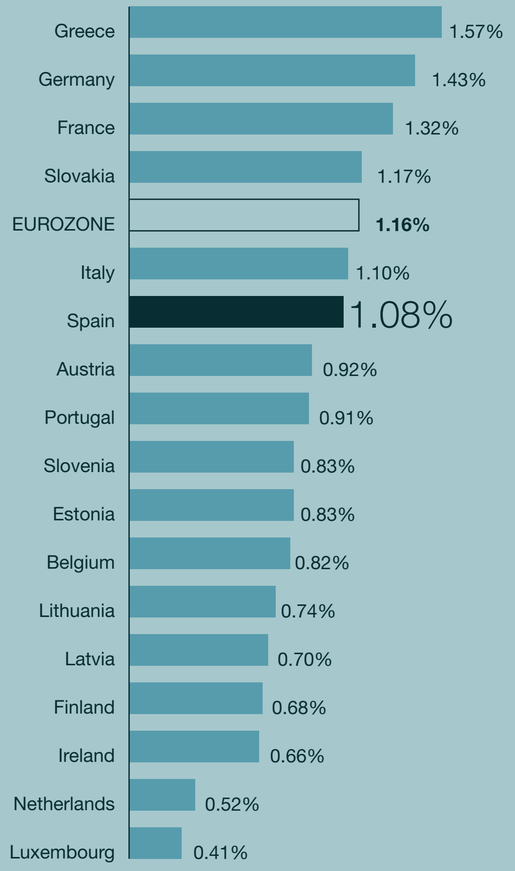
Comparison of public pharmaceutical investment in the eurozone (in current EUR)



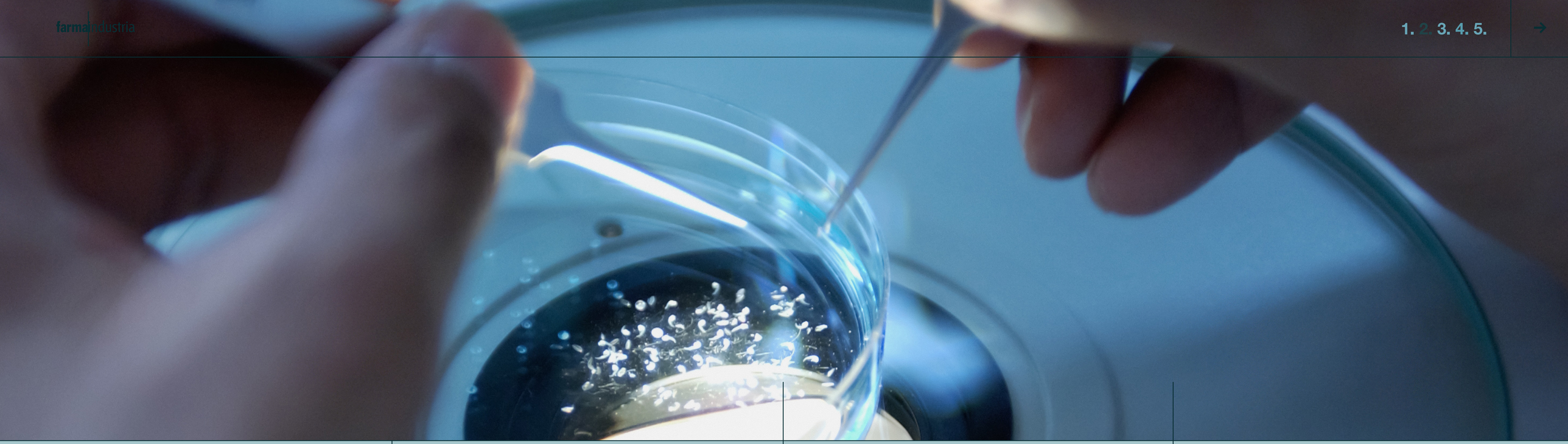
Source: Farmaindustria based on OECD Stat Extracts (2020, latest available data)

11.

Comparison of public pharmaceutical investment in the eurozone (as % of GDP)



Source: Farmaindustria based on OECD Stat Extracts (2020, latest available data)



Future outlook

The following table summarises the global pharmaceutical market forecasts published by consulting firm IQVIA in January 2023:

Highlights:

- The average annualised growth estimated by IQVIA for the global market (in constant USD) over the next five years (2023–2027) is in the range of 3–6%, below the 6.1% average recorded over the previous five years (2018–2022).
- Breaking it down by country blocks, developed countries will grow at an average annual rate of 2.5–5.5% over 2023–2027, also below the 5.7% recorded in the previous five-year period.
- Emerging countries, on the other hand, will have higher average growth rates (5–8%) similar to the previous five-year period, which was 7.2%.

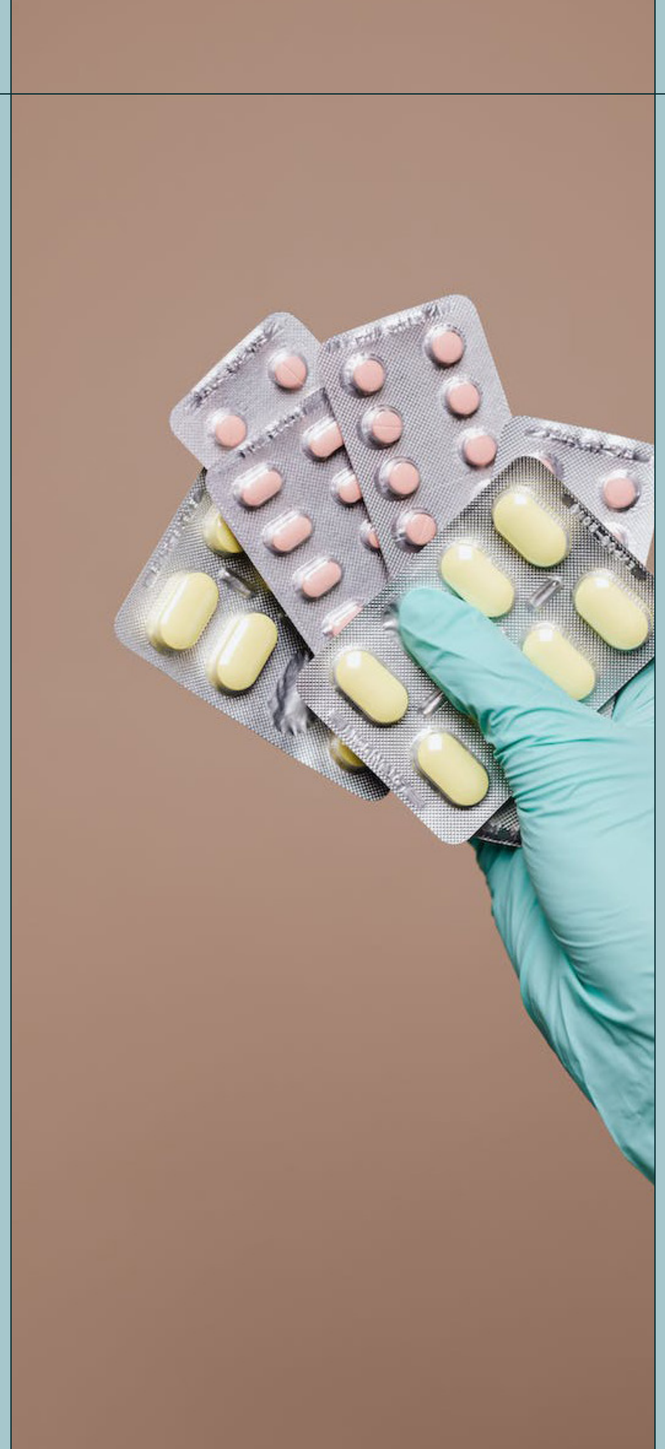
Source:
IQVIA Market Prognosis, Sep 2022; IQVIA Institute, Nov 2022.

12.

Total public investment in medicines over the past five years and forecast for the next five years (average annual rate of change in constant USD)

	2018-2022	2023-2027
Global	**6.1%**	**3%-6%**
Developed countries	**5.7%**	**2.5%- 5.5%**
— Top 10	5.7%	2.5%-5.5%
— Other	6.4%	4%-7%
Emerging countries	**7.2%**	**5%- 8%**
Low-income countries	**6.0%**	**4.5%- 7.5%**

2.2 Market information

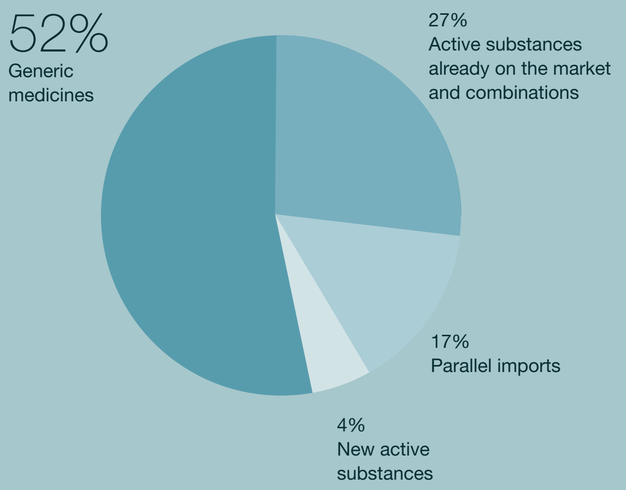


New launches

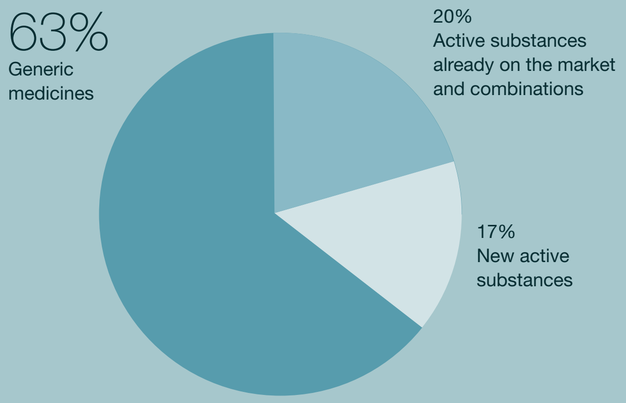
In the retail pharmacy channel, 267 new medicines were marketed in 2022, of which 139 (52%) were generics, 46 (17%) were parallel imports and 11 (4%) were medicines with new active substances. The remaining 71 (27%) were medicines with active substances or combinations already on the market.

In the hospital setting, 163 new medicines were marketed in 2022, of which 102 (63%) were generics and 28 (17%) were products with new active substances, including 7 orphan products. The remaining 33 (20%) were medicines with existing active substances or combinations.

New medicines at retail pharmacies: 267



New medicines in hospitals: 163



Source:
Farmaindustria, based on IQVIA and own estimates.

Public investment in medicines in hospitals

With a 4.8% increase, the growth of hospital public pharmaceutical investment in 2022 has been the lowest of the last five years, as indicated in the following table.

Source:
Pharmaceutical and healthcare expenditure indicators. Ministry of Finance.

Hospital investment (Ministry of Finance and Public Function)

Year	(EUR million)	Increase (%)
2018	6,944	7.7
2019	7,490	7.9
2020	7,934	5.9
2021	8,491	7.0
2022	8,902	4.8

This market has been heavily impacted by the Reference Prices Order issued in November 2021, which resulted in estimated savings of €243 million, according to the Ministry of Health.

Another factor contributing to the low increase of 2022 was the marketing of the first generics of ten active substances, which experienced significant sales, and the fact that dispensed packs saw their lowest increase for the last five years: 3.9%, according to Ministry of Health data.

Source: Hospital consumption data. Ministry of Health

Hospital packs

Year	Increase (%)
2018	5.2
2019	8.5
2020	5.4
2021	9.6
2022	3.9

Retail pharmacy market

In 2022, market growth in retail pharmacies was marked by an increase in the number of dispensed units, which rose by 7.6%, the biggest increase in 15 years. By contrast, the average price dropped by 1.1%, which was also the biggest since 2012. These two behaviours resulted in an increase in pharmacy spending of 6.5% in values.

It is important to distinguish between the behaviour of the prescription medicines market and OTC medicines, since the former grew by 4.8% in value terms (5.4% in units) while the OTC medicines market soared 31.9% (30.9% in units). The main driver of this growth was the large increase in demand for flu and cough remedies and expectorants, which had a combined growth in excess of 100%.

In prescription medicines, the therapeutic groups with the biggest contributions to the growth in number of packs were CNS medicines, primarily non-narcotic analgesics, respiratory system medicines (anti-asthmatics, cough and flu remedies, anti-histamines) and anti-infectives (systemic antibacterial agents).

Sales of medicines through retail pharmacies by therapeutic group

Prescription market 2022

Therapeutic groups	Units (thousands)	Share (%)	Increase (%)	MSP sales* (thousands)	Share (%)	Increase (%)	Mean MSP	Increase (%)
NERVOUS SYSTEM	392,795	29%	5.1%	2,461,016	23%	1.0%	6.27	-3.9%
DIGESTIVE SYSTEM AND METABOLISM	205,326	15%	3.7%	2,277,738	21%	8.6%	11.09	4.8%
CARDIOVASCULAR SYSTEM	289,239	21%	2.5%	1,656,336	15%	4.4%	5.73	1.8%
RESPIRATORY SYSTEM	93,784	7%	14.3%	908,340	8%	7.5%	9.69	-5.9%
BLOOD AND HEMATOPOIETIC ORGANS	70,207	5%	1.3%	865,631	8%	3.2%	12.33	1.9%
GENITOURINARY PROD.	54,850	4%	2.8%	649,908	6%	3.1%	11.85	0.2%
MUSCULOSKELETAL SYSTEM	75,644	6%	6.9%	457,718	4%	6.5%	6.05	-0.4%
ANTINEOPLASTIC AND IMMUNOLOGICAL AGENTS	7,817	1%	2.7%	383,774	4%	3.7%	49.10	0.9%
SYSTEMIC ANTI-INFECTIVES	45,966	3%	22.3%	327,621	3%	9.8%	7.13	-10.3%
DERMATOLOGICAL AGENTS	39,953	3%	3.8%	259,843	2%	3.0%	6.50	-0.8%
HORMONES	26,481	2%	11.4%	235,692	2%	8.1%	8.90	-3.0%
SENSORY ORGANS	37,958	3%	5.8%	200,960	2%	1.3%	5.29	-4.2%
MISCELLANEOUS	1,518	0%	7.5%	58,174	1%	8.3%	38.31	0.8%
ANTI-PARASITICS	2,643	0%	45.9%	20,630	0%	85.4%	7.81	27.0%
HOSPITAL SOLUTIONS	3,959	0%	20.3%	4,908	0%	20.7%	1.24	0.3%
DIAGNOSTIC AGENTS	12	0%	-17.2%	263	0%	-9.3%	22.19	9.6%
Total	1,348,153	100%	5.4%	10,768,552	100%	5%	7.99	-0.5%

*Manufacturer selling price

Source:
Farmaindustria, based on IQVIA data

In the retail pharmacy market, the Reference Prices Order, issued in November 2021, entered into force in January 2022, with savings of €64.7 million according to Ministry of Health estimates.

In addition, generic medicines of ten active substances were marketed for the first time this year, which resulted in an average decrease of 40% in the MSP of the originator medicines.

The dynamic of homogeneous groupings combined with the creation of new groups in the reference price system meant that, at the close of 2022, **86% of units dispensed at retail pharmacies were medicines for which the originators and their corresponding generics were priced the same,** as shown in the chart below.

Units

86%
Reference Price System (RPS)
Homogeneous Groupings (HGs)

14%
REMAINDER

MSP values

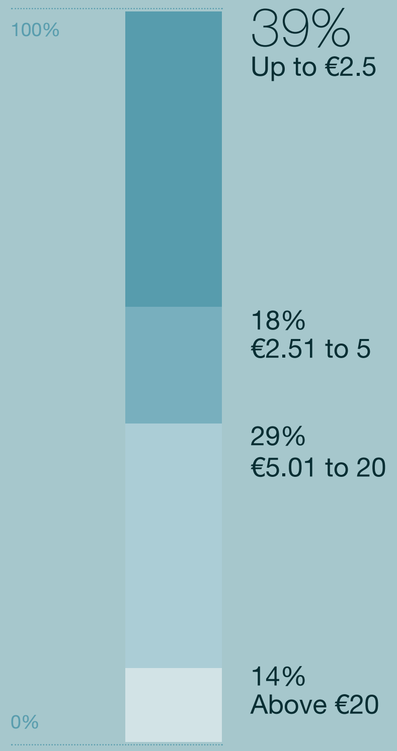
68%
Reference Price System (RPS)
Homogeneous Groupings (HGs)

32%
REMAINDER

Source:
Farmaindustria, based on IQVIA and own estimates.

In the retail pharmacy market, 57% of dispensed packs had a retail price (RRP) with VAT of less than €5 and only 14% of packs had an RRP with VAT above €20.

Retail pharmacy market structure by price bands (Units)

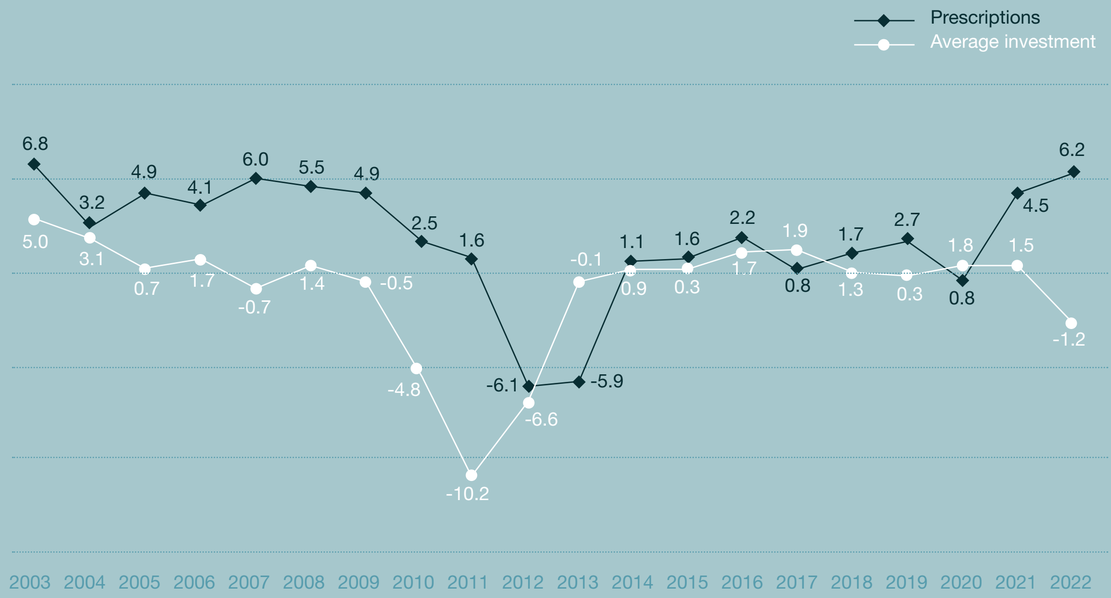


Source:
Farmaindustria, based on IQVIA data

Public pharmaceutical investment in retail pharmacies

The performance of public pharmaceutical investment in retail pharmacies was similar to that of the total medicines market in this distribution channel. Of the 4.9% increase in public expenditure in retail pharmacies, growth in dispensed packs totalled 6.2% (the largest growth since 2003), while average expenditure per prescription fell by 1.1%, the largest decline since 2012.

Trend in the number of prescriptions and average investment in retail pharmacies (%)



Source:
Prescription billing. Ministry of Health

3.

Institutional Activity

3.1 Market regulation and relations with public authorities

Institutional activity and relations with public authorities

Regulatory framework

In the year covered by this report, a number of regulations are in progress or have been approved and reported to the member companies through the Association's usual information channels (working groups, e-mails, newsletter, news flashes, etc.).
The Legal Services working group has continued to meet approximately once a month. In relation to the regulatory framework, which has been discussed in depth at the meetings of this working group, without prejudice to other regulations, the following are of note:

Consolidated text of the Law on guarantees and rational use of medicinal products and medical devices – Reference Prices

In July 2022, the Ministry of Health launched a public consultation prior to the preparation of a Preliminary Draft Law amending the consolidated text of the Law on guarantees and rational use of medicinal products and medical devices. During this procedure, the Association made a number of observations relating to the need to reform the reference price system, to establish the set daily dose for non-equipotent medicines and to update the minimum threshold and allow price increases up to the threshold, among others.

Nonetheless, Law 38/2022 of 27 December 2022 amended Title 11 on fees of the aforementioned consolidated text of the Law on guarantees and rational use of medicinal products and medical devices.
In November 2022, following the appropriate hearing, Order SND/1147/2022 of 23 November was published, updating the reference price system, whose only difference from the previous year was the exclusion of orphan medicines, reflecting the legal precedents. Ultimately, the Order did not reflect the Association's arguments relating to the non-review of strategic medicine prices, despite being conceptualised by the *Agencia Española de Medicamentos y Productos Sanitarios* (Spanish Medicines Agency, AEMPS as a subgroup of critical medicines, nor those concerning the formation of ATC5 groups, among others.
In light of this, and in accordance with the decision of the Governing Bodies of the Association, the order is being appealed through administrative review.

On the subject of the reference price system, Law 18/2022, of 28 September, on company creation and growth, in addition to measures relating to late payment and e-billing, allows the Government to modify this system in recognition of incremental innovation.

Health regulations

As this report was being finalised, two draft laws relevant to pharmaceutical companies were being put through parliament. With regard to the first of these, the Draft Law establishing the State Public Health Agency and amending General Public Health Law 33/2011, of 4 October, during the hearing procedure for the Preliminary Draft, Farmaindustria pointed out the need to allow access by the pharmaceutical industry, for research and innovation purposes, to the information that must be supplied by all public authorities, institutions and public and private sector agencies, and by natural or legal persons, and the possibility, through the regulatory development outlined in the third final provision, of establishing within the Agency an Advisory Board acting in an advisory capacity that would also provide technical and social assistance, to instrument the participation of scientific societies, the innovative pharmaceutical industry, patients and the public.

The second draft law is the Draft Law amending diverse rules to consolidate the equity, universality and cohesion of the National Health System that establishes the secondary use of data, modification of co-payments and of the Government Law to incorporate the health impact report.

R&D&i

In the field of research, Law 17/2022, of 5 September, amending Law 14/2011, of 1 June, on science, technology and innovation, incorporates a series of new developments to improve scientific and technical career pathways (a new form of open-ended contract linked to the development of scientific-technical activities), reduce the administrative burden of procedures for awarding aid and their justification by the beneficiaries, the development of public purchasing of innovation, and a restrictive application of the transfer of research results to the private sphere.

Industry

The Association also took part in the hearing of the Preliminary Draft Law on industry, which is of supplementary application to sectors lacking their own specific legislation. The arguments focused on ensuring the participation of business associations in the bodies of governance provided for in the Law: the State Council for Industrial Policy, which is defined as the advisory and collaborative body on matters affecting the industry to promote its growth, resilience and competitiveness, attached to the Ministry of Industry, Trade and Tourism, and the governing body of the Strategic Reserve based on National Industrial Production Capacities (*Centro de Coordinación y Promoción de la Industria Estratégica* – Centre for the Coordination and Promotion of Strategic Industry, CECOPIE).

Further, in relation to the obligations of aid beneficiaries, we proposed reducing the commitment to maintain production established in the Preliminary Draft Law from five to three years for large companies and from three to two years for small and medium-sized companies, given the great uncertainties of the world macroeconomic stage, since extending periods of high investment commitments could limit private initiative to set up new projects.

Collective actions

Other regulations included in the aforementioned Annual Regulatory Plan include the Preliminary Draft Law on representative actions to protect collective consumer interests, transposing Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020, which establishes a unitary system of collective protection regulating the processes for the exercise of representative actions (injunctive or of redress) motivated by any type of infringement that harms the collective rights and interests of consumers.

The Association has followed this initiative closely and has, through the Spanish Confederation of Employers' Organisations (*Confederación Española de Organizaciones Empresariales*, CEOE), made observations on a number of points, including the legitimation of consumer associations, calling for their guaranteed independence, and for the exercise of actions of redress to be sufficiently representative.

Public procurement

With regard to public procurement, Farmaindustria has continued its work on the amendment of the Law on public sector contracting, to allow direct purchasing of exclusive medicines outside the regulations, as set out in certain regional regulations.

At the regional legislative level, Law 11/2022, of 21December, on urgent measures for the promotion of economic activity and the modernisation of the Regional Government of the autonomous region of Madrid, is particularly relevant since it governs the operating system and functions of the Healthcare Procurement Agency (*Agencia de Contratación Sanitaria*) of the Madrid region.

The Association's activity includes monitoring medicinal product supply dossiers and taking the necessary actions to safeguard the interests of pharmaceutical companies in public procurement procedures, in accordance with the applicable regulatory framework.

Environment

In environmental matters, without prejudice to its regulatory development, Law 7/2022, of 8 April, on waste and contaminated soils for a circular economy, establishes the special tax on non-reusable plastic packaging and the extended producer responsibility system. Both matters are subject to continuous monitoring by the Association. Four regional projects are currently underway.

Pharmacoeconomics Observatory (Madrid)

The Department of Health of the autonomous region of Madrid intends to set up a Pharmacoeconomics Observatory that would provide an innovative perspective for a more in-depth approach to studies and the monitoring of cost/benefit and cost/efficiency ratios of medicinal products and medical devices funded by the National Health System, with a view to analysing the sustainability of the system.

In this context, Farmaindustria has proposed that pharmaceutical expenditure be linked to the improvements to population health that it generates and that a full analysis be undertaken of the economic impacts of pharmaceutical consumption from a wide-ranging social perspective, and that the Observatory be used to promote the generation of evidence from the production and collection of real-life data, incorporating the vision and preferences of patients and involving employers in the operations side of the Observatory to allow the transfer of reports, analyses or explanatory models of investment in medicines.

Pharmacy Commission (Madrid)

The Directorate General for Financial and Economic Management and Pharmacy of the Department of Health of the autonomous region of Madrid also considers necessary the creation of a Pharmacy Commission to standardise the criteria for use of high-impact medicinal products and medical devices in health clinics in the region, with a view to ensuring the accessibility and equity of citizens and to promoting the use of therapeutic resources based on scientific evidence. In addition to ensuring the sustainability of the healthcare system, the adoption of the regulation is justified by the need to provide quality, independent information and training in the correct use of medicines. Public authorities will be tasked with promoting continued and ongoing professional training on medicinal and therapeutic products and implementing an agile, effective and independent system that guarantees healthcare professionals access to up-to-date and objective scientific information, with the primary goal of ensuring equitable access to medicines within the scope of the Madrid Health Service.

Collective Bargaining Agreement

The 20th General Collective Bargaining Agreement of the Chemical Industry (*Convenio Colectivo General de la Industria Química*, CGIQ), signed by the Business Federation of the Spanish Chemical Industry (*Federación Empresarial de la Industria Química Española*, FEIQUE) with the trade unions CC OO Industria and UGT FICA, remained in effect in 2022, its second year. The agreement extends to sectors encompassed by the economic activity of the pharmaceutical industry, among others, and the most relevant development this year was the application of the agreed 2% salary increase for 2022.

On the subject of salary increases, due to the inflationary pressures of 2022, FEIQUE and Farmaindustria have conducted an analysis of the estimated impact in 2024 of the application of the clause in Article 38 of the 20th Agreement relating to the salary guarantee clause for 2021, 2022 and 2023. Under this clause, if the sum of the general Spanish consumer price index (CPI) for 2021, 2022 and 2023 is greater than the sum of the agreed increases (1%, 2% and 2%, respectively) for those years, a salary review will be implemented for the aforementioned difference without retroactive effects.

Given that, the CPI closed 2021 at 6.5%, and 2022 at 5.70%, in the absence of data for 2023 (forecast in 2022 as being slightly lower than the result for 2022, at around 5%) the result of the application of the clause is expected to be around 12%, so alternatives must be considered within the context of collective bargaining to mitigate its impact on companies.

In addition to the above, the impact of the labour reform implemented through Royal Decree-Law 32/2021 of 28 December on the Collective Bargaining Agreement was analysed in 2022 with a focus on hiring.

Human Resources

Towards the end of 2021, Royal Decree-Law 32/2021, of 28 December, on urgent measures for labour reform, the guarantee of employment stability and the transformation of the labour market (labour reform) was published. Therefore, at the start of 2022, the working group analysed this Royal Decree-Law and its impact on the Collective Bargaining Agreement. The impact of the labour reform has been heaviest in three areas:

— Hiring (temporary work and training)

— Temporary Redundancy Plans

— Collective bargaining

In addition to the above regulation, throughout 2022, the working group has reported on the extensive publication of employment regulations of relevance to members. These include pensions, retirement, the interprofessional minimum wage, vocational training, risk prevention, temporary disability, pay equality, contributions and reconciliation, among many others.

The regulations issued in relation to the COVID-19 pandemic and the measures for its prevention, containment and coordination have been continuously updated in the working group, both nationally and regionally.

The working group also reported on actions with a labour impact implemented by organisations like the Spanish Data Protection Agency (*Agencia Española de Protección de Datos*, AEPD), with its Report on Data Protection Impact Assessments (DPIAs) for the private sector, guide for healthcare professionals and, in matters concerning COVID-19, on the publication of a new section on health and data protection and a consultation by the AEPD on processing data from extra services (such as certain vaccines or extensions of recognition) provided to employees by preventive health services.

The following surveys were carried out during 2022:

01. Survey on remote working to learn about the different modes of working implemented by companies after the pandemic, when remote work was widely implemented.

02. Survey to ascertain the current and potential needs of professionals with higher or intermediate vocational training, as well as possible changes in such qualifications or the need to create new vocational qualifications to adequately meet the needs of the industry.

03. Survey on compensation for mileage and meals allowance for travel in big cities (with reference to sales representatives)

04. Survey on the numbers and percentages of female workers in factories and the type of activity.

05. Survey on remote work for an update to this situation in companies, with information about allowances for expenses or whether the remote work is voluntary, among other issues.

06. Survey on the scholarship programme and traineeship contracts.

07. Company car survey.

The working group also presented the results of the 2021 *Employment Survey in the Innovative Pharmaceutical Industry*, a report that sparked a great deal of interest in the general and specialised press, demonstrating that the innovative pharmaceutical industry is one of the strategic sectors that can contribute the most to economic reopening and boost our production model.

Lastly, the working group was introduced to the Mujeres en Farma (‘Women in Pharma’) initiative, an interactive community of men and women seeking to promote female talent. This initiative aims specifically to increase female presence in senior management positions in industry and raise the profile of the pharmaceutical industry as a leading sector of equity and inclusion. Additionally, Farmaindustria is involved in CEOE meetings impacting the workplace and has reported on the content of these, particularly through the Equality and Social Security and Social Dialogue Committees.

The life of medicines

For a marketing authorisation holder, the decision to apply for authorisation and maintain a medicinal product on the market requires compliance with a number of technical obligations affecting many stages of the life of the medicine, from the submission of the application dossier, authorisation procedure, manufacture, including compliance with environmental, storage and supply measures, monitoring of suspected adverse reactions while it is on the market and, potentially, its withdrawal.

To complete all these regulated processes, pharmaceutical companies rely on very senior experts in each area, which makes it far easier for Farmaindustria to monitor technical matters through a series of working groups coordinated by the Technical Department. Essentially, these groups analyse new regulatory obligations and outline the sector's position to the authorities in defence of its legitimate interests.

These working groups are ultimately the ones that help the Association to promote the needs of the sector and not only provide the possibility of outlining the sector's position to the authorities (primarily, the AEMPS), but also to highlight to society, through both the media and other public forums, the importance and difficulty of making medicines available to meet patient needs.

Insofar as concerns technical matters, many internationally regulated elements are channelled through the European Federation of the Pharmaceutical Industry (EFPIA). Farmaindustria and its counterparts at other EFPIA associations hold monthly meetings to ascertain the current situation of key technical issues in other EU regions.

The Association also interacts with global regulatory authorities on a regular basis. In 2022, Honduras hosted the 13th Meeting of Competent Authorities in Medicines of the Ibero-American Countries (*Encuentro de Autoridades Competentes en Medicamentos de los Países Iberoamericanos*, EAMI), attended by Farmaindustria. The event highlighted that allowing patients better and faster access to medicines is the purpose of regulatory intelligence practices and involves continuous monitoring and analysis of the regulations in addition to sharing these data.

Lastly, Farmaindustria represents the innovative pharmaceutical industry with the Spanish authorities in many areas and there are committees whose governing regulations determine the participation of a representative from the sector. Examples include:

01. Advisory Committee of the NHS, of which Farmaindustria is Vice-Chair. Every quarter, the committee reviews the diverse regulatory projects, action plans and health strategies of the Government.

02. The Committee for Medicines for Human Use ('CMH') is the collegiate body of the Spanish Medicines Agency representing the interests of society and overseeing transparency, objectivity, and scientific rigour in the decisions of the AEMPS regarding the marketing of medicines. The Committee is composed of 23 members, 10 by reason of their position and 13 appointed by the Executive Board of the AEMPS, one of them designated by Farmaindustria. It meets eleven times a year.

03. The Technical Coordinating Group of the National Action Plan on Antimicrobial Resistance (*Plan Nacional frente a la Resistencia a los Antibióticos*, PRAN) is tasked with drafting the proposed plan. Farmaindustria is involved in this plan to seek mechanisms to strengthen the marketing and supply of critical antibiotics in Spain or to study ways to incorporate new antibiotics with proposals designed to improve access routes to Spain and Europe.

The most significant activities in technical matters in 2022 are as follows:

Manufacturing and Traceability

In this regard, the operation of the Spanish System of Verification of Medicines (*Sistema Español de Verificación de Medicamentos*, SEVeM) is continuously monitored, with its Director providing a regular update at every working group meeting and analysing supply problems affecting the national market. Other topics discussed this year range from regulatory developments (including the publication of strategic medicines by the AEMPS or in EU regulations, strengthening the European Medicines Agency's role in supply matters, the impact of the new Annex I to GMP and the tax on non-reusable plastic packaging) to new trends in the labelling and supply of medicines in the hospital setting (such as the pilot scheme to eliminate paper patient information leaflets for certain medicines, tests for the supply of aggregate codes or the identification of unit doses with a non-serialised *Datamatrix*) and the streamlining of the qualification of suppliers and recipients of medicines based on official government databases.

In industrial matters, the working group participated in a number of official consultations to assess the impact of energy restrictions on the sector and has passed on information from production plants to prepare a study on the industrial implementation of Spain's pharmaceutical sector.

Environment

Throughout 2022, this working group worked closely with SIGRE to monitor national and European environmental legislation affecting the pharmaceutical sector: combating climate change, environmental quality and assessment, circular economy, environmental responsibility, water protection and treatment, and energy transition. Specifically, it studied the following:

01. Law 7/2022, of 8 April, on waste and contaminated soil for a circular economy.

02. Royal Decree 1055/2022, of 27 December, on packaging and packaging waste. Newly adopted measures include the extension of Extended Producer Responsibility (EPR) to industrial and commercial packaging. Under these new provisions, from 2024 pharmaceutical companies must take responsibility not only for household packaging waste from medicines, as has been the case up until now, but also for waste from healthcare facilities, which is a very significant change.

Farmaindustria also still sits on the Environmental Commissions of the CEOE and FEIQUE/the Catalan Business Federation of the Chemical Sector (*Federación Empresarial Catalana del Sector Químico*, FEDEQUIM)

Pharmacovigilance

The main issues posed by national and European pharmacovigilance regulations include the communication of information on the safety of medicines (DHPC) and materials on the prevention of risks (MPR), duly authorised by the AEMPS, through scientific societies. Farmaindustria has increased the number of collaboration agreements with the latter (a total of 70 have been signed). In relation to data protection and Farmaindustria's Code of Conduct governing personal data processing in clinical trials and other clinical research and pharmacovigilance, this working group attended a training session. In EU matters, a discussion was held around the EMA (European Medicines Agency) letter sent to *Qualified Persons for PharmacoVigilance (QPPV)* on how to manage the transfer to third countries of cases downloaded from *EudraVigilance* (personal data management). Lastly, there is an ongoing search for solutions to correct the errors detected in certain terms not correctly translated in the Spanish version of the MedDRA dictionary.

At each of its meetings, the group addresses six clearly defined topics: inspection and audits; risk management plans; the master file; expedited reporting; periodic safety reports and patient support programmes and other initiatives. An update is also given on the pharmacovigilance information published by the EMA.

Lastly, the Division Head of the Pharmacoepidemiology and Pharmacovigilance Department of the AEMPS participated as usual in the first meeting of the year to push on with the main issues expected to be of relevance in the coming months, such as streamlining reporting and the burden of suspected adverse reactions, improving access to public Spanish Pharmacovigilance, Adverse Reaction Data (*Farmacovigilancia Española, Datos de Reacciones Adversas*, FEDRA), or using real-life data in regulation, among others.

Vaccines

This group is primarily responsible for the regulatory and technical side of vaccines.

The group coordinates with Vaccines Europe (VE) and discusses aspects of the European agenda such as communication campaigns, the position paper on the policy of prioritising immunisation in adults in Europe, the pipeline, ways to improve access to vaccines and an article on the impact of replacing patient information leaflets for vaccines.
At national level, the group shared the updates on the Ministry of Health website on vaccines, vaccination programming, statistical data, preventable diseases and epidemiological situations.

This working group organised a workshop for European representatives of Vaccines Europe, members of the group and national vaccination experts (AEMPS, Directorate General for Public Health of the Ministry of Health and Spanish Association of Vaccinology) to share initiatives on ensuring adequate access to vaccines among the population and on improving vaccination rates. The discussions covered topical issues such as the National Vaccination Registry (*Registro de Vacunación COVID-19*, REGVACU) and the Vaccination Information System (*Sistema de Información de Vacunaciones*, SIVAIN), the monkeypox vaccination information system, electronic patient information leaflets in vaccines and EU common packs, as well as the preparation of the Spanish Presidency of the Council of the European Union during the second half of 2023.

Incremental Innovation

This group works to highlight the continuous improvement of off-patent medicines that can meet patient needs better through the application of technological innovation, repositioning of indications, reformulations, new combinations of active substances, new pharmaceutical forms, etc. Since recognition of this sort of innovation is low, Farmaindustria is promoting initiatives to have this type of medicine included in current regulations, so that they are not economically penalised by, for example, application of the reference price system.

Technical Regulation of Medicines

This working group focuses primarily on analyses and contributions to prepare the industry's position on regulations issued by European institutions and the AEMPS relating to procedures for the authorisation, registration and commercial release of medicines, particularly the implementing provisions of Royal Legislative Decree 1/2015, approving the amended text of the Law on guarantees and rational use of medicines and medical devices.

This working group analyses issues with a strong technical component, such as levies, labelling and patient information leaflets, authorisation applications and variations, approval of authorisations, classification of medicines with no commercial interest, etc. The group also conducts continuous monitoring of the functioning and decision-making periods of the AEMPS. Some issues of special interest, such as the effective marketing of medicines, the nitrosamine situation and multilingual labelling, led to proposed improvements submitted at specific meetings with the AEMPS representatives responsible for these matters.

At each of its meetings, this working group discusses eight specific subject areas:

01. Therapeutic Positioning Reports.

02. Early access.

03. Product information.

04. Biological medicines.

05. National procedure and management.

06. Quality regulation.

07. Risk management plan.

08. European procedures.

During 2022, the *ad hoc* group set up to promote the AEMPS-supervised *ePIL* pilot project for implementing the electronic patient information leaflet for medicines used in hospitals and the subsequent elimination of the printed patient information leaflet, has continued to meet to share experiences during its implementation. This project received an award at the second *E-nnova Health 2022* event of *Diario Médico y Correo Farmacéutico*, in the *Transformación Digital* category. Farmaindustria also presented the pilot project through a poster at the 26th scientific congress of the European Association of Hospital Pharmacists and it was selected as one of the top three projects in the *Good Practice Initiatives* category.

Lastly, a seminar was organised on the Regulation on medical devices for in vitro diagnosis with the participation of two representatives of the AEMPS, and a seminar on strategic medicines following the publication of the list of medicines of the AEMPS, attended by a representative of the agency.

Autonomous Regions

Political scenario. Elections and regional governments

In 2022, the Andalusia and Castile and Leon regions called early regional elections.

They were held in Castile and Leon on 13 February, resulting in a coalition government with the VOX party. The new Government was made up of President Alfonso Fernández Mañueco (PP), Vice-President Juan García Gallardo (VOX) and ten ministers. Alejandro Vázquez Ramos (PP), who served as Head of the Department of Health after replacing Verónica Casado in December 2021, continues in charge of this department.

Andalusia called elections on 19 June, at which the Partido Popular (PP) won an absolute majority. The new regional Government was made up of 13 regional ministers, with Catalina García appointed Head of the Department of Health and Consumer Affairs. On the subject of healthcare, one of the most relevant commitments of the PP's electoral campaign was the complete elimination of medicine tenders, through the amendment of Andalusia's Law 22/2007 on Pharmacy. It also included: (i) the promotion of "public-private partnerships for increased patient access to medicines, while ensuring the prescription freedom of the physician"; (ii) the promotion of initiatives for "innovative public procurement, pacts, results-based payment agreements or payment-volume agreements"; (iii) the creation of "a management and negotiation unit with the pharmaceutical and technological industry", and (iv) in health research, the commitment that investment in R&D&i will rise steadily to 2% of GDP.

In addition, this year has brought changes to the leadership of health departments in four communities: Raúl Pesquera in Cantabria (March 2022); Manuel Balcells in Catalonia (October 2022); María Somalo in La Rioja (January 2022) and Miguel Mínguez Pérez in the Valencia region (May 2022).

Healthcare budgets & expenditure and pharmaceutical provision

In 2022, the general budget laws of 15 autonomous regions (Aragon, Asturias, Balearic Islands, Canary Islands, Cantabria, Castile-La Mancha, Catalonia, Extremadura, Galicia, Madrid, Murcia, Navarre, the Basque Country, La Rioja and Valencia) were approved, while the 2021 budgets of Andalusia and Castile and Leon were extended. The total budget of the autonomous regions for this financial year amounted to €249,710.72 million (7.63% from the previous financial year), of which €72,489.29 million were allocated to the healthcare budget (4.05% from the 2021 budget). Pharmacy-based pharmaceutical services amounted to €10,492.08 million, 0.65% more than the initial total budget for 2021 but 18.09% lower than the actual prescription expenditure generated that same year, which totalled €12,808.62 million.

This budget is at similar levels to the consolidated public expenditure of 2014 (€10,388.54 million), when the lowest expenditure of the 2007–2022 time series was recorded. Public pharmaceutical investment through retail pharmacies reached €12,325.96 million in 2022, similar to the expenditure of 2021, dropping to levels below those of 2008.

With regard to public pharmaceutical expenditure in hospital settings over 2022, the Ministry of Health has published the following data: (i) number of packs of medicines consumed: 78,141,495, up 3.88% on 2021 figures. And (ii) the actual cost of medicine use: €8,970.17 million, up 4.91% from the actual cost in 2021.

Institutional contacts and meetings

Although the health situation triggered by the COVID-19 pandemic has restricted the hosting of meetings, particularly during the first half of the year, Farmaindustria has continued its vigorous promotion of relations with regional health officials, scientific societies and professional and academic organisations, with which it has discussed the chief concerns of the Association.

Specifically, communication was maintained with different regional officials of the autonomous regions (Andalusia, Aragon, Balearic Islands, Castile and Leon, Castile-La Mancha, Catalonia, Extremadura, Galicia, La Rioja, Madrid, Murcia, Navarre, the Basque Country and the Valencia region), along with scientific societies and healthcare organisations such as the Federation of Spanish Scientific Medical Associations (*Federación de Asociaciones Científico Médicas Españolas*, FACME), the Spanish Society of Medical Oncology (*Sociedad Española de Oncología Médica*, SEOM), the Spanish Society of Cardiology (*Sociedad Española de Cardiología*, SEC), the Spanish Society of General and Family Physicians (*Sociedad Española de Médicos Generales y de Familia*, SEMG), the Spanish Society of Family and Community Medicine (*Sociedad Española de Medicina Familiar y Comunitaria*, SEMFYC), the Spanish Society of Primary Care Physicians (*Sociedad Española de Médicos de Atención Primaria*, SEMERGEN), the General Council of Official Medical Associations (*Consejo General de Colegios Oficiales de Médicos*, CGCOM) and the Royal National Academy of Medicine (*Real Academia Nacional de Medicina*, RANM)

Health policy in the autonomous regions

A. National scope

In 2022, the autonomous regions played an active role in the pharmaceutical policy of the NHS through the Permanent Pharmacy Commission (*Comisión Permanente de Farmacia*, CPF), the drafting of therapeutic positioning reports (TPRs) and the Interministerial Commission on Medicine Prices (*Comisión Interministerial de Precios de los Medicamentos*, CIPM).

Participation of the autonomous regions in the CIPM (representative members with full voting rights):

01. First half of the year: Castile-La Mancha, Canary Islands and Balearic Islands.

02. Second half of the year: Extremadura, Madrid and the Basque Country.

In 2022, the CIPM met on ten occasions in total (3 February, 3 March, 7 April, 5 May, 2 June, 7 July, 29 September, 27 October, 24 November and 15 December).

Digital health projects in the National Health System

Farmaindustria monitors the development of the Digital Health initiatives developed by the Ministry of Health, particularly those affecting pharmaceutical provision in the autonomous regions, such as digital clinical histories and electronic prescriptions and approvals.

Electronic prescription

— The electronic prescription has been implemented at all levels of healthcare (health centres, clinics, hospitals and pharmacies) in all autonomous regions. The percentage of electronic prescriptions dispensed for the NHS as a whole was 98.39%. The region with the highest percentage was Catalonia (99.98%), while the lowest was in Galicia (87.70%).

— Interoperable electronic prescription (*Receta electrónica interoperable*, RESNS): implemented in the 17 autonomous regions and the Spanish National Institute of Health Management (*Instituto Nacional de Gestión Sanitaria*, INGESA). In 2022, almost all autonomous regions had incorporated the mutual companies with public coverage into the RESNS system.

— European interoperable prescription (*ePrescription/eDispensation*): allows a medicine prescribed in a given country of the European Union (EU) to be dispensed by a pharmacy of another EU country. In Spain: (i) eight autonomous regions have set up prescription interoperability (Andalusia, Aragon, Canary Islands, Castile and Leon, Catalonia, Extremadura, Madrid and the Basque Country); (ii) six autonomous regions and the autonomous cities of Ceuta and Melilla are in the testing phase (Asturias, Castile-La Mancha, Galicia, Murcia, Navarra and Valencia), and (iii) three autonomous regions are currently in the development phase (Balearic Islands, Cantabria and La Rioja).

Digital clinical history

— The NHS digital clinical history (*Historia clínica digital SNS*, HCDSNS): this allows access to the clinical information relevant to a patient's health care from anywhere in the NHS. Around 91% of the population with an individual health card is now covered. The Navarre region has the greatest coverage of its population (99.91%) in contrast to Asturias with 46.14%.

— European Digital Medical Record (MyHealth@EU): this will allow interoperable health data available in countries of the EU to be shared so that European citizens can receive care in any EU country taking account of their relevant clinical information (European Patient Summary, EUPS).

— In 2022, this project was operational in six Spanish regions: Andalusia, Aragon, Catalonia, Navarre, Basque Country and Valencia, and it was in the testing phase in a further four: Canary Islands, Castile-La Mancha, Madrid and Murcia.

Approval of medicines

— Electronic approval: almost all regions have implemented electronic approval, linked to their electronic prescription system. The authorisation times for electronic approval vary between autonomous regions, from 24 to 72 hours.

Nursing indication

— Farmaindustria monitors the development of the indication, use and authorisation of the dispensing of prescription medicines. The regulations stipulate that two requirements must be met: (i) the indication must be in accordance with approved protocols and guidelines of clinical and healthcare practice, and (ii) the professionals must be duly accredited by the competent authority of their region.

— Clinical and healthcare practice guidelines are drafted by the CPF of the Inter-regional Council of the NHS and validated by the Directorate General for Public Health. The Ministry of Health has set up a dedicated space for them.

— In 2022, following the approval of the regulations of Murcia (September 2022) and of the Madrid region (November 2022), a regulated procedure is in place in all autonomous regions and INGESA for the accreditation of nursing professionals.

— Some autonomous regions (Galicia, Balearic Islands and Castile-La Mancha) are adapting their electronic prescription modules to include the nursing indication.

Medical Representative Visits

— The Central Government's Annual Regulatory Plan for 2022 includes the draft Royal Decree governing the advertising of medicines for human use, aimed at updating the regulations, incorporating legal changes for the comprehensive regulation of the advertising of medicines for human use and medical devices, defining the powers of the central government and autonomous regions in advertising and adapting the regulations to technological advances.

— Farmaindustria has liaised with the autonomous regions, particularly those with the greatest involvement in this project (Catalonia and Madrid) to highlight the potential impact of this regulation on the pharmaceutical industry, specifically on scientific information and the promotion of medicines, visits by medical representatives and relations with healthcare professionals, and on employment in the sector. The Association's commitment to transparency in its relations with professionals was underscored by the Code of Good Practice of the Pharmaceutical Industry and the Self-regulation System.

— With regard to the post-pandemic restrictions on medical representative visits put in place during the first half of 2022 by the autonomous regions, the Association continued to monitor the situation through the Medical Representative Visits Working Group until the situation returned to normal.

B. Regional scope

In 2022, the autonomous regions played an active role in the pharmaceutical policy of the NHS through the Permanent Pharmacy Commission (*Comisión Permanente de Farmacia*, CPF), the drafting of therapeutic positioning reports (TPRs) and the Interministerial Commission on Medicine Prices (*Comisión Interministerial de Precios de los Medicamentos*, CIPM).

Farmaindustria analyses and monitors regional provisions and actions with an impact on the sector's activity. Highlights from 2022 include:

Aragon

Aragonese initiative for public health sustainability and efficiency

— This is designed to pinpoint and tackle the problem areas of the NHS, in the scope of its regional powers, by means of long-term political commitments for the whole of Spain.

— It was presented at the plenary session of the Parliament in September 2022, triggering a national debate on how to achieve sustainability in the public health system.

— Farmaindustria is following the initiative.

Andalusia

Cessation of medicine tenders (regulated by Decree-Law 3/2011 of 13 December)

— Since they began, 14 medicine tenders have been called and concluded. During its electoral campaign of 2018, the PP pledged to abolish these tenders.

— In March 2022, the regional government launched a prior public consultation to amend Law 22/2007 on pharmacy for the purpose, among others, of revoking the articles providing for tender of medicines in the region. The procedure was interrupted by the announcement of elections, which were held in June 2022.

— Draft Decree establishing the Permanent Autonomous Commission of Pharmacy and Therapeutics (*Comisión Autonómica Permanente de Farmacia y Terapéutica*) within the Public Health System of Andalusia (*Sistema Sanitario Público de Andalucía*, SSPA), whose prior public consultation process launched in December 2022. The Commission will be a collegiate advisory and decision-making body of the SSPA, tasked with the optimisation and harmonisation of pharmaceutical provision and the rational use of medicines. Its purpose is to centralise the procedure for access to medicines, replacing the current hospital-by-hospital access with a centralised assessment for the whole region. This is done with a view to reducing turnaround and ensuring homogeneity, thereby preventing inequities in access to these therapies.

Balearic Islands

Law on urgent measures to stimulate economic activity. Public procurement of medicines.

— The Balearic Islands regulated the purchase of medicines for hospital use through Decree-Law 8/2020, validated by Regional Balearic Islands Law 2/2020, of 15 October, on urgent and extraordinary measures to boost economic activity and administrative simplification in the field of public administrations to mitigate the effects of the crisis caused by COVID-19. In 2020, five contracts for a total of €20M were processed under this procedure.

— The regulation was challenged by the Spanish Government and, following negotiations through the Bilateral Commission (Ministry-autonomous region) and to avoid the filing of an appeal for unconstitutionality, by means of the Decision of 8 July 2021, articles 16 to 18 were repealed in early 2022.

Castile-La Mancha

Central Commission of Pharmacy and Therapeutics of Castile-La Mancha Health Service.

— This year saw the continued processing of the draft Decree creating and regulating the Central Commission of Pharmacy and Therapeutics of Castile-La Mancha Health Service (SESCAM), which was approved in 2023.

Madrid

Strategic Pharmacy Plan (announced by the Directorate General of Pharmacy in March 2022). This outlines the key directions for pharmaceutical policy in Madrid. Specifically, it covers:

a. Pharmaceutical policy focused on efficiency and rational use of medicines. This includes: (i) the promotion of biosimilars at hospitals of the Madrid Health Service (*Servicio Madrileño de Salud*, Sermas), (ii) the creation of the Pharmacoeconomics Observatory (scheduled for 2023), and (iii) the formation of the Regional Pharmacy Commission (scheduled for 2023).

b. Specific plans for high-impact medicines.

c. Optimisation of the centralised purchasing of medicines and medical devices.

d. Improved safety of medicines

e. Other objectives: (i) to set up the Centralised Pharmacy Commission (*Comisión Centralizada de Farmacia*) under the Pharmaceutical Care programme at health and welfare centres; (ii) to promote the conduct of clinical trials (CTs) and the Registry of Clinical Trials in Hemato-Oncology programme (under the REFAREC), to raise awareness of ongoing CTs and support patient enrolment.

Proposed reform of the CIPM. In October 2022, the Head of the Regional Department of Health submitted a proposal to the Ministry of Health to introduce changes to the functioning of the CIPM, prepared by the Directorate General for Economic and Financial Management and Pharmacy of Sermas, with the aim of reducing the current time-frame for incorporating into the pharmaceutical provision of the NHS new medicines undergoing price and reimbursement processing.

Law 11/2022, of 21 December, on urgent measures for the promotion of economic activity and the modernisation of the Regional Government (Ómnibus Act). (Circular CAM/8bis/22)

Article 41 of this regulation provides for the creation of the Health Procurement Agency (attached to the Sermas), which will exercise centralised procurement functions for Sermas sites attached or linked to it.

— On several occasions, Farmaindustria has liaised with the Directorate General for Economic and Financial Management and Pharmacy, which announced the launch in March 2022 (02/03, 09/03, 21/06, 27/09).

Centralised purchasing of medicines for Sermas hospitals.

— Order 889/22 establishes the centralised purchase of the "Supply of exclusive medicines for all hospitals within Sermas – 187 batches" (Circular CAM/8/22), to be procured by means of a framework agreement by negotiated procedure without prior publication due to exclusivity, in accordance with Article 218 et seq. of Law 9/2017, on Public Sector Contracts.

Law 13/2022, of 21 December, on pharmaceutical regulation and care.

— This regulates and orders the pharmaceutical care provided by pharmaceutical establishments in the region, including pharmacies, pharmaceutical first-aid kits, medicine stores, radiopharmacy units and pharmacy departments or units.

— It includes measures for: (i) the implementation of at-home pharmaceutical care, (ii) personalised dosing systems, (iii) pharmaceutical care in residential social service centres with fewer than 100 beds.

Navarre

— **Regional Law 17/2021, of 21 October, amending Regional Law 2/2018, of 13 April, on public contracts.**

— This amendment is aimed, inter alia, at regulating the purchase of medicines for hospital use (twenty-first additional provision).

— This precept was appealed by the Central Government before the Constitutional Court and is currently pending a decision.

Autonomous region status reports and thematic reports

— Throughout 2022, Farmaindustria drafted status reports for the autonomous regions of Aragon, Cantabria, Catalonia, Castile and Leon, Extremadura, Madrid and the Basque Country. They contain the key relevant data for the pharmaceutical industry: key health data, budgets and pharmaceutical expenditure through prescriptions and hospitals, prescription and dispensing policies, pharmaceutical and healthcare policy, research, composition of regional governments, etc.

— In addition, a number of reports have been updated, namely those on prescription by active substance and dispensing of GMPs in the diverse autonomous regions, nursing indication, and the political map of regional governments.

23rd Farmaindustria–Autonomous Regions Forum

On 17 and 18 November, Palma de Mallorca hosted the 23rd Farmaindustria–Autonomous Regions Forum, which, this year, focused on the following topics:

01. Access to innovative medicines and the pricing and financing procedure.

02. The EU regulation on Health Technology Assessment (HTA).

03. The Law on public sector contracts, with a special focus on the purchasing of exclusive medicines.

The Forum was attended by heads of pharmacy and similar from 13 autonomous regions.

Centralised purchasing of medicines in the National Health System through INGESA

The table below shows the status of centralised procurement procedures for the NHS, called through INGESA in 2022:

Medicines out for tender	Clotting	Biologics with biosimilars	Epoetins	Immunosuppressants
Status	— Called in July 2021. — Awarded in March 2022, following the partial estimation by the Madrid Court of Contractual Appeals of several special procurement appeals.	— Called in December 2021. — Awarded between August 2022 and October 2022, following the filing of several special appeals on the subject of procurement (Farmaindustria and other organisations) and the subsequent publication of new specifications.	— Called in September 2022. — Awarded in November 2022.	— Preparation underway. — Following several meetings between Farmaindustria, pharmaceutical manufacturers and INGESA, the initial approach of the MA is being reconsidered in order to safeguard the confidentiality of the MSP to obtain a model satisfactory to all parties that would bring this project to fruition.
Procedure	Negotiated without public notice.	Open procedure by ordinary processing and subject to harmonised regulation	Negotiated without public notice.	Negotiated without public notice.
Contracting administrations	11 regions (Aragon, Balearic Islands, Canary Islands, Cantabria, Castile-La Mancha, Castile and Leon, Extremadura, La Rioja, Murcia, Navarre, Valencia Region) and INGESA (Ceuta and Melilla).	10 regions (Aragon, Asturias, Balearic Islands, Cantabria, Castile and Leon, Extremadura, La Rioja, Madrid, Murcia, Navarre), INGESA (Ceuta and Melilla) and the Ministry of Defence.	10 regions (Aragon, Asturias, Balearic Islands, Cantabria, Castile-La Mancha, Extremadura, La Rioja, Madrid, Murcia, Valencia), Ministry of Defence, INGESA (Ceuta and Melilla).	10–12 autonomous regions expected to join.
Batch formation	Trade name.	Active substance.	Active substance.	Diverse batches of pens and syringes prefilled from vials.
Batches out for tender	10	10	4	35–25 PA
Batches awarded	10	10	4	Not applicable

3.2 Access to medicines

Access

In matters of access, Farmaindustria works to ensure that, after the long processes of R&D and regulatory authorisation, new medicines and their indications to improve the treatment of disease are made available to patients as soon as possible, taking into account the financial sustainability of the public health system and the contribution to improving the pharmaceutical provision of our NHS and, as a consequence, the health of Spain's population.

Biomedical innovation and the commitment of pharmaceutical companies to research new medicines remain highly relevant in spite of the pandemic, as evidenced by the latest annual report of the European Medicines Agency (EMA) on treatment approvals, dated 2022. According to this report, 41 new active substances were given the green light and a total of 89 positive approvals were issued, many for medicines with high potential for patients without treatment options. It is especially noteworthy that 16 of the 41 new therapeutic options (39%) were classed as orphan medicines – the largest number in recent years. This reaffirms the commitment of the innovative pharmaceutical industry to conducting research into rare and uncommon diseases, as demanded by professionals, patients and their families.

After the regulatory phase, newly authorised medicines in Spain must pass the notification of relevance for marketing in Spain. At this point, the national code is assigned and the pricing and reimbursement decision phase begins, which is of exclusive national competence and precedes the effective marketing of a medicine in Spain.

Lack of availability to new medicines and indications or delays in their access to the public health system are a serious problem for patients, for the physicians treating them, for the healthcare system itself and also for the industry (access is the key competitive factor of the pharmaceutical industry). In Spain, this availability is closely linked to the inclusion of medicines and their new indications in the pharmaceutical provision of the NHS.

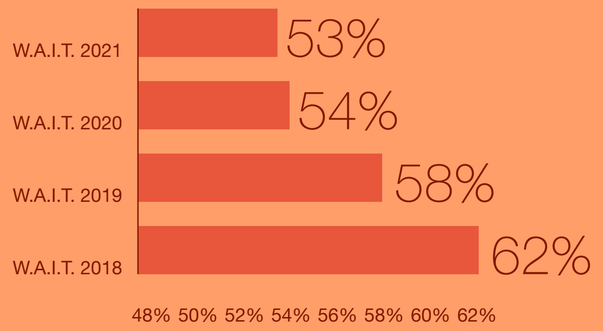
International indicators of access

The Waiting to Access Innovative Therapies report in Europe (*W.A.I.T. Indicator 2021*), prepared by consulting firm IQVIA for the European Federation of Pharmaceutical Industries and Associations (EFPIA), has been produced on an annual basis for a number of years. This report offers an estimate of the trends in availability and time to access in Spain of new medicines authorised in Europe in the previous years, allowing comparison with the indicators of neighbouring countries.

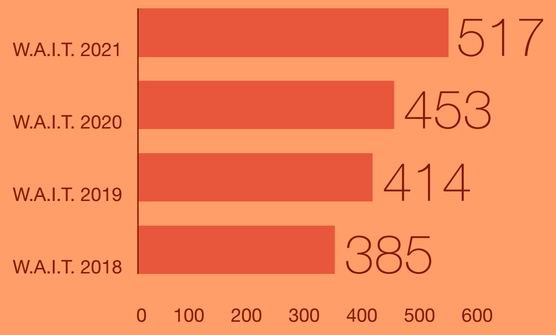
The *W.A.I.T. Indicator 2021* report for 2021 (analysing new medicines authorised in Europe in the four-year period from 2017 to 2020) confirms that these indicators – already negative for Spain in the 2020 report – have grown worse:

- The availability of the 160 new medicines in Spain is 53%.
- The average time to access has increased to 517 days (17 months).

Trend in the availability of new medicines in Spain (%)

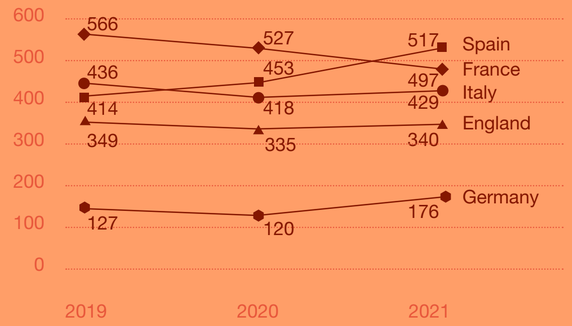


Trend in the mean time to availability of new medicines in Spain (days)

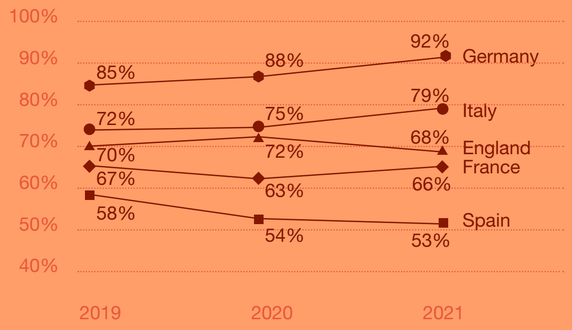


- Compared with the countries in our economic environment, inferior levels and a declining trend can be observed in Spain over the past two years. Time to access in Spain is also far higher than in these four countries. The following charts illustrate this information.

Trend by countries and years in the mean time to availability of new medicines (days)



Trend in the availability of innovations by country and year (% medicines)



- In addition to this poorer availability and longer waiting times, there is also a high percentage of medicines that are financed with a restriction on the candidate population for treatments beyond that indicated in the authorised summary of product characteristics (41% in Spain). The countries with which Spain compares itself not only have more medicines, but their share of medicines with restricted access ranges from 1% in Germany to 39% in England, both lower than Spain's percentage.
- The delay in approval and availability in Spain also impacts areas of particular importance for patients, such as oncology and rare diseases.
- The average time to access for new cancer medicines in 2021 has increased by 74 days from 2018, with the delay now reaching 469 days. In addition, the percentage of availability of cancer treatments approved in Europe between 2017 and 2020 stands at 61% in Spain, the lowest figure among our neighbouring countries. For example, availability is 100% in Germany, 90% in Italy, 85% in England and 80% in France.
- For orphan medicines, the average time to access in Spain has increased by 184 days from the 2018 report, standing in 2021 at 696 days, which represents a delay of almost two years. In addition, just 44% (25 of 57) of these treatments authorised in Europe over the last four years are available in Spain. This is the lowest percentage of the countries we have referred to here: Germany has 95%, Italy has 75%, France has 72% and England has 61%.

W.A.I.T. Report 2022

Interministerial Price Commission

The Regulation of the Interministerial Commission on Prices of Medicinal Products provides that the Commission shall meet on an ordinary basis at least ten times a year. The number of scheduled meetings was maintained throughout 2022 (3 February, 3 March, 7 April, 5 May, 2 June, 7 July, 29 September, 27 October, 24 November, 15 December).

There have been significant changes to the members and the persons holding the vice-presidency. In September, a new Vice-President, César Hernández García, was appointed as Director General of Pharmacy. There have also been changes in the members representing the autonomous regions. In the first six months of the year this was the case of the autonomous regions of the Balearic Islands, Castile-La Mancha and the Canary Islands, while Extremadura, Madrid and the Basque Country made their changes during the second half.

The Access Department creates access indicators for 2022 of the agreements reached in the CIPM. In 2022, 220 new medicines and indications were addressed. The table below summarises the percentage of favourable agreements by medicine type.

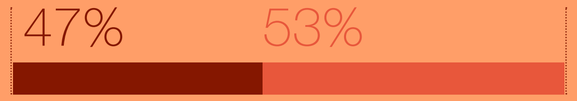
New formats
25 medicines (11%)

New indications
65 medicines (30%)

New active substances
80 medicines (36%)

Combinations
12 medicines (5%)

Marketed active substances
38 medicines (17%)



Favourable
Unfavourable

With regard to orphan medicines and financed new active substances, 63% of those financed are non-orphan medicines, whereas only 46% of the orphan medicines dealt with at CIPM meetings in 2022 were included in the provision.

Analysing the decisions reached for new medicines and oncological versus non-oncological indications, it can be seen that 76% of new non-oncological indications were financed versus 53% of oncological indications; for medicines, this percentage is 68% and 33%, respectively. Oncological medicines and indications have the highest percentage of unfavourable proposals.

Of the 88 new medicines/indications to obtain a favourable proposal during 2022, 57% had some type of therapeutic and/or economic restriction. The majority had therapeutic restrictions.

	Oncological		Non-oncological		TOTAL	
	No.	**%**	**No.**	**%**	**No.**	**%**
With restricted indication or financing conditions	**12**	**48%**	**38**	**60%**	**50**	**57%**
— Indication and conditions	2	17%	10	26%	12	24%
— Financing condition only	1	8%	4	11%	5	10%
— Indication restriction only	9	75%	24	63%	33	66%
No restriction on indication or financing conditions	**13**	**52%**	**25**	**40%**	**38**	**43%**
TOTAL	25	100%	63	100%	88	100%

It is noteworthy that just 30% of new medicines and 31% of new indications are agreed to be financed at the first CIPM meeting to which they are presented.

A generally more positive trend can be observed if we compare the years 2021 and 2022. Last year, compared to 2021, restrictions on therapeutic indication decreased and economic restrictions increased.

In 2022, there have also been more changes to the prices of medicines. The individualised decreases affecting entire therapeutic groups are of particular note. Conversely, there have also been upward price changes, which have been requested by pharmaceutical companies. A high percentage of these upward reviews have occurred with strategic medicines. The majority of downward price reviews at retail pharmacies correspond to DOACs, agents for diabetes, asthma/COPD and urological medicines. In hospitals, the downward price reviews have affected oncology, multiple sclerosis, HIV and orphan medicines.

	Number of medicines	% average change
Pharmacies	**87**	**13%**
— Upward	39	23%
— Downward	18	-10%
Hospitals	**29**	**5%**
— Upward	11	34%
— Downward	19	-10%
Total	86	11%

Therapeutic Positioning Reports and TPR Consolidation Plan

The Therapeutic Positioning Reports (TPRs), regulated by Additional Provision 3 of Law 10/2013, are intended to establish on a scientific-technical basis the place that a medicine occupies in the pharmaceutical provision of the NHS and its comparison with other therapeutic alternatives for the same disease for which it is indicated. They began in 2013 with the aim of serving as one of the bases for selective reimbursement and, where applicable, their pricing, also to serve as a reference for any action related to the purchasing and promotion of the rational use of medicines.

The purpose of these reports has changed, as they are now required and necessary for the financing decision-makers prior to the presentation of the price proposal to the CIPM. Hence, to complete the assessment of medicines with a theoretical economic assessment, the Plan for the Consolidation of Therapeutic Positioning Reports (TPRs) was drafted by the Ministry of Health. This Plan provides for the creation of a ReValMed network, implemented for all medicines and new indications authorised through the centralised procedure. It also establishes a prioritisation for the preparation of these reports. Some medicines have been selected on a pilot basis for the performance of an economic assessment in addition to an assessment of their comparative efficacy.

Briefly, the Plan has generated further delays in access, incorporates an economic assessment – with methodological weaknesses – and maintains the low and tardy participation of scientific societies and patients. It is also linked to the financing and pricing process, which is halted until the assessment is completed.

Over the course of 2022, the Department of Access conducted a detailed monitoring and analysis of the advances in these new TPRs, both in the methodology used for their evaluation and the monitoring of deadlines and their influence on the reimbursement and pricing decisions of the CIPM.

Biomarkers and personalised medicine

Precision medicine, the result of the advancement of disciplines such as proteomics and functional genomics and the unstoppable process of digitalisation, represent a paradigm shift in pharmacological advances, since these treatments are tailored to the specific needs of each patient or group of patients. The majority of the new oncology medicines approved in Europe – 40 in the past three years – are for personalised medicine. Many have been approved based on new clinical trial designs, different from standard medicines, such as in oncology with basket trials, in which patients are not selected based on tumour origin and type, but on their molecular profile. To date, there have been major hurdles to incorporating these medicines into the pharmaceutical provision of the NHS.

Throughout 2022, Farmaindustria held meetings with the Ministry of Health to explain that, despite significant advances in the development of personalised precision medicine at research level, access to molecular diagnosis in healthcare is still limited and unequal across – and even within – the different autonomous regions. As a result, during the public hearing and information process of the Draft Order amending annexes I, II, III, VI and VII of Royal Decree 1030/2006, of 15 September, establishing the common services portfolio of the National Health System and its updates procedure, Farmaindustria made written submissions with the contributions of its members. The order seeks to create a genetic catalogue that would allow for the more dynamic inclusion and updating of biomarkers.

In the area of gene or genome analysis, we noted that, with regard to the genetic tests to be included in the common portfolio of NHS services, it should be explained that these focus on both germline and somatic changes, which are the most common in oncology. With regard to the analytical and clinical validity of the gene or genome analyses to be included in the portfolio of services, it ought to specify the required validation type (in the context of the IVDR), the need to automatically include the biomarker when the medicine is included in the nomenclature of the pharmaceutical provision of the NHS, that the incorporation of biomarker measurements in the portfolio of services should follow a transparent, agile, evidence-based procedure that involves scientific societies and patient associations and guarantees that stakeholders are heard, and that a list of the sites with capacity for genetic testing and counselling, along with the types of tests available at each site, should be published.

With regard to the newly created Advisory Committee attached to the Directorate General for Common Services Portfolio of the National Health System and Pharmacy, among other aspects, specification of which professionals may perform the genetic counselling is requested, together with the criteria for their selection and the need to advertise appointments, and the inclusion of a representative of Farmaindustria on the Committee. Their tasks should include the harmonisation, measurement and monitoring of the implementation of this portfolio throughout the NHS to achieve equitable access across all the autonomous regions.

The Order was not published in 2022.

VALTERMED and pharmaco-clinical protocols

The Access Department also monitors pharmaco-clinical protocols drafted by the Directorate General for the Common Services Portfolio of the NHS and Pharmacy. These protocols are agreed in financing decisions and have the inconvenience that they are drawn up after the decision that is sent to the pharmaceutical companies. They are approved by the Permanent Pharmacy Commission.

Most are linked to a results-based payment agreement and information is collected through the VALTERMED platform.

In 2022, just two pharmaco-clinical protocols were published. Onasemnogén abeparvovec in the treatment of patients with spinal muscular atrophy and Volanesorsén in the treatment of familial chylomicronemia syndrome.

Four reports have also been published with the main health findings obtained from the follow-up in Valtermed of patients treated with inotuzumab ozogamicin, dupilumab, davadstrocel and remdesivir.

Medicines included in the Reference Price System. Reference Price Order

The Ministry of Health processes the Reference Price Order annually. The Access Department conducts the technical analysis of the affected medicines and, together with the Legal Department, coordinates the drafting of submissions and all the contributions of members. A new development for 2022 was a submission relating to the request to maintain the price of strategic medicines as essential medicines for our NHS and to establish a different defined daily dose (DDD) for medicines whose summary of product characteristics indicates this and which are not equivalent in effective dose to the other presentations of their reference group.

Advisory committee for the financing of NHS pharmaceutical provision

Just one report was published in 2022, entitled *Recommendations on the criteria and procedure to guide pricing and the inclusion and exclusion, on or after market entry, of a medicine under public coverage*. The document is limited to medicines in the exclusive period and, as such, excludes generics and biosimilars.

Some of its recommendations are aligned with the position of Farmaindustria and this is stated in the proposals document drafted and published to improve access to medicines in Spain. They include the need for more predictability, clarity and objectivity in procedures and decisions relating to the pricing and reimbursement of innovative medicines, along with the requirement for complete regulation and legal certainty of the system for regulating and setting the price of new medicines and their reimbursement by the NHS, issuing detailed and complete implementing regulations and technical guidelines so as to reduce as far as possible the margins of interpretation, arbitrariness and litigation and to achieve a high level of legal certainty. They propose results-based payment formulas, but recommend defining the explicit criteria for the uncertainty and the formulas to be applied in each of these cases, and publishing a guide. For the efficiency analysis, they recommend starting by adopting the NHS perspective, although this should evolve over time to adopt a broad social perspective. In addition, the efficiency criterion should not be the only assessment criterion.

Farmaindustria publications:

Access to medicines in Spain: diagnosis and recommendations report

In July 2022, Farmaindustria published its report *Access to medicines in Spain: diagnosis and recommendations* outlining the proposals submitted to the Government to reverse the decline in access to innovation indicators. In the report, it describes the current situation, analysing the chief causes and setting out a series of measures to reverse the decline in access to innovation indicators in Spain.

Proposals to improve patient access to orphan medicines

Just 44% of orphan medicines approved in Europe are available in Spain, according to the latest report on indicators of access to innovative therapies in Europe (W.A.I.T. Indicator 2021), drawn up by consulting firm IQVIA for the European Federation of Pharmaceutical Industries (EFPIA).

The document outlines 12 specific measures for ensuring that Spanish patients with rare diseases have the greatest number of opportunities for receiving treatment, on a par with European patients.

3.3. International relations

Association approach

Farmaindustria's international activity revolves around two key aspects:

01. Stable relations with international associations and federations of the pharmaceutical industry.

02. Close monitoring of European Union (EU) legislative initiatives affecting the innovative pharmaceutical industry. In foreign trade, we work to strengthen the presence of Spanish companies in third markets.

Through these broad areas of action, we are able to establish the international position of Farmaindustria with national and international institutions and bodies to defend the interests of the sector and to define the strategic actions of our association, as well as to enable companies to prepare for new regulatory scenarios.

The international positions and practices of the pharmaceutical industry are a valuable reference for the Association in these tasks. Hence, it is fundamental for the Association to interact and participate in:

a. The European Federation of the Pharmaceutical Industries and Associations (EFPIA), through active participation on its governing bodies (General Assembly), strategic committees (National Campaign Implementation Committee – a temporary committee formed as a union of the European Markets and European Advocacy Management committees) and working groups.

b. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), with representation on its governing bodies (Council and General Assembly) and on the Heads of Associations Committee.

Equally relevant are the many bilateral and multilateral relations established by Farmaindustria with other national associations in the sector, including the US association (PhRMA) and European associations, through the G1 group (Germany, Spain, France, Italy, United Kingdom and Switzerland) and the G2 group (Belgium, Denmark, Netherlands and Sweden).

Key areas of action

Meeting with the Spanish President and Government ministers

On 21 December 2022, some twenty presidents and CEOs of national and global pharmaceutical companies, along with representatives from Farmaindustria, EFPIA and IFPMA, met at La Moncloa with the President of the Government of Spain, Pedro Sánchez, and the ministers of Industry, Trade and Tourism, Health, and Science and Innovation to lay the foundations for a Strategic Plan to promote the development of the innovative pharmaceutical industry in Spain and to address the most critical aspects of the review of European pharmaceutical legislation.

The high-level meeting, which confirms the industry's clear commitment to innovation and access in Spain and the rest of the EU, laid the foundations for the future Strategic Plan for the Pharmaceutical Industry 2023–2025, which includes sector objectives for a global investment of more than 8 billion euros in Spain over the next three-year period to boost biomedical research, digitisation and the strategic production of medicines.

During the meeting, President Sánchez announced that he would set up a working group between the government and the sector to develop the actions of this Strategic Plan while maintaining an ongoing dialogue to define the lines to adopt during the Spanish Presidency of the Council of the EU in the second half of 2023, with a view to promoting the competitiveness of the innovative pharmaceutical industry operating in Europe through reform of the current pharmaceutical legislative framework.

European Health Union

Building on the lessons learned from COVID-19, and with a view to addressing other potential pandemics or serious cross-border public health threats in a holistic and consistent manner based on cooperation and coordination among Member States, in November 2020 the European Commission published a package of proposals laying the foundations for a European Health Union. The package consists of a Communication explaining the EU's health objectives, accompanied by three legislative proposals developing its content in greater detail:

01. Regulation to extend the mandate of the European Centre for Disease Prevention and Control (ECDC).

02. Regulation to extend the mandate of the European Medicines Agency (EMA).

03. Regulation on serious cross-border threats to health.

The Regulation to extend the EMA mandate was adopted in January 2022, while the Regulation on serious cross-border threats to health, the Regulation to extend the mandate of the ECDC and the Emergency Framework Regulation to equip the European Health Emergency Preparedness and Response Authority (HERA), were adopted by the Council of the EU in October.

European Pharmaceutical Strategy: a review of European pharmaceutical legislation

In November 2020, the European Commission published the European Pharmaceutical Strategy, marking the start of a process that includes an ambitious programme, in the short and medium term, with 55 flagship actions and other complementary actions whose implementation will require both legislative and non-legislative initiatives.

To address the goals of the Strategy, the European Commission has decided to amend European basic pharmaceutical legislation and the regulations on orphan and paediatric medicines.

Throughout 2022, Farmaindustria has advocated intensively – by organising events, among other activities – with national authorities (Government, competent ministries, AEMPS and Spanish MEPs) and other relevant agents, with a dual aim:

01. To address the reduced protection of regulatory data and their link to new regulatory obligations, and a restrictive definition of unmet medical needs.

02. To highlight the opportunity presented by this review to achieve the necessary balance in the access and innovation binomial.

The European Commission originally announced that its proposed review would be published by the end of December, but due to the complexity of the legislative initiative, it has undergone several delays. The reform will consist of a Directive (replacing Directive 2001/83 on medicinal products for human use) and a Regulation (replacing Regulation 726/2004 laying down Community procedures for the authorisation and creation of the EMA, and incorporating and amending Regulation 141/2000 on orphan medicinal products, and Regulation 1901/2006 on paediatric medicinal products). On the subject of antimicrobial resistance (AMR), the Commission also plans to publish a proposal for a Council Recommendation and a Communication to step up actions to combat this silent pandemic, which is one of the chief public health threats worldwide.

The proposed review is structured around a set of objectives covering the full life cycle of the medicine:

01. Promoting a single market for medicines to ensure that all patients in the EU have prompt and equitable access to safe, effective and affordable medicines.

02. Updating the regulatory framework using digital tools to create an appealing and innovation-friendly ecosystem that promotes the research, development and production of medicines in Europe.

03. Reducing the administrative burden by streamlining evaluation procedures and reducing approval time-lines for medicines, with a view to accelerating patient access to new treatments.

04. Addressing antimicrobial resistance and the presence of pharmaceutical products in the environment through the One Health approach.

05. Making mediciness more environmentally sustainable.

The European Commission's approach in certain aspects of the future proposal raises major concerns for the European pharmaceutical industry. This is particularly the case of the reduction in regulatory data protection from 8 to 6 years, which can only partially be recovered if the new medicine is sold in all EU markets in the first two years after marketing authorisation is granted. Like the EFPIA, Farmaindustria believes that this approach penalises European innovation and will not effectively address access problems. It would be very difficult for pharmaceutical companies to comply fully with this regulatory obligation, since delays and differences and inequities in access in Europe have a number of non-industry causes and should be addressed jointly with the competent national authorities without recourse to a European legislative intervention that would reduce incentives. Far from solving the problems, this reduction in incentives would make it difficult to attract R&D investment and retain talent in Europe, thwarting the recovery of the competitiveness lost over the previous two decades.

Antimicrobial resistance

As part of its policy to combat AMR, the European Commission launched a Call for Evidence for AMR in February 2022, in which Farmaindustria engaged in coordination with EFPIA. In its response, our Association underlined the importance of adopting the Transferable Exclusivity Extension as an incentive to ensure sustainable R&D in this type of medicine. The Commission will use the stakeholder feedback to draft a set of proposals on AMR that will form a coordinated and effective approach to the diverse initiatives contained in the European One Health action and the Pharmaceutical Strategy for Europe.

European Green Deal: new rules for cleaner water

In the context of the European Green Deal, in October 2022, the European Commission published a proposal for a review of the List of Surface and Groundwater Pollutants and the Urban Waste Water Treatment Directive. Both proposals will impose stricter rules on water treatment for the elimination of pollutants with a direct impact on the pharmaceutical industry (with annual costs exceeding 3.5 billion euros from 2040).

The proposed directive focuses on the fact that 92% of the toxic micropollutants present in wastewater come from pharmaceutical (human and veterinary) products and cosmetics, and proposes a new system of extended producer responsibility, in accordance with the "polluter pays" principle, which will require it to cover the costs of wastewater treatment to dispose of these micropollutants.

In this regard, Farmaindustria, in line with EFPIA, has pointed out that:

01. The pharmaceutical industry continuously evaluates its processes to minimise the environmental impact of its products.

02. The extended producer responsibility model is discriminatory because it requires the industry to bear the costs of improving water treatment processes when a large number of micro-pollutants are of a different origin.

03. On the basis of the "polluter pays" principle, an unprecedented, disproportionate, inefficient and unfair charge can be imposed on medicines, thereby increasing the burden on pharmaceutical companies.

Action Plan on Intellectual Property Rights

In November 2020, the European Commission adopted an Action Plan on Intellectual Property Rights, which is general in scope because it affects not only the pharmaceutical sector but all industrial sectors as a whole, given that the aim is to help European innovative industry maintain its global leadership, while at the same time speeding up the environmental and digital shift in the EU.

The Plan's references for the pharmaceutical sector include the launch of a unified mechanism for granting supplementary protection certificates (SPCs) for patents and the creation of a unified patent title. Along these lines, in March 2022, the European Commission published a call for evidence, to which Farmaindustria responded – in collaboration with EFPIA – to underline the importance of a harmonised SPC system for greater legal certainty.

European Health Data Space

In February 2020, the European Commission published a set of documents whose work programme for 2019–2024 expressed the need for a digital transformation strategy. In the area of health, the Commission's digital strategy covers a number of initiatives, the most notable of which is the creation of a European Health Data Space (EHDS).

Along these lines, the Commission presented its proposal for a Regulation creating the EHDS in April 2022, setting 2025 as the final date for its full implementation. The EHDS promotes a single market in the health sector and sets the stage for an interoperable system with secure and reliable access to health data. The Regulation has two objectives: firstly, in relation to primary use, it wants to allow citizens to share their health data, clinical history and prescriptions within the EU to ensure better health care, and secondly, it looks at secondary uses of these data for bio-pharmaceutical research and innovation.

Europe's Beating Cancer Plan

The stimulus behind Europe's Beating Cancer Plan is the desire to help Member States improve cancer prevention, control and care, given the steady rise in cancer incidence, high mortality and disparities among European countries.
In February 2021, the European Commission published this plan, structuring it into four policy areas:

01. Prevention

02. Early detection

03. Diagnosis and treatment

04. Improved quality of life

In this respect, in February 2022, the European Commission launched a set of new measures aimed at ensuring equal access to cancer prevention and treatment for all EU citizens. Lastly, in November, the Commission published a proposal for a review of the 2003 Recommendation on Cancer Screening to strengthen and align it with Europe's Beating Cancer Plan.

Patent waiver for COVID-19 vaccines

On 17 June 2022, during the 12th Ministerial Conference and after more than 18 months of negotiations, the Member States of the World Trade Organization (WTO) adopted a Ministerial Decision on the TRIPS Agreement to temporarily exempt certain aspects of the rules on compulsory licensing for COVID-19 vaccine patents. The approved text included a point urging WTO members to adopt, within six months (i.e. by 17 December 2022), a decision on extending the scope of this Ministerial Decision to include COVID-19 treatments and diagnostics. On 16 December, given the lack of evidence for extending the exemption to treatments and diagnostics, the TRIPS Council called on the WTO General Council to postpone the adoption of this measure.

Throughout 2022, Farmaindustria worked alongside IFPMA and EFPIA advocating with the national authorities (Ministry of Industry, Trade and Tourism, State Secretariat for Trade and Spain's Permanent Representation in Brussels, REPER), initially to underline the importance of maintaining the *status quo* on patents and, after the adoption of the Ministerial Decision on the TRIPS Agreement, its concerns regarding the extension of the exemption to treatments and diagnostics, asking the Spanish Government to adopt the position of defence of the protection of industrial property rights with the WTO. Farmaindustria, with support from the CEOE, has contributed to the drafting of several documents and letters from BusinessEurope and BIAC (Business at OECD) emphasising the position of the innovative pharmaceutical industry on patent waivers in the context of COVID-19.

Pandemic Treaty

With a view to creating a framework for responding to future pandemics, the World Health Organization (WHO), with the support of a group of Member States (Brazil, Egypt, Japan, Netherlands, South Africa, and Thailand), prepared a draft Pandemic Treaty that was unofficially made known at the end of 2022.

Although the draft is conceptual and many negotiations and meetings must be held before it is submitted to the WHO General Assembly for adoption, in its current state, it contains a number of aspects not shared by the industry, namely:

01. A line of argument that accords greater weight to public-sector R&D, manufacturing and distribution of medicines and vaccines, promoting the creation of regional manufacturing hubs without specifying how these would be financed;

02. The request to implement the flexibilities of the TRIPS Agreement and an exemption from industrial property rights and the use of mechanisms for technology transfer;

03. Implementation of the Access and Benefit-Sharing approach of the Nagoya Protocol, which would slow down the industry's ability to investigate potential pandemic pathogens and thus develop treatments;

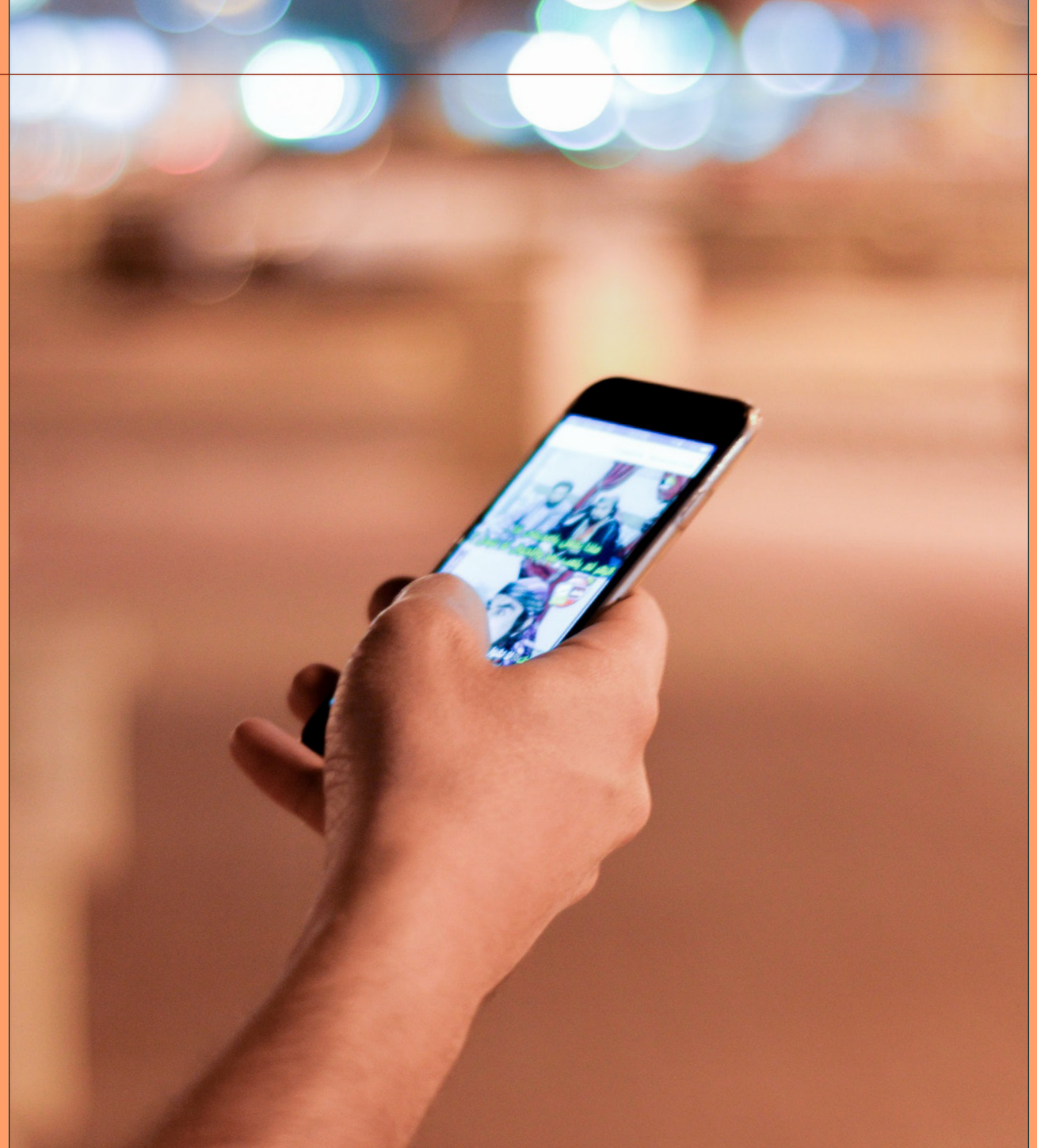
04. The support for a single approach to responding to future pandemics (which would reduce flexibility to operate in a pandemic context) by proposing, inter alia, conditions to promote R&D funded by the public sector and put in place safeguards in relation to producer responsibility; and (v) the request for transparency of the costs of manufacture, distribution and, where applicable, the public funding of R&D, as well as the prices of treatments, vaccines and diagnostics used to combat pandemics.

Competitiveness and internationalisation activities

In the context of overseas trade, Farmaindustria acts in coordination with the EFPIA through specialist working groups, the ultimate aim being to improve the presence of its pharmaceutical member companies on international markets.

In 2022, the European Commission monitored current agreements of association (such as the EU–UK Trade and Cooperation Agreement and the EU–Canada Free Trade Agreement) and continued to make progress with the negotiations on agreements yet to be concluded (EU–Mercosur Association Agreement, the Modernised EU–Mexico Global Association Agreement and the EU–Australia and New Zealand Free Trade Agreements).

3.4 Communication



Communication

What did we do this year?

In 2022, Farmaindustria's communication strategy focused on normalising our presence in society, following the enhanced visibility of the pharmaceutical industry during the COVID-19 pandemic, presenting the sector as a strategic player in Spain from the three-pronged perspective of health, economy and society.

With this in mind, the media, social media and our own channels were leveraged to announce to society the key pillars of the Association's Strategic Plan: the promotion of medicinal production and research in Spain and dialogue with the Government to solve current delays in access to pharmaceutical innovation by Spanish patients.
Emphasis was also placed on other areas where the pharmaceutical industry is a benchmark in Spain, such as gender equality across the workforce and its pioneering commitment to protecting the environment, with the recycling of medicines through the SIGRE initiative.

How did we do it?

25
press releases:
2 per month

135
briefing notes:
2 to 3 per week

7
in-depth reports

80
forums and conferences attended by Farmaindustria:
2 forums per week

20
radio and television interviews

Social media interaction:
We are the pharmaceutical employers' association with the second highest number of followers globally on Twitter and LinkedIn and the fourth highest on Facebook and Instagram.

What did we achieve?

More than 6,000 media mentions in 2022. This amounts to an average of 125 mentions per week. We have consolidated our media presence following the increase we witnessed after the coronavirus outbreak.

Internet and social media

In 2022, our website received 147,251 visits, slightly fewer than the visits received in 2022 (156,000 visits).

This year, the time spent reading our website topics increased to an average of 1 minute and 37 seconds, 10% more than in 2021.
In 2022, all Farmaindustria's social media platforms witnessed another increase in their region.

Twitter:

In 2022, we had 407 new followers, reaching almost 35,500.

In comparison with similar associations, Farmaindustria ranks second, topped only by its US counterpart:

01. PhRMA – USA: 84,434 followers.

02. Farmaindustria – Spain: 35,407 followers.

03. Leem – France: 31,474 followers.

Instagram:

In 2022, we gained 317 followers, an increase of 30.87% on 2021 figures.

The total now stands at 2,654 followers.

Compared with other associations, Farmaindustria is in fourth position, although our account is one of the youngest, along with ABPI (United Kingdom) and Leem (France), both set up this year.

01. VFA Pharma – Germany: 23,700 followers.

02. Farmindustria – Italy: 21,500 followers.

03. PhRMA – USA: 3,552 followers.

04. Farmaindustria – Spain: 2,654 followers.

05. Leem – France: 1,671 followers.

06. ABPI – UK: 533 followers.

LinkedIn:

In 2022, we gained 8,159 followers, an increase of 15.01% on the figures for 2021.

The total number of followers is 53,832.

Compared to other associations, Farmaindustria ranks second, outranked only by France.

01. Leem – France: 83,362 followers.

02. Farmaindustria – Spain: 53,832,752 followers.

03. PhRMA – USA: 45,375 followers.

Facebook:

In 2022, we gained 380 followers, 14.50% more than in 2021. We have reached 3,084 followers.

With regard to other associations, Farmaindustria is in fourth position.

01. PhRMA – USA: 102,000 followers. Interactions are few and far between and the number does not change from year to year.

02. Farmindustria – Italy: 38,000 followers. It gained fewer than 500 followers in the past year.

03. Leem – France: 14,968 followers. Almost zero interactions, and its followers have dropped in the past year.

04. Farmaindustria – Spain: 3,084 followers.

Top 15 Milestones

21 December

Meeting between the pharmaceutical industry and Spanish Government

The President of the Government of Spain, Pedro Sánchez, and the Minister of Industry, Trade and Tourism, Reyes Maroto, the Minister of Health, Carolina Darias, and the Minister of Science and Innovation, Diana Morant, held a meeting with more than twenty presidents and CEOs of national and global pharmaceutical companies along with Farmaindustria representatives.

The high-level meeting laid the foundations for the 2023–2025 Strategic Plan for the Pharmaceutical Industry, which includes sector targets with a global investment of more than 8 billion euros in Spain over the next three-year period.

13 December

Record R&D investment

The innovative pharmaceutical industry in Spain has hit its highest ever level of R&D investment, as evidenced by the latest R&D Activities Survey conducted by Farmaindustria each year among its members. In 2021, the R&D investment of the Spanish pharmaceutical industry topped 1,267 euros million, 9.2% more than in 2020, when its second highest investment figure of 1,160 million euros was reached. This record investment figure confirms the upward trend in these investments that began with the beginning of the economic recovery in 2014 and was even sustained in 2020, despite the exceptional difficulties caused by the pandemic.

30 November

Ten years of the Somos Pacientes platform

In 2022, the online community *Somos Pacientes* (“We are Patients”) turned ten. Over the last ten years, the platform has become a benchmark for associations everywhere, with more than half a million annual visits to its website and nearly 2,000 registered patient associations, persons with disabilities, relatives and carers, making it the largest map of patient organisations in Spain. This year’s event, face to face this time after two years of virtual hosting, was held in Madrid under the title *Mapping the Future with Patients*. It discussed effective patient participation in every setting, from clinical research to healthcare management and integration in the work environment.

For the first time this year, an Outstanding Figure Award was presented to support patients and/or persons with disabilities. This year it fell to Paralympic swimmer Teresa Perales.

10 and 11 November

High-Level Forum on the Value of Medicines

Farmaindustria chose the Ramón Areces Foundation in Madrid to host its High-Level Meeting on *Medicines and the Social Value of Investing in Health*. Over two days, Spanish and European health authorities, renowned national and international economic experts and representatives from academia and pharmaceutical companies came together to discuss the social value of medicines and health investment. The forum speakers included the Minister of Industry, Trade and Tourism Reyes Maroto, the President of the Economic and Social Council Antón Costas, and the Secretary of State for Economy and Business Support Gonzalo García Andrés.

During the meeting, Columbia University economist Frank R. Lichtenberg shared the main conclusions of a study on cancer treatment in Spain showing that the marketing of new cancer medicines has increased the life expectancy of cancer patients (delaying the mean age of death) in Spain by 2.77 years. He concluded that 96% of the increased cancer life expectancy during this period in Spain was due to new medicines.

27 October

Jesús Ponce, the new President of Farmaindustria

The General Assembly of Farmaindustria unanimously elected Jesús Ponce as its new President. The President of Novartis Group in Spain replaced Juan López-Belmonte in his post. This was done in accordance with the Articles of Association of Farmaindustria, which establish the requirement to alternate the presidency among the three groups of companies that form the Association according to the origin of their share capital: national, European/international and US. Over the next two years, the presidency is assigned to the group of companies with European/international ownership.

4 October

Media seminar in Madrid

For the eighteenth year, Farmaindustria held the Pharmaceutical Industry and Media Seminar in Madrid, a traditional conference at which the Association's management team spend the day with the journalists who regularly report on our sector, reviewing topics of interest and responding to all the media's questions. This time, around thirty media outlets from across Spain attended the Seminar, which also served to present the new Director General of Farmaindustria, Juan Yermo, to the media, having taken up his position in May.

14 September

More than 100 medicine manufacture sites in Spain

The pharmaceutical industry has a total of 103 manufacturing sites for medicines for human use in Spain, 11 of which produce biological medicines. This data was obtained from the Study on the industrial implementation of the pharmaceutical sector in Spain, conducted for Farmaindustria by consulting firm ManageArt, which was presented to the media at the Association's headquarters. For the first time, the study details what they are, the type of activity they carry out and the impact of this sector's production plants, and includes an updated map with the location of every plant in Spain, classified by site type.

8–9 September

21st Meeting of the Spanish Pharmaceutical Industry

The 21st Meeting of the Spanish Pharmaceutical Industry was held this year at Menéndez Pelayo University in Santander with the title *The Contribution of the Pharmaceutical Industry to Health Challenges*. Over two days, the event drew more than 130 representatives from public administrations, academia, centres of research, scientific societies, patients and pharmaceutical companies to analyse health challenges and the sector's potential as a healthcare, economic and social engine.

The participants included the Minister of Industry, Trade and Tourism Reyes Maroto, the Minister of Health Carolina Darias, the President of the Economic and Social Council Antón Costas, the new Director General of the Common Portfolio of the NHS and Pharmacy César Hernández, Pa well represented Spanish Medicines Agency (AEMPS), inluding its Director María Jesús Lamas, the Director General of Economic Policy of the Ministry of Economic Affairs and Digital Transformation, and the President-elect of the Spanish Society of Hematology and Hemotherapy (Sociedad Española de Hematología y Hemoterapia, SEHH), María Victoria Mateos.

24 July

'El País' Gender Equality Forum

The newspaper *El País* and Farmaindustria organised an event to discuss the challenges, progress and obstacles to gender inequality in Spanish companies. The participants of the debate included Teresa Riesgo, Secretary General of Innovation of the Spanish Government; Paloma Domingo, Deputy Director of the General Foundation of the Spanish National Research Council (*Fundación General del Consejo Superior de Investigaciones Científicas*, FGCSIC); Pilar Toboso, Professor of Contemporary History at the Autonomous University of Madrid and Director of the University Institute of Women's Studies (*Instituto Universitario de Estudios de la Mujer,* IUEM); Rafif Srour, Vice Dean of Programmes at IE University; and Fina Lladós, General Manager of Amgen for Spain and Portugal and member Farmaindustria's Executive Board.

19 July

Document of proposals to improve access to innovation

Farmaindustria has drafted a document of proposals that it has submitted to the Spanish Government in a bid to reverse the declining indicators of access to pharmaceutical innovation in Spain. The report, entitled *Access to Medicines in Spain: Diagnosis and Recommendations*, describes the current situation, analyses the causes and proposes measures to address the main problems identified.

27 June

Medicines, now Spain's fourth biggest export

The pharmaceutical industry operating in Spain increased foreign sales by 41% in 2021 to EUR 17,076 million, hitting an exports record for the sector. This figure – which is short-term in that it relates primarily to sales of COVID-19 vaccines produced in Spain – adds to the growth sustained over recent years and increases the share of pharmaceutical exports to 5.4% of the total, making medicines Spain's fourth biggest export.

25 April

Europe's pharmaceutical industry calls for R&D boost in Madrid

In Madrid, a top-level delegation of the European pharmaceutical industry, made up of representatives of the European Federation of Pharmaceutical Industries and Associations (EFPIA), called on public administrations to work together to recover ground lost in biomedical research in Europe over recent years to the United States and Asia.

At an event organised by EFPIA and Farmaindustria, which also included representatives of the Spanish Medicines Agency (AEMPS), researchers, clinicians and patient associations from Spain, the European pharmaceutical sector recalled how, in the early 1990s, Europe had been the top region - ahead of the United States and Japan – for investment in the R&D of new medicines. Up to 43% of new medicines entering the market were researched and developed in Europe, compared with 21% in the United States. Since 1997, however, this trend has been reversed and now 47% of new medicines are developed in the United States, compared to 23% in Europe.

9 March

Juan Yermo becomes new Diretor General of Farmaindustria

The General Assembly of the National Trade Association of the Spanish-based Pharmaceutical Industry (Farmaindustria) approved the appointment of Juan Yermo as its new Director General. On 3 May, he replaced Humberto Arnés, who had headed the Association for the previous twenty years.

Yermo has a PhD in Economics from Oxford University and a Master's in Financial Economics from Cambridge University. He has developed his career at companies such as Bankers Trust International in London and international institutions such as the World Bank in Washington and the Organisation for Economic Co-operation and Development (OECD), where he has held a number of roles over the past twenty years until his appointment in 2014 as Deputy Chief of Staff to the Secretary-General and subsequently Chief of Staff.

25 February

First personal data code in clinical trials

The Spanish Data Protection Agency (*Agencia Española de Protección de Datos*, AEPD) has approved the Code of Conduct regulating the processing of personal data in clinical trials and other clinical research and in pharmacovigilance sponsored by Farmaindustria. This is the first sectoral code of conduct to be approved since the entry into force of the General Data Protection Regulation (GDPR). The code governs how data protection regulations are applied by the sponsors of clinical studies with medicines and contract research organisations (CROs) that wish to adhere to it. Although the scope is currently national, it aspires to be a European benchmark as the first such code to be approved in Europe.

17 February

More than 53% of workers in the research-based pharmaceutical industry are women

Over 53% of workers in the research-based pharmaceutical industry are women (the national industry average is 26%), rising to 67% in R&D departments. Specifically, the female workforce has grown over the past four years at an average annual rate of 2.8%. This is evidenced by the latest 2021 Employment in the Innovative Pharmaceutical Industry survey, for which Farmaindustria polled its members. The survey points to new growth in the number of workers. The number of employees in the research-based pharmaceutical industry totalled 44,068 employees.

4.

Member Services

4.1 Spanish Technology Platform for Innovative Medicines

The Spanish Technology Platform for Innovative Medicines (*Plataforma Tecnológica Española de Medicamentos Innovadores*, PTEMI) has been consolidated as an initiative promoted by the pharmaceutical industry in collaboration with academic institutions, researchers and public administrations to promote pharmaceutical R&D in Spain.

During 2022, it focused its activity on Preclinical and Clinical Research.

Preclinical research

The Farma-Biotech partnership programme was launched in 2011 to promote collaboration between the pharmaceutical industry and biomedical research, and includes small biotech companies and public research centres.

Developments are studied across a wide range of therapeutic approaches, including the central nervous system, oncology, the respiratory system, inflammation and autoimmune diseases.

Since the launch of the Farma-Biotech programme:

22
interactive meetings held

51
Spanish biomedical start-ups taking part

36
research centres and hospitals taking part

141
advanced research projects presented

48
interested pharmaceutical companies

In 2022, the 22nd Farma-Biotech Cooperation Meeting was held, at which eight of the almost 90 projects received were presented for evaluation according to the criteria indicated by the pharmaceutical industry.

This year, we also analysed the current situation in order to develop an initiative in collaboration with other public and private partners to provide a functional, operational and agile response to the problematic gap between the point where research on new medicines is normally stopped in hospitals, public research centres and spin-offs and the point where the pharmaceutical industry starts to take an interest in some sort of partnership agreement for the development of new medicines.

In addition, we have monitored the calls launched by the State Research Agency (*Agencia Estatal de Investigación*, AEI), the Public-Private Partnership Advisory Committee of which we have been a member since 2021. We have also participated with the Centre for Technological and Industrial Development (*Centro para el Desarrollo Tecnológico e Industrial,* CDTI) in both the Innovative Health Initiative and in national actions of relevance for the industry or in collaboration with public centres through the Carlos III Health Institute (*Instituto de Salud Carlos III,* ISCIII).

Clinical research

Spain is a global benchmark for the conduct of clinical trials to test the efficacy of new medicines developed by pharmaceutical companies. This is thanks to the collaborative work carried out for years by health authorities, hospitals, researchers, patients and the pharmaceutical industry, and which allows Spain to participate in cutting-edge international trials of benefit to patients.

The Clinical Research area is centred on the strategic and promotional aspects of competitiveness in clinical research in Spain, facilitating processes and improving performance indicators, and on dialogue with the different public and private stakeholders engaged in the R&D of medicines in Spain.

The BEST Project, headed by Farmaindustria, groups together the leading public and private agents comprising the medicinal knowledge generation and clinical research system in Spain.

59
pharmaceutical companies

55
hospitals

13
autonomous regions

6
independent clinical research groups

1
CRO

The BEST Project was set up to foster R&D investment by monitoring the status of clinical research processes in Spain, identifying different practices and adopting measures to enhance efficiency and competitiveness.

In the period covered by this report, this working group on Clinical Research held a total of four meetings.

In 2022, almost one thousand new clinical trials were authorised in Spain, according to the Spanish Clinical Studies Registry (*Registro Español de Estudios Clínicos*, REEC), coordinated by the Spanish Medicines Agency. These data show that the diverse participants in research have a strong commitment to attracting investment to Spain and, primarilyl, to give answers to the many patients for whom participating in a clinical trial is the only therapeutic alternative.

Over the last year, initiatives have been launched to advance excellence and increase competitiveness before the full implementation of the EU Regulation establishing common procedures for the authorisation of clinical trials across Europe, calling on the Member States to cooperate from a common position. The cornerstone for applying the new principles of this regulation is the development of the Clinical Trial Information System (CTIS), a portal managed by the European Union whose voluntary entry into force took place on 31 January 2022.

To ensure that sites, clinical trial sponsors and regulators were ready to work with this new portal, and in the context of the collaboration between Farmaindustria and the AEMPS, a number of meetings and workshops were held with the latter Agency to resolve practical and technical issues.

The COVID-19 health crisis highlighted the digital transformation of healthcare and, along these lines, an *ad hoc* Working Group on Decentralised Clinical Trials was set up to analyse diverse elements, such as e-Consent, satellite/collaborating sites, at-home nursing services, digital enrolment, telemedicine and home delivery of investigational medicines. This type of clinical trial would be an opportunity for more patients across Spain to take part and would allow for the inclusion of a more diverse population, resulting in enhanced scientific quality for the study.

Similarly, for the purpose of analysing the current situation of clinical trials in primary care and identifying strengths and weaknesses to promote clinical research in this healthcare setting, a mixed working group on Clinical Research in Primary Care was set up in December 2022, composed of the three primary care scientific societies (SEMERGEN, SEMFYC and SEMG), nine pharmaceutical companies, the heads of research of more than five autonomous regions, and the managers of foundations and research institutes. Its chief aim is to draft a series of recommendations to promote research at this healthcare level, which represents an opportunity for Spain.

Also during 2022, the Guide for Excellence in the Conduct of Clinical Trials at Hospital Pharmacies was published in collaboration with the Spanish Society of Hospital Pharmacy (*Sociedad Española de Farmacia Hospitalaria*, SEFH). The purpose of this guide is to collate criteria, incorporate improvements to communication, and harmonise and digitise processes for the conduct of clinical trials at hospital pharmacy departments.

Likewise, progress has been made on the new Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance, which replaces and aligns the previous code with current regulations, approved by the AEPD in February 2022.

The Association has taken part in a considerable number of conferences, meetings and publications under this heading. These include the Fifteenth Annual Conference on Technology Platforms, co-organised by Farmaindustria, Asebio, Nanomed, Fenin and Veterindustria and held online on 1 June 2022 under the title *Challenges and Opportunities in Biomedical Research*. With more than 700 participants signing up this year, the Annual Conference on Biomedical Research Technology Platforms has become a benchmark for forums discussing Spain's main challenges and opportunities in biomedical research. It drew representatives from public administrations, regulatory agencies, universities and enterprise, as well as clinical researchers and patients.

In the area of interaction with patient groups, the focus was on participating in workshops to explain what taking part in a clinical trial involves, the applicable legislation and the role of the AEMPS and mpRECs. Progress has also been made, in partnership with Hospital Sant Joan de Déu, with the dissemination of the *Recommendations for Organising the Participation of Paediatric Patients in the R&D of Medicines*. This was launched in October 2021 and is aimed at increasing and improving the involvement of children and adolescents and their families in research for new treatments.

The *Bringing Science to Schools* programme also addresses outreach activities on the R&D of medicines for high school students, in partnership with Spanish hospitals and research centres. During the period covered by this report, three workshops were organised with high school students (Hospital Sant Joan de Déu in Barcelona, Fundación Jiménez Díaz in Madrid and IBIMA in Malaga).

Also in 2022, the Association was heavily involved in diverse national and international forums on the promotion of biomedical R&D, and organised specific workshops and seminars on issues of interest for agents in the sectoral system of science-technology-enterprise.

Farmaindustria has participated in the Ethics Committee of the IMI EHDEN project since 2019. This public-private initiative addresses current challenges affecting the generation of information and evidence from real-world clinical data. In September 2022, this advisory board published an article entitled *A concentric circles view of health data relations facilitates understanding of sociotechnical challenges for learning health systems and the role of federated data networks*, explaining the main challenges in using life data and the potential of using federated data networks.

Much of the dissemination and promotion of actions among all agents of the science-technology-enterprise system is carried out through the Platform's website innovative medicines, which is updated daily. In addition, a monthly newsletter, which reached number 135 in December 2022, is published and distributed to more than 3,000 people and contains the main news and events of interest in biomedical research.

4.2 Self-regulatory system of the Pharmaceutical Industry in Spain

The current version of the *Code of Good Practice of the Pharmaceutical Industry* had to be updated twice during 2021. The first of these updates took place in June as a result of the entry into force of Royal Decree 957/2020 governing observational studies with medicines for human use, and the second in September as a result of the judgement handed down by the High Court of Justice of the Basque Country, which ruled as to the moment from which a medicine can be promoted. This ruling recognises the possible promotion of a medicine from its marketing authorisation, even if it does not yet have or will not have a financing decision.

In 2022, and in relation to the latter, mention should be made of the judgement of 17 June 2022 issued by the High Court of Justice of Madrid, which imposed a penalty on a pharmaceutical company for “advertising a medicine before obtaining the decision on pricing and reimbursement conditions in Spain, which is essential for its promotion, since the price data and its inclusion or otherwise in the pharmaceutical provision of the NHS are part of the minimum compulsory content of advertising intended for persons qualified to prescribe or dispense medicines”.

Besides the supervisory and monitoring functions of the Professional Ethics Supervisory Unit for ensuring the consolidation and compliance of the new versions of the Code, other relevant issues in 2022 were as follows:

01. Conducting a Self-Regulatory System survey for employees of companies formally designated by their companies as Internal Supervisors or as Meeting, Study or Service Communicators. The survey results revealed a positive view of the Self-Regulatory System, along with areas and elements for improvement, which were implemented and adopted over the year.

02. The submission and approval by the Governing Bodies of the Association of an initiative called Certification of Knowledge of the Code. This was a voluntary test to determine knowledge of the code among professionals linked to the pharmaceutical industry with relations with healthcare professionals, healthcare organisations and patient organisations. The initiative will formally start in 2023 with the first call for registrations for the certification examination.

03. The approval by the Governing Bodies of the Association of the new limits applicable to training materials and articles of medical utility (Article 10) and the limits applicable to hospitality (Articles 11 and 17). In both cases, a new maximum of 70€ (including taxes) was established, applicable from 1 January 2023.

With regard to the three communication procedures outlined in the Code, during 2022 the changes in the volume of interrelations and activities communicated by pharmaceutical companies, driven mainly by the COVID-19 pandemic, are being consolidated. In this regard, in the past three years (2020, 2021 and 2022) there have been no significant differences in the number of scientific and professional meetings, market research studies and projects reported by companies.

As for transparency, it should be noted that for the fifth year running (seventh year since the approval of this initiative), pharmaceutical companies individually published all transfers of value made to healthcare professionals and organisations. Spain is the only country in the European Union that publishes this information individually under a Self-regulatory System. As in previous years, a survey was sent out sufficiently in advance to the pharmaceutical companies in order to obtain the information for publishing.

Comparison of the numbers published in June 2022 (relating to transfers of value made in 2021) with those published in June 2021 (relating to transfers of value in 2020) reveals a 35% increase in transfers of value made for possible attendance/participation in scientific and professional meetings and an increase of 25.7% in transfers of value associated with the provision of services by healthcare professionals and organisations, while transfers of value to healthcare organisations for donations and subsidies and those related to R&D have remained practically constant.

The continuity, consistency and coherence of the data published over the years evidences, reinforces and consolidates the model of the interrelationship in Spain between the pharmaceutical industry and its main stakeholders. A model of interrelationship based essentially on principles of trust, integrity, respect, legality, prevention and transparency.

Ethics Supervision Unit actions

In relation to the **dissemination of our Self-regulatory System**, the following activities can be highlighted:

01. Participation in multiple meetings with the relevant working groups, Strategic Code Committee (ComEst) and Code WP.

02. Collaboration and participation in the different Farmaindustria working groups to address issues related to the Code of Good Practice and meetings with companies to monitor and support transparency projects.

03. Meetings with the regional departments for health, most notably of Madrid and Catalonia, to address issues related to the Self-regulatory System.

04. Meetings with scientific societies, advising them to ensure that their initiatives and actions comply with the Code.

05. Delivery of training sessions specifically designed to meet the needs and demands of companies

06. Joint delivery of training sessions on the Code, in the framework of specialised courses, doctorates, masters, etc.

07. Participation in Farmaindustria conferences with the media and heads of the autonomous regions.

08. Participation in EFPIA working groups responsible for ensuring the transposition, implementation and consolidation of the approved standards to the applicable codes in each national association.

09. Active member of the Codes Committee (Chair), the Strategic Committee, the Ethics & Compliance Committee (Vice-Chair), the Disclosure Working Group and the Medical Education Working Group of EFPIA.

10. Continuous collaboration with IFPMA: Chair of the Appeal Group of the complaints procedure of the IFPMA Code and participation in the working groups for: Responsible interrelations with the key groups of stakeholders, scientific meetings and congresses, and social media.

11. Active participation in meetings to develop informative guides on social media, collaboration with healthcare professionals at scientific congresses and virtual interactions with healthcare professionals on topics including sponsorship and collaboration at congresses and hospitality limitations, driven by the pandemic.

With regard to relations with patient organisations, Farmaindustria has worked to ensure that pharmaceutical companies comply with the commitment to provide updated information about joint projects completed in 2021.

Consultancy and joint projects

The Professional Ethics Supervisory Unit (*Unidad de Supervisión Deontológica*, USD) continued its collaboration and support tasks through:

— Review, adaptation and improvement of the internal procedures implemented by pharmaceutical manufacturers to ensure compliance both with the Code and with the regulations in force in the promotion of medicines.

— Continuous and ongoing support for pharmaceutical manufacturers and third parties involved, primarily scientific societies, technical secretariats and service providers in general.

— Active participation in meetings and forums organised by Farmaindustria, attendance at international meetings and forums organised by EFPIA and IFPMA, the Professional Ethics Supervisory Unit being an active member of these groups.

Monitoring and prevention

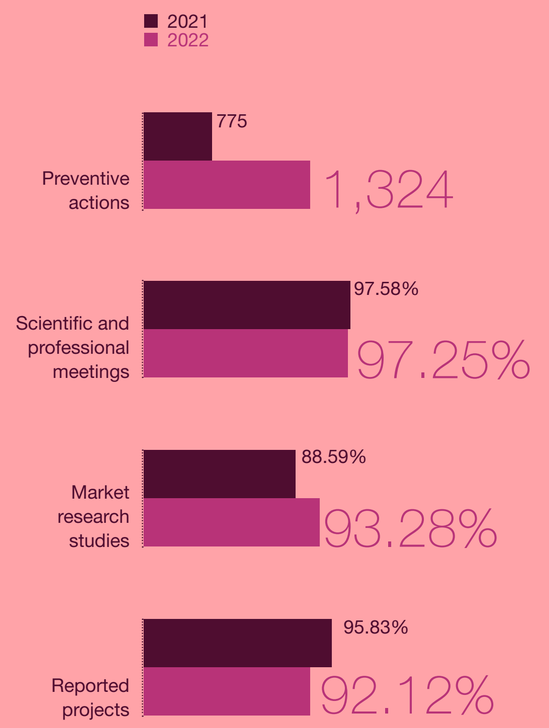
The number of preventive actions carried out (1,324) was almost double the number carried out in the previous year (775). The Professional Ethics Supervisory Unit filed a single complaint in 2022, which was resolved through mediation before the Professional Ethics Committee.

In 2022, the number of scientific professional meetings analysed and verified totalled 2,230 (1,419 fewer than in 2021). In percentage terms, the level of alignment of the meetings was 97.58% (compared with 97.25% in 2021).

There was a slight decrease in the number of market research studies analysed, which amounted to 238 (25 fewer than in 2021), although their alignment in percentage terms increased from 88.59% in 2021 to 93.28% in 2022.

In service provision, there was a decrease in the number of projects reported by pharmaceutical companies, with a total of 876 projects reported in 2022, compared with 984 reported in 2021. In all events, a relevant volume of communications was maintained, mainly due to the modification approved in the 2021 Code with regard to the number of healthcare professionals from which reporting is mandatory (decreasing from 20 to 10), and the increased organisation by companies of on-demand training projects, which are smaller and mostly performed in virtual or digital format, involving the recruitment of healthcare professionals as speakers. However, the level of compliance of projects in percentage terms remains almost constant (92.12% in 2022 versus 95.83% in 2021).

The table on the next page summarises the figures for the Unit (yearly and cumulative) from when it began operations up until 31/12/2022.



		2004-2012	2013	2014	2015	2016	2017	2018 (c)	2019	2020	2021 (d)	2022	Cumulative
EVENTS	**ANALYSED**	**30,501**	**4,954**	**5,566**	**5,337**	**5,382**	**5,377**	**3,894**	**3,884**	**1,452**	**1,419**	**2,230**	69,996
	No incidents	26,699	4,412	5,124	4,867	5,110	5,084	3,747	3,772	1,321	1,380	2,176	63,692
	% compliance	87.53%	89.06%	92.06%	91.19%	94.95%	94.55%	96.22%	97.12%	90.98%	97.25%	97.58%	90.99%
STUDIES (a)	**ANALYSED**	**2,549**	**400**	**449**	**300**	**317**	**293**	**262**	**310**	**285**	**263**	**238**	5,666
	No incidents	1,924	332	368	251	280	271	249	300	275	233	222	4,705
	% compliance	81.25%	83.00%	81.96%	83.67%	88.33%	92.49%	95.04%	96.77%	96.49%	88.59%	93.28%	83.04%
SERVICES (b)	**ANALYSED**	**687**	**306**	**350**	**368**	**363**	**364**	**290**	**373**	**303**	**984**	**876**	5,264
	No incidents	554	230	292	301	274	321	270	354	285	943	807	4,631
	% compliance	80.64%	75.16%	83.43%	81.79%	75.48%	88.19%	93.10%	94.91%	94.06%	95.83%	92.12%	87.97%
PREVENTIVE ACTIONS		**20,294**	**2,112**	**2,180**	**2,138**	**1,483**	**1,674**	**1,513**	**1,633**	**771**	**775**	**1,324**	35,897
USD COMPLAINTS		**84**	**9**	**7**	**7**	**2**	**3**	**3**	**3**	**4**	**0**	**1**	123

(a) System for Reporting Studies approved in 2008 Code

(b) System for Reporting Services approved in 2010 Code

(c) Change in procedure for publication of Third-Party Events (USD Circular 02/18) in force since February 2018

(d) Change in reporting procedure for Services in 2021 Code

CIRCULARS	2004-2012	2013	2014	2015	2016	2017	2018 (c)	2019	2020	2021 (d)	2022	Cumulative
Healthcare Professionals	**93**	**9**	4	5	11	3	5	3	10	7	5	161
Patient organisations	**5**	**1**										

Activity of the Professional Ethics Committee

In 2022, the Professional Ethics Committee provided advice, guidance and training on the Code of Good Practice for the Pharmaceutical Industry, among other duties. It also processed complaints received for breaches of the Code and mediated between parties to settle disputes arising during this year.

The Professional Ethics Committee held a total of 11 meetings in 2022. As for mediation cases, four grievances were filed with the Professional Ethics Committee, and these were processed in accordance with the ordinary procedure set out in Article 32.2 of the Code.

Total	4
Professional Ethics Committee	**4**
Committee Mediation	3
Agreement	2
Agreement+Contribution	1
Self-Regulation Jury	1
Pending	1
Contribution Agreements	1 for EUR 10,000

Plaintiffs	
USD	25%
Member companies	75%

Defendants	
Member companies	75%
Adhered companies	25%

Code of Conduct for Data Protection in Clinical Research and Pharmacovigilance

Following the AEPD's approval in February 2022 of the *Code of Conduct governing personal data processing in clinical trials and other clinical research and in pharmacovigilance*, the Governing Body was established on 30 March of that same year, with a composition approved by the Association's Board of Directors. The body is composed of three members, three alternate members and a Secretary, a position filled by the Director of the Legal Department of the Association. The six members are highly respected and experienced professionals. The current occupants, renowned experts in the field, are:

Alexis Rodríguez, clinical pharmacologist at Hospital Vall d'Hebron, Barcelona.

Itziar de Pablo, Clinical Pharmacology specialist at Hospital Ramón y Cajal, Madrid.

Pilar Nicolás, PhD in Law from Deusto University.

The alternate members for these persons are: Emma Fernández de Uzquiano, pharmacist and technical secretary of the medicinal products Research Ethics Committee of Hospital Universitario La Paz, Madrid; Francisco Abad, Clinical Pharmacology specialist at Hospital La Princesa, Madrid, and Mikel Recuero, PhD in Law from the University of the Basque Country. Appointments are for four years and members can be re-elected for periods of the same duration.

The functions assigned under the Code of Conduct to the Governing Body include the dissemination, interpretation, compliance and monitoring of its implementation, working actively with signatory entities to ensure compliance, deal with any queries and promote, develop and carry out training on the Code. It also approves membership applications from companies, both members and non-members of Farmaindustria, CROs and other entities sponsoring clinical trials that voluntarily adhere.

There are currently 16 entities adhered to the Code of Conduct, with the result that over 70% of the clinical R&D performed by member companies of Farmaindustria is covered by the Code.

Notably, during this first year of approval of the Code of Conduct, no grievances were filed that required activating the out-of-court dispute resolution procedure.

The Committee worked closely with the AEPD on the drafting of the document and this continues to be the case today. Proof of this can be found in the note issued by the AEPD late last year on the relationship between Farmaindustria's Code of Conduct and the European proposal on clinical trials, in the context of the drafting of the European Code of Conduct. Should the European code ultimately opt for legal bases for clinical trials other than those set out in Farmaindustria's Code of Conduct, it would serve as a reminder that the regulation of health research in Spain covers a broad and flexible range of applicable legal bases that would allow for its adaptation to the criteria of the European Data Protection Committee. Were this to happen, the AEPD would promote the criteria relevant to adapting Farmaindustria's code of conduct to any interpretative developments that may arise.

4.3 Working groups

Organised by spheres of interest to the pharmaceutical industry and coordinated by the different departments of Farmaindustria, these groups seek to encourage the active participation of companies in the Association, to publicise legislative or regulatory initiatives of the different public authorities, to prepare sectoral arguments or follow action plans on relevant sectoral matters, so that the Association can forward them to the corresponding authorities and contacts in a timely manner.

The groups are governed by specific functional directives, including in particular principles of confidentiality, personal data protection and compliance, all strictly complying with standards in the field of competition, the contents of which prevail over all meetings of the Association's working groups.

In October 2022, the renewal of the governing bodies of Farmaindustria also coincided with the updating of the working groups for a further term of two years. By virtue thereof, and with the dual aim of covering the needs arising of members and adapting to the context of the sector, three Groups have been dissolved (Biological and Orphan Medicines, GT BIO-HUER), Brand Defence (GT DM) and Medical Appointments (GT VM), though they could be reactivated in the future if necessary, and a new group, Real World Evidence (GT RWE), has been created from scratch.

In addition, with the aim of exploring diverse aspects in greater depth, a number of *ad hoc* groups operate with a smaller scope, the results of which are elevated to the plenary of the group to which they belong.

At present, the list of active working groups at Farmaindustria is as follows:

1. Access

Monitoring of access to market of medicines and existing cases. Monitoring of the procedures, criteria and decisions of the Ministry of Health and its competent collegiate body on pricing and reimbursement, reviews, exclusions and the establishment of special financing conditions for medicines. Functioning of the CIPM. Therapeutic positioning reports. Reference prices. Analysis of parliamentary and regulatory initiatives related to economic regulation, sustainability of the NHS and measures to contain pharmaceutical expenditure. In coordination with the INT and HTA working groups, monitoring of the current situation in EU egislation affecting this area, and cooperation between EU member countries. Preparation of position papers on matters of access. The ad hoc Orphan Medicines Group is part of this group.

2. *Health Technology Assessment*

This group brings together the heads of pharmacoeconomics and health outcomes of pharmaceutical companies to make proposals and develop technical documents relating to the economic evaluation of medicines, relative effectiveness, therapeutic positioning, level of innovation, selective funding, measurement, analysis and use of health outcomes in decision-making on healthcare, etc. The group analyses technical issues on relevant aspects of the assessment of medicines both nationally and internationally (in this latter area, in coordination with the EFPIA Health Technology Assessment working group). One of the primary aims of the Group is to formulate arguments to establish common industry positions in this area. The HTA working group also monitors regional and local initiatives relating to the assessment of medicines from these perspectives, analysing their fit with the assessments made at national level.

3. *Real-world Evidence*

New group created with a number of objectives:

01. Perform advocacy and explain the value of using RWD (real-world data)/RWE (real-world evidence) in all areas where it is useful.

02. Analyse and outline legislation, regulations and codes of conduct impacting RWE, at both national and European level.

03. Monitor operational developments in RWE at regional, national or European level.

04. Identify the resources (databases) currently available in Spain to conduct studies with RWD.

05. Make contact with the authorities (healthcare and non-healthcare), autonomous assessment agencies, health service providers, clinicians, researchers, scientific societies, etc. to understand needs and propose solutions for using RWE in the research and assessment of medicines.

06. Organise meeting spaces with the diverse agents involved in RWE, including patients, healthcare professionals, industry, regulatory agencies, assessment agencies, payers, academia, etc.

07. Build contacts with service providers in the field of RWE to explore projects of interest to member companies.

08. Analyse the operational deficiencies of the national and regional health authorities for the purpose of conducting RWE studies.

09. Study the legislative changes required to conduct this type of studies and maximise their practical use.

4. Financial Directors and Collections

In recent years, the Group has monitored and conducted a detailed analysis of all economic, financial and accounting matters relating to the Collaboration Agreement signed with the Government and in force from 2016 to 2019. At its quarterly meetings, it analyses the latest available information on discussions with Central Government regarding the implementation of the Strategic Plan for the Pharmaceutical Industry, with the aim of trying to anticipate the possible economic and financial implications that could arise with its first pillar (areas of access and sustainability). It also monitors ongoing regulatory projects that could entail a cost for or further economic contributions from the sector.

In late payment matters, it focuses mainly on the public domain, with monthly monitoring of sectoral figures on debt and average payment period (DSO) of the regional health services for hospital pharmaceutical supplies.

In the private sphere, special attention is paid to the potential impact of the State Observatory for Private Delinquency (*Observatorio Estatal de la Morosidad Privada*), currently under development. Within this Group, the ad hoc e-billing subgroup monitors the progress of e-billing with the state public sector. It also monitors the legislation mandating e-billing in B2B and its regulations under development. Further, it coordinates with the Digital Society Committee of the CEOE on related aspects.

5. Hospitals Market

Monitoring of the hospitals market in the autonomous regions and the National Health System (INGESA). Detection and analysis of national and regional initiatives for the purchasing of mmedicines for hospitals, particularly regulation, centralised procurement, regional tenders with significant peculiarities, management agreements that can limit supply and access to innovative medicines, and prescribing freedom. Special focus on regulations on originator and biosimilars and medicinal product assessment committees in hospitals.

Alignment with decision-makers and key agents in this field, fostering relations of trust and highlighting the importance of innovation in medicines ad their contribution to health. Promoting a system to monitor hospital medicine procurement tenders and, where applicable, centralised purchasing contracts, to verify their regulatory compliance. Ad hoc reporting in this area. Close coordination with the DF, AC, and ACC working groups.

6. Biological and Orphan Medicines

This group has the dual purpose of monitoring all aspects of biological medicines (including biosimilars) and orphan medicines. Its lines of work focus on monitoring the regulation affecting biological medicines and authorisation processes with regard to their health and economic aspects, access problems and centralised purchasing procedures. The WG also regularly reviews national and European legislative initiatives on orphan medicines, as well as cases and problems relating to this type of medicine. Contributions for position papers are also collected, particularly in the field of biosimilars, in line with documents prepared by other organisations (EFPIA, IFPMA, EBE, EUROPABIO-ASEBIO).

7. Technical Regulation of Medicines

Review of regulations and provision of contributions to prepare the industry's position in relation to the technical regulations on procedures for the authorisation, registration and marketing of medicines. The group studies provisions issued by the Ministry of Health, in particular, the rules for implementing Legislative Royal Decree 1/2015 in the technical field of fees, labelling and patient information leaflet requirements, authorisation applications and variations, validation of authorisations, the setting of conditions for application of the Sunset Clause and temporary marketing suspension, therapeutic gap status and the classification of strategic medicines, among others. This group monitors EFPIA's various regulatory initiatives. Ad hoc groups are also set up as necessary to address specific issues.

8. Manufacturing and Traceability

Review of regulations and provision of contributions for the industry's position in relation to technical regulations on the manufacture of medicines, logistical operations, guaranteed supply and minimisation of counterfeits. In particular, the group monitors provisions concerning the distribution of medicines, requirements relating to active substance manufacturer auditing, serialisation requirements, adaptation of pharmaceutical companies to the regulations that govern them, including EU regulations and, in particular, delegated acts on these matters.

9. Environment

Review of national and European environmental legislation relating to the pharmaceutical sector. Monitoring of regulatory developments in IPPC, waste, environmental responsibility, water policy and circular economy. Environmental impact assessment, VOC, air quality, air protection, climate change and carbon footprint reduction. Close collaboration with SIGRE in these matters.

10. Pharmacovigilance

Monitoring of the implementation of the Pharmacovigilance Directive and the new requirements of EU Good Pharmacovigilance Practice Modules. Regulatory development of the Royal Decree on pharmacovigilance: future application of the Royal Decree on observational studies. Assessment of the inspection requirements of the competent authorities. Review of the pharmacovigilance part of Farmaindustria's Data Protection Code of Conduct.

11. Vaccines

Monitoring of aspects related to vaccine singularities. Proposals for institutional and media contacts to raise awareness of the value of these products in line with EC proposals on the subject (Vaccines Europe). Vaccine access: vaccination campaigns, dates, returns and follow-up. Analysis of the vaccine contracting model and the national and European vaccination schedule, placing special emphasis on the value of prevention.

12. Incremental Innovation

Highlight the importance of continuous improvement for off-patent medicines. These medicines are now in a better position to meet patient needs due to the application of technological innovations, repositioning of indications, reformulations, new combinations of active substances, new pharmaceutical forms, etc. Follow up on the action plan approved by the Governing Bodies with the strategy to adopt to promote the marketing of these patient-centred therapeutic innovations. Follow up on the list and updates of strategic medicines published by the AEMPS.

13. Farma-Biotech

The Farma-Biotech Programme uses the current *open innovation* model to encourage collaboration between the pharmaceutical industry and the biotech setting (start-ups, spin-offs and public research centres) to link the pharmaceutical sector with the positive aspects of biotechnology. Promote platforms and instruments of public-private R&D collaboration. Participation in the Innovative Health Initiative and Horizon Europe Programme, and in other European programmes (e.g. Mission in Cancer) and the actions of the Spanish Platform for Innovative Medicines (*Plataforma Española de Medicamentos Innovadores*).

14. Clinical Research

Focuses on aspects of strategy and the promotion of clinical research competitiveness in Spain, facilitating processes and improving relevant indicators of efficiency and quality in the conduct of clinical research in accordance with Royal Decree 1090/2015. Promotion of the best setting in which to conduct clinical trials (CTs), with a special emphasis on the early phases and on implementing the list of excellence criteria. Collaboration with public and private agents to eliminate obstacles and foster research (promotion of clinical trials in primary care and clinical trials in paediatrics).

This working group also addresses the regulatory and technical aspects of clinical research in relation to the Ministry of Health, the AEMPS and the autonomous regions, including the monitoring of Royal Decree 1090/2015, the EU Clinical Trials Regulation and, among other topics, the review of sample CT contracts, common contractual clauses, digitisation in CT management (e-Consent, remote verification of source data, etc.) and the monitoring of inspections by the AEMPS and regional authorities in research matters.

It also works to extend the reach of biomedical research in collaboration with hospitals and other organisations. In addition, it works alongside the PAC working group to implement recommendation documents for the participation of adult and paediatric patients in R&D.

15. Legal Services

This group comprises representatives of the Legal Departments of the pharmaceutical companies and its tasks include: reviewing relevant legal news for the sector and for members by analysing state and regional legal and regulatory provisions and Community regulations with an impact on the sector; monitoring bills and proposals for legislation in parliament and studying arguments in the phase of prior public consultation and of public hearing and information for relevant regulatory projects; analysing the case-law of the CJEU, the Constitutional Court and ordinary jurisdiction; monitoring of appeals lodged by the Association through administrative and judicial channels with the Ministry of Health and other state and regional authorities in the sector; public procurement and transparency; monitoring of self-regulatory actions (Code of Good Practice of the Pharmaceutical Industry and Code of Conduct for Personal Data Protection); information, monitoring and participation in the resolution of issues with legal implications addressed in other working groups.

16. Taxation

Monitoring and analysis of tax issues affecting the pharmaceutical sector. This group hosts an annual seminar on new developments open to all members. Timely development of monographic meetings on tax issues of relevance for the industry. Drafting of objections to pending tax regulations in close coordination with the CEOE Tax Committee. Continuous monitoring of the doctrine of the Directorate General for Taxation and relevant case-law in this regard. Contact with the tax authorities on the basis of the sector's issues and special characteristics.

17. Human Resources

Composed of the human resources managers of the pharmaceutical companies, this group is tasked with monitoring and reporting on Community, state and regional legislation and regulatory projects in the area of labour that are of relevance for the sector, including objections on public consultation and public hearing and information procedures, in addition to parliamentary initiatives. It also monitors relevant case-law, notes, recommendations and instructions issued by institutions with a potential impact on the world of work, including the Spanish Labour Inspectorate, the Ministries of Labour and Social Economy and Equality, and the AEPD. Additionally, it conducts a continuous analysis of the impact of employment measures adopted by the public authorities.

Through its representatives, it participates in the Negotiating Committee for the Collective Bargaining Agreement of the Chemical Industry and Joint Committee, and in other CEOE committees (Committee on Social Dialogue and Employment, Committee on Social Security and Occupational Risk Prevention, Labour Market Observatory) and FEIQUE (Social and Labour Committee, Joint Committee on Occupational Health and Safety and the Environment of the Collective Bargaining Agreement and the Committee for the Study of Alcohol and Drug Controls in Companies of the Collective Bargaining Agreement), conveying the sector's position, including the transfer of amendments channelled through the CEOE. The group also follows up on CEOE and trade union communications in diverse areas of interest. Lastly, it conducts surveys and reports (with aggregated results) on specific workplace issues, either at the request of members or based on current regulations or the negotiation of a Collective Bargaining Agreement.

18. Code of Good Practice

Monitoring of the operation of the self-regulatory system and the drafting of proposals to improve its effective application. Adaptation of the text of the Code to legislative changes and cases, improving its application in a manner compatible with antitrust rules and in line with EFPIA and IFPMA guidelines.

19. Trademark Protection

Monitoring of the application of current regulations on the prescription of medicines to break down barriers that still exist in relation to prescribing by brand. Raising the value of brand prescription to all stakeholders that play a role in the medicine from its political and technical regulation, prescription, indication and dispensing by healthcare professionals to the possibility of patients choosing their brand of medicine.

20. International

The ultimate aim is to align and coordinate the actions of Farmaindustria and its member companies with the positions, priorities and practices of the international pharmaceutical industry through EFPIA and IFPMA. This aim is implemented by:

01. Monitoring and following up European and international policies and priorities, placing a strong emphasis on access to new medicines with a view to contributing to the design of the strategy and action plan of the pharmaceutial industry in Spain.

02. Gathering information obtained from EFPIA and IFPMA and from interactions with national institutions (ministries of Health, Economy and Industry, Research, Foreign Affairs, REPER, AEMPS and OEPM, to name but a selection) and with international institutions (European Commission and Parliament, OECD, WHO, WTO, EPO, etc.).

03. Bilateral exchange of information between Farmaindustria and the national associations of European markets.

04. Close collaboration and coordination with the ACC, HTA, RTM, CCAA and COM working groups.

21. Medical Representative Visits

Monitoring of national and regional regulatory projects and similar initiatives that could impact visits by medical representatives. Establishing a system of information and monitoring of medical representative visits in different communities, including regulations for the hosting of congresses, workshops or similar. Institutional contacts with autonomous regions, scientific societies, business associations of medicines and medical devices and professional corporations to raise awareness of the importance of medical representative visits as a means of interrelationship and scientific and technical communication between manufacturers and healthcare professionals. Maintaining a line of communication with associations of medical representatives to study the operation of representative visits. Monitoring of court decisions on the regulation of medical representative visits and any initiatives that may arise from the European Union. Drafting of proposals on sector positions in this area.

22. Relationships with Regions

Monitoring and follow-up of regional pharmaceutical policy, with a particular focus on regulatory developments and regional initiatives affecting pharmaceutical provision, equity in access across territories and market unity. Reinforcing communication and collaboration with governments and exploring scenarios of trust to strengthen strategic partnerships with key actors. Participating in political, scientific and professional forums to help raise awareness of the value of the pharmaceutical industry and the contribution of medicines to improving the health of the population and reinforcing Farmaindustria's position as a benchmark in this regard. Setting up a regional early-warning system to detect and monitor regional prescribing and dispensing policies. Drafting intelligence reports that incorporate strategic information on key health and pharmaceutical policies to help identify threats and opportunities for our members arising out of the different regional policies and initiatives. Close coordination with the SSJJ and MH working groups and the relevant ad hoc groups.

23. Communication and ESG

Study and proposal of communication strategies and actions for the pharmaceutical industry and improvement of its social image. Implementation of the Association's Communication Plan and coordination and alignment of these communication strategies with European (EFPIA) and international (IPFMA) employer associations. Channelling of sector initiatives in ESG and relations with all stakeholders of the sector.

24. Patients

Channelling relations between the Association and patient organisations, which is primarily organised around the Permanent Round Table with Patient Organisations. This working group also helps to raise awareness of the initiatives and activities of these groups and to act as an informative tool for them through the activity of the online *Somos Pacientes* community.

25. Cybersecurity

Generating a channel of collaboration with the institutions responsible for National Cybersecurity. Setting up a channel with the associated industry for sharing related information. Analysing the current situation of member information systems and implementing actions to enhance security in all aspects of work (manufacturing processes, products, IT environments and staff).

4.4 Barcelona Delegation

Farmaindustria’s delegation in Barcelona holds regional representation of the Association in Catalonia.

As a result, in 2022 it continued its efforts to make contact with diverse Catalan stakeholders in order to convey the Association's priorities to them, engaging directly with the public authorities and institutions in Catalan healthcare, social agents and business organisations, and offering the industry's assistance when they have needed the collaboration of the sector.

The Delegation is represented on the governing bodies of other national federations in the chemical sector (FEIQUE) and of cross-sector federations (Foment del Treball), participating in the meetings of their governing bodies with voting rights and participating in the various committees of the latter. It is also a member of the Board of Directors of the Catalan Business Federation of the Chemical Sector (*Federación Empresarial Catalana del Sector Químico*, FEDEQUIM) and a representative on a number of the Federation's specialist committees.

In training matters, the Delegation is a business representative on the sector councils of the Council of Training and Professional Qualification of Catalonia (*Consejo de Formación y Cualificación Profesionales de Cataluña*, CFQPC) and a member of the Advisory Committee of the University of Barcelona, collaborating in the design of specialised lifelong learning programmes in the field of pharmacy for the pharmaceutical industry.

The underlying principle of all the Delegation's activities is its focus on serving members, providing advice and dealing with diverse queries from member companies in general and from those based in this autonomous region in particular. It offers specific support to Farmaindustria statutory groups, such as the Joint Group and the National Group. Specifically for the latter, it serves as technical secretary at its statutory meetings, coordinating the Group's own initiatives and managing and updating information of special relevance for national member companies.

The Delegation likewise assists in organising the Association’s working groups, which are renewed every two years, and coordinates a number of Farmaindustria working groups. It also undertakes cross-functional and multidisciplinary collaboration with the other departments of the Association, jointly managing matters of interest for the sector and dealing with specific member queries while providing technical and administrative support to other working groups and departments on the subject.

4.5 Online services

It is now 20 years since Farmaindustria made a firm commitment to the digital transformation of its information systems.

Both administrative procedures and communication services were deployed as integrated in our network of portals, giving us a speedy means of reaching out to our members and the general public.

To begin with, our general interest portals (Members Intranet, Public Portal and Self-regulatory System) and our thematic sites (Innovative Medicines Platform, Code of Conduct and Proprietary Drug Classification) serve to structure and channel any information of potential value to society and our members.

Furthermore, different tools are maintained to handle Farmaindustria's commitments in membership processes and to manage regulatory procedures, including the application of deductions arising from Royal Decree-Law 8/2010, or returns due to the differences between Notified and Reimbursed prices.

Go to portal

Corporate Portal – Industry Intranet

For the exclusive use of member companies, this contains over 100,000 documents grouped into over 50 categories, including circulars, news flashes, publications, departmental areas, newsletters, regulations, etc.

It includes a personalised home page for each of the 2,000+ registered users in the industry, allowing them to choose the information displayed on their page or allowing them to directly manage their subscriptions to alerts, newsletters and the association newsletter.

Each of the Working Groups at Farmaindustria has a private space, providing simple, secure and orderly access for their 1,700+ members. This also includes documentation repositories for the Association's Statutory Groups.

It can support almost 100,000 site accesses, with the most popular pages being the departmental areas and documents on the Code of Good Practice, strategic medicines, reference and financing prices, regulations, therapeutic positioning and the autonomous regions and international affairs.

One of the new features is a survey section, in which the 1,700 members of the working groups were asked to rate the groups, their content, appropriateness, periodicity, etc.

Go to portal

Public website

The Farmaindustria public website was specially designed to convey information clearly, quickly and openly to anyone with an interest in the Spanish pharmaceutical industry.

Some years ago, as part of the communication plan, a weekly newsletter was included with relevant content on the industry and medicines.
The newsletter is sent out to more than 10,000 subscribers each week and acts as a voice for the industry's current situation and needs.

Go to portal

Innovative medicines

Following the complete overhaul of the portal, which was recently completed, it has become a tool for showcasing the efforts made through the public-private structure of teamwork, led by the industry.

The portal received over 33,000 queries in 2022 from over 8,000 different addresses. The 15th Annual Conference on Biomedical Research Technology Platforms has received the most visits.

Its monthly newsletter has also become established, having grown 30% in number of subscribers to the current 3,100 recipients.

Go to portal

Somos Pacientes

This is a community providing a shared forum for information, participation, training, services and collaborative efforts, intended for all patient associations in Spain.

The portal offers an extensive array of content, services and tools to facilitate interrelationship and generate a sense of community among patient associations, and to provide information and opinions to patients, relatives, professionals and other citizens with an interest in the world of health.

Go to portal

Code of Conduct governing personal data processing

The new *Code of Conduct governing personal data processing*, which replaces and aligns the earlier 2009 code with current regulations, is a step forward in the protection of the data of participants in the activities that it governs. The Code will likewise serve to strengthen clinical research and pharmacovigilance, fields where Spain is considered an international benchmark. While the scope is currently national, it aspires to become a benchmark across Europe given that it is the latter's first code in this area.

The new portal, developed during 2022 entirely with Association resources, has the clear aim of raising the profile of the work of control bodies, their procedures, regulations, ways to adhere, training and related news.

Go to portal

Self-regulatory System website

The pharmaceutical industry's Self-regulatory System is a voluntary response from manufacturers to the demands of stakeholders and society at large to establish criteria and standards of conduct guaranteeing trust and credibility in the promotion of medicines and the interrelations of the pharmaceutical industry.

With the aim of supporting the establishment of these standards and criteria of conduct, this portal and its site have developed the Code of Good Practice.

This website provides access not only to the Code of Good Practice and the Practical Case Test, but also full information on transparency, control bodies, regulatory framework and list of training activities, in addition to an area reserved for the management and reporting of scientific meetings, market studies and services provided by healthcare professionals and healthcare organisations.

Go to portal

Four Proprietary Drug Classification micro-sites

To facilitate access by manufacturer market analysis teams to the Billing and Prescribing Nomenclature of the Ministry of Health and the AEMPS, Farmaindustria has developed four micro-portals.

This is a tool for querying and filtering the information provided by the two institutions that also incorporates change control, which can be used to find out how the information changes from month to month.

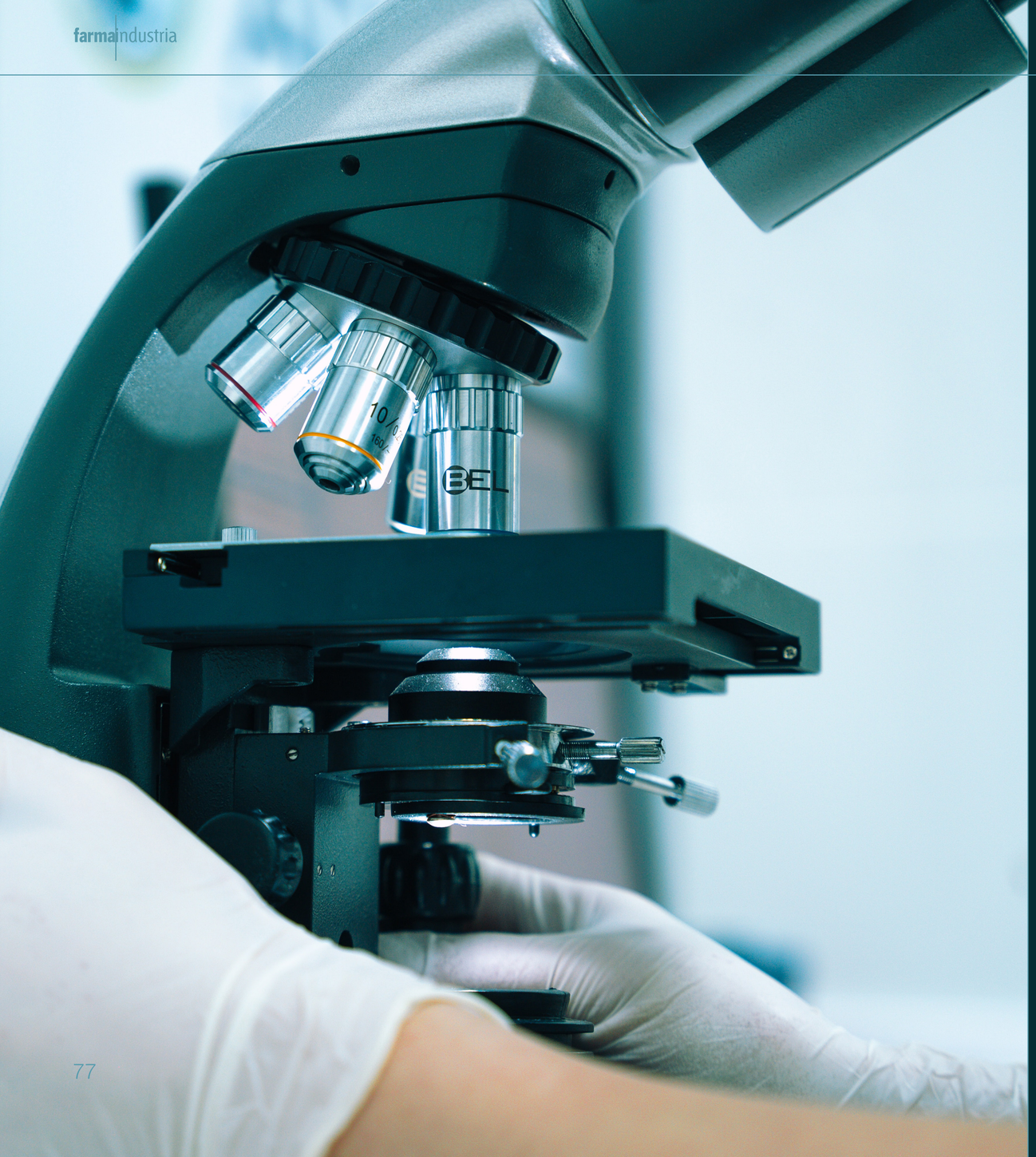
In addition to specific improvements, all the fields have been added to the query generator and the Registration Number has been added to the Prescription/AEMPS field filter, which allows queries with several Registration Numbers or National Codes simultaneously or the selection of Therapeutic Groupings by ATC 3/4/5.

Websites for the management of Royal Decree-Laws 8/2010 and 9/2011

These are four portals allowing the application of deductions derived from the application of the two Royal Decrees-Law.

Each month, Farmaindustria collects just over 25 million euros from pharmaceutical companies and pays them to the official associations of pharmacists. Through these four tools, the official associations of pharmacists, pharmaceutical manufacturers, the General Council of Official Associations of Pharmacists (*Consejo General de Colegios Oficiales de Farmacéuticos*, CGCOF), and the bank carrying out the transactions can comply with the agreed procedure.

They also allow the definition of the amounts that the 200+ manufacturers will need to deposit, along with the 52 transfers that the bank will need to make to each association, all under the supervision of the CGCOF.

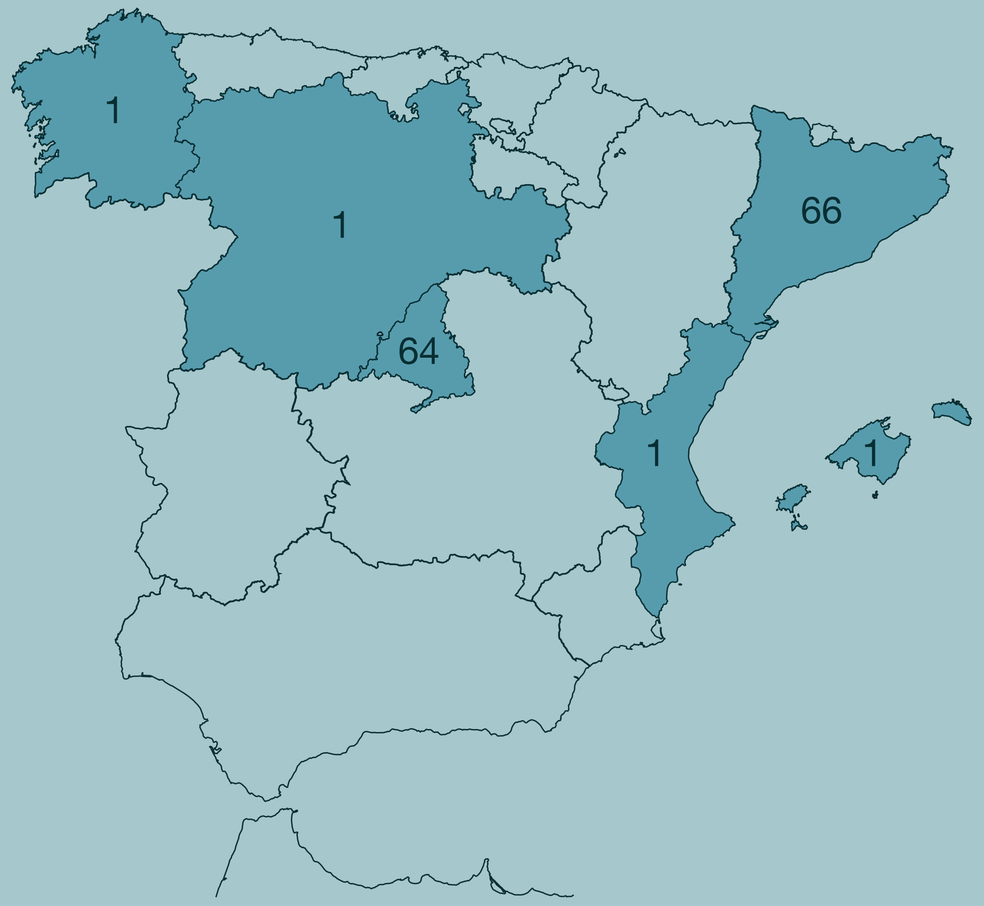


5.

Who We Are

5.1 Member companies

At the time of publishing this Annual Report, the number of member companies of Farmaindustria amounted to 134, geographically distributed as follows:



In sales terms, Farmaindustria members represent 70.80% of the total prescription market (retail pharmacies and hospitals).

Pharmaceutical manufacturers by group

National: 46		International: 88	
		American	European
Total	46	17	71
Large	5		
Large	41		

Germany	7
France	10
Mixed	34
United Kingdom	10
Switzerland	10

5.2 Governing Bodies

The General Assembly comprises all Association members and is the highest governing body of Farmaindustria, expressing the collective wishes of the companies.

Governance of the Association comprises:

01. The Executive Board, made up of the president and 33 representatives of member companies (9 representatives from domestically-owned companies and 24 from foreign owned companies, of which 15 are European/international companies and 9 are US companies).

02. The Governing Council, made up of the president and 22 members appointed by the Executive Board from among its members, of whom 11 are vice-presidents (3 from the sector of domestically owned companies, 3 from the sector of US-owned companies 5 from the sector of European/ international companies), the remaining 11 being members, drawn from the following: 3 with domestic capital, 3 from companies with US capital, and 5 from companies with European/international capital.

Elections were held in October 2022 to renew the governing bodies of the Association. In fulfilment of the article establishing the rotation of the presidency every two years, Jesús Ponce Sancho of Novartis Farmacéutica, S.A., a company from the European/International Group, specifically the Swiss Group, was appointed president, taking over from Juan López-Belmonte Encina, who had been president up to that date and hailed from a National Group company.

The composition of the Governing Bodies of Farmaindustria on the date of this Report is the following:

Governing Council

President:

— Mr Jesús Ponce Sancho

Vice-Presidents

— Sergi Aulinas Guillaumes
— Nabil Daoud
— Cristina Henríquez de Luna Basagoiti
— Bernardo Kanahuati
— Fina Lladós Canela
— Juan López-Belmonte Encina
— Lidia Martín Pereda
— Federico Plaza Piñol
— Francisco Quintanilla Guerra
— David Solanes López
— Raquel Tapia Rodríguez
— Roberto J. Urbez Plasencia

Members:

— Juan Carlos Aguilera Rodríguez
— Ana Argelich Hesse
— Aurora Berra de Unamuno
— Ignasi Biosca Reig
— Ricardo Jorge Castrillo Pelaz
— Giuseppe Chiericatti
— Luis Díaz Rubio Amate
— Jordi Muntañola Prat
— Felipe Pastrana Molina
— Peter Plöger
— Rick Suárez

Executive Board

President:

— Mr Jesús Ponce Sancho
NOVARTIS FARMACEUTICA, S.A.

Vice-Presidents

— Lidia Martín Pereda
ALMIRALL, S.A.

— Fina Lladós Canela
AMGEN, S.A.

— Bernardo Kanahuati
BAYER HISPANIA, S.L.

— Roberto J. Urbez Plasencia
BRISTOL-MYERS SQUIBB, S.A.

— David Solanes López
LABORATORIOS ERN, S.A.

— Francisco Quintanilla Guerra
FAES FARMA, S.A.

— Sergi Aulinas Guillaumes
LABORATORIOS GEBRO PHARMA, S.A.

— Cristina Henríquez de Luna Basagoitti
GLAXOSMITHKLINE, S.A.

— Nabil Daoud
LILLY, S.A.

— Federico Plaza Piñol
ROCHE FARMA, S.A.

— Juan López-Belmonte Encina
LABORATORIOS FCOS. ROVI, S.A.

— Raquel Tapia Rodríguez
SANOFI-AVENTIS, S.A.

Members:

— Felipe Pastrana Molina
ABBVIE SPAIN, S.L.U.

— Jesús David Zapatero Arconada
ARTIS PHARMA, S.L.

— Rick Suárez
ASTRAZENECA FARMACEUTICA SPAIN, S.A.

— Christiano Silva
BIOGEN SPAIN, S.L.U.

— Peter Plöger
BOEHRINGER INGELHEIM ESPAÑA, S.A.

— Giuseppe Chiericatti
CHIESI ESPAÑA, S.A.U.

— Jordi Muntañola Prat
ESTEVE PHARMACEUTICALS, S.A.

— Tomás Olleros Izard
GRUPO FARMASIERRA, S.L.

— Ricardo Jorge Castrillo Pelaz
FERRER INTERNACIONAL, S.A.

— Juan Carlos Aguilera Rodríguez
FERRING, S.A.U.

— Guillermo de Juan Echávarri
GLAXO WELLCOME, S.A.

— Aurora Berra de Unamuno
IPSEN PHARMA, S.A.

— Luis Díaz Rubio Amate
JANSSEN CILAG, S.A.

— Ignacio González Casteleiro
LABORATORIOS MENARINI, SA.

— Manuel Zafra Rubio
MERCK, S.L.

— Ana Argelich Hesse
MERCK SHARP & DOHME DE ESPAÑA, S.A.

— Javier Barreiro García
MUNDIPHARMA PHARMACEUTICALS, S.L.

— Carlos Eduardo Murillo Medina
PFIZER, S.L.U.

— Ignasi Biosca Reig
LABORATORIO REIG JOFRE, S.A.

— Carlos Rubió Badía
LABORATORIOS RUBIO, S.A.

— Juan José Francisco Polledo
TAKEDA FARMACÉUTICA ESPAÑA, S.A.

— Antonio Buxadé Viñas
LABORATORIOS VIÑAS, S.A.

5.3 Executive organisation

The Director General of Farmaindustria is the head of the executive organisation, which is structured into functional departments. The Association headquarters are in Madrid, and it also has a delegation in Barcelona.

The functional organisational chart of Farmaindustria in 2022 is as follows:

Juan Yermo

Director General

Javier Urzay

Deputy Director General

Ana Bosch

Director of the Legal Department

Emili Esteve

Director of the Technical Department

Pedro Luis Sánchez

Director of the Studies Department

Icíar Sanz de Madrid

Director of the International Department

José Ramón Luis-Yagüe

Director for Relations with the Autonomous Regions

Francisco J. Fernández

Director of Communications

Isabel Pineros

Director of the Access Department

I.

Annex

SIGRE

The pharmaceutical industry's commitment to sustainable development, exemplified by SIGRE

Over 20 years ago, the pharmaceutical industry launched the non-profit SIGRE Medicamento y Medio Ambiente (“SIGRE Medicines and the Environment”). Through this entity, the industry collectively guarantees the correct environmental management of waste from medicines and their domestic packaging in Spain.

This initiative reflects the pharmaceutical industry’s commitment to sustainable development and is an example of a sector alliance, given that all agents in the medicine supply chain play an active role: industry, distribution and pharmacies.

325
pharmaceutical companies

farmaindustria
anefp
aeseg

22,080
retail pharmacies

Farmacéuticos
Consejo General de Colegios Farmacéuticos

143
distribution warehouses

fedifar
federación de distribuidores farmacéuticos

Organisations representing agents of the pharmaceutical sector in SIGRE and the number of agents participating in the system as of 31 December 2022.

SIGRE pursues a twofold objective:

- Environmental: foster the introduction of ecodesign measures to reduce waste generation and ensure the proper environmental treatment of generated waste.
- Health: encourage the regular review of household medicine cabinets to avoid the unnecessary accumulation of medicines in homes and raise awareness of the health risks posed by the misuse of these products.

SIGRE achieves these aims through sustainable solutions in three areas of action:

- Prevention at source, by drafting Business Prevention Plans on pharmaceutical packaging and offering ecodesign advice to pharmaceutical companies.
- Responsible waste management through a reverse logistics system that provides numerous social, health and environmental benefits.
- Raising awareness of environmental issues through a range of varied training and communication tools.

SIGRE operates on the principles of the circular economy, applied from a One Health perspective. This allows it to contribute to meeting the Sustainable Development Goals (SDGs) of the United Nations 2030 Agenda most closely related to health and the environment.

SDG Report Year 6: The sector-based approach of the 2030 Agenda developed by the United Nations Global Compact Spain highlights SIGRE as an example of a business synergy for building a fairer, more inclusive and more sustainable future.

SIGRE’s priority SDGs

International benchmark

Knowledge of the pharmaceutical industry's work with SIGRE has spread beyond Spain's borders and its operating model has become an international benchmark.

The Organisation for Economic Co-operation and Development (OECD) recently published a new report on the management of waste from expired or unused medicine. According to the report, Spain has one of the highest collection rates, which has made SIGRE a benchmark for countries seeking to implement a system that guarantees the correct management of such waste.

Another example of the above is its participation in the Ibero-American Network of Post-Consumption Programmes for Medicines (*Red Iberoamericana de Programas Posconsumo de Medicamentos*, RIPPM), an alliance formed for the exchange of experiences among Ibero-American countries to promote the creation of new post-consumption programmes for medicines.

SIGRE also actively participates in a range of environmental and healthcare forums to raise awareness of its work and to highlight the contribution of the pharmaceutical sector as a whole to creating a more sustainable society.

Innovation for the environment

SIGRE is committed to achieving efficiency and continuous improvement in all of its activities and processes, as evidenced by AENOR's audit of its ISO certifications in Quality Management (ISO 9001:2015), Environmental Management (ISO 14001:2015), Energy Management (ISO 50001:2018) and Occupational Health and Safety (ISO 45001:2018).

The audit certified that SIGRE continues to follow the established guidelines to maintain this quadruple certification, highlighting the organisation's firm environmental commitment through diverse initiatives and its management of all supporting documentation of the Integrated Management System and the correct identification of risks and opportunities in its contextual analysis.

A further example of this is the Medicinal Product Packaging and Waste Classification Plant, a facility equipped with world-leading technology in which artificial intelligence is used to separate waste fractions correctly. This results in improved recycling rates for packaging materials while non-recyclable waste can be prepared for energy recovery.

The company has also improved the accuracy of the information it reports to the environmental authorities by refining the SIGRELAB software tool, an application designed to ensure updated qualitative and quantitative information about each of the pharmaceutical presentations marketed by pharmaceutical companies.

Relations with pharmaceutical companies

SIGRE offers multiple spaces open to dialogue with all its affiliated companies, in fulfilment of its commitment to transparency, information and accountability.

Additionally, SIGRE conducts a biennial survey to gather opinions from its affiliated companies in order to assess overall satisfaction with the service it provides to them. The latest data once again point to the organisation's solid relationship with pharmaceutical companies, which have a deep appreciation for SIGRE's work both for the industry and for society in general.

88%
expressed a **high level of satisfaction** with their relationship with SIGRE

98%
consider that it performs **responsible ESG management**

92%
highlight SIGRE's **contribution** to the **circular economy**

96%
consider SIGRE's answers to their queries to be **very useful**

92%
rate SIGRE's **ecodesign** work very highly

77%
appreciate SIGRE's work to combat **antimicrobial resistance**

86%
consider SIGRE's activity to help demonstrate **the industry's environmental commitment**

92%
are of the opinion that SIGRE provides **quality** information

Year upon year, the informative meetings organised by SIGRE are the most popular and highly rated among pharmaceutical companies.

More than 170 environmental managers attended training sessions on the SIGRELAB Form, in which they had hands-on experience of the tool, specifically designed to make it easier for affiliated companies to submit the information required by environmental regulations.

In June, as in previous years, the Encuentro Industria + SIGRE event was held, allowing SIGRE to share with pharmaceutical companies the latest developments in environmental issues and innovations in ecodesign and the circular economy. The event was inaugurated by José Manuel Jiménez, Director General of Environmental Infrastructure and Sustainability of the Regional Government of Castile and Leon, who highlighted the positive collaboration between the organisation and the Regional Government's Department of the Environment over the past 21 years of operation. Following the inauguration, SIGRE's achievements were reviewed and an outline was given of the key points of the new Law on waste and contaminated soils for a circular economy and the then Draft Royal Decree on packaging and packaging waste. An analysis followed of the industry's results in the first monitoring report of the Enterprise Prevention Plan (*Plan Empresarial de Prevención*, PEP) for pharmaceutical sector packaging 2021–2023.

This year, the event was held for the first time at the *Planta de Clasificación de Envases y Residuos de Medicamentos* (the medicinal waste and packaging classification plant, in Tudela de Duero, Valladolid) and included a visit to the facilities so that attendees could see first-hand how it works and the different processes performed to ensure the proper management of waste medicines.

Public awareness

Citizen engagement is essential for the proper management of waste medicines. To encourage cooperation from the public, SIGRE organises an outreach campaign every year to raise awareness of the importance of recycling empty packaging and leftover medicines properly using a SIGRE Point at a pharmacy.

In 2022, a new campaign was launched under the slogan *Tú tienes la receta para cuidar el planeta* ("You have the prescription to care for our planet"), reminding the public of the importance of the recycling medicines and highlighting the social and environmental commitment of pharmaceutical agents.

Environmental achievements

Over the past year, pharmaceutical companies have adopted 165 ecodesign measures whose environmental results have included reducing by 1.79% the average packaging weight of medicines marketed in Spain in 2022, saving 1,700 tonnes in packaging materials.

This was confirmed by the second monitoring report of the Enterprise Prevention Plan for pharmaceutical sector packaging (PEP) 2021–2023, the eighth plan drafted and coordinated by SIGRE to set out the roadmap of the pharmaceutical industry towards a circular economy in medicinal packaging.

It also points to a positive trend in public cooperation, with a 5% increase in waste from medicines collected during 2022. The recycling rates for recovered packaging materials also reached 67.83%.

The actions of SIGRE and of the entire sector working together have prevented the emission of more than 54,000 tonnes of CO2 into the atmosphere and the consumption of over 400 million kWh and 64 million litres of oil, all of which help to combat climate change.

104.4 g
of containers and leftover medicines collected per inhabitant year

67.83%
recycling rate for packaging materials deposited at SIGRE Points

165
ecodesign measures implemented

>94 M
containers impacted by ecodesign measures

1.79%
overall reduction in average weight

1700 t
of packaging materials saved through ecodesign measures

Future challenges

Royal Decree 1055/2022 on packaging and packaging waste was published on 28 December 2022, updating the legal regime applicable to packaging and packaging waste to prevent and reduce its impact on the environment over its life cycle.

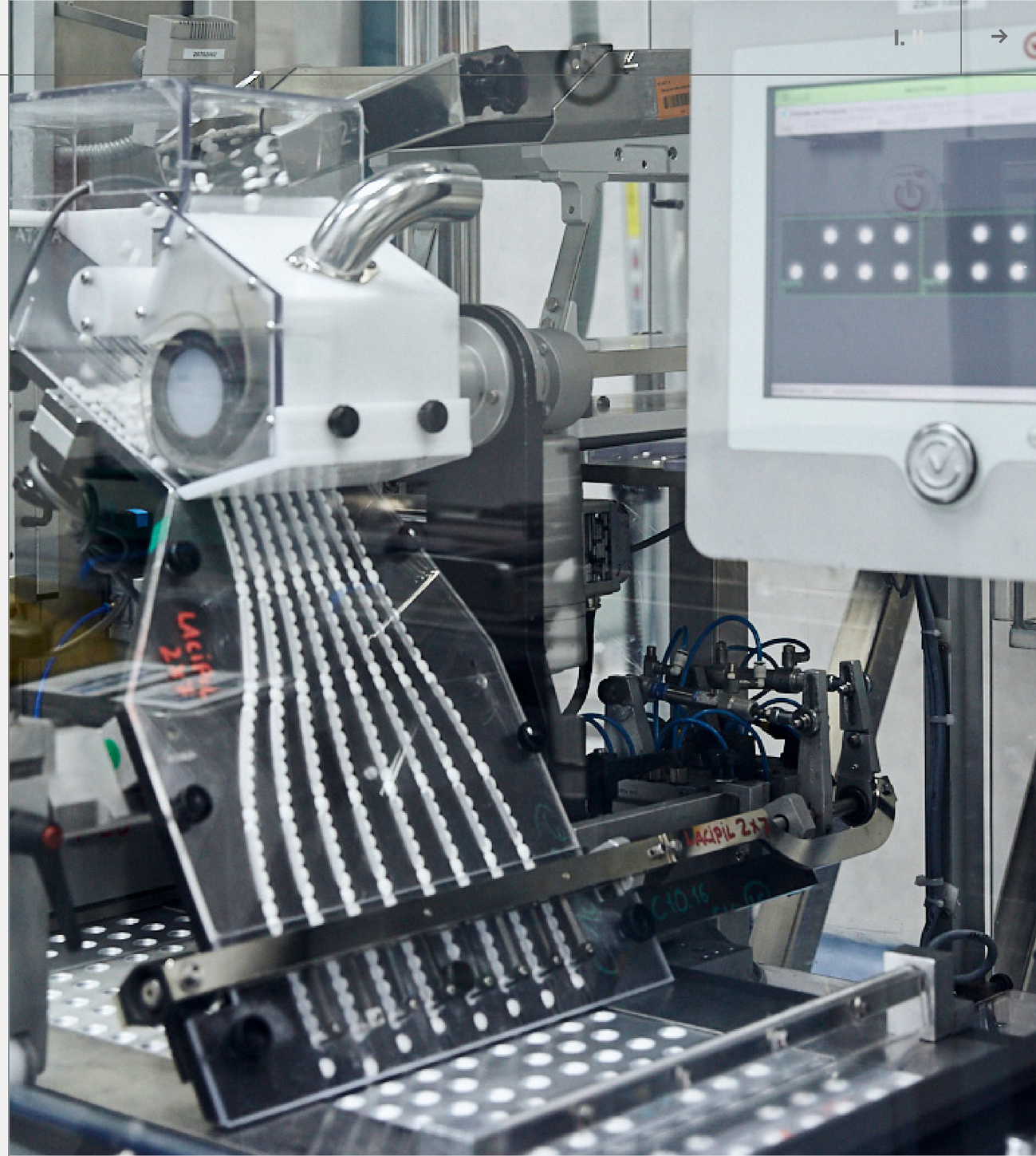
This is the first time that a regulation has been approved in the Spanish legal regime specifically on the management of medicines of domestic origin, establishing in its first additional provision that this waste must be delivered and collected through the same channels used for its distribution and sale to the public. In so doing, the regulation recognises the reverse logistics system implemented by SIGRE for the collection of waste through pharmacies and pharmaceutical distributors.

The most significant developments introduced by the new Royal Decree include the extension of extended product responsibility such that, now, the entities responsible for placing a packaged product on the market must also organise and finance the management of the commercial and industrial packaging waste.

For the pharmaceutical industry, this obligation will require guaranteeing the collection and management of waste from pharmaceutical packaging generated at all Spanish healthcare facilities (hospitals, specialist clinics, outpatient clinics, etc.) and at the facilities of logistics agents engaged in the distribution of medicines (pharmaceutical distributors, pharmacies, etc.).

To rise to this important challenge, Farmaindustria's Board of Directors approved SIGRE's request to extend its scope of action, thus far limited to household waste, to include the management of the pharmaceutical industry's commercial packaging.

SIGRE has the experience and tools it needs to tackle this new scenario successfully and continue to play its part in caring for the health of people and the planet.



II.

Annex

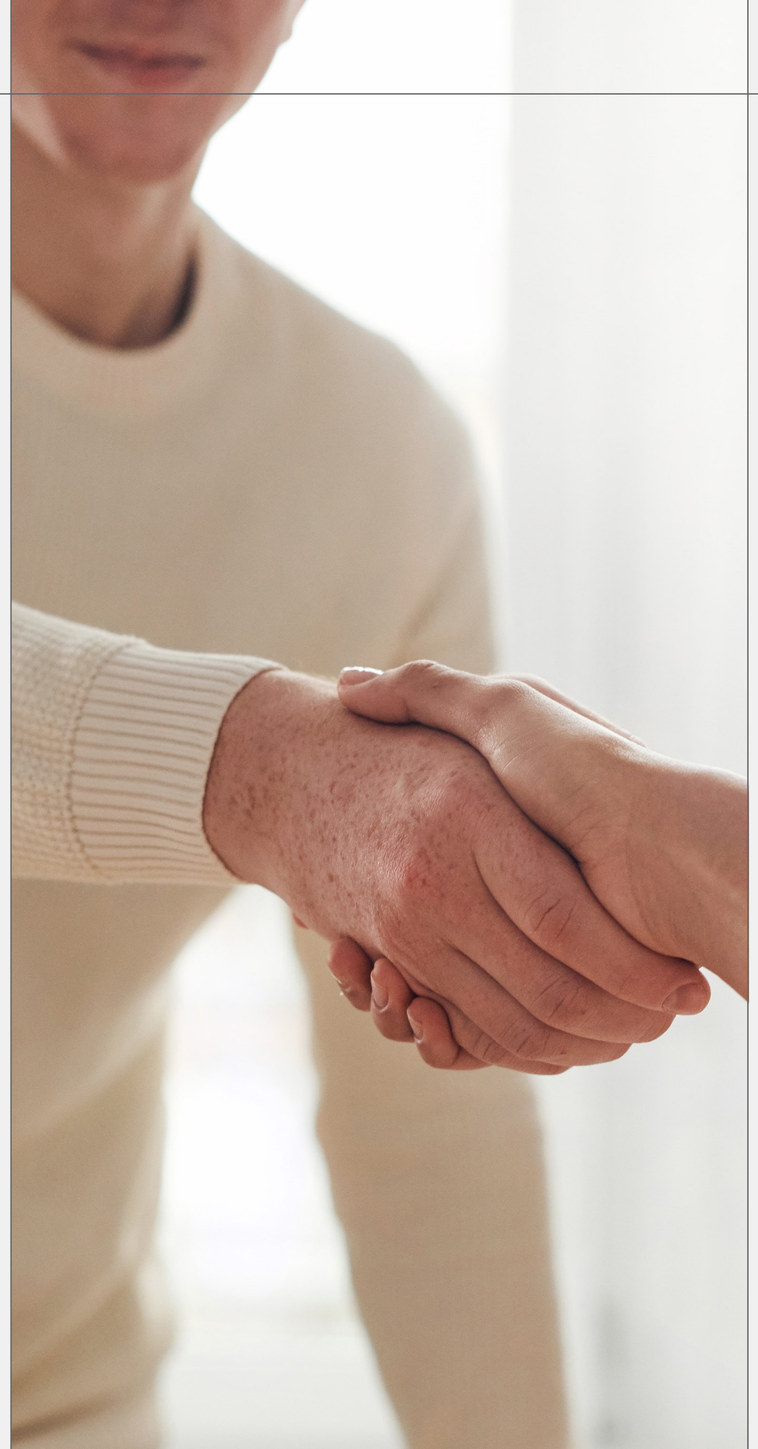
SEVeM

Spanish Medicines Verification System

Objectives and composition

The Spanish Medicines Verification System (*Sistema Español de Verificación de Medicamentos*, SEVeM) was founded on 21 July 2016 and began operation on 1 September of the same year as a non-profit limited liability company in order to develop, implement and administer the Spanish medicines verification system in accordance with EU Directive 2011/62. The corporate purpose of SEVeM likewise includes ensuring that information about SEVeM-authenticated medicines will be used to calculate the reimbursement owed by retail pharmacies to pharmaceutical manufacturers and distribution organisations of those medicines dispensed outside the NHS.

SEVeM was set up by the main agents in the medicinal supply chain: the pharmaceutical industry, distributors and retail pharmacies, which, as the shareholders of the entity, play a role on its Governing Bodies. Alongside the technological challenge of launching the verification system, particular mention should be made of the essential need for collaboration between these agents and the health authorities.



Governing bodies

The General Assembly is made up of the SEVeM members: Farmaindustria, AESEG, the General Council of Official Associations of Pharmacists (*Consejo General de Colegios Oficiales de Farmacéuticos*, CGCOF) and the Federation of Pharmaceutical Distributors (*Federación de Distribuidores Farmacéuticos,* FEDIFAR), while the governing body of SEVeM is its Board of Directors, which had the following composition in 2022:

In addition, in accordance with the founding bylaws of SEVeM, when the Board of Directors deals with matters concerning the development and functioning of the Spanish repository, the Spanish Medicines Agency is invited.

President:

— Mr Humberto Arnés Corellano

Directors:

— Ms María Álvarez Fernández

— Mr Jesús María Aguilar Santamaría

— Ms Ana Bosch Jiménez

— Mr Emili Esteve Sala

— Ms Marta Galipienzo Jiménez

— Ms Raquel Martínez García

— Mr Ángel Luis Rodríguez de la Cuerda

— Ms Matilde Sánchez Reyes

— Ms María Icíar Sanz de Madrid Ibrán

— Mr Javier Urzay Ramírez

Non-director secretary

— Mr Pedro Yanes Yanes

Non-director vice-secretary

— Mr Miguel Valdés Garaizábal

Delegated bodies

The delegated bodies of the SEVeM Board of Directors are the Operations Committee and the Audit Committee.

The Operations Committee comprises representatives of the four SEVeM members (Farmaindustria, AESEG, FEDIFAR and CGCOF) and representatives of the authorities (AEMPS, Directorate General for Pharmacy and Medical Devices and the autonomous regions). In 2022, the Operations Committee met eight times by video conference and addressed issues related to new system functionalities, developments in alerts and the AEMPS inspection, among others.

The Audit Committee, which comprises representatives of the four members, met on three occasions during 2022 to review the annual accounts and to supervise the generation of the company's income and expenditure budgets to be presented to the Board of Directors. At the proposal of the Audit Committee, and taking into account the company's results in previous years, the Board of Directors agreed to reduce the fees payable by Marketing Authorisation Holders (MAHs) to SEVeM from 2023. The new approved fees were as follows:

Revenues from MAHs per serialized product	Fee
< EUR 1,250,000	EUR 1,000
> EUR 1,250,000 and < EUR 50,000,000	0.08% of revenue
< EUR 50,000,000	EUR 40,000

Regulatory Framework

Delegated Regulation (EU) 2022/315 amending Delegated Regulation (EU) 2016/161 was published in 2022, introducing an exception to the obligation of wholesalers to decommission the unique identifier of medicines exported to the United Kingdom and to generate a different alert depending on whether or not the verification is performed from markets dependent on the United Kingdom (Northern Ireland, Cyprus, Ireland or Malta).

Following the appeal filed by the CGCOF and FEDIFAR against certain precepts of Royal Decree 717/2019 for the integration of the SNSFarma Node into the Spanish medicines verification repository, the Spanish High Court in 2022 submitted a request to the Court of Justice of the European Union (CJEU) on three preliminary questions to clarify the compatibility of the SNSFarma Node with the Delegated Regulation, processing of the Ministerial Order was subsequently suspended because it would establish the conditions for the integration of the SNSFarma Node into the national repository.

In its January 2023 judgement, the CJEU determined that the SNSFarma Node was compatible with the European regulation, provided that its development does not interfere with the proper functioning of the national repository. Subsequently, in March 2023, the High Court dismissed the appeal filed by the CGCOF and FEDIFAR on the basis that, since the technical characteristics of the SNSFarma Node have not yet been defined, it cannot be determined whether or not these interfere with the proper functioning of the Spanish repository. Following on from the recent judgement, there are plans to resume the negotiation of the agreement between SEVeM and the Ministry of Health on the SNSFarma Node.

Activity in the Spanish Medicines Verification System

In 2022, more than 20,700 medicinal SKUs and 5,500 unique identifiers were loaded into the system. More than 2.2 billion unique identifiers have been decommissioned since the system launched.

During 2022, the verification and decommissioning of unique identifiers increased from 40 million transactions per week to 45 million, reaching a mean decommissioning percentage out of the estimated market share for serialised medicines in Spain of 75%. To ensure the proper functioning of the National Repository given the increase in transactions and the large volume of stored data, technical enhancements have been introduced and progress is being made with the EMVO and the other Member States on the general approach for managing data over 5 years old, taking into account the obligations set out in the Delegated Regulation regarding the safekeeping of data.

Moreover, in May 2022, a new interface (version V5) was implemented at the connection with end users, with important security improvements such as verification of the product code with its corresponding national code, information about the name of the medicine in the transaction result and new fields indicating to the end user whether a package was previously decommissioned and, if so, whether there is time to reverse the decommissioned status because ten days had not yet passed since the initial decommissioning. It also incorporates technical improvements to support future functionalities, such as new error messages for compliance with Delegated Regulation (EU) 2022/315 and the latest changes made at European level to facilitate the management of false alerts caused by incorrectly configured scanners.

AEMPS inspection of SEVeM

On 12, 13, 14, 15 and 16 December 2022, SEVeM was inspected by the Spanish Medicines Agency (AEMPS). The inspection took place at SEVeM offices and included visits to the offices of the CGCOF and Equinix MD2 headquarters.

The inspection reviewed compliance with the requirements established in Delegated Regulation (EU) 2016/161 of 2 October 2015 and Royal Decree 717/2019, of 5 December. The conclusion of the inspection was satisfactory, with some observations that were analysed by SEVeM to propose an action plan that has been accepted by the AEMPS. The implementation of this plan will equip SEVeM with an even more robust quality system and improve aspects chiefly related to:

- Implementation of the functionality for viewing the complete audit trail of packaging, regardless of the country where the unique identifier is loaded or the country of the users verifying it.
- The quality of the data of the products and batches loaded into the SEVeM repository via the European hub.
- Reporting yield.

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